Australian Government

Australian Law Reform Commission

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Dear Secretary

ALRC submission to Senate Standing Committee on Community Affairs Inquiry into Gene Patents

The Australian Law Reform Commission (ALRC) makes the following submission to the Senate Standing Committee on Community Affairs inquiry into gene patents. In making this submission, the ALRC draws on its experience from its major inquiry into the intellectual property aspects of genetic material and technologies, which culminated in the final report *Genes and Ingenuity: Gene patenting and human health* (ALRC 99, 2004).

A hardcopy of ALRC 99 is *enclosed*, which contains a convenient Executive Summary as well as a consolidated list of the 50 recommendations for reform made in the Report. An electronic version of the report, the preceding two community consultation papers, and other associated materials (such as summaries and media releases) are freely available on the ALRC's website at: <www.alrc.gov.au/inquiries/title/alrc99/index.html>.

Unfortunately, there has not yet been any formal Government response to the Report, although it appeared that such a coordinated response was close to completion on a number of occasions in previous years. Apart from the Committee inquiry, the ALRC has been informed that IP Australia is currently investigating reforms to Australia's patent legislation, some of which will address concerns raised in *Genes and Ingenuity*.

As the ALRC's findings and recommendations on the relevant issues are set out fully in the Report, and these have not changed in the intervening period, the ALRC does not intend to provide any further or different material in relation to the Committee's current inquiry. The core subject matter of the Committee's Terms of Reference was squarely considered as part of the ALRC's 18-month long inquiry, and these issues were addressed in *Genes and Ingenuity* (see especially Chapter 7).

The Committee's Terms of Reference focus very narrowly on the granting of patents in Australia over human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form. With respect, the ALRC is concerned that this peculiar over-emphasis on one matter will inhibit the Committee from addressing the main issues facing Australians in this area—namely the provision and costs of healthcare; access, equity and quality in the delivery of clinical genetic services; and facilitating investment (public and private), innovation and progress in medical and scientific research undertaken in Australia.

During the extensive expert and community consultation exercise that the ALRC undertook as part of the Gene Patenting Inquiry, we frequently heard concerns that claims over genetic sequences should not be patentable because the sequences—being naturally occurring—could only amount to 'discoveries', rather than 'inventions', as is required under intellectual property laws in Australia and overseas.

Whatever the merits of that argument—and the ALRC was certainly sympathetic to it—we are faced with the hard and inconvenient fact that since the 1980s—in Australia and internationally—many tens of thousands of patents have been granted on genetic sequences, provided they have been isolated from their natural state and otherwise satisfy the statutory requirements for patentability.

If the ALRC had been conducting its Inquiry 20 years earlier, it may have been in a position to influence law and practice in this area so as to expressly prohibit the patenting of genetic sequences. However, faced with the practicalities of the contemporary situation, the ALRC concluded in 2004 that if there had been a time to recommend that gene sequences should not be patentable, that time had long since passed. Rather, it was far preferable to focus on reforms that would directly address the existing problems and make the system work better.

Further, there is little doubt that many important genetic technologies in daily use by health authorities—such as DNA testing kits and PCR machines—are 'patentable'. Such technologies clearly satisfy the legislative requirements of novelty, inventive step, and useful application. Again, the ALRC found that the key factor in ensuring both the accessibility of quality health care and the facilitation of further research is the smooth functioning of the system regulating licensing and use.

Many submissions to the ALRC inquiry considered the manner in which a patent holder or its licensee exploits gene patents in the marketplace. During the course of the ALRC Inquiry, it became apparent that the behaviour of a small number of patent holders or licensees—and the same few names were offered time and again— generated most of the serious concerns about the impact of gene patents and licences. Many of the concerns expressed were anecdotal or hypothetical, and evidence of problems in practice—outside that small number of well-known examples—was more difficult to verify. The ALRC's task, therefore, involved crafting reforms that would help the patent system deal with obdurate behaviour, without stifling future innovation and investment in genetic technologies and the development of the Australian biotechnology industry.

The ALRC was not directed to undertake a general review of the patent system in Australia. Nevertheless, it became apparent that often it was neither possible nor appropriate to suggest amendments directed exclusively at the patenting of genetic materials and technologies in legislation of general application. And, indeed, there was evidence that the every new wave of scientific inventions places stress on the patent system as examiners try to come to grips with the new science and technology. Inevitably, some inappropriate and overly broad patents are granted in the first flush of applications, but then the system settles down as examiners become more expert in understanding the nature, complexities and boundaries of the new field. This was true, for example, in relation to the patenting of isolated chemical compounds prior to the 'genetics revolution', as well as to the patenting of 'business systems' after gene sequences became relatively old hat. To the extent that gene patents highlighted any deficiencies in the patenting system generally, the ALRC considered it preferable to craft solutions aimed at correcting systemic weaknesses, in order to ensure that the system remains sufficiently robust to anticipate and respond to future challenges.

Further, to propose specific laws for genetic materials and technologies may have had implications for Australia's compliance with obligations under various international agreements, including TRIPS and specific provisions in Free Trade Agreements (such as the AUSFTA).

As a result, some of the recommendations in *Genes and Ingenuity* are aimed at improving the patent system in general, including a suite of reforms directed at Patent Office (IP Australia) practice. Other recommendations are directed to the appropriate use and exploitation of gene patents and to the relationship

between the patent system and the three sectors to which the ALRC was required to have regard—research, biotechnology and healthcare.

Genes and Ingenuity makes important recommendations for reform, but it does not suggest any radical interventions into the integrity of the patents system. Some key recommendations call for targeted changes to the *Patents Act*, including: (a) increasing the burden of proof on applicants to prove the 'usefulness' of their claimed invention; and (b) introducing a research exemption (which is widely, but incorrectly, believed to exist already) to permit 'study or experiment' on the subject matter of the invention without the need to negotiate a licence.

Most of the recommendations, however, do not require legislative change. Rather, the ALRC's preferred approach was to pursue a broad strategy aimed at substantially improving knowledge, practice and procedure in this area. Consequently, the recommendations in *Genes and Ingenuity* are addressed to a wide range of parties, and not merely to the Australian Government. (The ALRC attached an 'Implementation Schedule' to the Report, listing the actions required of each of the various public and private bodies in order to address the 50 recommendations, so that success or otherwise may be monitored over time.)

For example, the ALRC asked **IP Australia** to:

- revise its examination guidelines;
- 'skill-up' patent examiners in genetic science and technology; and
- improve examiners' access to specialist expertise (assessors) in cutting-edge areas.

The ALRC asked the **Commonwealth—in conjunction with the State and Territory Health Departments**—to take a much more informed, engaged, coordinated and strategic approach to these issues, including by:

- developing their in-house legal and strategic capacity in this field;
- monitoring patent and licensing practices in this area;
- being prepared to resist or challenge dubious patent claims;
- facilitating good (model) licensing practices;
- utilising their bulk-buying and single-payer power to negotiate favourable licensing arrangements—in much the same way Australia leads the world in relation to access and pricing of pharmaceuticals through the PBAC/PBS system; and
- considering the use, in appropriate cases, of the Commonwealth's *existing legal powers* in relation to Crown use and compulsory licensing.

The ALRC asked the **Australian Consumer and Competition Commission** (ACCC) to begin to engage more fully with this emerging and important field, and specifically to:

- issue Guidelines on the relationship between the exploitation of IP rights and the requirements under competition law (per the Ergas Report); and
- begin to monitor the conduct of biotech/gene patent holders for evidence of anti-competitive conduct, such as unreasonable licensing practices.

The ALRC asked **Australian universities and research institutes** to do more to raise consciousness in the research community about law, practice and strategic issues relating to patenting and other forms of intellectual property; technology transfer; and commercialisation of IP. The ALRC found that existing practice is highly variable, with some institutions doing this much more effectively than others.

The ALRC asked **Australian research funding bodies,** such as the **NHMRC** and the **ARC**, to develop policies, guidelines and practices which provide the right mix of incentives for patenting and commercialising IP in the genetics area, while at the same time ensuring that the results of taxpayer-funded research confers appropriate public benefits.

For example, the latter may be promoted by requiring research results to be placed in the public domain, or that a publicly-funded patented invention be widely licensed at low cost. The ALRC particularly pointed to the very good example set by the US National Human Genome Research Institute (one of the National Institutes of Health, or NIH), which published all of the data from the Human Genome Project and the subsequent International Haplotype Mapping Project (HapMap) on Open Source databases, publicly accessible via the internet.

The ALRC did *not* favour the creation of residual 'march-in rights'; for instance, as found in the US in the *Bayh-Dole Act*—but noted that there may be capacity to add conditions to grants to limit the commercialisation of certain publicly funded research, where it is in the public interest to do so.

Finally, the ALRC asked the various players comprising the **biotech industry** (public and private) to take practical steps to promote easier and broader licensing of gene and gene technology patents for research purposes and clinical use, including by:

- developing model licence agreements;
- pursuing industry initiatives, such as the creation of 'patent pools'; and
- developing education programs for researchers about IP laws, practices and issues in this field.

Conclusion

The ALRC's *Genes and Ingenuity* inquiry was one of the first in the world to undertake a comprehensive survey and analysis of IP law, policy and practice in the emerging area of genetic material and technologies. As noted above, the ALRC concluded that the patenting of gene sequences—however unfortunate—is *not* the major obstacle to providing cost-effective healthcare to Australians in the era of the 'New Genetics', nor do the effective solutions to equitable access to healthcare or the further promotion of investment and research activity in the biotech sector lie in the retrospective mass cancellation of many tens of thousands of patents granted around the world—and whose recognition and enforcement is often guaranteed by international instruments. That would be the recipe for an enormous amount of unnecessary controversy, litigation and cost—a combination rarely regarded as an effective health promotion device.

Furthermore, this is yesterday's battle. The monopoly exploitation rights granted by a patent extend (with some limited exceptions) for twenty years—which means that, by definition, many or most of the problems caused by patents granted over gene sequences, or overly broad patents, are transient ones. The unfortunate patents granted by overwhelmed Patent Offices around the world in the 1980s and early 1990s are coming towards their end (if they have not already been invalidated for other reasons).

With the successful completion of the Human Genome Project and further rapid advances in sequencing technology, it is increasingly unlikely that a competent patent examiner would now approve an application for patent rights over a pure gene sequence. As Dr Ségolène Aymé of the (French) National Institute for Health and Medical Research Institute stated last year, when the European Parliament was considering this matter:

> Nowadays, identifying new genes is very obvious, and all the methods are well-established, so it should not be patentable anymore. What is patentable is the inventive process—if you can describe how to use a gene for a specific purpose—but not the gene itself.

As detailed above, the ALRC's strongly preferred approach in *Genes and Ingenuity* was to focus on the real-world problems of refining the *Patents Act*; promoting smarter and better Patent Office practices; facilitating

smoother licensing regimes; and encouraging much more strategic thinking, capacity and activity by funding bodies, researchers, research institutions and Health Departments.

The ALRC's findings and recommendations in *Genes and Ingenuity* have been validated and adopted (expressly or coincidentally) by virtually all of the major international reports that have followed in the last five years, including the OECD's *Guidelines for the Licensing of Genetic Inventions* (2006) (available online at <http://www.oecd.org/dataoecd/39/38/36198812.pdf>).

In the United States, the Secretary of Health and Human Services' Advisory Committee on Genetics, Health and Society (SACGHS) has established a Gene Patenting Task Force, in association with Duke University's highly regarded Center for Genome Ethics, Law and Policy. The Task Force is in the final stages of public consultation on the policy options presented in the draft report, with the final report due to be presented in October 2009. However, it has already conducted and analysed a series of case studies, including tests for such genetic conditions as hereditary breast and ovarian cancers (BRCA1/BRCA2), Alzheimer's disease, Tay-Sachs and Canavan diseases, and Long QT syndrome.

As a result, the Task Force has drawn a number of preliminary conclusions (reported in December 2008 at <http://www.genomeweb.com/hhs-committee-will-seek-public-comment-upcoming-gene-ip-policy-draft-report>), including that:

- there is no clear relationship between patents and the price of a genetic diagnostic test;
- the use and enforcement of IP rights—and not so much whether a gene is patented or unpatented—is what potentially creates barriers to clinical use of the gene;
- access to genetic tests is assisted by efforts to enhance transparency in patents and licensing; and
- the regulation of IP rights may not be the best action for fixing problems regarding the quality of genetic testing, as these issues may be better addressed through evaluation and regulation of genetic tests and by coverage and reimbursement systems.

We trust that the Senate Standing Committee on Community Affairs will find these comments of value, particularly taken together with the findings, recommendations and supporting research and commentary contained in the ALRC's *Genes and Ingenuity* report.

With kind regards

Yours sincerely

Enclosure