DNA©: Copyright Protection for Novel Genomes

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I. Introduction

The primary goal of synthetic biology is the construction and reconstruction of life at the genetic level.[1] This involves the assembly of various nucleotide sequences to build novel genomes, and hence an entirely new species, from scratch. The field of synthetic biology has the potential to address some of the most serious challenges facing mankind, however, it is unclear what intellectual property rights (IPRs), if any, can be granted over the nucleotide sequence of these novel genomes. This dissertation endeavours to answer this question by first, reviewing the current scientific literature underpinning synthetic biology, before entering into a discussion on why IPRs are necessary to protect the nucleotide sequence of novel genomes. Next, this dissertation enters into an analysis of the forms of IPRs available, and concludes that copyright offers the most appropriate means of protection for the nucleotide sequence of novel genomes. Finally, this dissertation discusses the ability of novel genomes to satisfy the requirements for copyright protection under the Copyright Act 1994. Ultimately, it is submitted that novel genomes are literary works that satisfy the criteria for copyright protection under the Copyright Act. This assertion is largely based on the analogy between novel genomes and computer programs which have already been afforded explicit statutory protection. Although novel genomes can be classified as literary works under the current form of the Copyright Act, it is recommended that an appropriate clarifying amendment is desirable though not actually necessary.

II. The Science Behind Synthetic Biology

A. Introduction

Synthetic biology is a new interdisciplinary field that involves the application of engineering principles to biology.[2] While there is no universally accepted definition of synthetic biology, the least contested defines synthetic biology as "the design and construction of new biological parts, devices and systems and the redesign of existing natural biological systems for useful purposes".[3] The three overarching aims of synthetic biology are the modification

[1] Drew Endy "Foundations For Engineering Biology" (2005) 438 Nature 449, at 449
[2] Synthetic Biology Engineering Research Centre (Synberc) "What is Synthetic Biology" (2014) Synberc <http://www.synberc.org/what-is-synbio>
[3] Synthetic Biology "FAQ" Synthetic Biology <http://syntheticbiology.org/FAQ.html>

of existing organisms to achieve certain functionalities; the creation of 'minimal genome' organisms via the deletion of superfluous genes; and the construction of novel genomes from a set of standardised DNA "parts" (shorter nucleotide sequences) which are then inserted into a host microbe or cell. [4]

Synthetic biology can be distinguished from genetic engineering in terms of scale and ambition. Traditional genetic engineering involves the transfer of *pre-existing* individual genes from one species to another.[5] Conversely, synthetic biology has been given the moniker "genetic engineering 2.0" because it uses a set of standardised genetic parts to assemble novel genomes which are then introduced into a host microbe or cell.[6] So instead of simply transferring pre-existing genes into an existing genome, synthetic biologists create entirely new genomes, and by extension an entirely new species.

B. Applications of Synthetic Biology

There are a number of applications where synthetic biology has the potential to make society more economical and environmentally sustainable. Key areas of research include biofuel and alternative energy production, bioremediation, medical therapeutics and food production.[7]

Currently, there are number of research programmes targeted at improving environmental quality through the production of biosensors to monitor the environment and detect contamination,[8] as well as the development of improved treatment methods for solid organic wastes, sewage, industrial waste water and polluted soil and underground water.[9] Other research programmes endeavour to reduce climate change by developing alternative bio-hydrogen, microbial and algae–based biofuels.[10] Some researchers have gone further, trying to "cure" climate change by modifying microbes to capture, store and recycle carbon

[4] Berthold Rutz "Synthetic Biology and Patents: A European Perspective" (2009) 10 *EMBO Reports* 14, at 14-15
[5] Arti Rai and James Boyle "Synthetic Biology: Caught between Property Rights, the Public Domain and the Commons" (2007) 5(3) PLoS Biol 58, at 58
[6] Marc Gunther "GMO 2.0: Genetically Modified Foods with Added Health Benefits" *The Guardian* (online ed, London, 20 June 2014)
[7] Markus Schmidt "Executive Summary" in M Schmidt, A Kelle, A Ganguli-Mitra and H de Vriend (eds) S*ynthetic Biology: the Technoscience and its Societal Consequences,* above n 3, at XXI
[8] At XXIII
[9] At XXIII
[10] At XXIII

dioxide in order to reduce atmospheric carbon dioxide levels.[11] There are also research teams seeking to alleviate food and fresh water shortages in both the developed and third world. These teams aim to engineer microbes capable of desalinating water,[12] and modify various plant species to achieve desired traits such as disease and pest resistance, drought, flood and heat tolerance and increased nutritional value.[13] It is clear then that the field of synthetic biology represents a new frontier for genetic modification and manipulation. Indeed, "if the science truly succeeds, it will make possible to supplant the world created by Darwinian evolution to one created by us".[14]

C. The Physical and Non-Physical Aspects of Synthetic Biology Innovation

The products of synthetic biology innovation have both a physical and non-physical aspect. From a physical stand point, various kinds of biological matter including DNA and protein molecules, cells, genomes and whole organisms have a material presence.[15] In addition, biological molecules such as DNA sequences and genomes also contain non-physical genetic information. The distinction between physical biological materials and non-physical biological information is an important one for the law.[16] This is because legal systems use different regimes to allocate access to and control over physical objects than they do over information.[17] In regards to the physical molecules themselves, society has long accepted that property rights can exist in complex higher life forms such as plants and animals.[18] Similarly, researchers can assert property rights over the physical DNA molecules, proteins and cell lines within their laboratories.[19] In respect of the non-physical aspects of synthetic biology innovation, both DNA molecules and genomes contain valuable genetic information.[20] Often, the property rights in the information encoded by these molecules - that is the right to copy, use and sell access to this information - have greater commercial

[11] At XXIII
[12] Markus Schmidt, above n 7, at XXIII
[13] Anne Osbourn, Paul O'Maille, Susan Rosser and Keith Lindsay, above n 11, at 674
[14] Michael Spector "A life of Its Own: Where Will Synthetic Biology Lead Us?" *The New Yorker* (New York, 28 September 2009) at 57
[15] Richard Gold "Exclusive Rights in Life: Biotechnology, Genetic Manipulation, and Intellectual Property Rights" in John Jackson and Hans Linskens (eds) *Genetic Transformation in Plants* (Springer, New York, 2003) 1, at 3
[16] At 2
[17] At 2
[18] At 4
[19] At 3
[20] At 4

value than rights over the physical molecules themselves.[21] This dissertation focuses on protecting and capturing the value implicit in the information encoded by the nucleotide sequence of novel genomes, as opposed to protecting the physical form of the genome itself.

III. The Justification for Intellectual Property Protection

The previous discussion clearly illustrates that many applications of synthetic biology have significant commercial potential. In any area where innovation has a commercial value, the question of IPRs arises. "IPRs" is a catchall term used to describe the property rights by which the products of intellectual innovation and creativity are protected.[22] There are various types of IPRs although the main forms are copyright, patents and trademarks.[23] It has been argued that the biotechnology industry should shun these traditional forms in favour of an open source model.[24] This argument is largely based on the assertion that similar technologies, such as computer programs, have continued to thrive in an open source environment.[25] However, it is submitted that some forms of IPRs are necessary to protect the nucleotide sequence of novel genomes. This contention is based on the traditional rationales for intellectual property protection as well as the acute need for IPRs in high-risk, knowledge intensive industries, such as the synthetic biology industry.

A. The Traditional Economic Justification

Economic growth is a natural phenomenon of industrialisation and relies to a large extent on technological progress and innovation.[26] In order to stimulate the innovation and creativity that is necessary for economic growth, States have established IP regimes.[27] IPRs are widely considered to be catalysts for further innovation, as they provide economic

[21] At 4
[22] Wei Shi *Intellectual Property in the Global Trading System: EU-China Perspective* (Springer, New York, 2008) at 24
[23] Susy Frankel *Intellectual Property in New Zealand* (2nd ed, LexisNexis, Wellington, 2011), at [1.6.1]
[24] Ethan Fitzpatrick "Open Source Synthetic Biology: Problems and Solutions" (2013) 43 Seton Hall Law Review 1362
[25] At 1362
[26] Wei Shi, above n 22, at 24
[27] At 25

incentives which influence the behaviour of inventors, authors and other creators.[28] The incentive argument in relation to IPRs is threefold: incentive to invest, create and innovate; incentive to use and allocate resources more efficiently and the incentive to disclose the products of such intellectual endeavour.[29] Each of these economic incentives will now be considered in turn.

First, IPRs provide the "prospect of reward".[30] IPRs grant an inventor or creator exclusive monopoly rights for a defined period of time. During this period, the inventor or creator has the "first to market" advantage and can therefore charge whatever price they deem appropriate for the product. This gives the inventor or creator an opportunity to profit from and recoup the costs associated with the production of the product.[31] In the absence of IPRs, there is a reduced incentive to create and innovate.[32] This is because inventors and authors are unlikely to be able to recover the costs associated with the research, and development of a particular product.[33] In comparison to production and distribution costs, product development is an expensive process. Individuals would prefer to copy or "free-ride" off the ideas of others as opposed to investing in the creation of new ideas themselves.[34] Consequently, few new innovative products and creative works would be produced - an outcome which is detrimental to society as a whole.[35] Therefore, IPRs incentivise investment in creation and innovation by providing a means through which the costs of such intellectual enterprise can be recouped.

Second, IPRs encourage the efficient use and allocation of resources.[36] The dynamic efficiency argument contends that in a world devoid of IPRs, where individuals are free to use others' ideas, innovative and creative activity would be biased towards works that could

[28] Birgitte Anderson "The Rationale for Intellectual Property Rights: The Twenty-First Century Controversies" (paper presented to the DRUID Summer Conference on Creating, Sharing and Transferring Knowledge, Copenhagen, June 2003), at [5]
[29] Birgitte Anderson, above n 28, at [3]
[30] At [3]
[31] At [5.1]
[32] At [5.1]
[33] At [5.1]
[34] Mark Lemley "Ex Ante Versus Ex Post Justifications for Intellectual Property" (2004) 71 U.Chi.L.Rev 129, at 129
[35] At 129
[36] Birgitte Anderson, above n 28, at [3.2]

be kept secret, as opposed to works that are the most beneficial to society.[37] The availability of IPRs ensures that inventors and creators channel their resources into developing works or products that are the most competitive, rather than products of which the underlying IP can be kept secret.[38]

Finally, IPRs promote and facilitate the sharing of technical and creative knowledge. In the absence of IPRs, inventors and authors will refrain from disclosing the products of their innovation and creation. Therefore, it is in society's best interests to induce the inventor or author to disclose their work for use by others. IPRs incentivise the dissemination of creative and technical knowledge by granting exclusive monopoly rights to the author or inventor in exchange for the disclosure of their invention or creative work.[39] The granting of exclusive monopoly rights allow inventors, authors and other creators to divulge their work and be confident in the knowledge that such work will not be unfairly exploited.[40] In exchange, the dissemination of information serves society as a whole because often the protected product provides a basis for further innovation or creation.[41] This is particularly true in the synthetic biology industry where innovation is derivative, with new technologies often building upon previous research.[42] The disclosure of such information also prevents the duplication of research, wasting valuable funds.

B. The Traditional Rationale of Protecting the Moral Interests of the Inventor(s) and Author(s)

In addition to the traditional economic rationale, IPRs are also designed to give expression to the moral sentiment that an inventor or author should be entitled to enjoy the fruits of their intellectual endeavour.[43] The need to protect the moral interests of inventors, authors and other creators is clearly articulated in the United Nations International Covenant on

[37] Richard Posner *Economic Analysis of Law* (4th edition, Little, Brown and Company, Toronto) at 32-39
[38] At 38, 39
[39] Henry Olssen, "Intellectual Property in a Knowledge Based Society: The Role of Copyright and Future Challenges to Creators, Industry, Legislators and Society at Large; Inventors' and Creators' Rights as Basic Human Rights (summary paper of the Second International Forum on Creativity and Invention – A Better Future for Humanity in the 21st Century, Beijing, May 2002), at [8]
[40] At [8]
[41] At [8]
[42] Birgitte Anderson, above n 28, at [3.2]
[43] Wei Shi, above n 22, at 23

Economic Social and Cultural Rights 1966 (ICESCR). The ICESCR obliges signatory States (including New Zealand) to recognise the right of any individual to "benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is author".[44]

C. Licensing

IP regimes use licenses to ensure that adequate protection can be afforded without compromising the ability of others to access and use a protected invention or work. A licence grants permission to do something that would, in the absence of permission, infringe IPRs. The rewards obtained by the licensor in exchange for the grant of rights can include a lump sum payment, ongoing royalties, equity, services, milestone payments, research and development funding and access to improvements.[45] Licensing schemes can be either voluntary or non-voluntary. Currently, all forms of IPRs have voluntary licensing schemes.[46] The existence of voluntary licensing schemes means that individuals and corporations are able to access and use the nucleotide sequence of a novel genome in exchange for some form of consideration. However, a fundamental problem with a voluntary licensing scheme is that it presumes a right holder is invariably willing to grant a licence for their protected work. This is not always the case. A purely voluntary licensing scheme means that the State has little or no recourse when it comes to preventing unwilling licensors from retaining the valuable knowledge contained in a protected work, to the detriment of the wider public.

To address the issue of unwilling licensors, many IP regimes employ the use of compulsory licenses. Compulsory licensing is when a State allows another party to use or produce a protected product without the consent of the IPR owner.[47] Compulsory licenses are seen as a legitimate safeguard to check the misuse and abuse of the monopoly rights conferred by IPRs.[48] Essentially, a compulsory license is a legal remedy, used as corrective to the exclusive monopoly rights granted to an IPR holder, for the purpose of redressing the

[44] United Nations International Covenant on Economic Social and Cultural Rights 1966, Art 15(1)
[45] James and Wells "Considerations in Licensing" <http://www.jaws.co.nz/information/category/commercialisation/considerations-in-licensing>
[46] James and Wells, above n 45
[47] Muhammad Zaheer Abbas "Pros and Cons of Compulsory Licensing: An Analysis of Arguments" (2013) 3 IJHSS 254, at 254
[48] At 255

balance between the competing interests of IPR holder and those of the general public.[49] Although compulsory licenses limit the rights of the IRP holder, they do not remove those rights altogether.

The rights of States to grant compulsory licenses have been recognised in international law under the Berne Convention for the Protection of Literary and Artistic Works 1886 (Convention). Although the Convention acknowledges the exclusive rights of authors to control the use of their works,[50] the Convention allows signatory States to determine the conditions under which those rights are exercised.[51] Under the Convention, any legislation that encroaches upon an author's exclusive rights, must not prejudice the moral rights of the author, nor their right to obtain equitable remuneration.[52] Compulsory licenses are also permissible under the Agreement on Trade Related Aspects of Intellectual Property 1994 (TRIPS), provided certain conditions aimed at protecting the legitimate interests of the patents holder are protected.[53] It is clear then that the granting of compulsory licences is permissible under international law.

It has been argued the availability of compulsory licenses dilutes the incentive to create and innovate.[54] However it is submitted that there is no evidence to support this conclusion.[55] Compulsory licensing schemes for patents, copyright and plant variety rights (PVRs) have been in place for an extended period of time, yet there has been no appreciable reduction in innovation.[56] In fact, there is a significant body of literature which shows that industries that are subject to compulsory licensing schemes spend more on research and development than industries that are exempt from compulsory licensing.[57] Furthermore, international

[49] Robert Gottschalk "Compulsory Licensing: Patent Incentives" (1972) 39 Vital Speeches Day 21
[50] Berne Convention for the Protection of Literary and Artistic Works 1886, Art 6*bis* (1)
[51] Art 5
[52] Art 6
[53] Agreement on Trade Related Aspects of Intellectual Property 1994, Art 31
[54] Robert Gottschalk, above n 49
[55] Colleen Chien "Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?" 18 Berkeley Tech.L.J. 853
[56] At 879
[57] Reto Hilty and Kung-Chung Liu (eds) *Compulsory Licensing: Practical Experiences and Ways Forward* (Vol 22, Springer, New York, 2014), at 438,439

law compels compulsory licensing schemes to equitably remunerate the IPR owner.[58] So while the owner is prevented from charging an exorbitant fee, the owner still receives fair price. Indeed, many schemes allow the complainant and right holder to negotiate a fair price. Finally, many licensing schemes contain provisions which allow an appropriate authority to impose any other conditions upon the licences as it thinks fit. In the majority of cases, these conditions favour the IPR owner of the protected product by imposing further licence restrictions.[59] Therefore, it is clear that the introduction of compulsory licensing schemes does not dilute the incentive to innovate.

The preceding discussion illustrates the desirability of compulsory licensing provisions within IP regimes. It is submitted that any form of IPRs used to protect novel genomes should incorporate such a scheme. Currently, compulsory licensing provisions exist in relation to patents and PVRs, but not in regards to copyright.[60] Therefore, the Copyright Act would need to be amended to include compulsory licensing scheme. A discussion on the form such a scheme should take is discussed later in this dissertation.

D. IPRs in Relation to the Synthetic Biology Industry

IPRs have played a fundamental role in the development of the biotechnology industry on several levels. First, the extension of IPRs to the life sciences created new classes of property rights in objects that were originally outside the bounds of ownership.[61] Consequently, these objects became commodities with a prescribed value, exchanged and circulated in markets which in turn encouraged productivity.[62] Second, many research companies are high risk, long-term investments which will not return a profit, or dividend, to investors for several decades.[63] The availability of IPRs plays a key role in attracting investors and venture capital to the industry.[64] Indeed, for an industry that has yet to return a profit as a whole, often IP portfolios constitute the most valuable assets owned by

[58] Berne Convention, Art 6; Agreement on Trade-Related Aspects of Intellectual Property 1994 (TRIPS), Arts 13, 31
[59] Reto Hilty and Kung-Chung Liu, above n 66, at 438
[60] Patents Act 2013, Plant Varieties Act 1987
[61] Sheila Jasanoff *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton University Press, Princeton, 2007), at 203
[62] At 203
[63] Emma Toumi "In Defence of Gene Patents" (2003) J Commerc Biotechnol 135
[64] At 135

synthetic biology companies.[65] Third, IPRs provide additional certainty to investors by establishing a system through which the competing claims of various interest groups such as academic researchers, universities, start-up firms, government organisations and industry, can be resolved.[66]

Finally, private companies that engage in synthetic biology research are publically beneficial because they discover and commercialise new products at a much higher rate than the public sector.[67] Prohibiting IPRs over novel genomes would confine a significant proportion of research to the public domain, which has considerably less resources than the private sector.[68] This is problematic because there is a positive relationship between monetary investment and scientific discovery.[69] Breakthroughs are often attached to significant price tags which the public sector alone cannot afford.[70] Therefore, prohibiting IP protection for novel genomes could actually impede future research by creating funding shortages. Hence, there is a strong public interest argument in favour of protecting the synthetic biology industry and encouraging continued investment in private sector research.

In summary, it is evident that that some forms of IPRs are required both generally and in relation to the synthetic biology industry. IPRs play a fundamental role in stimulating creativity and innovation in society, and affording protection to the products of intellectual enterprise.[71] The availability of IPRs is particularly pertinent in high-value, knowledge intensive industries, such as the synthetic biology industry. Indeed, IPRs have played a fundamental role in the establishment of the synthetic biology industry and the future of the industry relies heavily upon the continued availability of such rights for ongoing investment.[72] Furthermore, there is a need to recognise and protect the moral interests or natural rights of inventors, authors and other creators to benefit from their intellectual endeavour. Finally, the use of licensing schemes (both voluntary and compulsory) ensures

[65] Sheila Jasanoff, above n 70, at 203
[66] At 204
[67] Marcy Damocvsky and Jesse Reynolds "The Battle to Patent Your Genes" *The American Interest* (Washington D.C., September/October 2009)
[68] Marcy Damocvsky and Jesse Reynolds, above n 67
[69] Emma Toumi, above n 63
[70] Marcy Damocvsky and Jesse Reynolds, above n 67
[71] Birgitte Anderson, above n 28, at [5]
[72] Sheila Jasanoff, above n 61, at 203

that adequate protection can be afforded without compromising the ability of others to access and use a protected invention or work. It is clear then that the synthetic biology industry cannot rely on an open source model alone and that some form of IPRs are required to protect the nucleotide sequence of novel genomes.

IV. Which form of Intellectual Property Rights?

The previous section clearly illustrates that some form of IPRs are necessary to protect the nucleotide sequence of novel genomes. However, as synthetic biology sits at the interface between various fields, it is unclear exactly how these novel genomes will be incorporated into the existing IP law framework. Indeed, the way in which IP law has struggled to assimilate the two key technologies from which synthetic biology is derived, namely biotechnology and computer programs, is an ominous sign for the field.[73] Several forms of IPRs, including trade secrecy, trade marks, patents and copyright have been suggested as possible mechanisms for protecting the nucleotide sequence of novel genomes. Trade secrecy and trademarks can readily be shown as being inadequate at protecting the nucleotide sequence of such genomes.

Broadly speaking, a trade secret is any confidential information which provides an organisation with a competitive edge.[74] Trade secrets and confidential information cannot be registered; however, they can be protected through non-disclosure and confidentiality agreements as well as actions for breach of confidence.[75] It has been suggested that the nucleotide sequence of novel genomes can be protected by trade secrecy.[76] However, it is contended that such protection would be completely inadequate. This is because, in order for the nucleotide sequence of novel genomes to be protected by trade secrecy, the sequence must, naturally, remain a secret.[77] Information is classified as a secret if it not

[73] Arti Rai and Sapna Kumar "Synthetic Biology: The Intellectual property Puzzle" (2007) 85 Tex.L.Rev 1745, at 1748

[74] World Intellectual Property Organisation "What is a Trade Secret?" <http://www.wipo.int/sme/en/ip_business/trade_secrets/trade_secrets.htm>

[75] Simpson Grierson "New Risk in the USA to New Zealand Business Secrets" (18 July 2013) <http://www.simpsongrierson.com/intellectual-property-new-risk-in-usa-for-nz-business-secrets/>

[76] OECD "Emerging Policy Issues in Synthetic Biology" (2014), at 107

[77] Greg Arthur and Matt Sumpter "Intellectual Property for Non-Specialists" (paper presented at New Zealand Law Society Seminar on Intellectual Property for Non-Specialists, August 2008), at 545

public knowledge.[78] However, once an organism or cell containing a novel genome is made available for purchase, it will not be possible to keep the nucleotide sequence of that genome a secret. This is because competitors can easily obtain a DNA sample from the organism or cell containing the novel genome, and determine the nucleotide sequence the genome using whole genome sequencing techniques. Essentially, competitors would be able "reverse engineer" the novel genome. Therefore, trade secrecy would fail to adequately protect the nucleotide sequence of novel genomes.

Similarly, it is not possible to rely on the use of trade marks to protect the nucleotide sequence of novel genomes. A trade mark is defined as "any sign capable of being represented graphically and distinguishing the goods and service of one person from those of another".[79] Trade marks are concerned with protecting the brand surrounding a particular product as opposed to protecting the intellectual innovation or creativity behind the product itself. This focus on marketing rather than intellectual endeavour renders trade marks unsuitable for protecting the nucleotide sequence of novel genomes.

It is clear then that both trade mark and trade secrecy law would be wholly inadequate at protecting the nucleotide sequence of novel genomes. Whether patent and copyright law can provide a more suitable means of protection requires a much fuller discussion.

V. Patents

Historically patents have served as the primary form of IP protection for the biotechnology industry. Patents have been granted over key genetic technologies including naturally occurring and isolated genetic sequences as well as genetically modified organisms.[80] Although, it has been suggested that patent law can be used to protect the nucleotide sequence of novel genomes,[81] it remains unclear whether the nucleotide sequence of novel genomes can be classified as patentable subject matter under the Patents Act 2013. It is assumed for the purpose of this dissertation that the nucleotide sequence of novel genomes

[78] *AB Consolidated Ltd v Europe Strength Food Co Pty Ltd* [1978] 2 NZLR 515
[79] Trade Marks Act 2002, s 5(1)
[80] Ian Finch (ed) *James and Wells Intellectual Property Law In New Zealand* (2nd ed, Brookers, Wellington, 2012) at [2.4.13]
[81] Andrew Torrance "Synthesising Law for Synthetic Biology" (2010) 11 Minn. J. L Sci. &Tech 629

can be patented. Given this assumption, it is submitted that there are several issues with patent law which, from a policy standpoint, render patents an undesirable mechanism for the protection of novel genomes. Each of the policy issues will now be considered in turn.

A. Foundational Patents, Patent Thickets and the Tragedy of the Anti-Commons

There is a concern that whole-genome patenting will result in foundational patents and patent thickets which can result in the "tragedy of the anti-commons". Foundational patents make broad claims over a large percentage of work in a particular field.[82] A considerable body of evidence suggests that broad patents on foundation research can slow the growth of that particular industry.[83] Foundational patents pose a particular threat to the synthetic biology industry. This is because interrelatedness, interoperability and standardisation are key features of synthetic biology.[84] If a single "part" (shorter nucleotide sequence that is one of the pieces to construct a novel genome) becomes standardised or is used so often that is acquire a quasi-standard character, individuals becomes "locked-in" and completely dependent on the use of that part.[85] This creates an opportunity for the right holder of that particular part to charge an excessive licensing fee, or sue for unauthorised use. These companies and individuals are known as patent trolls or patent sharks because, instead of continuing to innovate, they choose to aggressively exploit the patent.[86]

There is also the possibility of a plethora of narrow patents over the individual parts which are used to construct a novel genome.[87] These individual parts may be protected by multiple patents, which can be owned by a variety of patent holders. This situation creates what is known as a patent ticket. Patent thickets take a considerable time to negotiate which creates a delay in the continuation of research.[88] Patent thickets have already arisen in relation to the products of synthetic biology. For example, the genetically modified

[82] Sapna Kumar and Arti Rai "Synthetic Biology: the Intellectual property Puzzle" (2007) 85 Texas. L. Rev 1745, at 1751
[83] At 884-909
[84] Berthold Rutz, above n 4, at 516
[85] At 516
[86] At 516
[87] Sapna Kumar and Arti Rai, above n 82, at 1756
[88] At 1757

"golden rice" required more than 70 patent rights to be cleared before product development could continue.[89]

Broad patents and patent thickets can result in what is known as the tragedy of the anti-commons whereby complex, interconnected and ambiguous claims generate the worst of all worlds, deterring investment and impeding research in the process.[90] When overly broad and ambiguous patent claims are granted, the potential risk of patent infringement increases.[91] This forces innovators to engage larger and more expensive legal teams to consider the IP implications of particular research and development choices; and avoid any projects where the risks or costs prove too high.[92] Ambiguous claims on upstream foundational research can be particularly harmful to downstream commercial applications.[93] When there are enforceable upstream and downstream rights, the "reach-through" costs for downstream innovators increases.[94] In these situations, innovators must determine exactly which of the various upstream property rights may "reach-through" and require licensing.[95]

Therefore, the granting of patents over the nucleotide sequence of novel genomes would generate the potential for foundational patents and patent thickets. Foundational patents and patent thickets create ambiguity in property rights claims which, in turn, reduces innovation by impeding basic research and deterring the investment required to grow the industry.[96]

B. The Specific Nature of Patents

Even if the nucleotide sequence of novel genomes is classified as patentable subject matter, it is submitted that patents would provide limited protection due to the precise nature of patent specifications. In order to obtain a patent, the applicant must submit a patent

[89] Ingo Potrykus "Golden Rice and Beyond" (2001) 125 Plant Physiol 1157
[90] Kenneth Oye and Rachel Wellhausen "The Intellectual Property Commons and Property in Synthetic Biology" in M Schmidt, A Kelle, A Ganguli-Mitra and H de Vriend (eds), above n 3, 121, at 124
[91] Kenneth Oye and Rachel Wellhausen, above n 90, at 124, 125
[92] At 125
[93] At 125
[94] At 125
[95] At 125
[96] At 124, 125

specification which precisely describes the invention and outlines the claims which will define the protective boundaries of the invention.[97] Given these requirements, it will be necessary for the applicant to specify the exact nucleotide sequence of the novel genome in order to obtain a patent.

The specific nature of patents limits the ability of patent law to provide adequate protection for novel genomes. This is because a patent will only protect a single nucleotide sequence of a novel genome. However, in the vast majority of cases, there are a multiple nucleotide combinations that can produce a genome that functions in the same way. A functionally identical genome is one that encodes the same behaviour or the same gene product. A patent will only protect the nucleotide sequence of one of these functionally identical novel genomes. Any variations which encode an identical gene product or metabolic behaviour will remain unprotected, unless further patent applications are filed. Therefore, patents are an inefficient and costly mechanism for protecting functionally identical but genetically different novel genomes.

C. Patents Have Failed to Protect Similar Forms of Technology

For novel genomes as for computer programs, the underlying works are technology.[98] This has always been the domain of patent law. However the failure of patent law to protect the misappropriation of computer programs suggests that the same thing may happen to the products of synthetic biology, particularly novel genomes.[99] This assertion is based upon the similarities between computer programs and novel genomes which render both forms of technology vulnerable to misappropriation. For both technologies, the cost of development greatly exceeds the cost of duplication.[100] This is because both technologies can serve as the template for their own reproduction.[101] For computer programmes, the source and object code can be easily deciphered and copied resulting in an unlimited number of perfect copies. Similarly, the DNA of a novel genome can be easily sequenced

[97] Patents Act 2013, s 36(1), Ian Finch, above n 80, at 39
[98] Dennis Karjala "Protecting Innovation in Computer Software, Biotechnology and Nanotechnology" (2011) 16(1) Va. L.J & Tech 1, at 54
[99] At 55
[100] Christopher Holman "Copyright for Engineered DNA: An Idea Whose Time has Come?" (2011) 113 W.Va.L.Rev 699 at 715
[101] At 715

and reproduced. Even more significantly, both computer programs and novel genomes are vulnerable to viral replication. This is because any copy of the original work can function as another template for additional replication.[102]

Although this argument is indicative rather than conclusive, given the salient technological similarities between computer programs and novel genomes, it seems highly likely that patents will also prove ineffective at providing adequate protection for the nucleotide sequence of novel genomes.

D. Patent Law Applies a Strict Liability Standard

Patent law applies a strict liability standard which provides limited exceptions to cases of infringement.[103] Even the use of patented inventions for educational or research purposes can incur infringement liability.[104] This strict liability regime can impede academic research and private study, despite such activities posing little or no economic threat to the patent owner.[105] Indeed, many commentators and scientists consider that the current patent-centric approach to biotechnological inventions has had a chilling effect on scientific progress, and would welcome a regime with a robust fair use exemption for academic research.[106]

E. Summary of Argument

It is clear that there are significant policy issues associated with patent protection for novel genomes. The primary concern is that foundational patents and patent thickets will result in the tragedy of the anti-commons. However there are also concerns regarding the strict liability standard imposed by patents as well as the ability of patents would be able afford adequate protection to functionally identical but genetically different novel genomes. Indeed, the track-record of patents at protecting similar forms of technology provides little comfort. Therefore, even if the nucleotide sequence of novel genomes can be classified as

[102] At 715
[103] Andrew Torrance, "DNA Copyright" (2011) 46 Val.U.L.Rev 1, at 37
[104] At 38
[105] At 38
[106] At 39

patentable subject matter, it is submitted that patent protection should be rejected on policy grounds.

VI. Copyright

The previous sections clearly illustrate the inability or undesirability of other forms of IPRs to protect the nucleotide sequence of novel genomes. It is submitted that there are several features of copyright law which render copyright a more appropriate means of protection. These features include independent creation as well as research and education safe harbours. It is argued that these features allow a reasonable level of protection to be conferred, whilst simultaneously allowing society to benefit from the products of synthetic biology research more readily than other forms of IPRs, such as patents. The main problem with copyright protection is the voluntary nature of the licensing provisions. However, this issue can be resolved by amending the Copyright Act to include a compulsory licensing scheme. Each of these issues will now be considered in turn.

A. Independent Creation

Copyright is a property right that exists in original works.[107] The concept of originality is not defined under the Copyright Act; however, the Act does describe when a work is not original and this provides some guidance when defining the concept of originality. Under the Act, a work is not original if it is, or to the extent that it is, a copy of another work or if it infringes the copyright in, or to the extent that it infringes the copyright in, another work.[108] This does not mean that that the work must be novel.[109] Originality relates to originality of thought as opposed to originality of expression.[110] Therefore, the independent creation of a work that is coincidently the same as an existing copyright work will not incur liability.[111] An independent creator may even look to other works for inspiration, regardless of whether or not those works are protected by copyright. Independent creation allows a researcher to autonomously develop the nucleotide sequence of an existing novel genome, and, more significantly, go onto further develop that sequence without incurring liability. Therefore,

[107] Copyright Act, s 14(1)
[108] Copyright Act, s 14(2)
[109] *Henkel KGAA v Holdfast New Zealand Ltd* [2006] NZSC 102
[110] *University of London Press Ltd v University Tutorial Press Ltd* [1916] 2 Ch 601 (EWHCCh), at 608
[111] Andrew Torrance, above n 103, at 37

independent creation, as a feature of copyright law, reduces the barriers to autonomous research as well as ongoing research and development.

B. Permitted Acts

Copyright law provides significant safe harbours within which socially valuable activities such as education and academic research can continue. The Copyright Act outlines certain permitted activities which relate to fair dealing for the purpose of research and private study,[112] copying for educational purposes[113] and use by libraries and archives.[114] These permitted acts afford a reasonable level of protection, whilst simultaneously allowing society to benefit from the products of synthetic biology research more freely than other forms of IPRs, such as patents.

1. Fair dealing

Fair dealing for the purpose of research or private study will not infringe the copyright in a work.[115] What constitutes research and private study is undefined in the Act. The leading case on this point is *Television New Zealand v Newsmoniter Services Ltd*.[116] In this case, Blanchard J accepted the definition of research as "the searching into a matter or subject or the investigation or close study of it".[117] His Honour then went on to define "private study" as "a form of study which is personal to the person undertaking it".[118] A key finding in this judgement is that research and private study can be undertaken by a corporation or business organisation and may have a commercial purpose.[119] What constitutes "fair dealing" for the purpose of research and private study will depend on the particular facts of the case.[120] When determining whether the copying is fair, the courts will consider several factors including the purpose(s) of copying; the nature of the work copied; the possibility of acquiring the work within a reasonable time frame and at an ordinary retail price; the effect on the potential market for and value of the work; and the substantiality of the part of the

[112] Copyright Act, s 43
[113] ss 44-49
[114] ss 50-57A
[115] Copyright Act, s 43
[116] *Television New Zealand v Newsmoniter Services Ltd* [1994] 2 NZLR 91, at 105
[117] At 105
[118] At 105
[119] At 105-106
[120] Susy Frankel, above n 23, at [6.7.5(3)]

work that has been copied.[121] For example, copying for commercial purposes is likely to be considered less fair than copying for academic research or private study.[122] Similarly, copying a work that is available for sale or licence at a reasonable price is also unlikely to constitute fair dealing. In light of these considerations, the courts are unlikely to find that copyright has been infringed in cases where there is partial copying of a work for a non-commercial purpose.[123] It appears then that the fair dealing provisions under the Copyright Act would allow a student to copy the nucleotide sequence of a novel genome for use private study. Alternatively, a researcher would also be able to copy the nucleotide sequence of a novel genome for use in academic research.

2. Educational purposes

In addition to fair dealing, the Copyright Act allows the use of copyrighted works for educational purposes. The copyright in a literary work is not infringed by the copying of the whole or part of the work if:[124]

a. the copying is done by means of a reprographic process or by any other means; and
b. the copying is done in the course of preparation for instruction, for use in the course of instruction or in the course of instruction; and
c. the copying is done by or on behalf of the person who is to give, or who is giving a lesson at an educational establishment; and
d. no more than one copy of the whole or part of the work is made on any one occasion.

Under these provisions it is permissible for a teacher or lecturer to copy the nucleotide sequence of a novel genome, either in whole or in part, for use in classrooms and teaching laboratories.

3. Use by libraries and archives

Sections 50-57A of the Copyright Act, outline the circumstances in which a library or archive may make a copy of a protected work, in whole or in part. When read together, these

[121] Copyright Act, s 43(3); *Longman Group v Carrington Technical Institute Board of Governors* [1991] NZLR 574
[122] *Television New Zealand v Newsmoniter Services Ltd*, above n 133
[123] Andrew Torrance, above n 103, at 39
[124] Copyright Act, s 44(1)

sections mean that a prescribed library may supply, to any of its users, or to a user of another prescribed library, for the purpose of research and private study:

a. a reasonable proportion of any literary, dramatic or musical work, including any artistic work which appears within the proportion copied;
b. the whole of a periodical article; or
c. more than one article from the same periodical if the articles relate to the same subject matter.

Implicit in the research and private study requirement is that the user requests the copying.[125] It is also only permissible to copy a "reasonable proportion" of a non-periodical work. What is considered a "reasonable proportion" will depend on the facts of the case; however, users should balance their own need to copy the material with their ability to obtain material without copying. In addition to copying for their user's research and private study, libraries and archives may supply copies of protected works contained in books to other libraries that cannot obtain the book. The cumulative effect of these provisions is to allow researchers and students to obtain a copy of the nucleotide sequence of a novel genome that has been published within a book or periodical.

C. Licensing

The lack of any compulsory licensing provisions under the Copyright Act has been cited as a key reason against extending copyright to encompass the nucleotide sequence of novel genomes.[126] This dissertation previously considered the desirability of compulsory licensing and concluded that any form of IPRs used to protect novel genomes would need to include compulsory licensing provisions. Based on this earlier conclusion, it is recommended that the Copyright Act be amended to introduce a compulsory licensing scheme for novel genomes. The form of such a scheme is discussed later on in this dissertation.

VII. Comparison of How Copyright and Patents Deal with some Problematic Areas

[125] *Copyright Licensing Ltd v University of Auckland* [2002] 2 NZLR 76, at [103]
[126] James Silva "Copyright Protection of Biotechnology Works: Into the Dustbin of History?" (2000) B.C. Intell. Prop. &Tech. F. 012801

The previous two sections have considered the policy issues surrounding copyright and patent protection in isolation. This section summarises the key distinguishing features between copyright and patent protection, particularly in relation to problematic areas. Ultimately, it is concluded that copyright provides a more appropriate form of protection than patent law.

A. Protecting Functionally Identical But Genetically Different Novel Genomes

The specific nature of patents limits the ability of patent law to protect novel genomes. This is because, in the vast majority of cases, multiple nucleotide sequences will result in a genome that functionally identical.[127] A patent will only protect a one of these sequences. Any other variations will remain unprotected unless further patent applications are filed. It is for this reason then that patents are an inefficient and costly mechanism for protecting functionally identical but genetically different novel genomes. In contrast, copyright law is much more efficient at protecting functionally identical but genetically different novel genomes. This is because copyright protection vests automatically in any creation that satisfies the criteria for copyright eligibility under the Copyright Act. There is no need to formally register a copyright, put a copyright notice on the work, publish the work or do anything else in order for the work to be protected.[128] An original work is protected from the time it is first recorded either in writing or in some other manner.[129] In this way then, copyright provides a more efficient means of protecting functionally identical but genetically different novel genomes.

B. Independent Creation

Independent creation, as a feature of copyright law, allows a researcher to autonomously develop the nucleotide sequence of an existing novel genome, and, more significantly, go onto further develop that sequence without incurring liability. Conversely, the strict liability standard imposed by patent law means that a researcher, who independently arrives at the patented nucleotide sequence, will incur liability.[130] Furthermore, that researcher will not

[127] Scitable "Genetic Code" "Genetic Code" Scitable by Nature Education <http://www.nature.com/scitable/definition/genetic-code-13>
[128] Susy Frankel, above n 23, at [5.4]
[129] At [5.4]
[130] Andrew Torrance, above n 103, at 37

be able to continue to research and develop that nucleotide sequence without first obtaining the permission of the patent holder. Therefore, unlike patent law, independent creation reduces the barriers to ongoing research and development.

C. Safe Harbours and Partial Use of Works

Patent law applies a strict liability standard that offers few and limited exception to cases of infringement. For example, even the use of patented inventions for educational or research purposes can incur infringement liability.[131] In contrast, copyright law allows for significant safe harbours within which socially valuable activities such as education and academic research can continue.[132] The strict liability standard imposed by patents also means that the use of a smaller section or part of a protected novel genome will infringe the patent. In comparison, the copyright in a protected work is only infringed if the whole or a substantial part of the work is copied.[133] What constitutes a substantial part is a matter of "fact and degree".[134] For example, a substantial part may be qualitatively significant but quantitatively may only constitute a small portion of a work.[135] Regardless of the legal ambiguities, the key point is that copyright allows individual to use an unsubstantial part of the protected nucleotide sequence. In doing so, copyright provides greater access to and use of a protected nucleotide sequence than patent law allows.

D. Licensing

The absence of any compulsory licensing provisions under the Copyright Act is as a key reason against the extension of copyright law to encompass the nucleotide sequence of novel genomes. This dissertation previously concluded that any form of IPRs used to protect novel genomes would need to include compulsory licensing provisions. Given this conclusion, it is submitted that the Copyright Act be amended to introduce a compulsory licensing scheme for novel genomes. The form this scheme should be based on existing licensing provisions in relation to patents and PVRs, which are almost identical in drafting and in application. For both patents and PVRs, the central tenant of the compulsory

[131] At 37
[132] Copyright Act, s 43
[133] Copyright Act, s 29(2)(a)
[134] *LB (Plastics) Ltd v Swish Products Ltd* [1979] RPC 551
[135] *Ladbroke (Football) Ltd v William Hill (Football) Ltd* [1964] 1 WLR 273 (HL); *Bleiman v News Media (Auckland) Ltd* [1994] 2 NZLR 673

licensing provisions is the reasonable supply of, or price for, the protected product. This overarching aim is retained in the draft statutory provision for the compulsory licensing of novel genomes (outlined below). The language of the provision is based on the drafting of the compulsory licensing schemes under the Patents Act and the Plant Varieties Act. The choice of the Copyright Tribunal as the body for determining applications for compulsory licenses is a natural one. This is because already the primary function of the Copyright Tribunal is to hear and determine licensing disputes under existing licensing provisions.[136]

Compulsory licensing of the nucleotide sequence of novel genomes

(1) Any person may at any time after the expiration of 3 years from the date of creation of the novel genome apply to the Copyright Tribunal for a licence to use the nucleotide sequence of the novel genome.

(2) The Copyright Tribunal may only grant a licence once satisfied that the nucleotide sequence of the novel genome:

   a. is not being supplied in New Zealand; or

   b. is not being supplied on reasonable terms in New Zealand.

(3) If a licence is granted under subsection (1) to a person, that person must pay to the copyright owner the remuneration –

   a. that is agreed between that person and the copyright owner; or

   b. that is determined by a method agreed between that person and the copyright owner; or

   c. that is determined by the Copyright Tribunal on the application of that person or the copyright owner in default of an agreement.

(4) The Copyright Tribunal may also impose any other conditions upon a licence granted under subsection (1) as the Copyright Tribunal thinks fit.

(5) Any licence granted under this section:

   a. is not exclusive; and

   b. must not be assigned otherwise than in connection with the goodwill of the business in which the protected nucleotide sequence is used; and

[136] Copyright Act, Part 10

c. is limited to the use of the protected nucleotide sequence predominantly in New Zealand.

(6) Any licence granted under this section may, on the application of an interested person, be terminated by the Copyright Tribunal if the Copyright Tribunal is satisfied that the grounds on which the licence was granted have ceased to exist.

(7) Appeals against the granting or terms of any licence under this section are to the High Court.

It is recommended that a compulsory licensing scheme for novel genomes take an identical or similar form to the provision above.

E. Summary of Argument

This discussion clearly illustrates that copyright can confer adequate protection without unduly compromising the ability of others to access and use the protected work. This is because copyright law provides significant safe harbours within which socially valuable activities such as education and academic research can continue. Furthermore, independent creation, as a feature of copyright law, means that a researcher can autonomously develop the nucleotide sequence of an existing novel genome, and, more significantly, go onto further develop that sequence without incurring liability. Copyright also provides a more adequate and efficient means of protecting genetically different but functionally identical genomes. The main issue with the current copyright regime is the voluntary nature of the licensing provisions. However, the preceding discussion clearly illustrates how this issue can be resolved via the introduction of a compulsory licensing scheme. For these reasons then, it is submitted that copyright offers a more appropriate form of protection than patents. Given this conclusion, it now becomes necessary to consider whether the nucleotide sequence of novel genomes can be protected by the Copyright Act in its current form.

VIII. Novel Genomes under the Copyright Act 1994

A. Introduction

The previous sections concluded that copyright offers the most appropriate form of protection for the nucleotide sequence of novel genomes. It is now necessary to consider whether the nucleotide sequence of novel genomes can be protected by New Zealand copyright law in its current form or whether legislative amendments need to be made. The law of copyright in New Zealand is entirely statutory and derives from the Copyright Act 1994.[137] Copyright protection is a property right that vests automatically in any works that satisfy the requirements of the Copyright Act.[138] DNA has yet to be recognised as eligible for copyright protection in New Zealand. However, it is submitted that novel genomes are works of genetic authorship that satisfy the criteria for copyright protection under the Act. This assertion is largely based on the analogy between novel genomes and computer programs (which have explicit statutory protection as literary works).[139] This section explores the analogy between novel genomes and computer programs before considering whether novel genomes to satisfy the statutory requirements for copyright protection.

B. DNA as a Literary Work: The Analogy Between Novel Genomes and Computer Programs

When faced with challenge of adapting copyright law to accommodate new technologies, both the legislature and the courts have relied heavily upon the use of analogy. For example, the decision to extend copyright protection to computer programs was largely based upon the perceived analogy between computer programs and traditional literary works.[140] Several commentators have explored the similarities between computer programs and novel genomes and have concluded that copyright protection is available for nucleotide sequences both generally and as computer programs.[141] It is therefore pertinent to explore the similarities between computer programs and novel genomes to see whether such an analogy can warrant the extension of copyright law in the New Zealand context. Ultimately, it is concluded that the nucleotide sequence of a novel genome can be classified as a literary work, based on the analogy between novel genomes and computer programs.

[137] *Bonz Group (Pty) Ltd v Cooke* [1994] 3 NZLR 216, at 40
[138] Copyright Act 1994, s 15(1), s 17(1), s 18, s 19, s 20
[139] s 2(1)
[140] Christopher Holman, above n 100 at 711
[141] Christopher Holman, above n 100; Andrew Torrance, above n 103

1. *Both computer programs and novel genomes are sets of instructions*

A computer program is a set of instructions which directs a computer or other digital device to perform a specific function. These instructions are represented in lines of object code or source code. When the program is in the requisite computer hardware, the hardware interprets and implements the instructions encoded in the program. Similarly, a genome is a set of instructions which directs a living cell to generate specific proteins. These instructions are represented by a sequence of nucleotides. When a genome is placed in the appropriate cellular environment, the cell deciphers and executes the encoded instructions through the processes of transcription and translation. In addition, the instructions encoded by computer programs and DNA can be modified, expanded and recombined in a predictable manner. [142]

2. *The issue of alternative codes*

Some commentators argue against the analogy due to the differing number of codes for computer programs and novel genomes. With regards to computer programs, a single instruction can be expressed in numerous ways using different program languages.[143] In contrast, the single genetic code (DNA) means that there is only one language in which the nucleotide sequence of a novel genome can be expressed. These commentators argue that the single genetic code substantially limits the number of ways in which nucleotide sequences can be expressed.[144] Based on this reasoning, these commentators contend that novel genomes are ineligible for copyright protection.[145]

However it is clear that this argument cannot survive additional scrutiny. The genetic code is simply a "a set of rules defining how the four-letter code of DNA is translated into the 20-letter code of amino acids, which are the building blocks of proteins."[146] For these writers to assert that alternative genetic codes are required in order to allow novel genomes to be copyrightable is tantamount to arguing that alternative software codes are required to

[142] Christopher Holman, above n 100, at 736, 737

[143] Brian Gargano "The Quagmire of DNA Patents: Are DNA Sequences more than Chemical Compositions of Matter?" (2005) 3 Syracuse Sci. & Tech. L. Rep 5;James Silva "Copyright Protection of Biotechnology Works: Into the Dustbin of History?" (2000) B.C. Intell. Prop. &Tech. F. 012801

[144] Sapna Kumar and Arti Rai, above n 82, at 1764

[145] Brian Gargano, above n 143; James Silva, above n 143

[146] Scitable, above n 127

render computer programmes copyrightable or, for that matter, alternative alphabets are necessary to allow a traditional literary work, such as a novel, to be copyrighted.[147] The genetic code, alphabets and software codes are simply the raw materialised utilized by authors to communicate expressive content.[148] Each of these "languages" provides considerable scope for creative expression. For example, there are only 26 letters in the English alphabet however it is apparent that this has not hindered the capacity of authors to produce a wide range of expressive works using the same, small collection of letters.[149] In regards to the genetic code, one only has to observe the significant diversity that exists between living organisms, the vast majority of which use an identical genetic code (DNA), to appreciate the significant expressive potential of DNA.[150] For example, all organisms that occupy the three domains of life, namely eukarya (plants, animals, fungi), archaea and bacteria, all use the same genetic code – DNA. Therefore, to argue that alternative genetic codes are required, not only highlights a fundamental misunderstanding of copyright law, but also the science behind synthetic biology.

3. DNA as an actual form of software

Some commentators go even further and suggest that DNA may already be an actual form of software.[151] Andrew Torrance argues that synthetic biology is primarily based upon the conception that genomes and cells are programmable.[152] Indeed, one of the primary goals of synthetic biology is to engineer cells and genomes to become increasingly similar to computer hardware and computer programs.[153] A cell reads the instructions for the production of proteins and acts in response to them. Therefore, the instructions can be used, either directly or indirectly, by a cellular computer to bring about a certain response. There are already several applications which suggest that synthetic biology is well on the way to using cells as computers and genomes as computer programs.[154] Given these applications, Torrance argues that it is plausible that cells and genomes can already be

[147] Christopher Holman, above n 100, at 730
[148] At 730
[149] At 730
[150] At 730
[151] Andrew Torrance, above n 103, at 33
[152] At 32
[153] At 32
[154] Drew Endy, above n 1, at 452

considered computers and computer programs.[155] If so, then the nucleotide sequence of novel genomes would already be classified as literary works.[156]

4. The "floodgates" argument

"DNA is far from unique in its ability to convey information".[157] Many other biological compounds such as hormones and neurotransmitters have the ability to convey biological information.[158] There is a concern that the extension of copyright law to encompass DNA genomes would mean that there would be no principled basis for excluding other molecules capable of communicating biological information.[159] This could potentially result in an opening of the floodgates "to a dramatic and unwise expansion of copyrightable subject matter".[160] However, it is contended that this argument does not withstand scrutiny for three reasons. First, similar "floodgate" arguments were raised when copyright protection was extended to computer programs;[161] however, this extension has not resulted in a significant expansion of copyrightable subject matter In New Zealand or other jurisdictions.[162] Although this argument is not conclusive, it certainly has persuasive value and gives an indication of the flow on effects (or lack thereof) that the expansion of copyrightable subject may have.

Second, DNA is instilled with "informational characteristics that distinguish it from other molecules in ways that are both fundamental and qualitative".[163] In a living cell, specialised cellular machinery transcribes the instructions encoded in the DNA and then translates these instructions into functioning cellular components.[164] However, no such cellular machinery exists for other biological signalling molecules. Also, DNA is capable of conveying

[155] Andrew Torrance, above n 103, at 33
[156] Copyright Act, s 2(1)
[157] At 734
[158] Scitable "Unit 4: How Do Cells Sense Their Environment?" Scitable by Nature Education < http://www.nature.com/scitable/ebooks/essentials-of-cell-biology-14749010/118241092>
[159] Christopher Holman, above n 115, at 734
[160] At 734
[161] Scott Garren "Copyright Protection of Computer Software: History, Politics and Technology" (BSc Thesis, Massachusetts Institute of Technology, 1991)
[162]Christopher Holman, above n 100, at 734; Gerald Dworkin and Richard Taylor *Blackstone's Guide to the Copyright, Designs & Patents ACT 1988* (Oxford University Press, Oxford, 1989) at 181, 182; Copyright Act 1968 (Cth), s 47AB; Copyright Act 1985 RS C 1985 c-42, s 2
[163] Christopher Holman, above n 100, at 734-735
[164] Scitable "Ribosomes, Transcription and Translation" Scitable by Nature Education http://www.nature.com/scitable/topicpage/ribosomes-transcription-and-translation-14120660

complex, multi-instructional signals.[165] In contrast, the overwhelming majority of other biological signalling molecules are highly specialised and are only capable of communicating a single instruction.[166] Finally, DNA can be modified in a predictable manner.[167] However the same cannot be said for other biological molecules. For example, there are no predictable ways to modify signalling molecules such as hormones or neurotransmitters in a manner which causes the molecule to transmit a different message.[168] It is contended that these differences provide a principled basis for the limitation of copyright protection to DNA genomes.

C. Remaining Criteria for Copyright Eligibility under the Copyright Act

1. The idea-expression dichotomy

A fundamental tenant of copyright law is the idea-expression dichotomy which stipulates that copyright will only protect expression of an idea, the not the underlying idea itself.[169] Although the New Zealand courts are reluctant to apply the idea-expression dichotomy, at least in name,[170] the principle must surely apply in New Zealand given the appropriate facts.[171] Indeed, the finding of a casual connection, but a lack of objective similarity, may be another way for the courts to say that the work in question is an idea rather than an original expression.[172] Although there was no reference to the idea-expression dichotomy, the Court of Appeal in *UPL Group Ltd v Dux Engineers*[173] and *Beckmann v Mayceys Confectionary Ltd*[174], found for the defendant on the basis of insufficient similarity - despite the presence of a causal link. Based on these judgments, it appears that the idea-expression dichotomy applies in New Zealand.

[165] Christopher Holman, above n 100, at 736
[166] Scitable, above n 164
[167] Christopher Holman, above n 100, at 737
[168] Christopher Holman, above n 100, at 737
[169] Susy Frankel, above n 23, at [5.6.3]
[170] Nik Marsh and John Lulich Nik Marsh and John Lulich (eds) *Copyright and Design* (LexisNexis, Wellington, 2013) at [2075]
[171] At [30.7]
[172] At [2075]
[173] *UPL Group Ltd v Dux Engineers* [1989] 3 NZLR 135
[174] *Beckmann v Mayceys Confectionary Ltd* (1995) 3 IPR 543

Some commentators, writing in other jurisdictions, have cited the idea-expression dichotomy as posing a barrier to the copyright protection novel genomes.[175] These writers note that copyright law restricts protection to works that do not monopolise a particular function.[176] With regards to novel genomes, these commentators argue because a certain nucleotide sequence represents the only way in which a particular gene product can be produced, the idea-expression dichotomy is invoked.[177] However, it is submitted that this argument is based upon a fundamental misunderstanding of the science behind synthetic biology. For any given gene product, there are multiple nucleotide sequence combinations which can result in a functionally identical gene product.[178] Substantial alternations can be made to nucleotide sequences without disrupting the function of the gene product. It is simply incorrect to assert that "a particular sequence is scientifically required to produce a protein. Any significant variation will result in no protein or production of a useless protein".[179] Therefore, because there are multiple ways in which the nucleotide sequence for a gene product can expressed, the nucleotide sequence of novel genomes can be classified as an expression, rather than an idea. Consequently, the idea-expression dichotomy is unlikely to prevent the extension of copyright law to encompass the nucleotide sequence of novel genomes.

2. *Recording requirement.*

Under the Copyright Act, copyright does not exist in a literary work unless and until the work is recorded, in writing or otherwise.[180] The courts have taken a liberal approach when determining what constitutes a recording of a particular work.[181] "Writing" is widely defined to include concepts that surpass the traditional notions and includes any form of notation or code, whether by hand or otherwise and regardless of the method by which, or medium in or on which it is recorded.[182] It is also unnecessary for the writing to be produced by human input, or for the record of writing to be intelligible to humans.

[175] James Silva, above n 126
[176] Andrew Torrance, above n 103, at 648
[177] James Silva, above n 126
[178] Scitable, above n 164
[179] James Silva, above n 126
[180] Copyright Act, s 15(1)
[181] *Green v Broadcasting Corporation of New Zealand* [1988] 2 NZLR 490,
[182] Copyright Act, s 2(1)

Whole genome sequencing means that novel genomes can satisfy the recording requirement. Whole genome sequencing is a laboratory process that determines the complete nucleotide sequence of an organism's genome. The sequence is recorded using the four letters A, T, C, and G which denote the base in each half of the DNA double helix. The machine that sequences the genome issues a printout of the DNA nucleotide sequence in a similar manner as illustrated below. The two rows denote the two stands of the DNA double helix.

A	**G**	**T**	**T**	**C**	**G**	**A**	**C**	**T**	**T**
T	**C**	**A**	**A**	**G**	**C**	**T**	**G**	**A**	**A**

It is possible then to record the entire nucleotide sequence of novel genome using a 4 letter alphabet. Therefore, novel genomes, once sequenced, satisfy the recording requirement under s 15(1) of the Copyright Act.

3. Originality Requirement

Some writers oppose copyright protection of novel genomes on the basis that the nucleotide sequences used to construct such genomes are facts or discoveries rather than original works of expression.[183] This assertion is based on that premise that many of the nucleotide sequences used to construct the novel genomes can be found in nature.[184] As copyright does not protect facts or discoveries,[185] these commentators argue that these sequences do not satisfy the requirement of originality.[186]

However, it is submitted that this approach is incorrect under New Zealand law. When considering whether a work is original, it is necessary to consider the work as a whole. It is incorrect to subdivide the work into its modular parts and then consider whether copyright may attach to the individual parts themselves.[187] "Copyright, if it exists at all, exists in

[183] Brian Gargano, above n 143; Sapna Kumar and Arti Rai, above n 82, at 1764; James Silva, above n 126
[184] Brian Gargano, above n 143; Sapna Kumar and Arti Rai, above n 82; James Silva, above n 126
[185] *Cramp & sons v Frank Smythson* [1944] AC 329
[186] Brian Gargano, above n 143; Sapna Kumar and Arti Rai, above n 82; James Silva, above n 126
[187] *Bonz Group (Pty) Ltd v Cooke*, above n 137

relation to the work as a whole".[188] Therefore, when considering the originality of a novel genome, it is necessary to differentiate between the nucleotide sequences used to construct the genome and the genome itself. Under this analysis, novel genomes satisfy the originality requirement because they do not exist in nature and are instead engineered by researchers to perform specific desirable functions. In developing these novel genomes, researchers are essentially creating a new, man-made species. Therefore, it is submitted that novel genomes, when considered as a single entity, satisfy the originality requirement under the Copyright Act.

D. Summary of Argument

It is submitted that the extension of copyright to include novel genomes is entirely consistent with the historical development of copyright law which has continually evolved to encompass new technologies, such as computer programs. The preceding discussion clearly illustrates that the nucleotide sequence of novel genomes satisfies the criteria for copyright protection under the Copyright Act. This assertion is primarily based on the analogy between novel synthetic genomes and computer programs. In light of this close analogy, the extension of copyright law to encompass the nucleotide sequence of novel genomes presents a relatively modest increase in copyrightable subject matter. Although the absence of specific reference to DNA in the Copyright Act does not preclude the protection of novel genomes, it is contended that an appropriate clarifying amendment to the Copyright Act is desirable. Such an amendment would alleviate uncertainty and prevent litigation to decide the question of law.

IX. Conclusion

Even in its nascent state, it is clear that the field of synthetic biology has the potential to address some of the most serious challenges facing mankind. Indeed, many synthetic biology research programmes have already produced applications with significant commercial potential. In any area where innovation has a commercial value, the question of IPRs arises. However, as the field of synthetic biology sits at the interface between various fields, there has been some confusion as to what IPRs, if any, can be granted over

[188] At 219-220, per Tipping J

the nucleotide sequence of novel genomes. It has been suggested that the synthetic biology industry should shun traditional IPRs in favour of an open source model. However it is submitted that the industry cannot rely on an open source mode alone and that some form of IPRs are necessary. This assertion is based on based on the traditional economic and moral rationales for IP protection as well as the heightened need for IPRs in high-risk, knowledge intensive industries such as the synthetic biology industry.

When considering what form of IPRs are appropriate, it is submitted that copyright offers the most appropriate form of protection. This is because copyright law provides significant safe harbours within which socially valuable activities such as education and academic research can continue. Furthermore, independent creation, as a feature of copyright law, means that a researcher can autonomously develop the nucleotide sequence of an existing novel genome, and, more significantly, go onto further develop that sequence without incurring liability. Copyright law also provides a more adequate and efficient means of protecting genetically different but functionally identical genomes, in comparison to patent law. The main issue with the current copyright regime seems to be the voluntary nature of the licensing provisions. However, this issue can easily be resolved via the amendment of the Copyright Act to include a compulsory licensing scheme. The overall effect of these features of copyright law is to confer a reasonable level of protection whilst simultaneously allowing society to benefit from the products of synthetic biology research more freely than other form of IPRs, such as patents, are able to afford. Based on this reasoning, it is concluded that copyright provides the most appropriate form of protection for the nucleotide sequence of novel genomes.

Given this conclusion it becomes necessary to consider whether the nucleotide sequence of a novel genome can be protected by the Copyright Act in its current form or whether certain amendments need to be made. Ultimately, it is submitted that novel genomes are literary works that satisfy the criteria for copyright protection under the Copyright Act. This assertion is, to a large extent, based on the analogy between novel genomes and computer programs which have already been afforded explicit statutory protection. Although novel genomes can be classified as literary works under the current version of the Copyright Act, it

is recommended that an appropriate clarifying amendment is desirable though not actually necessary.

Bibliography

Cases

New Zealand

AB Consolidated Ltd v Europe Strength Food Co Pty Ltd [1978] 2 NZLR 515

Beckmann v Mayceys Confectionary Ltd (1995) 3 IPR 543

Bleiman v News Media (Auckland) Ltd [1994] 2 NZLR 673

Bonz Group (Pty) Ltd v Cooke [1994] 3 NZLR 216

Copyright Licensing Ltd v University of Auckland [2002] 2 NZLR 76

Green v Broadcasting Corporation of New Zealand [1988] 2 NZLR 490

Henkel KGAA v Holdfast New Zealand Ltd [2006] NZSC 102

Longman Group v Carrington Technical Institute Board of Governors [1991] NZLR 574

P S Johnson & Associates Ltd v Bucko Enterprises Ltd [1975] 1 NZLR 311

Television New Zealand v Newsmoniter Services Ltd [1994] 2 NZLR 91

University of Waikato v Benchmarking Services [2004] NZCA 90

UPL Group Ltd v Dux Engineers [1989] *3 NZLR 135*

United Kingdom

Cramp & sons v Frank Smythson [1944] AC 329 (HL)

EMI v Lissen [1939] RPC 23 (HL)

Ladbroke (Football) Ltd v William Hill (Football) Ltd [1964] 1 WLR 273 (HL)

LB (Plastics) Ltd v Swish Products Ltd [1979] RPC 551 (HL)

MacMillan & Co Ltd v K & J Cooper (1923) LJPC 113(PC)

University of London Press Ltd v University Tutorial Press Ltd [1916] 2 Ch 601 (EWHCCh)

Legislation

New Zealand

Copyright Act 1994

Patents Act 2013

Plant Varieties Act 1987

Trade Marks Act 2002

Australia

Copyright Act 1968 (Cth)

Canada

Copyright Act 1985 RS C 1985 c-42

Treaties

Agreement on Trade-Related Aspects of Intellectual Property 1994

Berne Convention for the Protection of Literary and Artistic Works 1886

United Nations International Covenant on Economic Social and Cultural Rights 1966

Texts

Gerald Dworkin and Richard Taylor *Blackstone's Guide to the Copyright, Designs & Patents ACT 1988* (Oxford University Press, Oxford, 1989)

Ian Finch (ed) *James and Wells Intellectual Property Law In New Zealand* (2nd ed, Brookers, Wellington, 2012)

Susy Frankel *Intellectual Property in New Zealand* (2nd ed, LexisNexis, Wellington, 2011)
Richard Gold "Exclusive Rights in Life: Biotechnology, Genetic Manipulation, and Intellectual Property Rights" in John Jackson and Hans Linskens (eds) *Genetic Transformation in Plants* (Springer, New York, 2003)
Reto Hilty and Kung-Chung Liu (eds) *Compulsory Licensing: Practical Experiences and Ways Forward* (Vol 22, Springer, New York, 2014)
Sheila Jasanoff *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton University Press, Princeton, 2007)
Nik Marsh and John Lulich (eds) *Copyright and Design* (LexisNexis, Wellington, 2013)
Richard Posner *Economic Analysis of Law* (4th edition, Little, Brown and Company, Toronto)
Kenneth Oye and Rachel Wellhausen "The Intellectual Property Commons and Property in Synthetic Biology" in M Schmidt, A Kelle, A Ganguli-Mitra and H de Vriend (eds) S*ynthetic Biology: the Technoscience and its Societal Consequences* (Springer, New York, 2010)
Wei Shi *Intellectual Property in the Global Trading System: EU-China Perspective* (Springer, New York, 2008)

Journal Articles

Muhammad Zaheer Abbas "Pros and Cons of Compulsory Licensing: An Analysis of Arguments" (2013) 3 IJHSS 254
Colleen Chien "Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?" 18 Berkeley Tech.L.J. 853
Drew Endy "Foundations For Engineering Biology" (2005) 438 Nature 449
Ethan Fitzpatrick "Open Source Synthetic Biology: Problems and Solutions" (2013) 43 Seton Hall Law Review 1362
Brian Gargano "The Quagmire of DNA Patents: Are DNA Sequences more than Chemical Compositions of Matter?" (2005) 3 Syracuse Sci. & Tech. L. Rep 5
Robert Gottschalk "Compulsory Licensing: Patent Incentives" (1972) 39 Vital Speeches Day 21
Christopher Holman, "Copyright for Engineered DNA: An Idea Whose Time has Come?" (2011) 113 W.Va.L.Rev 699
Dennis Karjala "Protecting Innovation in Computer Software, Biotechnology and Nanotechnology" (2011) 16(1) Va. L.J & Tech 1

Sapna Kumar and Arti Rai "Synthetic Biology: the Intellectual property Puzzle" (2007) 85 Texas. L. Rev 1745, at 1764

Mark Lemley "Ex Ante Versus Ex Post Justifications for Intellectual Property" (2004) 71 U.Chi.L.Rev 129

Ingo Potrykus "Golden Rice and Beyond" (2001) 125 Plant Physiol 1157

Arti Rai and James Boyle "Synthetic Biology: Caught between Property Rights, the Public Domain and the Commons" (2007) 5(3) PLoS Biol 58

Arti Rai and Sapna Kumar "Synthetic Biology: The Intellectual property Puzzle" (2007) 85 Tex.L.Rev 1745

Berthold Rutz "Synthetic Biology and Patents: A European Perspective" (2009) 10 *EMBO Reports* 14

James Silva "Copyright Protection of Biotechnology Works: Into the Dustbin of History?" (2000) B.C. Intell. Prop. &Tech. F. 012801

Andrew Torrance "Gene Concepts, Gene Talk and Gene Patents" (2010) 11 Minn. J. L Sci. & Tech 157

Andrew Torrance "Synthesising Law for Synthetic Biology" (2010) 11 Minn. J. L Sci. &Tech 629

Andrew Torrance "DNA Copyright" (2011) 46 Val.U.L.Rev 1

Emma Toumi "In Defence of Gene Patents" (2003) J. Commerc. Biotechnol. 135

Internet Resources

Scitable "Genetic Code" Scitable by Nature Education http://www.nature.com/scitable/definition/genetic-code-13

Scitable "Ribosomes, Transcription and Translation" Scitable by Nature Education http://www.nature.com/scitable/topicpage/ribosomes-transcription-and-translation-14120660

Scitable "Unit 4: How Do Cells Sense Their Environment?" Scitable by Nature Education http://www.nature.com/scitable/ebooks/essentials-of-cell-biology-14749010/118241092

Simpson Grierson "New Risk in the USA to New Zealand Business Secrets" (18 July 2013) http://www.simpsongrierson.com/intellectual-property-new-risk-in-usa-for-nz-business-secrets

Synthetic Biology "FAQ" Synthetic Biology <http://syntheticbiology.org/FAQ.html>

Synthetic Biology Engineering Research Centre (Synberc) "What is Synthetic Biology" (2014) Synberc http://www.synberc.org/what-is-synbio

World Intellectual Property Organisation "What is a Trade Secret?" http://www.wipo.int/sme/en/ip_business/trade_secrets/trade_secrets.htm

Other Resources:

Birgitte Anderson "The Rationale for Intellectual Property Rights: The Twenty-First Century Controversies" (paper presented to the DRUID Summer Conference on Creating, Sharing and Transferring Knowledge, Copenhagen, June 2003)

Greg Arthur and Matt Sumpter "Intellectual Property for Non-Specialists" (paper presented at New Zealand Law Society Seminar on Intellectual Property for Non-Specialists, August 2008)

Marcy Damocvsky and Jesse Reynolds "The Battle to Patent Your Genes" *The American Interest* (Washington D.C., September/October 2009)

Marc Gunther "GMO 2.0: Genetically Modified Foods with Added Health Benefits" *The Guardian* (online ed, London, 20 June 2014)

Henry Olsson "Intellectual Property in a Knowledge Based Society: The Role of Copyright and Future Challenges to Creators, Industry, Legislators and Society at Large; Inventors' and Creators' Rights as Basic Human Rights (summary paper of the Second International Forum on Creativity and Invention – A Better Future for Humanity in the 21st Century, Beijing, May 2002)

Michael Spector "A life of Its Own: Where Will Synthetic Biology Lead Us?" *The New Yorker* (New York, 28 September 2009)