EXECUTIVE SUMMARY

Chapter 1

The terms of reference for the inquiry directed the Committee to consider the impacts of gene patents on healthcare, medical research and the health and wellbeing of Australians. The length of the inquiry was indicative of the complexity of many of the legal and scientific issues underpinning the inquiry's terms of reference, and the equally complex way in which these interact with the development and delivery of healthcare services and the conduct of medical research in Australia. The Committee regards the subject matter of the inquiry as being of fundamental importance to the quality and accessibility of Australia's health system.

Chapter 2

The background to the inquiry, discussed in Chapter 2 of the report, was concerns arising from the attempts by Genetic Technologies in 2002-03 and 2008 to enforce its patent rights over the BRCA1 and BRCA2 genes in Australia. Testing for these genes can indicate a predisposition to developing breast and ovarian cancer. Although Genetic Technologies did not ultimately enforce its patent rights, had it been successful in doing so it would have been able to become the sole tester for the BRCA genes in Australia, or to charge a licence fee to third parties for conducting the test. The potential for such a critical test to be subject to commercial exploitation on these terms led to widespread community concern, and resulted in the inquiry into gene patents being referred to the Committee.

Chapter 3

Chapter 3 of the report discusses the impact of gene patents on the provision of healthcare, training for medical specialists, medical research and the health and wellbeing of the Australian people. While the Committee heard of a number of cases where the provision of healthcare or the conduct of medical research in Australia has been impeded, the evidence did not show that gene patents are systematically leading to adverse impacts in these areas. The Committee's ability to make definitive conclusions in relation to these arguments was ultimately frustrated by the lack of comprehensive, systematic and accessible data in relation to gene patents. Accordingly, the Committee has made recommendations (Recommendations 1 and 2) which seek to improve the quality of available data and information regarding the impacts and use of patents (and gene patents in particular) in Australia. These measures would involve the Australian Health Ministers' Advisory Council (AHMAC) establishing processes for the economic evaluation of medical genetic testing and other new genetic medical technologies, and for examination of the financial impact of gene patents on the delivery of healthcare services in Australia. The Committee has also called for the establishment of consultative processes as a basis for establishing a transparency register for patent applications as well as other measures to track the use of patents dealing with genes and genetic materials.

Given the present uncertainty around the impacts of gene patents, the Committee intends to maintain a watching brief on this area, and improved capture of data and information on the impacts of gene patents will be critical to guide any future deliberations of the Committee. This approach is also justified by the high level of uncertainty about the impacts of gene patents on future, as yet unknown, developments in genetic science.

Chapter 4

Chapter 4 of the report discusses the proposal for an express prohibition on gene patents, and this was the central issue addressed in much of the evidence submitted to the inquiry. To the extent that this proposal was supported by claims that gene patents are, or could, adversely impact on healthcare and medical research, the Committee's ability to make a definitive conclusion was, as above, significantly frustrated by a lack of relevant data.

Further, the Committee heard conflicting evidence as to whether a prohibition on the patenting of genes and other biological materials (a) would be effective and (b) would not lead to unforeseen consequences in other fields of technology, particularly biotechnology research and development.

The Committee notes also that, in fact, current Australian law does not allow the patenting of 'a mere discovery' (that is, a product of nature as opposed to an invention) and, in the Committee's view, there is substantial doubt that IP Australia's approach to the granting of patents over genes conforms with the general prohibition in law on the patenting of a discovery. While the Committee acknowledges IP Australia's defence of the current approach as being analogous to other classes of patents, such as chemical products, the Committee strongly rejects the reasoning which says that, for the purposes of the *Patents Act 1990* (the Act), genetic information that is 'isolated' from its naturally occurring state in the human body may be classed as an invention, and therefore properly be the subject of a patent (where the other requirements of patentability are satisfied). The Committee considered this to be the strongest justification for recommending that the Act be amended to include an express prohibition. However, a number of considerations persuaded the Committee that it would not, at this point in time, recommend that the Act be amended to expressly prohibit the patenting of genes.

First, as noted above, there was a level of the uncertainty around the potential effectiveness and effect of such a prohibition. With improved data and information collection on the impacts of gene patents (as the Committee's first two recommendations seek to achieve), the case for or against such an express prohibition may be clearer in future.

Second, the Committee noted legal developments, both nationally and internationally, which are directly relevant to the application of the invention-discovery distinction to isolated genetic materials. In the USA, a legal challenge to the validity of the BRCA gene patents has recently been decided in the US District Court for the Southern

District of New York.[1] This case found that isolated genetic materials are not patentable subject matter (that is, are not inventions) and, in the event that this decision is confirmed by a higher court on appeal, this finding will become binding on the practices of the United States Patent and Trademark Office (USPTO). Further, on 29 October 2010, the US Department of Justice indicated that the US federal government had altered its policy to reflect the US District Court's finding (although it was not clear whether the USPTO would implement the revised policy). While changes to the law in the US will not be directly binding on IP Australia, the Committee notes evidence that IP Australia considers that a high degree of conformity between Australia's patent system and jurisdictions such as the US is desirable. The Committee therefore expects that the Government and IP Australia will seek to adopt any substantive changes to US patent law and practice around the granting of patents over isolated genetic materials.

In Australia, a similar challenge to the BRCA gene patents was commenced in the Federal Court in June 2010. If the court finds that isolated genetic materials are not patentable subject matter, IP Australia will be required to adjust its approach to conform to that decision.

The Committee will continue to monitor these important international and national legal developments, and notes that these cases may bring greater clarity to the application of the invention-discovery distinction to isolated genetic materials. As part of its watching brief on this area, the Committee may wish to revisit this issue if the area remains problematic following the outcomes of these cases.

Third, the Committee notes that the Australian Council on Intellectual Property (ACIP) is currently considering reforms to the manner of manufacture test, and that its recommendations in this area may also clarify the application of the invention-discovery distinction to isolated genetic materials. The Committee awaits the publication of ACIP's final report with interest.

Finally, the Committee notes that the international and national legal developments described above, as well as the ACIP review of patentable subject matter, may ultimately be superseded by the introduction of a private member's Bill, the Patent Amendment (Human Genes and Biological Materials) Bill 2010 (the Bill), into the federal Parliament. The Bill is intended to prevent the patenting of human genes and biological materials existing in nature, and would amend the Act to 'reinforce the distinction between discovery and invention and…apply that distinction by expressly excluding from patentability biological materials which are identical or substantially identical to those existing in nature, however made'.[2]

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1 *Association of Medical Pathology and Others v The United States Patent and Trademark Office and Myriad Genetics, Inc and Others* (the MPO case).

2 Draft Explanatory Memorandum, p. 3.

The Committee believes that the introduction of the Bill to the Senate will provide a further, and much-needed, opportunity for the arguments and questions around the impacts and effectiveness of an express prohibition on gene patents to be considered. The Committee is of the view that a Senate inquiry into the Bill should be undertaken, with a focus on the specific terms of the proposed amendments and the implications of their implementation for human health and other potentially affected fields of innovation. The Committee notes that its inquiry into gene patents has served a valuable purpose in bringing the issue of gene patenting to the light of public interest and attention, and provides a sound basis on which a targeted inquiry into the Bill can build. Accordingly, Recommendation 3 of the report requests that the Senate refer the Bill to a relevant Senate Committee for inquiry and report.

Chapter 5

Chapter 5 of the report discusses proposals for measures that would ameliorate the impacts arising from the granting of gene patents, including possible amendments to the Act. The Committee agreed on a number of recommendations that it believes could substantially address concerns about the impacts of gene patents on healthcare services and medical research, by improving patent quality and the operation of the patent system more generally. The recommendations are collectively intended to:

- increase the threshold requirements of patentability (improve patent quality);
- reduce the scope of patent claims;
- reinforce mechanisms and policies by which governments can and should intervene with the rights of patent holders; and
- assist judicial interpretation of the Act and establish an external accountability and quality control mechanism for the patent system.

The recommendations increasing the threshold requirements for patentability (Recommendations 6 to 8 and 10) are intended to improve patent quality. In simple terms, these recommendations seek to ensure that patents (including patents over genes and genetic materials) are granted only where an invention is, for example, sufficiently novel, inventive and useful. This will help to ensure that patents (which effectively grant an inventor a monopoly to exploit their invention) are not granted where their costs outweigh their intended economic and social benefits.

Recommendation 9 goes to the criteria for 'full description' and 'fair basis'. These requirements relate to the way in which a patent application sets out the scope of the patent claim and provides the information necessary for the invention to be replicated by others. This recommendation is intended to ensure that a patentee may not monopolise a greater field than they have disclosed to the public, and thus to prevent the granting of patents in relation to overly broad patent claims (including those relating to human genes).

Recommendations 11 and 12 relate to the development of clear policies regarding the circumstances in which the Crown use provisions contained in the Act should be employed by Government; and to clarification of the operation of the compulsory

licence provisions. In making these recommendations, the Committee observes that successive Australian governments have failed to properly engage with the Commonwealth's responsibility to ensure that such measures are contemplated and exercised where this is justified by relevant social or economic considerations. This failure to engage with and to oversight the operation of Australia's patent system is exemplified by the failure of successive governments to respond to the comprehensive review of gene patents conducted by the Australian Law Reform Commission (ALRC) in 2004. Noting the imminent completion of the ACIP review of patentable subject matter, as well as IP Australia's review of Australia's patent system, the Committee has recommended that the Government provide a response to the final reports of these reviews by mid-2011 (Recommendation 4). A comprehensive response to the work of these reviews should form the basis of the Commonwealth's ongoing engagement with the patent system into the future. To underpin the Committee's commitment to maintaining a watching brief on the impact of gene patents and the implementation of suggested reforms to the patent system, the Committee has also recommended that, following the tabling of the Government's response or at an appropriate time, the Committee be tasked with inquiring into the extent and impact of the implementation of any such reforms (Recommendation 5).

Recommendation 13 calls for the Act to be amended to include a broad research exemption. Such an exemption was widely supported by stakeholders, and is necessary to ensure certainty for both researchers and patent holders. The intent behind the Committee's recommendation is that any such research exemption should be sufficiently generous and broad to ensure that research, particularly medical research, can proceed without concern that a patent holder could sue for patent infringement.

Recommendations 14 and 15 call for the inclusion of anti-avoidance and objects provisions in the Act. These amendments are intended to assist in judicial interpretation of the Act, and to enable challenges to patents based on strategic or creative drafting of patent claims.

Finally, Recommendation 16 calls for the establishment of an external oversight authority in the form of a patent audit committee. The Committee envisages that this body will be comprised of members with relevant technical, scientific, economic and other relevant expertise, and be tasked with broadly assessing the operation and performance of the patent system, particularly in relation to areas of complex or emerging technology such as gene patents. Critically, the patent audit committee would act as an independent source of credible advice to guide and inform the Government's engagement with the patent system.