Chapter 18

Intellectual Property Protection and Commercialisation

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Introduction

Developing a successful health technology requires several critical steps in order to achieve success. The starting point is an innovative idea with market potential, meaning that after the idea has been technically developed, it then must have the potential to be accepted by the intended end-users. To ensure acceptance, the idea needs to be tested by involving the end user and/or interested stakeholders, particularly in the case of medical devices intended for clinical use, as patient safety is at stake (Manbachi et al., 2018). These stakeholders can also provide valuable feedback during the iterative process of creating a product from the idea and creating product prototypes. Intellectual property protection may need to be sought to prevent the concept from being used and perhaps even marketed by another party. Intellectual property protection is also important for acquiring funding which will assist the company to create a working market-ready form of the product because protection of the intellectual property provides potential funders with a guarantee of exclusive market opportunities once the product is fully developed. Depending on the type of product, another critical step may include regulatory approval which may have to be sought before the product is allowed into the market.

This chapter presents an overview of the intellectual property rights that can be sought for a new innovation and discusses ways of commercialising a product after intellectual property protection has been obtained. It concludes with factors biomedical engineers should consider when turning a health technology idea into a product.

Intellectual Property Management

Intellectual property (IP) refers to the legal rights awarded for the use of human intellect in the development of something new or original in the industrial, scientific, literary or artistic fields (WIPO, 2004a). Intellectual property rights protect creations and ideas, giving the creator(s) and other producers of the intellectual goods or services recognition for, as well as control of the use of, their creation and its commercialisation (Fisher, 2001; WIPO, 2004b).

Intellectual property laws and rules are socially and economically important as the success of many companies depends on them (Fisher, 2001). Obtaining investment for an idea or concept that is not protected can be difficult. The creator is incentivised to protect their creation to guarantee a competitive advantage upon commercialising it. While

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intellectual property law can drive innovation, it may also limit it, because IP rights limit the use of certain technologies by other people or companies (Flexman & Lazareck, 2007). A balance needs to be struck to foster economic development as well as future research (Spyropoulos, 2007).

In the sections below, the types of intellectual property rights and the steps in intellectual property development and protection are discussed.

Intellectual property can be categorised either as industrial property which consists of trademarks, patents, industrial designs and geographic indications, or as copyright (WIPO, 2004b). In some instances, multiple forms of protection can apply to an invention or creation.

Trademarks

A trademark is a word, phrase or symbol used to identify goods or services manufactured or supplied by a business. Trademarks can be awarded for the brand name, slogan, logo or shape and packaging of the product (Fisher, 2001, WIPO, 2004b). A trademark protects against counterfeiting by preventing the use of similar signs to market inferior products or services.

A trademark is obtained upon filing an application for registration with the national trademark office. If protection needs to be sought internationally an application needs to be filed at each national trademark office of interest (WIPO, 2004a). Alternatively, one can use the World Intellectual Property Organization's (WIPO) Madrid System which is a cost-efficient solution for registering and managing worldwide trademarks (WIPO, 2018a). A registered trademark can be protected for a lifetime if it is renewed every 10 years upon payment of a renewal fee. Trademarks can be sold, bought or licensed.

Patents

A patent is a right awarded for inventions (Fisher, 2001). The invention needs to be a product or process that is a new and non-obvious way of doing something or offers a new and non-obvious technical solution to a problem (WIPO, 2004b).

Patents protect the use of the invention and how it functions and last 20 years from the date of application (Streissguth, n.d.). In most countries, an annual renewal fee must be paid to keep a patent valid. In instances where the innovation is disruptive and has multiple inventions associated with it, an omnibus patent application should be considered (Capron & Wells, 2016).

Patents grant the owner exclusive rights to use, sell or license the invention. It also allows the patent holder to exclude others from manufacturing, using, copying, importing, exporting or selling the invention. When the patent expires, its protection ends and the

invention enters the public domain making it available for commercial exploitation by others. The exclusive rights only relate to commercial exploitation of the invention, they do not prevent a person from running experimental work using the technological information from the patent specification (WIPO, 1997). Patenting therefore does not protect against improving on the existing invention or discovering a different solution to satisfy the same market need. The patent owner is required to make all information regarding their invention available publicly. This enriches the body of technical knowledge in the world, promoting further creativity and innovation (WIPO, 2004b).

Patents are granted by national or regional patent offices. Regional patent offices include (WIPO, 2018b):

- African Intellectual Property Organization (OAPI)
- African Regional Intellectual Property Organization (ARIPO)
- Eurasian Patent Organization (EAPO)
- European Patent Organisation (EPO)
- Patent Office of the Cooperation Council for the Arab States of the Gulf (GCC Patent office)

The process of application differs from one regional office to the next. Filing an application with ARIPO involves specifying the member states in which protection is being sought. In OAPI, a single patent application is required when seeking protection in all member states while with the EPO the countries are selected after the patent has been granted.

Conditions of patentability

To be eligible for patent protection, an invention needs to meet several criteria, including that it must be: 1) useful, 2) novel, 3) inventive (non-obvious), 4) contain patentable subject matter (see below), and 5) have a comprehensive invention disclosure (WIPO, 2004a).

Patentable subject matter

Patent protection is available for inventions from all technology fields which can be categorised as: process, machine, manufacture, composition of matter or any new or useful improvement thereof (Rich, 1960; WIPO, 2004a).

In several countries computer software inventions, usually protected under copyright law, can be patentable. The computer software is patentable if its application is technical ("technical effect") such as instructing a person skilled in the art on how to solve a particular problem using technical means (WIPO, 2004a). In some countries, such as the United States, a software package itself can be patentable even without a technical effect.

Fields of technology exempted from the scope of patentable subject matter in most countries are (WIPO, 2004a):

- Discoveries of materials or substances that already exist in nature.
- Mathematical methods and scientific theories.
- Human or animal treatment methods or diagnostic methods.
- Business schemes, rules or methods.
- Plant and animals and biological processes to produce plants and animals.
- Inventions where the commercial exploitation would contravene public order or morality.

Business schemes may be patentable in the United States.

Industrial applicability

A patentable invention cannot be purely theoretical, it must have a practical purpose. If the invention is intended to be a product, then it should be possible to fabricate it. If the invention is intended to be a process, it should be possible to demonstrate it in practice (WIPO, 2004a).

Novelty

An invention is considered as new if it has not been presented in the prior art anywhere in the world; which is all the knowledge that exists on the area prior to the relevant filing of the patent application (WIPO, 2004a). Knowledge on the prior art could exist either in writing or as documented oral disclosure.

The three ways in which prior art is disclosed are (WIPO, 2004a):

- By description of the invention in published writing or publication.
- By description of the invention in spoken words.
- Using the invention in public, referred to as disclosure by use.

Inventiveness

To be patentable, and invention must also be inventive. This means that it must *not be obvious to a person generally skilled in the art who has knowledge of prior solutions*. This test is very subjective and often a sticking point in getting an invention through the patent system.

Inventorship

The individuals who contribute to the innovative concept are referred to as inventors. Inventorship is a legal determination which is based on the contribution to the concept.

In a patent application, the "true and only" inventors must be listed (Gattari, 2005). The omission of an inventor(s) or the inclusion of persons not involved in the inventive step is regarded as fraud and could result in the patent being nullified.

The invention process has two steps; first, the conception of the idea and second, the reduction of the idea into practice (Gattari, 2005). Reduction involves representing the invention in a physical form. Inventorship focuses on the conception step, therefore, an individual who only spent time and effort reducing the invention is not considered an inventor but an enabler.

Joint inventorship results when two or more people collaborate on an invention, with each contributing to the subject matter. There is no specification in the law of the lower limit of contribution required to qualify as a joint inventor; only that the contribution is significant and inventive (Gattari, 2005). A contribution is significant if it helped make the work patentable, meaning novel and non-obvious.

In the United States, each joint inventor can sell or license their share of the patent without the permission of any other joint inventor. This, however, does not hold true in all countries.

Invention disclosure

Invention disclosure is a confidential document written by the creator of the invention to determine whether patent protection should be sought for the described invention, discovery, research tool, process, know-how or software (University of Texas at Austin, n.d.). In most cases, the invention disclosure is the first official record of the invention. An invention disclosure addresses the technical aspects of the invention while highlighting its novelty and non-obvious nature. It should clearly state the science behind the invention, its advantages over prior technologies, its potential drawbacks and the scope of use (Silverman, 1994).

The invention disclosure may be used to file for a provisional patent application, initiating the patenting and commercialisation process. To facilitate this, the invention disclosure needs to include the technical specifications of the invention. The technical specifications must contain a description of the invention and the manner and process of making and using it in full and exact details that can be understood by a person skilled in the art (Silverman, 1994; WIPO, 2004a). Full disclosure is required for a patent to be granted, meaning that a person skilled in the art should be able to recreate the invention without undue experimentation. It is important to note that it may not be necessary to disclose the "best method or design" but merely "a method or design".

Public disclosure

Public disclosure of an invention involves making it readily available in enough detail that an individual with average technical knowledge in the area would be able to make and use the invention. Public disclosure could also include selling or offering to sell a prototype or showing or telling the ideas to a person who is not a collaborator or inventor of the technology and is not bound by a non-disclosure agreement (University of Texas at Austin, n.d.).

In most countries, patent rights are lost upon first public disclosure or publication. In the United States, however, the United States Patent and Trademark Office allows one year from the date of first public disclosure for one to file a patent (Silverman, 1994).

Patents are generally published by the respective patent offices. This usually takes place around 18 months from the first patent filing.

International Patent Classification (IPC)

The international patent classification is a hierarchical system used to classify patents depending on the technical area of application (WIPO, 2018c). The IPC has eight technology sections with about 70,000 subdivisions (Spyropoulos, 2007; WIPO, 2018c). This system assists with finding patent documents for research on prior art or in the development of technology. Other patent classification systems also exist.

Copyright

Copyright law protects original forms of expression such as, but not limited to: literary works, films, music, artistic works, computer programmes, databases and technical drawings (WIPO, 2004b). It is obtained automatically when the work is presented in a tangible medium without the need for registration. The right holder of the work can authorise or prevent:

- The reproduction of the work in any form.
- Its broadcasting.
- Its translation into other languages.
- Its public performance and communication to the public.
- Its adaptation.

Despite registration not being necessary, a copyright can be registered at the national or regional copyright office. Registration of the copyright is advantageous in that it provides proof of ownership and legal recourse in case of infringement. Copyright registration is effective on the date of submission of the completed application, filing fee and copies of the work being registered (Haskins, 2015). The duration of the copyright protection is

the life of the creator(s) plus a number of years after their death. Copyright can be passed down by inheritance.

Industrial or registered designs (Design Patents)

Industrial or registered design protects the ornamental and aesthetic appearance of a product (WIPO, 2004b). In the United States it is referred to as "design patent" (Horbal, 2014). Industrial design refers to the three-dimensional (shape) or two-dimensional (pattern or colour) features of the product. Industrial designs are applied to a wide range of products such as technical and medical instruments, jewellery, house wares, vehicles, textiles and architectural structures. Designs protected in this way need to be new or original and non-functional, i.e. for aesthetic purposes (WIPO, 2004b). In some countries, such as South Africa, it is possible to register a functional design. It differs from a true patent in that a functional design still protects the appearance of an article, only here the appearance is dictated by the function it is to perform, e.g. a shoe tread.

Industrial designs are protected as they add to the appeal of a product increasing its commercial value and marketability. The owner is, therefore, protected against unauthorised copying or imitation of the design.

If an industrial design is considered novel or original, in that it has not previously been disclosed in public, an application for registration can be filed at the regional or national IP office. The term of protection is generally for 5–15 years, and is limited to the country in which

the protection was granted. Sometimes maintenance fees are required to keep the design in force to the end of its term. In USA design patents last 14 years from the date of approval without any maintenance fee (Streissguth, n.d.).

Trade secrets

Trade secrets protect commercially available information such as food recipes or marketing strategies in an attempt to conceal them from competitors in the industry (Fisher, 2001). Information protected in trade secrets could be patentable if it is novel and non-obvious. Trade secrets are protected without registration for an unlimited period of time. There are, however, some conditions that need to be met in order for the information to be protected as a trade secret by Article 39 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which has 162 member nations (International Trademark Association, 1997) which protects against the unauthorised use of undisclosed information (Makoko & Olivier, 2017):

- It must have commercial value because it is secret.
- The information must be secret.
- It must be subject to reasonable steps by the holder to keep it secret.

If a product or process can easily be reverse engineered, an IP strategy would rather rely on patents. If it cannot be reverse engineered, then it may be beneficial to keep the information secret.

Geographical indications

Geographical indications are signs placed on products from a specific geographical origin and possess qualities or reputation that are due to that origin (WIPO, 2013). Geographical indication prevents the use of the sign for products that do not meet the standard. However, it does not protect against the product being made by replicating the same technique set out in the standards (WIPO, 2013). Geographical indications are used for agricultural products, foodstuffs, wine and spirits, handcrafts and industrial products (WIPO, 2013). Implementation of geographic indications is governed by the TRIPS Agreement in Articles 21-24 (International Trademark Association, 1997).

Steps in Intellectual Property Protection

With the variety of IP available, the first step would be to conduct an audit to determine the IP, registered or unregistered, for which one is eligible (Bridgett, 2015). Thereafter, it is essential to protect the brand, slogan, symbol, or company name as a trademark. Trademark databases can be checked to avoid using existing or protected trademarks.

If an invention meets the conditions of patentability, some factors need to be considered before filing (European Patent Office, 2011):

- Is the patent necessary or can a combination of other IP applications protect the invention?
- Is the cost of patenting (including annual costs) justifiable when compared to the earnings from the invention?
- What is the life cycle of the invention? The patenting process takes 3 to 4 years and in technological fields where products change rapidly, applying for a patent may be a limitation.
- The timing of the application needs to be planned. If it is filed too early the product may not be ready for commercialisation, with most of the patent lifespan spent trying to create a marketable product (this holds true particularly for medical devices and pharmaceuticals where clinical trials need to be factored into the development timeline). If the application is filed too late, someone else may file

first. In addition, the patenting process is a sequence of events determined by international conventions and treaties; once started they cannot be delayed.
- The patent owner is responsible for enforcing the patent, which will incur additional costs.

If patenting is justifiable, a priority application is filed in at least one country, typically the country of residence of the inventor. If it is necessary to apply for jurisdiction in other countries, this needs to be done within 12 months of first filing. One can either file directly in other countries at this point, or file an international patent application with the Patent Cooperation Treaty (PCT). With the PCT one can seek patent protection in over 150 countries depending on the application. With this single application, multiple patent applications are being made in different countries of interest.

The PCT process has two main phases, the international phase and the national phase. The international phase begins with filing and submitting the international application to a PCT-affiliated patent office. After filing a PCT, an international search by an International Searching Authority (ISA) identifies patents, publications and technical literature that relate to the invention and writes an opinion on the potential patentability of the invention. After 18 months from the earliest filing date, the contents of the international application are publicly disclosed. At the end of the international phase, about 30 months from the earliest filing date, is the national phase. At this stage, the applicant must select the countries where protection is sought. This can be done by filing the PCT patent specification at the individual patent offices. Regardless of the outcome of the PCT search report and opinion, the patent application will still be examined by each patent office individually; in most countries this would include a full patentability examination. However, the benefit of filing a PCT is that it postpones the decision to choose countries until 30 months after the first filing, which has a cash flow benefit for most companies and allows them more time to assess which markets are to be protected.

Commercialisation

The innovation process involves the ideation or conception phase, the design and development phase, the prototype phase and the production, marketing and commercialisation phase (Manbachi et al., 2018; WIPO, 1997). Commercialisation is therefore the final step of the innovation process. At this stage the invention is introduced to the market and can begin to generate income to compensate the innovators and manufacturers for their efforts.

Finding an innovative solution to a problem does not guarantee commercial success. Interaction with various stakeholders during the innovation and commercialisation stages is usually required. Networking and building formal networks with key players in industry, venture capitalists and business angels is essential for creating a successful

commercialisation strategy (Ismail, Omar & Majid, 2011). There are various avenues an inventor could use to commercialise; they include:

- Licensing the rights to the invention.
- Assigning or selling the patent rights.
- Starting their own business as a start-up or spin-off.

The following sections will describe these commercialisation paths in more detail.

Licensing

Licensing is the leasing of a legally protected property such as a trademark, copyright or patent to another party (CIPC, 2018; WIPO, 1997). The contractual agreement between the owner of the property (licensor) and the commercial partner (licensee) grants the licensee permission to use the property. Sometimes the licensee is allowed to sub-license the IP to a manufacturer. In exchange, the licensee must pay the licensor a fee or royalties for the access. Specific terms and conditions may be attached to the use such as the purpose of use (limited to certain applications or methods of use of the technology), a defined territory or nation, and a defined time (CIPC, 2018; Ismail, Omar & Majid; 2011; WIPO, 1997). Licences can be non-exclusive, where the licence may be granted to several companies, or exclusive to a single company (Ismail, Omar & Majid, 2011).

Assignment

Assignment is the sale of the IP transferring ownership of the IP to an assignee. This is a business strategy for those who prefer a lump-sum payment over smaller royalty payments over time (CIPC, 2018). The assignor losses all control of over the intellectual property upon payment, but the assignment agreement may include terms that allow for the IP to "fall" back to the assignor in an event where the assignee is not successfully commercialising the IP.

Start-up and spin-off companies

A start-up is a newly formed company which focuses on a product that is not being offered in the market or an alternative to a product in the market that the founders believe is inferior (Fontinelle, 2017; Robehmed, 2013).

In the initial stages, start-up companies have higher expenses than their revenue levels. This is due to the focus on development, testing and marketing of the product. Financing the start-up through loans, government funding, grants from non-governmental organisations or angel investors is essential for their success (Manbachi et al., 2018; Robehmed, 2013). Incubators and accelerators provide start-ups with capital, advice and work space (Manbachi et al., 2018; Robehmed, 2013).

A spin-off or spin-out is the creation of an independent company by a parent company or organisation (Financial Times, n.d.). In many cases, this refers to a company formed by a university to commercialise an invention designed by its academics or students. The disruptive nature of the IP is an important factor in the decision to start a company. In some cases, licencing might be a better option.

Additional considerations for biomedical engineers

One of the most important stages in bringing the products of biomedical engineering to the market, is obtaining regulatory approval. Regulatory approval could take years to obtain and requires a significant amount of money. This is because thorough preclinical tests followed by clinical evaluations are required to prove the safety and efficacy of the invention. Only if these tests are successful can one file an application for, and be granted, regulatory approval.

The adoption of an invention by the health care sector may take some time due to the resistance presented by clinicians to change (Wang, Butner & Darzi, 2006). Some technologies may require clinicians to move away from an established technique or process, introducing a new learning curve. In addition, reimbursement, for example via insurance, needs to be considered in parallel with the regulatory and clinical strategies to ensure that the product is affordable and accessible to its target market. Thus, the road to establishing a health technology company or bringing a health technology product to market, can be costly and long.

For academic biomedical engineers, the relationship with the university and the inventor must be clarified before any disclosure of an invention is made. A defined institutional policy benefits all parties as the inventor is guaranteed not only intellectual and academic rewards, but financial ones as well. The institution benefits by ensuring that its innovations are developed to maximize society's use in addition to promoting economic growth. They will also benefit financially in the event a product is successfully commercialized while retaining some of their most talented and productive faculty. For universities, profit should not be a motivator in bringing research to the market as it is not the primary mission of a university, the time lines to development are long, and it is near impossible to predict which discoveries will result in significant licensing fees, start-up companies or initial public offerings (IPOs).

The timeline for development of a successful commercial biomedical product from a university inventor may take as long as 15–20 years (Figure 1). The steps involved include:

1. *Research.* Whether funded locally or by an extramural source, this critical first step is essential in the development process. The university should nurture research activities that may lead to innovations that can benefit society. Only

a small fraction of the research activities in a university setting will result in a commercial success, however without research, there is no such success. It is almost impossible to select "winners" at the basic research level.

2. *Disclosure*. Inventors need to be educated about the benefit of initial disclosure of their product or invention. Eagerness to publish or present innovative results prior to disclosure can invalidate any future patent claim.
3. *Patents.* Not every disclosure warrants a patent submission. Approximately one half of disclosures will require a patent. Further development of the product continues after patent application.
4. *License.* Once a product or invention has been successfully developed to at least the prototype phase, the inventor has two options: 1) license the product to a commercial entity that can refine development and bring the product to market, or 2) form a start-up company which will continue the development and commercialisation. The licensing approach is certainly the easiest where the licensee takes on the development risks and costs, and the licensor (the university and inventor) accept a royalty in return for giving up the product rights. The start-up company approach is much longer and riskier for the inventor and requires starting a company, raising funds, clinically validating the product, performing market analyses and launching the product into the marketplace. Successful start-ups may be purchased or merged, or may raise more funds through an IPO. While the start-up approach is much more difficult and riskier, when successful, it is typically more profitable.
5. *Profits.* Figure 1 shows the typical time lines from research to profits at universities. In a robust academic research environment, many millions of dollars may be invested in research, resulting in, for example, 1000 disclosures. Of the 1000 disclosures, approximately 500 will typically be patentable. Of the patented products in such an environment, as many as 150 could be expected to be licensed and up to 15 new companies started. Of all the licensed products, only 1 or 2 would be expected to generate an annual licensing fee. Of the 15 start-up companies formed, it would be reasonable to expect that one IPO would occur.

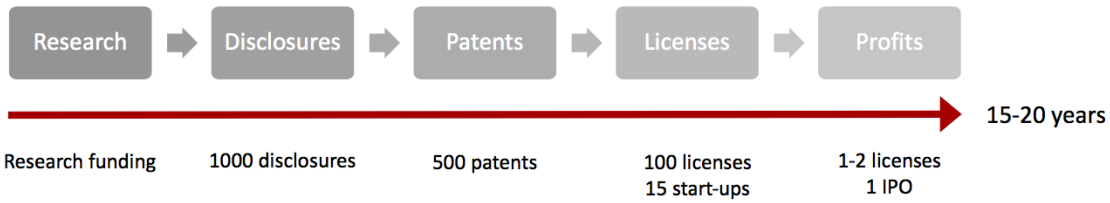

Figure 1. Adapted, with permission, from material provided by Professor Alicia Loffler, Innovation and New Ventures Office, Northwestern University.

Summary

Developing novel biomedical products including drugs, devices, assays, and equipment is a lengthy process that starts with an innovative idea that potentially meets a critical medical need. Research universities worldwide are filled with experienced and talented researchers capable of developing their innovative ideas into useful and valuable medical products. The process is long and high-risk, but rewarding on many levels. The university role ranges from educating the innovators to developing prototypes. Universities may even assist in licensing and start-up activities. A robust development pipeline involves identification and protection of the intellectual property and a clear, well defined partnership between the institution and its inventors.

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