A PRACTICAL GUIDE TO INTELLECTUAL PROPERTY FOR MEDICAL TECHNOLOGY COMPANIES
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The global MedTech industry is growing steadily by around 5% per annum and is expected to reach over $500 billion by 2022. Ireland is the largest per capita exporter of MedTech products in Europe and the seventh largest exporter of medicinal and pharmaceutical products in the world.

MedTech currently contributes over €12.6 billion per annum to the Irish economy. Over half the 450 MedTech companies currently located in Ireland are indigenous and over 60% are engaged in R&D activities. Meanwhile, the pharmaceutical industry in Ireland creates over €30 billion in annual exports; there are over 90 biopharma plants and over one third of these are approved by the US Food and Drugs Administration.

Both foreign direct investment and native Irish companies are climbing the value chain by delivering more research, development, design and marketing of innovative technologies across a broad spectrum of industry segments including vascular, orthopaedic, diagnostic and drug delivery devices; ophthalmic and hospital products, and also digital health and connected health solutions.

The Irish Medical Device Association 2020 strategy calls for embedding entrepreneurial thinking and developing a culture of commercialization as opportunities for further developing the Irish MedTech sector.
GIVEN THE SECTOR’S STRONG RELIANCE ON HIGH-QUALITY RESEARCH AND VALUABLE IDEAS, PROTECTION OF THE COMMERCIAL ADVANTAGE FROM INNOVATION IS VITAL.

18 OF THE WORLD’S TOP 25 MEDICAL TECHNOLOGY COMPANIES HAVE BASES IN IRELAND

Creating 29,000 JOBS

9 OF THE WORLD’S TOP 10 PHARMACEUTICAL COMPANIES HAVE BASES IN IRELAND

Creating 25,000 JOBS
2. WHERE DO IP RIGHTS FIT INTO BUSINESS STRATEGY?

Intellectual property (IP) refer to patents for inventions, registered and unregistered design rights, trade marks and copyright.

Medical technology and pharmaceutical companies have the potential to exploit every aspect of intellectual property protection.

In research intensive areas like MedTech, the focus is often on patents which protect the functional aspects of innovation, but the other registered rights of trademarks (which protect the identifiers of the origin of the product), and designs (protection of the aesthetic) should not be forgotten.

For best effect each registered right should be considered and also the importance of other unregistered rights such as copyright and trade secrets (confidential know-how should not be underestimated). It is the collective of intellectual property rights that serve to attribute greatest value to innovation and allow a company to distinguish in the market place.

At Hanna Moore + Curley we recognize that Ireland’s MedTech sector is very diverse, involving research, design and manufacturing, and ranging in experience from nimble start-ups to powerful multi-nationals. This guide broadly reflects the most relevant concepts and strategies across these different groups and sectors but for further information, specific to your needs, please get in touch for more tailored advice.
Q. CAN I AFFORD TO PROTECT MY INTELLECTUAL PROPERTY?

A. Can you afford not to? Investment in intellectual property can focus your company activities in the most fertile grounds, creates valuable assets, and can pay out for MedTech companies in many different ways. If you don’t take steps to protect your ideas, other people may copy the fruit of your labour free of charge - if you have obtained rights you may decide to license or sell them and harvest the value of what you have sown.

Q. AREN’T INTELLECTUAL PROPERTY RIGHTS EXPENSIVE AND SLOW TO OBTAIN?

A. There are different types of IP suited to different situations. The crucial key to success within your optimal budget and timeframe is to fully understand the choices which are available to meet your needs.

Patents in particular have a reputation for being expensive and slow, but costs are only required stage by stage so taking a few relatively inexpensive steps at an early stage can keep the option open for later, without actually committing a large upfront budget.

Trade marks and registered design rights are generally relatively inexpensive; there are even free intellectual property rights which you can avail of, such as unregistered design rights and copyright.

A SMALL KNOWLEDGE INPUT FROM AN EFFECTIVE IP PROFESSIONAL SHOULD DIRECT YOU TOWARDS THE MOST APPROPRIATE STRATEGY AND HELP YOU STAY WITHIN A PRAGMATIC BUDGET.
3. INTELLECTUAL PROPERTY CREATES VALUE IN MEDTECH

KNOWLEDGE OF IP HELPS COMPANIES IDENTIFY THE BLUE SKY OPPORTUNITIES.

It’s estimated that up to a third of R&D resources are wasted on inventions that already exist. Looking at an existing patent landscape can help smaller companies to save time by knowing what is already state of the art. This can also help companies target the best opportunities and avoid heavily patented technology spaces.

When new technologies emerge, there is typically a “land grab” to secure intellectual property rights. The MedTech arena is experiencing an explosion of synergies with other sciences. The capacities of information technology, data processing and artificial intelligence are advancing MedTech capacity. Other evolving sciences such as nanotechnology and genetic research are finding applications to offer novel solutions to healthcare problems. In vitro diagnostics, combined-treatment devices (such as drug eluting stents, antimicrobial catheters) connected healthcare and personalized medicine are just some of the exciting new hybrid territories for innovation – but as rapidly as prospects emerge, these opportunities are being sought and seized by forward-thinking players in the marketplace.
STRATEGIC EARLY MOVES SET YOUR COURSE TOWARD LASTING COMPETITIVE COMMERCIAL ADVANTAGES.

A strategic patent portfolio is often key to obtaining finance for start-up MedTech companies. For early-stage companies, patents are often the only way for investors to place value on the company’s technology and judge the potential success before sales. When companies are young and cash-flow is typically carefully monitored, it is generally advised to begin by protecting the key features by seeking patent protection which is broad but which offers sufficient patent protection to cover the technology. It is prudent to consider both current and future business objectives and contemplate ways that competitors may attempt to design around the patent.

BUILD WITH INCREMENTAL IMPROVEMENTS TO GROW AND FORTIFY YOUR PORTFOLIO.

As the company grows and makes improvements to its technology, incremental refinements or additions can be patented to ring-fence around the core technology. Trademarks and design rights may also be registered. A growing intellectual property portfolio can increase market share and attract financing through venture capital or private equity investment. Strategic patents can also lead to joint ventures, collaborations and licenses with strategic partners.

Filing international patent, trade mark and design applications strengthens a company’s intellectual property portfolio and expands company’s presence into the global marketplace. Often, it is worth filing in countries with a large target market for the product, countries where competitors’ manufacturing facilities are located, or countries that export such products to other regions. Europe, the United States, Japan, China and Brazil are now increasingly important in the global MedTech industry.

A CONTINUOUS FOCUS ON INNOVATION IS KEY FOR THE INDUSTRY TO THRIVE.

(IMDA Statement of Strategy 2016-2020)
INTELLECTUAL PROPERTY SHOULD BE A PRIMARY CONSIDERATION RIGHT FROM THE INITIAL IDEA THROUGH TO THE FINAL COMMERCIAL END USE OF ANY NEW MEDICAL PRODUCT.

How best to protect the value of your idea depends on your own unique situation, and evolves across time; typically, it may include filing patents to protect the inventive concept, trade marks to protect the brand and trading name, and registered designs to protect the shape and appearance of the medical device.
Diagram of typical IP considerations at the stages of medtech product development
5. INTRODUCTION TO PATENTS

A granted patent is a legal right to the exclusive use of the patented invention. In return for publicly disclosing the invention, the patent proprietor can exclude all others from exploiting (making, using, or selling) that invention for a period of time, usually 20 years. Patent proprietors can take legal action against third parties who use the same inventive concept without proper authorisation.

A patent may be obtained for an invention which is new (novel), not obvious (inventive) and has industrial applicability.

BENEFITS OF PATENTING YOUR INVENTION

Patents are a form of property and therefore may be licensed or assigned, so if you are seeking investment or hope to sell your business, holding a patent portfolio can increase the value and add to the attractiveness of your company for investors. Ireland’s Knowledge Box regime also offers favourable tax incentives to companies that derive income from patented inventions.

BE PREPARED

Existing intellectual property can provide a valuable source of information and so a search and analysis of previously published patents can focus the strategic direction of a project. Specific ‘novelty searches’ give an indication of what the new and inventive features of the invention may be before the patent application is filed. Such a novelty search is conducted using patent databases and should be considered as a preliminary indication of what a patent office may ultimately find as being relevant to your invention.

“Freedom to operate” searches can also help to establish whether any third parties have rights which could prevent you from launching your product.
IMPORTANT CONSIDERATIONS PRIOR TO FILING A PATENT APPLICATION

DON’T REVEAL YOUR INVENTION TOO SOON

If a valid patent is to be obtained, you must not disclose your invention to the public before your patent application has been filed. After an application has been lodged at the Patents Office, the features of your invention, so far as they are described in the patent application, may then be disclosed by you to the public. It is important that you understand where you may need to get ultimate protection and the costs associated, and develop a patent strategy accordingly.

Any prior disclosure can prevent you obtaining patent protection, so it is crucial that everyone involved in the development stage understands the need for confidentiality from the initial concept stage. IP rights created by employees in the normal course of their work are likely to be the property of the employer, it is nonetheless essential to confirm this by including appropriate clauses in your employee contracts. If you are collaborating with others, you should clearly document the ownership of any IP generated by way of a contract or formal written agreement. Ensure that non-disclosure agreements are in place with all relevant parties.

Q. Are European Patents just for large companies?

A. No. In 2016, the EPO reported that almost 30% of service users were SME and individuals.

http://documents.epo.org/projects/babylon/eponet.nsf/0/4E0C5A5BAE0B70C3C12580D5004E7F35/$File/epo_facts_and_figures_2017_en.pdf

Categories of Applicants for European Patents (2016)

- 66% Large Enterprises
- 28% SMEs and Individuals
- 6% Universities and Public Research
A BRIEF OUTLINE OF THE PATENTING PROCESS

The usual first step in the process of obtaining patent protection is to file an initial application for a patent at a Patent Office to obtain a priority date for the invention. The filing of an application provides a limited measure of protection in respect of an invention, and enables the commercial possibilities of the invention to be investigated.

Patents are national rights and it is usually necessary to obtain patent protection in every country that you wish to license or assert your rights. It is important that your business plan influences the patent strategy as it is not necessary to file in all countries immediately. The patent system is inherently a slow-paced process which facilitates spreading costs and postponing many decisions, but it is important that you choose the country of first filing in a manner appropriate to your business requirements.

The initial task involved is to draft a patent application that describes your invention, how it works and what you believe are the features that distinguish your invention from what is already known.

The cheapest country to file in is Ireland; once the patent application is finalised, an Irish application is sufficient to secure an Irish filing date allows inventors to state that the invention is “patent pending.” The significant drawback of an Irish filing is that it will provide no feedback from a patents office regarding relevant prior art.

We would suggest therefore that a better option is to file a UK or European patent application as the first filing as either of these two options will provide you with a patent office search within about 6 months from the filing. The benefit of this approach is that a search will be conducted and an opinion will be provided on the patentability of the invention which is extremely valuable as it will give you, and any potential investors, a good idea as to the likelihood of successfully protecting the invention with a patent. This first filing also serves as a flag in the sand and establishes a 12 month priority period for filing other applications elsewhere in the world that benefit from the first filing date.

If the US market is of interest then a first filing in the US may also be appropriate. Remember, you don’t need a US patent attorney to draft your US patent application.
After submitting the initial application, it is inevitably necessary to take further steps to progress through the examination process to eventually obtain a granted patent. The time line to grant of a patent can typically be between 2 and 4 years though some applications take longer than this. There are also ways to expedite this grant process - US patents can be granted as fast as 2 months.

Patent law is territorial so a patent is only useful in the country in which it is granted. To obtain broader protection for your invention, it is possible to apply for separate national or regional patent applications in all the countries in which you wish to obtain protection for your invention; or to file a single international patent application under the Patent Cooperation Treaty (PCT). Currently, the PCT allows you to seek patent protection in a large number of countries (152 Contracting States). This route is generally simpler and more cost effective, and postpones many decisions and costs while preserving rights.
6. INTRODUCTION TO TRADE MARKS

Trade marks are signs used to distinguish between your goods or services and those of competitors. Many recognisable indicators can function as trade marks, including letters, words, logos, images, colours, slogans or even sounds and three dimensional shapes.

Registering your trade mark provides you with a monopoly right to the use of your mark on your goods and services. Although it is not compulsory to register your trade marks, doing so provides a business advantage and trade mark proprietors can take legal action against third parties who use the same inventive concept without authorisation.

Holding a registered trade mark is an indicator that your brand is a valuable asset and suggests a level of professionalism which is attractive to investors. It immediately alerts other traders to your understanding of your legal rights, which is a strong deterrent to copycats. Without the legal clarity afforded by trade mark registration, enforcing your rights is considerably more difficult and can be very much more expensive.

Trade marks are registered with reference to your chosen list of goods and services, which need to be specified and categorised. Like patents, trade mark registrations are geographically-patched. Registration can be obtained nationally or across the EU through the EU Intellectual Property Office. There is also a system for extending international trade mark registration administered by the World Intellectual Property Office which provides a streamlined application for registration across many countries worldwide. This is called the Madrid System.

Trade marks can be a valuable asset for businesses, so it is worth giving careful consideration at the outset to developing a strong trade mark. Once you have filed your application, the changes that can be made are extremely limited. A successful registration lasts ten years across most territories and can be renewed indefinitely; however, if your trade mark is not used for a significant period of time for the goods and services that you have obtained registration, it may become vulnerable to attack. For all these reasons it is important to realistically consider your current and intended future needs when planning a trade mark registration.
Trade marks have to be capable of distinguishing your goods and services from those of others. Common obstacles encountered when attempting to register a trade mark include arguments that the mark is insufficiently distinctive or is purely descriptive of the goods or services. Trade marks can also be objected to by third parties if the application would conflict with prior rights, such as the rights already conferred on the proprietors of other trade marks. In the EU, for example, there are more than ten million registered trade marks already in existence, so it is strongly advised to investigate what rights may already exist before filing a new application.

Promoting and using your brand assets effectively is how you really create brand value. You should use your trade marks in the manner they are registered, as correct use is important in maintaining registration. Investing in advertising and promotion helps your consumers recognise your brand so they can correctly identify your products and services and associate them with the brand values you intended.

Like patents, trade marks may be licenced or sold, and are often a very valuable business asset. Trade mark proprietors should monitor the relevant trade mark registers in order to become aware of applications for trade marks which may conflict with their own in good time to take appropriate actions. Trade mark watching services are available to assist with this time consuming task.

BUILDING POWERFUL BRANDS

In today’s crowded markets, brands have to work hard to stand out as a recognisable, credible, and desirable visual and verbal expression of what your business offers. Through repeated exposure, trade marks become instantly recognizable and triggers associations in the mind of the customer about the quality and authenticity of your business. The strongest trade marks are

- Memorable and appealing
- Relevant and appropriate: present an image which aligns with the company’s stated values, and congruent with its behaviours
- Flexible - scale well, work well in black and white or colour, work across different media
- Sustainable - work across linguistic or cultural barriers, and last the test of time
- Used clearly, coherently and consistently
- Legally protectable

Inventing a great brand relies on a little imagination and a good deal of research. A unexpected name or word which has no direct connection to your goods and services will help differentiate you from others in your field, and will offer a greater chance of successful trade mark registration. Invented words can also work well as company names. It may require little more marketing effort to introduce and raise awareness of your company at first, but in the long term it creates a stronger identity. If you’ve got a list of possible new brand identifiers, narrow down by checking if others might be trading under similar names and removing any names which are in conflict. Registers of trade marks, company names and domain names can all be searched.

There are often alternative solutions to trade mark dilemmas. For example if you have already chosen a name which is proving difficult to register as a word mark, it may be possible to file a graphical version. Logos may also be registered independently, either as trade marks or as registered designs. A trade mark attorney should be able to discuss your options so you can decide the most appropriate strategy to suit your business and budget.
Effective design is a challenging, knowledge-rich and time-consuming aspect of the MedTech industry. The creative capacity to respond better to the combined requirements of patient and healthcare professionals – and to consider both physiological and psychological design issues – can both improve patient compliance and treatment outcomes and add a substantial commercial value. That intellectual property value which is inherent in a design is often overlooked.

Design rights, and particularly registered designs can be a very useful and relatively inexpensive way of protecting the appearance of a medical device or parts of its design. Design rights can be used to stop competitors making or selling a similar looking product, and are very useful as an anti-counterfeiting measure.

Design rights may be invoked even if a design is not registered, but registration of a design is strongly advised as it is simple, relatively inexpensive, and provides a longer lasting and more robust protection. Design rights can be obtained nationally or at EU level from the EU Intellectual Property Office. In order to be registerable, a design must be new and individual.
Both Irish Registered Designs and Registered Community Designs are valid for five years and can be renewed in blocks of five years up to a maximum of 25 years. Registered Community Designs have been registered for medical devices such as glucose monitors, nebulisers, stents and heart rate monitors to name but a few.

It is important to understand who owns the unregistered rights in designs, especially if the design is not done in-house under an employment contract. This can vary in different countries. Prior to commencing design of new products or refinements to existing designs, it may be advisable that your design team complete a suitable non-disclosure agreement, and that the company keep full records of every stage of the design and preserve original drawings and prototypes.
Technology-enabled care improves patient self-management, supports compliance with treatment programmes and medication, and provides monitored data and alerts to healthcare professionals. With growing technology use across the general population and rapid advancements in digital technologies, there are many opportunities but also challenges in the healthcare market. The breadth and intensity of R&D across the connected health space means that innovation has a significant potential for reward, but innovations must be shielded from release into the public domain too early, and fiercely guarded. Alongside the process of innovation, product design with the end user in mind is vital to attaining commercial success. How to navigate the product design process with all these, sometimes conflicting, factors at play, can result in IP aspects being forgotten about until it may be too late. IP tends to be integrally associated with the product design process and cannot be separated from it so it is always best to seek advice from your patent attorney at an early stage in a project.

EFFECTIVELY PROTECTING SOFTWARE-ENABLED MEDICAL DEVICES REQUIRES A BROAD UNDERSTANDING OF INTELLECTUAL PROPERTY

Your IP strategy needs to be aligned with your business strategy. So, the exact nature of your product, your commercial plans, your target market and your budget should all be considered to ensure your IP strategy fits with your overall market strategy. In the connected health space, typically, there may be a hybrid of a physical device which gathers data; and software to process, store or use that data; and present the processed data to a user, whomever that user may be. Protecting all aspects of a hybrid invention can be more challenging than a traditional medical device and so, obtaining effective protection for connected health innovations involving software tends to involve a combination of forms of IP protection, including trade secrets, technical know-how, patents and registered designs.

ARE SOFTWARE-RELATED INNOVATIONS PATENTABLE?

Software related inventions can be patentable but there are additional considerations to be taken into account compare with other technologies.
IS PATENTING OF CONNECTED HEALTH DEVICES EASIER IN EUROPE OR IN THE US?

Up to 2014, the US was seen as a more accessible route to achieving patents for innovative medical technology based on software for its operation. However, this changed as the result of the landmark US Supreme Court decision in the Alice case (referenced below) in 2014. This decision has created some uncertainty with regard to software related applications in the US. On the other hand, the European Patent Office (EPO) has strict but well-established criteria for patentability, and therefore appears to offer a more predictable outcome.

WHAT ARE THE KEY CRITERIA SPECIFIC TO SOFTWARE RELATED INVENTIONS IN THE EUROPEAN PATENT OFFICE?

The general consideration as to whether software is patentable at the EPO is whether the software presents a special technical effect which goes beyond the normal processing of data by a computer. If so, then it can be considered for patenting. However, if, for example, the innovation resides merely in automating the processing of patient data using a computer to implement the same techniques that a doctor would have used, then from a patent law viewpoint, this would be considered normal processing and would not be patentable.

PATENTING SOFTWARE RELATED INVENTIONS IN THE US

As mentioned above, the US has traditionally been relatively liberal in allowing software related inventions. However, in 2014, the procedures for assessing patent eligibility in the US changed as result of the now-infamous decision of the US Supreme Court, Alice v CLS Bank. In this decision the US Court ruled that an abstract idea does not become eligible for a patent simply by being implemented on a generic computer. This added a significant burden to prove that patent eligible subject matter is present and that a US patent could therefore be granted for the invention.

In more detail, a new two-stage legal test was introduced after the Alice judgement to assess if a patent claim is directed to patent eligible matter. The first stage of the test involves consideration of whether the patent claims is directed to a new and useful process or machine, or a new and useful improvement to a process or machine. If this first step criterion is not satisfied, then the patent application will be rejected by the USPTO. If the first hurdle is overcome, then secondly, the claim will be analysed to assess if it is directed to an ineligible matter or abstract ideas. In summary, the patent claim must at least identify some technical features which are more than an abstract idea.
However, in practice, the lack of definition of what is considered “abstract” in the two-step test introduced uncertainty which made the outcome of filing patent applications for computer-related technologies at the USPTO unclear. Since the Alice decision, many applications related to computer-related technology have been refused by the USPTO.

It is of note that the Alice decision was not specifically directed towards a device operated by “computer-related technology”. The dilemma concerning “computer-related technology” was more specifically addressed in the post the Alice decision concerning Enfish LLC v. Microsoft Corp (2016). In this later decision, the US Federal Circuit Court emphasized that claims directed to computer-related technology are not inherently abstract.

Although the Enfish case cast new light on patenting for computer-related technologies, the newly introduced requirements generally appear very strict. It is generally hoped that new case law will establish, more clearly, where opportunities are to be found for obtaining US patents in the connected health space.

### PROTECTING NON-PATENTABLE INNOVATIONS AND PROCESSES

Many valuable aspects of connected health may not be patentable. Keeping commercially sensitive information secret is likely to be very important to your business. If you imagine the intellectual assets of your company as an iceberg, patents would be the visible aspects and trade secrets the submerged part. In July 2017, the European Union Intellectual Property Office’s Observatory released a report examining the role and contribution of trade secrets within the IP portfolios of a number of EU firms which found that both patents and trade secrets are likely to be used by companies with internal R&D, and in particular trade secrets are likely to be used to protect process innovations and services. The range of information that can be kept secret is much broader than that for which intellectual property rights may be sought. Technical drawings and designs, prototypes, manufacturing processes, genetic materials and even fragrances may be considered trade secrets. Commercial trade secrets may include customer and supplier lists, business methods and strategies, costs and prices, and other sensitive business information.
Unfortunately legal protection for trade secrets has traditionally been underdeveloped across the globe compared to other areas of law. At present, there is no statutory protection for trade secrets in Irish or UK law and as such, any legal actions are likely to be based on case law relating to breach of confidence, which traditionally relied on three elements – that the information itself had a “necessary quality of confidence”; that the information was shared strictly under an obligation of confidentiality; and that there is evidence of the subsequent misuse of the misappropriated information.

The EU Directive 2016/943, which does provide statutory protection for trade secrets, was adopted on 8th June 2016 and has an implementation date of 9th June 2018. This new Directive will require each EU state to introduce new procedures and remedies, and to provide a minimum set of standards. This will not affect national rules on disclosure (such as Freedom of Information requests), which will be exempt and unaffected; also the Directive prevents retaliation against whistle-blowers “for revealing misconduct, wrongdoing or illegal activity, provided that the respondent acted for the purposes of protecting the general public interest”.

The new Directive mirrors closely the requirements of the UK case law, stating that a ‘trade secret’ means information which meets all of the following requirements:

a) it is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

b) it has commercial value because it is secret;

c) it has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

Potential disadvantages of trade secrets compared to registered Intellectual Property Rights, especially patents, include:

- trade secrets are not IP rights as such and therefore do not benefit from the associated protection;
- enforcement is generally difficult and providing sufficient evidence before courts is crucial
- requires investment and ongoing time and cost towards internal controls to protect against misappropriation
- the invention is not protected against reproduction through reverse engineering, independent discovery or inadvertent disclosures

Unfortunately, the main occurrence of trade secret misappropriation is by employees and therefore, if keeping confidential information secret is vital to your business, it is important to review your employment contracts carefully to ensure that the contracts sufficiently cover confidentiality and the protection of confidential information. Also we recommend that you review your training procedures and ensure you monitor adherence; and ensure that you include protective mechanisms such as non-disclosure agreements, appropriate policies and procedures and apply suitable security systems and document management systems.
PRODUCT DESIGN AND BRANDING IN CONNECTED HEALTH

Connected Health providers need to satisfy extremely high user demands. In 2014, the European Commission carried out a study into barriers to the deployment of connected health which cited healthcare professionals concerns around quality and reliability, and patient rights such as privacy and security. Even in a timeline of a few short years, incremental improvements in each of these areas has been transformative, boosted by the support and involvement of large pharmaceutical companies and accelerated by the entry of global technology companies such as Google and Apple to the healthcare market.

Research into the opinions of healthcare providers and end users, and acceptance of their contributions to the development and implementation of connected health solutions have enabled connected health developers to overcome resistance from both groups, by producing user-friendly products and trusted brands. Connected health products and apps are now in a sales environment in which positive results and outcomes must be proven, but also one where user-centric design and reputation are key to commercial success.

Registered rights to protect your reputation - the value of your brand - can include registered designs and trademarks. The registration processes for both are faster and less expensive than patenting.

Trade Marks are the key visual clues that tell customers your identity, and inspire confidence in your products or services.

Design rights protect the appearance of your product and can include shape, pattern and colours. In addition, to bolster your brand, copyright may be asserted over instruction manuals, leaflets and software code itself.
Medical technologies span a wide variety of products with more than 500,000 product types or 10,000 generic product groups available today. Innovation within the sector is primarily driven by short product lifecycles, similar to the field of information technology. Improvements to break through technologies are often iterative and continuous and innovation is often evolved by and for value-creation.

Technically complex medical devices may be protected by many dozens – or even hundreds - of patents covering the structure, function and/or methods of using the device. Also, surrounding knowledge may be treated as trade secrets or confidential know-how.

In October 2016 the European Patent Office and EU Intellectual Property Office published a joint study on the impact of IP rights on the European economy which concluded that €5.7 trillion is generated every year by IP-intensive industries. For the past 20 years, medical technologies have been the leading category among patent applications filed at the European Patent Office (EPO).

European patent filings are flourishing, with 160,000 new applications filed in 2016. 12,263 of these patent applications were for medical technologies; representing the largest single technology sector. What is interesting is that Philips are the largest single filer.

The latest statistics compiled in 2016 by the World Intellectual Property Organization show that worldwide over 105,000 MedTech patent applications were published in 2014 making MedTech one of the top five technology fields in the world.

How are you performing on this global stage?
10. SUPPORTS FOR THE MEDTECH INDUSTRY

According to Innovation 2020, business sectors that depend on and make strategic use of intellectual property (IP) represent an important and growing part of all modern developed economies. They are the greatest contributors to wealth creation and employment growth. This is part of the rationale for investing in research and the generation of new knowledge.

Key recent government-supported initiatives in this regard include the development of a comprehensive IP protocol that provides a framework for industry-academic collaboration, and the strengthening of the technology transfer offices within the higher education sector, coordinated through Knowledge Transfer Ireland.

Intellectual property is the core asset of knowledge-based enterprise, a strategic tool for value generation, and a key enabler of innovation. IP rights have become building blocks of entire business models, and they must be protected and used efficiently, in the same way as other assets. Effective IP management capability is a fundamental requirement for success in innovative industries.

Over the term of Innovation 2020, the Irish Government has pledged to take steps to:

• Raise awareness in industry of the importance of IP management, and of the opportunities arising from effective IP management.

• Ensure that Ireland is an attractive location for companies engaged in innovative, value-creating activities.

• Use the ‘Knowledge Development Box’, (KDB) announced in Budget 2016, as an incentive to companies engaged in R&D, as it enables them to claim tax relief on profits arising from qualifying IP. The Irish Knowledge Development Box is the world’s first implementation of the approach endorsed by the OECD for the treatment of R&D for tax purposes.

At Hanna Moore + Curley, we are experienced in working with tax specialists in this area and can review your business and advise if you have, or could apply for, qualifying patents or other suitable intellectual property that could benefit from the KDB. As the provisions are based on tax legislation, we strongly recommend that companies also always seek appropriate advice from a suitably qualified tax advisor to ensure they are appropriately informed and correctly positioned to avail of the benefits of the KDB.
DIRECTORY OF USEFUL SUPPORTS

The National Centre for Biomedical Engineering Science, National University of Ireland, Galway  
ncbes.nuigalway.ie  
Tel: +353 91 495165

The Network of Excellence for Functional Biomaterials, National University of Ireland, Galway  
www.nfb.ie  
Tel: +353 91 49 5833

The Centre for Research in Medical Devices (CURAM), National University of Ireland, Galway  
www.curamdevices.ie  
Tel: +353 91 495833

The Regenerative Medicine Institute (REME), National University of Ireland, Galway  
www.remedi.ie  
Tel: +353 91 495 166

CRANN (Nanotechnology Research), Trinity College, Dublin  
www.crann.tcd.ie  
Tel: +353 1 896 3030

Tyndall National Institute (ICT and data analytics), Lee Maltings Complex, Dyke Parade, Cork  
www.tyndall.ie  
Tel: +353 21 2346177

Materials & Surface Science Institute, University of Limerick  
www.ulsites.ul.ie  
Tel: +353 61 213127

Irish MedTech Association, IBEC, 86 Baggot Street Lower, Dublin 2  
www.irishmedtechassoc.ie  
Tel: +353 1 605 1500

Enterprise Ireland, The Plaza, Eastpoint Business Park, Dublin 3  
www.enterprise-ireland.com  
Tel: +353 1 727 2000

The Irish Patents Office, Government Buildings, Hebron Road, Kilkenny  
www.patentsoffice.ie  
Tel: +353 56 772 0111
This short questionnaire can be used as basic self-audit tool to help assess how up to date and comprehensive your IP strategy and portfolio currently are. If you would like to arrange a full IP Audit, or just to talk through aspects of your IP which could be strengthened, please contact us and one of our team would be happy to assist.

**IP AWARENESS AND STRATEGY**

1. Have you got an IP management strategy in place? (If so, when was it last reviewed?)

2. What training have your staff received on the topic of intellectual property?

3. What geographical areas does your company serve? Do its IP assets cover all relevant jurisdictions?
INVENTIONS / KNOW-HOW (PATENTS, TRADE SECRETS)

4. Does the company have a relationship with a professional Patent Attorney?

5. Has the company a file listing all patents and patent applications?

6. Are all patents and patent applications correctly assigned?

7. Are all maintenance fees up to date?

8. Are future renewal dates appropriately docketed?

9. Are the steps for prosecution of pending patent applications appropriately docketed?

10. Does the company keep a track of sales and profit figures based on their patents?

11. Does the company have an invention disclosure recordal procedure?

12. Have all employees executed appropriate invention assignment and confidentiality agreements?
13. Are all consultants and contractors required to execute appropriate invention assignment and confidentiality agreements?

14. Are employees subject to non-compete agreements and is the restraint imposed reasonable in scope?

15. Does the company operate from knowledge or know-how which is not generally known and not readily ascertainable.

16. How are processes or production information, operation manuals, technology information, prototypes or formulas protected or kept confidential in the company?

17. What physical barriers (locked or secured perimeters) or IT protections (passwords and encryptions) are in place to prevent unauthorised access to sensitive information.

18. Are components of trade secrets maintained on a need-to-know basis only (e.g. separated appropriately across departments)?

19. What oversight procedures exist to prevent inadvertent disclosures of sensitive information.

20. Copies of all licence agreements, whether the company is the licensor or licensee.
21. Is the company considering any form of rebranding?

22. Does the company have a relationship with a professional Trade Mark Attorney?

23. What distinctive marks are used to identify the source on your goods / services?

24. List all marks used and note whether they are used consistently or inconsistently across all internal and external communications channels.

25. Has the company conflict-checked any marks used to prevent infringement?

26. Has the company a file listing all registered trade marks and trade mark applications?

27. Are all trade marks and trade mark applications correctly assigned?

28. Are all maintenance fees up to date?

29. Are future renewal dates appropriately recorded and a reminder system in place?
30. Are there trade mark watching services in place internally or externally?

31. Does the company have brand guidelines documents or guides for proper mark usage specifying proper typeface, colour specifications, layout, etc.

32. What quality control steps or oversight processes exist to maintain appropriate use of trademarks by third parties?

33. Does the company have any registered designs?

34. Does the company have any unregistered new and original design for or applied to its goods?

35. Does the company have a list of any original creative works?
36. Compile a list of Business names and Trading names and ensure registration details are accurate.

37. Compile a list of all domain names that are currently registered and active.

38. Compile a list of all inactive / expired domain names.

39. Search for any confusingly similar domain names.
How we can help

Our expert team of patent attorneys is drawn from a wide range of technical backgrounds, including chemistry, engineering and electronics.

Examples of our medical technology experience include:

• medical devices
• instruments and materials used in medical devices such as stents, implants, catheters, syringes and other medical disposables
• dental, ophthalmic and orthopaedic materials
• ophthalmic devices and lenses
• drug delivery systems
• diagnostic instruments
• implantable sensors and other connected health instruments
• surgical instruments
• nanotechnology
• personalised medicine

All of our patent and trade mark attorneys provide practical, commercially-focused business advice. We can help ensure your IP rights are being exploited to the full and that your future filings are in line with your commercial goals. Our attorneys have considerable expertise in the strategic management of MedTech portfolios of all sizes, from international powerhouses to university spinouts to successful indigenous SMEs.

Our trade mark watching service can assist with monitoring trade mark registers for possible conflicts and our renewals service can help with payment of renewal fees for all IP rights across the MedTech sector.