THE DEVELOPMENT OF AN INTELLECTUAL PROPERTY STRATEGY FOR A BIOTECHNOLOGY COMPANY

BY

CHRISTINA HOULIHAN

A thesis submitted to Victoria University of Wellington

in partial fulfilment of the requirements for the degree of

Master of Advanced Technology Enterprise

Victoria University of Wellington

2015

Abstract

The 2014 Masters of Advanced Technology Enterprise (MATE) programme is a multi-disciplinary course with the goal of creating teams that explore the challenges of creating successful technology enterprises. NacreTech is the result of one of the enterprises which has been developed within this course. It has found a market application for a nacre-like material as a biodegradable osteoconductive load bearing materials for orthopaedic implants and developed a target product profile to help guide further material development to out-compete existing materials on the market. In addition a proof of concept testing plan, intellectual property strategy and regulatory analysis has been conducted.

This thesis is based on the author's experience working within NacreTech while applying current knowledge and thinking surrounding protecting intellectual property for biotechnology. In particular, the author has investigated the intellectual property aspects, such as the requirements of the complete specification, filing dates and locations, and existing strategy models, required for commercialisation of the NacreTech biomaterial and examines the factors which influenced the development of the intellectual strategy.

Acknowledgements

I would like to thank the following people for helping me to complete my thesis:

Michael Mettrick and Thomas Sobiecki. Thank you for being a part of the team and all the work you contributed in the effort to commercialise the material.

Melissa Yiannoutsos and Jennifer Anderson from Kerasi Ltd. Thank you for all your help as mentors for our team, we could not have gotten as far as we did with the business development plan without you.

David Ackerley. Thank you for being my supervisor, I know that I ended up having to write my thesis in a completely different field than you are experienced in but thank you for helping me as best you were able.

Richard Souness, Sarah Jane Clifford, Jenny Jebson and Simon Maguire. Thank you for your help with the editing and fact checking of my thesis.

Kathryn McGrath. Thank you for allowing us to use your research; it is a very interesting material with lots of potential.

Contents

Introduction

The purpose of the Masters of Advanced Technology Enterprise (MATE) course at Victoria University of Wellington is to develop commercially viable ideas, products or companies from research or intellectual property which has been created within Victoria University. The investigation into the commercialisation of a piece of scientific research has been completed by an interdisciplinary team formed by three MATE students (including the author). For the purpose of this research project, the team will be referring to themselves as "NacreTech". A business case for NacreTech has been produced by the team and is included within this document as Appendix A.

The aim of this thesis is to draw on the author's experience of the MATE course. The author contributed the intellectual property strategy, regulatory considerations, biological proof of concept, and has provided input into the business strategy in the development of the business case for NacreTech. This thesis is based on the author's experience working within the team while applying current knowledge and thinking surrounding protecting intellectual property for biotechnology. In particular, the author has investigated the intellectual property aspects required for commercialisation of the NacreTech biomaterial and will now examine the factors which influenced the development of the intellectual strategy. The final section of this thesis is a critical reflection upon the author's experience within the MATE course in particular regards to the enterprise, the team and the role.

The Research

The invention which the team worked with is a material developed by Professor Kathryn McGrath. The material is derived from research to investigate and replicate the process by which molluscs (oysters and mussels) form a material in their shell called nacre. The result of the research is a nacre-like material which comprises a chitin scaffold which has been mineralised with calcium carbonate (Munro, Green, & McGrath, 2013).

The market opportunity identified for the nacre-like material is as a biomaterial for orthopaedic applications, specifically the use of the biomaterial as a biodegradable load-bearing bone screw. The identification of this particular market has led to the development of the target product profile which defines the characteristics of the biomaterial such as compression strength and pore size. The current method of making the biomaterial is unable to produce a 3D structure which meets the targets defined in the target product profile. The research team is currently developing the biomaterial to achieve these targets utilising 3D printing. Due to the additional material development the final composition and structure of the biomaterial are unknown, as it the final method of manufacturing the biomaterial. Additional information can be found in Appendix A.

What is Intellectual Property?

“Intellectual property refers to creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce” (World Intellectual Property Organization, n.d.-b). The protection of intellectual property by law allows the inventors to gain exclusive license for their creations and recoup the costs of innovation. One form of protecting intellectual property is through the grant of a patent. The purpose is to protect inventions. The modern form of a patent was created with the ‘Statute of Monopolies’ act by the parliament of England that was passed on 25 May 1624 (Moser, 2013). The ‘Statute of Monopolies’ incorporates the concept of a new manner of manufacture which forms the foundation for much of the patent law of the common law countries.

In addition to patents, there are three other key types of intellectual property protection; these are trademark, copyright and trade secrets. A trademark is a symbol or word(s) which are legally registered or established by use as representing company or product. Trademarks are commonly used to protect a company’s brand icons, which help differentiate their products from their competitor’s products. The most valuable trademark are owned by Apple, Microsoft and Google (Retter & Badenhausen, 2013).

Copyright is the protection of original work which are created, published or performed. Such protectable rights are literary, dramatic, musical, artistic, sound recordings, films or communication works(Intellectual Property Office of New Zealand, 2013). It is important to note that copyright does not protect physical creations and such inventions are protected by patents.

Trade secrets are the final type of IP protection. A trade secret is an invented formula, process, design or other piece of information which is relevant to a company’s success. These secrets are not registered or filed with a governmental agency or granted any rights. Rather, the IP is kept secure within the company itself and withheld from publication.

Patents

A patent is a limited exclusive monopoly to an invention that is granted by a governing body to the inventor of the invention. The grant of a patent and limited exclusive monopoly entitles the owner of the patent the right to make, hire, sell, use, import or license the invention (Patents Act 2013 (NZ), s.18(2)). In order to be granted the exclusive monopoly to the invention, the invention is required to be novel (has not been publically disclosed), inventive (would not be obvious to a person skilled in the art), and useful (has commercial significance).

Benefits

The primary benefit of protecting an invention by patent is the grant of the limited exclusive monopoly to manufacture or sell the invention for a period of 20 years (Patents Act 2013 (NZ), s.20(1)). This limited monopoly allows the inventors to reclaim the expenditure involved in the development of invention and receive revenue from marketing of the invention.

The protection of a patent further provides the right for the owner of the patent to prohibit or sue (Patents Act 2013 (NZ), s.152) third parties or competitors which manufacture or sell the patented invention without license (Patents Act 2013 (NZ), s.140). Therefore if a competitor were to perform the invention the owner of the patent can prevent the competitor from performing the invention and suing for damages or an account of the profits, thereby protecting their investment into the invention.

A patent is generally considered to be of benefit to secure investment in an invention. Investment is of particular importance within the biotechnology, pharmaceutical and medical device industries, as the amount of investment needed to reach market can often exceed $100 million (Makower, Meer, & Denend, 2010). An investor will therefore usually require the invention they are investing in is protected. For medical devices, this is most commonly by a patent as the exclusive monopoly increases the probability that the investors will see a return on their investment.

Disadvantages

One disadvantage to protecting an invention through a patent is that the exclusive monopoly is limited to a period of 20 years from the filing date of the patent application. Once a patent expires the invention is available for public use and the company no longer retains that commercial advantage gained from the exclusive use of the invention.

The limited patent period has, of late, had a significant impact on pharmaceutical companies. In 2011, the patent for the drug Lipitor expired and the owner of the patent, Pfizer, experienced a decline in profit of 19% due to the availability of generic versions on the market (Ahmed, 2014). This effect is known as the patent cliff and between 2011 and 2014 many of the patents on the

blockbuster drugs produced by the pharmaceutical companies expired resulting in significant decreases in profits due to the introduction of generics.

In addition to the limited term of a patent, the cost of prosecuting a patent to grant can be prohibitive. The colloquially cited associated with filing a single patent in a single country is approximately $10,000-$20,000 (Quinn, 2011). This cost increases significantly if the company chooses to file in multiple countries. Every country the company files in will require additional patent attorney fees, foreign patent attorney fees, potentially translation fees, and additional filing, maintenance and/or examination fees. Additional costs will also be incurred if the company chooses to file an international application through the Patent Cooperation Treaty (PCT) system (Barrett, 2003).

Lastly, while the grant of a patent entitles the company the exclusive monopoly to perform the invention, the monopoly is only protected if the company chooses to enforce the patent. If a competing company decides to infringe on the company's patent, the onus is on the owner to litigate against the competing company for damages or profits. Therefore, a patent is only as strong as the company's ability and desire to defend the patent.

Patentable Subject Matter

Not all inventions which are created will be considered to be eligible for a patent. In the Trade-Related Aspects of Intellectual Property (TRIPS) Agreement under section 27.1 a patent should be available and the patent rights used without discrimination as to the place, the field of technology and whether products are produced locally or imported, provided the invention is new, has an inventive step, has utility, and the patent is disclosed in a sufficiently clear and complete enough manner for a person skilled in the art to perform the invention.

There are exclusions to patentability included within the TRIPs agreement. These include inventions that are contrary to morality (such as human cloning), use of diagnostic, therapeutic, and surgical methods, and plant varieties. The exclusions are also included within the statutory legislation of Europe, the United Kingdom, and New Zealand. In addition Europe, the United Kingdom, and New Zealand also exclude from patentability computer programmes, business methods, the presentation of information, discoveries, scientific theories and mathematical methods (Patents Act 2013 (NZ), s.15).

Australia and the United States have different exclusions from patentability. Australia excludes human beings and processes for their generation, and patents which are contrary to law, but Australia do allow patents regarding computer programmes and methods of medical treatment (IP Australia, 2010). In contrast, the United States excludes the use of a law of nature, a natural

phenomenon or naturally occurring relation or correlation, that is, a patent claiming an object which is found in nature (United States Patent and Trademarks Office, 2013).

Type of Invention

An invention is any new or useful process, machine, article of manufacture, or composition of matter (Lehman, 2003). It should be noted however that not all inventions which fall within the definition are best protected by patenting. Cohen, Nelson, & Walsh (2000) developed the terms “complex” and “discrete” inventions to define different types of inventions. A discrete invention is one where the invention is characterised by a limited number of distinct features, such as chemical or pharmaceutical compounds. In contrast a complex invention integrates a range of different technologies and relies on a strong interdependence between the features of the invention, such as electronic products.

A complex invention is generally more difficult to obtain full protection for due to the range of different features present within the invention. Often a company will find that aspects of the invention have already been patented, thus requiring the company to cross-license technology patents. In contrast, discrete inventions are more likely to be patented as the nature of the invention (such as a chemical compound) generally makes them easier to be reverse engineer and therefore not suitable for protection by other methods, such as by trade secret which is discussed in page 31 (Hall, Helmers, Rogers, & Vania, 2014).

Reflection

The intellectual property strategy discussed in Appendix A is centred on protecting key aspects of the invention. These aspects are the composition of the biomaterial, the method of making the biomaterial and the use of the biomaterial. The decision to protect the identified areas of the intellectual property was influenced primarily by the type of invention which the biomaterial is. The biomaterial is considered to be a discrete invention which can be easily reverse engineered by competitors. As a result, a patent is considered to be the best form of protecting the invention as this will allow NacreTech to prevent third parties from using the invention.

The effect of the exclusions to patentability is not considered to affect the ability to protect the key aspects of the invention. The use of the biomaterial as a bone replacement substitute is considered to be patentable, so long as the claims are formulated as a Swiss-type claim in New Zealand and the United Kingdom or as described in Article 54(5) of the European Patent Convention in Europe then the use of the biomaterial in therapeutic applications will be patentable.

The decision to patent was further influenced by the need to secure investment in order to commercialise the invention. The business case estimates that approximately $70 million (Makower

et al., 2010) will need to be raised to complete clinical trials of the biomaterial. Due to the size of the investment, a patent for the invention will almost certainly be required by any investor who will invest in NacreTech. Therefore, registered intellectual property protection such as a patent is considered to be a necessity.

The disadvantages of using patents as the method of protecting the biomaterial have been considered and strategies to negate the risks associated are discussed further on page 12.

Patent Strategy

The purpose of a patent strategy is to align the overall business strategy with the company's patent portfolio. A patent portfolio is the compilation of patents which are owned by a single corporation or individual. The patent strategy takes into consideration the intellectual property, business strategy, resources of a company and the actions of competitors to determine the best method to protect the company's intellectual property and thereby enhance the company's competitive advantage (Knight, 2002). Therefore, the patent strategy is developed in view of these different influences and will affect the final composition of the patent portfolio. A strong patent portfolio can be used to help the business achieve their objectives such as achieving a market position, protecting innovative products, generating revenue or building cross-license or royalty agreements.

The benefit to forming a patent strategy is that it can ensure that the company receives adequate protection for their invention without expending resources on unnecessary patents. The patent portfolio of a company which files for patents in an *ad hoc* manner and without a strategy may find that the portfolio includes patents which provide no advantage to the company's business strategy and may lack patents necessary to the company's business strategy. As such, the patent portfolio may not cover the core invention or contain patents that have been filed in markets with little or no value (Barrett, 2003). The result is that the company will have utilised valuable resources, often capital, in the filing and prosecution of patents with very little benefit to the company itself.

The Military Model

A potential model on which to develop a patent strategy is the Military model proposed by H Jackson Knight in his book "Patent Strategy for researchers and research managers" and is based upon a set of principles which guide the development of strategies of war or campaigns. The purpose of the principles is to break down the overall task of developing a patent strategy into a manageable set of guidelines, decisions and actions. There are eight principles outlined in the Military strategy model;

1. *Identify an objective*
2. *Identification of intellectual property*
3. *Identify the competitive advantage*
4. *Concentrate resources towards these advantages*
5. *Preventing extraneous use of resources*
6. *Consider the position of competitors*
7. *Coordination of filings and countries*
8. *Security: Protection of unprotected property*

Principles 1-6 and their influence on the development of the patent strategy for NacreTech are discussed below. Principle 7 will be discussed on page 23 and principle 8 on page 31.

Identifying an objective

Identifying a clear and attainable objective is the first step that should be made when developing a patent strategy as it will need to closely aligns with business strategy of the company. A clear objective is required to help guide future decisions when considering later principles. If the objective is unclear, the strategy will not be cohesive, resulting in a patent portfolio which does not adequately protect the invention. The objective needs to be attainable by the company otherwise the effort to achieve the patent strategy will divert company resources away from the commercialisation of the intellectual property. The objective could be as simple as inhibiting the capabilities of competitors through the use of patents (an aggressive objective), making money through licensing (a profit motivated objective), or the protection of core inventions to gain competitive advantage (a defensive objective) (Gasnier, 2008).

Identification of intellectual property

The identification of intellectual property which the company owns or in the process of developing is a key principle underpinning the patent strategy. The clear identification of this intellectual property will ensure that all key aspects of the invention(s) are protected. It also enables any parts of the invention which are not owned by the company to be identified. In identifying any missing intellectual property, the strategy can then consider acquiring the additional intellectual property through licensing or purchase and/or developing the required intellectual property either in-house, on a contract basis or through joint-development.

Identify the competitive advantage

The identification of the aspects of the invention which provide the competitive advantage and how the company plans to maintain this advantage through intellectual property protection is the core to the patent strategy. The aspects that produce the greatest competitive advantage over the competitors' products are considered to be the core invention.

In a defensive strategy, the core invention is the focus of the patent strategy as the legal security gained by the protection of this core invention prevents competitors from gaining the company's competitive advantage. The protection of the core invention is typically a strategy utilised by the pharmaceutical and biotechnological sectors (Gasnier, 2008).

Concentrate resources toward these advantages

The concentration of resources towards the perceived competitive advantage relates to the allocation of resources to ensure that the patent strategy does not commit too much capital into the filing and maintenance of the patent portfolio. This is important as costs associated with the filing and maintenance of patents increase rapidly with the number of patents filed and number of countries filed in.

The cost of filing and maintaining a single U.S patent application (including the associated legal fees) can cost between $10,000-$20,000 depending upon the technology of the patent, complexity of the invention and length of the complete specification (Quinn, 2011). If the patent is filed internationally, the costs associated with the single patent family can approach US$100,000 due to international attorney fees, filing fees, maintenance fees, translation costs and/or PCT international fees.

The amount of capital available to allocate to a patent portfolio is dependent upon company size. A larger company will have more outward focused strategies to either block competitors or to more securely protect their core invention (Industry Canada, 2013). Therefore the patent portfolios will be larger in size and as a result require significantly more capital. An example of the patent portfolio of a larger company is the medical technology company Smith & Nephew, which owns in excess of 5,000 patents and patent applications (Smith & Nephew, 2013). Assuming that each patent is only filed in United States and each patent costs $20,000, the patent portfolio owned by Smith & Nephew would cost at least US$100,000,000.

The strategy followed by small to medium sized companies is generally to protect the core invention initially as resources are restricted and the company cannot afford to allocate significant amounts of capital to protect a large patent portfolio (Industry Canada, 2013). Once additional research or capital has been acquired, the company can then look at patenting further incremental improvements in the technology to form a "picket fence" of patents around the core invention (Barrett, 2003). The benefit of this strategy is that it reduces the costs of building the patent portfolio, which is an advantage as smaller companies or start-ups often do not have the extra revenue to dedicate to building such a portfolio.

Considering the position of competitors

The granting of a patent gives the owner the exclusive license to exclude competitors from practising the invention. Therefore, the action of perceived competitors is important and significantly influences the development of a patent strategy. How the competitor's actions affect the development of a patent strategy is dependent on the objective of the company.

A company with a more aggressive objective will focus on preventing the opposition from gaining the competitive advantage. A blocking strategy called "ring-fencing" involves the filing or acquisition of patents that prevent a competitor from protecting further invention on their core patents. The result is that a competitor may have protected their core invention, but any further advancement is blocked by a ring of patents owned by the company. The only option for the competitor to practise their further innovation is to form a licensing agreement with the company. This is advantageous to the company as every dollar the competitor spends in the licensing agreement is a dollar away from their research and development budget and as well as being a dollar towards the company's profits.

This therefore creates a two dollar difference between the company and their competitor and as a result the company gains the competitive advantage (World Intellectual Property Organization, 2010).

A similar reasoning is applied if a competing company is developing the same or a similar invention, then a company will file a patent to prevent a competitor from patenting the invention and thereby gain the commercial advantage (Kultti, Takalo, & Toikka, 2006). The advantage to this reasoning is that even if the company does not choose to further develop the patented invention, the company may increase revenue by licensing the patent to the competing company or by suing for infringement.

A further strategy to prevent a competing company from gaining the competitive advantage is to publically disclose research in the area in which the competitor is developing their invention (Hall et al., 2014). The public disclosure will prevent any patents from being filed in regards to that particular subject matter. Such a strategy is beneficial if the company does not have the funds necessary to file a patent to protect that subject matter or if they do not possess enough research to prosecute a strong enough patent on the subject matter.

In contrast, a defensive strategy focuses on protecting the competitive advantage of the company and maintaining that advantage from the opposition. A defensive strategy seeks to prevent competitors gaining the competitive advantage by the methods discussed above and therefore utilises strategies to prevent them. To prevent a competitor from creating a “ring-fence” around the core invention of the company, the company can create its own “picket fence” which surrounds the core invention, enabling the company to utilise any commercially viable advances without the interference of competitors. Any patents within the “picket-fence” which are not considered to be commercially significant to the company may be licensed to other companies to provide income. The “picket fence” can also be used to prevent competitors from designing around the core invention, as the protecting patents would be infringed by any such design around.

Reflection

The patent strategy for the biomaterial has been developed with flexibility in mind as the development of the material is still in a very early stage and there are two proposed business strategies. As discussed in the ‘Strategic Plan and Exit Strategy’ chapter of Appendix A, one of the proposed strategies is the high-risk/high-reward option of creating a subsidiary company from Victoria Link Ltd (VicLink). The other business strategy discussed in the appendix is to license key areas of technology to larger corporations (such as Stryker) or to work co-operatively with the larger corporations to develop the biomaterial into the end product.

The objective of the patent strategy for NacreTech is to protect the core invention as robustly as possible while minimising the cost of the patent portfolio. This objective is suitable for both of the business strategies as it provides a core of patents from which the portfolio can expand for the business strategy of creating a subsidiary company. The focus on the core invention is considered suitable for the license strategy as the patents will allow the biomaterial to be licensed for alternative markets.

The key aspects of the invention were determined by identifying the intellectual property that had been produced by the research group. This was considered to be the method of producing the biomaterial and the biomaterial itself. The intellectual property which is currently in development or will need to be acquired was considered next. This was considered to be the use of the biomaterial as a bone substitute material and a method of 3D printing the biomaterial. The patent strategy is based upon the protection of the biomaterial and the use of the biomaterial in the medical application. The method of 3D printing the biomaterial will be addressed in the trade secret section.

The principle of identifying and protecting the competitive advantage was not deemed to be particularly relevant to the development of the current patent strategy due to the small amount of intellectual property present. All intellectual property was considered to be part of the core invention and therefore requiring protection.

The cost of filing and maintaining a patent were taken into consideration when forming the patent strategy. The rights to the intellectual property are owned by Victoria University of Wellington and are assigned to VicLink to manage and commercialise. VicLink have a set budget with regards to the protection of intellectual property and therefore must decide how best to invest across the portfolio of intellectual property generated by the whole university. In view of budget limitations, a large patent portfolio was not considered to be the best course of action. The patent strategy focused on the protection of the core invention at minimum cost.

The closest competitor would appear to be Stryker, through patents this company obtained through acquisition of Orthovita. The Stryker patent (US2014/0271914) discloses the use of a biomaterial made of calcium phosphate and chitin for use as a bone substitute material, however the biomaterial described this document utilises freeze-drying to create the porosity. Freeze-drying to create porosity reduces the overall strength of the chitin material. This indicates that Stryker may not have a method of making the biomaterial in a 3D structure with any significant strength. As a result, there may be a cross-licensing or co-development opportunity.

If NacreTech does succeed in developing a method of 3D printing hydrogels (and thereby the biomaterial), then a potential strategy to strengthen the patent portfolio would be to license the use

of the Stryker patent and thereby prevent any possibility of an infringement suit. Alternatively, the development of the 3D printing method is the key to the commercial advantage and may help in the exit strategies regarding acquisition of NacreTech by a competing firm.

In view of the different proposed business strategies and the perceived limitations, the patent strategy has been developed to reduce costs while maintaining a strong position in relation to Stryker and also for the protection of the biomaterial. In particular, the core invention (biomaterial) will be protected by filing patents regarding the composition of the biomaterial, the manufacture of the biomaterial and the use of the biomaterial in therapeutic applications. This will provide the base upon which further patents can be filed as the technology is improved.

Patent Landscape

A patent landscape or freedom to operate search is an examination of existing knowledge and information that relates to the proposed invention or a company's strategic direction. A patent landscape will investigate the patents which have been filed in the surrounding technical areas and record the current spaces in which perceived competitors have filed patents. It will also investigate non-patent documents such as journal articles and trade knowledge. The documents which are returned are considered to be the relevant "prior art".

It is noted that there is no industry standard in the methodology used in order conduct a prior art search. The following prior art search methodology is that used by the Intellectual Property Office of New Zealand and as advised by the Danish Patent and Trademark Office (Find, 2011).

The first step to canvasing a patent landscape is to identify the key areas of the invention which need to be protected in order to maintain a company's strategic advantage. In regards to the biomaterial these areas were considered to be:

- The composition of the biomaterial (chitin + calcium chloride)
- The formation of the aragonite crystal structure
- The method of manufacturing the biomaterial
    - The method as per the patent previously filed
    - 3D printing
- The use of the biomaterial in therapeutic applications, specifically orthopaedic related

Key search terms are words or phrases which relate to the identified areas and are used to define the invention; using the first bullet point above as an example the key search term is the word 'chitin'. However, these key search terms are narrow and do not fully encompass all possible parts to the invention, therefore the key search terms are expanded to identify all synonyms and related words. For the example of 'chitin' additional terms were 'chitosan', 'N-acetylglucosamine', '$(C_8H_{13}O_5N)_n$', and 'nacre'.

Additional search terminology specific to patents, is classification codes. These are designed to organise patents into the different areas of technology in which they belong. There are three main types of classification codes, the International Patent Classification System (IPC) developed by WIPO, the Cooperative Patent Classification (CPC), developed by both the European Patent Office (EPO) and the United States Patent and Trademark Office (USPTO), and the United States Patent Classification (USPTC) which was developed by the USPTO. The relevant IPC and CPC classifications for the first bullet point above are A61K 33/10 (use of carbonates in a medical preparation), and A61K 31/722 (use of chitin in a medical preparation).

The relevant search databases were then identified; these were considered to be Espacenet, PatentScope and Google patents. Espacenet is run by the EPO and has a database of more than 80 million patents (European Patent Office, 2011), it has patent documents from as early as 1836 and from 92 countries. There are search limitations on Espacenet, in particular search strings cannot have more than 10 terms but the site is able to translate foreign language documents. PatentScope is the database run by WIPO, it covers more than 43 million patent documents from 41 countries and includes PCT applications (World Intellectual Property Organization, 2015b). While PatentScope can allow for longer search strings, it does not have the ability to translate as many foreign language documents. Google patents can search the entire USTPO database and also has access to PCT, World Intellectual Property Organization (WIPO), EPO and Canadian patents. Google utilises its typical natural language search algorithm, which makes it difficult to find relevant results using complex search strings.

The discussed databases above are the free to use databases. Additional databases such as Thompson Innovation, Delphion, Orbit, PatBase, Epoque and STN have increased search capabilities (such as searching by term proximity) and combine the free databases into a single search. However, due to cost restrictions these databases were not utilised.

In addition to patent databases a search of journal publications, books and general website information was conducted. This was primarily conducted using a combination of Google, Google Scholar, Google books, ProQuest, Science Direct and the library. Lastly, a thorough search of the patents held and filed by the identified market competitors was conducted. A summary of the relevant prior art is discussed in the ‘Patent Landscape’ chapter of Appendix A.

Contents of the Specification

The complete specification of a patent discloses what the invention is, how to perform the invention and the specific limitations on the monopoly. There are four key parts to the complete specification, the title, the background, the description of the invention, which includes examples and figures, and claims. The specification is written in consideration of the identified areas of protection, patent landscape and should accurately reflect the patent strategy.

The background needs to clearly define the problem in the art which the invention is addressing and relevant common general knowledge. The description, examples and figures define all the aspects of invention and potential embodiments, with a key feature of the description being that it must enable the skilled person to perform invention.

The claims must define the limitations of the monopoly, that is, they describe the invention which the patent is intended to protect (Patents Act 2013 (NZ), s.39(1)(e)). The claims, therefore, is the section of the complete specification which legally defines the boundaries to which the invention is protected and is the measure which defines whether a third party has infringed the patent. In order for the patent to be granted, the claims must be clear and concise, supported by the description and conform to the requirement for unity of invention (Patents Act 2013 (NZ), s.39(2)). In addition, the invention claimed within the specification is required to be novel and possess an inventive step.

Novelty

Under the New Zealand Patents Act 2013, the requirements for novelty and inventive step are detailed under Sections 6 and 8. Novelty and inventive step are examined in relation to the prior art base, wherein the prior art base is any information regarding a product, process, or similar invention which was has been made available to the public.

The determination of whether the claimed invention meets the requirements of novelty is achieved by comparing the claimed invention to existing publically available knowledge at the priority date of the invention. The relevant New Zealand case law for determining novelty is *General Tire v. Firestone* [1972] RPC 457 wherein Sachs L.J. stated

> *"If the prior inventor's publication contains a clear description of, or clear instruction to do or make, something that would infringe the patentee's claim if carried out after the grant of the patentee's patent, the patentee's claim will have been shown to lack the necessary novelty, that is to say it will have been anticipated".*

Sachs L.J further states

> *"To anticipate the patentee's claim the prior publication must contain clear and unmistakable directions to do what the patentee claims to have invented… A signpost, however clear, upon the road to the patentee's invention will not suffice. The prior inventor must be clearly shown to have planted his flag at the precise destination before the patentee"*

Therefore, in order for the claimed invention to be anticipated by prior art, the prior art must clearly disclose the claimed invention in such a way that if performed it would infringe the claim of the patent. This is commonly referred to as the "reverse infringement test".

The reverse infringement test was taken into consideration when conducting the prior art search. While it is acknowledged that there are not specific claims for the prior art to anticipate, the reverse infringement test was applied to the general concept of the invention. For example, in searching the biomaterial the invention was broadly construed as a material consisting of chitin and calcium carbonate in a three-dimensional structure with an internal interconnected macro- and micro- pore structure.

The prior art search returned that the combination of chitin and calcium carbonate is well known in the art in film or bead form and that the method of making the biomaterial as currently known has been disclosed by the inventor. However, the generation of a porous three-dimensional structure of the biomaterial would appear to be novel; as a result the team decided that there was the freedom to further develop the biomaterial.

As mentioned in the 'Patent Landscape' chapter of Appendix A the closest prior art to the invention would appear to be US2014/0271914 which suggests the use of calcium phosphate and chitin, with a specific macro- and micro- internal pore structure. However as the document discloses where that the material contains calcium phosphate it is not considered to anticipate the invention. As if a person skilled in the art were to perform the invention as described in US2014/0271914 they would not infringe the invention.

Inventive Step

An invention, so far as claimed in a claim, involves an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms the prior art base (Patents Act 2013, s.7). The concept that an invention must not be "obvious" and contain an inventive step is common across jurisdictions, however the legal tests which jurisdictions apply differs.

The New Zealand Patents Act 2013 is based up on the United Kingdom's Patents Act of 1977, as a result inventive step in both New Zealand and the United Kingdom is determined using the test

described in *Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd* [1985] R.P.C 59 and reformulated in *Pozzoli SPA v BDMO SA* [2007] EWCA civ 588. The European method for determining if a claimed invention possesses an inventive step is by a "problem-solution approach" (European Patent Office, 2014).The United States method to determine non-obviousness (equivalent to inventive step) is stated in *Graham v. John Deere Co*., 383 U.S. 1 (1966).

Across the different jurisdictions the method for determining inventive step comprises of at least three key steps; determining what the prior art discloses, identifying what the inventive concept or problem/solution in the claim is, and then evaluating whether this inventive concept or problem would be obvious to the person skilled in the art. However, due to the differences in interpretation, ordering of the steps and common law between these jurisdictions, each examination can result in different determinations of inventiveness. As a result of these differences in inventive step examinations across the jurisdictions and the indeterminate nature of inventive step, a precise judgement upon whether the biomaterial would be considered to contain an inventive step could not be made within the strategy.

However, the formulation of what is the inventive concept of the intellectual property developed by NacreTech can be considered in general at this stage. The inventive concept is defined in *Generics (UK) Limited v H Lundbeck A/S* [2009] UKHL 12 as the

> *"the identification of the core (or kernel, or essence) of the invention —the idea or principle, of more or less general application (see Kirin-Amgen, [2005] RPC 9 paras 112- 113) which entitles the inventor's achievement to be called inventive. The invention's technical contribution to the art is concerned with the evaluation of its inventive concept—how far forward has it carried the state of the art? The inventive concept and the technical contribution may command equal respect but that will not always be the case."*

The inventive concept of the biomaterial developed by NacreTech is considered to be the relationship between osteoconduction/porosity, strength and degradation as described in the 'Biomaterial Concept' chapter of Appendix A. Specifically the precise interconnected macro- and micro- pore structure allows for the improved osteoconductive qualities of the biomaterial compared to existing orthopaedic biomaterials. The formation of the aragonite (calcium carbonate crystals) and chitin polymer matrix increases the strength of the biomaterial and allows for the pore structure. The specific porosity and use of chitin reduces the degradation rate compared to existing biomaterials which are known to degrade quickly. This inventive concept has not been addressed by the existing materials currently on the market nor has it been identified in the prior art search. NacreTech believes this entitles the biomaterial to be called inventive.

In addition, the mechanical and biological proof of concept testing have been planned to support the envisaged inventive concept. The mechanical testing is intended show that the biomaterial has increased strength, the *in vitro* degradation testing will provide an initial measure of the rate of degradation and the biological testing will demonstrate enhanced osteoconductive capabilities. These tests will be performed in parallel with existing biomaterials and the chitin based material disclosed in US2014/0271914 to clearly demonstrate the improved features of the NacreTech biomaterial.

Support

In addition to ensuring that the claimed invention is novel and includes an inventive step, the claimed invention must be supported and enabled within the complete specification. In the New Zealand Patents Act 2013, the requirements for support and enablement are described in section 39(1)(a) and 39(2)(c)such that the specification as filed "*must disclose the invention in a manner that is clear enough and complete enough for the invention to be performed by a person skilled in the art*" and the claimed invention must "*be supported by the matter disclosed in the complete specification*".

The requirements for support and enablement in New Zealand are the same as described in the United Kingdom Patents Act 1977, section 14(3) and 14(5) and are similar to Article 83 and 84 of the European patent convention. The requirements in the United States are slightly different in that 35 U.S.C § 112, states that the specification will describe the invention in full, clear, concise and exact terms as to enable any skilled person to make and use the invention and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The difficulty arises when trying to determine specifically how much of the invention must be disclosed in a clear and complete enough manner for the skilled person to perform the invention. Patent strategies for filing in the biotechnology or life sciences area can involve filing an initial provisional application which partially described the invention until full *In vivo* data is obtained and a complete specification can be filed (Longshaw & Houlihan, 2013). However, under the New Zealand Patents Act 2013 such a strategy will not support the invention filed at priority date as the invention would not be described in a clear enough or complete enough manner, in view of the decision in *Biogen v. Medeva* [1995] RPC 25, wherein it was decided that

> *"…it would be illogical to hold that a specification, which is insufficient at its date of filing, could be rendered sufficient by subsequent publication of the additional subject-matter thereby making this known by the publication date of this application"*

As a result, the first provisional application must provide full details on all three aspects of the invention (manufacture, composition and use). This is considered to include all possible

embodiments of the invention, in particular the use of the biomaterial in bone substitute applications and a full description of such applications and the steps of the methods which will be carried out in the biological proof of concept test. Further provisional applications will be filed as soon as those *in vitro* test results become available.

Unity

Lastly, unity of inventions was considered, in the New Zealand Patents Act 2013 unity is described in s39(2)(a) as the claims *"must relate to one invention only*". Unity is typically considered in view of Rule 13 of Paris Cooperation Treaty International. Rule 13 states that that the application shall relate to one invention only or a group of inventions linked as to form a 'single inventive concept'.

It is considered that the 'single inventive concept' is the biomaterial itself, but if it is determined that the biomaterial cannot be the unifying feature between the biomaterial, method of producing the biomaterial and the use of the biomaterial then there needs to be the ability to divide out the biomaterial and the use of the biomaterial into separate applications from the initial application. This is anticipated to overcome the unity objection; however it will increase the cost of the patent portfolio.

Filing Date/Timeline

A granted patent has a patent term of 20 years; this period begins on the day of filing the patent application and is referred to as the priority date. The priority date is important as any publication which discloses the invention before the priority date is considered to anticipate the invention. The priority date also represents the start of the applicant's entitlement to the monopoly.

There are two primary methods of filing for patents which are discussed below. The first is to file a PCT application with WIPO and then enter the intended protection countries through national phase. The second is to file an application independently at the national office of each intended country of protection. Both of these methods are dependent upon the rights entitled to the applicant under the Paris Convention Treaty.

Paris Convention Treaty

The Paris Convention Treaty provides what is commonly referred to as the "Convention priority right". The convention priority right allows an applicant from one state 12 months from the priority date of their initial application to file a patent application for the same invention in any of the other contracting state and maintain the original priority date (Frankel, 2002)**.** For example, if an applicant filed a patent application in New Zealand on the 3rd February 2015; the applicant would have until the 3rd February 2016 to file an equivalent application in one of the other contracting states such as the United States of America. The Paris Convention Treaty currently has 176 contracting member states (World Intellectual Property Organization, 2015a).

Patent Cooperation Treaty

The PCT filing method simplifies the process of filing patent applications in multiple contracting states; it is currently available for 148 countries all of which must be members of the Paris convention treaty (World Intellectual Property Organization, 2014). The process involves the applicant filing the application through one of the PCT filing offices, one of which is New Zealand.

Upon receiving the application the receiving office forwards the application to WIPO, wherein approximately 16 months after the priority date of the application the international search report (ISR) and written opinion is produced. The ISR and written opinion are produced by the search authority nominated by the applicant. There are five main search authorities Europe, United States of America, Korea, Japan and Australia. Each of these authorities has different advantages and disadvantages. In general searches conducted by Korea and Japan are not as expensive as the other authorities. They are colloquially regarded in the field as not producing high quality reports due to a tendency to produce ISR's which are based entirely on Asian language documents. The European and United States search authorities are more expensive and are generally regarded as producing higher quality reports; however they do have delays which result in a longer wait for receiving the ISR and

written opinions. Finally Australia, which produces reasonable quality reports of medium cost and produces the ISR and written opinions within a reasonable time frame. There is also the capability to file a Chapter II response to the ISR and written opinion to WIPO, this allows amendments to be made the claim to address the novelty, inventive step and utility issues identified by the international examiner.

At 18 months the PCT application is published and at 30 or 31 months the applicant can choose to enter national phase of various countries.

The advantage to filing a PCT application is that it allows for the easy filing of the same patent application into large numbers of countries. Further, the initial ISR and written opinion examination provides an initial opinion by an examiner as to the novelty, inventiveness and utility of the invention. This can provide guidance into whether or not to enter national phase, reduce national phase entry countries or increase confidence in the possibly of receiving a granted patent. It is noted that the PCT guidelines and examination are not binding on the member countries upon entry into national phase.

Independent

The other method of filing patent applications in the intended countries is to file independently in each of the countries national offices. Filing by this method reduces costs, as the applicant does not have to pay the international filing fee or the search costs required by a PCT application. However it is less efficient if filing in a large number of countries. In addition, this method does not produce an ISR and written opinion and therefore no prior art considerations can be made as to whether or not filing in the countries is worth the cost of the patents.

Provisional applications

The last aspect to consider when filing a patent is the capability to file a provisional application. A provisional application allows the applicant 12 months from the filing date to file a complete specification (Patents Act 2013 (NZ), s.37(2)). A provisional application must provide basis for which the complete specification is written on and must disclose the invention because the filing date of the provisional specification acts as the priority date of the complete specification. A further advantage of a provisional application is the ability to cognate several provisional applications into a single complete application (Patents Act 2013 (NZ), s.37(4)). This allows the applicant to file several different provisional applications and retain the priority date of the specific invention disclosed in those documents. Provisional applications are not published.

Reflection

The determination of the best time to file a patent application for the biomaterial is difficult, as there are very similar patents currently being published in the same area. Therefore, the patent needs to be filed as soon as the development of the biomaterial is completed in order to prevent further art anticipating the invention. In contrast, in terms of development the biomaterial will need to undergo full clinical trials, which will be done after the patent is filed and are estimated to take between 6-8 years. As a result, the length of time in the protected market is significantly decreased and therefore the priority date should be as late as possible in order to increase the amount of time available to recoup research and development costs.

The patent strategy contemplated in Appendix A attempts to take into consideration all the relevant timelines and restrictions in order to sufficiently protect the invention. In particular, it was considered that due to the increased research in the area of biomaterial by potential competitors, a patent with an earlier priority date would be of more importance than trying to delay the priority date to preserve market exclusivity.

Secondly the cost of filing for a patent, in New Zealand under the Patents Act 2013 is $115 (not including patent attorney fees). Upon filing the first provisional application, NacreTech would have 12 months to file a complete specification with PCT international. In view of the discussion around sufficiency and enablement, the complete specification will need to include all experimental data surrounding the mechanical and biological properties of the biomaterial. Therefore, the first provisional application will be filed immediately after finalising the composition of the biomaterial, the manufacturing method and completing the associated mechanical testing. This information will become the foundation of the patent application.

Additional provisional applications will be filed after the completion of the *in vitro* biological testing; this is considered to be approximately six months after the first provisional application. The final provisional will include the small model animal testing and should be complete approximately 10-11 months after the filing of the first provisional application. The three provisional applications will be combined to create a single complete specification which will be filed with PCT international before the 12 month Paris convention treaty time expires.

A possible disadvantage to this method of filing is that some overseas offices may consider claims which contain subject matter filed in the later provisionals are not entitled to the priority date of the initial provision. To prevent this from occurring, the first provisional must contain all details regarding the use of the biomaterial as a bone scaffold and therefore sufficiently describe the invention at that initial priority date.

An additional potential problem is that the biological testing may take longer than 12 months to complete. If this occurs then an additional patent landscape search should be conducted in order to determine if any prior art has been published between the first provisional filing date and the second provisional filing date which anticipates the invention. If there is no prior art, then NacreTech can decide to forgo the first provisional priority date.

Alternatively, NacreTech can decide to separate the composition and manufacture of the biomaterial into a separate application, removing any reference to the use as a biomaterial when filing the complete specification, thereby maintaining the initial priority date for the composition and manufacture of the biomaterial. An additional application can be filed upon receiving the biological testing results and falling back to the second priority date for the use of the biomaterial as a bone scaffold.

The patent strategy utilises the PCT international filing method rather that the individual method due to the extra 30/31 months available before requiring entrance into national phase. The extra 30/31 months provides a buffer between the outlay of costs required by entering into national phase and the inherent risks involved in business development aspects such as scaling up the manufacturing of the bioactive bone screw or the clinical development such as pre-clinical testing of the bone screw. In addition the ISR and written opinion provides an initial examination into the novelty and inventiveness of the biomaterial which may influence company strategy at that early stage.

Acquisition or licensing of additional intellectual property

The patent strategy discussed in the appendix has primarily focused on the intellectual property which has been created by the research team. However, it is apparent at the current stage of material development that additional intellectual property will be required regarding the structure of medical device itself.

As discussed in the 'Future Project Development' of Appendix A the final specification of the bone screw has not yet been identified. This is due to the uncertainties surrounding the properties and capabilities of the biomaterial. As a result, additional intellectual property surrounding the design, specification and internal structure of the bone screw has not been considered in detail by the intellectual property strategy in Appendix A**.**

Once these uncertainties have been resolved, it will be possible to determine the specific bone screw(s) and surgical operations which the bone screw can be used in. The determination of the precise application of the biomaterial will then allow a complete intellectual property landscape to be conducted within this area to determine if it may be possible to license or acquire the intellectual property for the structure of the bone screw. Alternatively NacreTech may decide to develop its own bone screw medical device structure.

Trademark

Another method of protecting intellectual property is through the use of a trademark. A trademark is a unique item which is associated with a company's brand; and can be an image, word, phase, sound or other symbol. The purpose of a trademark is to protect the brand which is associated with the product or service which a company offers and to distinguish their products from competitors. In New Zealand, the registration of a trademark gives you a monopoly for that trademark under the Trademark Act 2002 (Intellectual Property Office of New Zealand, 2011).

The process for filing an application for a trademark requires a specification and classification. The specification is a description of the goods and services which the trademark is intended to be used. The Nice Classification of the trademark is used to classify the goods and services which trademark are used in (Frankel, 2002). For the purposes of filing a trademark application, the applicant will select which classifications best fit what the company does (Intellectual Property Office of New Zealand, 2015). It is noted that the classification does not protect the trademark across the entire scope of the classification but only those described in the specification.

Registered vs Un-registered

There are two different types of trademark, un-registered trademark which are accompanied by the symbol ™ and registered trademark which are accompanied by the symbol ®. A registered trademark is entitled to legal protection to deter others from attempting to imitate a company's brand or products. Legal protection can include suing for infringement of a confusingly similar mark and preventing others from using your trademark (Intellectual Property Office of New Zealand, 2011). An un-registered mark does not have the protection granted to a registered trademark.

In the common law countries such as New Zealand, Australia and the United Kingdom, an un-registered trademark can be protected under the law of passing off. The law of passing off does not confer monopoly rights to a trademark but serves to prevent misinterpretation during trade. It is decidedly more difficult to sue for infringement under the law of passing off than under the Trademark Act 2002 (Frankel, 2002). In the United States of America, unregistered trademark are only enforceable within the geographic region or locale where the trademark owner is using the mark in business and are protected by state common law under the law of unfair competition.

Madrid Protocol

A company may file for a trademark independently in each country which they intend to operate. The alternative method is to file through the Madrid Protocol which is managed by WIPO. The Madrid Protocol is very similar to the PCT system used for patents; it allows a single application to be filed to allow for registration in 90 countries. The process of filing a trademark registration starts by

filing an application though an Office of Origin (such as the Intellectual Property Office of New Zealand). WIPO receives the application and confirms that the correct fees have been paid and that the specification is correct. WIPO then forwards the applications on to the designated countries.

The classifications determined for the trademark are used to calculate the fees. If NacreTech were to file for the trademark NacreTech in Australia, New Zealand, European Union, United Kingdom and the United States, the filing costs alone would cost approximately NZD$6,294.99 (World Intellectual Property Organization, n.d.-a). Additional costs are required every 10 years per country to maintain registration of the trademark.

Reflection

A trademark for the term NacreTech was considered in the Intellectual Property strategy. It was decided that filing for a registered trademark at the current stage of material development is too early. While the material is still under development, remaining with an un-registered Trademark for NacreTech would be sufficient. Once it is shown that the material meets the targets set in the target product profile and it is commercially viable, then applying to register the trademark should be considered.

The basis for this reasoning is partially due to section 66(1)(a) of the New Zealand Trademark Act 2002 and article 19(1) of the TRIPS agreement, which states that the registration of a trademark may be cancelled after an uninterrupted period of at least three years of non-use. As NacreTech would not be considered to be trading for at least two years due to the further development of the biomaterial, registering a trademark at this stage of development increases the risk that it may be revoked due to non-use.

In addition, NacreTech is the name given by the MATE team during the course of the program and has not been confirmed as the final name for the biomaterial platform or company. As it is unclear whether the business strategy will involve incorporating a subsidiary company of VicLink or just licensing the use of the patents, a trademark may not be required in the overall intellectual property strategy.

Trade Secrets & Copyright

Computer software & Copyright

Computer software is not generally considered to be patentable subject matter, in particular article 52(2)(c) of the European Patent Convention specifically excludes the patentability of computer programmes. Similarly, section 11 of the New Zealand Patents Act 2013, contains the provision that a computer program is not an invention and not a manner of manufacture, i.e. not a patentable invention, as such.

It is the language “as such” within the New Zealand Patents Act 2013 which introduces ambiguity into whether or not a computer programme can be considered to be a patentable invention. The example provided in the act attempts to provide clarification around this point by stating that if the contribution to the art does not reside solely in the computer program, but rather the computer program produces a new result (such as making a washing machine work) then that contribution may be protected through a software patent.

Often the intellectual property lies within the coding of the programme itself, which is not considered to be patentable but the specific code within the software is protected under copyright. The core problem with computer programmes being protected by copyright is that the final product for example, a database, can be reverse engineered without infringing the copyright on the code itself. Therefore, often the best method of protection for computer programmes is market based, such as being the first to market advantage. The competitive advantage is in the business strategy of the company rather than the invention. Alternatively, the software may be protected as a trade secret.

Trade Secrets

A trade secret is a form of intellectual property which provides a company with a competitive advantage which the company chooses to keep as a secret, rather than to make it public. A trade secret is not registered or given any official form of protection but rather the protection is provided through maintained secrecy; as the secret is not registered there is no time limit to the length of the protection as such it will remain protected so long as it remains undisclosed. However, a trade secret does not prevent a third party from utilising the IP after it has been discovered (Mohr, 2013).

Type of Invention

A trade secret is not suitable for discrete inventions which can easily be reverse engineered, for instance chemical compositions or pharmaceutical formulations (Hall et al., 2014). The best method of protecting this type of intellectual property is through the use of a patent. The public disclosure of the intellectual property in this form clearly defines the monopoly of an invention that would be easily determined if there was an attempt to keep it secret.

Trade secrets are considered to be more suitable for complex inventions the processes and systems behind the manufacture of the product, rather than the product itself as it is harder to reverse engineer a process or a system then a physical product (Henry & Ruiz-Aliseda, 2012). An example of this is the drug Premarin, the pharmaceutical composition of the drug itself was patented in the 1940s however no generic form of the drug currently exists on the market. The reason is that the extraction process behind the manufacture of the drug Premarin was not patented and remained a trade secret. As no third party has yet discovered how to successfully extract Premarin, the owner of the trade secret Pfizer has an exclusive monopoly to the drug without the need for a patent (Lobel, 2013).

Protection of a Trade Secret

A trade secret is only considered to be a trade secret so long as the company takes all reasonable measures to ensure that the IP remains a secret. If the company discloses the IP, then it is a secret and hence, not protected. However, under the Uniform Trade Secrets Act 1979 (USA) and article 39 of the TRIPS agreement, if the company takes all reasonable measures, such as an employee with a non-disclosure agreement and that employee releases the trade secret, than the company has the right to sue for the disclosure of the trade secret. The only disadvantage is that once the secret has been disclosed it is very difficult to ensure that the intellectual property remains a trade secret.

Reflection on the use of Trade Secrets

While a substantial portion of the Intellectual Property strategy has been focused on the protection of the biomaterial and use of the biomaterial in a therapeutic application, there is some consideration into protection by trade secret. An assumption was made that the process for creating the internal interconnected pore structure by 3D printing is a result of using the programming of a known 3D printer in a new method.

While it is acknowledged that as the contribution to the art is the creation of a new result and therefore may be considered a patentable invention in New Zealand in view of *Hughes Aircraft Company application* P1995/3, 3D printing processes cannot be protected in all international jurisdictions (such as Europe). Therefore, patenting is not considered to be the best method of

protecting the invention. It is further acknowledged that the specific code used to programme the 3D printers is protected by copyright.

The 3D printing of the biomaterial is anticipated to be difficult to reverse engineer. In particular, the precise timing of layer addition, pH of the solution, curing of the chitin scaffold and then the precise internal structure of the biomaterial (porosity) would require significant investment and experimentation to replicate.

As a result, it was considered that the process of 3D printing the biomaterial in a 3D structure would be best protected as a trade secret as the process is significantly complex enough that attempts to reverse engineer the material would not be successful, such as with the extraction of Premarin. Therefore, a similar strategy as used for the drug Premarin will be adopted. The composition of the biomaterial will be protected by patents while the precise process to create the 3D structure and mineralisation of said structure will remain a trade secret. This should in theory extend the period of monopoly past 20 years assuming that a third party does not uncover the process behind the 3D printing.

If the assumption that the material development utilises a known 3D printer proves to be false and the material development results in the generation of a novel 3D printer device, then this device should be protected by a patent. The specific programming of said device to 3D print the biomaterial should remain a trade secret.

Overall Reflections

Enterprise

The team recognised at the start of the year that the use of the biomaterial in a medical application would require more than a single year to get a product to market. As a result, it was decided at the beginning that success would be the identification and investigation of the viable market application for the biomaterial and a plan to achieve commercialisation of the biomaterial. Based upon what the team considered to be success at the start of the year, I would consider the business case which the team has produced to be successful.

I believe there are some development of the enterprise which could be improved upon. Firstly, we should have asked more questions at the start of the course about the biomaterial and what was known about the biomaterial. As we found we were consistently rediscovering information that was already known. Secondly, it would have been advantageous to have been able to identify specifically how much the existing biomaterials cost, as that would have been able to guide whether an initial projected manufacturing cost of $446 per screw is an acceptable figure.

Team

One of the learning objectives of the MATE course is the use of collaborative, team-based approach to achieve a successful outcome. The team which has worked on the commercialisation of the biomaterial is comprised of Thomas Sobiecki, Michael Mettrick and Christina Houlihan. Each of the team members came from different disciplines and therefore the team was comprised of people with experience in biological science, engineering and business. The team itself did not function cohesively as a single unit, which affected the development of the business strategy and business case. On reflection, I believe that there are two primary causes which resulted in the lack of cohesion, communication and leadership.

At the start of the project, no one was given the role of team leader as it was decided that we as a team should be able to be responsible for our own work, take initiative and meet deadlines independently. However, this lack of leadership resulted in a lack of communication between team members as each member worked as an individual, only sharing details when asked or when needed in presentations and reports. Further the team would agree to deadlines for completion of work, such as preparation for the presentation, and these deadlines were not met by all team members and never caught up on. I believe a team leader would have ensured that all members of the team communicated effectively and meet proposed targets.

Role

My role within the team was to consider the biological, intellectual property and regulatory aspects for the commercialisation of the biomaterial. As discussed in Appendix A**,** the role was originally intended to focus on testing the hypothesis that the biomaterial is capable of osteoconduction. In June it was determined that the biomaterial was not able to be manufactured to produce the samples required to test the osteoconductivity of the biomaterial, therefore my role significantly changed focus.

Regulatory aspects

The role of considering regulatory aspects focused on whether or not the biomaterial would be able to gain regulatory approval and what preliminary problems in gaining approval could be expected. The difficulty I had within this role was a lack of experience within the regulatory environment. The FDA regulations and the Medical Device Directive are complex statutory documents that require a significant working knowledge of the regulatory environment to navigate successfully. A significant portion of the role was devoted to gaining a basic understanding of the regulatory systems and determining what class of device the biomaterial would be classified as.

What I learnt from the role is a basic understanding of the requirements to gain regulatory approval and an overall understanding of the regulatory process. If I had the opportunity to perform this role again, I would focus more on the processes that other similar companies have utilised to gain regulatory approval and the problems they encountered and how they overcame them. The specific plan for how to gain regulatory approval should be performed by a regulatory specialist with significant experience in the field.

Intellectual Property

The role of considering intellectual property aspects focused on the development of an intellectual property strategy. The difficulty I had within this role was due to the early stage of the material development. I had to make a significant amount of assumptions regarding the biomaterial. These assumptions were that the biomaterial that was produced at the end of the material development stage would be chemically different from the current , protected, biomaterial, that the 3D printing method of producing the biomaterial would not result in the generation of new intellectual property and that the biomaterial would meet the target product profile specifications and capable of osteoconduction.

What I learnt from the role is that patenting is not always the best method to protect intellectual property. In beginning the role, I thought that my focus would be solely on patents as the form of protecting the intellectual property. However during the development of the intellectual property strategy, I learned the value and benefits to protecting intellectual property as a trade secret.

If I had the opportunity to perform this role again I would improve my communication in the final outline of the business strategy and the intellectual property strategy, specifically relating to the licensing of the biomaterial. The business strategy focuses primarily on the licensing of the entire patent portfolio as an exit strategy and does not address the manufacture of the biomaterial which relies on the 3D printing of the biomaterial (trade secret). The final outline of the business strategy does not align with what had been previously discussed and agreed upon by the team and it was these discussions which had formed the basis for the intellectual property strategy.

Bibliography

Ahmed, R. (2014, July 10). The Patent Cliff: Implications for the Pharmaceutical Industry. Retrieved from http://triplehelixblog.com/2014/07/the-patent-cliff-implications-for-the-pharmaceutical-industry/

IP Australia. (2010, August 2). Existing exclusions from patentability. Retrieved February 27, 2015, from http://www.alrc.gov.au/publications/7-exclusions-patentability/existing-exclusions-patentability

Barrett, W. (2003). The patent gamble: Strategic insights for playing the worldwide patent game. *Nature Biotechnology*, *21*(12), 1515.

Find, A, B. (2011, October) How to Perform Comprehensive Patent Landscape Searches? International Conference on Intelligent Computing, Barcelona, Spain.

Cohen, W. M., Nelson, R. ., & Walsh, J. (2000). Protecting their intellecutal assests: Appropriabity Conditions and Why U.S. Manufacturing Firms Patent (or Not). NBER Working Paper No. 7552.

European Patent Convention. 15th Edition (2013, October). Retrieved http://www.epo.org/law-practice/legal-texts/epc.html

European Patent Office. (2011, July). Global Patent Data Coverage: A comprehensive overview of the coverage of the worldwide patent database managed by the EPO. Retrieved from http://documents.epo.org/projects/babylon/eponet.nsf/0/2464E1CD907399E0C12572D50031B5DD/$File/global_patent_data_coverage_0711.pdf

European Patent Office. (2014, September 26). Guidelines for Examination, Part G - Patentability. Retrieved from http://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_vii_5.htm

Frankel, S. McLay, G. (2002). *Intellectual property in New Zealand* (1st ed). Wellington: LexisNexis Butterworths.

Gasnier, A. (2008). *The Patenting Paradox: A Game-based Approach to Patent Management*. Eburon Uitgeverij B.V. Retrieved from https://books.google.co.nz/books?id=qJ0nRwULEaAC&pg=PA65&lpg=PA65&dq=patent+strat

egy+models&source=bl&ots=zAB5f2tFYF&sig=EVLceT1DzQXrEMrXGdKHn5dqSTU&hl=en&sa=X&ei=0GPlVNzDB4L_8QWK44HoDA&ved=0CCkQ6AEwAzgK#v=onepage&q&f=false

Hall, B., Helmers, C., Rogers, M., & Vania, S. (2014). The choice between formal and informal intellecutal property: A literature review. *Journal of Economic Literature*, *52*(2), 1–50.

Henry, E., & Ruiz-Aliseda, F. (2012). *Innovation Beyond Patents: Technological Complexity as a Protection Against Imitation* (SSRN Scholarly Paper No. ID 2034088). Rochester, NY: Social Science Research Network. Retrieved from http://papers.ssrn.com/abstract=2034088

Industry Canada. (2013). *International Patent Strategies for Biopharmaceutical SMEs in Canada*. Retrieved from https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01760.html

Intellectual Property Office of New Zealand. (2011, February 14). What is a trademark? [Intellectual Property Office]. Retrieved from http://www.iponz.govt.nz/cms/trade-marks/what-is-a-trade-mark

Intellectual Property Office of New Zealand. (2013, August 27). What is copyright? [Intellectual Property Office]. Retrieved from http://www.iponz.govt.nz/cms/copyright/what-is-copyright

Intellectual Property Office of New Zealand. (2015, January 19). How to apply for a trademark [Intellectual Property Office]. Retrieved from http://www.iponz.govt.nz/cms/trade-marks/how-to-apply-for-a-trade-mark

Knight, J. (2002). *Patent Strategy for Researches and Research Managers* (Second Edition). West Sussex, England: John Wiley & Sons Ltd.

Kultti, K., Takalo, T., & Toikka, J. (2006). Simultaneous Model of Innovation, Secrecy, and Patent Policy. *American Economic Review*, *92*(2), 82–86.

Lehman, B. (2003). The Pharmaceutical Industry and the Patent System. Retrieved from http://users.wfu.edu/mcfallta/DIR0/pharma_patents.pdf

Lobel, O. (2013, November 21). Filing for a Patent Versus Keeping Your Invention a Trade Secret. Retrieved February 27, 2015, from https://hbr.org/2013/11/filing-for-a-patent-versus-keeping-your-invention-a-trade-secret

Longshaw, D. V. M., & Houlihan, D. E. E. (2013, July 6). In vitro results may lack sufficiency to protect in vivo applications - balancing deadlines for projects, patents and profit | Lexology. Retrieved February 27, 2015, from http://www.lexology.com/library/detail.aspx?g=1480bc6a-39c1-43f8-8fa0-2e24613385ce

Makower, J., Meer, A., & Denend, L. (2010). FDA impact on U.S. Medical Technology Innovation.

Mohr, J., M. (2013, August 1). Rethinking Trade Secret Protection. Retrieved February 27, 2015, from http://www.genengnews.com/gen-articles/rethingking-trade-secret-protection/4939

Moser, P. (2013). Patents and Innovation: Evidence from Economic History. *The Journal of Economic Perspectives*, *27*(1), 23–44.

Munro, N. H., Green, D. W., & McGrath, K. M. (2013). In situ continuous growth formation of synthetic biominerals. *Chemical Communications*, *49*(33), 3407–3409.

Patents Act, No. 64. (1953). Retrieved from http://www.legislation.govt.nz/act/public/1953/0064/latest/DLM280031.html

Patents Act, No. 68. (2013). Retrieved from http://www.legislation.govt.nz/act/public/2013/0068/latest/DLM1419043.html

Quinn, G. (2011, January 28). The Cost of Obtaining a Patent in the US. *IPWatchdog*. Retrieved from http://www.ipwatchdog.com/2011/01/28/the-cost-of-obtaining-patent/id=14668/

Retter, C., & Badenhausen, K. (2013, November 6). The World's Most Valuable Brands. *Forbes*. Retrieved from http://www.forbes.com/sites/kurtbadenhausen/2013/11/06/worlds-most-valuable-brands-behind-the-numbers/

Smith & Nephew. (2013). *Smith & Nephew: Annual Report 2013*. Retrieved from http://www.smith-nephew.com/global/assets/pdf/corporate/smithnephew_annualreport_2013_complete.pdf

Trade-Related Aspects of Intellectual Property Rights. Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, (April 15, 1994). Retrieved https://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm.

United States Patent and Trademarks Office. (2013). Manual of Patent Examining Procedure §2106. Retrieved February 27, 2015, from http://www.uspto.gov/web/offices/pac/mpep/s2106.html

Wagner, K, L. (2014). US2014/0271914. Washington, DC: United States Patent and Trademarks Office.

World Intellectual Property Organization. (2010). WIPO Patent Drafting Manual. World Intellectual Property Organisation. Retrieved from http://www.wipo.int/edocs/pubdocs/en/patents/867/wipo_pub_867.pdf

World Intellectual Property Organization. (2014). The PCT now has 148 Contracting States. Retrieved from http://www.wipo.int/pct/en/pct_contracting_states.html

World Intellectual Property Organization. (2015a). WIPO - Administered Treaties. Retrieved from http://www.wipo.int/treaties/en/StatsResults.jsp?treaty_id=2&lang=en

World Intellectual Property Organization. (2015b, January 21). National Collections - Data Coverage. Retrieved from https://patentscope.wipo.int/search/en/help/data_coverage.jsf;jsessionid=0E987E85335BA99489DEB5546F01A869.wapp2nA

World Intellectual Property Organization. (n.d.-a). International Registration of Marks - Fee Calculation. Retrieved from http://www.wipo.int/madrid/en/fees/calculator.jsp

World Intellectual Property Organization. (n.d.-b). What is Intellectual Property? Retrieved from http://www.wipo.int/about-ip/en/