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**Solving the Non-Obvious: Biotechnology Patents and
the Inventive Step Requirement**

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I Abstract

The requirement that a claimed innovation have an inventive step in order to be granted a patent presents particular difficulties for biotechnology. It is notoriously difficult to predict what an examiner or the court will deem to be inventive, creating uncertainty for biotechnologists. Despite the difficulties in predicting the application of the inventive step, the requirement can play an important gatekeeper role, limiting the number of biotechnology innovations that receive patents to those whose contribution outweighs the social costs of imposing a monopoly. This paper will discuss how the inventive step requirement has been interpreted for biotechnology papers, and the role that the requirement plays in the biotechnology industry, comparing it to the other patent requirements. It argues that despite the difficulties in application of the inventive step, and the difficulties it creates for biotechnologists, biotechnology as an industry benefits from its imposition as without it there is the risk of patents on products or processes that are obvious developments hindering future research.

II Introduction

The New Zealand biotechnology market is one of the fastest growing biotechnology markets in the world.¹ Biotechnology is the science of making or modifying specific products using biological systems, living organisms or their derivatives for commercial or technical purposes. It is a field of science with potential to solve many of the food supply, energy, healthcare and pollution issues we face. Patents play an important role in the biotechnology industry and therefore if biotechnology growth in New Zealand is to be sustained, the New Zealand patent system should aim to be understandable and accessible to biotechnologists.² A patent grants a monopoly enabling the inventor to recover the costs of development and reward his or her efforts. Patents have a particular

¹ The University of Waikato “Biotech in New Zealand” 16 November 2007 Biotechnology learning hub

<http://biotechlearn.org.nz/themes/new_zealand_views_on_biotech/biotech_in_new_zealand>.

² Esteban Burrone “Patents at the Core: The Biotech Business” (2006) WIPO

<http://www.wipo.int/sme/en/documents/patents_biotech_fulltext.html>.

importance to the biotechnology industry where development costs are often higher than in other areas of technology,³ and more importantly, patents can signal to potential investors that there is a profit to be made.⁴

One of the four requirements that must be met for a patent to be granted in New Zealand is that there be an inventive step. This is also called the non-obviousness requirement. In addition the Patents Act 2013 requires that an innovation be a manner of manufacture under the Statute of Monopolies, be novel and be useful in order for a patent to be granted.⁵

In the more traditional areas of technology such as mechanics, the inventive step has acted as the main gatekeeper to patent grant.⁶ Inventiveness, however, as inventions have progressed from mechanics, to chemical and electrical, has become increasingly harder to determine.⁷ Biotechnology represents a further step away from the traditional mechanical inventions that the patent system was developed to protect and as a result assessing the inventiveness of biotechnology claims, as biotechnology evolves further is increasingly more difficult.⁸

This paper will discuss how the inventive step requirement should be interpreted for biotechnology patents and whether it remains an effective gatekeeper, preventing the grant of patents that are not sufficiently innovative to justify the social costs associated with imposing a monopoly. This paper will focus on the application of the inventive step requirement for patents to genetic biotechnology in New Zealand, using decisions primarily from the United States and the United

³ E Burrone, above n 2. Additionally there are further regulatory requirements on biotechnology products, such as under Hazardous Substances and New Organisms Act 1996, that further increase cost.

⁴ Clarissa Long “Patent Signals” (2002) 69 University of Chicago Law Review 625, at 627-628.

⁵ Patents Act 2013 s 14.

⁶ Hazel VJ Moir *Patent Policy and Innovation – Do Legal Rules Deliver Effective Economic Outcomes?* (Edward Elgar Publishing Limited, Cheltenham UK, 2013) at 5.

⁷ At 5.

⁸ See part IV.

Kingdom as examples and examine whether the non-obviousness requirement is an effective gatekeeper to patent grant on biotechnological inventions.

III Patents and Biotechnology

To understand the role that the inventive step analysis has on biotechnology patents, the role of patents generally in biotechnology must first be understood. Patents play an important role in the biotechnology industry.⁹ They signal to potential investors,¹⁰ who often know little about biotechnology, that the company has something worth investing in. Biotechnology is a research-intensive industry. Biotechnology companies will invest between 40 per cent and 50 per cent into research, as compared to five per cent in the chemical industry or 13 per cent in the small molecule pharmaceutical industry.¹¹ Such investment is generally risky as biotechnology is inherently unpredictable. Patent protection is important, as manufacturers of imitations, which can enter the market with relative ease, do not have the same high risk and high research and development costs.¹² Investors in biotechnology are well aware of the centrality of patents to biotechnology. Often as part of the due diligence before investing into a biotechnology firm, investors will check the Intellectual Property (IP) of both the firm they are investing in, and of potential competitors to ensure that the firm they are investing in will be able to operate freely.¹³

When examining a patent application, particularly in the common law tradition, we look back to previous decisions in order to achieve consistency. However biotechnology is not a consistent art. It changes at a rapid pace. It looks forward. Something that might have been deemed impossible a few years ago, now holds significant promise. An example of this is induced pluripotent stem cells (iPSCs).

⁹ E Burrone, above n 2.

¹⁰ C Long, above n 4 at 627-628.

¹¹ E Burrone, above n 2.

¹² E Burrone, above n 2.

¹³ E Burrone, above n 2.

Stem Cells have the potential to differentiate into a number of different cells.¹⁴ Stem Cells can be divided into three classes. Pluripotent cells can give rise to any kind of cell, including extraembryonic membranes¹⁵ or placental cells. As such they can only be found in the embryos in the first few cell divisions following fertilisation.¹⁶ Totipotent cells can give rise to any body cells, and multipotent cells are semi-differentiated cells that can give rise to multiple different cells but not all body cells, these are commonly known as adult or somatic stem cells.¹⁷ An example of a multipotent stem cell is a hematopoietic stem cell,¹⁸ as found in blood marrow that gives rise to all blood cell types.¹⁹ While multipotent stem cells have some therapeutic applications,²⁰ pluripotent cells have the greatest therapeutic potential.²¹ Use of pluripotent cells is, however, not without controversy. The only natural origin of an embryonic stem cell is from embryos,

¹⁴ National Institutes of Health, US Department of Health and Human Services “Stem Cell Basics” (5 March 2015) Stem Cell Information < <http://stemcells.nih.gov/info/basics/pages/basics1.aspx>>.

¹⁵ Extraembryonic membranes are membranes that form outside the embryo but are essential for development of the embryo. They include the amnion (sac filled with amniotic fluid), yolk sac (food source for the embryo), chorion (participates in gas exchange between the embryo and the outside) and the allantois (waste storage). John W Kimball “Extraembryonic Membranes” (19 May 2008) Kimball Biology Pages < <http://www.biology-pages.info/E/ExtraembryonicMembranes.html>>.

¹⁶ NYSTEM New York State Stem Cell Science “What is the difference between totipotent, pluripotent and multipotent?” < <http://stemcell.ny.gov/faqs/what-difference-between-totipotent-pluripotent-and-multipotent>>.

¹⁷ National Institutes of Health, US Department of Health and Human Services “Stem Cell Basics”, above n 14.

¹⁸ Hematopoietic stem cells (HSCs) are stem cells that form blood and immune cells. National Institutes of Health, US Department of Health and Human Services “Hematopoietic Stem Cells” (20 January 2011) Stem Cell Information <<http://stemcells.nih.gov/info/scireport/pages/chapter5.aspx>>.

¹⁹ National Institutes of Health, US Department of Health and Human Services “Stem Cell Basics”, above n 14.

²⁰ Hematopoietic stem cells have been used in treatment of inherited blood disorders such as sickle cell anaemia and severe combined immunodeficiency. Patients are given bone marrow transplants (containing the HSCs. The transplanted HSCs do not carry the mutated gene and therefore differentiate into healthy cells. National Institutes of Health, US Department of Health and Human Services “Hematopoietic Stem Cells”, above n 18.

²¹ National Institutes of Health, US Department of Health and Human Services “Stem Cell Basics”, above n 14.

and extraction of the stem cells results in the embryo becoming non-viable, and is therefore subject to opposition similar to opposition to abortion.²² iPSC's are adult/multipotent stem cells, which have through use of signalling factors expressed in high levels in embryos had pluripotency restored. This allows for pluripotent cells to be obtained without needing to destroy embryos.²³

Biotechnology is constantly evolving, looking forward to new frontiers. In contrast, the precedent-based legal system looks backwards for guidance. Lower courts and examiners are obliged to follow previous decisions of higher courts. It is rare for a biotechnology patent to be the subject of litigation in the higher courts and as such the law is, compared to the technology, almost static. Most disputes are simply not worth pursuing in the higher courts. By the time the case is heard, the technology or product at issue has been replaced by something newer, and better, or the claim is amended or simply abandoned and focus shifted to the next innovation. As a result, many of the 'leading' decisions on obviousness in a biotechnology patent are from a different age of technology, and are not easily applied to more recent innovations. For example, the House of Lords in 1996 decided *Biogen Inc. v Medeva*, which concerned a patent on genetic engineering from 1978, when recombinant DNA technology was in its infancy,²⁴ since then the technology has advanced significantly, but the law remains unchanged.

The issue is not with biotechnology. The patent system aims to reward the innovators and inventors who make valuable contributions to the industry by allowing them to profit off the product of their invention before allowing copies, generics, or imitations of their invention to enter the market and thereby encourage further invention and innovation. The commercial reality of

²² Kristina Hug "Embryonic stem cell research: an ethical dilemma" (5 November 2015) Euro Stem Cell < <http://www.eurostemcell.org/factsheet/embyronic-stem-cell-research-ethical-dilemma>>.

²³ Vimal K Singh, Manisha Kalsan, Neeraj Kumar, Abhishek Saini and Ramesh Chandra "Induced pluripotent stem cells: applications in regenerative medicine, disease modelling, and drug discovery" (2 February 2015) 3 *Frontiers in Cell and Developmental Biology* 2.

²⁴ *Biogen Inc v Medeva Plc* [1996] UKHL 18

biotechnology requires patent protection.²⁵ Therefore biotechnologists need to be aware of the potential intellectual property in their work. The patent system, however, should not require biotechnologists to alter the course of their research substantially in order to fulfil patent requirements, otherwise the nature of the innovation produced by the biotechnology industry may be altered, preventing realisation of the full potential of biotechnology.

IV The Inventive Step Requirement in New Zealand Law

A The Patents Act 2013

The requirements for a patent are established by section 14 of the Patents Act 2014.

14 Patentable Inventions

An invention is a patentable invention if the invention so far as claimed in a claim, -

- (a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and
- (b) when compared with the prior art base -
 - i. is novel; and
 - ii. involves an inventive step
- (c) is useful; and
- (d) is not excluded from being a patentable invention under section 15 or 16.

The previous Act did not impose the same requirements.²⁶ “Usefulness” and “Inventive step” were not examined upon application for a patent, they were, however, grounds for opposition or revocation.²⁷ The changes made in enacting the 2013 Act made New Zealand patent law compliant with the Agreement on Trade Related Aspects of Intellectual Property (TRIPS Agreement),²⁸ and was

²⁵ E Burrone, above n 2.

²⁶ Patents Act 1953.

²⁷ Patents Act 1953 ss 21 and 41; (5 May 2009) 654 NZPD 2884.

²⁸ Article 27(1) of the TRIPS Agreement requires Patents to be available for “any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and a capable of industrial application.”; Agreement on Trade-Related Aspects of

intended to reduce the disadvantages endured by New Zealand firms and consumers resulting from the grant of monopolies that would not have been issued elsewhere, restricting New Zealander's access to new technologies.²⁹

The meaning of inventive step is defined in s 7.³⁰

7 Meaning of Inventive Step

An invention, so far as claimed in a claim, involves an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the prior art base.

The 1953 Act allowed for objections to a patents for want of an inventive step when:³¹

...the invention so far as claimed in any claim of the complete specification, is obvious and clearly does not involve any inventive step having regard to matter published as mentioned in paragraph (b) of this subsection, or having regard to what was used in New Zealand before the priority date of the claim.

Lack of inventive step was also a ground for revocation of a patent under the 1953 legislation:³²

...the invention, so far as claimed in any claim of the complete specification, is obvious and does not involve any inventive step having regard to what was known or used before the priority date of the claim in New Zealand.

The 2013 Act was intended to raise the standard required to fulfil the inventive step.³³ Inventive step, as with novelty, is now assessed against all information publically available anywhere in the world, rather than against what was available in New Zealand as was the case under 1953 Act.³⁴ The 2013 definition of inventive step further requires assessment by the Commissioner on the balance of

Intellectual Property Rights 1869 UNTS 229 (signed 15 April 1994, entered into force 1 January 1995) (TRIPS Agreement), Article 27 (1).

²⁹ (5 May 2009) 654 NZPD 2885.

³⁰ See Patents Act (UK) 1977 s 3.

³¹ Patents Act 1953, s 21(1)(e).

³² Patents Act 1953, s 41(1)(f).

³³ (5 May 2009) 654 NZPD 2884.

³⁴ (5 May 2009) 654 NZPD 2884, Patents Act 2013 s 8, Patents Act 1953 s 21(1)(b).

probabilities, in contract to practice under the 1953 Act, which was to give the applicant the benefit of the doubt.³⁵

B Policy of the Inventive Step

Patents seek to encourage innovation by rewarding innovators with monopoly rights to their invention for a set period of time, usually 20 years,³⁶ allowing inventors to profit from their innovation before copies flood the market.³⁷ This incentive however must be balanced against the social cost of allowing such monopolies.³⁸ Patents are intended to encourage innovation, but if they are granted too freely may stifle innovation as others are prevented from using the patented product or process during the patent term, delaying further innovation.³⁹ When considering patent applications, a balance should be sought between the increase in innovation encouraged by the availability of patents, and the social costs of monopoly, such as restraint on use and increased costs to consumers.

The inventive step requirement is intended to ensure that patents are not granted for inventions that although new, are obvious developments upon the existing technology, or would likely occur without patent incentive as a matter of routine.⁴⁰

The inventive step doctrine was developed in an age where inventions were largely mechanical and obviousness was easily determined. Determining the

³⁵ (5 May 2009) 654 NZPD 2884.

³⁶ The TRIPS Agreement mandates a minimum patent term of 20 years, and many countries have chosen to offer 20 year terms, with options to extend in some circumstances. See Agreement on Trade-Related Aspects of Intellectual Property Rights above n 28 art 33, Patents Act 1977 (UK) s 25, Patents Act 1990 (Cth) s 67 and 35 USC 154 as examples of a 20 year term.

³⁷ Hazel VJ Moir *Patent Policy and Innovation – Do Legal Rules Deliver Effective Economic Outcomes?*, above n 6.

³⁸ Patents Act 2013, s 3.

³⁹ Angus C Chu, Guido Cozzi, Silvia Galli “Does intellectual monopoly stimulate or stifle innovation” (May 2012) 56(4) *European Economic Review* 727.

⁴⁰ Rebecca S Eisenberg “Obvious to Whom? Evaluating Inventions From the Perspective of PHOSITA” (2004) 19(3) *Berkley Technology Law Journal* 855 at 855.

obviousness of electrical and chemical patents has proven more difficult for the courts and examiners, as the doctrines developed for mechanical inventions are not always easily applied to different technologies.⁴¹ Biotechnology represents a further step away from the nature of invention in mechanical innovations, and inventiveness has been even harder to determine.⁴² It is essential that any interpretation of the inventive step enable the striking of a good balance between encouraging innovation and development, and preventing the grant of patents on claims whose social cost cannot be justified by the contribution the invention makes to the industry.

C Approach to The Inventive Step in New Zealand Law

Interpretation of the inventive step requirement in New Zealand has been influenced by the interpretations adopted in other nations. The New Zealand Patent Acts have been largely based on the Patent Laws of the United Kingdom. The 1953 Act was modelled on the United Kingdom Patents Act 1949, and the 2013 Act modelled on the Patents Act 1977 (UK).⁴³ The New Zealand Courts have generally followed decisions of the United Kingdom courts.

The Supreme Court, in *Lucas v Peterson Sawing Systems Ltd*,⁴⁴ confirmed that the approach to determining inventive step set out by the English Court of Appeal in *Windsurfing International Inc v Tabur Marine (Great Britain) Ltd* [*Windsurfing*],⁴⁵ was to be used in New Zealand.⁴⁶

The *Windsurfing* approach to testing for inventiveness/non-obviousness has four limbs.

1. Identify the claimed inventive concept.

⁴¹ H Moir, above n 6 at 5.

⁴² Brian C Cannon “Toward a Clear Standard of Obviousness for Biotechnology Patents” (March 1994) 79 Cornell Law Review 735 at 736.

⁴³ (5 May 2009) 654 NZPD 2884; Patents Act 2013 (explanatory notes).

⁴⁴ *Lucas v Peterson Portable Sawing Systems Ltd* [2006] NZSC 20.

⁴⁵ *Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd* [1985] RPC 50.

⁴⁶ *Lucas v Peterson*, above n 44, at [54].

2. Assume the mantle of the normally skilled but unimaginative addressee in the art at the priority date and to impute to him what was, at that date, common general knowledge of the art in question.
3. Identify that, if any, differences exist between the matter cited as being 'known or used' and the alleged invention.
4. Decide, without any knowledge of the alleged invention, whether these differences constitute steps which would have been obvious to the skilled man or whether they require any degree of invention.

Jacob LJ in *Pozzoli SPA v BDMO SA* [*Pozzoli*]⁴⁷ reformulated the *Windsurfing* test for application under the Patents Act 1977 (UK). The New Zealand Intellectual Property Office in the Patent Examination Manual recommends use of this reformulated test in the patent examiners manual.⁴⁸ The reformulated test is:

- (1)(a) Identify the notional 'person skilled in the art'
- (1)(b) Identify the relevant common general knowledge of that person;
- (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
- (3) Identify what, if any, differences exist between the matter cited as forming part of the 'state of the art' and the inventive concept of the claim or the claim as construed;
- (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention.

The fourth step in the *Windsurfing/Pozzoli* tests is to ask the question initially posed by the statute.⁴⁹ The preceding three steps help to remove the risk of hindsight or ex post facto analysis on the part of the examiner or the court.⁵⁰

In *DSM NV's Patent*, Neuberger J identified that the four-step approach ensures:⁵¹

⁴⁷ *Pozzoli SPA v BDMO SA* [2007] EWCA Civ 588 at [23].

⁴⁸ Intellectual Property Office of New Zealand (IPONZ) *The Patent Examination Manual Section 7: Meaning of inventive step*, at [9].

⁴⁹ At [43].

⁵⁰ IPONZ *The Patent Examiners Manual – Section 7: Meaning of inventive step*, above n 48, at [12].

That one does not go straight to the question of obviousness by reference to a general impression as to the evidence as a whole. By adopting the structured approach one ensures that there is a measure of discipline, reasoning and method in one's approach. Indeed, it helps to ensure that there is a consistency of approach in different cases involving the issue of obviousness.

Construction of the hypothetical person with the common general knowledge and skills of those in the industry helps to remove the risk of understating the true inventiveness of the claim. While it is not strictly necessary to apply the four-step test in order to satisfy the statutory test - and one could simply apply the fourth step - approaching the ultimate obviousness question in this manner helps to properly identify the prior art, ensuring consistency and fair assessment of the obviousness of claimed inventions.

V The Inventive Step in Biotechnology Patents.

There has not been a decision in the New Zealand courts on a biotechnology patent post-enactment of the Patents Act 2013. However, decisions revoking patents for want of inventive step under the 1953 Act can offer some guidance on how to interpret the inventive step in New Zealand. Additionally, while cases such as *Lucas v Peterson*,⁵² *Windsurfing*⁵³ and *Pozzoli*⁵⁴ are not decisions on biotechnology patents they offer generalised guidance on interpretation of the inventive step requirement.

Scientific advisors can be appointed to assist the court.⁵⁵ In *Beecham Group Ltd v Bristol-Myers No.2*, where a patent for a semi-synthetic penicillin was at issue, counsel agreed on the appointment of Professor Ferrier as scientific advisor to

⁵¹ *DSM NV's Patent* [2001] RPC 35, at [58].

⁵² *Lucas v Peterson*, above n 44.

⁵³ *Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd*, above n 45.

⁵⁴ *Pozzoli SPA v BDMO SA*, above n 47.

⁵⁵ The English Court of Appeal used a scientific advisor in *Valensi v British Radio Corporation Ltd* [1973] RPC 337.

Barker J.⁵⁶ This was the first time a scientific advisor had been appointed to a New Zealand court. Ferrier was encouraged to comment on any scientific matters made by counsel in their submissions to the court. At the conclusion of the hearing, it was intended that the scientific advisors role end, however, Ferrier was requested to provide further assistance by checking that all scientific details in the judgement were correct.⁵⁷ The use of such an advisor should be encouraged. Determination of an inventive step is ultimately a legal question, however it must be made with regard to the relevant facts. Appointment of a scientific advisor when complex biology or chemistry is fundamental to the claim may help to ensure that decisions are made on relevant scientific distinctions, increasing the likelihood that any distinctions made are justifiable on both scientific and legal grounds.⁵⁸

D The first three windsurfing/Pozzoli steps.

The reformulated approach of Jacobs LJ in *Pozzoli* switches the order of the first two steps of the *Windsurfing* approach, preferring to establish what the common general knowledge of the skilled addressee was before identifying the inventive concept.⁵⁹ This is because only someone holding the common general knowledge of the person skilled in the art can accurately identify the true inventive concept in a claim.⁶⁰

⁵⁶ *Beecham Group Ltd v Bristo-Myers Company (No.2)* [1980] 1 NZLR 192 at 195 [*Beecham No.2*].

⁵⁷ At 5.

⁵⁸ The decision in *Association for Molecular Pathology v Myriad Genetics* (2013) 133 S.Ct 2107 [*Myriad*] has been criticised as the distinction made allowing for the patenting of cDNA but not DNA is not justifiable scientifically. See Noam Prywes “The Supreme Court’s Sketchy Science” (14 June 2013) Slate

<http://www.slate.com/articles/health_and_science/science/2013/06/supreme_court_patent_case_science_the_justices_misunderstand_molecular_biology.html> as an example of such criticism.

⁵⁹ *Pozzoli SPA v BDMO SA*, above n 47, at [15].

⁶⁰ *IPONZ*, above n 48 at [10]; *Pozzoli SPA v BDMO SA* above n 47, at [15].

1 The Person Skilled in the Art and the general common knowledge held by that person

The first step in the *Windsurfing/Pozzoli* test requires identification of the hypothetical person skilled in the art, and the common general knowledge deemed to be held by that person.

Using the hypothetical skilled person, with the common general knowledge of those in the profession, helps to ensure that the claim is genuinely inventive, and not deemed inventive simply because it is new and unknown to a layperson. This is particularly important for an industry such as biotechnology, where the specialist knowledge of those working within the industry can significantly affect their perception of the obviousness of a claimed invention. To someone unfamiliar with biotechnology, the novelty and usefulness of a claim, combined with the technical nature may give the false impression of invention.

In *Lilly-ICOS v Pfizer* Laddie J identified that;⁶¹

The question of obviousness has to be assessed through the eyes of the skilled but non-inventive man in the art. This is not a real person. He is a legal creation. He is supposed to offer an objective test of whether a particular development can be protected by a patent. He is deemed to have looked at and read publically available documents and to know public uses in the prior art. He understands all languages and dialects. He never misses the obvious nor stumbles on the inventive. He has no private idiosyncratic preferences or dislikes. He never thinks laterally. He differs from all real people in one or more of these characteristics. A real worker in the field may never look at a piece of prior art – for example he may never look at the contents of a particular public library – or he may be put off because it is in a language he does not know. But the notional addressee is taken to have done so.

The difficulty with constructing the person skilled in the art is that this person is not just hypothetical, he or she is a fiction. For a biotechnologist, innovation is not extraordinary. Biotechnology is a science wholly based in invention. It aims to

⁶¹ *Lilly-ICOS v Pfizer* [2001] 59 BMLR 123, [2001] FSR 16 (patents court) at [60].

take something and apply in it a new situation, or modify it in order to improve its function. To characterize the hypothetical skilled person as non-inventive but skilled is an oxymoron in biotechnology as it removes the essence of the biotechnologist. Applying the inventive step analysis to a high technology such as biotechnology is therefore very artificial.⁶²

The hypothetical skilled person may have the characteristics of a team of hypothetical skilled people. This has particular relevance to the biotechnology field where normal practice is to work in teams, each person with different skills and specialties.⁶³ For example in the identification of the sequence of the t-PA protein, the patent for which was at issue in *Genentech Inc's Patent*,⁶⁴ a team worked on the sequencing. Natural t-PA was extracted by Dr. Collen at the Centre for Thrombosis and Vascular Research of the University of Leuven in Belgium, and provided to Genentech, with Dr Collen acting as a consultant. Dr Goeddel a biochemist who specialised in recombinant deoxyribonucleic acid (DNA)⁶⁵ procedures headed up a team in the Genentech laboratory including Drs Pennica and Holmes who specialized in manipulation of messenger ribonucleic Acid (mRNA)⁶⁶ and production of complementary DNA (cDNA)⁶⁷ libraries. Two

⁶² *Re Genentech Inc's Patent (Human Growth Hormone)* [1989] RPC 147 (CA), at [13.17].

⁶³ Trevor Cook *Pharmaceuticals, Biotechnology and the Law* (2nd ed, Butterworths, London, 2009) at 108 [5.62].

⁶⁴ *Genentech Inc's Patent (Human Growth Hormone)* above n 62.

⁶⁵ Deoxyribonucleic Acid (DNA) is the genetic material. It is self replicating and through a series of nucleotides contains the genetic code, which can be translated into proteins allowing cellular function. See US National Library of Medicine "What is DNA" (23 August 2016) Genetics Home Reference <<https://ghr.nlm.nih.gov/primer/basics/dna>> for more information, recombinant DNA is where DNA from two or more sources is cleaved then ligated (joined using ligase enzymes) together see Biology Online "Recombinant DNA" (30 November 2015) Biology Online <http://www.biology-online.org/dictionary/Recombinant_DNA> for more information.

⁶⁶ Messenger ribonucleic acid (mRNA) is a form of RNA that is transcribed in the nucleus from DNA capable of transportation out of the cell for translation into proteins, see Scitable "Messenger RNA/mRNA" (2014) Scitable by Nature <<http://www.nature.com/scitable/definition/mrna-messenger-rna-160>>.

⁶⁷ Complementary DNA (cDNA) is DNA formed through use of the reverse transcriptase enzyme from mRNA. It is useful in biotechnology as it allows for creation of eukaryotic DNA strands that do not contain introns and can therefore be expressed in prokaryotes see New England Biolabs

chemists assisted them, one specializing in protein sequencing, the other a protein chemist.⁶⁸ Biotechnologists at Victoria University of Wellington often work as part of teams. This may either be a situation where one person has the lead idea and others in the department assist,⁶⁹ as often for the idea to be realised long, tedious and repetitious test must be carried out. In other situations, different companies may come together. Such was the case when Auckland Uniservices Limited created molecules that they believed to be able to detect, in a non-invasive manner, nitroreductase enzymes in patients. They partnered with the biotechnology department at Victoria University of Wellington, who discovered nitroreductase enzymes capable of activating the Uniservices molecule. Another team in Pennsylvania were found to be working on something similar. To avoid potential infringement of each others' intellectual property, the three teams worked together and filed a patent for "compounds and methods for imaging and/or selective ablation of nitroreductase-expressing cells and/or biological agents."⁷⁰

It is important that the person, or team of people, that the hypothetical skilled person represents, is one selected based on the nature of the problem addressed by the invention, not the solution arrived at by the claim.⁷¹ If the knowledge of hypothetical skilled person is based on the solution arrived at and the solution is found in an area that would not have been expected to provide a solution, the

"Reverse Transcription (cDNA synthesis)" (2016) New England Biolabs
<<https://www.neb.com/applications/cloning-and-synthetic-biology/dna-preparation/reverse-transcription-cdna-synthesis>> for more information.

⁶⁸ *Genentech Inc's Patent (Human Growth Hormone)* above n 63 at [4.02]

⁶⁹ An example of this kind of situation at Victoria University of Wellington is the use of a blue-pigment synthesising enzyme. This invention is patented by David Ackerley, Alistair Brown and Katherine Robins "Methods of detecting and measuring glutamine and analogues thereof, and methods related thereto" WO2015084189 A1, Filed 5 December 2014, <<http://www.google.com/patents/WO2015084189A1?cl=ko>>.

⁷⁰ Robert Forbes Anderson, Jeffery Bruce Smaill, Adam Vorm Patterson, Amir Ashoorzadeah, David Francis Ackerlry, Janine Naomi Copp, Alexandra Marie Mowday, Elsie May Williams, Christopher Paul Guise, Cameron Koch, Alex Kacchur, William R Dolbier Jr "Compounds and methods for selective imaging and/or ablation" WO 2014007650 A1, filed 21 December 2012 <<http://www.google.com/patents/WO2015084189A1?cl=ko>>.

⁷¹ IPONZ, above n 48, at [15].

inventiveness will be understated. The same can be said regarding a team. The hypothetical team constructed needs to be one that would usually exist at the priority date or be likely given the problem at hand, not one only created in hindsight of the claimed innovation. If the team constructed is not one that would be likely put together, there is inventiveness in using that combination of people to solve the problem at hand and therefore the hypothetical person skilled in the art cannot be deemed to have the qualities of that unique team otherwise the inventiveness of the claim will be understated.

The hypothetical skilled person/team is deemed to knowledgeable, but they are not deemed to have read everything in the prior art base.

Luxmore J in *British Acoustic Films* identified that:⁷²

A piece of particular knowledge as disclosed in a scientific paper does not become common general knowledge merely because it is widely read, and still less because it is widely circulated. Such a piece of knowledge only becomes general knowledge when it is generally known and accepted without question by the bulk of those who are engaged in the particular art.

It is not however limited to material that someone skilled in the art would have memorised. Laddie J in *Raychem Corp's Patents*:⁷³

It includes all material in the field he is working in which he knows exists, which he would refer to as a matter of course if he cannot remember it and which he understands is generally regarded as sufficiently reliable to use as a foundation for further work or to help understand the prior art.

However if information can be readily found and it would be obvious to the skilled person that they might find something if they conducted a search, that is sufficient to be considered general common knowledge.⁷⁴

⁷² *British Acoustic Films* 53 RPC 221 at [250], as cited in IPONZ, above n 48, at [22].

⁷³ *Raychem Corp's Patents* [1998] RPC [31], as cited in IPONZ, above n 48, at [18].

⁷⁴ Intellectual Property Office (UK) *Manual of Patent Practice - Section 3: Inventive Step* (1 June 2016) at [3.30.0], see also *Teva UK Limited & Anor v AstraZenca AB* [2014] EWHC 2873 (Pat).

Material directly relevant to the issue purported to be solved by the alleged invention should not be excluded from this lightly, for it is unlikely that someone actively working on finding a solution would not have searched to see if anyone had already attempted to solve the issue or if there was existing knowledge on the organism, cell, protein, DNA sequence or process that they planned to work on.

Unlike when assessing the novelty of the claim, when assessing the inventiveness of a claim, it is possible to combine different pieces of the prior art – this practice is known as mosaicing.⁷⁵ For example, if a sequence for a particular gene had been disclosed, and a gene of a similar size had previously been successfully ligated⁷⁶ into a plasmid,⁷⁷ it would not be inventive to put the sequence in that particular plasmid, even if no one had used that plasmid for that sequence previously. For a combination of documents and/or knowledge to be used to deny a claim by reason of obviousness there needs to be a reasonable basis or motivation for the hypothetical skilled person to put the documents/other knowledge together, based on the problem the claimed invention seeks to solve.⁷⁸ It must be logical from the perspective of the skilled man to put the documents and/or knowledge together and the reason for combination must be made clear before a mosaic of documents/knowledge can be used.⁷⁹

Once the hypothetical skilled person, or team of persons, is identified, along with the general common knowledge they are deemed to hold, the inventive concept of the claim can be accurately identified. This person is, however, highly artificial

⁷⁵ IPONZ, above n 48, at [32].

⁷⁶ Ligation is the process by which DNA fragments are joined together by DNA ligase enzymes. See Nick Oswald “DNA Ligation: How it works” (5 December 2014) BitesizeBio <<http://bitesizebio.com/10279/the-basics-how-does-dna-ligation-work/>>.

⁷⁷ Plasmids are small, circular pieces of double stranded DNA that exist separately to a cells chromosome. See Scitable “plasmid/plasmids” (2014) Scitable by NatureEducation <<http://www.nature.com/scitable/definition/plasmid-plasmids-28>>.

⁷⁸ IPONZ, above n 48, at [37].

⁷⁹ At [33].

and must be understood as a legal construct rather than the average biotechnologist.

2 *Inventive concept*

Identification of the inventive concept requires identification of the core of the claimed invention. It is found by asking what the skilled person would have understood the patent claim to mean.⁸⁰

Biogen v Medeva (1996) illustrates how the identification of the inventive concept affects a finding of obviousness. At issue was the validity of a patent for recombinant DNA incorporating the genetic code for antigens⁸¹ of the hepatitis B Virus (HBV).⁸² HBV can only infect eukaryotic organisms⁸³ and as such has eukaryotic proteins. Biogen inserted the sequence for the HBV antigen into a bacterial cell (prokaryotic cell⁸⁴). At trial, Aldous J identified the inventive concept as “the idea or decision to express a polypeptide⁸⁵ displaying HBV antigen specificity in a suitable host”, or making HBV antigens by recombinant DNA technology.⁸⁶ This interpretation of the inventive concept led the Court of Appeal to hold the invention obvious, as using bacterial cells was, at the relevant time, the only way to produce recombinant DNA. However, this general idea of using recombinant DNA technology to express the HBV antigen misses the true inventive concept of the claim and the House of Lords found that it failed to address the real problem overcome by the invention. Unlike prokaryotic DNA, the

⁸⁰ At [28].

⁸¹ An antigen is a substance capable of stimulating an immune response. See Encyclopedia Britannica “Antigen” (14 May 2015) Biochemistry < <https://www.britannica.com/science/antigen>>.

⁸² *Biogen Inc v Medeva Plc*, above n 24.

⁸³ Eukaryotes are organisms whose genetic material is contained within a nucleus. See Scitable “Eukaryotic Cells” (2014) Scitable by Nature < <http://www.nature.com/scitable/topicpage/eukaryotic-cells-14023963>>.

⁸⁴ Prokaryotic cells are cells where the genetic material is not contained within a nucleus. See Scitable “Prokaryote/procariote” (2014) Scitable by Nature < <http://www.nature.com/scitable/definition/prokaryote-procariote-18>> for more information.

⁸⁵ Chain of amino acids joint by peptide bonds. This forms the primary structure of a protein.

⁸⁶ *Biogen Inc v Medeva*, above n 24 at [49].

DNA of eukaryotes contains non-coding regions of DNA, known as introns,⁸⁷ which are spliced⁸⁸ out before translation of the genetic code into proteins. The presence of introns means that usually a eukaryotic DNA sequence will not produce a functional protein when inserted into a prokaryote. The presence of introns in the eukaryotic DNA mean that skilled person with the common general knowledge of the art would not consider it obvious to attempt to express the HBV antigen in a prokaryotic/bacterial cell. The House of Lords in *Biogen v Medeva* framed the inventive concept as expression of “unsequenced eukaryotic DNA in a prokaryotic host” and therefore found that the invention was not obvious.⁸⁹

This illustrates the effect of switching the first two steps of the *Windsurfing* approach as in *Pozzoli*.⁹⁰ In a highly technical field such as biotechnology, the specialist knowledge of those working in the field can lead to significant differences in the perceived issue from may be identified by a layperson. If the inventive concept is not identified from the perspective of those skilled in the art, there is the potential for the inventiveness of a claim to be missed entirely, or alternatively, for patents to be granted on work that is merely a matter of routine but may appear inventive for those less familiar with the industry.

3 *Differences between the inventive concept and the state of the art at the priority date*

There must be a difference between the claim and the state of the art; otherwise the claim will lack novelty.⁹¹ The question in this stage is therefore not “is there a

⁸⁷ Introns are non-coding (do not code for a protein) section of RNA and DNA. For more information see Scitable “intron/introns” (2014) Scitable by Nature <<http://www.nature.com/scitable/definition/intron-introns-67>> for more information.

⁸⁸ Splicing is the term used for removal of introns from mRNA transcripts, it is facilitated by a Spliceosome. For more information see Suzanne Clancy “RNA Splicing: Introns, Exons and Spliceosome” (2008) 1(1) Nature Education) 31 accessed at <<http://www.nature.com/scitable/topicpage/rna-splicing-introns-exons-and-spliceosome-12375>>.

⁸⁹ *Biogen Inc v Medeva*, above n 24, at [53].

⁹⁰ *Pozzoli SPA v BDMO SA*, above n 47, at [15].

⁹¹ Trevor Cook *Pharmaceuticals, Biotechnology and the Law* above n 63 at 106 [5.61].

difference?” but “what is the difference?” It is the scale of this difference that is assessed in the final stage of the analysis.

E The final Windsurfing/Pozzoli step.

The fourth step of the *Windsurfing/Pozzoli* approach is to ask the question presented by the statute, is the claimed invention obvious?

Courts have used different criteria to determine obviousness depending on the circumstances surrounding each claim. An analysis of decisions on obviousness in biotechnology patents shows that the courts have switched between different doctrines in order to accommodate the evolution of biotechnology. This flexibility can create issues of certainty for applicants, but allows for changes in the nature of the industry to be acknowledged. Switching between doctrines has been observed in the case law of the United States of America regarding use of the obvious to try test.⁹²

The Patents Act 2013 has not yet led to a decision in the courts on the obviousness of a biotechnology patent, however previous decisions under the Patents Act 1953 on objection or revocation of a patent give guidance on how the New Zealand Courts and Intellectual Property Office approach assessing the obviousness of a claim.

Under the 1953 Act the standard of obviousness applied differed between patent objections and patent revocations. Section 21(1)(e) in which obviousness was established as a ground for opposition, required that the invention be “obvious and *clearly* does not involve any inventive step” (emphasis added),⁹³ where as section 41(1)(f) providing for revocation when a claim was deemed obvious did not use

⁹² This is further discussed below. See E Gendloff “The Evolving Obviousness Standard for Biotechnology and Pharmaceuticals in U.S. Patent Law” (2010) 29(4) Biotechnology Law Report 381.

⁹³ Patents Act 1953 s 21(1)(e).

the word “clearly”,⁹⁴ indicating a difference in the onus in each situation.⁹⁵ The 2013 Act does not use the word “clearly”, suggesting that the standard applied in a revocation case is closer to what is to be used under the 2013 Act than what was applied when assessing an objection.

Biological molecules are often complex structures upon which a small change may cause a dramatic shift in function.⁹⁶ Biological structures are often not fully understood, and it is often impossible to predict the effect of altering the structure. It is rare for a novel biological product, statutorily capable of being patented, to be structurally obvious. As such if a purely structural obviousness test is applied, it is unlikely that any claims will be rejected on obviousness grounds, and too many patents will be issued, stifling innovation. Biotechnology products are however, often the result of application of a known process. The obvious to try test for inventiveness may therefore be of use. The obvious to try test has been applied to biotechnology patents,⁹⁷ however its application in New Zealand may be limited following the decision of the Court of Appeal in *Beecham*.⁹⁸ Cooke J, recognising the need for medical research, felt that it would be regrettable if pursuit of one of any number of obvious lines of research would automatically make a claim void for obviousness. The Court of Appeal found that a chemical produced by an obvious method could be inventive if it displayed a sufficient advantage.⁹⁹

⁹⁴ Patents Act 1953 s 41(1)(f).

⁹⁵ *Beecham No.2*, above n 56 at 230.

⁹⁶ An example of this is the sickle cell anaemia mutation, one base pair in the DNA is changed resulting in a change from glutamic acid to valine and the haemoglobin molecules do not form correctly and clump together, meaning they cannot carry as much oxygen as a normal haemoglobin cell. For more information see University of California Museum of Paleontology “A case study of the side effects of mutation: Sickle cell anaemia” Understanding Evolution <http://evolution.berkeley.edu/evolibrary/article/mutations_06>.

⁹⁷ *In re Marek Z Kubin and Raymond G Goodwin* 561 F.3d 1351 (2009). [*Re Kubin*]

⁹⁸ *Beecham Group Ltd v Bristol-Myers Company* [1981] NZLR 600 at 609 [*Beecham*].

⁹⁹ At 609.

Parliamentary debates on the Patents Bill suggest that parliament believed New Zealand's patent law to be too lenient. Terms such as "clearly obvious"¹⁰⁰ do not appear in the 2013 Act, meaning that unlike under the 1953 Act, the decision whether a patent may be granted, must be on the balance of probabilities.¹⁰¹ These changes to the legislation provide the New Zealand Intellectual Property Office and Courts the opportunity to adjust their approach to the inventive step in order for the Act to be able to reflect the purposes of the Patents Act 2013 of "providing an appropriate balance between the interests of inventors and patent owners and the interests of society as a whole" and that patents only be granted in appropriate circumstances.¹⁰²

The Patents Act 2013 has the further purpose of ensuring "that New Zealand's patent legislation takes account of developments in the patent systems of other countries".¹⁰³ Decisions from overseas therefore can be of great assistance when determining how to interpret the inventive step requirement for biotechnology patents in New Zealand. Therefore despite the reluctance of the Court of Appeal in *Beecham*,¹⁰⁴ the acceptance of the doctrine in other jurisdictions and the intention to raise the obviousness standard means that obvious to try should be considered.

The evolution of the obviousness standard in the United States of America demonstrates how obvious to try has fallen in and out of favour with courts considering biotechnology patents. *Re O'Farrell* (1998) held that an invention could be deemed obvious, if it were obvious to try with a reasonable expectation of success.¹⁰⁵ The applicants in *Re O'Farrell* claimed a heterologous

¹⁰⁰ Patents Act 1953 s 21(1)(e).

¹⁰¹ (5 May 2009) 654 NZPD 2886.

¹⁰² Patents Act 2013, s 3.

¹⁰³ Patents Act 2013, s 3(e).

¹⁰⁴ *Beecham*, above n 98 at 609.

¹⁰⁵ E Gendloff, above n 96, at p382.

protein¹⁰⁶ produced in bacterial cells. The examiner, in light of two previous publications deemed this invention to be obvious and rejected the application.¹⁰⁷ On appeal, the court found that the invention was obvious as previous publications suggested there was a reasonable expectation of success. The predictability of the outcome was linked to the obviousness of the claim.¹⁰⁸

This standard was applied in *Amgen Inc v Chuagi* where the applicants claimed the sequence of the isolated human erythropoietin (EPO), a protein which stimulates the production of red blood cells.¹⁰⁹ Previous publications did not predict that the method used to isolate the gene would have been successful, and therefore the claim was deemed to be non-obvious, even though the method used may have been obvious to try based on publications in the prior art.¹¹⁰

Re Bell and *Re Deuel* instead of considering the methods used to obtain the product, considered the obviousness of the structures claimed.¹¹¹ *Re Bell* concerned claims to the DNA and RNA sequences of human insulin like growth factors I and II (IGFs).¹¹² *Re Deuel* considered claims for DNA and cDNA for heparin-binding growth factors (HBGFs), which stimulate cell division.¹¹³ In both, the Federal Circuit Court of Appeals decided that the obviousness of the method used to identify the sequences was not relevant, as it was the product not the method that was claimed.¹¹⁴ The amino acid sequence of the IGFs claimed in

¹⁰⁶ Protein with a different origin species to the species it is expressed in.

¹⁰⁷ *In re Patrick O'Farrell, Barry A Polisky and David H Gelfand* 853 f.2d 894 (1988), at IV [*Re O'Farrell*].

¹⁰⁸ E Gendloff, above n 96, at 382.

¹⁰⁹ *Amgen Inc v Chuagi Pharmaceutical Co Ltd and Genetics Institute Inc* (1991) 927 F.2d 1200 [*Amgen v Chuagi*].

¹¹⁰ *Amgen v Chuagi*, above n 109, at [4].

¹¹¹ *In re Graeme I Bell, Lesile B Rall and James P Merryweather* 991 F.2d 781 (1993) [*Re Bell*]; *In re Thomas F Deuel, Yue-Sheng Li, Ned R Siegel and Peter G Milner* 51 F.2d 1552 (1995) [*Re Deuel*]; E Gendloff, above n 96, at 383.

¹¹² *Re Bell*, above n 111.

¹¹³ *Re Deuel*, above n 111.

¹¹⁴ E Gendloff, above n 96, at 383.

Re Bell had been disclosed previously, however due to degeneracy in the generic code, there are 10^{36} possibilities for the genetic code. As there was no suggestion of which of the 10^{36} possible sequences was the human sequence, the sequence was deemed non-obvious. Similarly, the sequences in *Re Deuel* were found to be non-obvious, as, “a general motivation to search for some gene that exists does not necessarily make obvious a specifically-defined gene that is subsequently obtained as a result of that search.”¹¹⁵

The standard of obviousness applied in the United States changed following the decision of the Supreme Court in *KSR International Co v Teleflex* where it was held that the Teaching-Suggestion model used by the US courts had been applied too rigidly. An “expansive and flexible approach” to obviousness was to be preferred.¹¹⁶ The *KSR* decision determined that contrary to the decision in *Re Deuel*, the “obvious to try” test was relevant when determining the obviousness of a claim. This change in standard has resulted in a higher obviousness standard, affecting biotechnology patents as demonstrated by *Re Kubin*.¹¹⁷ In *Re Kubin*, the isolation of sequence for the Natural Killer Cell Activation Ligand (NAIL),¹¹⁸ and claims to the CD-48 binding region of NAIL proteins after identifying the increase in cytotoxicity¹¹⁹ of cells when NAIL binds to CD-48 on Natural Killer (NK) cells.¹²⁰ The amino acid sequence of the NAIL protein had been disclosed in the prior art, along with a monoclonal antibody that could be used to obtain the protein and DNA sequences. This antibody was used to find the DNA sequence. The Federal Circuit found this claim to be obvious, despite the claimed sequence

¹¹⁵ *Re Deuel*, above n 111, at [4].

¹¹⁶ E Gendloff, above n 96, at 384, citing *KSR Intern Co v Teleflex Inc* 127 S.Ct. 1727 (2007) at 415.

¹¹⁷ *Re Kubin*, above n 97.

¹¹⁸ Natural Killer Cells are part of the innate immune system. See Phillip Eissmann “Natural Killer Cells” (British Society for Immunology) <<http://bitesized.immunology.org/cells/natural-killer-cells/>>.

¹¹⁹ Cytotoxicity is the quality of being toxic to cells.

¹²⁰ *Re Kubin*, above n 97, at [1]

not being apparent from the prior art.¹²¹ As such the claim was found to be obvious as it was obvious to try following the *KSR* definition of obvious to try being where;¹²²

...there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, as person of ordinary skill as good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is the likely product not of innovation, but of ordinary skill and common sense.

This formulation of the obvious to try test is not necessarily in conflict with the *Beecham* criticism of the test. Cooke J regarding obvious to try stated;¹²³

The search for medical advance is to be encouraged. It can be long, expensive and fruitless. The pursuit of one of a number – perhaps many—obvious lines of research may produce a signal or particularly valuable discovery. In deciding on patentability it would seem to us regrettable, and not in accord with a primary purpose of patent law, to have a rule this out automatically in the name of obviousness. We think that the pursuit of an obvious line of research, in the synthesising and testing of a new chemical compound, may be held to culminate in an invention which is not obvious and does involve an inventive step, if a sufficiently distinctive advantage is discovered. It is a question of degree and different words have been used in defining the idea.

Beecham calls for the use of balance. It does not prevent the patenting of an obvious outcome to an process that was obvious to try, allowing claims that result in a valuable addition to the art to be protected.

The Patents Act 2013 was largely adapted from the Patents Acts 1977 and 2004 (UK),¹²⁴ and therefore decisions made under the United Kingdom Acts are highly persuasive. Obvious to try has been an accepted method of assessing the

¹²¹ E Gendloff , above n 96, at 385.

¹²² *KSR Intern Co v Teleflex Inc* above n 116 at [6].

¹²³ *Beecham Group Ltd v Bristol-Myers Company* [1981] NZLR 600 at 610

¹²⁴ See Explanatory Notes Patents Act 2013; (5 May 2009) 654 NZPD 2887.

inventiveness of a claim in the United Kingdom since 1967.¹²⁵ It is, however, not always appropriate. The nature of the invention claimed must be taken into account in each case. Jacob J in *Angiotech Pharmaceuticals v Connor Medsystems Inc* found that:¹²⁶

In the end the question is simply “was the invention obvious?” This involves taking into account a number of factors, for instance the attributes and [common general knowledge] of the skilled man, the difference between what is claimed and the prior art and so on. Some factors are more important than others. Sometimes commercial success can demonstrate that an idea was a good one. In others ‘obvious to try’ may come into the assessment. But such a formula cannot itself necessarily provide the answer. Of particular importance is of course the nature of the invention itself.

To assess the obviousness of a biotechnology patent accurately, the nature of the claimed innovation must be taken into account. Each innovation will have slightly different circumstances that will affect the obviousness of each claim. Obvious to try is not appropriate in all cases, but can be of assistance where a known process is applied to a different substrate, with the expectation of success. It is the expectation of success that is key. Only when the application of a known process gives the expected result is the product obvious. If the result is above expectation, or different in any other way, it is not obvious, and therefore provided the other criteria are met, a patent may be granted.

It is unlikely that allowing use of an obvious to try test for assessing obviousness of a biotechnology patent will result in a significant number of claims being denied. The unpredictability of biotechnology means that few results can truly be predicted, those that can, should not be able to be patented in order to maintain a good balance.

The difficulty is that it is hard to predict how this final obviousness question will be answered. In order to fulfill the requirements of the legislation, and strike an

¹²⁵ *John-Manville Corporation's Patent* [1967] RPC 479 (CA).

¹²⁶ *Angiotech Pharmaceuticals & Anr v Conor Medsystems Inc* [2007] EWCA Civ 5 at [45]

effective balance, the factors taken into account need to vary in each case.¹²⁷ This approach, whilst allowing for the rapid changes in biotechnology, makes it difficult for biotechnologists and their lawyers to predict whether their claim will be deemed obvious. In this way, the inventive step requirement is inherently difficult, and does not easily apply to biotechnology, however without it, the risk that patents which unjustifiably prevent further innovation are granted is run. Without it, further progress in biotechnology could be inhibited.

VI Role of the Inventive Step Requirement.

The inventive step requirement has significant potential to limit patent grant, providing the standard of inventiveness applied, is high enough. If the standard applied is too low the increased innovation encouraged by the availability of patents, and the increased investment made, will be outweighed by the costs of monopoly. Such costs include prevention of further research, and increased cost for consumers of the products. As such despite the difficulties with predictability of its application, the inventive step requirement plays an important role for biotechnology.

It is arguable that other patent criteria are better gatekeepers to patent grant.

Most biotechnologies are affected more by patent requirements than other areas of technology. The statutory requirements for patentable subject matter or manner of manufacture along with the usefulness requirement have limited the number of biotechnology innovations that are capable of patent protection.¹²⁸

The Patents Act 2013, in addition to introducing the inventive step requirement, introduced a usefulness requirement, similar to that in the United States.¹²⁹ A claim must now demonstrate that the invention has specific, credible and

¹²⁷ IPONZ, above n 48, at [43] citing *Generics v Lundbeck* [2007] RPC 32, at [72].

¹²⁸ See *Myriad*, above n 58; *D'Arcy v Myriad Genetics* [2015] HCA 35 [*D'Arcy*].

¹²⁹ Patents Act 2013 ss 14 and 10, 35 USC § 101.

substantial utility.¹³⁰ The requirement that a claim be useful is in part a response to the rise of gene patents.¹³¹

Specific utility means that the claim must have a well-defined use. It cannot be a general utility such as “pharmaceutically active” or “gene probe” for a DNA sequence or “diagnostic ability”.¹³² Rather a specific use must be disclosed such as the specific condition that might be diagnosed, or the actual pharmaceutical effect.¹³³ Credible utility requires that the claim works as stated, based on whether a person skilled in the art would consider the claimed invention, “logical and consistent with the state of the art”.¹³⁴ This does not mean that something completely out of left field cannot be patented, it must however be regarded as plausible or reasonably credible by the person skilled in the art.¹³⁵ Substantial utility requires that the claim correspond to a significant real world utility.¹³⁶ If the claim requires further research to identify or confirm a “real-world utility”, it is not deemed to be substantially useful.¹³⁷

The standard on which the inventive step is measured is criticised for being too low.¹³⁸ Combined with the difficulty in determining whether there is an inventive step in a biotechnology invention discussed above, it may be that the usefulness requirement is a better gatekeeper against granting of unjustifiable biotechnology patents. The usefulness of a biotechnology invention is often easier for a layperson to understand. Unlike the obviousness assessment, it is not necessary to

¹³⁰ Patents Act 2013, s 10.

¹³¹ A Heath “Preparing for the genetic revolution – the effect of Gene Patents on Healthcare and Research and the need for Reform” [2005] *CanterLawRw3*; (2005) 11 *Canterbury LawReview* 59.

¹³² IPONZ *Patent Examiners Manual: Meaning of useful*; The United States Patent and Trademark Office (USPTO) *2107 Guidelines for Examination of Applications for Compliance with the Utility Requirement*

¹³³ USPTO, above n 132; see *re Fisher* (2005) 421 F. 3d 1365.

¹³⁴ IPONZ, above n 132, at [10].

¹³⁵ At [11].

¹³⁶ At [18].

¹³⁷ At [19].

¹³⁸ Hazel VJ Moir *Patent Policy and Innovation – Do Legal Rules Deliver Effective Economic Outcomes?* Above n 6 at 7.

understand the underlying science to understand the application of most biotechnology inventions and thereby their usefulness. The utility requirement is more certain than the inventive step. As discussed above there is necessary unpredictability in the inventive step assessment. It is therefore difficult for biotechnologists and their lawyers to predict whether or not a claim will be granted a patent. In contrast usefulness can be predicted with relative ease.

The usefulness requirement ensures that the claim has a practical application before the patent can be granted. This excludes the patenting of genetic material upon mere identification, however does not prevent the patenting of sequences where use of that sequence might be obvious such as in *Re Kubin*.¹³⁹ Development of new biotechnology products starts with a known issue. By starting with the known issue the usefulness of a product is almost guaranteed. This requirement prevents malicious patenting of random isolated sequences or proteins, with random modifications, but does not prevent patenting of obvious solutions to a known problem. As such the inventive step requirement has a continued relevance to biotechnology claims.

Compared to other areas of technology, patentable subject matter has proven harder to determine for biotechnologies. Decisions such as *Diamond v Chakrabarty* (1980) where it was held that a live, human-made microorganism was patentable subject matter,¹⁴⁰ created a precedent that “anything under the sun that is made by man” is patentable.¹⁴¹ As biotechnology has expanded, such an approach has fallen out of favour. The mere isolation of genes, on the grounds that an isolated gene could not be found in nature, has previously been considered patentable. More recent decisions, such as *Myriad*¹⁴² and *D’Arcy*,¹⁴³ however,

¹³⁹ *Re Kubin*, above n 97.

¹⁴⁰ *Sidney A Diamond v Ananda M Chakrabarty* (1980) (1980) 447 US 303 [*Diamond v Chakabarty*].

¹⁴¹ At III, citing the Committee Reports accompanying the 1952 Patents Act (US).

¹⁴² *Myriad*, above n 58.

¹⁴³ *D’Arcy*, above n 128.

have limited what may be patented. Statutory limits have also been placed in many jurisdictions limiting the kinds of biotechnology product that may be patented. For example in New Zealand patents are not permitted on things contrary to public order or morality,¹⁴⁴ human beings and biological processes for their generation,¹⁴⁵ methods of treatment for human beings,¹⁴⁶ methods of diagnosis practiced on humans,¹⁴⁷ and plant varieties.¹⁴⁸

It is arguable that the limitations on patentable subject matter along with the usefulness requirement should be sufficient to prevent the grant of biotechnology patents whose social cost is too high to justify. These requirements however are not always enough. Some biotechnology products, particularly in medicine, are developed in order to find a solution to a known problem. An example of such a product is the thrombin aptamer.¹⁴⁹ Thrombin is a protein needed for blood clotting.¹⁵⁰ During surgery, blood clots must be prevented; one mechanism used to prevent blood clotting is to inhibit the activity of thrombin.¹⁵¹ Once surgery is completed, the blood needs to clot otherwise the patient is at risk of significant blood loss if wounds do not close. The thrombin aptamer operates by binding to the DNA/mRNA preventing translation to the protein, an antidote to the aptamer can be administered post surgery in order to remove the aptamer, and allow blood

¹⁴⁴ Patents Act 2013 s 15.

¹⁴⁵ Section 16(1)

¹⁴⁶ Section 16(2)

¹⁴⁷ Section 16(3)

¹⁴⁸ Section 16(4)

¹⁴⁹ Aptamers are single stranded DNA or RNA molecules that can bind to pre-selected targets. They can act as bio-sensors and have therapeutic applications. See Base Pair Biotechnologies “What is an aptamer” (2016) Base Pair Biotechnologies < <http://www.basepairbio.com/research-and-publications/what-is-an-aptamer-2/>>.

¹⁵⁰ Thrombin is a protease (enzyme) that catalyses the conversion of fibrinogen to fibrin and activates factors V, VIII, XI and XIII in blood causing platelet aggregation, allowing for blood to clot, preventing excessive bleeding. JTB Crawley, S Zanadelli, CKNK Choin and DA Lane “The central role of thrombin in hemostasis” (2007) 5 Journal of Thrombosis and Hemostasis 95

¹⁵¹ John W Kimball “Blood Clotting” (5 January 2012) Kimball Biology Pages < <http://www.biology-pages.info/C/Clotting.html>>.

to clot again.¹⁵² Aptamers are generated randomly and selected by their ability to bind to the thrombin (or other target) gene.¹⁵³ As such, the usefulness of the final product is known from its inception. While an aptamer is a DNA or RNA sequence, it would be considered a manner of manufacture and therefore is patentable subject matter.¹⁵⁴ It is in this situation, where usefulness and patentable subject matter are easily established, that the inventive step can play an important role. It ensures that there is something above ordinary in the claim. While aptamers can be patented, as this line of biotechnology advances, there is a real risk that if aptamers generated as a matter of routine are patented the monopoly could prevent further research.

Therefore, despite the difficulties in applying the inventive step analysis to an evolving technology such as biotechnology, the inventive step remains an important gatekeeper from the grant of patents whose social cost cannot be justified.

VII Conclusions

As it stands, the inventive step requirement is not easily applied to biotechnology. It creates uncertainty for biotechnologists, as it is often difficult to predict whether a claim will be deemed inventive/non-obvious by an examiner or the courts and is therefore a source of frustration for biotechnologists and their lawyers. The *Windsurfing/Pozzoli* method helps to remove some of the risk of using hindsight

¹⁵² See Charlene M Blake, Haichen Wang, Daniel T Laskowitz and Bruce A Sullenger “A Reversible Aptamer Improves Outcome and Safety in Murine Models of Stroke and Hemorrhage” (February 2011) 21(1) *Oligonucleotides* 11.

¹⁵³ Aptamers are usually generated by the SELEX (Systematic evolution of ligands by exponential enrichment) method. In this potential aptamer candidates (oligonucleotides) are mixed with the target molecule. Oligonucleotides that bind to the target are randomly mutated, and mixed with the target to see if the introduced mutation increases affinity for the target. See Stephanie M Schuitt “Modified Nucleoside Triphosphate Applications: An overview of the SELEX process” (2016) TriLink Biotechnologies < <http://www.trilinkbiotech.com/tech/selex.asp>>.

¹⁵⁴ See *Myriad*, above n 58; see *D’Arcy*, above n 128; see Patents Act 2013 s 14; see Statute of Monopolies 1623 21 Jac c 3.

when assessing the obviousness of a claim but does not lead to a predictable outcome on a patent application for biotechnologists.

Despite the inherent difficulties with determining the obviousness of a biotechnology patent, the inventive step requirement plays an important role. Biotechnology is an industry in which patents play a large role, helping to secure investment, and enabling biotechnologists to profit from their inventions before copies enter the market. These patents however, can have a detrimental effect potentially restricting further research. Therefore there is a need for balance. The inventive step requirement can help achieve this balance. By ensuring that patents are only issued when something above ordinary has been made, the likelihood of the social costs of monopoly outweighing the social benefit of the patent system is decreased. In this way, despite the difficulties in its application, the biotechnology industry needs the inventive step requirement to maintain a balanced approach to patent grant.

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