



Intellectual Property Fact Sheet

This is part of a series of fact sheets designed for innovators by the Eastern AHSN Innovation and Industry team.

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2. Product Development
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Download a digital edition from the Innovation Pathway hub on the Eastern AHSN's website:

www.eahsn.org/our-work/innovation-and-industry/the-innovation-pathway

Each fact sheet forms a comprehensive but not exhaustive source of information outlining the intricacies of the Innovation Pathway and are designed to help you navigate your way to a successful outcome. At the end of each fact sheet you will find the hyperlinks to referenced organisations.

You can also access Funding Resources directory at www.eahsn.org/our-work/innovation-and-industry/funding-resources

Overview

Intellectual property (IP) is a term used to describe the rights which protect ideas, inventions, knowledge and other information relating to intellectual creation. IP allows people to own their innovation and creativity, an intangible asset, in the same way as physical property.

IP refers to an agreement between an innovator and the State, and is a recognition for the innovation or creation being made public. The State provides a limited legal monopoly to the owner of the IP. This excludes others from making, copying, importing, displaying or using the innovation for a limited period of time.

The appropriate management of IP is central to commercial success. Without IP protection, an organisation leaves itself exposed to the risk that new ideas, and even a brand, may be copied and stolen by competitors.

There are different types of IP protection to consider that varies from patents to protect technical innovations, registered designs to protect 2D and 3D shapes, and trademarks to protect names, brands and logos. Some products may have aspects that are protectable under each type of IP.

Understanding the requirements to protect, manage and enforce rights in the context of the product development process is essential. This is particularly pertinent where budgets are limited, to ensure appropriate and timely action is taken.

NHS/ Academic Contracts

If you are employed through either an academic institution or an NHS organisation, and engaged in the development of intellectual property, it is advisable to consult an employment contract and employer's intellectual property policy. This will ensure that correct procedures are maintained and an innovator is provided with professional advice and support as and when required.

Types of IP

An innovative business should carefully think about the type of IP protection it may require. To best inform their decision making they should consider different types of IP:

Patents

A patent is a territorial right granted by a country's government to cover inventions that are new, original (involve an inventive step) and capable of industrial application. Patents are monopoly rights to ensure that other individuals or organisations cannot make, use, distribute or sell an invention in the country where the patent was granted without the owner's consent. The owner can licence others to use the invention under agreed terms. In the UK, Patent rights last for up to 20 years, provided annual renewal fees are paid.

Disclosure and Publication

In most countries it is necessary to keep your innovation confidential until after a patent application has been filed, as premature public disclosure could result in an application failing. Public disclosure covers written and oral disclosures, including journal articles, online publishing, conference presentation or in general conversation with people outside of your organisation. Prototypes already on view in a public domain or in use by patients may also count as disclosure.

The exception is where disclosures are covered by an obligation of confidentiality (see Confidentiality section at the end of this leaflet).

Copyright

Copyright is created automatically as soon as a work is embodied in any material form, such as writing, a sound recording, or in electronic form.

It covers a broad range of materials including original literary & artistic works, music, films, sound recordings, broadcasts, and most pertinently, for medical technology development and software. Depending on the nature of the work, the duration of copyright lasts between 50 and 70 years from the death of the creator. There is no official registration process or associated fees.

The purpose of copyright is to allow the author to gain financial rewards for their creative efforts and/or labour and stimulates future creativity and the development of new material. Without any form of protection, it would often be easy for

others to exploit material without compensating the creator. Therefore, most uses of copyright material require permission from the owner but there are exceptions and some minor uses may not infringe copyright.

Design right

Design right protection is very broad and includes the appearance of products or parts of products, logos, graphic symbols, screen displays, typefaces and packaging. There are two kinds of design right in the UK, unregistered and registered.

Unregistered design right arises automatically when a design is recorded in material form and lasts for a maximum duration of 15 years.

Registered design rights must be approved by the Patent Office and if granted, it lasts for a duration of 25 years from the filing date. The requirements for a design to attain design right through registration are that it is new and has individual character which is different to any other design publicly available.

Trade marks

A trade mark can be any sign which is capable of graphic representation and can distinguish the goods and/or services of one trader from the other. Trade marks are often words, but can also be in the form of logos, sounds or 3D objects.

A UK trade mark registration gives its owner the exclusive right to use the registered trade mark in respect of those goods and/or services for which the trade mark is registered.

It is possible to seek UK trade mark registration for up to 45 classes of goods and services, however official fees are charged by class by the UKIPO. It is also necessary for an applicant to confirm they intend to use or has a bona fide intention to use the trade mark for all the goods and services specified.

If a mark is registered for multiple goods and services but then not used for some or all of them, the registration could be vulnerable to cancellation on non-grounds, at least in respect of those goods or services for which there has been a failure to use the mark.

The UK trade mark registration procedure is relatively swift. Examination of an application by the UK IPO usually takes place within a month

of filing. It is possible to secure a registration in 4 to 5 months if there is no official objection by the UK IPO or an opposition by a third party. UK trade mark registrations are renewable at 10 yearly intervals, calculated from the date of application and official fees are payable upon each renewal.

Trade secrets and know-how

Trade secrets include any secret of value which a business wants to keep out of the public domain e.g. formulae or process. Know-how is the expression for 'tricks of the trade' and experience which can make a great impact on the effectiveness of an industrial process.

Know-how can also include 'know-who' and 'know-where'. The scope of know-how is very hard to distinguish and prove. While other individuals can be stopped from using a know-how in principle, this often merges with 'skills' which individuals cannot be stopped from using.

The law recognises the value of trade secrets and know-how which are often used as an extra licensing tool. Unauthorised use of trade secrets and know-how is very hard to detect and once they have been transferred into the public domain their dissemination cannot be stopped. It is therefore very important to protect both trade secrets and know-how with confidentiality agreements.

Researching your freedom to operate

1. While an initial idea is being developed, several IP questions should be considered to help understand whether the work or IP protection should be pursued. Is the product or any aspects of it new and inventive? If so, a patent could be a suitable route for protection. What is the potential scope of the patent production available?

A company may choose to file patent applications for inventions, which may enable them to:

- Protect the company against competitors imitating the invention;
- Define the IP rights on offer, enabling either licensing or selling of the invention;

- Provide confidence to the company to continue to support development of the product, and to similarly provide confidence to external investors interested in investing in the company.

A patentability search of existing technology, patents and published patent applications is recommended before spending the time and money in drafting and filing a patent application. Trademark searches can also provide reassurance before adopting a product name, and assist in developing a brand protection strategy.

2. How similar is the idea to other available products or to inventions that are described in patents/patent applications in patent databases?

Understanding freedom to operate is key. Spending time and effort on good quality searches and results analysis can avoid the need to create costly revisions of a patent application at a later development phase or avoid a late-stage project closure. Patent searches can be carried out by third parties such as patent agents or freely available patent databases, such as Esp@cenet which can be searched relatively easily using keyword descriptive terms.

3. Do any third parties own IP rights that could block its progress into a commercial product?

Third-party rights should be considered along with what dealings might be required with a third party, such as negotiations for in-licensing of rights.

Development Phase

As a product is developed and tested, it is important to ensure confidentiality of the idea, and that up-to-date IP protection is in place. A regular review of the IP status should be carried out and further patent applications filled if the product has materially changed.

For medical devices, development often involves third parties, such as, clinical trials which carries a real risk of confidentiality being breached. Care must be taken to ensure that any IP protection is filed before a device becomes publicly available.

Production Phase

When the product is approved and on sale, understanding of the IP rights owned and a realistic view of their strength will inform and determine the extent to which an organisation can defend the product against competitors.

Equally, when product modifications are made, associated IP protection should be reviewed, even for minor modifications. There may be impact on the protection the owned IP can offer or infringement of IP owned by external parties.

Competitor analysis is recommended and ideally should include a review of the technology, inventor and company level. Information relating to patents being issued, applications being filed or the release or modification of products in the marketplace can provide valuable market and competitor intelligence.

Patent Filing Procedure

Patents generally cover products or processes that possess or contain new or technical aspects and most patents are the subject of incremental improvements to existing inventions. A patent is granted nationally as a statutory monopoly for a specified period, typically 20 years from the filing date.

The first step towards patent protection begins with filing a request for a patent at the Patent Office. This initial disclosure gives the applicant a year of grace from the date of application to seek further, international protection. During this year, it is advisable to determine if the invention has commercial potential. While filing an application early is often recommended, if filed too early and major changes in the invention are being considered, the application may require re-filing.

Close up spacing

The UK Intellectual Property Office has outlined the eight steps for applicants to undertake when applying for patent protection in the UK:

1. A search should be performed to identify any similar patents to ensure an invention is new;
2. Prepare a patent application;
3. File the patent application and request a search from an Intellectual Property Office;
4. A search report will be received (usually within 6 months) and should be reviewed to assist in making the decision on whether to continue with the application;
5. A patent application will be published 18 months after filing;
6. A ‘substantive examination’ can be requested within 6 months of publication;
7. Applicants need to respond to comments from IPO’s ‘substantive examination’. This examination may take place several years after the filing of the application; and
8. The application will be granted or refused.

The time taken to apply for a patent should take no longer than four and a half years, although some applications can be processed more quickly.

International IP Rights Abroad

Patents are territorial rights therefore a separate application is necessary in each country and costs vary from country to country.

Patents in the UK are governed by the Patents Act 1977 and are awarded by the UK Patent Office (UK IPO). Once a UK patent application has been filed, there is a one year period before action must be taken to continue protection in the UK and seek it in other countries.

There are a variety of routes to obtaining IP protection internationally, in addition to filing in overseas countries directly there are international IP conventions and treaties (such as the European Patent

Convention (EPC) or Patent Cooperation Treaty (PCT)). Utilising these approaches can reduce costs and overheads when seeking IP rights in multiple territories.

Due to the costs associated with filing a patent application in multiple countries, companies will often file selectively, tactically considering whether sufficient protection will result if a patent application was filed:

- only in countries where manufacture is likely to take place; and / or
- in countries where most sales are likely to occur.

Costs

Patent protection can be costly. A professionally drafted patent application is important and should be considered a necessary expense within the overall investment. Engaging a patent agent to draft and prosecute the patent application through to grant will ensure the best possible scope of protection for the invention.

Aside from initial drafting and filing fees, further costs relating to international filings, translations, responses to patent examinations and general formalities should also be budgeted for.

The fees involved in obtaining and maintaining IP rights abroad vary between countries and can be unpredictable. For example, post-filing costs are dependent upon the complexity of the IP and whether objections are raised by local patent examiners during examination of the patent.

Additional costs will also be incurred during the patent lifetime, such as renewal costs payable on the fourth anniversary of filing (www.gov.uk/renew-patent). There may also be the costs of legal action if a patent or patent application requires defending.

Due to the associated costs of prosecuting a patent application in multiple territories, there is a strong imperative to understand the market potential and to determine a robust filing strategy.

Confidentiality

The development of an innovative concept will almost always require close working with colleagues, often requiring a range of disciplines. Whilst the disclosure of sensitive data to colleagues employed by the same organisation is usually referenced in the confidentiality clauses of employment contracts, it is important to protect the disclosure of sensitive information when discussing innovative concepts with third parties whom may be contracted by other organisations.

Careful control of information and public disclosure for inventions not yet filed, should be considered carefully. If innovation is disclosed and is regarded as no longer ‘novel’ it may not be eligible for future protection by patent offices. A key operating principle is to only share sensitive information when disclosure is absolutely necessary.

Confidential disclosure or non-disclosure agreements (CDAs/NDAs), are used when there is a requirement to disclose data to third party, either individuals or organisations. These agreements ensure all parties are aware there is a legal obligation to keep the information shared confidential. Any information that is shared with another organisation that is sensitive should be recorded, and marked as confidential.

An organisation that breaches such an agreement can be taken to court. However, even with a CDA in place, it is prudent to consider whether it is necessary to disclose the full details of an innovation.

Summary

- Prior to starting product development it is recommended that the IP landscape is understood. This enables potential competitors to be identified along with hurdles and opportunities and form a robust patent filing strategy.
- Ensure that any discussions with third parties regarding your intellectual property are governed under a confidentiality agreement.

Useful links

Protecting your UK IP abroad

www.gov.uk/government/publications/protecting-your-uk-intellectual-property-abroad

Getting Help

British Library's Business and IP Centre

www.bl.uk/business-and-ip-centre

CIPA IP Clinics

www.cipa.org.uk/need-advice/ip-clinics

www.gov.uk/government/news/intellectual-property-clinics

IPO Health IP Check

www.ipo.gov.uk/iphealthcheck

PatLib Centres (Patent Libraries)

www.gov.uk/government/publications/uk-patlib-network

A network of advice and support covering all UK regions

Esp@cenet

A database of the full text and drawings for patents and applications

http://worldwide.espacenet.com/advancedSearch?locale=en_EP

Details of the IP Act 2014 and relevant background

Overview provided by the UKIPO on the Intellectual Property Act 2014

www.ipo.gov.uk/types/hargreaves/hargreaves-ipbill.htm

Intellectual Property for Business

www.wipo.int/sme/en/ip_business

IP for business tools

www.gov.uk/government/publications/intellectual-property-for-business/ip-for-business-tools

Guide to Patent Searching

<http://knowledge.nic.nhs.uk/documentDetails.aspx?docId=17>

Apply for a patent

www.gov.uk/apply-for-a-patent

Patent and Trade mark Attorneys

www.itma.org.uk

www.cipa.org.uk

Speaking to a local patent attorney or other professional advisor: many offer their first consultation for free

Directory of International Property Offices

www.wipo.int/directory/en/urls.jsp

Office for Harmonisation in the Internal Market Trademarks and Designs (OHIM)

Registers Community trade marks and Community designs

<http://oami.europa.eu/ows/rw/pages/index.en.do>

Community Trade Mark Enquiry

Searching facilities to find out details and status of a European Community trade mark from the number or the mark

<https://oami.europa.eu/ohimportal/en>

Nominet

This site is the registry for UK Internet domain names

www.nominet.org.uk

Community Registered Design Enquiry

Searching facilities to find out details and status of a Community Registered Design

<https://oami.europa.eu/ohimportal/en>

This fact sheet is for your guidance only. It is not exhaustive nor is it meant to replace any official NHS policies or guidelines.