UNIVERSITY OF TECHNOLOGY SYDNEY

23 February , 2011

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Committee Secretary
Senate Legal and Constitutional Committees
PO Box 6100
Parliament House
Canberra ACT 2600
Australia

Dear Sir/Madam,

RE: Senate Committee inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010

Please find enclosed a submission from Dr Ann Kurts, Dr Mark Lutherborrow and me in relation to the Senate Committee inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010. Please note that our submission does not necessarily represent the views of our respective institutions.

We each hold qualifications in a field of biotechnology. Dr Kurts is a registered Patent Attorney and teacher in the UTS Master of Industrial Property. Dr Lutherborrow is a lecturer and researcher in the Faculty of Medicine at UNSW and I am the Director of the Master of Industrial Property as well as the Chair of the Intellectual property, Media and Communications Research Network at UTS and a registered legal practitioner in NSW.

We appreciate the opportunity to provide comment on this proposed legislation and welcome the opportunity to address the committee should public hearings be scheduled.

Our submission raises a number of concerns not least of which relates to the failure of the proposed amendments to achieve the intended outcomes. The language relating to the exclusion of biological materials has far broader reach than human genes and will impact our agricultural, chemical, pharmaceutical and biotechnological sectors without impacting access to, for example, medical testing.

Accelerating the adoption of the experimental use exemption to infringement of patents and adopting other measures recommended in 2004 by the Australian Law Reform Commission in Report 99 would be more effective.

We would be pleased to provide further information and elaboration on each of the issues raised in our attached submission.

Yours sincerely

Professor Natalie Stoianoff

Submission regarding

The Patent Amendment (Human Genes and Biological Materials) Bill 2010

February 2011

Contributors:

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Dr Mark Lutherborrow

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Contents

Contributors

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Executive Summary

We submit that the proposed amendments to subsections 18(1)(a) and 18(1A)(a) are superfluous as the existing statute clearly provides for the purpose and intent of the reference to the Statute of Monopolies.

We submit that to the extent that there is any lack of clarity in the wording of subsections 18(1)(a) and 18(1A)(a) and associated definitions, these are not remediated by the proposed amendments.

We submit that the proposed amendment to subsection 18(2), namely an additional exclusion from patentable subject matter, ignores the further criteria for patentability (novelty, inventive step, utility and no secret use), does not achieve the intended outcome of the Bill but has far reaching unintended consequences due to the vagueness of the language of the proposed amendment, is potentially in breach of Australia's international obligations, including potentially denying Australia's Indigenous communities an opportunity to share in the benefits derived from the utilisation of their knowledge relating to Australia's biological resources, and would damage investment in domestic research and development.

We submit that the stated purpose of the Bill would be better served by accelerating the adoption of the experimental use exemption to infringement of patents and adopting other measures recommended by the Australian Law Reform Commission in Report 99 in 2004.

The proposed amendments

The Patent Amendment (Human Genes and Biological Materials) Bill 2010 proposes amendment to section 18 of the Patents Act 1990 to change the statutory requirement for patentable subject matter. Part of the proposed amendment would impact all technologies while other parts of the proposed amendment will eliminate patent rights for many aspects of biotechnology but leave other aspects that critics have challenged untouched.

The proposed amendment would alter the text of s18 in the following ways (amended text shown in red):

> ***PATENTS ACT 1990 - SECT 18***
>
> ***Patentable inventions***
>
> *Patentable inventions for the purposes of a standard patent*
>
> *(1) Subject to subsection (2), an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim:*
>
> *(a) is a manner of manufacture within the full meaning, including the proviso, of section 6 of the Statute of Monopolies; and*
>
> *(b) when compared with the prior art base as it existed before the priority date of that claim:*
>
> *(i) is novel; and*
>
> *(ii) involves an inventive step; and*
>
> *(c) is useful; and*
>
> *(d) was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.*
>
> *Patentable inventions for the purposes of an innovation patent*
>
> *(1A) Subject to subsections (2) and (3), an invention is a patentable invention for the purposes of an innovation patent if the invention, so far as claimed in any claim:*
>
> *(a) is a manner of manufacture within the full meaning, including the proviso, of section 6 of the Statute of Monopolies; and*
>
> *(b) when compared with the prior art base as it existed before the priority date of*

that claim:

(i) is novel; and

(ii) involves an innovative step; and

(c) is useful; and

(d) was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.

(2) The following are not patentable inventions:

(a) human beings, and the biological processes for their generation; and

(b) biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature.

Certain inventions not patentable inventions for the purposes of an innovation patent

(3) For the purposes of an innovation patent, plants and animals, and the biological processes for the generation of plants and animals, are not patentable inventions.

(4) Subsection (3) does not apply if the invention is a microbiological process or a product of such a process.

(5) In this section:

***biological materials**, in section 18, includes DNA, RNA, proteins, cells and fluids.*

Amendment proposed to s18(1)(a) and s18(1A)a

The explanatory memorandum accompanying the Bill explains that Section 18 of the Patents Act 1990 provides the patentability criteria for the grant of a valid patent monopoly. The memorandum asserts that the primary criterion of patentability according to section 18(1)(a) and section 18(1A)(a) is that the invention so far as claimed is "a manner of manufacture within the meaning of section 6 of the Statute of Monopolies."

The explanatory memorandum observes that in 1623 the English Parliament passed the Statute of Monopolies:

> *Under section 1 of the Statute of Monopolies all monopolies except those expressed exempted were "utterly void and of none effect." Section 6 of the Statute of Monopolies, being one of the express exceptions, provided that "manners of new manufacture" could be the subject of "Letters Patent and Grants of Privilege" provided they were not "not contrary to the Law, nor mischievous to the State, by raising Prices of Commodities at home, or Hurt of Trade, or generally inconvenient".*

and further:

> *Thus the Bill (a) reinforces the applicability of the proviso in section 6 of the Statute of Monopolies within the meaning of section 18(1)(a) and section 18(1A)(a), ...*
> *The amendments proposed in the Bill therefore:*
> *1) amend subsection 18(1)(a) and subsection 18(1A)(a) by (i) inserting the word "full" before the word "meaning" and (ii) inserting the words "including the proviso" after the word "meaning";...*

We submit that the existing statute clearly provides for the purpose and intent of the reference to the Statute of Monopolies through the following two definitions included in Schedule 1 of the Act:

> ***"invention"*** means any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the Statute of Monopolies, and includes an alleged invention.
>
> ***"Statute of Monopolies"*** means the Imperial Act known as The Statute of Monopolies.

We submit that amendment of the relevant parts of s18 to modify reference to the Statute of Monopolies is superfluous.

Exclusion of natural phenomena and discoveries

The other change the proposed amendment seeks to make is to create certain exclusions from patentable subject matter.

The explanatory memorandum argues:

> *Section 18(2) provides that "human beings, and the biological processes for their generation, are not patentable inventions." Thus while section 18(1)(a) and section 18(1A)(a) mandate that patent eligible subject matter must be a manner of manufacture within the meaning of section 6 of the Statute of Monopolies, if that subject matter falls within the prohibition provided in 18(2) it is ineligible for the grant of a patent monopoly regardless.*
>
> *This means that unless the subject matter of a patent is a "patentable invention" it is ineligible for the grant of a valid patent monopoly.*

It is clear however from the wording of s18 that the manner of manufacture requirement is only one element of a four part requirement relating to subject matter (manner of manufacture), novelty and inventiveness, utility and a lack of prior secret use.

The requirement for subject matter should not be confused with the need for the invention to be new, useful and to involve the required level of inventiveness or innovation. We suggest that both Courts and commentators sometimes struggle with this distinction and acknowledge that treating subject matter as a distinct issue is challenging. Nonetheless the distinction is an important one.

As we demonstrate below, some of the issues this proposed amendment seeks to address are properly addressed by novelty, utility and inventiveness requirements.

The explanatory memorandum also observes:

> *It has long been accepted that natural phenomena are not patentable inventions. This is because the elucidation of a natural phenomenon such as the discovery of a naturally occurring thing, while adding to the storehouse of human knowledge, does not transform it into a product of humankind. Discoveries are therefore excluded from patentability, while inventions, provided they do not fall within the prohibition in section 18(2), are not.*

This statement while essentially correct needs to be viewed with caution. Firstly, the terms "natural phenomenon" and "discovery" are not interchangeable. A natural phenomenon is essentially something that is not man-made. It is an occurrence of nature such as lightning, bacteria, volcanic eruptions etc. A discovery is the uncovering of the reason for a particular occurrence. So determining that there is a phenomenon that we now refer to as electricity and how it works is a discovery. While the distinction may seem slight, again it is important in relation to patent law.

The explanatory memorandum asserts that exclusion of natural phenomena and discoveries from patent protection is consistent with the language of the Statute of Monopolies. However, the Statute of Monopolies is silent on this issue.

The explanatory memorandum argues:

> *This distinction between invention and discovery has thus been an accepted part of English patent law for hundreds of years and was received law by the Australian colonies. After Federation the Australian parliament maintained that distinction in the Patents Act, 1903.*
>
> *Likewise, successive Australian parliaments followed suit in the Patents Act, 1952 and the Patents Act, 1990.*

The basis for an exclusion of natural phenomena or discoveries from patentability does not reside in the language of the Statute of Monopolies. Rather, the Statute of Monopolies is intended to provide a broad definition of patent eligible subject matter to enable patent law to accommodate technologies that had not even been dreamt of at the time that legislation was enacted.

The basis for excluding natural phenomena from patent protection resides in the fact that such phenomena already exist and thus there is no new invention that could attract a monopoly right for teaching something new. So a naturally occurring bacterium as it exists in its natural environment is not an invention because there is nothing new.

As technology develops so too the techniques that are used in that technology develop. In the case of gene technology, use of many of the techniques for isolating and cloning genes that were once considered to give rise to an invention is now routine so that the simple isolation of a previously unisolated gene will not give rise to an invention without something more. This is particularly so in the case of human genes since the completion of the Human Genome project.

The basis for excluding discoveries from patent protection resides in the fact that a discovery without disclosure of a means of putting the discovery to practical use will lack utility. There is no need to amend the Act to create an exclusion of natural phenomena and discoveries from patent protection; it is already in place.

The discovery of electricity does not provide a useful outcome until a way of using electricity to create a particular useful outcome is realised. So electricity itself was not patentable but the electric light bulb was.

A biological example is penicillin. The antibiotic penicillin is produced by a naturally occurring fungus. Fleming discovered this phenomenon. Its utility as a medicine was identified giving rise to a Nobel Prize for Howard Florey. Penicillin manufacture was extremely challenging and total stocks worldwide in the early forties were only sufficient to treat 10 people. The development of synthetic forms and production processes has been the subject of patent protection and has provided the world with valuable medical treatment options. Penicillin is a naturally occurring substance so penicillin *per* se could not be the subject of patent protection. Further, early findings relating to its isolation were published without patent applications being filed. The synthetic analogues that have been the subject of patent protection would likely be deemed ineligible for patent protection under the proposed amendment.

Introduction of a new specific exclusion

The explanatory memorandum continues:

> *That said it was felt necessary, with the passage of the Patents Act, 1990, for certain subject matter to be expressly excluded from patentability as provided by section 18(2). This express exclusion, however, was not intended to neutralise or render redundant the proviso contained within section 6 of the Statute of Monopolies and*

referred to in section 18(1)(a) and section 18(1A)(a). Rather, it was inserted into the Patents Act, 1990 so as to avoid the possibility, which biotechnology enables, of patent monopolies being granted for inventions which would transgress socially acceptable norms. Thus it is for this reason, and only for this reason, that "human beings, and the biological processes for their generation" are not eligible for the grant of patent monopolies.

At the time the Patents Act 1990 was enacted, biotechnological research had developed to the extent where the use of that technology to engineer human beings was conceivable. Moreover, such an occurrence could have given rise to an artificially created state of affairs that might have been considered patent eligible, namely an engineered human being. However, the Act already provided a safeguard with respect to that possibility in s50:

Application or grant may be refused in certain cases

(1) The Commissioner may refuse to accept a request and specification relating to a standard patent, or to grant a standard patent:

(a) for an invention the use of which would be contrary to law; or

(b) on the ground that the specification claims as an invention:

(i) a substance that is capable of being used as food or medicine (whether for human beings or animals and whether for internal or external use) and is a mere mixture of known ingredients; or

(ii) a process producing such a substance by mere admixture.

(2) The Commissioner may refuse to accept a specification relating to a standard patent containing a claim that includes the name of a person as the name, or part of the name, of the invention so far as claimed in that claim.

The explanatory memorandum asserts:

The purpose of this Bill is to advance medical and scientific research and the diagnosis, treatment and cure of human illness and disease by enabling doctors,

clinicians and medical and scientific researchers to gain free and unfettered access to biological materials, however made, that are identical or substantially identical to such materials as they exist in nature.

Experimental use exemption has received attention and is the subject of an IP Australia discussion paper. In essence the purpose is to provide researchers with an opportunity to deal with patented materials for the purposes of further non-commercial research and certain classes of exempt commercial research.

The explanatory memorandum continues:

These biological materials even if they have been isolated, purified or synthetically made have not been transformed from products of nature into products of humankind.

Thus the Bill (a) reinforces the applicability of the proviso in section 6 of the Statute of Monopolies within the meaning of section 18(1)(a) and section 18(1A)(a), (b) reinforces the applicability of the distinction between discovery and invention and (c) applies that distinction by expressly excluding from patentability, biological materials which are identical or substantially identical to such materials as they exist in nature, however made.

The proposed wording of the amendment raises a number of issues. Firstly, it is asserted that further distinction between discovery and invention is needed. We submit that it is not. The distinction is already addressed by the requirement for novelty, inventive step (or innovative step) and utility.

Moreover, if there were a need for such reinforcement it would not rest exclusively with biological inventions and so language that creates an express exclusion for one particular field of technology cannot be defended on this basis.

The explanatory memorandum asserts that "*biological materials even if they have been isolated, purified or synthetically made have not been transformed from products of nature into products of humankind".* The memorandum presents this opinion as a matter of fact. It is not. It is a disputed point that lies at the heart of the debate regarding patenting of

biological materials. It is submitted that there is a contrary argument to this position which is essentially that the acts of isolation, purification and synthesis are transformations that can render the relevant subject matter patentable provided it satisfies the requirements for novelty, inventiveness and utility.

These constraints are not insignificant. A PhD could be obtained for amplifying and characterising a gene in the 1980s. Today gene amplification is covered as an undergraduate topic in a single 1 hour lecture in molecular biology courses. Since the completion of the Human Genome Project (HGP) a patent seeking to monopolise a native gene sequence without a novel use would not be inventive over the HGP annotated genome sequence.

The actual wording of the express exclusion that the Bill seeks to introduce encompasses not only naturally occurring substances but also *biological materials which are... substantially identical to such materials as they exist in nature, however made.* This language would potentially deny patent protection for a synthetic drug that is an analogue of a naturally occurring substance and is completely synthetically made. This would affect not only the biotechnology industry but the pharmaceutical industry as well.

Further, the term "substantially identical" is ambiguous. It is unclear as to what quantum or character a lack of identity with a naturally occurring substance would be required before a synthetic molecule would be considered patentable. The use of this language introduces further ambiguity rather than clarifying the definition of patentable subject matter.

The proposed amendment also embraces components and derivatives of the biological substances it seeks to exclude. It is not clear from the wording of the proposed amendment that these further substances are excluded only if they are identical or "substantially" identical to a naturally occurring molecule. If that is not the case then the proposed amendment reaches well beyond the territory it asserts should not be patent eligible.

Scope of the proposed exclusion

The scope of biological substances the proposed amendment seeks to capture is extremely broad. The amendment includes the following definition:

> *"biological materials....includes DNA, RNA, proteins, cells and fluids".*

The Senate enquiry which preceded this Bill was directed to the impact of gene patenting on human health. To date there has been no enquiry or any other basis for asserting that biological materials in general should be excluded from patent protection.

The language of the proposed amendment is not restricted to human biological materials but also encompasses all animal and plant biological materials.

The language of the proposed amendment also presents further issues. Patents directed to biological substances typically claim other aspects of the invention in addition to the methods of using the substance and formulations comprising the substance. Both therapeutic and diagnostic methods are patentable under current Australian law. Exclusion from patenting of the substance would not prevent patenting of these methods or formulations. Thus this Bill will not achieve the purpose it expressly states it is designed to achieve. The Myriad BRCA patents are a case in point. Claims that have given rise to concern internationally relate to methods for diagnosing predisposition to breast and ovarian cancers and the use the exclusive licensee has made of the granted monopoly. Concerns such as these will not be addressed by the proposed amendments.

This matter has been the subject of a number of reviews

This amendment revisits an issue that has been the subject of a number of reviews, none of which have concluded that there is a clear need for a statutory exclusion of biological materials, but particularly genes from patent protection.

The Australian Law Reform Commission (ALRC) reported on this issue in 2004 with respect to genes and genetic technologies[1]. The report observed that if there had been a time to recommend that gene sequences should not be patentable, that time had long since passed. The ALRC concluded that inventions involving genetic materials and technologies should be assessed according to the same legislative criteria as other inventions. Rather than seeking to exclude genetic materials and technologies from protection the report concluded it is preferable to focus on reforms that would make the system work better. Examples of amendments they deemed necessary and appropriate related to assessment of the

[1] http://www.alrc.gov.au/sites/default/files/pdfs/publications/ALRC99.pdf viewed 14 February 2011

usefulness of an invention under Australian law and the need for an experimental use exemption.

The ALRC recommended that the Patents Act 1990 should not be amended to exclude genetic materials or technologies from patentability; nor to provide a medical treatment exclusion; nor to expand the existing circumstances in which social and ethical considerations may be taken into account in decisions about granting patents.

The ALRC did recommend however that the responsible Minister should initiate an independent review of the appropriateness and adequacy of the 'manner of manufacture' test as the threshold requirement for patentable subject matter under Australian law, with a particular focus on the requirement that an invention must not be 'generally inconvenient'.

The proposed amendment purports to emphasise the presence of the test of "general inconvenience" as part of the test for manner of manufacture but does not address the issue identified six years ago by the ALRC, namely that the ambit of that constraint is unclear.

Impact on research and industry

The ALRC concluded that the biotechnology industry's dependence on patents and inventions constitutes a significant impediment to amending the Patents Act 1990 to exclude genetic materials from patentability.

Opponents suggest that researchers are concerned about infringing gene patents or that they may not be able to obtain a licence on fair terms. However the ALRC concluded that the lack of infringement proceedings and other means of patent enforcement suggest it is doubtful that research is being hindered in Australian research institutes by patents.

The ALRC also observed that while some organisations suggest that gene patents may be hindering research, these concerns are directed more towards the complexities of the patent system, difficulties in negotiating commercially viable licences and excessively broad patents restricting research.

A survey by Nicol and Neilsen[2] found that reported concerns regarding the impact of gene patenting seem to be misplaced. It was rare that researchers were concerned about the long term effects of gene patents on their research and in most cases where there was a concern the research simply proceeded in a modified fashion.

Often overlooked in this debate is the potential for gene patents to attract funding for research institutes and an institutes ability to convert a gene patent to a marketable product. Patents provide a prospect to attract funding from commercial and government sources for institutes to continue their research. Secondly few Australian institutes have the funds, experience or expertise to conduct the clinical trials and tests required to obtain regulatory approval. Patents provide a means to attract commercial investors to provide funds for third parties to perform these tests.

Australia's international obligations

As a member of the World Trade Organisation, Australia is a party to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs).[3] This agreement establishes the basic standards of intellectual property protection that each member nation must implement. The standards established for patentable subject matter are found in Article 27 of TRIPs which confirms at paragraph one that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application". Further, there is a requirement that "patents shall be available and patent rights enjoyable without discrimination as to …the field of technology". The impact of the Bill's proposed section 18 (2)(b) clearly discriminates against both the biotechnology and pharmaceutical industries.

While there are exclusions permitted under TRIPs Article 27, their scope does not extend as far as the proposed amendments under the Bill. Paragraph two of Article 27 of TRIPs enables nations to exclude from patentability those inventions for which commercial exploitation has been prevented on the basis of protecting *ordre public* or morality and

[2] Nicol D and Nielsen J (2003), Patents and medical biotechnology: an empirical analysis of issues facing the Australian industry *Centre for Law and Genetics Occasional Paper No. 6*, at 172

[3] Australia is a party to many international conventions and agreements relating to intellectual property (including the Australia United State Free Trade Agreement), however, TRIPs is a key agreement for patent purposes.

further “that such exclusion is not made merely because the exploitation is prohibited by their law”. The Bill is not intending to prevent the commercial use of biological inventions, rather, the explanatory memorandum confirms its purpose is

> *to advance medical and scientific research and the diagnosis, treatment and cure of human illness and disease by enabling doctors, clinicians and medical and scientific researchers to gain free and unfettered access to biological materials, however made, that are identical or substantially identical to such materials as they exist in nature.*

This is more in line with either providing an *experimental use* exception to infringement in the case of scientific research or the granting a compulsory licence to use the research of others but without any compensation for the use of that research. This is not what is intended by paragraph two of Article 27 of TRIPs and what is essentially intended to be a compulsory licence should be in compliance with Article 31 of TRIPs and result in an appropriate amendment to the compulsory licence provisions in the Patents Act 1990, not an amendment to patentable subject matter in section 18.

Paragraph 3 of Article 27 in TRIPs provides the final possibility for exclusion from patentability:

> *3. Members may also exclude from patentability:*
>
> *(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;*
>
> *(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.*

The ALRC, as have the Courts, has already expressed the view that there need not be an exclusion from patentability in relation to medical treatment. As for the potential exclusion under paragraph 3(b) of Article 27 of TRIPs, the current subsections 18 (2), (3) and (4) of the

Patents Act 1990 address the extent to which the legislature was prepared to incorporate such an exclusion. Clearly the intent is to enable the prevention of the patenting of higher order living creatures, namely, a newly engineered species of plant or animal. It does not enable the exclusion of biological materials from patentability.

Australia is also a party to the Convention on Biological Diversity which includes provisions relating to promoting benefit sharing for indigenous peoples with respect to the utilisation of genetic resources and traditional knowledge. Denying patent protection for biological materials would impede our ability to fulfil our obligations with respect to this Convention. Today, traditional owners such as David Claudie Kaanju, chairman of the Chuulangun Aboriginal Corporation are seeking to develop locally driven enterprises based on traditional medicines. The right to protect the substances that lie at the heart of the efficacy of traditional medicines is an important tool in realising benefits for traditional owners of this knowledge.

The European position

The exclusions under Article 27 of TRIPS reflect general provisions of the European Patent Convention (EPC). The EPC in turn provides a clear statement of what is and is not allowable subject matter and importantly is subject to implementing rules and directives which have been formulated following a lengthy review to specifically address whether genes in particular and biological substances in general as well as their uses and methods of production should be patentable.

Article 52 of the European Patent Convention provides:

> *(1) European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.*
>
> *(2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:*
>
> *(a) discoveries, scientific theories and mathematical methods;*
>
> *(b) aesthetic creations;*
>
> *(c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;*

(d) presentations of information.

(3) Paragraph 2 shall exclude the patentability of the subject-matter or activities referred to therein only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.

Article 52(2)(a) EPC is interpreted in accordance with implementing Rule 23e(2) EPC which states:

"(2) 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"

Directive 98/44/EC of the European Parliament and the Council on the Legal Protection of Biotechnological Inventions issued on 6 July 1998. This Directive provides a lengthy summary of the diverse factors recognised as material to the question of how protection for biotechnology should be addressed including the importance of the biotechnology industry and the economic rationale for rewarding innovation, the need for harmonisation, certainty and consistency with international obligations, the need for the law to be robust to accommodate developing technology and at the same time to offer adequate opportunity for ethical concerns, human health needs and the protection of biodiversity to be addressed.

Amongst its provisions the Directive includes the following in relation to the patentability of biotechnological inventions:

For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

and

Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

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 application.[4]

The European Union has had in place for over a decade a very clear acceptance of the principle that genes are fit subject matter for pant protection.

Conclusions

The scope of the proposed amendment is at once both too narrow and too broad to address the societal concern that it purports to answer. This leads to the conclusion that the true purpose of the amendment is to create an exclusion from patent eligibility for discoveries. However, that exclusion already exists. The language of the Patents Act that relates to patentable subject matter is intentionally broad. At the same time it is constrained by specific requirements of novelty, inventiveness and utility that prevent patenting of inventions based on natural phenomena or discoveries where no invention and use is provided.

[4] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML viewed 18 October 2010