The Royal College of Pathologists of Australasia
ABN 52 000 173 231

Durham Hall 207 Albion Street Surry Hills NSW 2010 Australia
Telephone 61 2 8356 5858 Facsimile 61 2 8356 5828

RCPA
The Royal College of Pathologists of Australasia

# ALRC Inquiry – Gene Patenting & Human Health – Issues Paper No. 27
# Response from
# Genetics Advisory Committee
# The Royal College of Pathologists of Australasia
# October 2003

## Chapter 4: Ethical, Social and Economic Dimensions

**Q. 4-1** – *What are the principal ethical and social concerns in Australia about patents on genetic materials and technologies*?

The explosion in genetic information and technology has the potential to revolutionise health care in the coming decades. Genetic medicine will inevitably shift the focus of medical practice in developed countries more towards disease prediction and prevention. Ultimately, this should improve the quality and rationalisation of health care. It also has the potential to make billions of dollars for the companies involved.

**Much of the current concern regarding the potential adverse effect of gene patents stems from the increased commercialisation of biomedical science during the past 20 years.** This shift has resulted in a blurring of the distinction between not-for-profit science (previously conducted largely by universities and public hospitals) and for-profit science (previously mostly conducted by private companies). Spurred by government policy, previously wholly academic institutions, mainly in the US, have adopted business-like practices and have spun off numerous biotech companies. Underpinning these ventures are patents on genetic materials and technologies, derived largely from publicly funded basic research. A wave of new diagnostic and therapeutic inventions, based on genetic research is coming to the market. Their development has been funded in large part through private capital. These academic institutions and private companies have developed new strategies and business models for legitimate commercial exploitation of their patents, which aim to take maximum advantage of the very broad claims often included in their patents. While many of these new products will be highly beneficial, some of the new commercial practices also threaten the optimal provision of genetic healthcare and the integrated clinical services in the public sector. These largely unforseen consequences are the direct result of the imbalance between the commercialisation of science and the provision of public health care. This requires governments to devise new ways to protect public health interests from commercial excesses that arise from regulatory oversight.

A major concern regarding the commercialisation of research is that it results in disproportionate effort being placed on discoveries and inventions that would maximise short-term profits to the investor by targeting large, potentially lucrative markets, rather than on discoveries that would maximise long-term benefit to society. This exacerbates the disparities in the availability of diagnostic tests and treatments across socio-economic and ethnic groups within countries and between developed and developing countries. In addition, research into “genetic solutions” can overshaddow research into disease prevention in less glamorous, but more important, contributors to disease prevention. It is worth remembering that modifiable behavioural factors such as obseity, inactivity and smoking account for over 70% of cases of stroke, 80% of coronary artery disease and over 90% of adult-onset diabetes in developed countries and that infectious

diseases account for the majority of disease morbidity and mortality in the developing world. Overall, genetic factors account for a small proportion of human suffering. There can be little doubt, therefore, that humankind would receive much more benefit if the private funds currently invested in biotechnology were instead spent on basic public health.

**The principal ethical, social and economic issue in relation to gene patenting is to ensure that the patent process facilitates a balanced and sustainable outcome over the long term for both commercial and societal interests.** Balance is crucial because if patent protection is too weak, the development of technology or products may be inhibited by lack of incentives for investment. If patent protection is too strong, consumers may not gain sufficient benefit while the patent owner may gain profits that are far in excess of a reasonable reward for the research and development.

**In the context of genetic health, these concerns relate primarily to equitable access to affordable genetic testing and therapies for those who require them**. The challenge is to balance public access to genetic health services with appropriate commercial returns for socially beneficial research. **A major concern regarding gene patents is the <u>potential</u> for commercial patent holders to create genetic monopolies.** The potential for abuse of monopoly power will increase if a handful of large biotechnology companies emerges from existing small and medium-sized biotechnology firms. Commercial monopolies are the anti-thesis of public health because they serve the commercial interests of shareholders rather than the public.

**A patent holder's absolute control of diagnostic methods is not in the public's best interest**. The general public, however, is presently oblivious to the extent of genetic patenting and its potential impact (positively and negatively) on healthcare delivery. About 127,000 human genes and gene sequences are now covered by patents or applications for patents – about four times the number of human genes. To date, very few have had an impact on the delivery of clinical services but this is beginning to change. It is only in the last year that the possibility of enforcement of genetic patents in Australasia has brought the matter of gene patents to public attention. This has revealed that there is concern that patent laws may fail to provide the balance required. The public are not fools. They recognise that commercialism ultimately distils down to power and profit dictating priorities and products. They sense that big money is now calling the shots and that our public institutions are slow to respond to their needs and concerns. This feeling of disempowerment has been an important element in the rise of negative public sentiment in relation to the impact of genetic technology (eg genetically modified organisms) on human nutrition and the environment.

Holders of gene patents and licenses need to recognise that they have ethical and social responsibilities and be responsive to government, health care provider and community concerns as well as their shareholders' interests. Socially responsible patent and license holders strive to return a reasonable profit without disrupting the existing healthcare framework and by maintaining equitable and affordable access to testing. Size appears to be an important factor which seems to dictate how patent and license holders behave. Large pharmaceutical and biotechnology companies and universities are able to balance their patent portfolios to return a reasonable and sustainable profit (eg Roche PCR patent, Stanford University's Cohen-Boyer patent on recombinant DNA) without impeding research or health care provision. Smaller biotechnology companies (especially single patent holders) do not have this luxury and their economic reality and commercial aspirations sometimes force some to adopt more aggressive practices (eg exclusive testing licenses, monopoly laboratories, higher license and royalty fees, and to threaten legal proceedings for alleged patent infringement) that limit choice and affect equitable and affordable access to research tools and clinical testing.

The debate relating to gene patents is one manifestation of the collision between forces of intellectualism and commercialism. Intellectualism encourages freedom of enquiry and freedom to innovate and requires uninhibited access to information, reagents and methods. Commercialism encourages secrecy and requires protection of intellectual property. This difference is exemplified in the polarised philosophical viewpoints of the public vs private agencies involved in the Human Genome Project.

Government, business, legal, healthcare, research and community leaders need to engage the community in informed debate about how this balance can be best achieved. If we fail to do this, commercial interests will prevail and there will be a backlash from the neglected and uniformed elements of society.

**Q. 4-2** – *Should ethical and social concerns about patents on genetic materials and technologies be addressed through the patent system? Are there other or better approaches for dealing with these issues?*

**The patent system is an indispensable component of economic prosperity and technological advancement.** It has provided enormous benefit to society. It is also a tried and tested system and works well most of the time.

**The monopoly power provided by patents can act against the public interest by hindering further research and innovation and by restricting access to health care**. This is exemplified by the failure of pharmaceutical companies to make affordable anti-retroviral therapies available to HIV-infected individuals in developing countries, until recent international criticism forced them to do so.

International bodies, such as UNESCO, have expressed concern about the morality of patenting human genetic material. This debate, however, has failed to influence patent policy in any meaningful way. The prime reason is that intellectual property law in many countries is not structured to handle social policy considerations. As long as patent applicants satisfy the technical requirements of their region's patent office, a patent will be issued. The European Patent Convention, however, does prohibit patentability where the commercial exploitation of an invention would be contrary to "order public" (public policy) or morality. Such provisions, however, are intended to prevent major moral transgressions, such as the development of biological weapons and to prohibit the cloning of humans, rather than to ensure equitable access to health care.

Since the patent system is essentially a social contract, it is important that it is perceived to be socially beneficial. The patent system, however, is a purely legal process and takes no account of moral, ethical or economic considerations. At present, societal concerns resulting from the misuse of patents seem to fall into "no-man's land". Society requires a system of checks and balances to ensure that the power provided by a monopoly is not misused or abused. Any attempts to address societal considerations by altering the patent system, however, could remove incentive and therefore discourage legitimate and socially responsible commercial interests. This could have unforseen and devastating consequences. Any changes to the patent system would therefore have to be made with great care and foresight.

**It is probably wiser to protect society from the occasional misuse or abuse of monopoly power by imposing conditions or restrictions on the use of gene patents and by enhancement of defences, exemptions and "downstream" regulations rather than alter the patent process itself.**

**Q. 4-3** – *Is there any need to make special provision for individuals or groups whose genetic samples are used to make a patented invention to benefit from any profits from the patent? Are there any separate or special considerations that apply in this context in relation to indigenous people?*

Patients and patient groups are becoming more active in the promotion and facilitation of pre-clinical and clinical research. Various groups have started foundations for the funding of research, compiling disease-specific registries of patients and genealogical and medical databases, establishing tissue and DNA banks to provide resources crucial for genetics research, and developing scientific expertise that can make substantive contributions to the direction and performance of research. The motivation behind these contributions as well as the commercial interests have not been fully recognised by researchers and research organisations (Merz *et al*, Am J Hum Genet 2002;70:965-971).

There is evidence that some individuals and groups feel aggrieved at the patenting of their genes. 150 families from around the world, with children afflicted with Canavan disease, participated in an extensive research collaboration with researchers at the Miami Children's Hospital (MCH), which eventually led to the discovery of the aspartoacylase gene in 1993. These families participated in the studies, helped identify, solicit and collect blood samples from other affected families, and secured funding support from various religious groups, charities and Foundations. They also facilitated access to 6000 stored blood samples to estimate the population frequency of the mutation in the Ashkenazi Jewish population. Unbeknownst to the families, the researchers at the MCH secured in October 1997, US patent 5,679,635, which covered all diagnostic and therapeutic uses of the gene. MCH then embarked on what the families believed to be a restrictive and unduly expensive licensing programme. (Merz *et al*, Am J Hum Genet 2002;70:965-971). In October 2002, some of the families and organisations involved filed a suit against MCH in an attempt to prevent continued use of the patent in the manner they believe was immoral, unfair to those who made the research possible and likely to restrict access to the test (Greenberg v Miami Children's Hospital 2000). This dispute arose because gene patents create a conflict of ownership.

In the mid-1990's, a patient affected by psuedoxanthoma elasticum (PXE) created PXE International. The Foundation helped identify and solicit participation from affected families, established a registry and a biorepository, and raised money to support studies through the use of these resources. PXE International negotiated with researchers to whom they provided support and access to biomaterials for research and, through the use of Material Transfer Agreements, retained authorship in any papers and ownership rights in any patents to ensure broad and affordable downstream development (Merz *et al*, Am J Hum Genet 2002;70:965-971). The gene implicated in PXE was identified in 2000.

These two examples get to the heart of the paradox about "who owns your genes". All individuals have natural ownership of their genetic material, which they share with their genetic relatives and ultimately with all life. According to the principles of patent law, because genomic DNA is a naturally occurring substance, it is not patentable. Yet, tens of thousands of patents have been granted on DNA sequences that are identical to their natural form. These patents effectively confer ownership rights because they allow these sequences to be used, sold, traded, licensed and can be used to prevent others from doing so. The effect is that gene patents rob individuals of their natural ownership of their genetic material. Individuals, their families and their healthcare providers understandably become concerned when this limits access to genetic testing or genetic therapies.

The current stakeholders in genetic research include patients and families, disease-associated advocacy groups, foundations, government agencies, medical practitioners, hospitals, researchers, universities, biotechnology firms and pharmaceutical companies. All have common goals - the discovery of the genetic causes of disease and the broad availability of testing to patients and ultimately the development of treatments or cures. However, the various stakeholders have varied motives and incentives for performing, funding, participating in and promoting research. It is important to understand those interests so that strategies can be developed that best satisfy all of the parties. It is clearly unacceptable to presume that all stakeholders are pure altruists, as some policies and practices now do presume, especially when these stakeholders have contributed in some meaningful way to the research enterprise. It is unfair to these stakeholders for their "investments" to be wholly appropriated by universities and companies with no commitment to return to the community something of value that they can both access and afford (Merz *et al*, Am J Hum Genet 2002;70:965-971). Such views are in agreement with recent policy statements issued by the Human Genome Organisation (HUGO) (Science 2000;290:49).

There are ethical, moral, practical and economic concerns with a general claim that subjects should share in the financial rewards of research: subjects often stand to benefit indirectly as consumers, it may be unmanageable to provide individuals with any share in potential profits, the burden of such royalties might impede downstream research, and the contribution of individual subjects may be quite minimal given that they bear little of the risk. Furthermore, financial reward may establish a legal precedent to permit the sale of body tissues, eg kidneys for transplantation.

Entities involved in commercial aspects of research should be expected, as a matter of public policy and research ethics practice, to openly negotiate with individuals, foundations, disease associated advocacy groups to resolve issues of ownership, downstream control, limits on financial profit sharing and other acknowledgements of all contributions before the research is done. These processes should be incorporated into national guidelines (eg those of the National Health and Medical Research Council (NH&MRC)) on the ethical practice of research.

Furthermore, any use of human genetic samples from indigenous Australians must take into account their cultural values and wishes.

## Chapter 5 : Funding for Research and Development

**Q. 5-1** – *What are the implications of the grant of gene patents to institutions or companies whose research was publicly funded for: (a) encouraging further research into human health: or (b) maintaining cost effective health care in Australia?*

Governments rightly seek to boost commercialisation of basic biomedical research where there are health benefits. This is accomplished by various funding mechanisms and incentives.

The US Bayh-Dole Act (1980), which allows recipients of government funding to patent their inventions, is seen as being a major factor in the emergence of the biotechnology sector in the US and their dominance in the market. It is an excellent example of a social contract between government and inventors that has had highly beneficial effects. In Australia, an employing organization is still entitled to claim ownership of any intellectual property rights arising out of its

employees' research. This provides no/minimal incentives for individual researchers to develop their basic research into a commercial product.

To ensure that patent holders behave in a socially responsible manner the National Institute of Health (NIH) in the USA has promoted guidelines to discourage restrictive licensing and anti-competitive practices. **Similar guidelines should be developed in Australia, perhaps sponsored by the NH&MRC.**

**Consideration should also be given to exempting non-commercial research and public genetic testing from patent infringement for inventions arising from publicly funded research.**

There is an urgent need to clarify the attribution of priority when a patent is awarded to an inventor who was the "first to cross the line" in a research endeavour that involved multiple researchers, often in different jurisdictions, funded by a variety of public and private sources. For instance, *Myriad Genetics* obtained the BRCA1 patent but much of the break-through work was performed within, and was funded by, the public sector.

**Q. 5-2** – *Should holders of gene patents that have implications for human health pay a levy on any royalties with such royalties to be used for future genetic research or for health care infrastructure? If so, should it make any difference whether or not the research leading to the patent was publicly funded?*

There is no need to invoke a levy for gene patents related to health care. Firstly, it makes much more sense to directly reduce or limit royalty and license fees. Secondly, it would be inequitable compared to other technologies.

**Q. 5-3** – *In the United States, the government retains certain residual rights to intellectual property developed from publicly funded research. These include 'march-in' rights, the right to a government use license and the right to limit exclusive licenses. Is there any need in Australia for these or similar rights to be a condition of public funding of genetic research with implications for human health?*

Yes. The US government retains march-in rights to allow government to use patented inventions, funded by public funds, for the public good. This includes government-use licenses to exempt government from license and royalty payments, the right to limit exclusive (anti-competitive) licenses and to take title when the patent holder is slow to translate the invention for public benefit.

**Considerations should be given for the Australian Government to retain similar march-in rights for publicly funded research (eg via the NH&MRC).**

**Q. 5-4** – *What are the implications of the government retaining intellectual property in any contracted genetic research with implications for human health?*

As the employing agency in contracted genetic research the government should retain IP rights. Government agencies (e.g. CSIRO) are, however, not necessarily the most suitable vehicles for product development and commercialisation.

Governmental and other agencies often use patents to block commercial interests from creating a monopoly e.g. the UK charity, *Cancer Research Campaign*, awarded the NHS free access to its BRCA2 patent and was able to block *Myriad* from enforcing its rival patent in the UK. Likewise, following the recent outbreak of SARS, the Centre for Disease Control (CDC) in the US lodged a patent application covering the sequence of the coronavirus responsible. Their motive was not commercial advantage; it was simply to ensure that the viral genome was freely available to researchers and public health laboratories everywhere. The CDC clearly recognise the potential for gene patents to limit vital research in public health.

**Governments and government agencies should therefore retain all IP resulting from publicly funded research that relates to public health.**

## Chapter 7 : Gene Patents and the Healthcare System

**Q. 7-1** *Do gene patents pose any distinct problems of cost for the Australian health care system beyond those applicable to new technologies generally?*

It is important to acknowledge that patent law does not apply uniformly to health care technologies and to recognise that gene patents may need to be treated differently. Medical skills (eg clinical examination, surgical procedures, histopathological evaluation) are a form of biotechnology that cannot be patented. Should this also apply to genetic testing?

One major difference between gene patents and those on pharmaceuticals, diagnostic tests/kits, radiological equipment etc, is that the latter can be improved and invented around. A fundamental tenet of patent law is that full disclosure permits others to try to improve the invention. DNA however, is so elemental that it cannot be improved or invented around. (Who can create a better BRCA1 gene?).

The other major difference is the relative ease of developing genetic tests compared to other technologies such as pharmaceuticals. The cost of developing, evaluating, manufacturing and marketing pharmaceuticals is so large that it requires rigorous IP protection and a secure monopoly. Genetic information and materials required to perform tests for most mutations in most genes are freely available from public domain databases or readily purchased from commercial suppliers. Genetic testing is therefore on a much smaller scale and can be established in virtually any accredited laboratory. Does this investment require the same degree of monopoly protection as for pharmaceuticals?

**Q. 7-2 -** *What specific problems do gene patents and future developments in genetic technologies pose for the cost and funding of genetics services?*

Gene patents *per se* do <u>not</u> pose a distinct problem to Australian health care. The potential problems arise from the way in which the monopoly power granted by patents is <u>used</u>.

Provided that genetic testing occurs in an open environment, fostering healthy competition between private sector companies and public sector organisations, then the competition will help keep costs manageable and access reasonable. Patents that preclude competition, research and innovation, whether they are patents on genes or any other item, can only harm the community.

A major problem facing clinical genetics services in Australia is the division of funding and responsibility by the State-Federal model of health care service delivery. The States are responsible for the costs of public health care, but the Federal Government is responsible for the operation of Australia's patent laws. The Federal Government is shielded from the immediate financial impact of decisions about the patentability of genes. The States will feel the impact more immediately but lack the responsibility for addressing the matter. The same issue lies at the heart of difficulties in developing a national genetics program. The Provincial Governments in Canada ran into the same problem when *Myriad Genetics* sought to enforce the BRCA patents in Canada. The Canadian Federal Government wouldn't act, and the Provinces were forced to act individually because of the financial and social costs involved.

Concern has been expressed about the potential for the enforcement of "non-coding DNA" patents held by *Genetic Technologies Limited* to adversely affect the delivery of genetic testing in New Zealand. The royalty and license fees requested from Auckland Hospital by *Genetic Technologies* (as reported by *Four Corners*) would be a significant proportion of the annual budget of many Australian diagnostic genetics laboratories. If Australian laboratories were to receive similar requests for payment, it would be difficult, in the College's view, for them to sustain a fee of that magnitude and continue to deliver their services.

A major problem likely to be experienced by diagnostic genetics laboratories in the next few years will be the difficulty of obtaining and paying for licenses to use gene patents to screen genomes for haplotypes and expression profiles. These tests will examine thousands of genes simultaneously. Thousands of individual licenses will have to be obtained from numerous separate companies. The administrative burden alone will be prohibitive.

**Q. 7-3** – *What steps, if any, should be taken to facilitate the economic evaluation of the impact of gene patents on the cost of genetics services and other healthcare in Australia?*

There are no national programs in clinical genetics and hence no vehicle for national evaluation of issues such as this. All of the costing analyses in clinical genetics services are being done with very limited resources at the level of individual laboratories and States.

**There is an urgent need for a national approach addressing service delivery and evaluation in clinical genetics.** This program should include, but not be limited to, economic evaluation of the impact of gene patents on the delivery of clinical genetics services.

The OECD is reported to have concluded: "The few examples used to illustrate theoretical economic and legal concern [about gene patents] … appear anecdotal and are not supported by economic studies" (paragraph 10.47). It is true that there have been limited studies of the impact of gene patents on health care. However, there has been limited opportunity so far for gene patents to impact on health care. This is a new field and the advent of genomic medicine is very much in its infancy. It is inappropriate to suggest that a lack of evidence about the adverse impact of gene patents represents evidence of a lack of adverse impact of gene patents. It is essential that there be careful evaluation of the <u>potential</u> impact of gene patents on the delivery of health care. History is not necessarily a useful guide in a new discipline.

## Chapter 8 : Overview of Legal Framework

**Q. 8-1** *Do applications for gene patents raise special issues that are not raised by patent applications relating to other types of technology? If so, what are those issues and how should they be addressed?*

There clearly have been specific issues relating to the issuing of gene patents. This is exemplified by the US Patent and Trademark Office (USPTO) largely ignoring, in their granting patents on genes in the late 1980s and early 1990s, the requirement that a patent have substantial and specific utility. Recognizing that many of these patents, mainly those on ESTs with no known function, lacked utility the USPTO revised its utility guidelines specifically for gene patents.

There has been widespread concern that the USPTO has been too generous in its interpretation of novelty and inventiveness and too expansive in defining the scope of patents. This generosity flows to other nations who are required to follow suit because of their obligations under various international agreements that harmonize patents. These concerns need to be addressed by ensuring that patent offices apply the above criteria stringently and consistently.

**Q. 8-2 -** *Under Australian law, two types of patent protection are available—a 20-year term for a standard patent and an eight-year term for an innovation patent. Should the duration of gene patents be limited to a term less than 20 years? Would this conflict with Australia's obligations under the TRIPS Agreement? (See also Question 9 - 1.)*

The College has no specific comment to make.

**Q. 8-3 -** *Under the Patents Act 1990 (Cth) (Patents Act), in order to accept a standard patent application (or certify an innovation patent), an Australian patent examiner must be 'satisfied' that an invention is novel and inventive (or innovative) and must 'consider' that no lawful ground for objection exists. Should the threshold for acceptance of an application for a gene patent be raised? If so, what should the threshold be?*

This probably lies at the heart of many of the controversies arising from gene patents. The goal of patent officials is to apply the technical rules of patent law to permit the greatest number of patents. As such, the criteria that determine whether a patent application should be denied are generally narrowly interpreted.

The requirement that the examiner be "satisfied", "consider" and decide on "the balance of probabilities" appears to be too lenient. From an administrative perspective such lax guidelines allow the examiner discretion and flexibility. However, it also permits mistakes and misjudgements as well as omissions, and misinformed or deceptive patent applications to go uncorrected. More stringent criteria, based on objective evidence, clearly need to be developed and implemented. If a patent application is judged to be novel or inventive then the examiner must be certain, not satisfied, that this is indeed the case.

Do patent examiners have sufficient specialised knowledge and training to make informed decisions in complex areas such as biotechnology? This is especially pertinent when an application makes an excessively broad claim or does not fully disclose all prior art. Similarly, how are the various contributions to be attributed when an application overlaps with, builds on or

pieces together several pieces of prior art? Do these new applications eclipse all previous patents? These are not simple issues and require depth of knowledge and breadth of experience.

**Q. 8-4 -** *Are the mechanisms available under the Patents Act to challenge an accepted patent application or a granted patent (ie, opposition, re-examination and revocation) adequate in relation to gene patents and applications? What additional or alternative mechanisms might be required?*

The opposition, re-examination and revocation procedures are all effective mechanisms, however, they are not easily accessible. The process can be expensive and time consuming. Smaller organizations and companies are much more likely to make a pragmatic commercial decision to cease the alleged infringement activity or pay the requested licenses and royalties even though they may believe the patent to be invalid or illegitimate.

A very serious issue is the availability of "patent insurance". A patent holder can take out patent insurance on the grounds that a hostile challenge from a larger competitor could spell ruin. Patent insurance, however, can also be used to defend a weak patent, even one that should never have been issued in the first place. Once a patent-holder takes out patent insurance the merit of the patent becomes immaterial – it merely becomes an issue of money. The value of the patent then lies, not in its intrinsic worth, but in the cost of the legal proceedings. A patent holder protected by patent insurance is in a virtually unassailable position compared to small companies or institutions that cannot afford a costly legal battle. What little equality there may be in opposing the patent in the courts is lost. **Patent insurance therefore places much more responsibility on the patent office to ensure that patents are stringently assessed.**

The public sector has additional difficulties with these provisions. When public institutions face an infringement notice or wish to challenge a patent they believe to be invalid they have neither the resources to mount a challenge nor the support of government. Governments are understandably wary of opposing patents as it suggests that their patent laws and processes are flawed, yet they alone have the resources to mount a public challenge that may takes years and millions of dollars to resolve.

**Q.8-5 -** *Does IP Australia have the capacity to scrutinise applications for gene patents effectively? Is there a need for IP Australia to develop new procedures or guidelines in this area?*

The College has no specific comment to make.

**Q. 8-6 -** *Would the administration and enforcement of gene patents benefit from concentrating jurisdiction for patent matters in a single court? If so, how might concerns about the cost and complexity of enforcing gene patents be addressed?*

The College has no specific comment to make.

## Chapter 9 : Patentability of Genetic Materials and Technologies

**Q. 9-1 -** *Would changes to the requirements for patentability under Australian law for inventions involving genetic materials and technologies, or to the application of those requirements to such inventions, conflict with Australia's obligations under the TRIPS Agreement?*

**A key principle of the publicly funded Human Genome Project was that all human genetic sequences be freely available to all people as a resource for research, development, and wonder.**

Dr Francis Collins, Director of the National Human Genome Research Institute in the US, is of the view that genes, except those that encode therapeutic substances (such as insulin), should never have been patented. He is not alone in expressing disquiet about gene patenting. Communities and legislatures in the USA, Canada, and Europe have vociferously opposed the granting of gene patents by their own patent offices.

The fact that gene patents are currently accepted in other jurisdictions does not *per se* indicate that Australia should follow suit. Under Section 27.3 of the TRIPS agreement, Australia does not forgo its right to make its own examination of patent applications and can grant exemptions. Genes could be declared as being exempt from patenting in Australia because gene patents represent a hazard to society. Such an exemption, however, would represent a major deviation from the spirit and the letter of current patent law in Australia and the TRIPS agreement.

**Q. 9-2 -** *How should the novelty requirement apply to applications for patents over isolated genetic materials or genetic products? Are special considerations relevant in assessing the novelty of such inventions?*

Natural materials are only novel in the sense that they had not previously been discovered by humans. Natural DNA sequences are the result of over a billion years of evolution and exist independent of inventors.

**Q. 9-3 -** *In light of the DNA sequencing technology now available, does the identification and isolation of genetic material involve an 'inventive step' or an 'innovative step' under current Australian law? Are the current tests for 'inventiveness' and 'innovation' appropriate for assessing the patentability of genetic materials and technologies? What alternative or additional considerations might be relevant in assessing the 'inventiveness' or 'innovation' of such inventions?*

The invention of methods for sequencing DNA was one of the most significant and revolutionary advances in biological science. The sequencing of genes in the late 1970s and 1980s was a heroic task. Today, all the reagents and equipment required for sequencing known and unknown DNA sequences are commercially available and it can be performed on an enormous scale.

Are the criteria for inventiveness still being met today? The methods for DNA sequencing are now obvious to people working in this field with good knowledge and experience of the subject. The test of inventiveness, therefore, now rests entirely on whether the sequence of a particular gene was not obvious. This test will apply in most instances because the sequence of bases of an unknown gene cannot be known before it was isolated. This, however, is a test of novelty not inventiveness, highlighting the problems and confusion that arise when biological discoveries are (wrongly) regarded as inventions. The issue is further confounded because information from homologous genes in other species, known functions and *in silico* predictions etc can all provide some clues to the sequence of a gene.

The process of identifying unknown DNA sequences is now commonplace and can be easily performed by someone skilled in the art, even if the sequence is novel and non-obvious.

**Identification and isolation of unknown genetic material today is routine and it is, therefore, difficult to justify it as being innovative or inventive.**

**Q. 9-4** - *In applying the 'usefulness' requirement for patentability under Australian law to inventions involving genetic materials and technologies:*

- *Do patent applications claiming such inventions raise specific issues that are not raised by other technologies? If so, what are those issues?*
- *What alternative or additional considerations might be relevant in assessing the 'usefulness' of such inventions? Would it be appropriate to require that inventions demonstrate 'specific, substantial and credible' utility to be patentable?*
- *Should 'usefulness' be considered as part of the examination of a patent application? Should lack of utility also be a ground upon which a patent application might be opposed or re-examined?*

One of the major criteria for patentability is demonstration of utility. **One of the major problems relating to the utility of genes is that we do not know the varied roles of most genes and claims about their actual or potential utility are largely grounded in ignorance.**

Further complications arise because patent law has not firmly established how much knowledge the inventor must possess of the specific function of a novel genetic sequence. The requirement for patents to have substantial and specific utility was largely ignored by the USPTO in granting patents on genes until the late 1990's. Recognising that many of these patents, mainly those on ESTs with no known function, lacked credible utility, the USPTO revised its utility guidelines to require demonstration of utility that was specific, substantial, and credible. With regard to *IP Australia*'s approach, it is important that the criteria for "usefulness" of a genetic patent be the same as the criteria for other patent applications. There should not be special rules regarding the utility of genetic patents.

It seems sensible to include an assessment of usefulness in an opposition or re-examination of a patent – however, it is unlikely that anyone would seek to oppose or re-examine a patent on an invention that was not useful.

**Q. 9-5 -** *In applying the 'sufficiency' and 'fair basis' criteria to applications for gene patents:*

- *Do claims in applications for gene patents raise specific issues that that are not raised by other technologies? If so, what are those issues?*
- *Are any additional or alternative considerations relevant to assessing the appropriate scope of patent claims involving genetic materials or technologies?*

Claims in genetic patents do not raise specific issues that require special consideration. Genetic patents should be assessed using generally applicable criteria.

However, the patent office is not always adequately equipped to assess complex applications relating to genetic materials and technologies. This is especially problematic when an application relates to a claimed method that has broad applicability. If the basic nature of the claim is genuine then such broad claims may be appropriate. However, unreasonably broad claims may be approved as a result of lack of expertise on the part of patent examiners. In the early 1980's the USPTO granted a number of broad patents in the newly developing area of software. They subsequently reviewed and revoked some of these patents because they were recognised as being too broad.

**The patent office therefore needs to maintain specialist expertise in emerging technologies, including genetics.**

**Q. 9-6 -** *Should ethical considerations be relevant in assessing applications for gene patents? If so, should a specific provision to that effect be introduced into the Patents Act 1990 (Cth), or is the current 'manner of manufacture' test sufficient to accommodate such considerations?*

This is difficult. Ideally, gene patents should not be treated any differently from other types of patents. **The existing rules, however, need to be stringently and consistently applied**.

However, there has to be some recognition that the patent offices have been too lenient in issuing gene patents and have potentially created a enormous problem with ethical and social implications. The best way to address these issues is through broadening the defense and exemption criteria for infringement (ie declare that private use includes non-commercial genetic testing of individuals), rather than by incorporating ethical considerations into the patent process.

**Q. 9-7** - *If ethical considerations became relevant in assessing applications for gene patents, who should be responsible for developing guidelines, providing advice, and ultimately making determinations about such issues?*

The proposed Human Genetics Commission of Australia may provide a mechanism for assessing the ethical and societal consequences of certain genetic patents and for implementing and overseeing "downstream" processes.

**Q. 9-8** - *Should isolated genetic materials and genetic products be regarded as 'discoveries' rather than 'inventions' for the purposes of Australian patent law, and thus excluded from patentability?*

**The distinction between a discovery and an invention is an unresolved issue in the current debate about gene patenting.** The word "discovery" means finding something that is already there. The word "invention" refers to the process of using human ingenuity to put something together that could not have existed otherwise.

In Europe and most other countries, patent law excludes the protection of discoveries. In the US, although both discoveries and inventions can be protected under patent statute, in practice the law does not permit the patenting of discoveries. In Europe, the US and elsewhere, a discovery that has a useful application can be protected by a patent if it is claimed as part of an invention.

There are two polarized ideological viewpoints regarding the patentability of genetic material. Both pivot on whether it is inventive to determine the sequence of DNA that has been isolated from its natural state. One view maintains that a novel isolated substance cannot be regarded as an invention because nothing that did not exist before has been created. The BRCA1 gene, for example, could not (and still cannot) be improved, there is no prospect of another person inventing a better version in the future, and there is no conceivable way that it could be made redundant by a new invention. The other view, in essence, argues that a novel isolated substance is an invention because it has been rendered useful.

In 1988, the European Patent Office (EPO), the USPTO and the Japan Patent Office issued the following joint statement clarifying their position on this matter: ”Purified natural products are not regarded as products of nature or discoveries because they do not in fact exist in nature in an isolated form. Rather, they are regarded for patent purposes as biologically active substances or chemical compounds and eligible for patenting on the same basis as other chemical compounds” (Crespi. Bio-Science Law Review 2001; 3; 199-204). Isolated human genes and their variations are therefore deemed to be patentable, if they are of demonstrable utility despite their origin as products of nature. Furthermore, patent offices have chosen to regard each gene as a new chemical compound and to grant “composition-of-matter” patents, which cover the use of the substance for any potential use, even ones not disclosed or known to the patentee. The USPTO rejected the counter-argument that genes should not be treated as novel chemicals but as biological software comprising a programme written in the sequence of the nucleotides and hence subject to copyright rather than patent law. Patent offices have instead taken the view that without isolating a gene, it is not possible to know its sequence. Genetic material, although contentious from a biological perspective, is now well established in law as being an invention.

Overall, this approach is socially preferable because the advancement of genetic science and medicine requires knowledge of the DNA sequence. Arguments that patents on human genes in particular should remain within the public domain have also lost out to the pragmatism of the patent offices.

**Q. 9-9 -** *Should methods of diagnostic, therapeutic and surgical treatment of humans involving genetic materials or technologies continue to be patentable under Australian law? If not, how should the exclusion of such inventions from patentability be justified, and what should be the scope of the exclusion?*

Yes, the College agrees that genetic materials and technologies should continue to be patentable. However, holders of gene patents need to recognize that society has effectively granted them control of access to everyone’s genetic material.

**The RCPA believes that there should be a social contract that guarantees freedom of access or affordable access to genetic sequences for non-commercial research and genetic testing for health care. This could be achieved within the framework of the existing patent system by imposing specific conditions or restrictions, by permitting defense under the “private use” provisions or by governments granting exemptions for performing non-commercial research and genetic testing for health care reasons.**

## Chapter 10 : Licensing and Enforcement of Patent Rights

**Q. 10-1 -** *Is sufficient information available to holders of Australian gene patents to allow them to protect their patent rights? If not, what alternative or additional information or facilities might be required?*

The College has no specific comment to make

**Q. 10-2 -** *To what type of gene patents are Australian companies, researchers, health care providers or other organisations seeking or granting licenses? What uses are being made of such licensed gene patents?*

Most genetic tests are currently developed and evaluated "in house" using commercially available reagents and genetic information that is freely available from public domain databases and publications. A laboratory performing a genetic test that uses patented genetic information may require a license from the patent holder to legally perform that test. However, such licenses are rarely requested by the testing laboratory or demanded by the patent holder. As such, many laboratories may be performing a number of their tests "illegally" and may be leaving themselves open to being sued.

In relation to patents covering genetic materials (ie gene sequences) used in diagnostic genetic testing in Australia, it appears that patent and license holders are not pursuing their rights. Of the 200 or so genetic tests listed on the HGSA website, over 40 are covered by patents filed with the Australian Patent Office (Nicol D. Today's Life Sciences Sept 2003). However, the RCPA is not aware of a single example of an Australian company seeking licenses from, or granting licenses to, Australian diagnostic laboratories. The College understands that *Genetic Technologies* has an exclusive license from *Myriad Genetics* to perform BRCA1 and 2 testing but has issued a statement that this will not be enforced against other laboratories in Australia.

Patents covering genetic technologies (ie methods and reagents) fall into two groups – those with and without products. Most companies sell products and incorporate royalty payments in the product price. In the US, *Bio-Rad* sell a kit for haemochromatosis testing. The company permits laboratories to perform the haemochromatosis test using in-house methods and reagents but charges royalty and license fees that, on a per test basis, are considerably more than the cost of using the test kit. A survey of US laboratories previously performing this test revealed that approximately one third of laboratories ceased performing the test because of patent considerations (Merz et al, Nature 2002; 415:577-9)

Of particular concern are the detrimental effects that could occur if a patent or license holder refused to license, issued cease and desist orders or imposed onerous or unreasonable terms in the license. Such terms may relate to test price, the quantity of tests that can be performed, which laboratories the tests can be performed in, whether further research is allowed to improve the quality or specificity of the test or its applicability to a particular ethnic group and so on. This is a very real concern to most diagnostic genetics laboratories.

**Q. 10-3 -** *Are requests for licenses to Australian gene patents being refused by patent holders? If so, why? If not, are the terms of such licenses fair and reasonable?*

The College is not aware of any refusals to grant licenses for Australian gene patents.

**Q. 10-4 -** *Are gene patents being enforced against Australian companies, researchers, healthcare providers or other organisations? If so, what types of gene patents are being enforced and by what means (for example, with cease and desist letters, offers to license, or the threat of infringement proceedings)?*

A US study (Cho M, J Molecular Diagnostics 2003;5:3-8) identified 12 genetic tests that US laboratories have stopped performing due to patent enforcement. *Myriad Genetics* has effectively

prevented all laboratories in the US, other than its own, from performing BRCA1 and 2 testing. Notably, seven of the 12 tests mentioned above are covered by equivalent Australian patents or are subject to patent applications in Australia. Therefore, Australian laboratories may be exposed to such actions in the future (Nicol D, Today's Life Science. Sept/Oct 2003;22-27)

The RCPA is not aware of any Australian company seeking to enforce gene patents against Australian diagnostic laboratories. The RCPA, however, had been concerned following the announcement by *Genetic Technologies* on October 28 2002 that it had acquired an exclusive license from *Myriad Genetics* to perform BRCA1 and 2 testing and had been quoted in the media as saying that "public clinics providing the screening service were operating illegally" (Watts K, West Australian December 7 2002 and Quinlivan B, Business Review Weekly January 16 2003). Concerns over possible litigation resulted in one Australian public laboratory temporarily ceasing BRCA testing. Subsequently, in July 2003, *Genetic Technologies* issued a statement that it "does not intend to enforce these *Myriad* patents".

Of more immediate concern are *Genetic Technologies'* "non-coding DNA" patents. Various aspects of human genetic research and a number of common genetic tests performed by diagnostic laboratories could infringe these patents. Several Australian organizations have received offers for licenses from *Genetic Technologies*. *Genetic Technologies* has negotiated a range of sums from nominal fees eg $1500 for Sydney University (Smith D, Sydney Morning Herald Aug 4, 2003) to $ $2.5 million for CY O'Connor ERADE Village Foundation ( http://www.gtg.com.au/) from Australian organizations and companies. Concern has been expressed about the potential for the enforcement of "non-coding DNA" patents held by *Genetic Technologies* to adversely affect the delivery of genetic testing in New Zealand (see response to Q7.2).

Ultimately, Australia may be protected by virtue of its small market size, by the fact that most genetic testing in Australia is performed free of charge by public hospital laboratories, and because patent holders might be wary of creating adverse publicity by targeting public institutions. Nevertheless, it is hardly desirable for the cloud of patent infringement proceedings to hover over the delivery of health care services (Nicol D, Today's Life Science. Sept/Oct 2003;22-27).

**Q. 10-5 -** *Are the potential costs involved in litigating patent infringement actions preventing the enforcement of Australian gene patents? Are there any other factors influencing the decisions of holders of Australian gene patents about whether or how to enforce such patent rights?*

The high costs of litigation are an issue for any company contemplating pursuing patent infringements.

## Chapter 11: Patents and Human Genetic Research

**Q. 11-1 -** *Is there any evidence about whether gene patents or licenses are encouraging or inhibiting research in biotechnology in Australia?*

Patent protection is clearly an indispensible aspect of commercial biotechnology. This is best summarised by the well known business maxims "if you can't patent it, don't invest in it", "no

patent - no product" and "technology is only as strong as its patents. " The importance of patents to biotechnology can also be assumed from the maintainance of a pro-patent liberal policy framework.

It is important to distingush between two types of invention or innovation - breakthrough discoveries and those that improve on existing technology by creating a better or alternative product. Prior to 1980 basic "upstream" discoveries, such as the H2 receptor responsible for gastric acid secretion, were considered to be in the public domain. Only specific tests or therapies ("downstream discoveries") that harnessed this basic knowledge, such as H2-receptor antagonists, were patentable. Following a 1980 landmark decision of the US Supreme Court, upstream discoveries such as genetic sequences and genetic variants became patentable. Excessively broad patents, particularly on an upstream discovery, can block or place severe constraints on the ability of others to develop new tests or therapies that build on the patented discovery or invention. There is evidence that such practices have inhibited research in biotechnology (Heller and Eisenberg, Science 1998;280:698-701, Knoppers. Nature Genetics 1999; 22; 23-26).

Many researchers, particularly in academia, assume that basic experimental "upstream" research is exempt from patent infringement. In the US, the so called "research exemption" is rooted in an 1813 case (*Whittlemore v. Cutter* [9.F Cases 1120 D.Mass, 1813]). In approving a jury instruction that defined patent infringement as "the making of a machine fit for use, and with a design to use it for profit, " Justice Story speculated that "it could never have been the intention of the legislature to punish a man, who constructed a [patented] machine merely for philosophical experiments." (Eisenberg R, Science 2003;299:1018-9). However, such gratuitous statements have no binding legal authority which has led to calls for this dicta to be given statutory status (Bruzzone, Am Intell Prop Law Assoc 1993;21:52, Parker, J Int Law 1994; 16:615). The US Federal Circuit, however, has been signalling its discomfort with the experimental use defence for almost 20 years (Eisenberg R, Science 2003;299:1018-9).

The recent ruling in the *Madey vs Duke University* case (No 01-1567, Federal Circuit Court of Appeals, 3 October 2002) is about to turn the long-standing belief in the research exemption on its head. The judgement held that academic research is not "philosophical inquiry" but rather a means to advance the 'legitimate business objectives" of a university that "increase the status of the institution and lure lucrative research grants, students and faculty". It is hardly surprising that the court should hold that such exemptions no longer apply since universities have been increasingly acting like commercial entities, profiting from their own patents and suing infringers. In the two decades since the Bayh-Dole Act, US universities have embraced the patent system as patent owners and have been in the vanguard of claimants seeking patents on "upstream" research discoveries that would have looked far too removed from the commercial marketplace to qualify for patent protection just a generation ago. As their patent portfolios have grown, universities have become more aggressive about enforcing their patents in court. The University of California's $200 million settlement with Genentech (Barinaga M, Science 1999; 286;1655) and the University of Minnesota's $300 million settlement with Glaxo-Wellcome (www1.umn.edu/urelate/newsservice/newsreleases/99_10glaxofacts.html) have emboldened others to follow with their lawsuits. However, universities have barely begun to contemplate the implications of the patent system for their interests as users of the patented technology of others. Generally, it is only when scientists have sought access to materials and data that they could not readily duplicate for themselves that universities have entered into negotiations. They have largely ignored the growing number of patents covering technology that their scientists use without license. While universities have become increasingly aggressive as patent owners, they have left themselves vulnerable to patent infringement claims as defendants. With their endowments and their habit of documenting their activities in scientific publications, universities

might make worthwhile and easy targets (Eisenberg R, Science 2003;299:1018-9). The full impact of this development is not yet known but it has the potential to significantly inhibit research if the payments requested of universities by patent holders are too high.

There is evidence that Australian patent holders have already begun requesting Australian researchers for royalty and license fees for research tools and methods once considered free for the picking. It has been reported that *Genetic Technologies* has sent letters to several Australian academic institutions requesting royalty and licence payments for use of their "non-coding DNA" patents, prompting leading international reseachers to criticise this practice (Smith D, Sydney Morning Herald, July 8, 2003).

So far there has been no documented adverse effect in Australia, however, the field is very new and there has been little time to observe such impact. It is not, however, appropriate to stand back and wait for problems to occur. Given overseas experience, it is particularly important that legal review be fostered pro-actively with a view to avoiding problems because it takes years for such processes to be completed. The failure to tackle similar issues rapidly in the late 1980s and early 1990s led to thousands of gene patents being filed and granted before the patent offices awoke to issues that have now been addressed with revised guidelines for patent examiners (e.g. new USPTO Utility Examination Guidelines were issued on 5 January 2001 [USPTO Fed Reg 66:1092, 5]). It will be difficult (if not impossible) to "wind the clock back" and have gene patents of unspecified utility or inadequate specificity revoked. The ALRC must learn from the overseas experience and evaluate not only the previous or current problems but also the potential problems. If we are to avoid retrospective legislation in an attempt to address problems after the event, then the ALRC must take a pro-active stance in looking for problems that have yet to arise. Given the ingenuity of Man and the billions of dollars at stake in genomic medicine, there is no doubt that problems can and will arise.

**Q. 11-2 -** *Do any of the following affect biotechnology research into human health in Australia: (a) broad patents over isolated genetic materials; (b) patents over expressed sequence tags (ESTs) of unknown utility; (c) patents over single nucleotide polymorphisms (SNPs); or (d) a multiplicity of patents (sometimes known as 'patent thickets')?*

Broad patent rights over genes and their mutations make it difficult for alternatives to be developed. This occurs because the broad patents granted on genetic material extend to all modes of diagnostic testing for that and any other disease associated with the gene, including methods that are subsequently discovered or invented by others. One US survey has suggested that research on genetic testing has been inhibited by patents on DNA sequences. Half of all research laboratories surveyed had ceased to pursue research because of existing patents (Cho, In Laboratory Medicine for the 21$^{ST}$ Century. 2$^{nd}$ ed. AACC Press, Washington DC, USA 1998;47-53). Broad claims, therefore, discourage others from undertaking research to identify new mutations and disease associations and from investing in improved testing methods. It would have been far more preferable for patent protection to have been applied not to the gene, but to specfic diagnostic methods. This would then provide an effective means of rewarding the inventor while providing an incentive for others to develop better alternatives.

A major concern is the potential for the extension of patents on ESTs to patent applications involving full length DNA sequences (containing the previously filed EST) of known biological function. This is because composition of matter patents extend to all potential uses of an invention including those subsequently developed by others. Research and development on the full length DNA sequence may, therefore, be inhibited by such "dependent patents" when they are held by different owners. The Human Genome Organisation has called on patent offices not to

issue patents on ESTs without having found a balanced solution to this problem  The College is not aware of any patents on ESTs that are affecting biotechnology research into human health in Australia. It is our understanding that very few patents on ESTs have actually been granted and that none have been challenged in court (Bobrow and Thomas,  Curr Opinion Molec Therapeutics 2002;4:542-7).

The SNP Consortium, a collaboration of several pharmaceutical firms and the UK Wellcome Trust (Masood, Nature 1999;398:545-6), is one mechanism researchers have found to overcome "patent thickets". Consortium members place commonly used SNPs in the public domain with the aim of  preventing research into the human genome from being impeded. Nevertheless, it is highly likely that patent applications will be filed to protect the "association" which links SNPs to particular coding region alleles or mutations. Many such associations, however, may be already covered generally by the "non-coding DNA" patents held by *Genetic Technologies.* These patents cover the use of PCR to amplify unspecified non-coding DNA regions containing at least one polymorphism and their use in genetic linkage, haplotyping and mapping. They are of particular concern because their breadth is enormous, applying to 97% of the human genome as well as to the non-coding regions of the genomes of all other eukaryotic species.

Royalties charged for gene tests affect cost and availability of clinical diagnostic testing. These are often in addition to substantial up front payments for permission to perform the test. Mostly the royalty fees are modest (eg $US20 for haemochromatosis testing). Of particular concern is the effect of multiple royalty payments on a single gene or royalty payments on multiple genes being tested for in certain ethnic groups.  Such "royalty stacking" occurs for laboratories that offer a panel of tests such as those for the Ashkenazi Jewish population, including testing for Tay-Sachs disease, Gaucher's disease, Niemann-Pick Disease and Canavan's Disease.

**Q. 11-3 -** *Is there any evidence that licenses granted to researchers in relation to patents over genetic materials or technologies encourage or hinder research into human health? Is there any evidence that materials transfer agreements encourage or hinder research into human health?*

Refer to response to Q. 11-1.

**Q. 11-4 -** *Does the recent amendment to the Patents Act 1990 (Cth), which permits a 12 month grace period before filing, encourage the publication of scientific results? Does the grace period overcome the problem of secrecy or delay in publication?*

The College has no specific comment to make.

**Q. 11-5 -** *Is there any need for Australian guidelines similar to those published by the United States National Institutes of Health to ensure that research is not being withheld from the public domain?*

The College has no specific comment to make.

**Q. 11-6 -** *Is publicly or privately funded research being impeded because of lack of access to data about human genetic material? If so, does the National Health and Medical Research Council's Celera Subscription provide an appropriate model for seeking to increase Australian researchers' access to information about the human genome?*

The College has no specific comment to make.

## Chapter 12 : Gene Patents and Healthcare Provision

**Q. 12-1 -** *Do existing patent laws and practices favour the development of genetic testing monopolies in Australia? If so, are reforms needed and what should they be?*

Existing patent laws and practices do favour the development of genetic testing monopolies in Australia. Exclusive licensing results in the patent or license holder effectively controlling access to and use of genetic material. There is, however, little empirical data about the effects of patents on the translocation of genetic discoveries into medical advances, so it is not clear how justified these concerns might be. The following examples describe some of the observed adverse effects of genetic monopolies:

- **grant patent holders the ability to dictate standards of care for genetic testing**

Ultimately, commercial considerations will dictate priorities and products, not the public need. Patents grant companies the ability to dictate what kind of test may be done (eg sequencing instead of less sensitive but substantially less costly screening methods such as dHPLC or protein truncation tests) or limit the conditions in which testing may be done (eg refusing to perform prenatal testing for late-onset diseases).

- **restricting research on disease genes by other parties**

Freedom to undertake research on disease genes is critical to genetic health care. A lot of clinical study is needed to validate and extend the early discovery of a disease gene and much of this data emerges naturally from broad medical adoption of genetic testing. In respect of *Myriad's* patents, European researchers discovered that deletions account for approx 28 % of all BRCA1 mutations associated with breast cancer risk in Dutch families (Hogervorst *et al*. Cancer Research 2003;63:1449-53). In other nations, including Australia, such exon deletions may account for 5-10% of all the mutations identified in the BRCA genes. These mutations may have remained undiscovered had *Myriad* successfully enforced its patents in Europe because *Myriad's* testing methodology is unable to detect these deletions.

The function and diagnostic utility of a gene may not be apparent to the patent holder. There are many examples of genes whose functions have taken years to untangle. At first, *Human Genome Sciences* did not appreciate the relevance of their patent on the CCR5 gene in relation to AIDS research and treatment. Had this research not been performed by another laboratory, in defiance of the patent, this may have gone undiscovered.

- **restriction of access to research materials**

In a national survey of data withholding in genetic research in the US (Campbell *et al* JAMA 2002;287;473-80), 47% of geneticists who asked colleagues for additional information, data or materials regarding published research reported denial of at least one request in the preceding three years. In 28% of cases, the respondents were unable to replicate the published research as a direct result of this refusal to share information.

- **loss of consumer choice**

Take, for example, the situation where a particular test is licensed exclusively to a limited number of commercial genetic laboratories within specific geographic regions. An exclusive licensing practice effectively creates a diagnostic monopoly. For example, in North America, it is our

understanding that *Myriad Genetics* requires all diagnostic BRCA gene testing be done at its laboratories in Utah. Licenses to test these genes have not been provided to other laboratories.

- **loss of competitive pricing of the gene test**

In Canada, the cost of BRCA gene testing by the public sector laboratories was 2-3 times less than the cost of testing through *Myriad Genetics*. The likely effect of such pricing on publicly funded genetic services would be to significantly reduce the number of tests available.

- **loss of access to testing**

For example, when *Myriad Genetics* enforced the BRCA gene patents in Canada, the public health services in British Columbia determined that it could not bear the increase in cost and ceased to offer testing. More recently the Province has started testing of the BRCA genes again, choosing to act in defiance of the patents rather than pay the prices requested.

Another example concerns Haemochromatosis which is the most common genetic disorder in Caucasians and is readily treated by regular phlebotomy. Accordingly, there was very rapid adoption of testing by US laboratories soon after the cloning of the HFE gene was published and before the patent was issued. In October 2001, the current patent holder, *Bio-Rad* began offering a kit for haemochromatosis testing and negotiating licensing terms with laboratories that perform testing without its kit. A survey conducted during this period revealed that 30% of laboratories that had set up HFE testing stopped testing due to concerns regarding patent infringement (Merz *et al*, Nature 2002; 415:577-9).

- **disruption of testing from clinical and counselling services.**

Mandatory referral of samples to licensed laboratories disrupts the normally close relationship between clinical genetic and laboratory services. This is especially important for complex genetic disorders. Notably, the NH&MRC and HGSA both recommend that genetic testing should be performed according to best practice guidelines, which include the use of laboratories with close links to clinical genetics services.

- **inhibition of further development of tests on the gene**

License terms often exclude the development and use of complementary or alternative technology.

For example, several diagnostic laboratories in Australia are now offering tests for BRCA1 deletions. These tests are performed using affordable kits ($35 per test) that are commercially available from Europe. Not all American women are tested for these mutations because all BRCA genetic testing in the USA is provided by *Myriad Genetics*.

Another example is the two common mutations that account for 99% of the cases of haemochromatosis in Caucasians. Different mutations are more prevalent in other ethnic groups and these communities require different tests. The kit developed by *Bio-Rad* only tests for the presence of the two Caucasian mutations, but does not detect the rarer mutations.

- **lack of data about the prevalence and penetrance of genetic variants in populations.**

Interpretation of genetic test results and the prediction of the risk of developing genetic disease require detailed knowledge of the prevalence and penetrance of genetic variants. This often varies by ethnic population. If there are no readily available assays to test for a variety of mutations in the haemochromatosis gene, then research into the frequency and impact of mutations in haemochromatosis in different ethnic groups will be curtailed.

*Myriad Genetics* has accumulated a database on 10,000 cases with BRCA1 and 2 mutations. This data has been published in limited form (Frank *et al*. J. Clin. Oncology 2002;20;1480-90) that is not useful clinically.

- **delays in access to testing**

The paper reporting the cloning of the HFE gene was submitted more than a year after the first US patent application was filed and several months after the last of the four applications. Because laboratories can rapidly develop, validate and offer clinical tests, delay in publishing scientific findings of clinical importance can adversely affect patients by delaying access to diagnostic testing. A survey of over 2,100 biological scientists revealed that 20% reported delays in publication of 6 months or more to allow for patent applications, to protect their scientific lead, to slow dissemination of undesirable results, to allow time for patent negotiation and to resolve disputes over ownership of intellectual property (Blumenthal *et al* JAMA 1997;287;1224-8), indicating that delays are commonplace.

- **monopoly on subsequent research and testing**

If *Myriad* had succeeded in becoming the only laboratory to perform BRCA testing then its collection of DNA samples would have constituted the only sample bank in the World. This could create another monopoly concerning future research on other breast cancer predisposing genes and enable it to file more patents as a result of such discoveries.

Such monopolistic approaches to health care are contrary to the approach to public health taken in many European countries. Many prominent European research organisations, including the Institut Curie; the Belgian, Dutch, German, Danish and British genetics societies and various governments including the French, Belgian, Dutch and Austrian Ministries of Health and the European Parliament have declared their opposition to *Myriad's* monopoly (Lecrubier A, EMBO reports 2002;3;1120-2). The European Patent Office (EPO) is currently re-examining *Myriad's* BRCA patents. The French Ministers of Health and Research have both indicated their intention, if the EPO does not revoke any of *Myriad's* patents, to support an extension of the French *ex officio* system to genetic diagnosis (Lecrubier A, EMBO reports 2002;3;1120-2).

**The RCPA believes that monopolistic genetic testing is fundamentally wrong because:**

1) **It is the antithesis of the policy objective underlying the Australian public health care system which aims to ensure equitable access to health care for all Australians. Publicly funded hospitals and institutions provide these genetic tests through an integrated clinical framework that ensures they are offered equitably to individuals and families with strong evidence of hereditary disease. Monopolistic business practices and exclusive licensing arrangements disrupt this public system.**

2) **Patents on genetic material can act contrary to the fundamental policy objectives underlying the patent system – to foster innovation. Because genetic material is not an invention (see 8.9), it cannot be improved or invented around. Consequently, there is little or no incentive to improve diagnostic testing by the patent holder and the development of complementary or alternative testing methods, by third parties, can be retarded. Furthermore, because there is no real prospect of competition, patent holders are able to maximally exploit their monopoly position by adopting business practices that would not normally be tolerated by health care providers.**

**Recognising these issues, the Royal College of Pathologists of Australasia, Human Genetics Society of Australasia and the Amercian College of Medical Genetics all recommend that diagnostic genetic tests be broadly and non-exclusively licensed.**

**The most effective mechanism to curb these undesirable effects is to <u>introduce legislation that prohibits the exclusive licensing of diagnostic genetic tests</u>.**

**Q. 12-2 -** *What are the implications of current patent laws and practices for the cost and public funding of, and equitable access to, medical genetic testing and to related health care services such as genetic counselling?*

See response to 12.1

**Q. 12-3 -** *Is medical practice compromised by exclusive licensing arrangements that limit the types of medical genetic tests that can be performed using a genetic sequence covered by a gene patent? If so, in what ways, and with what possible consequences?*

Medical practice can be compromised by exclusive licensing arrangements. If testing were restricted to one laboratory it would limit the current model of health care delivery in a number of ways:

- the testing would be divorced from the essential related genetic counselling
- there would be loss of the current strong clinical/laboratory liaison
- the sole laboratory would not be able to participate in peer-reviewed quality assurance
- no drive to develop better/cheaper tests by others or by the patent holder
- no opportunity for clinical research on gene variants
- there is potential loss of local expertise in being able to provide this type of testing
- should the providing laboratory cease its function, there would be no backup service available to the community.

Overseas experience has confirmed fears about the use of exclusive licenses to monopolise genetic tests. In a 1999 US study (Schissel et al, Nature Genetics 1999;402;118), of 33 patents that broadly cover the diagnosis of human genetic disorders (13 for neurological, 6 for cardiovascular, 6 for metabolic and 3 for immunological disorders, and 5 for cancer), 14 (42%) were subject to exclusive licensing arrangements that were used by the license holder to monopolise genetic testing services. Two thirds of the patents were based on research funded, at least in part, by the US Government. In a subsequent study (Henry, Science 2002;297:1279), although non-profit organisations, such as universities, were found to generate more genetic discoveries and were less likely to file genetic patent applications than for-profit companies, they tended to favour exclusive licensing. Overall, an average of 68% of all licensed genetic patents from non-profit research organisations were exclusive, compared to 27% for for-profit companies. This suggested that academic institutions, which would be predicted to grant non-exclusive licenses, preferred exclusive licensing in order to minimise licensing expenses and to maximise short-term revenues.

**Q. 12-4 -** *What potential do patent laws and practices have to encourage the inappropriate marketing and supply of genetic testing services and products?*

At a time when patients seek out information from a variety of sources it is important to acknowledge that the health care system is not the only source of information to individuals at genetic risk of disease. Advertising is one vehicle for information delivery. The prime purpose of advertising is not education but to increase awareness and sales of a commercial product. The

recent launch of a television and magazine advertising campaign in the US by *Myriad Genetics* to market BRCA tests to consumers is an example of this (Gray S, Olopade OI. J. Clin Oncol July 21, 2003). Whilst in the US, the Food and Drug Administration (FDA) and Federal Trade Commission share responsibility for regulating and monitoring the advertisement of genetic tests, they have no clear guidelines for what must be included or excluded in advertisements for genetic testing.

Arguably, genetic testing is a much more complex "product" than prescription drugs with a variety of associated medical, legal and psychosocial risks. Pharmaceutical companies in the US have been cited for violating existing regulations, charged with the oversimplification of drug risks and indications and overstatement of drug benefits. There is, therefore, concern, that commercial pressures to increase test requests will encourage a similar oversimplification of the risks and benefits of genetic testing and the creation of an environment of fear.

Direct-to-consumer marketing of genetic testing also challenges one of the most fundamental components of genetic counselling - careful patient selection. Currently, there are no commercial genetic tests approved for general screening of the population and it is the general population who are exposed to direct-to-consumer marketing. Furthermore, there is the additional concern that non-specialist medical practitioners may feel pressured to order genetic tests that are not indicated. It is well known that some medical practitioners are susceptible to patient pressure when prescribing drugs and ordering pathology tests.

None of the currently available cancer genetic tests have adequate sensitivity and specificity for general population screening. Put simply, positive tests do not always mean that an individual will develop cancer and a negative test is not a guarantee that they will remain cancer-free. There are complexities such as missed genes, polymorphisms, low penetrance genes, and sporadic mutations that factor into the interpretation of genetic tests and cancer risk. In fact, a major limitation of genetic testing for common cancers is the number of negative or inconclusive results, leaving consumers and their healthcare providers confused and frustrated. There is no guarantee that either the consumer or the health care provider will accurately interpret a genetic test result outside of specialist centres. It is very difficult, therefore, to expect individuals to decide if they are suitable for genetic testing given the limited information they receive through advertising. It is especially difficult to expect them to make an accurate assessment of their risk when the advertisements build a strong case for testing based on fear and an ignorance of both epidemiology and risk assessment tools.

There have been no examples to date of direct-to consumer or inappropriate marketing of genetic tests in Australia.

Another concern is the inappropriate supply of genetic tests. Commercial genetic practices and laboratories are more likely to request and perform tests on patients with lower genetic risk than public services. For example, when Caulfield and Gold compared *Myriad* Genetics' indications for its BRCA test with those recommended by independent academic bodies, they found that the latter exclude women without a family history of breast or ovarian cancer, whereas *Myriad's* guidelines include these lower risk women (Caulfield and Gold, Clin Genet 2000; 57:370-5). One may argue (correctly) that individuals deemed ineligible for a particular test or treatment within the public health care system should be allowed to purchase these out-of-pocket.

Without controls on direct-to-consumer marketing and test requesting, similar to those in place for pharmaceuticals, over-consumption is likely to occur. **Guidelines, therefore, need to be developed for the advertisement, marketing and requesting of genetic tests and the laboratories that provide them.**

The above concerns arise from commercial practices and not from the patent system *per se*.

**Q.12-5 -** *Are gene patents necessary to encourage investment in research that leads to the development of new, clinically useful, medical genetic tests?*

The rationale for patent protection is based on the assumption that patents are necessary to encourage investment in research and development. Genetic patents were intended to be beneficial through more rapid access to innovations that improve the health and well being of society. Thus it is appropriate to ask whether the intended benefits from patenting of genetic materials are actually occurring, and whether these assumptions are actually borne out in practice.

Patents are certainly necessary to encourage investment in research and development in the private sector, however, much genetic research is performed within and is funded by the public sector. The entire sequence of the human genome is available on the internet as a result of publicly funded research. Furthermore, the majority of the disease-associated genes and their mutations were identified by publicly funded research institutions (NIH, public hospitals, universities) or charities (eg UK Cancer Research Campaign discovered BRCA2) and several of those that were discovered by private companies (BRCA1) were based on ground-breaking basic research performed by public institutions.

Some of the discoveries made by public institutions have been patented, but not for the purpose of commercial exploitation. They were patented to stop others from not making the information freely available to all for the benefit of humankind. Others were patented and licensed because the researchers and their institutions wished to cash in on the windfall profits from research supported in part by taxpayers (Cho and Merz, Nature 1997;390:221). Indeed, the NIH is one of the largest owners of US patents that claim rights over human genes (Cook-Deegan *et al*, Science 2001;293:217) from which it receives approximately US$50 million/year in royalties. The need for patent protection to foster the discovery of human disease-related genes is unclear, and it can be argued that genetic discoveries made by private companies would have been made shortly thereafter anyway by public endeavours. It is presently unclear whether a twenty year monopoly is a price worth paying to have a gene discovered by a private company six months earlier than a public enterprise.

The private sector has been much more active in filing patents on large numbers of, often anonymous, human genetic sequences. The US company, *Human Genome Science Inc*, for example, has filed 450 patent applications with claims to more than 34,000 sequences (Bobrow and Thomas, Curr Opin Molec Therapeutics 2002;4;542-7). This genetic “gold rush” has been and continues to be stimulated by international enthusiasm for the commercial applications of biotechnology. There has certainly been a speculative aspect to this, presumably grounded in the optimism of major shareholders in some biotechnology companies that the USPTO would readily grant broad patents on genes with no demonstrable function or utility. Once granted the broad scope of gene patents would give the patent holder exclusive use of the genetic sequence for all conceivable uses including medical testing and pharmaceutical products. These companies presumably hoped to stake as many claims as possible with the anticipation that some would eventually turn out to be important disease-associated genes. Although the USPTO rejected an application for human ESTs with no known biological function in 1991, large numbers of patent applications on ESTs have since been filed. Most, however, would now probably fall below the threshold of the USPTO’s new Utility Guidelines. Also notable, is the fact that exceedingly few of these discoveries have been translated into clinically useful products.

The elemental nature of DNA also has the paradoxical effect of encouraging investment during the discovery phase while discouraging downstream research and development. Since it is not possible to improve DNA sequences, it is effectively impossible to create a new “invention”. Even if it were possible to improve DNA sequences, the fact that patent protection on genetic material extends to all imaginable uses, means there is no incentive for others to undertake downstream research and development. This paradox is another example of the problems and confusion that arise when biological discoveries are (wrongly) regarded as inventions.

In contrast to gene discovery, the role of the private sector, and hence patent protection, are almost indispensible in bringing most diagnostic medical products to the market place. Very few public institutions are able to commercially develop and market new, clinically useful, diagnostic medical tests. Because many of these tests can be easily copied, patent protection allows companies to prevent unauthorised “free-riding” which is a major cause of market failure. This, however, does not necessarily apply to genetic tests. The vast majority of diagnostic genetic laboratories develop tests “in house” using genetic sequences freely available from public domain databases and publications as well as equipment and reagents obtained from commercial suppliers. The latter invariably incorporate their royalty fees and license agreements into their products. Most clinically useful genetic tests, therefore, are presently based on discoveries made by public institutions and involve payment of appropriate royalties for use of patented reagents and methods.

It is important to keep in perspective what patented genes will be used for. Some genes will be used as therapeutic agents (gene therapy), as diagnostic reagents and as targets for drug discovery. The vast majority, however, will be used as research tools in biological investigations. It is, therefore, worth asking whether pharmaceutical companies and academics really need to have “ownership” of these genes? Certainly, there are a handful of genes such as those used in gene therapy or that encode proteins that could be novel therapeutic agents (eg human growth factor, insulin, erythropoietin, granulocyte colony stimulating factor) that require patent protection analagous to that afforded by other drug development. Pharmaceutical companies, however, only need access to, not ownership, of genes as potential drug targets (eg G-protein coupled receptors, tyrosine kinases). Indeed, making successful new drugs is difficult and expensive and it is in the public interest that there is extensive competition to invent the best drugs against each target. Monopolies on gene targets are therefore not in the public interest.

When a gene sequence has diagnostic utility (eg screening for mutations that confer predisposition to breast cancer), the inventive step is the development of the assay not the discovery of the gene. The best assay should win in the market so claims on a gene sequence that covers uses in all diagnostic assays are unlikely to be in the public interest. All of these potential uses can be accommodated by “method-of-use” patents. It is therefore difficult to justify on utilitarian grounds, why genes have been afforded the status of ‘composition of matter’ patents.

The validity of the conventional wisdom, that monopoly control, which comes with the granting of a gene patent, will serve as an incentive to innovate needs to be questioned. Put simply, gene patents encourage private sector investment in biotech, add value to biotech companies, and provide windfall profits for public institutions, but they are no guarantee that this will result in medically useful genetic tests or therapies. Likewise, many disease-associated genes and mutations have been discovered by not-for profit research organisations and developed into medically useful genetic tests by public hospital laboratories without the need for patent protection. It is questionable, therefore, whether patent protection is necessary for the discovery of genes and genetic variants associated with human disease and whether composition-of-matter

patents are necessary for the development of diagnostic genetic tests and therapeutic drugs. Almost all conceivable uses of human genes can be adequately covered by "method-of-use" patents.

**It is therefore difficult to justify the necessity for patent protection on human genetic material.**

**Q. 12-6 -** *What impact might patent laws and practices have on the future provision of gene therapy, medicines based on therapeutic proteins, and medical treatment involving stem cells?*

Gene patents have the potential to both encourage and limit the development of gene-based therapies. It is unlikely that public institutions will take the risk to progress a gene-based therapy through the rigorous regulatory processes, conduct clinical trials and market their products, especially those where the therapeutic potential is less obvious. The role of the private sector and the need for patent protection cannot be overestimated here.

**However, the broad scope of many patents on genetic material is likely to discourage competitors from investing in gene-therapy-based research.** Potentially useful therapeutic agents may not be developed when the patent holder is too small to support the risk or negotiates terms that are regarded as unreasonable. *Myriad Genetics* for example claims the rights to use the BRCA1 and BRCA2 genes for both diagnosis and potential therapies. There is no obligation, however, on *Myriad Genetics* to develop gene-based therapies based on BRCA1 and BRCA2, while the threat of legal proceedings for infringement or the imposition of license fees could discourage others.

**Q. 12-7 -** *Should government funding and purchasing power be used to control the cost of medical genetic testing that is subject to gene patents? If so, how might this best be achieved?*

No, the appropriate role for government is to create the legal and regulatory framework that achieves the right balance between the patent holder's right to profit from their inventions and the public policy objective of high quality, equitable health care.

**Q. 12-8 -** *Should there be new regulation of medical genetic testing to address concerns about the possible adverse consequences of patent laws and practices on health care provision? If so, how might this best be achieved?*

**Yes, there is a need to regulate all aspects of genetic testing.** In many instances this can be achieved through existing government initiatives eg National Association of Testing Authorities / Royal College of Pathologists of Australasia (NATA/RCPA), National Pathology Accreditation Advisory Committee (NPAAC), Therapeutic Goods Administration (TGA).

However, because the adverse consequences are largely a result of commercial practice that arise as a result of a monopoly granted by a patent, regulations alone may not achieve the desired outcome. If there is to be additional regulation it should be in relation to achieving a balance between commercial and trade practices and public health policy objectives. These are probably best achieved through the Trade Practices Act etc.

**Q. 12-9 -** *Should patent pools or clearing houses be created to make it easier for laboratories to obtain licenses for patented genetic inventions? If so, how might this best be achieved?*

The USPTO has recently suggested the use of patent pools, which are a form of cross-licensing agreement between patent holders allowing for sharing of technologies in a common field. This is likely to be attractive to the commercial sector particularly those companies with large gene portfolios. However, this will not assist researchers and laboratories who are currently developing genetic tests that examine hundreds or thousands of genes simultaneously. An effective administrative mechanism has to be developed if these tests are to be cost effective. Patent clearing houses are one possible option.

## Chapter 13: Patents and the Biotechnology Sector

**Q. 13-1** - *What effects do Australia's patent laws and licensing practices have on the development of Australia's biotechnology industry as it relates to human health?*

The College has no specific comments to make.

**Q. 13-2** - *Is there any evidence that broad patents, trivial patents, defensive patents, dependent patents, multiple patents or reach-through claims may adversely affect the development of Australia's biotechnology industry as it relates to human health?*

The College has no specific comments to make.

## Chapter 14 : New Defences

**Q. 14-1 -** *Should the Patents Act 1990 (Cth) (Patents Act) be amended to include a defence for research use? If so, should the defence be limited to activities involving research on an invention claimed in a gene patent? Should the scope of the defence also encompass research use of a gene patent directed to: (a) improving upon the claimed invention; (b) finding a new use for the claimed invention; or (c) creating a new product or process using the claimed invention?*

**Yes, serious consideration should be given to exempting non-commercial research from patent infringement, especially for inventions arising from publicly funded research.** This view is based on the principle that public institutions should be free to conduct research of a non-commercial nature. Although not codified in law, there is a long standing scientific convention that non-commercial research is exempt from patent enforcement (see 11.1).

The European Commission recently proposed an exclusion from the effects of European Union patents for "acts done privately and for non-commercial purposes" and for "acts done for experimental purposes relating to the subject-matter of the patented invention" (Commission of the European Communities, Proposal for a Council Regulation on the Community Patent, art 9 (1 August 2000), Off Eur Communities 43 (C 337E), P278 (28 November 2000), (available at europa.eu.int/eur-lex/pri/en/aj/dat/2000/ce337/ce33720001128en02780290.pdf) The national

patent laws of many EU member states contain similar provisions, as does Japanese law (Muller J, Wash Law Rev 76,1 [2001]).

However, the distinctions between public and private institutions and commercial and non-commercial research are becoming blurred. Almost all public research institutions have active programmes to commercialise their intellectual property and conversely many private companies receive substantial public funding to support their research programmes and business development. This is, therefore, likely to make such proposals unworkable.

**Q. 14-2 -** *Should the Patents Act be amended to include a defence for private, non-commercial use of a patented invention? If so, what would be the relationship between a 'private use' defence and a 'research use' defence of the type identified in Question 14 - 1?*

**Yes, serious consideration should be given to including non-commercial genetic testing into the definition of private use.** A genetic test performed on an individual could be regarded as private use so long as the individual does not to seek to profit financially from the test result (ie share in any profit dervied from their genetic material).

**Individuals ought to retain a "natural" right of access to their own genetic material for their own healthcare. It would be ethically objectionable for this to be denied by a patent or license holder.**

The development of special defences and exemptions such as private-use genetic testing could, however, undermine commercial research into genetic disorders. There is a danger that such initiatives could lead to a cascade of other consequences, eg reduced investment in genetic technologies generally.

**Q. 14-3 -** *Should the Patents Act be amended to include a defence to allow for the use of a patented genetic material or technology by a medical practitioner for the purposes of medical treatment of humans? If so, who should qualify as a medical practitioner for the purposes of such a defence and what types of activities should be exempt? Should any activities be expressly excluded from the scope of such a defence?*

**Yes, serious consideration should be given to granting laboratories exemption from patent infringement to perform non-commercial genetic testing on patients for private purposes.** The exemption should apply to the approved pathology authority, approved pathology laboratory and approved pathology practitioner.

A similar scheme was proposed as an amendment to US patent law by Sen. Lynn Rivers.

**Q. 14-4** - *Would amendment of the Patents Act to include new defences, such as those identified in Questions 14 - 1, 14 - 2 and 14 - 3, be consistent with Australia's obligations under the TRIPS Agreement?*

The College has no specific comment to make.

## Chapter 15 : Crown Use and Compulsory Licensing

**Q. 15-1** - *Are the Crown use provisions in the Patents Act 1990 (Cth) (Patents Act) capable of applying to the provision of health care services using patented genetic materials and technologies? If not, should these provisions be amended to apply to such use?*

These provisions appear to be adequate and do not require changing specifically for gene patents.

**Q. 15-2-** *In relation to the provisions in the Patents Act relating to the grant of compulsory licenses:*

- *Do the provisions encourage patent holders to exploit or license gene patents?*
- *Is the grant of a compulsory license an adequate and appropriate mechanism to remedy the possible adverse impacts of gene patents on access to health care or the ability to conduct research related to human health? If not, should the current provisions be amended to make specific reference to such matters?*
- *Should compulsory licenses be available only by order of a court (as the Patents Act currently provides), or should the Act be amended to allow the Commissioner of Patents, or another tribunal or agency, to grant compulsory licenses?*
- *If compulsory licenses were to be granted more frequently, should the Patents Act be amended to provide increased protections for patent holders, such as mechanisms for determining the compensation due, or certain mandatory terms to be included in such licenses?*

**Yes, serious consideration should be given to loosening the criteria for granting compulsory licenses.** This is probably the most appropriate and effective solution for resolving disputes between patent and license holders and genetic testing laboratories, especially public laboratories which cannot afford to pay unreasonable license fees or bear enormous legal fees.

Likewise, **serious consideration should be given to create or appoint a patent ombudsman, tribunal or commissioner** to hear such cases and to grant compulsory licenses, determine appropriate fees and compensation, and to be empowered to penalise companies that behave in a socially irresponsible manner.

**Guidelines should also be established to determine reasonable fees and compensations** eg limited to 5-10% of the cost of performing the test.

Serious consideration should also be given to protecting laboratories from business practices by patent and license holders armed with patent insurance.

It is noteworthy that France has recently introduced legislation that permits the country's Minister of Health to grant compulsory licenses to provide a genetic test in return for a reasonable royalty, in order to protect the public health (*Projet de loi relatif a la protection des inventions biotechnologiques*. France Senat Seeion ordinare de 2001-2002; 2001 Nov 6 No 55, Article 11 – available: www.senet.fr/lcg/pjl01-055.html). This measure, being contemplated by other countries, would not only reduce the cost of genetic tests but would ensure that patients have acess to the most appropriate tests available. It would also ensure that all laboratories that wish to perform the

test could do so, as long as they meet their country's regulatory requirements and accreditation standards for genetic testing.

**Q. 15-3 -** *What latitude is there for amending the Crown use or compulsory licensing provisions of the Patents Act consistently with Australia's obligations under the TRIPS Agreement?*

The College has no specific comment to make.

## Chapter 16 : Copyright, Trade Secrets and Designs

**Q. 16-1** - *What role should copyright law play in dealing with genetic materials and technologies in relation to human health?*

It has been argued that genes should not be treated as novel chemicals but as biological software comprising a programme written in the sequence of the nucleotides and hence subject to copyright rather than patent law. This has the advantage that copyright law provides weaker commercial protection but is of longer duration. These arguments were rejected by the USPTO.

**Q. 16-2 -** *Does Australian copyright law provide adequate protection of databases that hold factual compilations of genetic sequences and other genetic data? What would be the implications of introducing into Australian law a special database right—as distinct from copyright—in relation to such databases?*

The College has no specific comment to make.

**Q. 16-3 -** *Does trade secrets law have any significant application to the conduct of genetic research and its commercialisation? If so, does the law require reform?*

The College has no specific comment to make.

***Q. 16-4 -*** *Do the existing or proposed design laws have any significant application to the conduct of genetic research and its commercialisation? If so, do the laws require reform?*

The College has no specific comment to make.

## Chapter 17 : Patents and Competition Law

**Q. 17-1 -** *Following the report of the Intellectual Property and Competition Review Committee in 2000, and the Federal Government's response, are there any competition issues specifically relevant to gene patents that need to be dealt with in the course of this Inquiry?*

The College has no specific comment to make.

**Q. 17-2 -** *How should competition law and policy deal with 'patent pools' relating to gene patents?*

The College has no specific comment to make.

**Q. 17-3 -** *Is there a role for the Australian Competition and Consumer Commission (ACCC) in monitoring prices that are charged for medical genetic tests or any other products or services arising from the grant of gene patents or licenses?*

The College has no specific comment to make.

**Q. 17-4 -** *Is there a role for the ACCC in monitoring the impact on competition of gene patents and licenses?*

The College has no specific comment to make.