Congratulations to the 'inventors' of our genes

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Introduction

Where do we come from? Who invented the genes[1] which play a major role in determining what we will look like, how we will behave and what diseases we will be susceptible to? Many will say God, others will maintain we are a product of evolution and natural selection. *None* will say the pharmaceutical companies. They may have isolated, sequenced, or determined the function of a gene or indeed expressed a protein but they have not invented life on earth or our genes.[2]

Patents are being issued in Australia and other countries for genes and gene sequences.[3] The average person on the street intuitively knows that there is something wrong with their genes being *owned* by someone other than themselves. In response, people are told they are inventing moral problems and that if patents are not allowed, drugs will not be invented. People are being accused of ignorance of genetics and science by those no more qualified than they are. Although many advocate there is nothing wrong with patenting genes:

> Our genes cannot be patented because they are not the inventions of those claiming them.[4]

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1 Genes consist of DNA.

2 In practice it is not usually the pharmaceutical companies who actually do the Research and Development. They acquire the patent rights from those who have done it.

3 "New gene rules demand precision: International News", (February 2000) *IPASIA*, 4 and Senate Question on Notice 449, 24 March 1997 in C. Lawson, "Patenting Genes and Gene Sequences in Australia", (1998) 5 *Journal of Law and Medicine* 364.

4 Some may argue they are the invention of God however, for example.

This is because the patent system only protects inventions. Discoveries or the mere acquisition of new knowledge cannot be patented. So what is made to seem like a complex scientific issue to intimidate people is not. The technical side is actually irrelevant. No matter how difficult it is to isolate, sequence, or determine the function of a gene or indeed express a protein coded for by a gene (referred to as "isolating a gene") the *gene itself* remains unchanged. The gene, as well as its sequence (including any mutations) and function are naturally occurring in most of the cells of our bodies and therefore are not anybody's invention. Producing the product that the gene codes for (protein) does not render the *protein itself* an invention either as it too is naturally occurring.

This paper will examine the definition of invention and discovery from the perspective of the law, scientific understanding (via an informal survey) and the dictionary. The classification of the isolation of genes is considered in light of these definitions. The definitions from the various sources are quite consistent. It is therefore interesting that the scientists viewed the isolation of genes as the acquisition of new knowledge or discovery, and not as an invention.

This raises the question. If it is a legal requirement that only inventions can be patented and our genes are not "inventions", why are patent offices world-wide issuing patents for them? It seems that commercial interests have been over-represented and that Patent Offices have been convinced that black is white.

The formal legal requirements of patent law form many barriers to obtaining patents in this field. The requirement that there be an "invention" is only one of them and is dealt with here as it is a threshold requirement which must be satisfied before other queries can be entered into.

Only inventions can be patented

Inventions but not discoveries are capable of patent protection in most countries[5] including the United Kingdom[6], United States of America[7] and Europe.[8] The traditional foundation of patent law is that there be an

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5 J. McKeough and A. Stewart, *Intellectual Property in Australia*, 2nd ed Sydney: Butterworths, 1997, 339.

6 *Patents Act* 1977 (UK) s(1)(2)(a)

7 P. J. Coyne and J.N. Coulby, "Man or Monster: A Recent Application for Chimeric Embryos Brings into Question What it is to be "Human"", (1999) Issue 116 *Patent World* 14.

8 See for example *Chiron Corp v Organon Teknika Ltd (No. 3)* [1994] *F.S.R.* 202. See also EPO Examination Guidelines Part C-IV, 2.3 cited by R. Teschemacher, "The Patentability of Living Matter" (1994) 63 *Nordiskt Immateriellt Rättsskydd* 46 at 52, cited in K. Ludlow, "Genetically Modified Organisms and Their Products as Patentable Subject-Matter in Australia", (1999) 6 *European Intellectual Property Review* 299.

invention as opposed to a discovery.[9] The Australian legislation makes this quite explicit: "...a patentable invention is an invention that..."[10] Coupled with the dictionary definition of invention, which refers to s 6 of the Statute of Monopolies,[11] which is regarded as "the touchstone of patentability" and can be traced back to 1623,[12] the traditional definition of invention still applies in Australia today.[13] The High Court of Australia has held that this imposes a threshold requirement that only inventions can be patented. Thus if inventiveness is not apparent on the face of the specification there is no need to inquire into novelty and inventive step.[14]

Definition of invention

The law

In Australia, invention is defined as "any manner of new manufacture within s 6 of the Statute of Monopolies".[15] This involves two separate queries.

> Is the claimed invention "new" or "inventive"?
>
> Does it concern a manner of manufacture for which patentability is afforded as a matter of policy?[16]

Manner of manufacture must be "disclosed as an essential ingredient of the invention itself, and cannot satisfactorily be found in the means by which the invention is exploited."[17]

Invention has been defined by the court as entailing a new product/result/process or combination, whilst a discovery adds to human knowledge by disclosing what had not been seen before.[18] It has also been held that naturally occurring organisms cannot be an invention: "No invention was involved in the mere discovery, or the mere identification, or the mere isolation by an unspecified method, of something that occurs

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9 M. Padbury, "Inventiveness apart from Novelty and Inventive step-The High Court's Decisions on Manner of Manufacture in Philips and Ramset", (1998) 9 *Australian Intellectual Property Journal* 169 from *N V Philips v Gloeilampenfabrieken v Mirabella International Pty Limited* (1992) 24 *IPR* 1.

10 Opening words s 18(1) *Patents Act* 1990 (Cth)

11 *Patents Act* 1990 (Cth) Sch 1, definitions, "invention".

12 The Statute of Monopolies 1623 (England) 21 *Jac I* c3.

13 *N V Philips v Gloeilampenfabrieken v Mirabella International Pty Limited* (1992) 24 IPR 1 at 664-665

14 Above at n 13, 664.

15 *Patents Act* 1990 (Cth) Sch 1, definitions, "invention".

16 Above at n 9, 162.

17 Re NV Philips' Gloeilampenfabriekens Application (1954) 71 RPC 192 at 193-194

18 Reynolds v Herbert Smith & Co. Ltd (1903) 20 RPC 123 at 126

in nature."[19]

In the UK, a patent may be granted for an invention that is new.[20] The Courts have held that "newness" is an element of invention and that a mere commercial decision to carry out a course of research is not enough.[21] Desirable substances "plucked" from nature are not inventions.[22]

Human technical intervention distinguishes a discovery from an invention in Europe.[23]

In the US, *Chakrabaty*[24] established that patents could be issued for "anything under the sun that is made by man." However, "this is not to suggest that Section 101 has no limits or that it embraces every discovery."[25] The Court also made it clear that "hitherto unknown natural phenomenon" would not be patentable.[26]

It has been said that the "distinction between discovery and invention is not precise."[27] There are always grey areas and there is of course overlap between the concepts, with inventions usually predicated by discoveries.

Dictionary

A discovery is a revealing or disclosure. A thing found out.[28]

An invention is a contrivance,[29] of that which did not before exist.[30]

Scientific understanding – Informal Survey

In order to gauge the scientific understanding of the words discovery and invention, eleven scientists were asked to define discovery and invention. Five of these people were doing their doctorates in Biochemistry at the University of New South Wales.[31] The others were from both Australia

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19 Ranks Hovis McDougall Ltd's Application (1976) 46 AOJP at 3918.
20 Patents Act 1997 (UK) s1(1)(a).
21 Linklaters and Paines, "Delivering the Goods? - The House of Lord's Decision in Biogen v Medeva", (1996) Issue 36 Intellectual Property News.
22 Genentech Inc.'s Patent (1989) RPC 147 (also known as Genentech Inc. v The Wellcome Foundation Ltd)
23 K. Ludlow, "Genetically Modified Organisms and Their Products as Patentable Subject-Matter in Australia", (1999) 6 European Intellectual Property Review 298.
24 Diamond v Chakrabarty, 206 USP.Q.197.
25 P. J. Coyne and J.N. Coulby, "Patenting the Sun", (1999) Issue 116 The Biotechnology Supplement (From the publishers of Patent World, Trademark World and Copyright world) 12.
26 Above at 24.
27 National Research Development Corp v Commissioner of Patents (1959) 102 CLR 252
28 *The Concise Oxford Dictionary: New Edition*, 6th ed Oxford: University Press, 1976.
29 Above at n 28.
30 The Universal English Dictionary, Maxi Books: Australia, 1981.
31 The author surveyed all willing people in the Biochemistry laboratory.

and Spain and have degrees in science, engineering and medicine and work in these fields[32]. The responses were consistent enough to give consensus definitions:[33]

A discovery is the finding out or revealing of something that already existed. It includes details which are exciting or thought provoking, having the capacity to change perceptions. An invention is the production or creation of something, including a process or theory, which did not exist before.

Interestingly, legal, dictionary and survey definitions accord.

> Invention: Creation or contrivance of something, which did not exist before. New and man made.
>
> Discovery: Finding out or revealing of something that already existed (including naturally) which has the capacity to change perceptions.

Application of definitions

The above definitions preclude isolated genes themselves being called inventions. In many cases it will preclude them being called discoveries also. A gene isolated from the human body or the DNA sequence of a gene or the function of a gene or the protein product of a gene, are not new. They are billions of years old. New uses or methods cannot make the genes or gene sequences new in themselves. Mutations are naturally occurring as are gene polymorphs[34] and are thus not inventions.[35] Genetically modified organisms may not be inventions either as the original organism and gene sequences occurred in nature.[36] There is no need to go beyond patenting the novel genetic construct.[37] Furthermore, there are more ways for genes to transfer than from generation to generation. Genes also transfer laterally when mosquitoes take DNA between species for example. Recombinant DNA technology emulates this.

Ludlow points out that scientists are only using genetic material, which

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[32] These people were personal contacts of the author.

[33] The detail of the surveys can be obtained from the author.

[34] "Opinion on a preliminary draft law incorporating transposition into the Code of intellectual property, of a European Parliament and Council Directive 98/44/CE, dated July 6, 1998 on the legal protection of biotechnological inventions", No 64-June 8, 2000 at www.ccne-ethique.org/english/start.htm

[35] Report 9 of the Council on Scientific Affairs (1-100), "Patenting of Genes and Their Mutations", (2001) *American Medical Association* at http://www.ama-assn.org/ama/pub/article/2036-3603.html 9/6/01

[36] K. Ludlow, "Genetically Modified Organisms and Their Products as Patentable Subject-Matter in Australia", (1999) 6 *European Intellectual Property Review* 303.

[37] "Patenting Biological Material-A Case of Injustice?" (2001) cited in http://biotechknowledge.com/showlibsp.php3?uid=681 [6/6/01].

is already in existence. "Synthetically" constructed gene sequences are based on existing genes. Science is thus currently taking genes from nature, not creating its own.[38] The genetic material is thus not new and hence not an invention.

Manner of manufacture is an essential element of the invention itself. Was the gene manufactured? Not if it has simply been isolated. The gene exists and thus cannot be manufactured. It can be copied or even altered synthetically (albeit using natural mechanisms) but this cannot render the gene itself 'man made'.

A gene sequence was held not to be an invention in *Genentech* in the English Court of Appeal.[39] It was further held that a gene sequence, might not be a discovery but only a claim to new knowledge. After all, Watson and Crick *discovered* the basic structure of DNA. It consists of guanine (G) paired off with cytosine (C). Three of these paired bases in a row forms a codon, which codes for an amino acid. The DNA is thus "read" to determine what amino acids are to be joined together to form proteins. Is the order of the base pairs of a particular gene a discovery, or is it just data? As will be seen below, numerous people surveyed thought it was just data or new knowledge. This is quite significant as it means that even if discoveries were held to be patentable (as opposed to inventions), there would still be a hurdle to patenting gene sequences as 'mere data' is not patentable on any view.

Scientific Understanding- Informal Survey

To avoid possible bias, only after the eleven people surveyed were asked to define discovery and invention were they asked to classify an isolated gene, gene sequence, gene function and production of gene product (e.g. protein) as a discovery or invention. No one classified them as an invention. In fact, many did not even classify them as discoveries, preferring to describe them as new knowledge or 'other'. A few responses indicated that a gene sequence or the product of a gene could be an invention if the sequence and function of the genes were altered to form a protein departing from what exists in nature in form and/or manner of production.[40] With the limitations of this small and informal survey in mind, it is still interesting that not one person entertained the possibility of an isolated gene being an invention.

It is also of interest that in relation to the isolation of genes the scientific

[38] Above at n 36, 303.
[39] *Genentech Inc v Wellcome Foundation Ltd* (1989) 15 IPR 423 at 425.
[40] This is a summary of the survey comments in this regard.

and legal literature as well as the press, uses the word discovery and not invention.[41]

Further Reasons why isolated genes should not be classified as inventions

- **It does not seem possible**

How did a pharmaceutical company invent an individual's gene *x* which their ancestors have possessed for millions or perhaps billions of years and which is shared with other life forms from zooplankton to trees to beetles? How does one invent an individual's gene *p*, which is identical[42] to the gene *p* carried by the individual's great, great, grandfather who lived before the "inventing" company was incorporated or the "inventor" born?[43]

What can be more basic to the study of genetics than to ascertain the genetic code or to isolate a gene? If this is not to be defined as an invention then there is no scope for discoveries in the field of genetics.[44] This would be a startling result for such a new field of endeavour!

- **No reason why isolated genes are inventions**

Arguments are not advanced in favour of why the isolation of genes should be classified as an invention. Blind assertions with no supporting evidence, are supplied instead. Crespi's article[45] for instance states that "it is becoming the received opinion in some circles that because genes exist in nature they cannot be invented but only discovered". He resorts to implying ignorance: "The superficial force of this viewpoint is based on an oversimplification of the legal issue". He states that the products should be given their "proper status as inventions" and also describes the categorisation of genes, as mere discoveries as "an arbitrary judgment"[46]

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41 See "Patent Applications booming in biotech", http://biodiversity.biotech.or.th/update/news/news/oldnews/september/356.html 6/6/01, ran on page D1 of the Boston Globe on 8/30/2000; Steve Dow, "Gene patent decision under fire", (10/6/97) *Age* 3; I. Purvis, "Patents and genetic engineering-does a new problem need a new solution?: Opinion", (1987) 12 *European Intellectual Property Review*, (page missing) and B. Healy, "Special Report on gene patenting", (1992) 327 *The New England Journal of Medicine* 664, for some examples.

42 That is, no mutations have occurred in any of the bases.

43 Potential examples are endless.

44 Above at 34.

45 S. Crespi, "Biotechnology Patenting: The Wicked Animal Must Defend Itself", (1995) 9 *European Intellectual Property Review* 431

46 Above at n 45, 431.

without explaining why this is so.

Crespi accuses those not in favour of gene patenting as using "emotive" language whilst he labels them the "anti-biotechnological *lobby*" (my italics) and refers to them "latching onto" arguments. He states that those against the patenting of "life" are resorting to "slogan"[47]. Whilst DNA is not 'life' it certainly plays a very important role in defining life forms. The claim that 'life' is being patented is therefore not so outlandish.

Arguments as to why gene sequences are inventions are substituted with reasons why it would be nice if they were indeed inventions. This includes the belief that product patents are the only way to reward research in this area and that hard work and monetary investment in the laboratory should be rewarded.[48]

The law in (mal)practice

Just over 50% of all biotechnology patent applications filed in the US are granted and applications are on the increase with 30,000 being granted in the year 2000.[49] By 1997, the Australian patent office had issued 2,100 patents for genes and gene sequences.[50] A further 1,307 have been issued from 1998 until 2001.[51] Patents have also been issued for gene fragments.[52] Patent office practice is based on two untenable propositions:

> Isolation of gene: That there is an intrinsic difference between DNA in a cell and outside of a cell;
>
> A useful application converts a discovery into an invention.

Isolation of gene

In Australia,[53] the United States and Europe, a purified natural product can be patented if it is not found in purified form in nature.[54] Article 5 of the European Directive demonstrates the inadequacy of this distinction.

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47 Above at n 45.

48 I. Purvis, "Patents and genetic engineering - does a new problem need a new solution?: Opinion", (1987) 12 *European Intellectual Property Review* 347.

49 "New gene rules demand precision: International News", (February 2001) *IPASIA*, 4

50 Senate Question on Notice 449, 24 March 1997, in C. Lawson, "Patenting Genes and Gene Sequences in Australia", (1998) 5 *Journal of Law and Medicine* 364.

51 IP Australia, Strategy and Projects (Personal Communication (2002))

52 Human Genome Project Information, "Genetics and Patenting", at http://www.ornl.gov/hgmis/elsi/patents.html 6/6/01

53 IP Australia (Patent Office), "AUSTRALIAN PATENTS FOR: Microorganisms; Cell Lines; Hybridomas; Related biological materials and their use; & Genetically manipulated organisms", Biotech-7.doc November 1998

54 K. Ludlow, "Genetically Modified Organisms and Their Products as Patentable Subject-Matter in Australia", (1999) Issue 6 *European Intellectual Property Review*, 303

Many European countries have struggled with paragraphs one and two, as they are irreconcilable.[55]

Article 5

The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent specification.

There is no intrinsic difference between DNA inside a cell or DNA outside of a cell. Removal or separation does not equal invention. It does not make the gene new or man-made. Even if synthesised by man this does not make the gene itself new, just because a new method for arriving at it is used.

It seems that this distinction is conveniently confined to biotechnology. Elements of the periodic table are found as oxides and in other chemically bound states in nature but patents for the elements themselves have been repeatedly denied for the isolation and purification of the element from its ore.[56]

It has been argued that a substance is "new" and can therefore be patented per se if it had no previously recognised existence.[57] This is not correct. It may be new to us but that does not mean that it is new in itself. This is a discovery or new knowledge. Furthermore, on what level are we to have no previous knowledge? We may have surmised that there would have to be *x* gene playing a part in *y* function. Thus we have some knowledge of it.

Useful application

It is widely accepted in the US and many European countries that genes of known function whether human or otherwise are patentable.[58] The

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[55] D. Carley, "UK Bites the Biotech Bullet: The EU Biotech Directive" Patent World November 2000 p 12 and "Patenting Biological Material- A Case of Injustice?" at http://biotechknowledge.com/showlibsp.php3?uid=681 6/6/01

[56] Above at n 25, 12.

[57] N. Jenkins, "In Brief: The Impact of the EU Biotechnology Directive on the Patenting of Biotechnology" (2000/2001) Issue 128 *Patent World* 10.

[58] A.L. Caplan and J. Merz, "Patenting gene sequence: Not in the best interests of science or society", (1996) 312 *BMJ* 926.

United States Patent and Trademarks Office released rules on 7 January 2001 requiring the function of a protein to be known before it can be patented.[59] This is based on the idea that a previously unknown substance freely occurring in nature can be patented if there is some useful application for it.[60]

Life on earth revolves around maintaining the integrity and ensuring the survival of our DNA.[61] It is therefore fairly certain that much DNA is bound to have a useful application! Furthermore, the one gene can have numerous functions and one condition, such as obesity will be the result of numerous genes (as well as numerous environmental factors of course). If a gene is expressed, it is virtually just a matter of time before its function is discovered. If anything, it is the application, which would have to be patented.

In any case the unsurprising fact that a gene may have a useful application cannot render it an invention! As suggested during surveying, atoms and electrons have uses - nuclear energy and the atomic bomb for example, but that does not make the atoms or electrons inventions in themselves. Usefulness does not satisfy the definition of invention.

What is happening?

The patent system has changed from focussing on conventional drugs to encompassing patents on biological molecules containing genetic information.[62] In doing so, the fundamental, threshold requirement that patents only be issued for inventions has been overlooked.

Although the word Biotechnology is intimidating in itself to many, biotechnology really is a baby science in the trial and error stage. An initial step in understanding our genetic make-up was to determine the sequence (order of base pairs) of our DNA (The Human Genome Project). This information is only raw data. It literally reads: ACGTTTACCATT etc. At this stage knowledge is being gained and discoveries made. Although inventions for methods are being developed for isolating DNA, it is likely to be some time before the "products" of biotechnology go beyond what is naturally occurring or capable of production by nature.

Large pharmaceutical companies see the potential of the biotechnological revolution and are jumping the gun. They don't have the patience to wait for the inventions. For with the victims of HIV in South Africa in

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[59] "New gene rules demand precision: International News", (2001) *IPASIA* 3.

[60] Above at no. 57.

[61] There are repair mechanisms which try to reverse mutations to maintain the correct DNA sequence for example. Although mutations are a source of variation and therefore an important part of natural selection and evolution most mutations are detrimental.

[62] M. Bobrow and S. Thomas, "Patents in a genetic age", (2001) *Nature* 409, 763-764, at http://www.nature.com/cgi-taf/DynaPage.taf?file=nature/journal/v409/n6822/full/409763a0_r.html&filetype= 6/6/01

mind and without passing judgment, it must be remembered that companies are motivated by the dollar. They see money and are prepared to call black white to tie up genes with their patents. It appears that patent offices and courts have been greatly influenced by claims that research to find cures to diseases will not be carried out if patents are not given. This issue is not so clear-cut however.[63]

It has been suggested that many patents would probably not stand up to legal challenge. But who has the resources and commitment to mount such challenges? Is this an ethical way to resolve far reaching social issues?

There is an international race to patent genes and no one wants to miss out.[64] The US government holds the largest number of gene patents,[65] partly owing to the "user friendly patent laws".[66] Europe and the rest of the world do not want to let the US run off with all the booty.[67]

What are the consequences?

Instead of encouraging people to work to inventions of genuine therapeutic or diagnostic value we are encouraging a frantic race to isolate and sequence DNA. Furthermore, multiple patents are being given for the same gene and patents are being given for parts of genes. A complex and overlapping patent system for this basic research can only inhibit further discoveries and possible future applications.[68]

It is quite disturbing to think that commercial interests have been able to run rough-shod over the requirements of the law, the concerns of the community and the interests and well-being of us all. Many papers have dealt with the ethical and philosophical problems with patenting genes. This has not been discussed here because the onus is on those who want to patent discoveries and new knowledge to give us very good reasons why. It is they who musts convince the community and the legislature, because:

> Our genes are not the inventions of those claiming them and thus cannot be patented.

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[63] Above at n 62; Second Reading Speech, A Bill to Amend the Patents Bill, Senator Natasha Stott Despoja, June 1996.

[64] J. Kluger, "Who Owns Our Genes", (11 January 1999) *Time*, 33; Report 9 of the council on Scientific Affairs (1-100), "Patenting of Genes and Their Mutations", (2001) *American Medical Association* at http://www.ama-assn.org/ama/pub/article/2036-3603.html 6/9/01.

[65] Report 9 of the Council on Scientific Affairs (1-100), "Patenting of Genes and Their Mutations", (2001) *American Medical Association* at http://www.ama-assn.org/ama/pub/article/2036-3603.html 6/9/01

[66] "New gene rules demand precision: International News", (2001) *IPASIA* 4.

[67] Above at no. 57, p 9.

[68] M. Bobrow and S. Thomas, "Patents in a genetic age", (2001) *Nature* 409 at 763-764, at http://www.nature.com/cgi-taf/DynaPage.taf?file=nature/journal/v409/n6822/full/409763a0_r.html&filetype= 6/6/01.