Reconciling Stakeholder Perspectives on Freedom to Operate reviews in Research Commercialisation

Graham Conroy Harris

A thesis submitted in partial fulfilment
of the requirements for the degree of
Master of Bioscience Enterprise.

The University of Auckland, 2010.

Abstract

There is little empirical research on how people assess and communicate the freedom to operate position for a research commercialisation project. At the same time there is evidence that mistakes in this area- proceeding without clear freedom to operate- are frequent and costly.

This study documents the working practices of thirteen stakeholders of different types (researchers, commercialisation managers, professional investors and IP professionals) in the US and New Zealand. Interviews provided insight into their personal practices and their drivers.

The study looks for similarities and differences between them. It finds that practices differ widely and that differences are not all attributable to individuals' rôles. There is sufficient difference in individual practitioners' approaches and expectations to raise concern that some projects' risks may not be communicated reliably.

This study researches US and NZ statute and case law to clarify the core legal issues. It also looks closely at the sources of information stakeholders use to assess freedom to operate and documents shortcomings in many of them.

It uses the business literature to provide frameworks for assessing risk and improving the quality of decision-making. The academic qualitative research literature provides techniques to tackle some of the difficult theoretical problems presented. The study presents systematic review as an approach to improve performance of freedom to operate reviews, and proposes theoretical saturation as a way to assess their completeness.

The thesis ends with concrete recommendations to make freedom to operate study and communication more reliable and useful. As well as techniques available today, the conclusion anticipates extra tools will become available that will make freedom to operate reviews easier and more certain to carry out.

Acknowledgements

To all those who participated in this study, thank you for the time you gave up and the insight I gained from your interviews.

To my supervisors,

Dr Mike Packer, Senior Research Scientist of the Cawthron Institute in Nelson

Rob Batty, Senior Lecturer in the Commercial Law Department, University of Auckland Business School

Thank you both for pulling me back on track when I wandered and for being supportive throughout.

Thank you also to the other lecturers whose guidance and encouragement got me to this point, and to my classmates for putting up with my questions.

My wife José has supported me through the last year or so with love, tenderness and uncritical acceptance of my decision to give up paid employment to study again. Thank you José, I could not have done this without your support.

Table of Contents

1 Introduction

Inadequate understanding of freedom to operate may be disastrous to those trying to commercialise research. Most commercialisation projects take some care to understand the position before launch.

Many people fill many roles in commercialising a piece of research. Apart from the researchers or inventors, a commercialisation manager is often involved to handle project decisions in a business-like way. These projects cost money, so professional investors get involved. Intellectual property professionals assist in checking the project's freedom to operate as well as in gaining patents. All these people need to have some understanding of the freedom to operate position. The range of factors seen as relevant varies from person to person.

Since these groups of people won't all individually research freedom to operate, they need to communicate with each other about it. If they don't agree what factors to consider, can they rely on each others' assessments of the position? Thus my first research question arises:

- From the points of view of different stakeholders, what makes a good freedom to operate review?

The potential difficulty of individuals communicating also leads on to the second research question:

- How can the freedom to operate position be communicated?

There is more to this question. Commercialisation projects go through multiple stages, often with a more or less formal evaluation gateway between stages. These evaluations often consider the freedom to operate position. Thus freedom to operate research is repeated between stages, and the freedom to operate research at one stage could provide a valid starting point for the next stage's research. This demands communication through time, which this study will also consider.

1.1 Problem and importance

Freedom to operate might be a business' ability to act without reasonable fear of being sued for infringing the rights of others.

An example of lacking freedom to operate is US Patent 5,625,035 for a binding factor that keeps the drug erythropoietin active, reducing the amount a patient needs by 90%. The binding factor must be mixed with erythropoietin. Amgen, patentees of synthetic erythropoietin, can control the new patentee's freedom to operate by choosing whether to license synthetic erythropoietin to be mixed with the binding factor.

1 Introduction

This research will show that the definition above is too simple[1] and would not be agreed between many of those involved in research commercialisation.

Different terms are used, largely interchangeably: in English alone, they include freedom to practise; clearance; right to use; right to market. Lawyers add the term non-infringement opinion.

Individuals also vary in the scope they attribute to the concept.

If the definition of freedom to operate is not shared between them, people may misinterpret each other's meaning when discussing it. Communication is vital between several groups of people (roles) in research commercialisation, from researchers to investors.

One important point in a product's life is the moment of launch. If a company launches a new product into a market and is accused of infringing another's patent, it has few choices. It may withdraw the product, negotiate urgently for a licence to use the other's patent or defend itself in court.

Therefore, just before launching, firms often commission a freedom to operate study from a patent attorney in the relevant market. The patent attorney will interpret any patents that are relevant to the product being launched, so as to warn the firm in advance. The firm will hope the patent attorney can provide it with an opinion saying that there is no patent identified that their new product is likely to infringe. In the US if they are shown later to have infringed a patent, this formal opinion may save them from a charge of willful infringement and perhaps also save the firms directors from personal liability.

The first action of an aggrieved intellectual property owner believing their rights infringed is likely to be to seek an injunction against the infringer. If granted, an injunction will freeze the allegedly infringing activity in its tracks. If the infringer is launching a new product the marketing spend and the initial stock may be wasted, with the firm's credibility in the marketplace.

If the infringing product has already been sold, the problem becomes more costly. The intellectual property owner will seek damages for their loss caused by the infringement. The loser's legal costs may be very substantial, and they may find themselves carrying the winner's legal costs too.

---

1 For example, the definition might be extended to cover factors other than strict intellectual property rights, such as regulatory factors and non-patent exclusivity. Some include trade marks though this study chose to avoid them. Freedom to operate study methods also provide valuable market intelligence for some practitioners. It might be applied to the choices an individual researcher makes in what topic to research and what tools to use.

1 Introduction

In large markets with much intellectual property, freedom to operate conflicts are common. Patent applications are published only around 18 months after they are filed. You may start a development unaware that a patent already filed will make your product unsaleable when it is finished. This is called the pendency problem.

The fear of being sued is reasonable enough. Risk is made up of probability and impact. (Lemley & Shapiro, 2005, p. 79) cites (J. Lerner, 1995) as showing that around 6% of biotechnology patents result in litigation.

If a company is sued, the impact is also rather large. In the US, legal costs alone may be from $500,000 USD (Amin & Pathak, 2009) or up to $4m USD (WIPO, 2010b) even if you win. If you lose, the victor will seek damages for lost profits and seek to turn the knife to receive their own costs and further damages, if they can.

Finding out about a competing patent just before a product launch would be a disaster for a business- destroying credibility and costing money. Therefore, they commonly want to predict ahead of time how much freedom they may have at launch. Businesses and individual researchers review freedom to operate more or less formally at various stages of development (Bonino, Ciaramella, & Corno, 2010, p. 30).

This thesis is about the reviews that different stakeholders undertake at those various stages. It explores who these stakeholders are and at what stages of product development they seek to understand the likely freedom they will enjoy to market or use the product. It aims to understand what all the stakeholders need in common and how they differ. It investigates how the results and intermediate results of earlier reviews may make later reviews more effective in managing development risks.

1.2 Contribution of this work to the Field

Little empirical research has been published on assessing and communicating freedom to operate. A search in Scopus retrieved 499 papers[2] published between 1932 and 2010, from a corpus of 23,600 journals. After excluding papers with only incidental mention and those presenting only high-level views of IP concepts, 18 were possibly relevant. None included any direct study of practitioners' approaches or preferences.

2 which mentioned any of the terms "right to use" OR "right to market" OR "non-infringement" OR "clearance search" OR "freedom to operate" OR "freedom to practise" in the title, abstract or keywords

1 Introduction

A similar search at legal database HeinOnline (narrowed using additional terms[3] and excluding cases, decisions and laws) resulted in 36 articles. Of these, one article included a description of a single firm's IP department including its freedom to operate activity.

Thus, there is little published prior art[4] in this area, making it an interesting subject for study.

This research aims to identify what makes a good freedom to operate review, so stakeholders can perform good reviews more reliably.

This research also looks at the problems of communicating an assessment of the freedom to operate position, in two distinct dimensions:

1. between people operating in different rôles, where the problem is communicating a valid summary of the position; and
2. between people in the same rôle at different points in the process. Here the problem is communicating enough detail for the recipient to build on the earlier work rather than repeat it.

The primary research methodology is a series of interviews with insiders to elicit their experiences and perception, supported by legal research to clarify the complex law that surrounds the topic. The use of interviews reflects the need to understand different individuals as "transmitters" and "receivers" of communication. It also reflects the lack of any identified secondary material on which to base a less exploratory, more quantitative study.

In summary, the cost of getting freedom to operate wrong is high and the lack of shared understanding described here increases risk. This thesis will demonstrate that stakeholders do not uniformly understand and communicate the concept, and suggest how the situation may be improved.

This thesis combines business and law research. The study of relevant business literature helps to understand what stakeholders in research commercialisation should be looking for in a freedom to operate study. The legal research is necessary to clearly understand the concepts around freedom to operate and how they are implemented in the courts. The interviews seek to understand actual practise, and look for good practise to highlight.

---

3 Intellectual property AND interview* AND patent* NOT trademark* NOT copyright*

4 Prior art is a term much used in intellectual property to mean all information published before a particular date.

1 Introduction

The following Background section will introduce the relevant legal concepts broadly, and then discuss some of the business problems in assessing freedom to operate.

2 Background

The objective of this section is to provide background that assists you in understanding the following Interview Results and Discussion section.

It builds on the broad assertions made in the Introduction, supporting them with facts and examples. It will cover the business background to retrieving information and making rational decisions, as well as the legal background at a high level. Some more detailed legal issues will be raised in the later Legal Research section, and the business concepts will be used to support later discussion.

2.1 Legal Concepts

This section includes the general concept of patent and its implementation around the world. It touches also on the interaction between patent and contract, thus leading into the next section on the Business Literature.

Many of the concepts of patent are fairly common to most nations, and this paper describes them as if they were universal. Some of the more important national differences will be covered in the section on Differences between Nations. For simplicity this thesis considers in any depth only the situations in New Zealand (NZ) and the US.

Trade mark is a separate issue. Trade marks may be very valuable and persist much longer than patent protection, but elements of branding such as trade mark can be changed at relatively late stages in the commercialisation process. Many researchers hand over their intellectual property to someone else for the latter stages of commercialisation, and hence have little interest in the trade marks under which they sell. This study considers only patent law.

2.1.1 Patent as a State-sponsored monopoly

The patent system has evolved to provide inventors an incentive to publish how their inventions work, in return for a limited monopoly. The presumed alternative the patent system avoids is that inventors keep their inventions secret. In this case the inventors profit from them without limitation, while society gains no wider benefit from their secret invention.

The effect of the monopoly is reasonably wide. The US definition of infringement covers "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the

United States or imports into the United States". It extends to products made overseas by a process patented in the US. The monopoly is intended to allow the patent owner to obtain a premium price for their product, through the absence of direct competition. Premium prices through the absence of competition are the opposite of what governments normally seek to achieve. Again, the bargain is that in exchange for this brief monopoly, the invention reaches the public domain afterwards.

The monopoly granted by a patent is limited in three ways: to the scope of the patent's claims, geographically and also in time. Each of these is discussed a little deeper below.

2.1.1.1 Subject Matter scope

A patent always includes an element of disclosure (how it works) and some claims which delimit what the applicant claims they have invented; what is new and unique. The claims as approved by the patent examiner set the subject-matter scope of the monopoly. To be approved, the claims must all be entirely within the bounds of the disclosure statement.

The disclosure statement must teach in enough detail to enable a reasonably skilled person[5] to replicate the invention. For example, if you claim a new chemical, you must describe the steps for producing so another experienced chemist could produce it. You must describe its characteristics in enough detail to convince the patent examiner (and ultimately the court) that you have indeed created it.

The disclosure may include supporting references as appropriate, rather than repeating their content. Drawings, diagrams, sequence listings and comparable representations should be included to complete the teaching. The inventor need not have made every claimed embodiment of the invention, provided the reasonably skilled person could produce all the embodiments using the information provided.

2.1.1.2 Jurisdiction

Patents are issued by individual nations and offer protection only in territory of the nation that issued them. When seeking to avoid infringing another's patents, an inventor need only look for freedom to operate in the nations where they intend to do business. For simplicity this thesis considers only the situations in NZ and the US in any detail, with otherwise generic references.

---

5 Who is a reasonably skilled person? That is a crucial question and one without a particularly easy answer. Case law (see section on the Rôle of Precedent) has built up to help answer the question. Legal terms for this include Person of (or having) Ordinary Skill in the Art and Person Skilled in the Art.

The cost of obtaining a patent can be substantial.[6] An inventor will patent their invention only in nations where the benefits of owning the patent outweigh the costs.

2.1.1.3 Time

Patents are always temporary, usually up to 20 years from the application.[7] The bargain for the inventor is the state backs their monopoly. In return the public gets the right to use the invention after the patent has expired.

The patent owner's willingness to pay renewal fees limits also the monopoly term.[8] Through this important feedback mechanism, patents that are not commercially successful enter the public domain early.

2.1.2 Patentability

Inventions must meet a series of criteria to be patentable- these are novelty, non-obviousness (inventive step) and utility (usefulness). The criteria are common but some nations name or describe and implement them differently.

- Novelty- To be patentable an invention must be new. There must be nothing exactly like it in a written publication.
- Non-obviousness- A US applicant must also demonstrate lack of obviousness. The invention must not be anticipated simply by combining two or more published references.
- Utility- An invention must be useful. This excludes devices like perpetual motion machines but not much else. The patent specification must describe the use, and the invention when realised must be able to deliver the effect described, or the patent is invalid.

In NZ, examiners check neither non-obviousness (known as inventive step) or utility (known as usefulness) before grant. A court may revoke a patent lacking them when challenged later.[9]

---

6 The government charges to file patents are usually not great. A provisional patent application costs $220 USD in the US and $50 NZD in NZ. A complete application (including the necessary examinations) costs about $2370 USD in the US, $250 NZD in NZ. Patent attorney fees to prepare the application and negotiate with the government patent examiner are much higher. Published examples suggest $10,000 USD in the US, $3,200 NZD in NZ, for a single national filing. Adding extra countries increases all the fees, though the legal fees may reduce as a proportion of the overall cost.

7 There are schemes, both within patent law and outside, where terms of monopoly can be extended if the process prevents the inventor using nearly the full term. 35 U.S.C. 154(b) extends the patent term if the US PTO processes the application too slowly. 35 U.S.C. §156 permits extension for a drug which must go through an extended approval process before it can be marketed.
NZ has a similar approach in the Patents Act 1953, s 31.

8 In the US, current renewal fees are $980 at 3.5 years after grant, then $2480 at 7.5 years and $4110 at 11.5 years. NZ renewal fees are due at intervals from filing the complete specification, rather than grant: $170 + GST at 4 years, $340 at 7 years, $540 at 10 years and $1000 at 13 years.

9 Patents Act 1553, s 41(1)(f) and (g)

The applicant must show the patentability criteria are met, and meet technical requirements such as disclosure, mentioned under Subject Matter scope above.

Each nation typically has some types of invention which cannot be patented. The US has relatively few limits; NZ has a few more.[10] Many nations do not allow patents on business processes and aspects of biotechnology which the US does allow. Typical exclusions are human life and reproduction, and inventions which would be illegal to make or operate.

2.1.2.1 Defensive Publishing

Freedom to operate is the absence of relevant intellectual property to infringe. One way to ensure the absence of relevant intellectual property is to publish information early enough to destroy the novelty anyone needs to seize the idea as intellectual property.

Often, an organisation will want to take intellectual property for its own purposes, so the idea of making it impossible to take is not immediately appealing. However, patenting inventions is expensive, time-consuming and uncertain.

An organisation wanting to ensure its freedom to practise an invention should define carefully what intellectual property is key to its goals and then consider publishing information about everything else it needs to use the key intellectual property.

This approach is particularly attractive to:

- organisations aiming to deliver a "public good" outcome, and those with limited resources.
- innovations that are not technically challenging and are easy to invent around.

The goal of defensive publishing is to be found by patent examiners searching for prior art. There are a number of well-known ways to achieve this:

- The US PTO enters Statutory Invention Registrations (SIR) into their database of prior art without examining them. Examiners search this database when evaluating applications.
- Anyone can submit prior art to the US PTO, with a statement of how it applies to an application or patent. The examiner will file the prior art but not necessarily act on it.
- Specialised Defensive Publishing service web sites eg Research Disclosure, IP.com

10 The Patents Bill currently being prepared seems likely to continue this distinction.

- India publishes a Traditional Knowledge Digital Library[11] for patent examiners worldwide to use. It contains English translations of textbooks and manuscripts listing natural medicines and traditional techniques.

Inventors can publish defensively to prevent a blocking patent being granted. It must be prepared well ahead of when it is needed. Inventors who assess the freedom to operate position early and take account of competing researchers' trajectories may find it valuable.

2.1.3 Civil enforcement

Though the monopoly of patent has the authority of the state, the state will not take action to uphold the patent owner's right. It is up to the individual patent owner to detect infringement of their patent, identify the infringers and take civil action.

A patent application is examined before issue in what is designed to be an rigorous negotiation between the applicant and an official patent examiner. The resulting patent carries the presumption of validity once issued. Thus in a patent infringement lawsuit, the patent proprietor does not have to prove the patent valid. Rather, the defendant has an option to try to prove the patent invalid as one defence against the charge, in US courts to a standard of "clear and convincing evidence." (Lemley & Shapiro, 2005, p. 80).

A patent owner's first resort on detecting infringement is often to seek an injunction preventing further infringement. The plaintiff must typically indemnify the defendant against their loss if the complaint is not upheld in court. Judges presume a patent valid, so may grant an injunction with relatively slight evidence to back it up. An injunction is a strong incentive for the defendant to stop their activity or negotiate for a licence. In court the patent owner's potential prize is typically just damages to the extent of lost profits, and costs are often not recovered, so an injunction may be the best result.

However the system has some fairly obvious flaws. (Lemley & Shapiro 2005) relate that "While the examination process at the Patent and Trademark Office takes nearly three years on average (Allison and Lemley, 2000), a patent examiner spends only 18 hours per application on average during those three years" and "Of patents litigated to a final determination ... 46 percent are held invalid". A patent owner thus begins infringement proceedings with some fear because their action may lead to

11 www.tkdl.res.in

the patent to being overturned, which would also cost them the amount for which they indemnified the defendant.

2.1.4 Patentability vs Freedom to Operate

As the research results will show, there can be confusion between the concepts of freedom to operate and patentability.

A patent gives the right to exclude others from the patented invention, but it may not be enough to allow the patent owner to practise their own invention. You may gain a patent on the core of your invention, but never be able to profit from it because someone else has a patent on another element needed to implement it. There is an example, of an erythropoietin extender, in the Introduction.

Neither does freedom to operate imply patentability. Freedom to operate may arise from publication in an expired patent, or in non-patent literature which precedes any current patent. Such prior art provides freedom to operate but precludes patentability.

Gaining a patent does not automatically give you freedom to operate. The search that a patent attorney would do to check whether an invention is patentable is largely ineffective in checking for freedom to operate.

2.1.5 Differences between Nations

Patents are national in scope and created by national law. National systems are different, but a series of international treaties makes them more similar- notably the Paris Convention[12] and the Patent Cooperation Treaty (PCT).[13]

Nations practically implement patent laws in substantially different ways. Some developing nations have not provided the support for intellectual property rights that the developed countries expected. The TRIPS Agreement[14] aims to harmonise laws and practices between signatories. Unlike other treaties, TRIPS has enforcement support though sanctions available under the World Trade Organisation (WTO). Nations submit to TRIPS to get the other benefits of WTO membership.

12 Paris Convention for the Protection of Industrial Property (opened for signature 20 March 1883, entered into force 20 March 1883)
13 Patent Cooperation Treaty (opened for signature 19 June 1970, entered into force 24 January 1978)
14 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (opened for signature 15 December 1993, entered into force 1 January 1995)

2.1.5.1 Rôle of Precedent

In the Common Law[15] countries (which includes NZ and the US) judges make binding law through their judgments. These judgments, called precedent or case law, are subordinate to statute (law made by the elected legislature) but build on it, filling in gaps in the statute.

Considerable case law has built up to clarify many details of the law, including the law of patent. Thus lawyers can consult the precedents to predict where a course of action might lead if it were to come to court.

This section has mentioned a few high-level differences between nations, and the reasons why there are differences and why there are not more differences. Some very pertinent differences between the US and NZ are covered in more detail under the heading of Legal Research.

The next section discusses the rôle of contract in intellectual property.

2.1.6 Contract

Intellectual property rights are personal property rights which their owners can sell or license.

2.1.6.1 Licence

When one wishes to use an invention patented by someone else, it is common to obtain a licence for the patent from them.[16] Holding a valid licence for a patent is a defence against a law suit for patent infringement,[17] provided one operates within the licence terms.

The patent owner grants the licensee the right to use the patented invention subject to limits of scope, commonly by geography and application. The licence does not give the licensee ownership in the patent,[18] only the right themselves to use the invention.

The licence may be exclusive, so no other licence will be granted for the same scope, or non-exclusive. There may be a fee, often including a royalty per unit of the invention sold but may also

---

15 Common law is the tradition in nations whose legal systems are derived from the laws of England. Other legal traditions include civil law as practised in many European countries and their ex-colonies; and religious and socialist law. Some nations blend more than one of these traditions.

16 Other common practises are to buy the patent, buy the patent owning entity and to try to invalidate the patent.

17 35 U.S.C. 271(a)

18 Ownership of a minority share in a patent gives the co-owner all the rights of the owner. NZ Patents Act 1953, s 63(2)

include other financial components such as initial and periodic minimum fees.

Research tools may come with licences. The tool-set for using the Polymerase Chain Reaction (PCR) method of multiplying nucleic acids is one such case. Polymerase chain reaction is a tool for recombinant molecular biological research, that has now become ubiquitous in other areas of biotechnology. Such tools commonly include a licence for research purposes only, specifically excluding any commercial application[19].

The licence may include restrictions which are important for research commercialisation. For example, a royalty might become due on products derived from the use of the patented product. Such royalties can have an important effect on the viability of commercialisation projects, particularly if a project entails paying multiple such royalty streams (royalty stacking). If the licence is signed by one person for an organisation, the terms and impact of the licence may not be apparent to those using the licensed patent in research.

2.1.6.2 Cross-licensing or Patent Pooling

Buying a licence is one way to increase your freedom to operate. It is common to need to license many patents (see quotation q:2). Where each license carries a fee, the stacking effect can make the enterprise uneconomic. One solution is to join a patent pool. Each pool member contributes their own patents to the pool and either grants a license to each other member or warrants that they will not assert their patent rights against one another.

2.1.6.3 Material Transfer Agreement

The Material Transfer Agreement (MTA)[20] is like a licence in that it conveys limited rights for consideration, with conditions. In this case the rights are for the use of a physical material which may not be patented but is not widely available. A common case in research is the use of a pure and well-characterised cell line (or plant or animal strain) or a gene (Kryder, Kowalski, & Krattiger, 2000, p. 6), which can be used to produce a complex chemical such as an enzyme or immunity molecule, or simply to understand a biological process better.

---

19 The licence from Roche companies for their PCR reagents is at https://www.roche-applied-science.com/new/legal/index.jsp?id=legal_000000 . The original PCR patents all expired on 28 July 2004, so the technique is in principle free to use but firms like Roche have introduced new equipment and reagents embodying new incremental patents. Researchers using the new tools are bound by current licences.

20 Also known sometimes as a either Technical or Tangible Property Transfer Agreement, or a by-use licence to distinguish it from a licence for intangible intellectual property.

MTAs may contain "reach through" clauses[21] which confer ownership of any intellectual property derived from the use of the transferred materials. Such a clause could have a devastating effect on the commercial value of a research project.

This section on the relevant legal concepts has discussed patent law at a high level, and how it meshes with contract law to enable a patent owner to benefit from their invention. Some more detailed discussion of intellectual property law, responding to issues uncovered by the interviews, is presented in the section on Legal Research. This study now turns to discuss the non-legal background to the research.

2.2 Business Literature

Freedom to operate reviews provide information to assess the risk of commercial trouble ahead of a course of action. The study therefore looks briefly at the theory of Risk.

Freedom to operate reviews should clarify the options available to decision makers, so the section after Risk looks at the theory of decision making.

It is difficult to scan the sheer volume of published information to identify possibly-blocking intellectual property. This is a problem in the Information Retrieval domain so this thesis goes on to consider some of the theory and practical issues there.

2.2.1 Risk

Risk management is widely practised in business. Recently international standardisation work has led to the publication of ISO 31000:2009 (Standards Australia & Standards New Zealand, 2009)

Illustration 2.1: ISO 31000:2009 Risk Management Process

21 F vered u

based upon joint work by Standards Australia and Standards New Zealand. The same group produced Handbook HB 296:2007 (Standards Australia & Standards New Zealand, 2007) for Legal Risk Management. Both standards describe a common process for risk management:

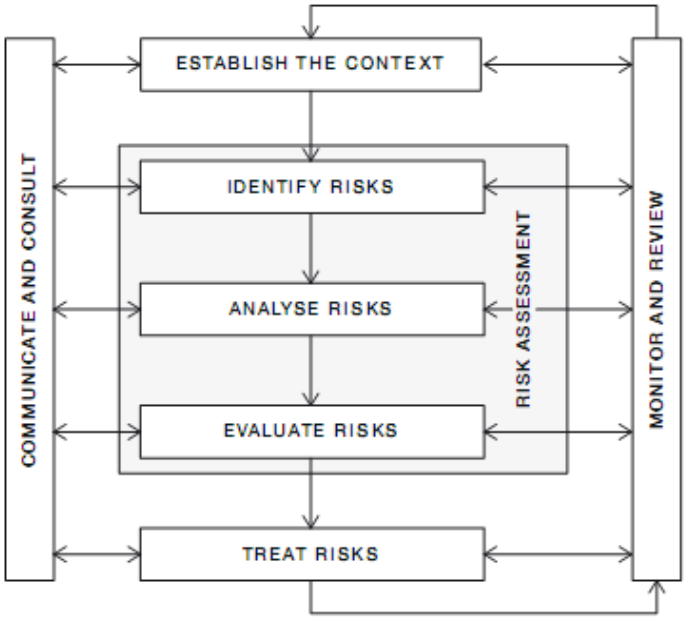


FIGURE 4.1 RISK MANAGEMENT PROCESS – OVERVIEW

It is easy to interpret freedom to operate reviews in this process structure.

- The researcher establishes context by briefing the freedom to operate searcher,
- The searcher identifies the risk components.
- Each potential component found must be analysed. In the first instance the searcher will analyse the found documents for relevance and select for further study only those above some threshold. Subsequently the searcher and others may analyse in more detail those found documents above the threshold. Each relevant competitor patent found (some would argue each claim of each relevant competitor patent) is treated as a separate risk.
- The researcher or their institution will then evaluate the risks found, and use the evaluation to make decisions.
- Finally the researcher/institution will treat the risks, that is take a deliberate course of action based upon the analysis and evaluation. The course of action may be just to note and ignore the risk. It may be to take definite step such as to adjust the direction of research or development, or to negotiate a collaboration or licence.

During the analysis stage, the risk is decomposed into the two dimensions of likelihood and consequence.

- Likelihood is how likely it is that the risk will eventuate, for example how likely is it that the owner of a found patent would sue if the researcher were to launch the intended product without first obtaining a licence from the patent owner.
- Consequence is what will happen if the risk eventuates, for example if the researcher were to be sued, how much would it cost them in legal costs, damages and royalties.

The evaluation stage takes into account the context, including the researcher's appetite for particular kinds of risk. Some organisations formally note their appetite for risk as a policy.

Some avenues for treating risks are discussed in the section below on Risk Management.

2.2.1.1 Risk Appreciation

Detailed and objective information about risk is not available in the early stages of a project before much work has been done. Therefore, project participants must judge risk based on inadequate information. This is a normal part of life- most people cross the street without knowing the pedestrian accident rate at that corner.

Project managers learn to capture information about risks in risk logs that evolve through the project's life, growing in detail as risks are better appreciated. For each risk the log should record its likelihood, consequence, trigger conditions, owner, mitigation and contingency.

Individuals' appreciation, or perception, of risk is influenced by several factors including misleading personal experiences (Slovic, 1987, p. 281). (Tversky & Kahneman, 1974, p. 1127) relate that individuals rely on "retrievable instances"; that is, they judge the risk of something occurring based on their personal knowledge of analogous situations. Thus if a researcher has never been sued over patent infringement, he is likely to estimate the likelihood of being sued lower than someone who has been sued.

2.2.1.2 Risk Estimation

Rational methods exist for estimating risk without any realistic way to measure it. Common methods include:

- Delphi/Expert method (Dalkey & Helmer, 1963) in which several experts are asked for their opinions in circumstances where they do not confer with each other. The researcher may

then tell the experts of each others' opinions and give them another "round" to adapt theirs, until the panel converges on a common view.

- Betting methods, where researcher repeatedly asks an individual whether they would place a bet on the risk event occurring at different odds (Golub, 1997, p. 168).

Such methods are not foolproof, but provide a systematic way to tackle a difficult issue.

Any technique to estimate risk is vulnerable to motivational bias: that is, a bias by the person estimating the risk in favour of the result that best suits them. Those individuals involved in a project may have the best tools to accurately estimate the risk but be prone to motivational bias. Therefore it would be useful to take estimates from someone not involved in the project (perhaps a patent attorney), even though their view may be less well informed than someone closer to it.

Once individual risks have been estimated it becomes fruitful to assess an overall risk position. A decision tree is an effective means to communicate risks and also to calculate a static overall risk value (Poltorak & P. J. Lerner, 2001, p. 51).

2.2.1.3 Risk Management

Risk treatment or management is an ongoing process in which a course of action is taken and the risk monitored as the action proceeds. Management can modulate action as the project and the risk develop. A risk which may occur well in the future need not be dealt with immediately. It may be more prudent to conserve resources to deal with risks which may occur sooner instead.

One approach is to take steps to mitigate the risk, that is to reduce its likelihood, consequence or both.[22]

Another approach is to earmark a contingency amount to cover the consequence if the risk were to eventuate (perhaps by buying an insurance policy), and otherwise proceed as if it will not occur. Given that patents are national, the contingency might be to be to withdraw from a country where a patent exists and continue selling in countries where no equivalent patent is found.

These two approaches are not mutually exclusive. Mitigating a risk may reduce its likelihood but it may still be appropriate to set aside a contingency in case it eventuates.

22 Obtaining a licence is a way of mitigating a risk of infringing intellectual property, but there are others: for example designing around the other intellectual property, or obtaining a non-infringement opinion from a qualified patent attorney.

Contingency amounts may be earmarked not for an individual risk but for a project as a whole. In a multi-project environment such as an institutional technology transfer office or a corporate research business, a contingency pool may be shared between many projects. A sufficient contingency pool is the larger of:

- enough to cover the largest consequence of any of the risks in the pool and
- the sum of all the risks for all projects in the pool, calculated for each risk by multiplying the likelihood by the consequence (Khamooshi & Cioffi, 2009, p. 174).

In practise organisations may not maintain a specific contingency pool, but use risk management policies that limit the consequence of any one risk to a size they can absorb from working capital. Larger risks they mitigate through avoidance or licensing.

Risks are factors in overall business decisions. The next section looks at business decision making more generally.

2.2.2 Decision Theory

Decision theory discusses the processes by which people make decisions.

(Deboys, 2004) provides a useful high-level introduction to decision theory specifically for patent searching and analysis. She notes that decisions around patent are "sequential decisions where uncertainties play a large part" as distinct from many business areas with "one off decisions where a group of alternatives ... must be compared". (Golub, 1997) describes this second type making in more detail- including the sage advice that "All models are wrong but some models are useful". This paper does not discuss them further.

Multi-stage decisions are typical in research commercialisation projects. In these it is useful to defer many of the decisions until as late as possible.[23] This approach allows decisions to be made when the best information is available and keeps open options until they must be closed off. (Boer, 2003) offers a means to value such projects, considering the decision points ahead and the risks estimated at each of those decision points. This valuation can show a justification for some projects capable of creating more than one product, where any individual product alone would not justify the development risk.

23 There is also a value in "failing fast and cheap"- the strategic approach of identifying the most critical unknowns in the whole process and specifically tackling them first, using the least possible effort to crystallise each risk. It is possible to combine them by crystallizing the biggest risks early (does it work?) and delaying other commitments till the last possible moment.

2 Background

Citing (Joy, 2000) Deboys describes Joy's hierarchy of decisions:

- Strategic: formal, planned through a step by step process.
- Tactical: informal and timely, based upon pre-determined rules.
- Operational: almost intuitive, without any risk analysis. She cautions that "the danger with this type of decision is that bad practices can become habitual".

Deboys lists what she feels characterises a good patent search:

> *• Decide what is searchable––frame the search problem as distinct from the original request.*
> *• Decide what can be expected from the search, given the available sources of information and their limitations, budgetary constraints, legal deadlines and company timeframe. Communicate it to others.*
> *• Decide on the timing and sequence of decisions to be made during the search–– plan a strategy for searching (use of online databases, Internet sources, print publications or expert contacts), document the search pathway and reasons for following it.*
> *• Decide where uncertainty will arise and manage it effectively––use methods of retrieval that will reduce uncertainty (e.g. citation searching to identify relevant coding), question and respond to results as they come up, revise the strategy accordingly, aim for comprehensiveness.*
> *• Decide how best to work with risks, and understand their consequences––keep up to date with search tools, their strengths and weaknesses, be informed about legal processes, maintain confidentiality.*
> *• Decide how to identify opportunities and create alternatives––be a detective, challenge assumptions, question the results (what exactly does it mean if you have zero hits?).*
> *• Decide how to deal with complexity and ambiguity–– decide when you have finished a search (see Edlyn Simmons' classic 1985 paper on patentability searching [16]), organise electronic files and papers, document the search strategies and choices made, annotate the results.*
> *• Legal decisions are made by attorneys as a consequence.*

The themes in this list will feature largely in the Interview Results and Discussion section. The Edlyn Simmons paper referred to is a disappointment, not contributing much to deciding when enough is enough.

2.2.3 Information Retrieval theory

Searching for prior art is a problem in the Computer Science discipline of Information Retrieval.

2.2.3.1 The Quantity Problem

In 2008,

- the US PTO received 485,312 applications and granted 185,224 patents (US PTO, 2010a).
- Worldwide 1.9 million applications filed and 777,600 granted (WIPO, 2010a, p. 8).
- for comparison, around 300,000 scientific papers from North America were published in journals (Science-Metrix, 2010, p. 8); around 1.1 million papers from all countries combined.
- 6.7 million patents were in force and 5.94 million potentially pending, 1.25 million of them pending in the US PTO (WIPO, 2010a, p. 10).
- The average European Patent Office (EPO) patent application in 2002 had 30 pages and 19 claims, both averages rising swiftly.[24] Biotechnology patents were the longest (averaging over 60 pages and 26 claims) (Vanzeebroeck, Stevnsborg, van Pottelsberghe de la Potterie, Guellec, & Archontopoulos, 2008).

Clearly published applications and patents represent a large store of information scientists and engineers could learn from. Equally though, Freedom to operate searchers must try to identify relevant prior art from far more material than a researcher might survey to create a literature review. The problem of finding needles of relevant information in such a haystack of published information has been a focus of research for several decades.

2.2.3.2 Precision and Recall

Even a simple search of a patent office's database, or a search of academic literature, is likely to uncover much material. Information scientists measure two dimensions on which to judge the success of information retrieval (Bonino et al., 2010, p. 34):

- Precision is the proportion of documents returned that are relevant.
- Recall is the proportion of all relevant documents that are returned.

24 The authors observed that "Therefore, US patent drafts have increasingly driven the observed phenomenon" of increasing patent length and number of claims- implying that US patents are longer.

Precision and recall is tested in annual academic competitions pitting experimental search tools against one another.[25] The "better" a search is, the larger proportion of all relevant material it retrieves (Recall) and the less irrelevant material it retrieves (Precision). It is possible to design "better" searches when you know exactly what you are looking for. Most searching though is in part exploratory and the trade-off is that a high precision search will have lower recall.

It is possible for a single search tool to score well on both precision and recall at the same time, but most tools optimise for one or the other. Precision is preferred by most public search engines like Google and Bing, since they expect public users to want to see the most likely solution to their question in the first page of results.

In freedom to operate studies, the cost of not finding a relevant reference is high- that will be the patent you infringe when you launch the new product. Thus, freedom to operate searches typically favour recall over precision, leaving the researcher with much manual effort to distinguish relevant and irrelevant found documents. This could be helped by ranking found documents, although the means commonly used do not help in this case.[26]

2.2.4 Incomplete Sources

Appendix A. presents evidence that all available sources are incomplete, in more detail than fits comfortably into the narrative flow of this thesis. The conclusions there are that sources all have limitations, often described by the source but sometimes the limitations are empirically found to be greater than the source describes.

This study goes on now to present a strategy for dealing with multiple incomplete sources.

2.2.5 Systematic Review

Systematic review originated in evidence-based medicine as a way to ensure that all relevant information was considered when evaluating medical interventions. Their topic of choice was the many clinical studies which often produce apparently contradictory results, leaving interested

25 Precision and recall can only be measured where there is a yardstick against which to compare the results returned by the search tool. This yardstick is the TREC test collections which contain known sets of documents. There are specific queries available for which the results returned by the search tools can be compared with exhaustive manual searching of the document sets. In 2001, a body of Japanese patent applications was made available in TREC for patent-specific information retrieval tests.

26 Google's unique algorithm PageRank takes into account how many other pages "point to" the page at hand. Other systems may rank found documents based on how many times the search term appears, whether the words in the search term appear in the same order in the document and so on.

Ranking does not affect either recall or precision.

observers able to select the results that best support their point of view. Specifically, the groups of researchers sought to establish "a replicable, scientific and transparent process, in other words a detailed technology, that aims to minimise bias through exhaustive literature searches of published and unpublished studies and by providing an audit trail of the reviewer's decisions, procedures and conclusions" (Tranfield, Denyer, & Smart, 2003).

Summarised by (Bryman & Bell, 2007, p. 101), Tranfield et al. broadened the method to management reviews more generally by simplifying it into three key stages:

1. Planning, using a review panel of experts to define the review's boundaries by creating a Review Protocol document, and monitoring it as it proceeds.
2. Conducting a review using sources (published and unpublished), keywords and other elements of search strategy from the Review Protocol to retrieve all relevant material, then analysing it as prescribed in the Review Protocol.
3. Reporting and dissemination by providing "a descriptive map of the research on the subject, who the contributors are" ... "A further criterion for reporting is accessibility and readability. The review process should make it easier for the practitioner to understand the research".

Tranfield et al.'s method provides a framework for surveys of published and available materials which are systematic, reproducible and auditable.

2.3 Conclusion of the Background section

This thesis investigates these two research questions:

- From the points of view of different stakeholders, what makes a good freedom to operate review?
- How can the freedom to operate position be communicated?

The foregoing section first offered a very high level view of the legal concept of patent and how it is applied to businesses. It touched on how and why the law and practice of patenting is similar in most countries, and also why it varies between countries. This is needed to establish what to look out for as a minimum in any freedom to operate study. Since the laws differ in different parts of the world, and since patent law and its application to freedom to operate is complex, the Legal Research section will return to it.

2 Background

Moving away from the law, this section reviewed aspects of risk and decision theory as they apply to business decisions in the face of the uncertainty that exists in research commercialisation. These are useful to inform the discussion around communicating the freedom to operate position.

Some concepts from information theory applicable to the problem of searching the patent and scientific literature were discussed. Finally, the section referred to data in Appendix A. which shows that all available sources of information are incomplete, and offered a potential way to minimise the effect of that incompleteness.

The next section describes the methodology of this research project, and why it was adopted.

3 Research Methods

This section aims to explain the choice of methods used in this research, which were respectively legal research and interviews with practitioners.

Legal research is necessary because some the interviews bring up subjects requiring a more complex understanding than the high level given in the Legal Concepts section. Without a good understanding of the law of patents, it is hard to know what to look for in a freedom to operate study (where should we draw the boundary between what is relevant and what is not?) or how to communicate the position (how likely are we to infringe? If they sue, what will be range of outcomes? what options do we have to avoid being sued?).

3.1 Legal Research

At its heart, freedom to operate is a legal concept embodying the ability to act in a chosen way without infringing another's intellectual property. Some of the participants in this study added extra meanings onto that, but understanding that legal concept in some depth makes it possible to understand the participants' positions.

Legal research follows one of several possible approaches (Kjervik & King, 1990, p. 214). The authors indicate that the best approach to a problem of this sort is the conventional legal method, taken in 90 percent of legal research in Canada by law professors. They state that "The major purpose of the conventional legal research method is to locate legal authority", and they give a useful list of steps to follow, which is rather similar to the list given by another source (Weiler & Rhodes, 2007).

Kjervik & King (1990)	**Weiler & Rhodes (2007)**
Identify the legally important facts	Present facts about the case
Legal issues must be framed	Identify the legal questions
Identify the relevant sources of law	Identify and explore the legal authority
	Analyze the pertinent law
Find the answer to the research question	Apply pertinent law to the legal questions
Communicate the answer to the research question	

Table 1 Alternative definitions of conventional legal method

In the Legal Research section this study will follow the approach of Weiler & Rhodes (2007) to address the legal questions with two modifications:

1. The legally important facts, normally the source of the controversy in a law case, are just the scope of enquiry here, freedom to operate restricted to patent law in the US and NZ jurisdictions. There is no need to document this as a separate process step.
2. The distinction between the fourth and fifth steps (analyse and apply the law, respectively) is too slight to preserve. Thus those two steps are joined into one.

3.2 Interviews

Interviews were necessary to gather first-hand information from practitioners on how they assess and communicate freedom to operate. Though there have been trade press articles describing how to conduct prior art searches or establish freedom to operate, no previous literature reported gauging how practitioners in fact approach assessing and communicating freedom to operate. This paper's contribution aims towards filling this gap in the literature.

The semi-structured approach avoids pre-judging what the answers might have been, giving instead a loose structure within which participants could describe their practise and experience in their own words. This was important to permit the expression of the different individual views which may exist. A questionnaire or a fully structured interview would probably have gained more depth in some ways but would also have masked some of the differences between participants.

3.2.1 Selection of Participants

Representatives of different stakeholder types were interviewed to understand their perspectives.

(Ahn, Gray, & Collier, 2010, p. 11) in their 2010 Working Paper on Innovation, Technology Transfer and Commercialisation in New Zealand chose to survey:

> *researchers/scientists (43%), entrepreneurs and management executives (17%), CRI technology transfer staff (7%), government officials (e.g., FRST, MoRST, TEC, NZTE) (7%), investors (e.g., Angel, Venture Capital) (6%), university technology transfer office staff (6%), key support professionals (e.g., patent attorneys, accountants, lawyers, headhunters) (4%), and other professionals in the national innovation system (e.g., company directors) (11%).*

The first list includes some people who probably do not have a distinct Freedom to Operate rôle in many research commercialisations. For example:

- Government officials may consider freedom to operate when making seed investments, but their perspective is that of the investor, not a unique government perspective.
- The distinction between CRI technology transfer staff and university technology transfer office staff may have been useful to Ahn, Gray, & Collier, but is too fine for this study.
- Directors in innovative firms may behave similarly to either technology transfer staff or investors, according to the project stage.
- Corporate lawyers in freedom to operate work may behave like Patent professionals.

(Bonino et al., 2010, p. 30) say "Current patent users are not only patent domain experts, but include new occasional actors such as managers, industrial researchers, academic faculty, and so on, each needing a different set of functionalities and a different degree of application complexity." This proposes a wide group and presages the differing needs of sub-groups.

Therefore, the appropriate set of stakeholder types to interview should be:

- Researchers/scientists and other inventors;
- Technology transfer staff (referred to as commercialisation managers);
- Investors;
- Patent professionals (includes patent attorneys, agents and professional searchers).

From informal discussion with members of the innovation community, it became clear that individuals move between these rôles over time. For example, scientists and patent attorneys may become technology transfer staff, and patent attorneys require a relevant technical background and so commonly move in from a researcher rôle. Therefore, each stakeholder agreed to respond from the perspective of their current rôle unless they identified a different perspective for a particular response.

3.2.2 Interview Structure

The interview phase of the research was exploratory, using semi-structured interviews to understand the particular concerns of each of the types of stakeholder. The interviews separate from the interviewees' daily work, so a technique like the verbal protocol (Bryman & Bell, 2007, p. 231) was not suitable. Since the interviews aim to get general information about the interviewees' approach

rather than examining a particular incident, the critical incident technique (Bryman & Bell, 2007, p. 227) was also not useful.

The most satisfactory structure for this study was a behavioural or experience-based interview (Rudman, 1994, p. 247) in which the interviewer prompts the interviewee to recount their involvement in one or more actual past events. This approach has been shown (Pulakos & Schmitt, 1995) to perform better than putting hypothetical situations to the interviewee. Each interview began with a discussion to set up the context in which the interviewee responded (eg clearly identifying the particular stakeholder perspective), and to enable the latter parts of the interview to be tailored to the interviewee.

Interviews were face to face where possible or otherwise by telephone, and averaged about one hour. The interview guide used is presented at Appendix C.

Selected graphics were presented and interviewees were asked to comment on them, to spur discussion on how information might be communicated.

3.2.3 Graphics

The whole topic of intellectual property is complex. People who do not work with intellectual property every day may not understand all its ramifications. This is no different from many other concepts in business. A chief executive need not understand the engineering details of his product or process, nor the way the corporate tax liability is calculated. They will rely upon colleagues and advisors to present the complex information to decision-makers in a form that is relatively easy to assimilate and use to make decisions.

One common way this is done in business is through the use of presentations involving tables and charts. The same approach might be useful in dealing with the complexity of communicating a freedom to operate position to decision-makers.

Eight-seven graphical or tabular representations (graphics) of patent positions were collected that might help communicating a freedom to operate position. Several of the graphs were taken from a publication of the Japan Patent Office (Invention Research Institute, 2000) which has a great many types of graphic, others from intellectual property consulting firms web sites and published reports such as (Buchanan, 2009).

Many of the graphics shared core characters with others. From the 87 examples, elements such as data types shown were extracted and tabulated for analysis. The analysis yielded 25 individual elements represented in the graphics, belonging to 7 groups:

1. Presentation, being Table or Graph;
2. Patent reference info such as patent number, jurisdiction, abstract and family;
3. Subject, including formal classifications and high-level groupings;
4. Time, including dates of application and grant, but also changes in quantity over time;
5. Quantity of patent applications;
6. Actors, being the inventors and assignees;
7. Citations, forward and backward.

Using these dimensions the graphics were classified into these 9 groups:

1. Applications over time
2. Flow of ideas including Patent Families[27]
3. Applications by Assignee
4. Collaboration Maps
5. Applications by Technology Group
6. Applications by Country/ Industry/ Assignee Type
7. Density map by Technology
8. Problem/Solution Charts
9. Table of Patent Families

For each group of graphics the example which best represented the group was selected. In most interviews there was time within the agreed period to table each of them for comment by the participant. The selected graphics and representative comments from participants are included in the Interview Results and Discussion section.

3.3 Transcription and Coding

Interviews were recorded electronically and mostly transcribed by the interviewer. In a few cases with permission of the participant an external transcriber was used. Two recordings could not be transcribed and in these cases only notes made during the interviews were used.

27 A patent Family is broadly a group of patents sharing a common ancestor (priority date). Definitions vary between sources- in some definitions, the inventors need to be common.

Each transcribed interview or set of notes was then converted into a table with one row per turn in the conversation and two columns. The transcriptions were reviewed and notes and codes were recorded in the second column.

Coding (Bryman & Bell, 2007, p. 585) began with some codes and categories designed to support the research questions, and new codes and categories were added as they emerged from study of the transcripts. Coding was approached iteratively, as each transcript was available. Earlier transcripts were re-evaluated as the coding scheme evolved with use. Coding was judged complete when all transcripts were coded and additional coding effort produced no additional codes.

The codes represent a controlled vocabulary method (Akers, 2003, p. 306), (Walters, 2008) which attempts to represent concepts consistently whenever found. This makes retrieving all instances of that concept later more reliable. A similar approach is used by some of the value-added proprietary patent database operators such as Thomson Reuters to add value to their data.

In the case of these interviews that approach was only partly successful- codes were applied imperfectly, which became clear as the coded transcripts and notes were further reviewed while writing. The coded transcripts and notes were incorporated into a full-text database (Xapian through a Recoll user interface).[28] This combination's advanced searching capabilities, such as stemming, wild cards and proximity searching aided considerably in finding the parts of each interview that bear on the concepts being explored.

The concepts of coding and full-text searching applied in the research for this project mirror closely some of the techniques used in searching for prior art.

3.4 Derived Theory

The approach in this study has been to start with an interesting set of questions, rather than propose a theory to test. The literature study helped understand the background to the questions, and create the interview guide. The themes chosen to present, interpret and discuss the findings come from the research participants through the words of their interviews, but also from the literature study and subsequent legal research. These themes give structure to the presentation and discussion.

Some of the themes emerging from the interviews have been tied back to theory from the literature to recognise good practice. Good practice is pointed out where found in the discussion within the themes.

28 www.recoll.org

The thesis concludes with a series of recommendations. These follow the good practice used by some of the participants, codified and sometimes extended with the support of theory.

3.5 Limitations of this Method

All research is limited by the available resources. This study drew on the experience and practices of thirteen practitioners and did not attempt to apply theoretical saturation itself. Therefore it could be improved by extension through more interviews. Using the insights gained from this study, it would be appropriate to adopt a more structured approach (questionnaire or interview) to that research.

All the first-hand information gained in this research was verbal, through the interviews. The research format did not allow very deep probing into the formats in which practitioners preserve and convey information about the freedom to operate position. It would be useful to review these formats in more depth to elicit good practise, but the confidential nature of the information held makes this difficult in a research project involving many participants.

This project originally planned a case study phase, using the proposed recommendations to validate them. The case study phase was not possible in the time available and the research therefore lacks this validation. It would be very valuable to use the recommendations in real research commercialisation projects to check their usefulness.

3.6 Conclusion of the Research Methods section

This section introduced the principles of legal research that will be used in the Legal Research section. It also discussed the approach to the primary research; the reason for interviews and in particular semi-structured interviews. Semi-structured interviews generate lots of data when transcribed, so the section also introduced techniques to extract information from the transcriptions and notes. It also noted that these techniques are similar to some of the techniques of freedom to operate study.

4 Legal Research

This section of the thesis explores in more depth the legal background to freedom to operate. This deeper understanding of the concept and its implementation is necessary to understand the points of view of the participants interviewed, but also to assess how far those points of view have legal validity and relevance to the study of freedom to operate.

This section applies a simplified form of Weiler & Rhodes (2007)'s steps as discussed in the Research Methods section:

1. Identify the Legal Questions
2. Identify and Explore the Legal Authority
3. Analyze and Apply the Pertinent Law

4.1 Identify the Legal Questions

In this section, legal questions are derived from the overall research questions.

The first research question is to identify what makes a good freedom to operate review. Though the boundaries may vary between people, the core is the legal concept of freedom to operate which about avoiding infringing someone else's patent. This requires a more detailed understanding of infringement. Thus the first legal question is:

> 1. How is patent infringement shown, and thus how can one avoid and defend against a complaint of patent infringement?

The Background section noted that freedom to operate review is about assessing and communicating risk. The problem of pendency (that patent applications are hidden until 18 months after filing) means that there can be no guarantees that a new product will not later infringe a granted patent. A valuable outcome of freedom to operate study is mitigating the risk. Reducing the size of the damages in a law suit is a start commonly mentioned in the freedom to operate context. Thus a second legal question:

> 2. If a market entrant cannot avoid infringing someone else's patent, what are the consequences and what factors can increase or decrease the severity of penalties?

4.2 Identify and Explore the Legal Authority

The second step on the legal research journey is to consider what law is relevant to the legal questions. This research is restricted to NZ and the US for these reasons:

- The laws of NZ are those which affect groups researching or trying to commercialise research in NZ so long as they and their ambitions stay within the confines of NZ.
- The US is commonly seen as the most attractive place to commercialise research, because of its large and rich domestic market and well-developed funding market for commercialising research. US investors' first concern may be their investments' viability in their own domestic market.
- Other markets share many of the same principles as the US and NZ, but the differences of detail are sufficient to over-complicate a study of this sort. Part of any freedom to operate study is to identify the relevant jurisdictions where freedom to operate is sought; at that time, the person assessing the position should consider how laws of those jurisdictions differ.

As noted in the section on Legal Concepts, within each of NZ and the US there is a separate set of pertinent law. (Kjervik & King, 1990, pp. 216-7) lists many sources of law:

> *Sources can be categorized into (1) court opinions; (2) statutes; (3) constitutions, (4) administrative regulations (a general rule promulgated by an agency); (5) administrative decisions (resolution of a specific controversy by an agency); (6) charters (law of a municipality or other local governmental body authorizing it to perform its functions); (7) ordinances (law passed by a local governmental body); (8) rules of court (procedural rules used by a given court); (9) executive orders (law issued by the chief executive according to statutory authority); and (10) treaties (agreements between two or more countries).*

The objective of this section is to identify and discuss what law is particularly pertinent to freedom to operate. Thus discussion on the hierarchy of sources of law will be restricted to those relevant to patent law.

When considering a point of law decided by a case, the researcher should consider whether it has been subsequently overruled or weakened (perhaps, its breadth of application has been narrowed) by a subsequent judgment. The major legal database providers offer ways to identify subsequent

judgments which support or reduce the impact of a judgment. The best known of these is perhaps Shepards but several case citation services exist.[29]

4.2.1 New Zealand

The most relevant statute in NZ is the Patents Act 1953. This was based upon the Patents Act 1949 (UK) but it has been amended several times subsequently. One way in which this Act is out of step with modern practice elsewhere is that it uses the doctrine of local, rather than global novelty. In principle, to get a NZ patent an inventor need only demonstrate that the invention has not been published in NZ before the application. In practice, patent examiners consider publication through the internet from anywhere as publication in NZ.

A Patents Bill 2008 235-2 is in hand in the NZ Parliament, and proposes many changes to the current Act (including adopting a global standard of novelty, and a new check for inventive step). This is not current law, but it can be useful to be aware of proposed changes since the objective of freedom to operate study is to predict what the position will be later.[30]

The Patents Act grants authority to the Governor General and the appointed Commissioner of Patents to make regulations for administration of patent law.

In NZ, the hierarchy of courts in patent cases starts with the High Court[31], and proceeds through the Court of Appeal and finally the NZ Supreme Court.

4.2.2 United States of America

Current US patent law is based on Title 35 of the United States Code enacted in 1952 (referred to as 35 U.S.C.). Titles were introduced from 1926 as codified collections of existing law. As Acts are introduced their relevant provisions are incorporated into Title 35 so the current version[32] of Title 35 gives the current legislation.

---

29 for example, the NZ Case Citator from LexisNexis NZ and KeyCite from Westlaw.

30 Bills commonly include measures to codify and modify judicial precedent.

31 Patents Act 1953 s 2(1) says that "Court means the High Court".

32 However, the PDF version downloadable from the US Government Printing Office web site, among a group of files purporting to represent the 2008 legislation does not include any amendments after August 2005. The version included as Appendix L to the Manual of Patent Examining Procedure (MPEP- available from the WIPO web site) is dated September 2007 and appears to include amendments up to July 27, 2006. The most recent Act referenced in the entire MPEP is the Consolidated Appropriations Act of 2005, while the most recent reference in Appendix L is to the Energy Policy Act of 2005.

There are also Regulations under the Code of Federal Regulations (CFR). Congress has delegated authority to the US PTO to make these regulations, which bind courts like statute:

- CFR US184 Title 37[33] - Patents, Trademarks, and Copyrights (as amended Dec. 2009 being the latest consolidated set at July 2010); and
- CFR US182 Manual of Patent Examining Procedure (Eighth Edition, Revision 7, July 2008)

In the US, patent cases are heard in the first instance in the 94 Federal District courts. The Federal District court for a particular case is chosen by the plaintiff subject to residence rules.[34] The United States Court of Appeals for the Federal Circuit (abbreviated to the Federal Circuit or CAFC) exercises subject-matter jurisdiction over patent appeals and a few other types of case. The final appeal is to the United States Supreme Court, which has made seminal judgments in biotechnology[35].

The US is out of step with other nations through its use of a doctrine of First to Invent. Under the more common First to File doctrine, if two inventors file patent applications making the same claims, the first of them to file their application[36] has priority.

This introduces extra complexity and uncertainty into the patent system for slight actual benefit to inventors. In a sample of 21,000 patents issued, only 0.1% were given priority based on an invention date before the filing date (Crouch, 2010, p. 7).

The First to Invent doctrine, and some transitional problems resulting from old US law, are useful to know about but not central to this thesis. They are discussed in Appendix B.

Having identified the salient legal authorities for the US and NZ patent systems, the next stage is to analyse and apply that law.

4.3 Analyze and Apply the Pertinent Law

This section aims to reason from the law to illuminate the issues in assessing and communicating freedom to operate. It is analogous to the stages in a scientific study of collecting and analysing

33 Title numbers in the Code of Federal Regulations do not align with those in the US Code.

34 Litigants often "forum shop" for courts likely to be sympathetic. The Eastern District of Texas is thought to be friendly toward patent owners, though recent cases have showed this to be limited.

35 For example, the judgment in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (LEXIS) which agreed that a living organism could, in some circumstances, be patented.

36 Including a provisional application and including an overseas Paris Convention or PCT application.

data, and drawing conclusions from it.

4.3.1 Patent Infringement

Ownership of a patent confers a legal monopoly on the manufacture, sale, importation or use of the products derived from the ideas claimed.[37] The defendant need not know they have infringed to be liable for having literally infringed.

If a patent exists for a process to produce a product, anyone producing that product has the burden to prove their product is not made by the patented process.[38]

In the context of proving infringement, the patented idea can be crystallised to mean the entire content of any one of the claims in the patent. An infringing item or action must include every element listed in the claim.

The elements of a dependant claim include the parent's claims. An independent claim is a claim that stands alone and needs no reference to any other claim to define its content. By contrast, a dependent claim makes reference to another claim. For example, an independent claim (1) and then a dependant claim (4) from US patent 4341038:

1. A process for obtaining oil products from algae, which process comprises:
(a) growing halophilic, unicellular, swimming algae, having no cell walls, in a saline solution and in the presence of carbonic anhydrase enzyme derived from such algae;
(b) harvesting said algae to obtain an algae-salt water slurry;
(c) extracting oil products from said slurry employing a solvent for said products; and
(d) recovering said oil products and an algae residue.
...
4. A process as in claim 1, 2 or 3 wherein said carbonic anhydrase is added to the saline solution of step (a)

To assert literal infringement of this claim 1, the patent owner must prove that the defendant has infringed by following all the steps listed in claim 1. Following almost all the steps is not enough; every element in the claim must be present in an infringing activity or product. On the other hand, adding a step doesn't prevent infringement.

Literal infringement of dependant claim 4 requires that the defendant followed all the steps of claim 1 and also the extra step of claim 4.

---

37 This is explicit in US law but only implicit in the NZ Patents Act 1953.

38 In NZ, section 68A(1) of the Patents Act 1953. 35 U.S.C. 295 provides a similar presumption in US law.

From a freedom to operate perspective, the dependant claims can be ignored since if a product infringes a dependant claim, it must also infringe the parent independent claim. This provides a useful short-cut for the person examining patents for their impact on freedom to operate.

Infringement is often not as clear-cut as direct copying. More commonly, the alleged infringer makes or does something rather like the patented idea, and the court has to rule as a matter of fact whether the alleged infringement has taken place.

One common way to bridge the gap between claims written in a patent and products or activities "in the wild" is to use the legal fiction of a person having ordinary skill in the art. The next two sections describe rôles played by this mythical creature in US and NZ patent law. Understanding its point of view is key to interpreting whether a patent will block your freedom to operate or not.

4.3.2 Doctrine of Equivalents

The doctrine of equivalents is case law applied to potential patent infringement in the US. It looks beyond the literal scope of a patent's claims to cover the substance of the claims, despite the infringer's product being out of literal infringement range.

The *Winans v. Denmead* case[39] is commonly used to help understanding of the doctrine. Ross Winans patented a conical coal-carrying rail car. The US Supreme Court ruled that a rail car where the top view was octagonal rather than round and the overall shape pyramidal rather than conical was held as equivalent. The doctrine has been much developed since.

Courts judge equivalence by imagining the view of the person of ordinary skill in the art at the time of alleged infringement. That view might be quite different to the view when the patent is filed or granted. Thus 15 years after a patent for an electronic device using valves, substituting a transistor for a valve may be equivalent.

Rapid technical change can make equivalence difficult to argue. Many elements of a patented device might be substituted so the new device is very different from the old, though it produces the same

39 *Winans v. Denmead*, 56 US 330 - Supreme Court 1854

result. Each individual change might itself be caught by the doctrine of equivalents, but taken together they may take the product out of range.

While the doctrine of equivalents seems well entrenched in US law, from its earliest times it has been subject to challenge. There was a strong dissenting opinion in the Winans case above. The boundary around equivalence is drawn individually for each case. The nearest to a definition, from the Graver Tank[40] case, is the three-prong (or function-way-result) test of "substantially the same function in substantially the same way to obtain the same result". Well-known interchangeability between the patented concept and its purported equivalent helps argue equivalence, but neither its absence[41] or presence[42] is determinative.

Equivalence may have started as a concept to deliver natural justice in a difficult case, to be used only in exceptional circumstances rather than as a general rule. It has recently become the norm though, commonly argued at least as a fall-back position where there is any doubt whether literal infringement has taken place. The courts must decide what is equivalent to what case by case and struggle with that choice.[43]

The doctrine brings a contradiction to patent law. On the one hand there is the principle that the claims define precisely what is protected. On the other the doctrine of equivalence gives the patent owner a wider interpretation of the invention than described in the claims.

This contradiction has increased uncertainty in both litigation and business. While uncertainty is usual in business, hard-to-manage uncertainty with large consequences may be deeply destructive of investors' confidence in business innovation. Perhaps a bad neighbourhood is a good analogy; mainstream businesses do not invest because the risk of being caught in a random violent episode is more significant than the lure of profits.

There are limits to the use of equivalence.

- It is applied at the level of individual claim elements, so an infringing product must include every element claimed, or an equivalent if an element is literally absent.
- It cannot extend a claim so far that it covers something that was prior art at the time of filing the patent.

40 339 U.S. 605 (1950)
41 *Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.*, 467 F.3d 1370, 1382 (Fed. Cir. 2006)
42 *Key Mfg. Gp. Inc. v. Microdot, Inc.*, 925 F.2d 1444, 1449 (Fed. Cir. 1991)
43 The US Supreme Court commented "one wonders how ever to distinguish between the intentional copyist making minor changes to lower the risk of legal action, and the incremental innovator designing around the claims, yet seeking to capture as much as is permissible of the patented advance" in *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 36 (1997)

- It cannot overcome an explicit limitation within a claim.
- When a scope limitation is agreed during prosecution to achieve patentability, even though it does not lead to an explicit limitation in the claim, equivalence cannot overcome that limitation. Where after prosecution the claim has less scope than the original claim, the patentee has surrendered all the ground between those points.
- It cannot capture embodiments disclosed but not claimed in the patent.

The doctrine of equivalents is a large complicating factor in assessing freedom to operate. The uncertainty of its application makes it a risk to be noted and perhaps mitigated, but one that cannot be avoided. It must be taken into account in the risk premium expected by investors.

4.3.3 Purposive Construction

NZ uses the purposive construction doctrine rather than equivalence. The Court of Appeal recently restated and upheld[44] the doctrine as applied in a previous Supreme Court case:[45]

> *a. The first and essential step is to construe the claim. Construction is a matter of law for the Court.*
> *b. A patent specification is to be read as a whole and given a purposive construction. It must be construed as it would be understood by an addressee skilled in the relevant art.*
> *c. Each part of the specification is to be read objectively in its overall context and in light of the function of that part. The claims are to be interpreted by reference to the object and description in the body of the specification.*
> *d. The claims define the scope of the monopoly conferred by the patent. They limit what others may do. They must clearly define the protected field so others may fairly know where they cannot go.*
> *e. The description in the body of the specification may assist interpretation, but it cannot modify the monopoly the inventor has clearly marked out.*
> *f. If the claim is formulated too narrowly so that imitators do not infringe, that cannot be rectified by reference to the description. If it is too wide, consequent invalidity cannot be saved by reading in limitations appearing in the description.*
> *g. The description of a preferred embodiment of the invention is just that and will not confine the scope of an invention claimed more broadly.*

44 *Hammar Maskin AB & Others v Steelbro New Zealand Ltd* [2010] NZCA 83
45 *Lucas v Peterson Portable Sawing Systems Ltd* [2006] 3 NZLR 721 (SC).

The concept of purposive construction[46] from English case law seeks the perspective of the person having ordinary skill in the art in interpreting the claims to determine non-literal infringement. In contrast with equivalence, purposive construction seeks the viewpoint at the time of filing (or perhaps publication) of the application.

Like the US doctrine of equivalents, purposive construction adds a layer of uncertainty onto the patent landscape. The impact of a patent on freedom to operate cannot be measured with any precision without a court ruling. As in the US, this uncertainty can only result in a higher risk premium on the finance costs of an innovative organisation.

4.3.4 Defences

When a charge is laid of patent infringement, the defendant has several avenues (not mutually exclusive) open to defend the charge. The most used defences are invalidity and non-infringement but unenforceability is another potential defence.

4.3.4.1 Invalidity

The defence most commonly used, and commonly successful,[47] is to argue that the patent they are alleged to infringe is invalid (or that its relevant claims are invalid). Inadequate examination before grant may be part of the cause. The high success rate in this defence is probably a strong disincentive to patent owners letting their patents be tested in court.

The test of validity in a US court is similar to that applied by patent examiners before grant (see the earlier section on Patentability) but with some important differences:

- Where the US patent examiner must give each claim its "broadest reasonable construction in light of the specification",[48] the courts may adopt a narrower construction.[49]

---

46 in *Catnic Components Ltd v Hill & Smith Ltd.* (1982) R.P.C. 183. In this case an inventor used the word Vertical to describe a construction component, then sued for infringement someone who set their component 6° off the vertical. The initial trial judge held that infringement had taken place under the "pith and marrow" doctrine. At appeal, Lord Diplock ruled that the courts should judge whether a person having ordinary skill in the art would "understand that strict compliance with a particular descriptive word or phrase appearing in a claim was intended by the patentee". In this case, the word vertical was deemed to express the inventors meaning accurately, so no infringement had taken place. Using the word upright instead of vertical may have had a different result.

47 "Of patents litigated to a final determination (appeal, trial, or summary judgment), 46 percent are held invalid" (Allison and Lemley, 1998; see also Moore, 2000) cited in (Lemley & Shapiro, 2005, p. 80).

48 CFR US184 Title 37 Consolidated Patent Rules § 1.56 and § 41.2000

49 Construction is the noun derived from the verb construe. Thus patent claim construction is the process of construing or interpreting claims, taking them apart rather than the process of putting them together.

- Patent examiners have limited time for prosecution[50] of a patent, leading perhaps to a high success rate in getting patents granted (Lemley & Shapiro, 2005, p. 79). Conversely, when a patent infringement comes to court, the defendant may be well resourced and highly motivated to prove invalidity.

As mentioned in the section on Patentability, in NZ a patent's inventive step and usefulness are not tested before grant, thus they are tested for the first time in court.

A patent may be proven in court invalid as a whole: for example, if the list of inventors omits someone who should be listed. Thus happened recently to U.S. patent 6,411,947.[51]

The court assesses each claim separately, giving the plaintiff perhaps several chances to prove infringement. The defendant must attack every claim individually and prove invalidity or non-infringement.

In a freedom to operate study, once relevant patents have been identified each should be subject to a more detailed examination. This should include finding out whether the patent has been invalidated (in whole or part) in court. There seems to be no central registry for this; you have to study records of judgments involving the patent owner. There are registries of other changes in legal status. INPADOC at the EPO has worldwide coverage (though it might be wise to check the granting nation's own records, such as the US PTO's Patent Application Information Retrieval service[52] PAIR).

4.3.4.2 Non-Infringement

In an infringement suit the plaintiff must prove[53] the defendant is infringing the patent, convincing the court the plaintiff's construction of the patent's claims are valid. The defendant has the opportunity to challenge and propose alternative constructions.

---

50 Prosecution is the process of negotiation between the applicant's representatives and the patent examiner, leading finally to either rejection of the application or the grant of a patent, perhaps with modified claims from the original application.

51 *Bright Response, LLC vs. Google, Inc., et al.* Case 2:07-CV-00371-CE, U.S. District Court, Eastern District of Texas, Marshall Division.

52 http://portal.uspto.gov/external/portal/pair

53 In the US, on the preponderance of the evidence; in NZ on the balance of probability

4 Legal Research

Claims are written in specific legal forms and while many of the words are given their ordinary meaning, certain words may be redefined by the applicant[54] and others have specific legal meanings. For example, the "preamble" of a claim is usually one of:

- "Comprising" means that all the elements recited must be present. A four-blade razor would infringe a patent for a razor comprising three blades.
- "Consisting of" means that all and only the elements recited must be present. A four-blade razor would not infringe a patent for a razor consisting of three blades.
- "Consisting essentially of" means that all of the elements recited must be present, and additional elements may be present provided they are only incidental to efficacy. Adding a blue stripe to a three blade razor will not excuse it from infringing the patent for a razor consisting essentially of three blades, even if it is described as being black.

There are other "terms of art" in each jurisdiction. The complexity is such that interpreting claims is best left to a lawyer or patent attorney qualified in the appropriate jurisdiction.

Applicants commonly make many claims in each patent application. These are divided simply into independent claims, which do not depend upon any other claim for their meaning, and dependant claims which add a refinement to an independent claim.

If a product does not infringe the independent claims of a patent then it also does not infringe the dependant claims. At first sight then, dependant claims may appear to be of no value to the patentee. However if an independent claim is invalidated, its dependant claims are not necessarily invalidated too since they define a narrower scope of invention. A dependent claim adds an element to an independent claim and the resulting combination may be valid even though the parent claim is shown to lack novelty or inventive step. The patentee may claim that a defendant infringes both independent and dependent claims, and has only to prove infringement of one of the claims to win the case.[55]

4.3.4.3 Unenforceability

In examining a patent application, the examiner seeks prior art evidence that it is not novel (and in the US that it is obvious or lacks utility), and grants the application only if they do not find such evidence. The evidence must be published, which broadly means available.

---

54 "the patentee is his own lexicographer". *Lear Siegler, Inc. v. Aerquip Corp. US.* Put. Q. 1984, 221, 1025-1034.

55 In the US, costs cannot be awarded to a plaintiff who has had a claim invalidated during the legal process. Costs in the US are only awarded in exceptional cases, one of which is mentioned in Damages in the US.

Under US law, a patent applicant is required to disclose any prior art of which they become aware before the patent is granted,[56] but not required to go looking for it. The sanction against them if they can be shown not to have declared known prior art is that in subsequent litigation, the court may find their conduct inequitable and declare any affected claim unenforceable. This does not invalidate the patent (Lemley & Shapiro, 2005, p. 86).

4.3.5 Consequences of Infringement and Modulating them

If accused of infringing another party's patent, an organisation has several choices (not mutually exclusive) including negotiating for a license, withdrawing the offending product or continuing as before and expecting to litigate over the patent. One pragmatic approach for small firms may be to offer to pool patents with the other party. Pool members either cross-license one another's patents or covenant not to assert patents against each other.

If the patent owner litigates and prevails, they will usually win damages from the infringer.

4.3.5.1 Damages in the US

In the US, damages are usually set using the principle of lost profits, but "in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court."[57] The costs mentioned are court costs, not attorneys' fees which in US civil cases the protagonists usually pay themselves.

However continuing the quote from 35 U.S.C "In either event the court may increase the damages up to three times the amount found or assessed." Triple damages are reserved for willful infringement. Additionally, "The court in exceptional cases may award reasonable attorney fees to the prevailing party."[58] Exceptional cases include willful infringement. This provides patent owners an incentive to litigate where they believe they can demonstrate willful infringement.

Until recently, infringing without checking the position first was treated as willful and the specific defence was to obtain in advance a patent attorney's opinion that the proposed activity will not infringe a given patent's claims. The particular relevance of this point is that a freedom to operate

56 The sanction against them is that in subsequent litigation, the court may find their conduct inequitable and declare any affected claim unenforceable. This does not invalidate the patent. (Lemley & Shapiro, 2005, p. 86)
57 35 U.S.C. 284 Damages
58 35 U.S.C. 285 Attorney fees.

study is often made just before product launch so that a patent attorney can prepare a non-infringement opinion.

More recently, the standard of willfulness has been raised. In *In re Seagate Technical., LLC*, 497 F.3d 1360,1368 (Fed. Cir. 2007)(en banc) the Federal Circuit demanded a standard "closer to negligence than recklessness" and reduced the weight given to a non-infringement opinion (Durham, 2009, p. 192) instead allowing other evidence to be considered.

4.3.5.1.1 Laches

In the US, the past system could encourage applicants to make use of opportunities in the patenting system to extend the period of examination. The patent application remained invisible until an industry grew up unable to move away cheaply from the technology. This has proved particularly profitable for the patentees of some concepts around microprocessors and bar codes.[59]

However US courts have also used the concept of laches, an unreasonable delay[60] in filing suit with material prejudice to the defendant, to limit the damages in such suits.

4.3.5.2 Damages in NZ

By contrast, in NZ the damages given for patent infringement may be at the plaintiff's option replaced by "an account of profits".[61] The plaintiff would benefit from any profit the infringer made by their infringement. This may be higher than the damages that would otherwise be due. The winner normally gets costs from the loser on a fixed scale. These scale costs notionally include lawyers' and patent attorneys' fees, but the scale is set unrealistically low so litigants do not normally recover all of their costs.[62]

---

59 US inventor Jerome Lemelson is probably the best known of those using Submarine patents with more than 500 patent applications to his name. His original bar code patent application was filed in the mid 1950s but through continuation in part applications he strung out the process so that applications were being granted into the 1990s, having priority from his original batch. Despite having never actually made a bar code reader, under then US law he gained 17 years of monopoly from the date of grant, and used it to demand royalties from the bar code industry that was by then flourishing. The Foundation he set up to inherit the patents and their royalties was eventually defeated in the bar code case in 2005 because of the unreasonable delay in prosecuting the patent (Gregory, 2006, p. 302) but accumulated over $1bn in revenues from various patents.

60 More than 6 years

61 Patents Act 1953 s 69

62 *Holdfast NZ Ltd v Selleys Pty Ltd* (2005) 17 PRNZ 897 gives an example of real ($93,103) vs scale ($15,940) costs. Real costs can be awarded if the litigation is vexatious.

An infringer may benefit from a finding of innocent infringement,[63] in which case the plaintiff receives neither damages nor an account of the infringer's profits. The grounds for this are that the infringer "proves that at the date of the infringement he was not aware, and had no reasonable ground for supposing, that the patent existed". This could be the case if the infringer copied an article not marked to indicate a valid NZ patent. Other circumstances include when the patent application had not yet been published, or if the patent has not been renewed on time.

4.3.6 Patent Quality

Quality is intrinsic to a patent, reflecting how likely it is to survive attempts in court to invalidate it or its claims. Having noted that where they reach US courts, 46% of patents are held invalid (Allison & Lemley, 1998, p. 23), the same study found that much the most common reasons for invalidation were findings of obviousness[64] (42%), lack of novelty (31%) and lack of sufficient description or enablement (27%). When obviousness is raised as a reason to invalidate, it succeeds in over 60% of cases.[65]

For a patent owner, losing and having your patent invalidated in a court case that you started is a very bad outcome. It makes sense to test only the best quality patents. If you cannot choose to own only top quality patents, at least you should assess which patents are not top quality so that you can avoid litigating over them.

From a freedom to operate point of view, assessing the quality of a potentially blocking patent can inform you which options are realistic. For example, if you discern that a blocking patent is of very low quality you may ignore it and dare the owner to litigate. Occasionally potential infringers even take a "reverse payment" licence; that is they obtain a fee from the patent owner and a licence to the intellectual property, in return for not invalidating the patent. The patent owner gains from this since they seem to have "forced" the infringer to license the intellectual property (warning others). The licensee now has a stake in preserving the monopoly (now a duopoly) and keeping other infringers out.

---

63 Patents Act 1953 s 68

64 Obviousness (US) is lack of inventive step (NZ). An invention may be novel in that there is no prior art which exactly matches it, but unpatentable because combining two or more pieces of prior art makes it obvious.

65 Allison & Lemley go on to point out that US juries invalidate patents far less often (around 33%) than judges (around 53%, many in pre-trial hearings). No wonder, they say, that the proportion of patent owners opting for a jury trial rose steadily, from 8.3% in 1978 to 70% in 1994.

4 Legal Research

Several groups have proposed measures of patent quality, mostly for predicting patents' lifetime value.[66, 67] (Hall, Jaffe, & Trajtenberg, 2005) pioneered the use of citations between patents as a measure of their value and concluded[68] that:

> *each ratio [R&D to assets stocks, patents to R&D, and forward citations to patents] significantly affects market value, with an extra citation per patent boosting market value by 3%. Further findings indicate that "unpredictable" citations have a stronger effect than the predictable portion, and that self-citations [citations of other patents held by the same assignee] are more valuable than external citations.*

When a patent or application is published, it includes a list of the patents and other prior art it cites (backward citations). From those lists, database services aggregating patent documents can create indexes of forward citations (later patents which cite the current patent). A patent that is more often cited is more likely to be original and hence survive court challenge for obviousness or lack of novelty, than one cited less often.

When assessing a found patent's impact on freedom to operate, its forward citation count may be a useful indicator of its quality. Keep in mind that citations grow over time after the patent is first published so more recent patents score lower.

One way to improve the quality of granted patents is to invite public scrutiny before grant. In principle the standard mechanism of publishing before grant accomplishes that. Publication by a patent office is usually without fanfare and unless people are monitoring the publications as they occur they are not likely to spot a relevant new patent application.

However there are now several experimental services[69] which publish patent applications more conveniently and even encourage members of the public to provide relevant prior art. Participation in these services seems for now to be voluntary on the part of the patent applicant. The applicant might get a narrower patent because of prior art volunteered to one of these services; but it is better to find prior art free before grant than at some cost during later litigation.

---

66 For example, www.PatentRatings.com

67 http://spectrum.ieee.org/computing/hardware/patent-power/0

68 words within [square braces] are mine, to make the meaning of the quotation clearer

69 for example, www.peertopatent.org

4.3.7 Infringement Differences between the US and NZ

4.3.7.1 Indirect and Contributory Infringement

There are additional forms of patent infringement in the US. Indirect infringement under 35 U.S.C. § 271(b)[70] is actively inducing someone to infringe a patent.

Contributory infringement under 35 U.S.C. § 271(c) is knowingly supplying a tool or component "especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use". NZ case law[71] recognises contributory infringement but statute does not yet.

4.3.7.2 Products of patented processes

If a method is patented, then by 35 U.S.C. § 271(c) a product made by the patented process may not be imported, sold etc. in the US. The important freedom to operate impact is that if a business produces a product for import to the US, its processes to produce that product must themselves have freedom to operate in the US too.

4.3.7.3 Experimental Use

The US has several "experimental use" exceptions. Case law permits non-commercial experiments (though a university's research is commercial). NZ has no such exception in statute, and case law does not provide certainty.

35 U.S.C. § 271(e) (and Section 68B of the Patents Act 1953) allow certain things that would otherwise be infringement, to prepare a drug or biological for commercial introduction through the regulatory processes.

For a NZ organisation, freedom to operate in research is influenced by the few patents granted in NZ. In 2008 NZ granted just 3203 patents, whereas the US granted 157,772 (WIPO, 2010a, p. 42). NZ researchers can therefore research far more fields without the hindrance of others' patents, and more products can be marketed in NZ for the same reason. However a NZ researcher wishing to commercialise their inventions wider than NZ must pay attention to their freedom to operate position in all relevant markets.

---

70 That is, section 271(b) of Title 35 of the U.S. Code

71 *Ashmont Holdings Ltd v Jurox Pty Ltd* [2001] 2 NZLR 130 (HC), judgement based on several references to the UK

NZ researchers are also bound by licences and Material Transfer Agreements they sign, even where the products and materials covered are not patented in NZ. In this case the researchers can be sued for breach of contract, not patent infringement.

4.4 Conclusion of the Legal Research Section

This legal research has shown that litigating over patent is notoriously uncertain, and that the outcome can be disastrous for either the patent owner (if their patent is invalidated) or the potential infringer. Additionally, win or lose, litigation costs are high and rarely recovered.

The objective of studying the freedom to operate position must therefore be to minimise the likelihood of litigation, by identifying paths which reduce the risk.

5 Interview Results and Discussion

This study began with the intention of interviewing four distinct groups of stakeholders in research commercialisation: researchers, commercialisation managers employed by research institutions, IP professionals and professional investors. The intention was to tease out what understanding and practices these groups shared and where they differed, so as to identify ways in which communication between them might be improved.

As the project was discussed with potential participants it became clear that some of them had past employment history from another rôle in the process, and that this would complicate the analysis.

Each interview therefore opened with a discussion on the participant's experiences of the four rôles. The result of this discussion was quite surprising. Few of the participants were "pure" in that they had only ever held one of the four rôles. Several participants acted in multiple rôles concurrently, and two had experience of three of the four rôles. It became clear that the perspectives could not be characterised by rôle.

As a result, the notes below make no attempt to attribute differences to rôles, though the patent attorneys have been distinguished from other rôles at times.

5.1 Participants

As discussed under Methods, the participants were selected with the aim to provide a good range of coverage of the four rôles, within the time available for the research. The participants identified themselves as having experience of the rôles thus:

Rôle	**Number of Participants**
Researchers	10
Commercialisation Managers	8
IP Professionals	3
Professional Investors	2

The relative preponderance of the first two rôles is perhaps best explained by career progression. Many of those in research commercialisation rôles were prepared for them by being researchers.

5 Interview Results and Discussion

Everyone in the IP professional and professional investor rôles was previously a researcher and two also held a commercialisation rôle.

Some information is present here about each participant interviewed, to provide some context for their words which as quotes make up most of this Results section.

Commercialisation Manager 1 works for a NZ university technology transfer office. He has never worked as a researcher, an IP professional or an investor.

Commercialisation Manager 2 works for a NZ university technology transfer office but has been a science researcher, and had sales and management rôles in pharmaceutical companies.

Investor 1 is a director of an Auckland venture capital company. His past includes substantial periods as a researcher, commercialisation manager and now as a professional investor.

US Patent Attorney was a researcher for 20 years before becoming a Patent Attorney specialising in life sciences and high technology.

Investor 2 is founder of an investment consulting company and previously director of a San Francisco merchant banking and venture capital firm. He was previously a researcher and still specialises in the life sciences.

Commercialisation Manager 3 is Business Development Manager at a US company commercialising algae to biofuel processes. His current rôle includes elements of research and a commercial management, and his background includes a Masters degree in in Physics Entrepreneurship and a spell as a research engineer.

Researcher 1 works for a US/NZ start-up on improving algal strains for industry.

Commercialisation Manager 4 is a NZ Business Development Manager whose past rôles have also been similar to the commercialisation manager rôle.

Researcher 2 is a Senior Research Scientist in NZ whose previous rôles have been research but he has start-up experience with a US pharmaceutical company.

Researcher 3 was CEO of an Australasian company focused on developing medical treatments. He has been a researcher for much of his career and later responsible for commercialisation.

Analyst works at an Auckland investment firm and has not worked in any of the rôles other than this commercialisation rôle.

IP Manager works for a NZ Crown Research Institute, and is also a business manager with responsibility for a specialist area. She has also worked as a research scientist.

NZ Patent Attorney has previously worked as a researcher.

The remainder of this results section presents quotations from the interviews. The quotes are edited only by omitting words where the words, if left in, would hinder understanding. Occasionally, the sense of a participant's input can only be realised by including the interviewer's preceding words. Where it is necessary the interviewer's part in the conversation is clearly distinguished.

Still it is dangerous to quote without complete context, and the quotes are not offered as evidence that those quoted consistently take a particular view or act in a certain way. The quotations are used liberally to ensure that their voices are heard in this section rather than mine.

Some participants have been quoted much more extensively than others. This reflects their styles of speech, which in some cases lend themselves to being quoted and in other cases less so. In two cases, the recordings made could not be transcribed and those participants' perspectives were understood from the interviewer's notes instead, ruling out direct quotes.

Quotations are numbered so that the same quotation can be referenced in more than one context.

The interviews are analysed under two major themes, Completeness and Communication, which seem to be important in the outcome of the research. Each is the subject of a succeeding section. However to make sense of the evidence in those sections this section begins by exploring what participants mean when they discuss freedom to operate reviews.

5.2 Purposes of Freedom to Operate Reviews

The purpose of studying freedom to operate was not uniform across the participants. All recognised the need to avoid practising another's patented invention without a licence, but each participant added other purposes alongside that core. These include:

- Identifying third-party licences needed to commercialise the product and their impact on profitability;

q:1 [Commercialisation Manager 2] but in order to use that you would need a licence from one or the other party. ... they might give you a licence. However, there might be such a high charge for that licence that your own proposition is probably over, you don't want to continue.

- Identifying potential investors, customers and collaborators as well as competitors;

q:2 [Researcher 3] You need five patents or 10 patents to get something to the market, that is why you partner with large pharmaceutical firms because they buy the entire set of patents, those firms buy patents from three or four investigators.

- Selecting countries in which to operate or patent;

q:3 [US Patent Attorney] You also want to know in what countries is that manufacturing capability so you can file patent claims drawn to the method of manufacturing.

- Identifying law and regulation that will impact on the marketability of the invention;

q:4 [NZ Patent Attorney] freedom to operate should encompass those regulatory issues that you may not ordinarily associate with that terminology freedom to operate.

- More generally, validating the commercial prospects of the invention;

q:5 [Analyst] specifically freedom to operate, not like what lawyer would do, I do screen technologies that might enter the market and look at the client's patents and see if there is anything that might infringe ... just to see how crowded the market is.

- Going back to the earliest stages, shaping the direction of research.

q:6 [Commercialisation Manager 2] I quite like it if it's early I know about it. The more I can help to shape, because you don't want it to go in the wrong direction. ... And usually if there are certain hurdles in the way there are usually ways around it, you just need to know how to search.

q:7 [US Patent Attorney] The whole idea of the FTO at this point is to really get a broad framework, a broad view, about who is out there, what kinds of things are they doing and what it might be worth taking a closer look at.

q:8 [Analyst] if we know the technology will be ready on the market in the next two years then we think it needs to sustain its competitive advantage for at least 5+ years to provide the return on investment for developing it. If there was a technology already out there or under production, maybe it heads off what we are working on and if that hits the market first and how will our clients technology generate enough of revenue to provide return on investment.

q:9 [IP Manager] at that stage, it's usually research areas rather than a specific target ... So it's just a broad … who's doing what to compete with this. So you might see big companies there ... a huge team, and they are regularly patenting things and …. We think "Oh, fantastic, I don't think we will go in there," and…but, "gosh, there's no one there that we can see that is approaching it using that sort of organism".

q:10 [Commercialisation Manager 3] we would be looking ultimately at what they are continuously working on. You know, if we have similar ideas, we may need to adjust our resources if its something we really want to pursue and may adjust our resources ... to try out-compete them.

These last two particularly exemplify how several participants think about predicting far into the future. They track who is working on their area of interest- and then act on the information by choosing who to compete with and who to avoid.

Uniformity was not expected on this; in fact it was one of the drivers for this research. Reconciling this lack of uniformity is a challenge for the recommendations later.

5.3 Completeness

This first major theme identified from the research deals with whether the review is trustworthy from the point of view of how complete the coverage is.

This section recognises and discusses strategies that participants have evolved to manage the risk of incomplete results. These are related back to theory and some ways to make them particularly effective are proposed.

5.3.1 Sources

In Information Retrieval theory (as discussed under the Business Literature section above), legal research problems are usually characterised as needing a high Recall, that is a high probability that all relevant documents will be found. Freedom to operate research is typical in this way. The commercial consequences of not identifying a patent which your planned product or process will infringe may be very severe.

The patent system is designed to allow applicants confidentiality for a period, and this makes all sources of current prior art incomplete. Pendency, the period between filing and publication of an application, is one of the issues that makes it difficult for any searcher to know for sure that they

have found all of the prior art for a patent application or freedom to operate search. In most jurisdictions applications are published 18 months after filing, unless they are formally withdrawn before that milestone. However pendency is not the only way in which sources are incomplete.

As this section will show, participants cited many different sources that they use. This may be evidence that no single source is comprehensive, or perhaps that participants' goals differ. Among the data sources that respondents mentioned were these:

Several participants use the US Patent and Trademark Office (USPTO), World Intellectual Property Organisation and European Patent Office web sites to search patents and some mentioned also the Japanese, Korean and Chinese patent offices.

One participant reported using Google Patents extensively, and one of the value-added features Google provides if you look carefully for it:

> *q:11 [Researcher 1] I use Google Patent, and then I search by keyword for patents and then go to a link down at the bottom ... that says "establish an RSS feed", something like that, and then I use an RSS reader like Google reader to read them.*

RSS is a means to have a site like Google alert you to changes that occur later. In effect, this lets you monitor the Google patents database for new records matching your search.

Several participants use the Thomson/Reuters Delphion family of databases which republish patent information with additional information and analysis. Some value-added features of proprietary patent databases like these are mentioned in Appendix A.

> *q:12 [IP Manager] we have the ability to do those sorts of things though some of the software that the knowledge navigators have ... Derwent ... Delphion ... But we have over the years tried out different software and seen what it can give them. A lot of these sorts of things are of general interest, but not for specific use. ... So, I would say that was useful at the beginning stage of a project, to see whether it is worth doing something in there.*

> *q:13 [Commercialisation Manager 1] I think they start to be more useful ... It just gives you a general feel of how busy the patent landscape is in a particular area.*

Several participants use Google to investigate non-patent literature and check on individual researchers or corporate bodies that might be competitors, licensees, collaborators and so on. The

common use of the word Google as a generic synonym for searching leaves some doubt whether participants were using it as a shorthand for (or a gateway to) many other systems.

Several free proprietary patent information databases exist, but the only one mentioned was www.PatentLens.net. PatentLens maintains some specialist tools for life sciences researchers such as "Patent Landscapes on Influenza Genes, Rice Genome and Adjuvants" and "Protein & DNA Sequence searching".

Appendix A. discusses some of these sources and their limitations.

One participant uses deal databases such as the Deloitte Recap system (www.recap.com) and its competitors. She also uses the US Securities and Exchange Commission (where Stock Exchange listed companies formally disclose information which may affect their share prices) filings, because as she says:

> *q:14 [Commercialisation Manager 2] if you have a biotech company they'll want to talk about it because it's important for their investors to know.*

She focusses largely on medical applications and uses clinical trials databases (the US www.clinicaltrials.gov and the European Medicines Agency equivalent) to identify players.[72]

The range of sources used reflects to some extent the different scopes individuals reported for their freedom to operate research. One potential source that was not much mentioned is old publications. As we have learned, any material accessible through the internet qualifies as prior art to invalidate patents; anything published, dated more than 20 years ago, by definition provides freedom to operate. One information specialist (not participating in this research) gave examples of recent "inventions", the previous publication of which in sources like Popular Mechanics seems to have been ignored.

72 Some trials explicitly name pharmaceutical companies as trial principals. In others you can identify a company by the designation given to the therapeutic agent. For example a designation beginning LY refers to an agent initially registered with the US Food and Drug Administration by Eli Lilly (though the current proprietor may be different).

5.3.2 Completeness of Search Effort

5.3.2.1 Search Strategy- Keywords

Participants overwhelmingly spoke of using keywords when they discussed searching for relevant prior art. A potential issue with keyword searching is vocabulary: will the patent author and the searcher use the same words to describe the same concept?

For example if one person "describes these molecules as being involved in 'translation', whereas another uses the phrase 'protein synthesis', it will be difficult for you - and even harder for a computer - to find functionally equivalent terms."[73] Such differences may be cultural (even where expressed in the same language) or represent drift over time.

When discussing how search terms were arrived at, some spoke of using a thesaurus and other sources to obtain wider keyword coverage:

> *q:15 [NZ Patent Attorney] Yes, we have to try and think of lots of synonyms, truncated words and all that. ... each database they will have their own sets of queries or stemming operators. So our searching staff are great at coming up with synonyms. I will always provide them with synonyms based upon the experience that we have in the area technology you are working in. ... I would also look at a thesaurus ... the Internet and I would possibly even look at other patent applications, patent databases to see what words people have used because you know it could change from country to country, there could be acronyms that are used a lot. ...*

This participant mentions the use of stemming, which can find variants of words- so if you search for "encapsulated" a search engine employing stemming might return documents mentioning "encapsulation" and possibly even "capsule". A related concept is lemmatisation- search for "running" in a search engine employing lemmatisation and you might get hits for "run" and "ran". These approaches are more sophisticated than the simple truncation operators offered by many search engines- a search for "run*" or "run$" would find "running" and "rune" but not "ran". Stemming and lemmatisation are sensitive to the natural language used- English and Japanese need quite different approaches.

Systems that offer stemming and lemmatisation may not helpfully report back what terms they used after expansion, but you can often find them highlighted as "hits" in the retrieved documents. Thus

73 http://wiki.geneontology.org/index.php/GO_FAQ

you can learn from systems that offer these capabilities and use the expanded list of terms in systems that do not.

Another approach was to ask others to identify keywords that might otherwise be missed:

q:16 [US Patent Attorney] Well I usually have a conversation. If there is a term of art that is well-known such as monoclonal antibody and the client says all we are in the monoclonal antibody yes I know what the synonyms are, there are monoclonal antibodies, there are McAbs, there are FAB fragments that prime, light chains, heavy chains and those sorts of terms are well-known in the art and they are well used but again I used just as an example the contrast with social networking in the Internet environment in which the terminology is not set. And so if a client uses a term [whose] meaning is not apparent I will ask well exactly what do you mean by that, and we will have a conversation in which I will try to identify whether or not the term is truly reflective of a new concept for a new thing or whether it is a reworking of an older idea. Re-workers tend to differentiate their play from competitors by renaming.

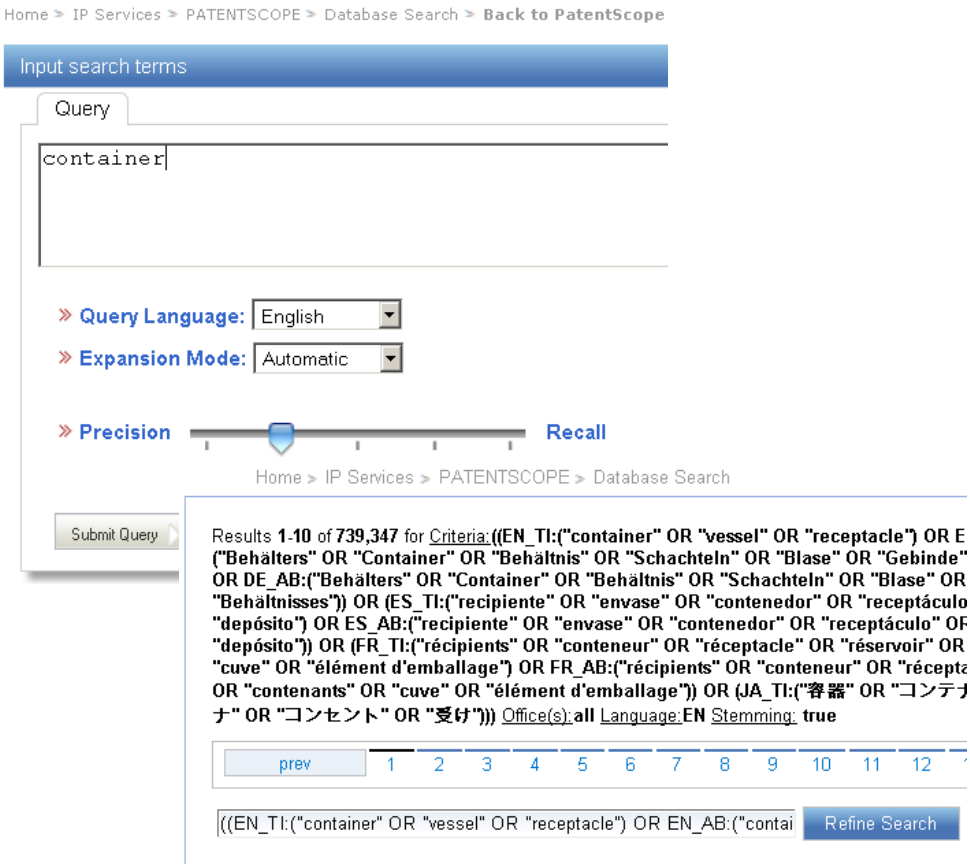
q:17 [Commercialisation Manager 2] You can brief a student on a certain area, you do your own search, you have a colleague who knows it better to discuss with people, and then you write a contract, either… other companies, or services, or consultants, or patents advisors.
[Interviewer] So the main strategy is coming from several different angles?
[Commercialisation Manager 2] yes.

Proprietary re-publishers of patent information sometimes apply "controlled vocabulary" indexing to the public data as described in the section on Incomplete Sources. This reduces the problem of searchers and applicants not sharing the same vocabulary.

5 Interview Results and Discussion

Google builds in some thesaurus-style expansion and WIPO Patentscope recently began to offer "Cross-Lingual Expansion",[74] creating synonyms for search terms in many languages.

Looking for more and less specific versions of the inventors' words, and related concepts, is good



practice for searchers. In the US at least, case law holds that the "genus anticipates the species" and the "species anticipates the genus".[75] Though these terms species and genus have technical meanings in biology, in law they simply stand for "more specific" and "more generic" manifestations of a common concept.

In future, search engines are likely to use ontologies to expand queries in this way. An ontology (as the word is used in science) is a structured, machine-readable list of words and the relationships between them;[76] for example, able to recognise that butanol is an instance of the larger group of

74 www.wipo.int/patentscope/search/en/clir/clir.jsp

75 *Den Beste v. Martin*, 116 USPQ 584, 586 (CCPA 1958). 35 U.S.C. 102 is often given as the authority but is not very explicit on this point.

76 An ontology is commonly implemented in Resource Description Framework (RDF), a rather general way to model information in Extensible Markup Language (XML).
XML, derived from SGML, is common as a structured machine-readable way of encoding information.
RDF has subject-predicate-object triples as its basic data type; the object of one triple may be the subject of another allowing them to be chained together.
The Web Ontology Language (OWL) is an extension of RDF which adds the ability to derive logical consequences (IF a AND b THEN c) and combine multiple ontologies.

alcohols and also a member of the group biofuels, and that obvious is an antonym for inventive within the context of patenting.

An ontology is domain-specific, so the examples of algae and patenting would come from different ontologies. Ontology tools allow them to be "stacked" so that you might transparently combine a biological ontology[77] with a legal ontology[78] and a general-purpose "upper" ontology[79] to give a wide interpretation of the words found in biological patenting.

Specialised software can follow chains of inference and, when provided with a complete enough ontology, reason using the texts provided. Thus software could identify synonyms in context such as 'translation' for 'protein synthesis'.

It seems likely that software using ontologies to reason with textual material will be used as engines to search publicly-accessible collections such as the WIPO patent collection. They may also be useful tools to manage an organisation's store of information about its freedom to operate position. Already EPO provides the full text of patent documents as text in XML structure[80] which lends itself to manipulation in this way. It may not be long before applications to manage private stores of "potentially relevant" documents become available.

The expanded list of keywords becomes an important artefact of the process, discussed further in the section on Passing information between Stages.

This sub-theme has been about expanding the list of keywords to find more of the relevant documents (improving recall). In contrast, participants often deliberately reduce the search scope to concentrate only on the most relevant documents (increased precision).

q:18 [Interviewer] So you talk about the process as well?

[NZ Patent Attorney] We do. So it should be quite clear what we have done and whether, to narrow the hits we have just search abstracts rather than full specifications or just reviewed the claims or titles. There obviously has to be something that helps us narrow down the key patents. That will be the title, the abstract or the claims but as you can see there could be a never-ending job.

77 perhaps from the Open Biological and Biomedical Ontologies at www.obofoundry.org

78 such as the LKIF-Core Ontology from www.estrellaproject.org/lkif-core

79 such as SUMO http://www.ontologyportal.org/

80 www.epo.org/patents/patent-information/free/open-patent-services.html

This is understandable if the budget is small and the processing is time-consuming. Knowing what has been done to narrow the scope gives no information on what will be missed by narrowing it.

Older patents may not have abstracts at all, and the claims may not be available for text searching- see Evidence of Incomplete Sources. Patent applicants prepare an abstract of their application (limited in the US to 150 words)[81] which is published when the application is published. This may not represent the application's content well both because of its brevity and because the applicant may not feel it is in their best interest to represent the application's content well. If the applicant makes the title and abstract of a patent uninformative and searchers limit their keyword searches to the title and abstract fields[82] to reduce false positives, the patent is unlikely to be found. The same keyword applied to the full text might well find the patent.

5.3.2.2 Classifications

Official classifications, by which patents are grouped according to their subject matter, featured in the thoughts of patent attorneys:

> *q:19 [US Patent Attorney] I think in a very mature art area I would tend to rely on keywords more than I would in a rapidly evolving art area. For example let us look at the social networking software side, Internet companies. The terminology of Internet is totally scattered, anybody can come up with their own term to mean anything they want it to mean that they do. So that if someone sees a prior art term called quality assurance metrics and I want to differentiate myself from them I can use exactly the same idea and is just give it a different name. Like the convergence criteria for example. So if you have these differences of language keyword searching will get you nowhere. Whereas classification searching might identify things.*

but less for the others:

> *q:20 [Investor 1] Keywords are more familiar to me than classifications, I don't think I see them referring to that.*

Classifications look complex (with forgettable formats like A01G 7/00 in the International Patent Classification and 47/1.4 in the US system) but are straightforward to use. Find some relevant

81 37 CFR 1.72(b).

82 Searching particular fields of data is sometimes known as faceted searching, to distinguish it from full-text searching which usually looks for a search term no matter what part of the data it occurs in.

patents or applications by other means then check their front pages for classifications and search those classifications to find more relevant documents.

Another way to identify appropriate classifications to search is to use the IPCCAT tool.[83] IPCCAT will find matching classifications based upon a document or fragment that you upload.

5.3.2.3 Other Search Strategies

Other patent metadata ("front page" information on patent documents) rarely came up in discussion, though participants were interested in the people involved in competing patents:

> *q:21 [Commercialisation Manager 3] I tend to use more search words but I also like to use the metadata. If I see a name of an inventor, for example, I tend… I almost inevitably will also look up that inventor to see if they are still working in the field, to see if they had issued anything else that might be related.... we would be looking ultimately at what they are continuously working on. You know, if we have similar ideas, we may need to adjust our resources if its something we really want to pursue ... to try out-compete them. Or try to work with them to become, you know, a co-inventor.*

Not everyone is actively using that strategy though:

> *q:22 [Investor 1] trying to see who else is working in the field ... it is a gap in our current practise. We cannot do that and we possibly should.*

The conclusion from these quotations echoes that of the discussion on sources above- there is no perfect search or perfect source. In academic research the problem of imperfect sources and research methods is tackled through triangulation,[84] the application of multiple methods and multiple sources to identify points where the results of more than one approach converge.

Thus to approach complete coverage, searchers should triangulate though multiple types of search (eg keywords, classifications and people) in multiple sources- not just relying on several different keywords in one source. Multiple searches in multiple sources will give more complete coverage. The degree of triangulation (where results are found by more than one search or source) helps assessing how good the coverage is.

---

83 WIPO's "Categorization Assistant in the International Patent Classification" at https://www3.wipo.int/ipccat/

84 (Mathison, 1988) explains how triangulation is useful, not only when all approaches converge on the same outcome but also for exploring the subject of study more effectively- through the sub-strategies of Data triangulation (multiple sources), Investigator triangulation (input from multiple investigators) and Methodological triangulation (in this case, multiple search strategies).

5.3.2.4 Are we Nearly There Yet?

All participants were asked how they know when they have done enough freedom to operate research for the current stage of the commercialisation project. Several participants who commission work to assess freedom to operate used an explicit budget to limit the effort:

> *q:23 [Researcher 3] you have to tell them what your budget is, and you know you are going to get a certain level of report.*

> *q:24 [IP Manager] So we would be aiming at the start say, do a $m-n size search. Say, these are the parameters that would fit in there, we know what we are likely to be excluding; we know what the risks are by narrowly defining its terms. So we pick up things in this space, but by not including these terms, you know that you won't pick up something that's slightly left-field but that's a risk you are prepared to take to start with.*

though some asked the IP professionals to propose a price for the work:

> *q:25 [Investor 1] in our hands we would never expect an FTO analysis to cost more than $x NZ dollars but that is because we almost set the parameters, we go in and say, all we want to know is the FTO. We want you to report on it but we do not expect you to make a meal of this, give us a quote. If they come back and say $y we fall about laughing and say no we did not mean $y. Remember this money is at risk, at everybody's risk at this time.*

In this context, some participants expressed the opinion that patent attorneys are governed by professional standards which set a floor of minimum completeness under the work they will undertake for a client. The professional standards for NZ patent attorneys[85] do not appear to include any such standard explicitly.

From the opposite side of the fence, both the participating patent attorneys felt obliged to do as complete or incomplete a job as the client required. Both were bound to inform the client of the limitations of the work performed, and confident that they could express those limitations clearly.

While the patent attorney can document the limits of the commission they have received to avoid any liability for over-promising, does that give the client any useful information on the completeness of the search?

---

85 www.nzipa.org.nz/Site/about_nzipa/CodeConduct.aspx . For US patent attorneys, the US PTO has published rules at www.uspto.gov/web/offices/com/sol/notices/73fr47650.pdf (55 pages) but a more concise form might be found at local Bar Association web sites.

Others reject the notion that a freedom to operate study can be performed for a fixed price:

> *q:26 [Researcher 1] Fee? No. I think everything is… especially in the patent area it's a case to case basis, so projects are just incredibly difficult, you know, nuanced; and some I think are much more straightforward than others.*

Many participants rely on their own experience, or that of a trusted or in-house IP professional.

> *q:27 [Commercialisation Manager 1] There is no documented system but there is a system based on [colleague]'s experience that he goes through in terms of keyword searches and that sort of thing and what databases he looks into etc.*

or perhaps the collective wisdom of a committee.

> *q:28 [Commercialisation Manager 3] Our committee ... is composed of our CEO, our head of research and development, myself and a couple of the more specialised researchers. ... We do have a lawyer on the patent committee. ... when you get all that brain power in the room, you have a lot more exposure to what other people know and we're relying on the expertise of the people in the room. ... At some point, somebody's probably going to ask "Have we done enough?" and everyone will give their opinion and answer.*

Despite this overt position, the same participant described the most systematic approach to assessing completeness, as a variation on the law of diminishing returns:

> *q:29 [Commercialisation Manager 3] I'd say whenever I start seeing the patents sort of run out. What I mean by that is, you know whenever reading one patent it has to have all the related literature with it. When I start seeing the same documents being referenced, when I start seeing the same patents going back to each other, they tend to always be referencing each other. When I see fewer and fewer actual new patents that are not being referenced a lot by the industry, then it's probably time to stop looking. ... if we stopped finding new stuff then yeah the committee will generally agree, okay, then there must not be much more out there.*

Several other participants suggested broadly the same methodology. None reported they had gone so far as to formalise it, and some gave the impression that they had used it unconsciously until now. This is operational decision making (see the Decision Theory section).

Judging completeness is a problem which academic qualitative researchers tackle regularly. They want to know when they have squeezed all of the insights out of the verbal and textual material at

hand. They must also assess when they have done enough data collection to know they have a credible understanding of the system under study. An effective common approach to this is called theoretical saturation.[86]

Essentially theoretical saturation involves keeping track of the effort expended in research and the new insights gained as time progresses. Theoretical saturation is achieved when additional effort- for example, trying a new technique or a new source- yields no new insights.

To use theoretical saturation operationally for freedom to operate study, the searcher would note sources and strategies (eg keyword, person or classification) searched and a list of the patents returned by each search (including "false positives"). As more strategies are tried at more sources, the new patents returned by each additional search should start to decline to a dead end when theoretical saturation is reached. The list of patents (and other documents) should be annotated as to their relevance.

5.3.3 Evaluating Found Materials (micro-analysis)

Each patent identified by a search is a risk in its own right- indeed each claim is a risk. Where a patent seems to have a bearing on freedom to operate, the easiest first step is probably to try to work out whether it is actually in force: for example it may have lapsed. This is covered in the section about Invalidity. For a patent with potential to block freedom to operate, it may be worth recording and diarising significant future dates; eg when maintenance fees are due.

If the patent seems to be valid, then its claims should be analysed, which takes more skill. In q:56, a participant reports in detail how they report the results of a freedom to operate study précised here:

> *"claim by claim basis or I may use infringement analysis to be based upon the Independent claims only ... I look at them from a legal viewpoint and ask what would a judge say that this claim means ... read the patent application for clues as to what the claim terms mean ... end up with what is called a properly construed claim".*

Claim construction, the art of properly construing claims, is a vital part of freedom to operate study and discussed in the section titled Analyze and Apply the Pertinent Law.

86 Perhaps first described by (Glaser & Strauss, 1967), but summarised well by (Eisenhardt, 1989, p. 545)

5.3.4 Evaluating the Results

Several participants drew attention to the need for the freedom to operate study to deliver advice, rather than a bare statement of position- see the section Recommending Actions.

Typically a study is carried out when a proprietor believes there is a commercial prospect for their idea, and has already invested time and money in development so far. Thus the advice they seek is how to continue with commercialising while avoiding future problems with others' IP, rather than a simple stop/go decision. One participant was clearly unimpressed with the approach of a hired consultant who reported rather baldly on the prior art for this reason.

> *q:30 [Analyst] obviously we do not want to have 100 patent applications to review. This is what one of the consultants has done; he just e-mailed us patent applications of other technologies that ... our technology might be infringing or potentially could infringe, he just sent that to us, and what are we supposed to do with that?*

Perhaps the consultant felt the prior art was overwhelming, but the client wanted a way through the swamp, not advice to turn back.

> *q:31 [IP Manager] when we get to major decision points after that's, so the PCT or the National Phase Entry stages of patenting, we have to put a recommendation up to the investment committee for approval.*

The process of research commercialisation is a gradual blending of commercial considerations into what starts out as a scientific or technical endeavour. There are specific points in the process where the business has to look hard at the science and judge whether it is appropriate to make a step change in the level of commitment to it. In an international patenting process, going into National phase is one of those points.

At those points, non-technical people with a broader responsibility typically play a larger rôle in decision making. These people may have less time to judge the risks for themselves and need to be able to see the opportunities in the wider context. They appreciate their colleagues' efforts to summarise and present the freedom to operate position succinctly and coherently.

Predicting the future is not perfect but it is possible to assess the risks of various events.

> *q:32 [Commercialisation Manager 2] it's a risk benefit discussion you have to have coming out of that search.*

q:33 [Investor 1] We do it for ... down side risk protection for us, and a side benefit for the company.

q:34 [US Patent Attorney] The first time that freedom to operate comes up is in assessing potential risks of encountering somebody else's intellectual property ... The investors will want to know something a little bit different. They will want to know what are the risks that I will lose my money? ... what the risks are of the investment going bad. ... freedom to operate can almost never be guaranteed so instead of asking how can I be assured that I have freedom to operate you ask what are the risks, or what is the likelihood that if I practise this invention they will sue me on this patent.

q:35 [Commercialisation Manager 3] so they are doing a risk assessment of how critical each one of these pieces of IP are for us as well.

Risk is tolerated by different people to different extents:

q:36 [NZ Patent Attorney] It is really about mitigating risk ... it really comes down to what is the risk profile of a client as well.

q:37 [Commercialisation Manager 3] it depends on the type of investment as well. You know, banks are extremely risk-averse so they are going to ... make sure that there is absolutely as little risk as possible.

Organisations may develop their own statements[87] of risk appetite within a risk management policy through which their stakeholders (for example, investors and employees) can better appreciate the organisation's approach to risk.

There was little enthusiasm for trying to measure risk:

q:38 [Interviewer] when you've got the research back from the patent attorney, how do you judge the extent of your freedom to operate …are you able to put any kind of numeric value on it, are you able to say, "Well, we think there's a very small risk of infringement here", or "We think this is a high risk"? How do you judge that? [Investor 2] Oh, how does one judge that? … depending on the magnitude of the barrier that's in front of us, all right? How does one judge? ... rely on the legal counsel.

87 eg www.conman.ualberta.ca/stellent/groups/public/@finance/documents/procedure/pp_cmp_059721.hcsp

q:39 [Interviewer] Then is there a way that you can report back how complete you think the search is? Is there any realistic way of gauging that?
[NZ Patent Attorney] What do you mean, how complete? As I said we can outline the limitations.
[Interviewer] Well there is a $x search or there is a $x00 search and I am trying to visualise how you would quantify the limitations.
[NZ Patent Attorney] In terms of risk. That is very difficult to do.
[Interviewer] So you do not have any kind of standard that you use to say that this is high, medium or low risk? I guess if they say here is $x you say this is high risk?
[NZ Patent Attorney] Exactly a lot of it depends upon the individual. It would be extremely difficult to put some sort of value on it quantitatively.
[Interviewer] Do people ever ask you to?
[NZ Patent Attorney] I have never been asked that but who knows, others might have.

q:40 [Interviewer] And when you are reviewing the riskiness of your strategy, so you are saying "Well, I appreciate we won't find those left-field ones …" do you try to put a number on that risk, at all?
[IP Manager] No. And I guess because usually we are not the commercializing party, we don't give any warrant of freedom to operate and that sort of thing, so it's … and it's usually a lot further back from the commercial aspect. So, no. We would communicate what the risk parameters were, but not say that.

Some participants distinguish the two major dimensions of risk: probability and impact:

q:41 [Commercialisation Manager 3] there will probably be some type of statement of risk. You know, in the sense that should the patent office reject it, what does it do to your operation? ...

q:42 [Interviewer] So you are not trying to work out whether their IP will be novel ... You are not trying to assess the risk of not having a business at all, only trying to assess the value of the upside if you like?
[Analyst] Yes I guess so, we do not usually look at a negative scenario. We do look at patent applications and technologies that are under development to see whether, what stage they might be in five or 10 years.

The evidence does not indicate that those not quoted here do not appreciate this distinction, only that it was not explicit in the interview.

5.3.5 Key Findings about Completeness

The key learnings from this section are that:

- All sources are more or less incomplete;
- Knowing how they are incomplete is important;
- Searchers' skills are always incomplete;
- Therefore searching will always produce incomplete results;
- We can use strategies to improve completeness; and
- We must judge how nearly complete.

Risk is complex to measure and most aspects of risk are complex to communicate. However assessing and communicating risk is the heart of freedom to operate study. The next section looks in more detail at the problems of communicating and the Conclusions and Recommendations section has some specific advice on communicating risk.

5.4 Communication

The other major theme is how the individuals (and entities) involved communicate questions and answers about the freedom to operate position to one another. How the freedom to operate research done earlier is made useful to later stages is included. The filters applied to such information before it is passed across the table between counter-parties in a commercial negotiation is also included.

The presentation of Communication is broken down into several sub-themes: Briefing the Searcher, Reporting the Results, Evaluating the Results, Sharing the Position, Room for Misunderstanding and Passing information between Stages.

5.4.1 Briefing the Searcher

5.4.1.1 Selecting a Searcher

There was surprising disharmony on the need for IP professionals with scientific expertise. Some participants thought this was axiomatic and would select their patent attorney firm on the basis of the firm's specific experience of the particular domain of science.

q:43 [Researcher 3] If you pick a very large firm they will have a lot of expertise but tend to be very diluted whereas if you go for boutique firms with specific interests in

> *molecular biology or in stem cell therapy you actually get a lot more out of those firms ... I would initially go with a boutique company that has a record of getting patents pushed through in a particular field, if you can find one like that then they are very valuable.*

Other participants neither expected nor sought any science domain knowledge from their professional IP advisors. For them, the science expertise would come from within their team:

> *q:44 [Commercialisation Manager 3] ... X is not an area where there is a lot of expertise in the law field yet to be able to handle the type of patents that we're doing.*

or be hired as a science consultant:

> *q:45 [US Patent Attorney] in the example of company having a use a broad patent on the use of antibodies to treat cancer the investor would be well advised to find something of similar expertise in the area of cancer therapeutics and antibodies, and use them as another point of contact in addition to the IP professional ... You would want to have some scientific experts who understand the technology and the risks of the technology.*

As with expectations around guiding research, there seems to be no link between a participant's rôle and their view on the need for the IP professional to have domain-specific experience. This is surprising since the US PTO insists that patent agents and attorneys have a specified science background. The usual practice in NZ is also to recruit patent attorney candidates from science and engineering backgrounds.

Two participants in this research are themselves currently scientists, generating intellectual property directly. Both would carry out some freedom to operate investigation as part of their ordinary research, and would focus mostly on the scientific content of papers and patents turned up by this. One is self-schooled in intellectual property law and takes a more detailed perspective on potential freedom to operate constraints than some of those he encounters:

> *q:46 [Researcher 1] colleagues ... say ... institute X and X, X and Y own this gene. Really, ... have you read the claims? Can you show me the patent?*

5.4.1.2 Interacting with the Searcher

Several participants agree that the briefing needs to include an element of discussion:

q:47 [Analyst] Oh they like talking to the client, they want to sit down with the client for about an hour and find out what the technology is actually about and where they think their intellectual property lies and there will also come up with recommendations saying that we think that this, you have not thought about this, we think this is part of the technology it is quite unique as well.

q:48 [IP Manager] we would often have the discussion with the patent attorneys and say "OK, we want to determine some freedom to operate. How can we define this narrowly and do, say, a search that would give us some good information but be quite narrow?"

It is difficult to communicate the brief succinctly in writing. Freedom to operate searchers and clients alike feel that a discussion is needed.

In some cases, this interaction between the client and the searcher is extended into the search itself, some with a greater degree of interactivity:

q:49 [IP Manager] stepwise through a freedom to operate search minimizing the costs and maximizing the benefits.
[Interviewer] "Stepwise" do you mean that you go to the patent attorneys ... and you use a bit of their time, get them to reflect back to you, review what they've done, send them out with another focus? Or is it…?
[IP Manager] Yes. So, the discussion, as we go, so... OK, we need to find out what is in this particular space, and how do they suggest that we approach it, and let's start with these search terms. And sometimes you put in some basic search terms and you get back, you know… a million hits so how are you going to narrow this down? ...
[Interviewer] OK. How interactive is this? Are you sitting with the patent attorney or the researcher while they are doing this search?
[IP Manager] Not while they're doing it. We would ... usually have a teleconference, have the patent attorneys and the scientists and the business person and myself, all discussing ...
[Interviewer] So, discussing with a piece of paper in front of them, rather than discussing while the search is going on ...
[IP Manager] Yes, yes.

Finally, one participant noted that over-briefing may limit the search scope too much:

q:50 [Commercialisation Manager 2] Briefing them give them the results. But you don't want to taint that too much as well. You don't want to give them all your results, but you want to support certain information that they should not forget about.

5.4.1.3 Own innovation

Many of the participants mentioned using "our" own innovation as the basis for briefing a third party to assess freedom to operate.

q:51 [Commercialisation Manager 2] And if you have a patent attorney, you want to give that person what you believe is the key inventive step.

This is useful when available, but freedom to operate is also needed where there is no "own innovation".

In some cases, the brief is really about preparing to file a patent and freedom to operate is seen as incidental:

q:52 [Researcher 1] I am making the whole first draft of a patent application, and I give it to them in a totally structured way, you know, that they are used to seeing things and then and then directly physically point to things to look for. It's not an open-ended exercise any more.

These last two quotations, among others to follow and some comments less easy to quote, hint that the concepts of patentability and freedom to operate are sometimes conflated.

As well as the description of "our" own innovation, the brief often includes collateral such as scientific papers and competitor brochures:

q:53 [Commercialisation Manager 1] They typically bring probably a structure, and say we believe that we have a novel structure and we do a bit more searching around it, but they might also say we have found this and that structure and they are interesting but we do not think that we have the freedom to operate position around this because of patents or publications they have identified. Sometimes they bring to you, in the best case scenario, even patents and publications that they have identified where there may be a freedom to operate issue, but others may not even have thought about it. It is a wide range.

Trial data is often relevant in the context of a patent application, to provide evidence that the claimed invention has been realised in practise.

> *q:54 [Analyst] Usually they ask for trial data because we work with client companies, engineering companies and you do not have a prototype unit so what improvements have been made since the provisional patent was filed.*

It is not so easy to see its relevance to freedom to operate. While never explicit in the interviews, the impression was given by some interviewees that at times they lost focus on the distinctions between freedom to operate and patentability.

It is unlikely that effort focussed on patenting would provide adequate freedom to operate examination. "To lose sight of which question is being addressed and what course of action is needed to resolve it is a common, and sometimes costly, mistake." (Heines, 2009, p. 5)

5.4.1.4 Players

Who is doing what is a valid input into a freedom to operate study, just as it is a useful output.

> *q:55 [NZ Patent Attorney] one way to cut search [is] to just focus on core companies or people you know that are working in that industry.*

5.4.1.5 Jurisdictions

As noted in the Background section, a patent is a monopoly granted by a nation covering just that state's territory. A patent granted in one nation has little bearing[88] on freedom to operate in another.[89] Thus a vital part of the briefing to a freedom to operate investigator is a list of the jurisdictions in which the client seeks freedom to operate. All other jurisdictions are of lesser interest as far as the legal view of freedom to operate, though they will of course have a bearing on the competitive position.

5.4.2 Reporting the Results

Where the object of an freedom to operate study is to obtain clearance for a product to be launched, the result typically needs to be an opinion that the product does not infringe some known intellectual property. The US Patent Attorney gave a detailed account of what his reports look like.

88 Apart from the status of Products of patented processes in US law- see the section of that name
89 Though it might suggest a patent application in process in the other state too

5 Interview Results and Discussion

The Legal Research section explored the legal terms he uses like non-infringement, claim construction and others.

q:56 [US Patent Attorney] what a freedom to operate evolves into is a series of non--infringement opinions or non-infringement analyses. ... generally they are structured the following way.

There is a first series of paragraphs, introduction, explaining the relationship that I have with the person that is requesting the opinion.

I also point out that I am operating on the basis of information that I have received and I am relying upon from the client.

And I will include some disclaimers about things I am not covering so as you might imagine Graham when I write such an opinion I do not ever call it freedom to operate opinion I call it a non-infringement opinion.

I will then list the patents that I am going to analyse in detail and then say that I am not considering other possible patents that are potentially relevant. So what I rely upon to a great deal is the information I have received from the vendor if I am operating on the vendor's behalf. And I rely similarly upon the team from the investor side if I am being hired by the investor.

Then the second section is a background of what the law of patent infringement and this is very detailed, this maybe 20 or more pages long and an explanation of what a claim is, how claims are interpreted, how what terms mean and then I will go ahead and analyse the individual patents at issue.

And then maybe on a claim by claim basis or I may use infringement analysis to be based upon the Independent claims only. And then I go through the independent claims very very carefully to what is called claim construction. Which is I look at them from a legal viewpoint and ask what would a judge say that this claim means. And so I would go through each of the claim terms, I would read the patent application for clues as to what the claim terms mean, I would look at the prosecution history, that is the communications between the patent office and the applicant in order to gain insight into what is meant by claims.

And then I would end up with what is called a properly construed claim, and properly take advisedly but at least my job.

They now have a section describing what the potential product would be that is what the client would want to do, it might be the product that vendor is trying to sell, it might be the product that investor wants to invest in, and then I would break the product down into its component parts and I would match those up with the claims

so that they may be claims to compositions, there may be claims to methods of use, there may be claims to methods of manufacture in devices.

It is clear from this participant's statement that in this case he is not searching himself, but rather evaluating results found by someone else. Elsewhere, he indicates that he does search himself at times, in which case some of the caveats may not apply.

Often the report back from the searcher includes a verbal presentation or discussion. One participant reported this in quotation q:49, and others in quotations q:28, q:29 and here:

q:57 [Commercialisation Manager 1] Quite often the bulk of the work is done by [colleague] and he and I will have a discussion about it, what do you think about my search and my opinion?

q:58 [Interviewer] And when this IP committee is reviewing the opportunities, is there a mandate, a format in which they must be presented?
[Commercialisation Manager 3] Not this level. No, not generally. It's more like, present your opinions, present your findings and you know that's why… that's why there is going to always be two people sort of reviewing it when it gets to this level: the inventors themselves and myself or one of the more commercial managers will give their opinion of the space at this point. But the next step after that is more formal because now we have to put together an actual provisional patent application.

q:59 [IP Manager] At the committee we have our science general managers, chief scientists, our general manager commercial, and two business managers on there. So…
[Interviewer] Balanced, then.
[IP Manager] Fairly balanced. And it relies a lot on the recommendation of the team, as they know most about it, putting the information up, then they'd come back as they've got questions. But it's basically, "Is the technology good?" "Have we got reasonable protection on it?" "Is somebody interested in it?" "Is there a good market for it?" Yes, those basics. And then you try and see what there's out as much as possible, and the more you get down the track the harder the decision is.

Again, the complexity of the problem lends itself to a conversational style of presentation. A concern remains that a conversation may cover some points at the expense of others, but none of the participants say that a conversation is the sole or even principal form of presentation. Other forms of reporting the results were brought up too:

q:60 [Interviewer] So for the internal reviews you write a document which is explaining the position in words, and you then stand up to explain it, of course.
[Commercialisation Manager 2] Yes, and we do that with slides yes. And you can have pictures. And whatever it is that… you should pick the points that you think are crucial, of course…
[Interviewer] But again, the style of the presentation may vary from case to case?
[Commercialisation Manager 2] Yes. Usually at high level.

This point echoes the previous one. Where the results are presented internally, the person providing the information on the freedom to operate position often presents at a high level, in summary form, using slides and a statement of opinion. The recipient of the information must have sufficient confidence in the provider to accept that opinion after some discussion.

When the provider and consumer of information are not within the same organisation, the tendency is for the information to be imparted more formally, in writing. Is the content any better or does the consumer just have to take the provider's expert opinion without question?

q:61 [Investor 1] And unfortunately the answer to that in our hands is that we are led, we actually do this and get a fairly superficial-looking report and we read it and we see that it has checked the box and we see that they have not shown us anything that we are worried about and we say that is good enough.

q:62 [Analyst] A lot of them have PowerPoint type format. They will read the claims and they will highlight the claims that the company should think about and then recommendations alongside. I think it was a three-page report but on one page there was one patent.
And then another one ... they actually wrote a cover letter saying this is what our findings are, and which was supported with a detailed report as well.
[Interviewer] And so, comparing those two different types of presentation, did you find one more useful than the other?
[Analyst] Yes, we liked the one that was with a cover letter. Because at least we got an overview straight away so we do not have to go through the whole document and look through 50 pages. We just looked at the letter and it is something that we can share with investors very easily as well.

q:63 [Researcher 3] Regarding the presentation styles I am not sure what you can say about them other than the fact that I expect that when you pay the patent counsel you expect a formal report. They will review each patent and there will be a summary on each patent and to what extent it interferes or does not impinge on your own patent and that is a standard format that is a standard tabular format, there will be an overall commentary and there will be individual one, you know like any report.
[Interviewer] Do you ever see any kind of graphical representation in the reports?
[Researcher 3] If it is appropriate, I have never seen that was actually essential.

5.4.3 Use of Graphics in Reporting

As discussed in the section on Research Methods, graphics might be valuable to communicate complex data like the freedom to operate position between people; particularly from those searching for prior art to those using it as a basis to make decisions.

In interviews with nine participants, there was sufficient time to show them a series of nine summary graphics which could perhaps be used to convey a freedom to operate position. They were asked to consider which of the graphic types they had seen used in a freedom to operate reports, or could see a value in using. The results are summarised in appendix Participants' comments on Graphics. The quotes selected may emphasise the virtues of the formats since participants were usually less forthcoming over the shortcomings.

Many of the less positive responses speak to the participants' difficulty in endorsing a format which has insufficient detail to represent the position completely.

q:64 [Researcher 3] your report would be this thick [gestures] and you do want to see a summary of each patent and comments from your counsel with regard to the claims in relation to your patent and then their assessment ... so there is just not enough detail in this though it is good as a reminder ... to go on your wall perhaps.

q:65 [Researcher 1] I find that anything patent-related is very, very difficult, doesn't lend itself to the spoken word at all. I think you have to, just to make a document, you have to sit down with claims, with documents in front of you, read what they actually say, you know, slowly kind of craft your analysis almost certainly written instead of verbal. You know, just to be able to handle all of the intricacies. ... Like I said, I think the devil's just in the gory details and it's just not really reducible to [graphics] …

Others do recognise though that their own need to understand the detail is not always shared by the people they need to communicated with:

q:66 [US Patent Attorney] You see in our environment here in the US the attorney-client privilege is very powerful and I would feel very free to disclose almost any of my work product to a client if they want it.
Sometimes they do not want it, sometimes they do not want to know all the detail. Some clients approach the attorney-client relationship from the point of view of, tell me what I need in order to make a decision. If there is no decision to be made, do not tell me anything.
Other clients want to know the details of, they say why didn't you tell me so and so and the reason is that I didn't think it was pertinent, well why is that, because this claim is construed differently here and here and therefore I think that risk of infringement is very low. ... clients are very different in that regard.

q:67 [IP Manager] it would have to be a very summarised form … they wouldn't need to know patent numbers, they wouldn't need to know dates or anything like that; they'd just need to know that things existed in that space, and that there are the players out there, ... Although, I think, our level of knowledge is pretty high in the organization, …there's still... all the specifics, the detail of patenting, is beyond most people.

The Table of Patent Families was valued by eight of the nine participants, and many of them use something similar in their own practice. The Problem/Solution chart was valued by seven of the nine, none of whom mentioned having used it before. The most immediately recognisable graphic, the Density Map, was valued by five of the nine but most were not clear how it was produced.

Overall participants expressed willingness to use graphical means to communicate the freedom to operate position, but had little experience of using graphics other than tables. There may be an unmet need for summary formats that adequately communicate the position to non-specialists.

5.4.4 Sharing the Position

The person initiating the freedom to operate study and receiving the results, may choose whether to share it with others, within and outside their organisation.

Patent attorneys recognise that the results belong to the client, and that if the client does share them there is some chance of a third party claiming negligence against the patent attorney. Patent

attorneys address this issue by including statements in their report which make clear the limitations imposed on the report by the terms of the engagement.

q:68 [Interviewer] But you would not be concerned about, for example, being sued on the basis of an opinion that you had given that somebody later decided to challenge? [NZ Patent Attorney] Yes, so if someone relied upon that information and they felt that we were negligent of course they could attempt to sue us if they wanted to ... the client has paid for that information, it is theirs and they can do whatever they want with that information. And we just have to live with that. And that is why in our advice is we always provide details of those limitations, that is for the client knowledge but also to protect us.

Some argue that the information should never be shared because it becomes discoverable in any subsequent court proceedings (overriding attorney-client privilege)

q:69 [US Patent Attorney] A legal opinion can be attorney-client privileged, that is it can be subject to the attorney-client privilege and it can be confidential.

q:70 [NZ Patent Attorney] We would recommend that it is done in a confidential basis of course.
[Interviewer] So that there is an agreement of confidentiality between Investor and investee?
[NZ Patent Attorney] Without prejudice and confidential.
[Interviewer] Without prejudice meaning?
[NZ Patent Attorney] Meaning that we are providing this information for the purposes of the discussions but they cannot then turn around and use that information against ... the client. ... So without prejudice discussion, confidential basis ... if the client just gives that information to everyone without stating that it is confidential then that could potentially waive privilege.

Some argue that the information is too valuable to be shared:

q:71 [Researcher 3] you do not share it unless you absolutely have to. If they do not invest $50 million or more ...

or that it is itself a valuable part of the intellectual property and its value should be realised as part of any intellectual property transaction:

q:72 [Researcher 3] you should make them pay for it, for your cost of patents and your freedom to operate which is expensive.

Others recognise that an investor may want to see it as part of their due diligence, though some doubt that an investor should give it credence:

q:73 [US Patent Attorney] And as adverse parties I would not advise an investor to rely upon a freedom to operate opinion or a non-infringement opinion received from the commercial entity.

Some feel constrained by other confidentiality agreements or expectations. This is particularly so for the researchers, who may sign confidentiality agreements to access other researchers' unpublished materials or carry out contracted research. Individuals may also operate under an ethical code which prevents them sharing further.

5.4.5 Room for Misunderstanding

The participants all recognised the term freedom to operate but as noted earlier, there was variability on where to draw boundaries of the term. Since the boundaries of freedom to operate are not universally agreed, when two individuals communicate on the subject, one might draw an unintended conclusion from what the other says.

Patent professionals are concerned that the term freedom to operate is not well understood:

q:74 [US Patent Attorney] freedom to operate is really a misnomer in my view. I understand what it means but I can never guarantee freedom to operate for anybody. ... So in a sense what a freedom to operate search evolves into is a series of non-infringement opinions or non-infringement analyses.

q:75 [IP Manager] freedom to operate is ... very misused and misunderstood.

There was an understandable interaction with the concept of patentability. Thus several participants remarked that they would look for freedom to operate in the course of a patentability study, or expect their lawyers to bring up any freedom to operate implications during patent preparation work:

q:76 [Researcher 3] your patent counsel will firstly approach the problem from the principles of whether it is patentable, you know, novelty, reduction to practice and so forth. But a good patent attorney should also look at freedom to operate at that level.

Some participants mentioned a lack of understanding among people they deal with of the strong current of time which flows through intellectual property:

q:77 [Interviewer] how cognizant are those people ... of these time-based issues? [IP Manager] I think that would very much vary. We possibly assume too much when we go in. In fact, some of our licensees, if they are much smaller parties, we have to lead them through the whole process of what it actually means.

5.4.6 Passing information between Stages

Again from the section on the Purposes of Freedom to Operate Reviews, freedom to operate reviews have quite different uses at different stages.

- The narrowest definition, based upon the fear of being sued for practising another's patented invention, is a concern when publicly making and selling a product (or delivering a service). This is a late stage of many commercialisation projects. The most useful information the is a formal opinion that you will not infringe any of the known patents.[90]

- The definition that includes a rôle in guiding research has meaning in every stage of the project from its earliest inception. In early stages an understanding of who is active in the same field, and what are doing, is useful alongside the prior art. Many sources of information other than the patent databases contribute this information. When looking at the patent databases, expired patents are of as much interest as current patents. Practising an expired patent will not earn royalties, but it can be a reliable way to avoid infringing later patents (see quotation q:82).

- For very early stage researchers, the personal decision on what to spend their time on needs an understanding of the freedom to operate position. Their career publications may be sidelined if they are preceded by others' research papers or patents.

5.4.6.1 Guiding Research

Several of the participants in this study clearly think that freedom to operate assessment is useful to guide research- see earlier quotations q:6 to q:10.

Other participants did not mention this in ways that are easy to quote, but the tone of some responses indicates that they do not associate freedom to operate with looking far ahead.

q:78 [Researcher 3] when you do a search it is at a particular time.

90 Some less absolute information may also be useful; for example, about the quality of competitors' patents or their commercial value.

q:79 [Investor 1] Your question about whether we look into the future, I suppose our blunt answer would be not often and not well.

q:80 [Commercialisation Manager 1] Quite short term, put that in context it is not necessarily looking at whether there is some formulation of IP that could be developed that causes freedom to operate problems. I guess it really focuses on what will be put into the provisional patent.

This difference in expectations might be explained by the parts these different participants play in the research commercialisation process. Those involved in the early stages might see guiding research as a valid objective while those focussing on the later stages would not have that option. These three quotations come from a grouping which does not support that theory- a researcher, a commercialisation manager and a professional investor.

Since the range of expectations exists, those involved in research commercialisation need to be aware of it when communicating about freedom to operate. Since it does not follow rôle-based lines, it is not possible to assume another party's expectations from their rôle.

If one party in a communication has a different expectation to the other party, then the communication may lead the recipient to believe something as a result that the other person did not intend to convey. Communication takes place in at least two directions, so the person intending to receive information should clearly convey their expectations. The person intending to provide information should tailor the information provided, to convey at least how far the information should meet the recipient's stated expectations. If either party is company, the communication is less effective and the commercial risk is increased.

5.4.6.2 Predicting new Freedom to operate Opportunities

One interesting aspect is predicting when patents will expire.

q:81 [Analyst] we get a list of competing technologies that are already out there and how long they have been already operating in the market and a review of their patent application and how long they have got until it is expires.

Apart from an expired patent no longer being a threat to your freedom to operate position, some see a larger benefit:

q:82 [US Patent Attorney] the best way to ensure yourself freedom to operate is to actually practise exactly an expired patent.

If what you seek to practise is entirely contained within the disclosure of the expired patent, no-one else should be able to patent it- it is a "safe harbor". Any one patent commonly covers only a fragment of the intellectual property needed to actually operate a business though.

5.4.6.3 Form of Information Carried Forward

Participants were asked what can be usefully carried forward between freedom to operate reviews at different stages. Some participants would expect the dossier of results to be preserved and used as a starting point for the next stage's review:

q:83 [IP Manager] That's in spreadsheet or in Endnote format, that's different formats so they can generate it in depending on how people like to use it, that's recorded there, that has the patent number, title and abstract. Often the first claim that's thought and kept with the science team. …

[Interviewer] you do have a reasonably systematic way of communicating the results between stages, from what you are saying. You get either an Endnote list or a spreadsheet of what you found.

[IP Manager] Yes.

[Interviewer] .... And that you also record the search strategy. And that bundle of information, then, is communicated not only back to the researcher who is responsible for making this into something, but also it's communicating as the input to the next stage of the process, so when you …

[IP Manager] Yes, and that's useful for the patenting process, where you need the information disclosure statements and things that you want to put through to, particularly the US patent office, so a lot of the information that you found is useful as well.

[Interviewer] Yes, OK. And that's something that everybody here knows, and that's kind of the… the standard they use.

[IP Manager] I would say that it is the standard, but it's variable, in its use, because we have just gone through a merger. And half of the company probably are better than the other half of the company.

Like the previous participant's team, others record the search parameters between reviews:

q:84 [US Patent Attorney] typically when one goes to an electronic database one can either do a Boolean type of search or some other type of search in which you input words, pieces of words, Boolean connectors and or etc. And typically then you go and if you operating in the search environment that does not retain these search

query you simply write down the search query longhand on a piece of paper of the query field or you take a screen-shot of the query field prior to executing it. For example in the United States patent and trademark office database search query is included at the top of the page of the search results. So that is easy to do.

q:85 [Interviewer] Do you keep, for example, search strategies that you used? ... I mean, is that part of what you record for carrying on from one stage to the next? So the search term that you use in the U.S. PTO site, that sort of thing. [Commercialisation Manager 3] Oh, yeah, yeah. Yeah. I do do that, yes. I frequently find myself forgetting whether or not I searched for this particular term or that particular term and what combination so I do do that.

Some participants monitor their sources for changes between reviews:

q:86 [NZ Patent Attorney] another aspect that is to just watching searches to see what kinds competitors are doing as far as filing patents and so for a number of those clients if they see a roadblock type a patent has been accepted by the NZ patent office they will actually launch opposition proceedings. Surveillance and then taking some action to attempt to ensure that patent is not granted. So they have the freedom to move really if they need it. ... If it is a monthly type of situation then we know that we have searched the database from say fifth of September back then the next month we know that we only have to search it from 5 October back to 5 September.

Using the same set of keywords again should produce the same result; or, if time has passed since the last search, should produce new results as well as the previous results. Thus, the searcher should be able to compare the result sets and see what has changed. Finding prior art is just the first part of the process- it must be interpreted and evaluated. Being able to identify the new found documents means that second stage of effort can be restricted to them, without wasting effort evaluating the same materials again.

As described in quotation q:11, one participant uses Google RSS to monitor for new patents being filed in his field. Some of the value added databases (see Third-party Re-publishers of Patent Data) have monitoring capabilities too for subscribers:

q:87 [IP Manager] there's a facility for setting up patent alerts, so if they done their ... search … they can get monthly updates from what's happening in that space.

In conclusion, there is a broad range of ways in which those investigating freedom to operate seek to pass information between project stages. Preserving results is common. Less common is preserving the way in which the results were found, or any information on those things that were looked at but not found to be relevant. The "irrelevant" found documents are relevant, in that they provide feedback on the quality of the search process.

5.4.7 Recommending Actions

As the section Evaluating the Results concluded, the person commissioning a freedom to operate study probably wants a recommendation as well as a list of facts. This section considers some of the potential recommendations.

Sometimes the best recommendation might be to buy a licence, or stop and walk away, but after investment has been made in proprietary research this may be hard advice to take. A more attractive recommendation might be a course correction: identifying a related application promising better freedom to operate, to which the project might divert its attention. Quotations q:6 to q:10 support this view.

Another option is Cross-licensing or Patent Pooling, which is particularly attractive to groups of smaller research teams for whom freedom to operate is more valuable than squeezing license fees for every incremental development that they patent.

Some other potential recommendations mentioned by participants follow in the next few sections.

5.4.7.1 Monitoring

During a commercialisation project the freedom to operate position will change. One solution proposed in q:11 and q:87 is to monitor the position. Several services offer to monitor patent publications, or non-renewal of patents, within the limitations of their Incomplete Sources. Spotting events as they happen opens up time-sensitive options such as Defensive Publishing, Opposition or Re-Examination.

5.4.7.2 Opposition or Re-Examination

This alternative to asking a court to revoke or invalidate a patent was suggested in q:86.

In NZ, within 3 months of the full specification of a patent application being published, anyone can oppose its grant on certain limited grounds including lack of novelty or inventive step.[91] In addition, within 12 months from grant anyone who did not oppose can ask the Commissioner of Patents to revoke a patent on the same grounds available for opposition.[92]

The US PTO can re-examine a patent at its own volition or on payment by the patent owner[93] or someone else,[94] at any time before expiry. Alleged infringers often request re-examination as a less expensive route than through court, and the court usually delays until this is completed. Patentees sometimes use it before suing for the same reason.

5.4.8 Key Findings about Communication

Verbal interaction is valued by all the participants for briefing the searcher and for communicating the results. Some extend this interactivity more or less into the conduct of the search itself.

Expectations for the form of the output varied widely. Participants' experiences ranged from 3-page slide presentations to thick detailed formal documents with patents attached. Early stage projects need less formal reports and they include information to guide ongoing research and identify collaborators and competitors. Graphics were little used, though participants recognised value in using them.

Participants varied in their willingness to share these outputs with potential investors. Some saw that freedom to operate has a value in its own right, distinct from the value of intellectual property.

There was little consistency in what freedom to operate information is kept for later use.

The need for the review to result in recommendations was common.

The Conclusions and Recommendations that follow now are based on the results just presented, and the preceding literature and legal reviews.

---

91 Patents Act 1953 s 21

92 Patents Act 1953 s 42

93 35 U.S.C. 301-307 cover "Office" and ex parte (unopposed) reexamination
94 35 U.S.C. 311-318 cover inter partes (adversarial) reexamination

6 Conclusions and Recommendations

Thus study investigated these two research questions:

- From the points of view of different stakeholders, what makes a good freedom to operate review?
- How can the freedom to operate position be communicated?

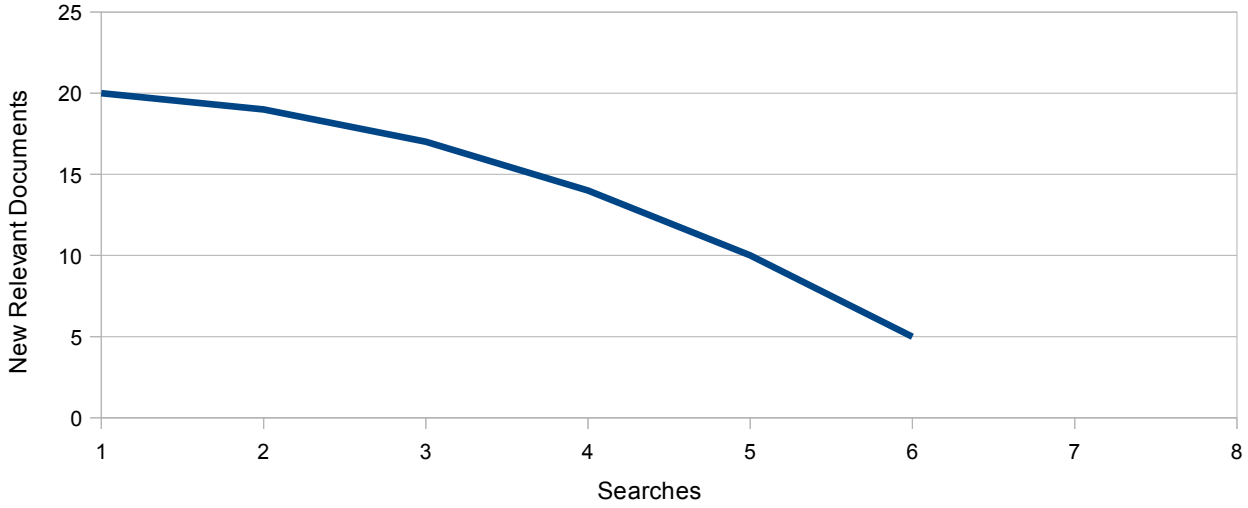
6.1 What makes a good freedom to operate review?

A good freedom to operate review needs to tackle the problem of completeness. Full freedom to operate depends on the absence of blocking patents, which requires exhaustive searching.

This need was identified in earlier research (Deboys, 2004, p. 87) but the solutions were unsatisfying.

That does not mean that a reviewer must (or can) provide a guarantee of completeness but that they should include an understanding of how complete it is. The concept which makes this possible is theoretical saturation, described in the section Are we Nearly There Yet?

Using theoretical saturation, it may be possible to model the approach towards completeness by graphing new relevant prior art found against efforts to find it, as in the fictitious example here:



The slope of the curve indicates how close the search effort is to the point of theoretical saturation where further search effort frinds no new relevant prior art. Thus the reviewer and sponsor can judge the cost and value of attaining theoretical saturation. This technique can be useful also in other forms of prior art research such as patentability studies.

Understanding how complete the search is goes hand in hand with methods to make it more complete. The systematic review approach, introduced in the Business Literature section, can help. Systematic review avoids the problem of any individual's biases or limitations skewing the results. This moves important decisions up Joy's hierarchy (see Decision Theory) from unreviewed operational decisions into the pre-considered tactical or strategic levels which provide more consistency and transparency in the outcome.

The effect of systematic review will be to ensure that multiple sources are consulted (see Appendix A. and the section on Incomplete Sources); and that multiple search strategies are used to overcome limitations in each individual strategy (see the section on Completeness of Search Effort).

6.2 How can the freedom to operate position be communicated?

This study has showed how a common understanding is sometimes lacking in the discussion of freedom to operate. The first communications recommendation is to define with precision, the activity for which freedom to operate is sought, the relevant concepts and terms and the method chosen to assess the position (the systematic review protocol). Unless the method and its strengths and weaknesses are well understood communications about it will be haphazard.

Part of the communication from the searcher needs to be a list of risk factors. This should include patents and the trajectories of other players' efforts (see the section on Other Search Strategies). The list should include as much detail as possible, to form the basis for comparison over time. The risk factors must be assessed for importance. The most relevant patent claims should be construed for comparison with the activity for which freedom to operate is sought.

The list is not just two-dimensional like a spreadsheet table. More complex concepts like multiple inventors, patent families, trees of classifications and claim constructions should be captured so that they can be reviewed and discussed. The list is best captured in the form of structured data and an example of that is the XML representation provided by esp@cenet's Open Patent Services (see the European Patent Office section).

The software tools for this do not seem to be fully formed yet. As they evolve the value of this approach will multiply because the data will become usable together with ontologies (see the section on Search Strategy- Keywords). This will provide a much more effective exploration of the

relationship between the commercialisation project and the prior art, with implications for patentability study as well as freedom to operate.

The position that must be communicated is a statement of risk. ISO 31000:2009 (Standards Australia & Standards New Zealand, 2009, p. 14) offers some guidelines on communicating risk but they are very general and may not be practically useful.

Probability is the most difficult dimension of risk to estimate. The betting method described in the section on Risk Estimation is useful even when there is only one expert to consult. To depict the risk big picture, the risk log format (see Risk Appreciation) is appropriate for early stages, adding a decision tree (see Risk Estimation) in later stages as more information becomes available.

In this communication, describing how the review was conducted is as important as what was found for the recipient to judge the completeness of the search- see the section on Form of Information Carried Forward. For that purpose, the charted progress towards theoretical saturation is useful, and is already available. The actual queries performed at each stage may not interest managers or investors, but are important to searchers at the next stage of commercialisation and should be included with the package of information.

6.3 Further Research

As noted in the section on Limitations of this Method, the data gathered could be improved by extension through more interviews. At that time, it would be useful to get some more concrete examples of the forms in which participants preserve information between project stages, and present it to others. The information handled is commercially sensitive and rarely published. If a researcher were able to remove the sensitive information and retain the form and structure it would provide valuable insights to other practitioners.

The idea that one can graph the approach to theoretical saturation, and hence predict the extra effort required to complete the study, needs testing. This project originally planned a case study phase, using the proposed recommendations to validate them. The case study phase was not possible in the time available and it would be very valuable to check the recommendations in real research commercialisation projects.

Tools to handle patent information in a fully (XML) structured form seem to be close. With semantic web concepts like ontologies they have potential to make all forms of prior art research

much more productive. A follow-up project could aim to put together a kit of these tools and validate it with a case study.

The topic of trade mark was deliberately avoided, though it has a bearing in the late stages of research commercialisation. Future research might perhaps look at trade mark freedom to operate considerations in these later stages.

Appendix A. Evidence of Incomplete Sources

Data for any country in an aggregated collection will be no better than that country's national database from which is sourced.

The databases of all the national patent offices are incomplete. They cannot search the full text for any but the most recent patents, and cannot even search the abstracts of some patents more than 30-40 years old. Before then, patents were recorded in manual filing systems. Only since the wide availability of computers and cheap data storage have these manual records been converted to on-line data and the rate and scope of conversion varies between nations. Several collections republish national data, and the remainder of this appendix considers some of these and their completeness.

I. World Intellectual Property Organisation

The World Intellectual Property Organisation (WIPO) administers the Patent Cooperation Treaty or PCT which is a step towards an international patenting process. In any WIPO country an applicant may application for a PCT patent. The one application acts as a provisional application in all countries where they may want to gain a patent monopoly.[95]

WIPO hosts Patentscope, which "enables you to do searches in 1,801,391 published international patent applications (PCT) and in 5,286,981 when including patent documents from Regional and National collections" but the national collections are limited.[96] As described above, not all of the patents have full text records (WIPO, 2010c).

---

95 PCT applications do not result in PCT patents, but rather in national patents in one or more countries which are party to the PCT. The applicant may choose also to have their application examined initially by an international examiner, whose work product will be made available to the national patent offices of all the countries where the applicant chooses to prosecute the patent application. This can reduce the aggregate work carried out by the national patent offices and hence the cost to the applicant. The break even- the point where it is cheaper to file through the PCT than make separate national applications with no PCT phase- is at about 7 countries.

Significantly a PCT application also reduces the applicant's risk. They can consider the results of the international examination before deciding whether to proceed with multiple national applications. With separate national applications, the applicant pays a fee in each country early in the process and each application may be rejected for the same prior art, wasting all those search fees when the same problem could have been found for one PCT fee. The time when the national fees (and patent attorney costs) become due is also much later: 30 months under the PCT rather than 12 months for the main fees in national applications. This allows the inventor time to better understand the potential in each country and hence avoid spending money on patents in less valuable markets.

96 to 12 countries (Korea being the most significant) plus the African Regional Intellectual Property Organization.

Patentscope thus allows searchers to find patent applications made through the PCT route, and links to the resulting national phase patent applications, but not follow the national phases in each country in detail. The coverage of 5,286,981 patents also needs to be put into perspective of WIPO's own report that 6.7 million patents were in force and 5.94 million potentially pending (see the section on The Quantity Problem).

II. European Patent Office

Like WIPO, the European Patent Office (EPO) provides an umbrella across national patent systems.

For patent searching, EPO offers esp@cenet (http://ep.espacenet.com). This is actually a collection of several different services with different sets of content. Firstly, esp@cenet offers a gateway to the national patent collections of its member European nations. It also offers two worldwide collections of bibliographic data (INPADOC and DOCDB, now merging), which enable it to discern families of patents. esp@cenet provides tools to explore patent status where available, and in some cases the patent's claims are presented as a helpful tree structure. It has some capability to translate patents between languages.

As well as conventional interactive patent searching through esp@cenet the EPO also provides a prosecution history service called Register Plus, access to decisions of the Board of Appeal (which handles appeals against EPO decisions). EPO's Open Patent Services[97] is potentially very significant, allowing searchers to retrieve fully-structured patent documents (not just page images). With those they can build a database of the state of the art for a particular project or organisation.

esp@cenet searches more than 60 million patent documents in over 90 national and international databases. It includes full text descriptions, claims and legal status information for some countries' patents but not others. EPO provides detailed coverage information[98] which identifies many gaps in coverage. EPO also offers several subscription services such as Global Patent Index which seems to offer more searching capabilities and more patent documents.

III. The US PTO web site

The US PTO offers full text of issued US patents only since 1976, and before that only "patent numbers and/or classification codes" (US PTO, 2010b) so searchers must beware this gap. There is

97 A machine to machine interface using Web Services and XML, two well known generic protocols.

98 at www.epo.org/patents/patent-information/raw-data/useful-tables.html

a separate interface to search published patent applications, offering another opportunity to miss prior art.

The US PTO also provides access to the prosecution history of patents and applications.[99] Prosecution history might record that the applicant has agreed that the scope is limited in a way not entirely reflected in the patent as published. This can be useful to consider for a patent that may block your own freedom to operate.

IV. Third-party Re-publishers of Patent Data

Many national patent offices license their databases out to third parties for re-publication in various ways. All the raw information is provided by national patent offices to international bureaux such as WIPO and EPO, and is available to other third parties too, since the declared aim of the patent system generally is to publish the information held in patents for the good of society. Once again, the underlying data provided to third parties is no better than the data available through the national patent offices direct.

One way in which re-publication can add value is through aggregation. Combining databases from multiple patent offices makes it possible to collate families of patents. Insights gained from the wording of a family patent in one country may be useful in interpreting a patent of the same family from another jurisdiction. Both the WIPO and EPO sites aggregate patent records in this way.

Google now indexes "the entire collection of issued patents and millions of patent application made available by the USPTO'from [sic] patents issued in the 1790s through those most recently issued in the past few months." ("Google Patent Search," 2010).

Compared to searching the USPTO database directly, Google has tried to add value by scanning the patent images provided by the USPTO to extract metadata and full text from them. See the note on Optical Character Recognition below for some comments on this.

Google is fairly inexplicit about how complete their database is, only saying that it "covers the entire collection of issued patents and millions of patent application *made available by the USPTO*" ("Google Patent Search," 2010), author's italics. Early users of Google patents noted that the index seemed incomplete. For example in 2008 a commentator noted:

99 http://portal.uspto.gov/external/portal/pair

Appendix A. Evidence of Incomplete Sources

> *"search the exact phrase (in quotes) "Eli Lilly" the field assignee name, using the entire USPTO issued patent database (quick search) or Google Patent Search (advanced search). The USPTO returns 3,793 hits dating back to 1971. Google returns only 527 issued patents dated to 1976, and very strangely, only 461 filings of any status (issued plus applications combined–yes this number is lower than issued patnets [sic] alone!), and just 46 patent applications (USPTO returns 94 applications)." (Cohen, 2008).*

On 8 November 2010, the same experiment was repeated and found that the USPTO returned 3961 issued patents while Google found just 518 issued patents.

Google also applies some of its standard search enhancement strategies to patents. For example Google applies stemming and a thesaurus by default so that searching for "enzyme" also finds pages referring to enzymes, and offers related terms such as amylase and catalase. This of course increases the number of items found by such a search. Google ranks its results according to proprietary, secret algorithms, which can be an advantage in some cases and unpredictably, a disadvantage in others.

Google Scholar is another tool within the Google family used by participants. It offers comparable facilities to the academic databases used by universities. The relationship between Google Scholar and academic databases is probably analogous to that between Google Patents and the USPTO database. While Google adds value in some dimensions, its coverage is probably not as large because of the publishers' commercial considerations.[100]

PatentLens claims to have data from the US PTO (patents from 1976 and applications since 2001), WIPO (all PCT applications since 1978) and EPO (granted patents since 1980) and Australian Patent Office (applications and grants since 1998). PatentLens previously focussed exclusively on the life sciences but has broadened its coverage recently. The completeness of PatentLens' data was not tested but given that Google Patents has had difficulty publishing the US PTO data it should be checked by comparing searches with the sources from which it is derived before assuming it is complete as advertised.

---

100 The computer program cb2bib was used to retrieve references for this thesis. cb2bib reads the computer's clipboard and tries to interpret its contents as an academic reference. If it seems to identify one, it looks up the reference in Google Scholar and other publicly available databases. Anecdotal experience is that Google Scholar was able to find the reference perhaps 3 times out of 4, though the full text of the reference was less available and often had to be retrieved through the University's database subscriptions.

Appendix A. Evidence of Incomplete Sources

The Derwent World Patents Index®- "the most comprehensive database of enhanced patent information in the world" (Thomson Reuters, 2010) which "covers more than 18.25 million inventions from 41 different international patent-issuing authorities" in "39.7 million patent documents currently in the database and over 2.5 million patents are added each year".

One of the value-added services provided by database services such as Derwent is professional and unbiased abstract-writing and indexing in English for each patent covered. Abstracts were not originally part of the patent application format, and were instead provided only by value-added services such as the Chemical Abstracts Service and Derwent.

Delphion claims that "Derwent adds value to patent data through a process of rigorous classification, abstracting and indexing".[101] The abstracting makes it more likely that the patent's core innovation will be made obvious. The indexing has the same effect by using a controlled vocabulary called Manual Codes to represent key concepts in the patent rather than allowing the applicant to define terms uniquely. This can overcome both accidental and deliberate obfuscation of patents. The objective of this effort is to make searching and summarisation of the database more consistently predictable. This sort of value added is particular to the database operator and entails ongoing effort and expense since it probably requires considerable manual input.

Derwent and its ilk are commercial services available on subscription or pay-per-use terms. The need to differentiate themselves from free services is likely to drive them to check their content for completeness as a further way to add value.

V. Pre-Electronic Prior Art

Recall and precision are effective measures of information retrieval when the information is stored in a format conducive to indexed retrieval; that is when it is stored as editable text. Much patent information is still only available as computer images of pages that can be downloaded and printed but not searched by their content. In these images the words are seen as patterns of dots rather than sequences of characters and are thus not available for indexing and searching on their content.

For example the US PTO has since 1979 has accepted patent applications as electronic text which is immediately searchable. Before then for the most part only the bibliographic metadata about the

101 Delphion and similar systems also provide convenient access to status information, where it is available. Other tools in the family allow sophisticated patent analysis. Typically this takes the form of statistical analysis of a collection of patents, rather than detailed analysis of the internals of a particular patent. The analysis facilities in Delphion are more or less available from other public and proprietary sources, and are reasonably easily performed in software if you have all the raw information available.

patent- the "front page" data like inventors' names, patent and application number, title and perhaps abstract were stored as editable text. Other parts of patents were stored only as either physical copies in Patent and Trademark Depository Libraries, or page images.

VI. Optical Character Recognition

Where pages are stored as images, automatic Optical Character Recognition (OCR) can convert those images into text for indexing and storage. Patent offices have used OCR software to capture the text content of patents. For example the US PTO has used OCR to prepare editable (thus searchable) text from patents granted before 1979.

Many OCR systems exist and all will recognise a proportion of the text depending upon its clarity, the font used and other factors but OCR systems do make errors.[102]

While a spell checker is useful to detect errors, the kinds of errors made by OCR systems are very different to the errors made by human typists. For example, spaces may be inserted within words, and one character interpreted as several (m read as rn or iii) or vice versa. Spell checkers intended to correct human errors are very poor at offering appropriate corrections for the kind of errors made by OCR systems (Taghva & Stofsky, 2001). Several approaches have been tried to alleviate this problem, including:

- OCR-specific spell checkers- that is, spell-checkers designed to detect and correct the kinds of mistakes that are particularly common in OCR documents.
- Multiple OCRs each reading the same document and voting on the interpretation of each character image (Lopresti & Zhou, 1997).
- Crowd-sourcing, whereby humans are induced to interpret images of words that OCR software has difficulty with (von Ahn, Maurer, McMillen, Abraham, & Blum, 2008).

The first two of these techniques may be employed in professional-quality OCR software. Crowd-sourcing is used to assist with digitising public collections of handwritten documents and documents in pre-computer typefaces. reCAPTCHA, a crowd-sourcing tool, is built into the login process at the US PTO's PAIR.[103]

---

102 (Holley, 2009) provides a good explanation of the accuracy of OCR of printed materials. Their focus is newspapers but the problems are similar.

103 http://portal.uspto.gov/external/portal/pair

Appendix A. Evidence of Incomplete Sources

The layout of printed pages also get in the way of getting usable results from OCR. For example, hyphenation breaks words and OCR typically does not reconstruct the word to its unbroken form, so a word hyphenated in print would not be found by a searcher.

Multiple columns of text were common in older patents. OCR may concatenate a line from the second column onto the adjacent line from the first column as if they formed part of the same sentence, which affects the use of proximity searching (A within x words of B).

Evidence of flawed conversion of older patents into searchable text is easy to find.[104]

This Appendix has provided evidence that all sources of information should be treated as incomplete. The means by which older material enters prior art databases (OCR) is inherently error-prone and the type of errors introduced are hard for a searcher to anticipate. There is empirical evidence that information is lost when databases are republished. Some re-publishers add value to the republished material through neutral abstracting and classification using controlled vocabulary techniques.

104 For example, consider US patent 4,341,038. The full text derived from the patent is available from both the US PTO and from Google Patents, as well as images. The full text available at Google is significantly degraded, with large sections visible in the images absent from the text version (see Example 1 in the patent). The text version at the US PTO is of much better quality than the version at Google and appears to include chunks that Google omits.

Appendix B. Significant differences in the US

I. First to Invent or First to File?

Under the US First to Invent doctrine, the patent examiner who identifies a conflict between two applications (one of which may already be granted) should declare an "interference" and put the applicants on notice of it. The US PTO conducts interference proceedings to determine which inventor has priority. During interference proceedings, the duelling inventors produce evidence of the dates they conceived[105] and then reduced their invention to practice.[106] If one inventor claims to be the first to conceive but is the latter to reduce to practice, the inventor conceiving first must demonstrate diligence in ongoing development between those dates and that they did not not abandon, suppress, or conceal the invention.

Providing this evidence is challenging and practice has built up of using carefully managed laboratory notebooks to provide the required chain of evidence. These are corroborated by routine witness signatures and evidence of good custodial practice. Inventors outside the US who wish to file US patents need to adopt these practices too, or risk being beaten to a US patent even though they may be able to patent elsewhere.

Several amendment Acts have been introduced to Congress over recent years including provisions to change this doctrine in favour of the "first to file" doctrine used elsewhere. None has so far been enacted.

105 "Conception is established when the invention is made sufficiently clear to enable one skilled in the art to reduce it to practice without the exercise of extensive experimentation or the exercise of inventive skill." (*Hiatt v. Ziegler*, 179 USPQ 757, 763 (Bd. Pat. Inter. 1973).). This must be corroborated by evidence, and must include a clear understanding of the invention's limitations as well as every feature of it which is to be claimed.

106 An invention is reduced to practice at the earlier of filing a patent application for it, or when you have a working model (in complex cases, the prototype need not be complete).

II. Transitional Problems

Two aspects historically differentiated US law from other jurisdictions:

- that applications were not published until grant,[107] and
- that the monopoly began at grant rather than at application.

Both have been reversed in recent years, but patents filed under the old regimes remain in force or in process, and thus still bear on the freedom to operate position today.

The patent prosecution process (formalised interaction between applicant and patent examiner) may take long time (Lemley & Shapiro, 2005, p. 81) particularly through continuation[108] applications, or may be delayed deliberately for some time after application.

Prior to June 1995, US patents conferred a monopoly for 17 years from grant rather than for 20 years from the priority date (commonly the filing date) in other countries. There may still be patent applications in the US system that will be granted in future, claiming a priority back to 1995 or earlier but enjoying a term of 17 years from issue.[109]

US applications before November 2000 were kept secret until granted (Quinn & Hernandez, 2000). Elsewhere, including under the PCT and Convention schemes they are published about 18 months after filing. Thus some older applications may be still awaiting grant and invisible to all but the US Patent and Trademark Office (US PTO) examiners. If the same invention were to be the subject also of a patent application outside the US, the application would be published around 18 months after filing and thus destroy the secrecy in the US market.

---

107 Unpublished applications (also known as Submarine patents because they lurk undetectable) have been a concern for some time. In the US system they can be detected during examination of a patent covering similar ground. The examiner who identifies the issue will declare an "interference" and inform both applicants who then have to prove to the USPTO and perhaps also a court, that their application should have priority on the basis of either they being the "first to invent", or that the other party was not diligent in reducing their invention to practice. If there is no interfering application they may surface only when the applicant decides the time is right to maximise their income from the patent.

108 Continuation Applications (US) are new applications sharing the same disclosure, priority date and at least one inventor (US) with an existing application. They can make additional claims and thereby extend the monopoly provided they stay within the original disclosure. A continuation may be examined long after the parent patent issues (though it will expire when the parent does).

Continuations-in-part (CIP) are like continuations except that they add extra disclosure and hence their claims can be wider. Their claims inherit the priority of the parent application only as far as they fit within its disclosure; claims relying on the new disclosure take priority from the filing date of the CIP application.

Patents of Addition under NZ law are a similar concept to Continuations, without a CIP equivalent.

109 35 U.S.C. 154(c)

Appendix C. Interview Guide

1 What is your current personal involvement with to Freedom to Operate?

1.1 Have you experience of working in more than one rôle with respect to research commercialisation? This study needs to distinguish between your experiences and views relating to each rôle.

2 Project Stage, and Purpose of Freedom to Operate review:

2.1 At what points is a Freedom to Operate review appropriate?

2.2 What is the primary purpose at those points?

2.3 How far ahead is it looking?

2.4 In what other ways is it important to the project?

3 Your Expectations around the Freedom to Operate review:

3.1 How much knowledge will the reviewer have to begin with?

3.2 What sources should the reviewer use?

3.3 How much research should the reviewer do?

3.3.1 How do you judge the degree of completeness reached?

3.4 How should the review be presented?

3.4.1 Are there any particular elements that are essential in the presentation?

3.5 How will the review quality be judged?

4 Your comments on the examples of presentation style provided.

5 Will the user supplement the review with their own research?

6 Will the user expect to share the information:

6.1 With colleagues in the same organisation?

6.2 With outside commercial contacts?

7 What ongoing element is there usually to the review?

8 In a project where you play a rôle in researching its Freedom to Operate;

8.1 What information could you usefully get from someone who had previously researched the same project's Freedom to Operate at an earlier stage?

8.1.1 In what form could you use it (comments on examples if available)

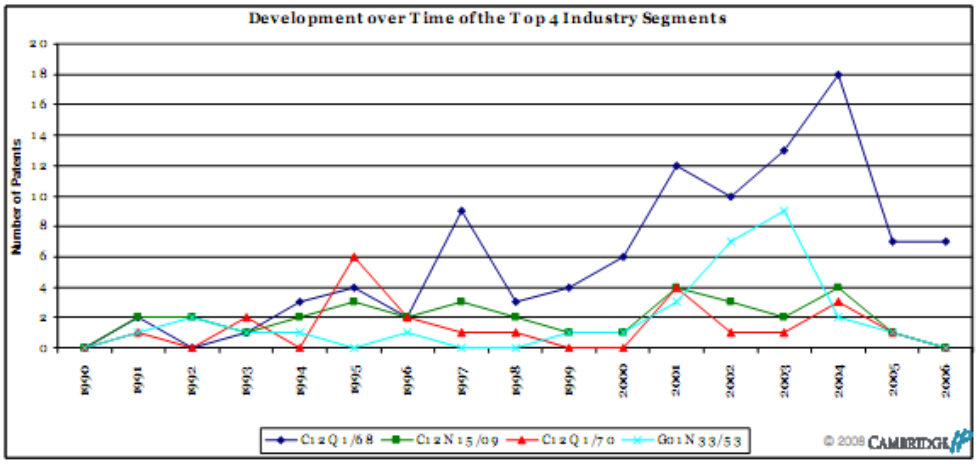
8.1.2 What constraints would you expect on its usefulness?

8.2 What information (and in what form) would you think worth retaining to hand over to someone else who later in the process needs once more to research the project's Freedom to Operate? (comments on examples if available)

8.2.1 In what form could you provide it (comments on examples if available)

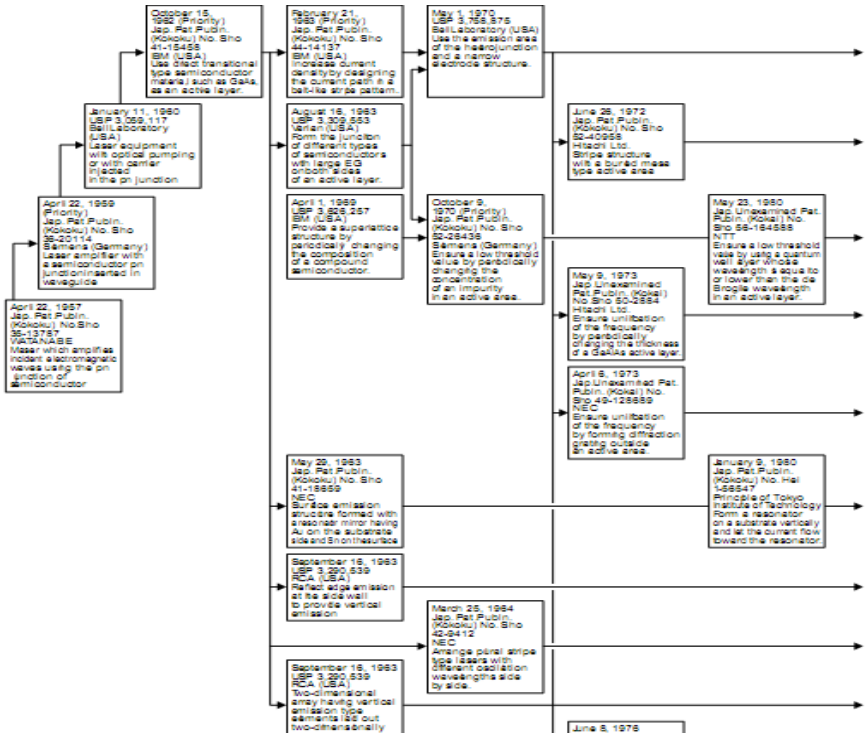
8.2.2 What constraints would you expect on its usefulness?

Appendix D. Participants' comments on Graphics

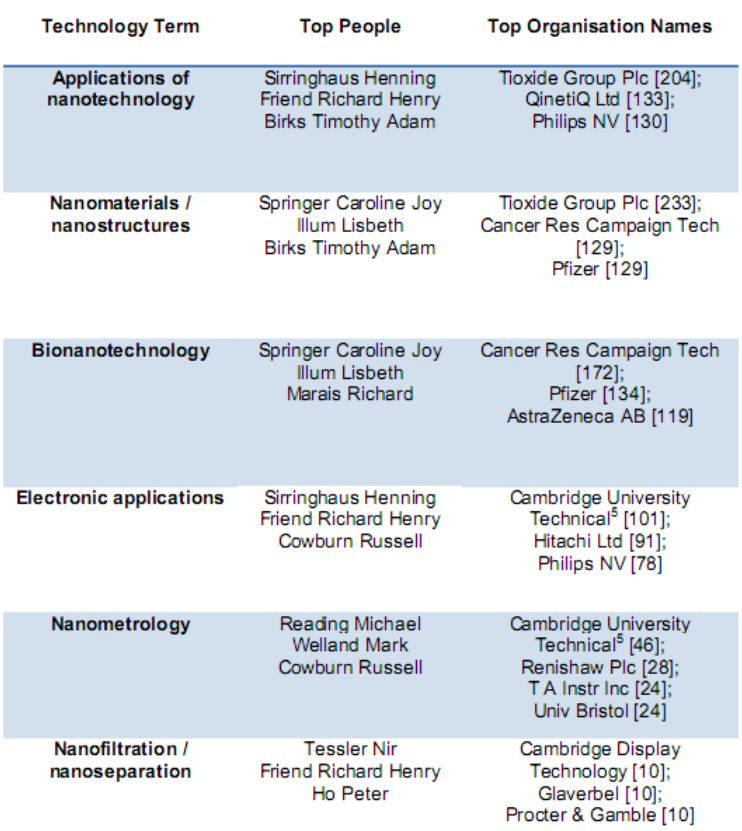
Graphic Type	Comments
Applications over time Valued by 56%	 *Illustration D.1:* This is a graph of patent applications within a Patent Office classification, in each of several successive years. *q:88 [Investor 1] at times we draw our own impression that this is a very crowded area with a lot of stuff going on, it would be nice to have a numeric analysis of that to say yes you are right there is a lot going on or conversely there is not very much going on would make me feel more comfortable* *q:89 [Commercialisation Manager 2] Well, I guess that's useful…but I think you can also convey that information in a sentence.*

Tech Code	Description
C12Q 1/68	MEASURING OR TESTING PROCESSES INVOLVING ENZYMES OR MICRO-ORGANISMS; COMPOSITIONS OR TEST PAPERS THEREFOR; PROCESSES OF PREPARING SUCH COMPOSITIONS; CONDITION-RESPONSIVE CONTROL IN MICROBIOLOGICAL OR ENZYMOLOGICAL PROCESSES > Measuring or testing processe
C12N 15/09	MICRO-ORGANISMS OR ENZYMES; COMPOSITIONS THEREOF; PROPAGATING, PRESERVING, OR MAINTAINING MICRO-ORGANISMS; MUTATION OR GENETIC ENGINEERING; CULTURE MEDIA > Mutation or genetic engineering; DNA or RNA
G01N 33/53	INVESTIGATING OR ANALYSING MATERIALS BY DETERMINING THEIR CHEMICAL OR PHYSICAL PROPERTIES > Investigating or analysing materials by specific methods not covered by groups > Immunoassay; Biospecific binding assay; Materials therefor;
C12Q 1/70	MEASURING OR TESTING PROCESSES INVOLVING ENZYMES OR MICRO-ORGANISMS; COMPOSITIONS OR TEST PAPERS THEREFOR; PROCESSES OF PREPARING SUCH COMPOSITIONS; CONDITION-RESPONSIVE CONTROL IN MICROBIOLOGICAL OR ENZYMOLOGICAL PROCESSES > Measuring or testing processe

Appendix D. Participants' comments on Graphics

Graphic Type	Comments
Flow of ideas Valued by 56%	 This is a tree of patents, linked together by citations. *q:90 [Commercialisation Manager 1] Yes I have seen this before and yes it is quite interesting.* *q:91 [Commercialisation Manager 2] Maybe if it was in this case that the title would tell me anything, but… I think often the patents' titles don't tell you a lot. And it's usually on purpose that they don't tell you a lot.* *q:92 [Investor 1] Yes I have drawn them myself in order to explain to other people in my team, which I have to in my investment committee, I have to table all the arguments as to why we are going to invest and I have been known to do almost then diagrams saying saying well all the green bubbles have come from this base patent and... but I do not think I have ever been offered one. I can understand where you are coming from there but I don't think I have ever seen it.*

Appendix D. Participants' comments on Graphics

Graphic Type	Comments
Applications by Assignee Valued by 56%	

Technology Term	Top People	Top Organisation Names
Applications of nanotechnology	Sirringhaus Henning Friend Richard Henry Birks Timothy Adam	Tioxide Group Plc [204]; QinetiQ Ltd [133]; Philips NV [130]
Nanomaterials / nanostructures	Springer Caroline Joy Illum Lisbeth Birks Timothy Adam	Tioxide Group Plc [233]; Cancer Res Campaign Tech [129]; Pfizer [129]
Bionanotechnology	Springer Caroline Joy Illum Lisbeth Marais Richard	Cancer Res Campaign Tech [172]; Pfizer [134]; AstraZeneca AB [119]
Electronic applications	Sirringhaus Henning Friend Richard Henry Cowburn Russell	Cambridge University Technical[5] [101]; Hitachi Ltd [91]; Philips NV [78]
Nanometrology	Reading Michael Welland Mark Cowburn Russell	Cambridge University Technical[5] [46]; Renishaw Plc [28]; T A Instr Inc [24]; Univ Bristol [24]
Nanofiltration / nanoseparation	Tessler Nir Friend Richard Henry Ho Peter	Cambridge Display Technology [10]; Glaverbel [10]; Procter & Gamble [10]

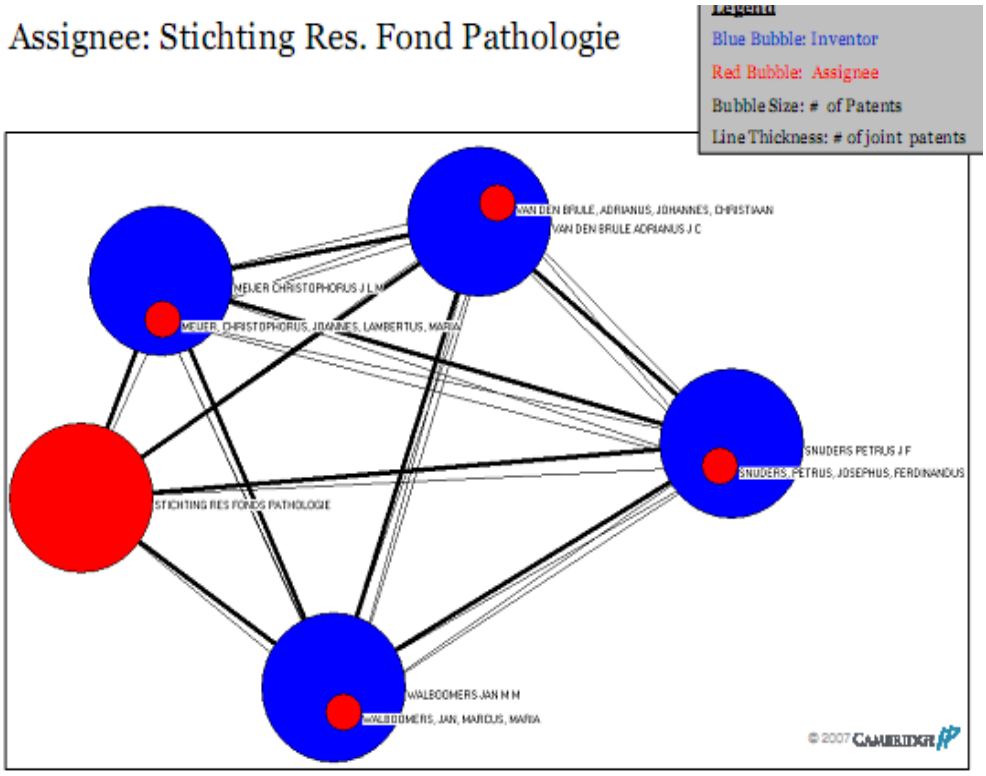
Illustration D.2:

This is a table showing the top (most named on patent applications) inventors and assignees in several related unofficial technology types.

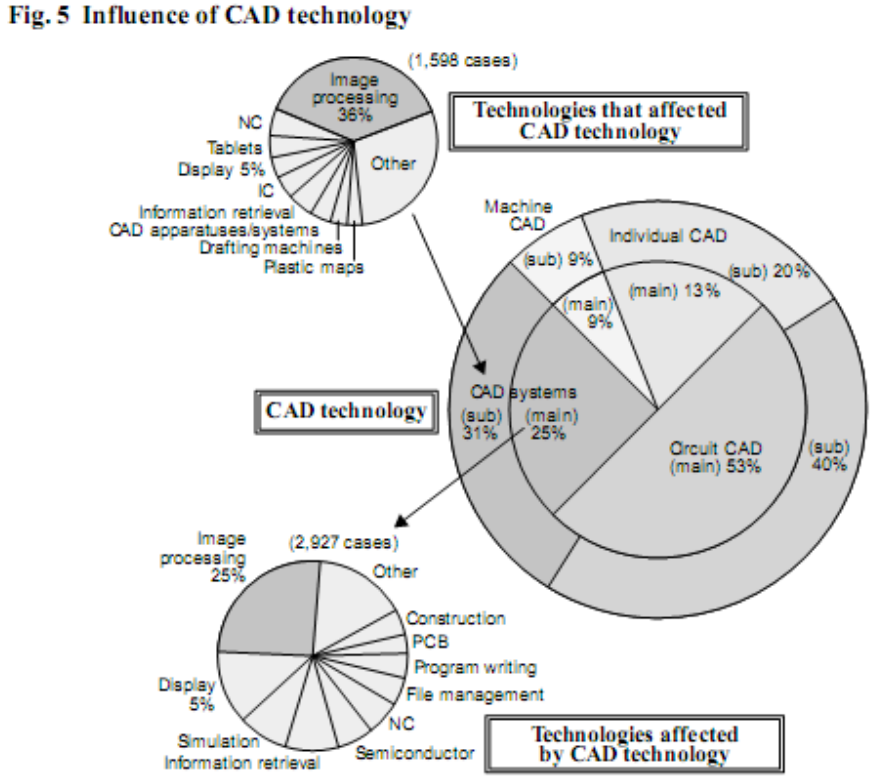
q:93 [Researcher 3] that is useful because you know who is doing what and you usually look to try and see if they are actually groups or companies and if there are big companies you want to know if they have, or what their program is.

q:94 [US Patent Attorney] Well that is certainly one way I would do it, like I mentioned you would identify top organisations and top people, that is a good way to do it. I would look and see, if it is a scientific area, not only what patents they have filed but I would also do a PubNet [http://pubnet.gersteinlab.org] search on their publications. You can often get a heads up as to what is going to be published in the patent domain based on what you see in the literature.

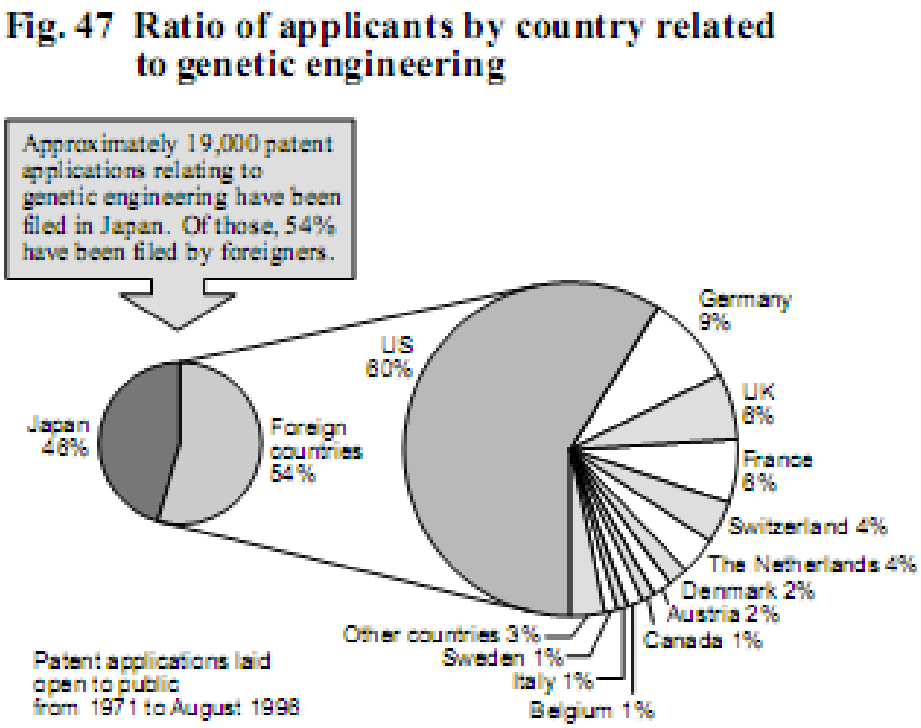
Appendix D. Participants' comments on Graphics

Graphic Type	Comments
Collaboration Maps Valued by 33%	 *Illustration D.3:* This is a graph with bubbles representing inventors and assignees. The circle sizes represent the number of patent applications each is named on, and lines of different widths join the bubbles to represent the number of patents shared by the inventors and assignees. *q:95 [Researcher 1] I suppose some of these things can be useful in certain spaces but I don't have anything to say about that.* *q:96 [IP Manager] I personally wouldn't have any interest in that but the scientists might. I mean, if they were trying to identify top people to collaborate with.*

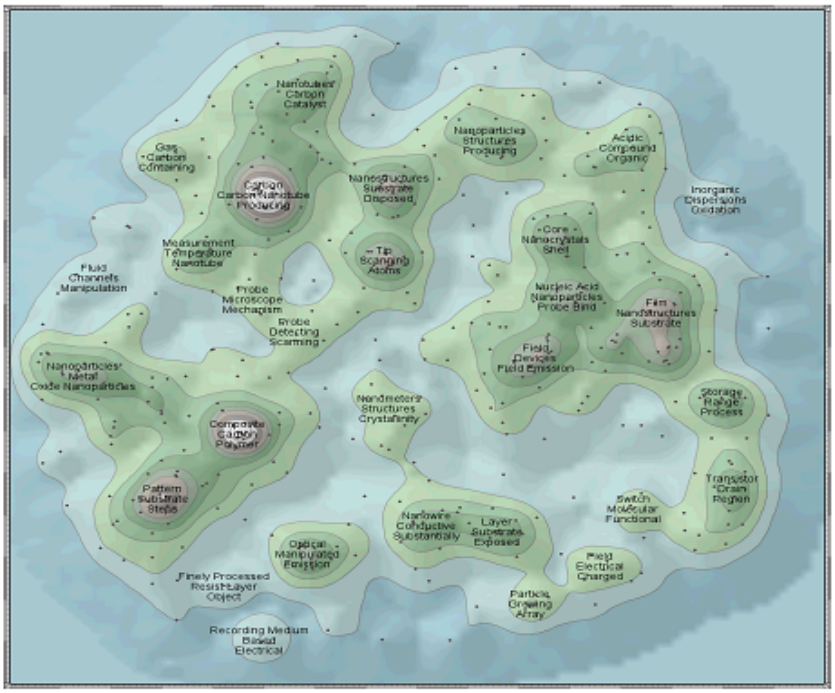
Appendix D. Participants' comments on Graphics

Graphic Type	Comments
Applications by Technology Group Valued by 56%	 *Illustration D.4:* This is a set of pie graphs with segments in the first pie representing core technologies, in the second pie technologies derived from the core technologies and in the third pie, applications built on the derived technologies. *q:97 [Researcher 3] I think this sort of thing is useful for platform technologies.* *q:98 [IP Manager] I think that's probably too high a level …* *q:99 [NZ Patent Attorney] I think that could be quite useful but I have not personally looked at it before. ... you might have a client that has a particular core focus in their business but there may be other alternative revenue streams for them by looking outside the square if that makes sense.*

Appendix D. Participants' comments on Graphics

Graphic Type	Comments
Applications by Country/ Industry/ Assignee Type Valued by 11%	 *Illustration D.5:* Two pie charts, one showing the nationality of applicants for genetic engineering patents in Japan, and the other expanding the non-Japanese slice of the first pie to allow other nations to be distinguished better. *q:100[Commercialisation Manager 1] Well this is ... really so broad.* *q:101[US Patent Attorney] I think this is actually a very useful diagram for the following purpose. When you are developing a business case as a vendor you will want to know what your important markets in which you would like to gain patent protection, lattice sales markets in other words where are the customers where are the people who are going to spend money. You also want to know in what countries is that manufacturing capability so you can file patent claims drawn to the method of manufacturing and also to the product so that I am looking in here and I do not see Ireland for example represented.*

Appendix D. Participants' comments on Graphics

Graphic Type	Comments
Density map by Technology Valued by 56%	 *Figure 45 Landscape map of EP dataset © Thomson Reuters* *Illustration D.6:* This graphic, produced from the Thomson/Reuters value added database system, looks like a topographical map of an island with contours. On each hilltop is a key phrase. By implication, the height of the hill represents how many patents use that key phrase. The arrangement of hills represents how similar the key phrases are based on patents that contain more than one. *q:102[Commercialisation Manager 1] You have to take that from two aspects. They would make it more challenging for IP perspective, to capture your normal pieces of intellectual property, but from a commercialisation perspective it also means that people are really interested in it in.* *q:103[NZ Patent Attorney] Yes and some clients are getting into this more and more. I think, depending upon who in the organisation is looking at the information. I think that some of the IP managers think that this is what the CEO wants to see. You know they just want a broad overview.*

Appendix D. Participants' comments on Graphics

Graphic Type	Comments
Problem/ Solution Charts Valued by 78%	**Fig. 23 Problems and solutions of typical patents for the processing of agricultural waste into fertilizer**

Objective/effect / Method/means	Promotion of fermentation '80 '85 '90				Improvement of fertilizer quality '80 '85 '90				Standardization of fertilizer quality '80 '85 '90				Cost reduction '80 '85 '90			
Pretreatment	x x		x	ẋ ẋ	x		x									
Additives					x		x	x ẋ								
Microorganisms				x x x x x				x x								
Aeration	x		x x	x x x x x ẋ							x	x x ẋ				x
Control			x	x x x				x			x					

x : Published or registered patents ẋ : Unexamined patents (pending)

Illustration D.7:

This complex table shows a Problem (labelled as Objective/Effect) on the horizontal axis, further broken down by year, and Solution (Methods/Means) on the vertical axis. An X at an intersection represents a patent application which uses a given technique to solve a particular problem. This table is from the Japanese Patent Office, and makes use of the natural structure or Japanese patent applications.

q:104[IP Manager] Well, this did attract me. I think it would be quite useful if you were trying to design a research programme around a particular problem.

q:105[Researcher 3] that looks very useful really if you are into manufacturing ... When we look at our process development and we say what are our issues.

Appendix D. Participants' comments on Graphics

Graphic Type	Comments
Table of Patent Families Valued by 89%	

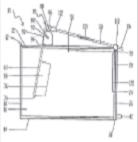
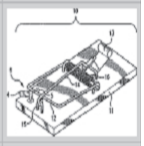
	Title	Common Family	Database	Patent	Kind	Date	Graphic Information
1 Link	Mouse trap	US 6990767	MicroPatent	US 6990767	B1	2006-01-31	
2 Link	Animal e.g. mouse, trap, has ball being support mechanism balancing trap door in open position, and holder moving trip mechanism to upset balance of sliding trap door on rod, when animal enters to trap to take bait.	US 6990767	Derwent World Patents Index	US 6990767	B1	20060131	
3 Link	SAFETY DISPOSABLE MOUSE TRAP	WO 2006036767	MicroPatent	WO 2006036767	A3	2006-09-14	
4 Link	Safety disposable mouse trap	WO 2006036767	MicroPatent	US 20060064922	A1	2006-03-30	
5 Link	Animal e.g. mouse, trap for use in e.g. house, has safety arm attached to top portion of screw attachment and maneuvered over bow, where safety arm is rotated by user with use of lever.	WO 2006036767	Derwent World Patents Index	US 2006064922 WO 2006036767	A1 A2	20060330 20060406	
6 Link	SAFETY DISPOSABLE MOUSE TRAP	WO 2006036767	MicroPatent	WO 2006036767	A2	2006-04-06	
7 Link	Rat or mouse trap comprises box whose entry is blocked by swiveling grille which is bent into V-shape whose point faces into the box so that a animal trying to get out of trap pushes wires at its base against trap floor.	WO 2006010279	Derwent World Patents Index	WO 2006010279	A1	20060202	
8 Link	Mousetrap	WO 05051079	PatBase	AU 2004292376 BR 200416076 EP 1691603 GB 200325446 KR 2006110287 US 2007017149 WO 05051079	AA A A1 A0 A A A1	2005-06-09 2007-01-02 2006-08-23 2003-12-03 2006-10-24 2007-01-25 2005-06-09	

Illustration D.8:

This table shows the international members of several families of patents for similar inventions.

q:106[Researcher 1] Actually, the title is not actually very useful at all. You can see that two matches in mousetraps, that really doesn't distinguish, you know, anything whatsoever. So I would strike the title column. You know the database column is irrelevant. I mean, it's just how you source I guess the document. I mean, it's the same document. You know? Just really another way you found it.

q:107[Analyst] When I say this is what I usually see this is what I would do myself rather than a given. It just tells me whether the person is filed under different countries and what the numbers are I think that is quite helpful to help me track of patents.

Bibliography

von Ahn, L., Maurer, B., McMillen, C., Abraham, D., & Blum, M. (2008). reCAPTCHA: Human-Based Character Recognition via Web Security Measures. *Science*, *321*(5895), 1465-1468. doi:10.1126/science.1160379

Ahn, M. J., Gray, B. J., & Collier, A. (2010). *Innovation, Technology Transfer and Commercialisation in New Zealand*. Centre for Entrepreneurship Working Paper Series. Victoria University of Wellington, University of Otago. Retrieved from http://www.otago.ac.nz/entrepreneurship/docs/Innovation_Technology_Transfer_Commercialisation.pdf

Akers, L. (2003). The future of patent information--a user with a view. *World Patent Information*, *25*(4), 303-312. doi:10.1016/S0172-2190(03)00086-3

Allison, J. R., & Lemley, M. A. (1998). Empirical Evidence on the Validity of Litigated Patents. *SSRN Electronic Journal*. doi:10.2139/ssrn.118149

Amin, R. M., & Pathak, A. (2009, December 4). Freedom to Operate Opinion Considerations. Retrieved June 24, 2010, from http://www.naturalproductsinsider.com/articles/2009/12/freedom-to-operate-opinion-considerations.aspx

Boer, F. P. (2003). Risk-Adjusted Valuation of R&D Projects. *www.boer.org*. Retrieved from www.boer.org/files/2003.pdf

Bonino, D., Ciaramella, A., & Corno, F. (2010). Review of the state-of-the-art in patent information and forthcoming evolutions in intelligent patent informatics. *World Patent Information*, *32*(1), 30–38.

Bryman, A., & Bell, E. (2007). *Business Research Methods* (2nd ed.). Oxford University Press, USA.

Buchanan, B. (2009). *UK innovation nanotechnology patent landscape analysis*. IPO Patent Informatics Project Report (p. 80). Intellectual Property Office. Retrieved from https://ktn.innovateuk.org/c/document_library/get_file?p_l_id=70035&folderId=100091&name=DLFE-1144.pdf

Cohen, F. (2008, May 3). Progress on Google Patent Search? Not enough. *Pharma's Cutting Edge*. Retrieved November 8, 2010, from http://www.pharmaweblog.com/?p=358

Crouch, D. D. (2010). Is Novelty Obsolete? Chronicling the Irrelevance of the Invention Date in U.S. Patent Law. *Michigan Telecommunications and Technology Law Review*, *16*(1). Retrieved from http://papers.ssrn.com.ezproxy.auckland.ac.nz/sol3/papers.cfm?abstract_id=1576564

Dalkey, N., & Helmer, O. (1963). An experimental application of the Delphi method to the use of experts. *Management science*, 458–467.

Deboys, J. (2004). Decision pathways in patent searching and analysis. *World Patent Information*, *26*(1), 83-90. doi:10.1016/j.wpi.2003.09.001

Durham, A. L. (2009). *Patent law essentials: a concise guide*. Praeger.

Eisenhardt, K. M. (1989). Building theories from case study research. *Academy of management review*, *14*(4), 532–550.

Glaser, B. G., & Strauss, A. L. (1967). The discovery of grounded theory: strategies for qualitative research. 1967. *London: Wiedenfeld and Nicholson*.

Golub, A. L. (1997). *Decision analysis : an integrated approach*. New York: Wiley, c1997.

Bibliography

Google Patent Search. (2010). . Retrieved November 8, 2010, from http://www.google.com/googlepatents/about.html

Gregory, J. K. (2006). Troll Next Door, The. *John Marshall Review of Intellectual Property Law*, *6*, 302.

Hall, B. H., Jaffe, A. B., & Trajtenberg, M. (2005). Market value and patent citations. *RAND Journal of Economics*, *36*(1), 16-38.

Heines, M. H. (2009). The Two Faces of Patent Due Diligence: A Case Study in Solar Cells and Nanotechnology. *Nanotechnology Law & Business*, *6*(1).

Holley, R. (2009). How Good Can It Get? Analysing and Improving OCR Accuracy in Large Scale Historic Newspaper Digitisation Programs. *D-Lib Magazine*, *15*(3/4).

Invention Research Institute. (2000). *Guide Book for Practical Use of Patent Map for Each Technology Field*. Japan Patent Office.

Joy, J. (2000). Risk and Decision Making in the Minerals Industry. In *A New Era in Mine Health and Safety Management*. Presented at the Queensland Mining Industry Health & Safety Conference, Townsville – QLD.

Khamooshi, H., & Cioffi, D. F. (2009). Program Risk Contingency Budget Planning. *IEEE Transactions on Engineering Management*, *56*(1), 171-179. doi:10.1109/TEM.2008.927818

Kjervik, D. K., & King, F. E. (1990). The legal research method: An approach to enhance nursing science. *Journal of Professional Nursing*, *6*(4), 213–220.

Kryder, R. D., Kowalski, S. P., & Krattiger, A. F. (2000). The intellectual and technical property components of pro-vitamin A rice (Golden Rice): a preliminary freedom-to-operate review. *ISAAA Briefs*, *20*, 74.

Lemley, M. A., & Shapiro, C. (2005). Probabilistic Patents. *The Journal of Economic Perspectives*, *19*(2), 75-98.

Lerner, J. (1995). Patenting in the Shadow of Competitors. *Journal of law and economics*, *38*(2), 463–495.

Lopresti, D., & Zhou, J. (1997). Using Consensus Sequence Voting to Correct OCR Errors, *Computer Vision and Image Understanding*, *67*(1), 39-47. doi:10.1006/cviu.1996.0502

Mathison, S. (1988). Why triangulate? *Educational researcher*, *17*(2), 13.

Poltorak, A. I., & Lerner, P. J. (2001). Introducing Litigation Risk Analysis. *Managing Intellectual Property*, *109*.

Pulakos, E. D., & Schmitt, N. (1995). EXPERIENCE-BASED AND SITUATIONAL INTERVIEW QUESTIONS: STUDIES OF VALIDITY. *Personnel Psychology*, *48*(2), 289-308. doi:10.1111/j.1744-6570.1995.tb01758.x

Quinn, B., & Hernandez, M. V. (2000, November 27). USPTO Will Begin Publishing Patent Applications. *US Patent & Trademark Office*. Retrieved November 8, 2010, from http://www.uspto.gov/news/pr/2000/00-72.jsp

Rudman, R. (1994). *Human resources management in New Zealand* (2nd ed.). Auckland, N.Z.: Longman Paul.

Science-Metrix. (2010). *30 Years in Science*. Science-Metrix. Retrieved from www.science-metrix.com/30years-Paper.pdf

Slovic, P. (1987). Perception of risk. *Science*, *236*(4799), 280-285. doi:10.1126/science.3563507

Bibliography

Standards Australia, & Standards New Zealand. (2007). *Legal risk management*. Handbooks. Standards Australia/Standards New Zealand.

Standards Australia, & Standards New Zealand. (2009). *Risk management – Principles and guidelines*. Joint Australian New Zealand International Standard. Standards Australia/Standards New Zealand.

Taghva, K., & Stofsky, E. (2001). OCRSpell: an interactive spelling correction system for OCR errors in text. *International Journal on Document Analysis and Recognition*, *3*(3), 125–137.

Thomson Reuters. (2010). Delphion's Derwent Searching. Retrieved November 8, 2010, from http://www.delphion.com/derwent/

Tranfield, D., Denyer, D., & Smart, P. (2003). Towards a methodology for developing evidence-informed management knowledge by means of systematic review. *British Journal of Management*, *14*(3), 207–222.

Tversky, A., & Kahneman, D. (1974). Judgment under uncertainty: Heuristics and biases. *Science*, *185*, 1124.

US PTO. (2010a, April 21). U.S. Patent Statistics Summary Table, Calendar Years 1963 to 2009. Retrieved November 18, 2010, from http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm

US PTO. (2010b, October 13). Search for Patents. Retrieved November 8, 2010, from http://www.uspto.gov/patents/process/search/index.jsp

Vanzeebroeck, N., Stevnsborg, N., van Pottelsberghe de la Potterie, B., Guellec, D., & Archontopoulos, E. (2008). Patent inflation in Europe. *World Patent Information*, *30*(1), 43-52. doi:10.1016/j.wpi.2007.05.010

Walters, W. H. (2008). Google Scholar Search Performance: Comparative Recall and Precision. *portal: Libraries and the Academy*, *9*(1), 5-24. doi:10.1353/pla.0.0034

Weiler, K., & Rhodes, A. M. (2007). Legal methodology as nursing problem solving. *Journal of Nursing Scholarship*, *23*(4), 241–244.

WIPO. (2010a). *World Intellectual Property Indicators, 2010* (No. 941). World Intellectual Property Organisation.

WIPO. (2010b, February). A Cost-Effective Alternative. Retrieved November 18, 2010, from http://www.wipo.int/wipo_magazine/en/2010/01/article_0008.html

WIPO. (2010c, November 24). WIPO - Search International and National Patent Collections. Retrieved June 27, 2010, from http://www.wipo.int/patentscope/search/en/search.jsf