



European IPR Helpdesk

Fact Sheet

Intellectual property considerations for medical devices

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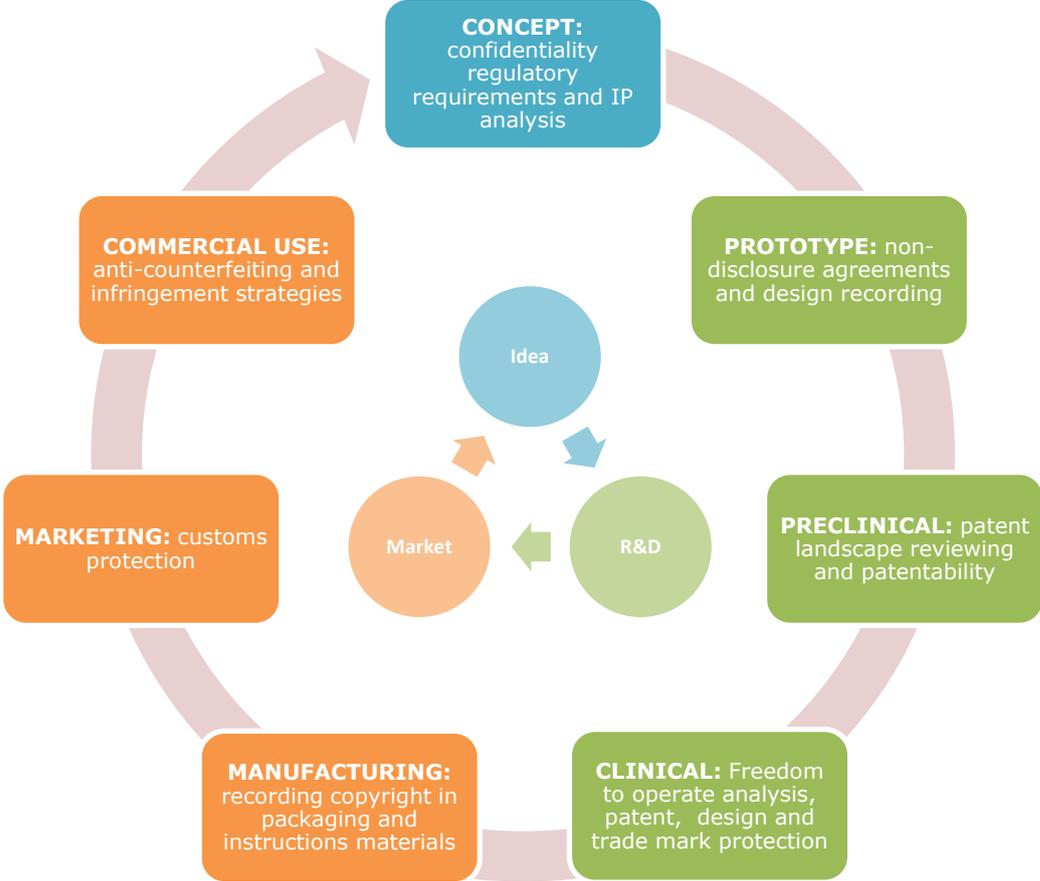
Introduction¹

Medical devices span a broad spectrum of products from simple mass-market products such as disposable gloves to highly technical complex and bespoke products such as surgical implants. They also include diagnostic kits and delivery systems for drugs. Some products are on the borderline between medical devices and medicinal products, and you may need to produce the same level of clinical trial evidence as needed for medicinal products to show that the devices are safe and effective.

Developing and placing a medical device on the European market requires consideration of regulatory requirements as well as Intellectual Property (IP) clearance and protection. Below is a typical product lifecycle for a medical device together with the IP matters to consider at each stage, which outlines the overall

¹ This fact sheet was written by Arty Rajendra and Mary Smillie, solicitors at Rouse Legal.

fact sheet structure. The activities are ordered according to the different stages for convenience, although in reality some activities will be continuous throughout the development. For example, freedom to operate searches should be undertaken for patents at the outset (concept stage) and be repeated at every stage. We have assumed that the medical device will undergo some preclinical and clinical testing although this may not always be needed.



1 Concept Stage

1.1 Educating the Project Members

When you conceive a new medical device, it is important that those involved in the project understand that they should keep confidential the concept, technical details and any design drawings or other documents which reveal the shape of the medical device. This is because certain types of IP protection will be lost if there has been prior disclosure. You should educate your project members and particularly inventors to understand this need for secrecy.

Generally, IP rights created by employees in the normal course of their work are owned by the employer. Care must be taken if you use an outside agency as you will not automatically own the resulting IP. You need to make sure that you acquire all the ownership rights you need, which may mean asking any outside agency to assign the IP rights to you. Ownership rights can often only be

transferred in writing so you should formalise ownership and assignment details clearly in a written contract.

1.2 Regulatory Requirements

Medical devices must comply with one or more of three European Directives which cover medical devices, implantable medical devices and in vitro diagnostic medical devices. These are:

- *Directive 93/42/EEC of 14 June 1993 concerning medical devices ('MDD')*
- *Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices ('AIMDD')*
- *Directive 98/79/EC of 27 October 1998 on in vitro diagnostic medical devices. ('IVDMDD')*

These Directives classify medical devices based on the risk of their causing harm to patients. Higher risk devices need to be assessed by an independent notified body and manufacturing facilities are inspected before the device can be placed on the market. Lower risk medical devices do not require close or any external monitoring.

EU Directives are implemented into the national law of each Member State so regulation is achieved at a national level. In practice, this means different Member States can interpret the law in different ways. For instance, in 2013 the Court of Justice of the European Union (CJEU)² held that the same product could be classified as a medicinal product in one Member State, and as a medical device in another Member State.

The manufacturer, Laboratoires Lyocentre, wanted its product Gynocaps to be classified as a medical device in all Member States, but this was refused in Finland where the Court held that the Finnish Regulatory agency was entitled to classify Gynocaps as a medicinal product even though it is sold as a medical device in other Member States.

However, this position will change when these Directives are replaced by two new Community-wide Regulations, one on medical devices and one on in vitro diagnostic medical devices. The texts of these new Regulations were adopted by the European Parliament in April 2014 and they are likely to come into force between 2018 and 2020. Unlike Directives, Regulations become binding automatically without the need to be implemented by national laws, so there is less scope for disagreement.

² The CJEU helps national courts interpret European law.

1.2.1 CE Marking

All medical devices put on sale in the European Economic Area (EEA) must bear a CE mark before the device is placed on the market. CE marking does not mean that a device was made in the EEA, but merely indicates that the device was assessed before being placed on the market in the EEA and conforms to the legislative requirements to be sold e.g. a harmonised level of safety.

If you are the manufacturer, you must carry out the conformity assessment. You must also issue the EC Declaration of Conformity and affix the CE marking.³

1.2.2 EMA Support

The European Medicines Agency ('EMA') has an SME helpdesk and, once registered by the EMA as an SME, you may seek free advice which can help with your product development; for example, advice on clinical trials and other tests. At the time of writing 33 out of just under 1000 companies assigned SME status by the EMA are listed as either developing or marketing medical devices.

If your product is on the borderline between a medicinal product and a medical device, you should consider seeking such advice. If there is a choice in developing your product as a medicine or a device, you should weigh up the pros and cons of the two routes carefully. Laboratoires Lyocentre (involved in the CJEU case mentioned above) presumably wanted to avoid the additional regulatory burden of registering Gynocaps as a medicinal product. But there may have also been other considerations such as the reimbursement price. As will be addressed later (under Patents), medicinal products may be eligible for longer patent protection than pure medical devices.

1.3 IP Analysis

At this early stage, you should carry out an analysis of IP. IP protection is available for new product designs, websites, marketing material, brand and trading names. You need to consider how best to protect your new medical device; by patent protection, design rights or by keeping your technical information confidential. You will need to allocate a budget to pay for the cost of registering patents, designs and trade marks.

It is estimated that one third of research and development is wasted on inventions that already exist, so you should be checking what already exists in the field you are working.

³ Further information on CE marking can be found on the European Commission website and in Regulation (EC) No 765/2008.

2 Prototype Stage – Need for NDAs and Confidential Information

This is when your new medical device starts to come alive. Again, it is important to recognise that the project and any prototypes are treated as confidential. If you need third parties outside your organisation to assist in the development of the prototypes, you should ask them to sign non-disclosure agreements (NDAs).⁴

You should also keep copies of any design drawings for the prototype(s) together with the dates and author details, as these may be needed in order to prove when the device was created and by whom. An IP landscape should be reviewed regularly as the design concept further develops into a fully functional design.

3 Pre-Clinical Stage – Patent Considerations

3.1 Patents – An Overview

When thinking about IP protection in the technology field, the first thing you need to consider is patents. Patents protect technical inventions which are novel and involve an inventive step. Importantly you must seek patent protection before the invention is disclosed outside the confines of strict written confidentiality agreements, or you will not be able to get a patent.

Just as importantly, you need to check whether anyone else owns valid patents which your new product might infringe.

You should put a process in place so that your R&D staff understand about confidentiality and have a system for letting management know about their inventions e.g. through the use of 'invention disclosure forms'. This will allow you to make an early evaluation as to whether the results of the research, including any improvements, are patentable and available for use.

Patent protection lasts for 20 years from the filing date and gives the owner a complete monopoly in the invention that the patent covers (assuming the patent is valid). That means you can take legal action against third parties who use the invention without permission. Patents are also licensable and assignable. If you are looking for investment or hope to sell your business in the long term, potential business partners will want to know whether you have good patent protection in place. Some Member States also offer favourable tax incentives to companies who derive income from their patents.

Patent applications can be filed individually in each Member State of interest. This may be a cost effective route to patent protection if only two or three Member States are relevant to your business. However, most companies apply for a single European Patent (EP) application through the European Patent Office (EPO) and designate the Member States in which they wish to seek patent

⁴ For details on non-disclosure agreements, please consult the fact sheet "Non-disclosure agreements: a business tool", which is available in our online library.

protection. The patent application is examined by the EPO and, once approved, is converted into national patent rights in each Member State designated.

3.2 Freedom to operate searches

At this time, you should find out whether any third parties have rights which would stop you from marketing your product. This is done by a search called a freedom to operate search.

Freedom to operate searches may be required throughout the medical device development programme. You can organise searches internally or employ an external agency; whichever approach you take, you need someone experienced in searching. Whoever does the searches or commissions the searches should talk to the project team on a regular basis to keep abreast of all developments. The project team may need to 'design around' any conflicting rights which are identified as a result of the searches, or you may need to obtain a licence from the earlier rights holder if a design around is not possible.

You should perform freedom to operate searches in the territories where you intend to make and/or market your product. The greater the number of countries you search, the greater the number of documents (patent families) which will be identified and require review. This will increase costs. Typically restricting a search to Europe and the USA will give a good idea of the patents and patent applications which exist in the field of your invention.

This however depends on the technology and it may be prudent to include Japan, especially if this is going to be an important target market for your product. Searching in Japan raises language issues (although mechanical translations of documents may be available) and an additional classification system.

The usual approach for searching is to use a combination of patent classification codes, key words, and what you are disclosing in your draft claims. The search could be restricted to concentrate on particular companies and/or inventors that you are concerned are working in the same field of invention.

The extent and frequency of your freedom to operate searches will depend on your budget. This is a suggested check-list to define what should be covered:

- (i) Countries to be included;
- (ii) Key words (and their synonyms);
- (iii) Language – is an English language search sufficient?;
- (iv) Classes to be searched – are there relevant patents in other fields?;
- (v) Competitor companies, if any, to specifically search against;
- (vi) Identification of what exists already, to assess whether your product is truly new or an improvement of an existing product or technical concept. If the latter, identification of the new features which the search should concentrate on.

The search will identify potentially relevant documents and you will be provided with either full copies or the references.

You should consider first the impact of any granted patents.

The status of relevant patents should be checked at each national patent office in the countries of interest to you. It is possible that the patent owner has not paid its annual renewal fee and the potentially blocking patent may have lapsed. The blocking patent may have been revoked by a third party as a result of court action.

If the patent has been recently granted by the EPO, and you think there is a strong argument that it is invalid (e.g. due to prior art you are aware of) you could consider opposing the patent. An opposition has to be filed within nine months of patent grant. An opposition may result in the revocation of the patent or amendment of the claims or the patent may be upheld. It can take 5 or 6 years or longer from the filing of the opposition to the final decision by the Technical Board of Appeal of the EPO.

The downside of filing an opposition is that you make your competitor aware of your interest in the same field of invention. There will also be some expense and management time used up during the years of an opposition. Filing an opposition may also increase the likelihood that your own patent may be opposed at the EPO once it has granted. Some companies opposing patents choose to hide their identity behind a 'straw man' company or a firm of patent attorneys.

Patent applications revealed by a freedom to operate search are the second class of documents to consider. The claims of a patent (which identify the scope of protection) can change during the prosecution of a patent application. Examiners in different countries may accept different amended claims, so when the patents are granted there may be differently worded claims in different countries even though they are all based on the same original document. Also beware of divisional applications which can be filed after the parent application; your new product may not be caught by the granted claims of the parent application but it may fall within the scope of a divisional application.

You may consider filing third party observations against a potentially blocking patent application at the EPO. These can be anonymous. Examiners, however, are more likely to take notice of third party observations when they know who has filed them. Third party observations can be used to raise a piece of prior art or common general knowledge which the examiner is not aware of. Consideration of third party observations may lead to a narrowing of the claims (which then avoid your new device) or rejection of the patent application altogether.

3.3 Patentability of Medical Devices

Patents for medical devices cover the physical product. Patents cannot be granted for “methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body”.⁵ However, this prohibition does not apply to “products, in particular substances or compositions, for use in any of these methods”.⁶

You can seek patent protection for surgical, therapeutic or diagnostic instruments or apparatus. But you cannot protect such instruments or apparatus if they are only new as a result of the way they are intended to be used in therapy or surgery. You should ensure that your patent application is drafted to avoid the exclusions relating to medical methods. For example, a method for operating a pacemaker so that its output to the heart was adjusted was refused patent protection because this amounted to a method of treatment.

You cannot obtain patent protection for a known medical device in respect of a second medical use. For example, if an injector pen is known for injecting insulin to treat diabetes, you will not be able to obtain patent protection for the same injector pen to deliver another drug to treat a different illness.

As previously mentioned, some products fall on the boundary between a medical device and a medicinal product. If your product is classified as a medicinal product, you may be able to extend the life of your patent by up to five years, by obtaining a supplementary protection certificate (SPC). The SPC is intended to make up for time lost in getting the product approved by the regulatory authorities before it can be sold. If you do obtain an SPC, you may also be able to extend its term by a further 6 months under the Paediatric Regulation if you conduct clinical trials in children. There have been different national decisions about whether an SPC can be granted for a medical device. Generally, medical devices do not qualify: for example, in 2014 the UK Intellectual Property Office turned down three SPC applications for medical devices. However, the situation may be different in other Member States such as Germany, France and Italy where occasionally SPCs for medical devices have been granted.

3.4 Consider Patentability

At this preclinical stage, you should consider whether patent protection is available for your new medical device. You should consider seeking patent attorneys’ advice since they can assist you in this complex task and provide information on the timing, territoriality and costs of patent protection.

Patents are national rights. This means an EP will not provide any protection in territories such as the United States and Japan. It is important to consider your international patent strategy at an early stage because the filing and publication

⁵ Article 53 (c) of the European Patent Convention.

⁶ Article 53 (c) of the European Patent Convention.

of your first application will usually mean that the invention is no longer new in other territories, and so cannot be patented after one year from the first patent filing. You should also note that inventions in the field of medicinal products and devices are handled differently by different countries, which may have a significant impact on the way in which you approach protection internationally.

4 Clinical Stage - Design Considerations

By the Clinical Stage, you will have a better idea of whether your medical device is worth further investment. You may have already carried out freedom to operate searches for patents⁷ and now is the time to consider doing them again for patents and also to consider designs⁸.

4.1 Designs – An Overview

Design rights can be a very useful and relatively inexpensive way of protecting your entire medical device or parts of its design. They can be registered or unregistered. Very broadly, they protect what your product looks like and can be used to stop competitors making or selling a similar looking product.

If your medical device is new and has individual character (see below), you will automatically have European unregistered design rights which will protect it from unauthorised copying. The European unregistered design right lasts for three years. With unregistered design rights you are additionally required to prove that your competitor has copied your design to succeed in a claim against it. There are also national registered design rights available in individual Member States but here we will concentrate on Registered Community Designs (RCDs), which cover the whole of the European Union.

Medical devices which deliver medicinal products can be, and are very often, protected by RCDs. Designs have been registered for medical devices such as blood sampling devices, diagnostic devices, stents and heart rate monitors. Images of some RCDs are shown below. RCDs may be easier to enforce than unregistered designs, because unlike unregistered designs, there is no need to prove copying.

4.1.1 Whether or not you apply for an RCD

RCDs are registered at OHIM (Office for Harmonization in the Internal Market) which is based in Alicante in Spain. They are valid for five years and can be renewed in blocks of five years up to a maximum of 25 years.

4.1.1.1 Priority

You can only get a valid RCD if it is new and has individual character. It will have individual character if the overall impression it produces on the informed

⁷ See paragraph 3.2 of this factsheet on patents

⁸ See paragraph 4.1 of this fact sheet on designs.

user is different from the overall impression produced by other existing designs. The date on which the product must be 'new' is the so-called 'priority date'. This is either the date you apply to register your design in OHIM, the date you apply to register the design in another design registration office, or the date on which you first market your product in the EU. Which of these three dates will count depends on the circumstances, so it is important not to publish your design anywhere in the world before considering its protection. You should consider seeking professional advice before deciding how you want to proceed.

Although you can leave registration of an RCD to later in the product development process, including after you have marketed your product, there are good reasons to consider registration as early as possible. The main reason is to make sure that your design is still counted as new when you apply to register, particularly as a competitor may register a similar design if you leave it too late.

4.1.1.2 Registration

RCDs are not subject to rigorous examination so it is relatively easy to obtain registrations by submitting suitable images of the designs. You can apply to OHIM to register on-line. It is important to supply good quality images because any infringing products will be compared against the design as registered.

There is no requirement for articles to be marked to show that design right is claimed, nor is there any symbol for design right equivalent to the © symbol used for copyright works or ® for a registered trade mark. You may wish to mark goods or packaging with the words "Design Right", the owner's name, registration number and year of first marketing. This should act as a deterrent to potential infringers, and assist in any claim against infringers.

When deciding what to register, it is also important to think about not only how your own product looks, but also how copycat products might look, and apply to cover those designs too if you wish.

4.1.1.3 Protecting your product

The fact that it is relatively easy to obtain RCDs is a double-edged sword because it is not unusual for RCDs to be found invalid by the courts during infringement proceedings. The validity of an RCD is considered in the light of similar designs which existed at the priority date and the amount of design freedom available to the designer – i.e. how much freedom the designer had when coming up with the design. Your RCD will be infringed by a product which produces the same overall impression on an informed user of the device as the RCD does. This is assessed by comparing the allegedly infringing object with the RCD to establish the extent of the similarities and differences between them.

RCDs can be very useful to help stop counterfeit products coming into the EU.⁹ They can also act as a deterrent to distributors of 'me-too' products who want to 'ride on the coat-tails' of a successful and innovative design.

4.1.2 Classification of Designs

Design registrations are not limited to any particular use. For example the designs for a laundry ball and a massage ball may have a similar appearance. One registration will cover both uses. This makes it difficult to be certain that a freedom to operate search has found all earlier similar designs. However, the Locarno Classification, established by the Locarno Agreement of 1968, is an international classification used for the purposes of the registration of industrial designs. Medical devices are usually classified in Class 24: Medical and Laboratory Equipment.

Devices which deliver medicinal products such as inhalers and pre-filled syringes and injector pens may also be classified in Class 28: Pharmaceutical and Cosmetic Products, Toilet Articles and Apparatus.

Electronic cigarettes which are considered medical devices by regulatory authorities may also be classed in class 27: Tobacco and smokers supplies.

4.1.3 Searches

Care must be taken when searching for earlier designs to ensure that all classes which medical devices can fall into are covered, so searches as a minimum should include classes 24 and 28.

4.1.4 So what can you register?

A search of designs for medical devices in class 28 which have been filed and registered in 2014 indicates that a wide range of approaches are currently taken by medical device manufacturers/designers.

Some companies have filed the same design in different colours e.g. Polar Electro Oy's heart rate monitor belt, which also includes images in different aspects.



⁹ See paragraph 6.2 of this fact sheet on customs protection.

Photographs can give clear images of the design but will give narrower protection. Generally it is preferable to file line drawings showing different aspects of the design. Pari Pharma GmbH has filed both photographs and drawings for its nebuliser (photographs) and part of nebuliser (line drawings) shown below.



Application No. 002411470

Line drawings which clearly show distinctive features are the best way to represent the design.

Designs are registered by different companies for the same type of medical device. For example, blood glucose monitor designs have recently been registered by Samsung and Akray Inc using line drawings.

As you can see from the examples of the nebuliser it is possible to register parts of the design.

4.1.5 How to avoid copying someone else's design

When approaching the design of your product it might be helpful to use a "clean room design". This is done by giving a technical specification for your product to an independent design team which has no connection with (nor awareness of) other products or designs. You then ask that team to produce designs for you which implement the specification. Because the design has not been copied, this "clean room" method offers a defence to any copyright or unregistered design right claim, which can only succeed if there has been copying. The new designs can then be reviewed against existing RCDs (where copying is not relevant) to select a design which will minimise the risk of encroaching upon existing registered rights.

4.1.6 Keep full records of every stage of the design and preserve original drawings and prototypes

National laws lay down rules about ownership of designs e.g. under UK law the basic rule is that the designer¹⁰ is the first owner of UK design right. If the design is created 'in-house' by an employee, in the course of employment, the design is owned by the employer. As discussed above, you should make sure that you have all the ownership rights you need, by way of a written assignment if appropriate.

5 Clinical Stage – Trade Mark Considerations

You will want to give your medical device a distinctive brand name which enables consumers/health care professionals to identify the origin of your product. Distinctive brand names (and logos) are protectable as trade marks.

5.1 Trade Marks – An Overview

Your brand name needs to be protected in the best possible way to stop third parties from using a similar name which confuses consumers/health care professionals or which otherwise takes advantage of your brand name's reputation. Broadly, registered trade marks protect distinctive marks against third parties' use of identical or similar marks on identical or similar goods. The registration lasts for 10 years, and can be renewed for further 10 year intervals on payment of renewal fees.

It is a good idea to register your trade mark before you launch your product. Trade mark applications can be filed in individual Member States if you wish but are more commonly filed for Community Trade Marks which cover the whole of the EU.

However, if you use your trade mark before it is registered, you can indicate that you are using it as a brand name by using a TM suffix e.g. PipelineTM.

When choosing your brand name, avoid names which overstate the efficacy of your device or imply that it is unique in its effectiveness or claim superiority over similar products which cannot be substantiated.

Like other IP rights, trade marks give rise to two concerns – clearance and protection.

5.2 Trade Mark Clearance

Clearance is needed to ensure that your brand name does not infringe a third party registered trade mark, exposing you to legal proceedings resulting in withdrawing your product/changing your brand name, handing over your stock

¹⁰ the designer is the person who creates the design or makes the arrangements for computer-generated design

and paying damages or profits to the prior trade mark holder. Unregistered marks can also be enforced against your product in passing off or unfair competition proceedings. It is wise to plan your trade mark clearance strategy at least 12 months before launching your product and conduct the clearance in stages. For example, you may wish to start with the UK, Germany and France first, and then move on to searching in other Member States.

Properly done trade mark searches should reveal all the pre-existing registered trade marks which are similar or identical to your proposed mark.¹¹ However, since many medical devices are branded with partially descriptive names (which are not always registrable), in addition you should carry out an 'in-use' search of unregistered trade marks being used by third parties, particularly your competitors.

If you find marks identical or similar to your mark as part of your trade mark clearance process, you may decide to find and apply for an alternative trade mark or make changes so that you avoid conflict with any pre-existing rights.

5.3 Trade Mark Protection

Trade marks for medical devices may be registered in different classes, which, unlike design registration classes (see above) will affect the scope of the protection they give you. As a minimum, you should consider filing for protection in classes 5 (pharmaceutical and veterinary preparations) and 10 (surgical, medical, dental and veterinary apparatus and instruments). Class 9 (electrical and electronic items) is also of increasing importance for devices in the MedTech sector.

It is common for medical device manufactures to file in several classes. For example, a trade mark for an in vitro diagnostic test for blood glucose is currently registered in:

- (i) *Class 5:* In-vitro diagnostics for medical purposes; chemical products for checking in-vitro diagnostic test results for medical purposes.
- (ii) *Class 9:* Computer software and computer hardware for medical purposes; electronic data management systems in the medical sector.
- (iii) *Class 10:* Surgical and medical instruments, equipment and apparatus; apparatus for conducting in-vitro diagnostic tests for medical purposes.
- (iv) *Class 41:* Providing of training, education and tuition for medical purposes.
- (v) *Class 42:* Computer programming in the medical sector; consultancy in the field of diabetes for professionals and patients; data management for medical purposes.

¹¹ To help you understand how these searches are performed, consult the fact sheet "How to search for trade marks", which is available in our online library.

If you file for trade mark protection across a very broad range of goods or services you increase the possibility that your trade mark application will be opposed by a third party. Oppositions before OHIM (which is responsible for the Community Trade Mark) and national trade mark offices (which are responsible for national trade marks) can take several years.

It is prudent to apply for more than one trade mark if there is a risk of your first choice being successfully opposed or rejected. In the case study below, the time from application to final rejection of the application for a Community Trade Mark was almost three years.

Case Study: Application for the trade mark 'Pipeline'

Chestnut Medical Technologies Inc filed an application in 2008 for a Community trade mark for the word PIPELINE in Class 10 'Medical devices, namely devices used in the treatment of aneurysms'. The product was launched in 2010.

The Community trade mark application was examined and in January 2009 it was refused for registration on the basis that it was descriptive, not distinctive. Chestnut appealed, but the refusal was upheld in June 2009. Chestnut appealed to a higher tribunal in August 2009, but once again the refusal was upheld. Finally, Chestnut appealed to the General Court of the Court of Justice of the European Union but the case was not heard until 2011 (and the product had to be launched in Europe under an unregistered brand name). The General Court also refused the application.

Chestnut were purchased by a company owned by Covidien.

Covidien applied for and obtained registration for the stylised trade mark below in 2012 within 5 months of filing. This was assisted by narrowing the classes and specification after application.



What lessons can be learned from the case study?

- Avoid marks which are purely descriptive of your product. The name chosen should be unique and as distinctive as possible.
- File your trade mark application as early as possible and have a back-up in case your first choice is refused or opposed.

6 Manufacturing Stage – Copyright Considerations

Artwork and text on packaging, instructions leaflets and advertising is likely to be protected by copyright.

6.1 Copyright – An Overview

Copyright protects, amongst other things, original artistic and literary works. The works have to be original in the sense that they are not copied from pre-

existing works. Copyright arises automatically and usually vests in the employer if the work has been created in the course of employment. If you are commissioning a third party, such as a graphics designer or advertising agency, to produce works for you, it is best to obtain an assignment of the copyright, in writing.

Copyright is a national right but the law is harmonised to some extent across the EU. The term of copyright protection is harmonized across the EU, but what is protected by copyright, and when it can be enforced, varies from Member State to Member State. There are differences in the periods within which works which have been commercially produced or exploited can be enforced against third parties.

Copyright is infringed by copying. Copying can sometimes be identified and proved by the copying of errors or deliberate 'mistakes'. It is not an infringement if a third party creates artwork or text completely independently.

It is helpful to mark any packaging, instructions leaflets and advertising with a © notice as this may deter potential infringers and is generally prima facie evidence of ownership.

7 Commercial Use – Anti-Counterfeiting Considerations

Once your product is on the market, third parties may be tempted to copy it. You should by now have IP protection in all countries where you intend to manufacture and sell your products. Now is the time to start using them.

7.1 Customs Protection

IP rights such as trade marks, patents, designs and copyright, can be recorded with EU Customs authorities. Customs are able to check goods as they enter the EU for the first time. If the goods are suspected of infringing an IP right which has been recorded with them, they may be at risk of detention by EU Customs. For anything other than very small consignments, the IP owner and importer is notified of the detention. Ultimately, customs have powers to seize and destroy goods which infringe IP rights in their Member State.

Customs are very good at spotting goods which infringe trade marks and RCDs, particularly counterfeit goods, and are becoming increasingly adept at spotting and detaining patent infringing goods.

It is recommended that you record your IP rights with customs as this is a very effective border enforcement measure against allowing counterfeit goods entering the EU market.

It is useful to have a written anti-counterfeiting standard operating procedure so that someone internally is responsible for dealing with any counterfeits and can notify and liaise with the appropriate regulatory bodies if necessary.

7.2 Overseas protection

Successful products, including medical devices, are targets for counterfeiters. China and India are known source countries for counterfeit medical devices. So even if you do not sell your product in those countries and have no plans to sell there, you may consider obtaining IP and customs protection there so that you can tackle the Chinese and Indian manufacturers and exporters of counterfeits at source.¹²

8 Commercial Use – Infringement Considerations

Now you are on the market, you may find third parties making and selling products which you feel are too similar to your own device. Third parties will also be watching you.

It is useful to have an internal procedure to deal with infringements, whether offensive (suing a third party infringing your IP) or defensive (being sued by a third party for infringing their IP rights). The costs and procedures of IP litigation vary across Member States but it is prudent to set aside a budget for IP cases so that you have a fighting fund if needed.

If you assert your patent against a competitor, it is very likely that they will try to revoke your patent. Such disputes can become multi-jurisdictional and lead to different outcomes across Europe for the national designations of the same EP. However, in the future (2016 at the earliest) a new unitary patent is to be introduced, together with a new Unified Patent Court (UPC). The UPC will determine patent disputes for all 25 participating Member States for unitary patents and opted-in EPs. This is expected to bring down the cost of litigation of patents and make it more accessible to SMEs.

As the market for medical devices grows and becomes ever more crowded, getting a commercial edge over your competitors is of even more importance.

Good IP protection is one way to do that and the value of your IP, particularly if you are looking for investment or to sell your business to a larger corporation, should not be underestimated. There is plenty of publicly available information and specialist advisers can provide more bespoke advice.

The European IPR Helpdesk can provide first-line advice through its Helpline and can help you find contacts of IP professionals near you, since it is important to contact someone with the right skills and experience.

¹² The European Commission funds services that provide first-line assistance on intellectual property in China and India. The services are provided by the China IPR SME Helpdesk and the European Business and Technology Centre (EBTC) in India.

Useful information

- *Fact sheet on "Confidential business information":*
<http://www.iprhelpdesk.eu/node/1265>
- *Fact sheet on "Non-disclosure agreements: a business tool":*
<http://www.iprhelpdesk.eu/node/969>
- *Fact sheet on "How to search for patent information":*
<http://www.iprhelpdesk.eu/node/665>
- *Fact sheet on "How to search for trade marks":*
<http://www.iprhelpdesk.eu/node/1387>
- *Fact sheet of the China IPR SME Helpdesk – "Guideline on Medical Device Industry IPR Protection in China":*
http://www.china-iprhelpdesk.eu/docs/publications/Medical_Devices_Guide.pdf

GET IN TOUCH

For comments, suggestions or further information, please contact

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ABOUT THE EUROPEAN IPR HELPDESK

The European IPR Helpdesk aims at raising awareness of Intellectual Property (IP) and Intellectual Property Rights (IPR) by providing information, direct advice and training on IP and IPR matters to current and potential participants of EU funded projects focusing on RTD and CIP. In addition, the European IPR Helpdesk provides IP support to EU SMEs negotiating or concluding transnational partnership agreements, especially through the Enterprise Europe Network. All services provided are free of charge.

Helpline: The Helpline service answers your IP queries within three working days. Please contact us via registration on our website – www.iprhelpdesk.eu – phone or fax.

Website: On our website you can find extensive information and helpful documents on different aspects of IPR and IP management, especially with regard to specific IP questions in the context of EU funded programmes.

Newsletter and Bulletin: Keep track of the latest news on IP and read expert articles and case studies by subscribing to our email newsletter and Bulletin.

Training: We have designed a training catalogue consisting of nine different modules. If you are interested in planning a session with us, simply send us an email at training@iprhelpdesk.eu

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