

CHAPTER 1

INTRODUCTION

Terms of reference

1.1 On 11 November 2008, the Senate referred matters relating to the patenting of human genes and genetic materials to the Senate Community Affairs Committee (the Committee) for inquiry and report by the last sitting day of 2009.¹ On the basis of the official schedule of sittings, the Committee was therefore required to report by 26 November 2009.

1.2 On 24 November 2009, the Senate agreed to an extension of time for the Committee to present its report. The Committee sought this extension because it required more time to consider the extensive evidence received and the complex nature of many issues associated with this inquiry. Further extensions were granted on 23 February 2010 (until 17 June 2010) and 16 June 2010 (until 2 September 2010).

1.3 On 19 July 2010, the Governor-General prorogued the 42nd Parliament. The Committee tabled a brief report on 26 August 2010, which stated that, after due consideration, the Committee had determined it was unable to provide a comprehensive report and would reconsider these issues in the event that the inquiry was re-referred to the Committee in the new parliament. On 30 September 2010, the Senate agreed to a request by the Committee for the inquiry to be re-referred with the original terms of reference and a reporting date of 25 November 2010.

1.4 The terms of reference for the inquiry directed the Committee to inquire into:

The impact of 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 particular reference to:

- (a) the impact which the granting of patent monopolies over such materials has had, is having, and may have had on:
 - (i) the provision and costs of healthcare;
 - (ii) the provision of training and accreditation for healthcare professionals;
 - (iii) the progress in medical research; and
 - (iv) the health and wellbeing of the Australian people;

1 Following the restructuring of Senate Committees on 13 May 2009, the inquiry was continued by the Senate Community Affairs References Committee.

- (b) identifying measures that would ameliorate any adverse impacts arising from the granting of patents over such materials, including whether the *Patents Act 1990* should be amended, in light of the any matters identified by the inquiry; and
- (c) whether the *Patents Act 1990* should be amended so as to expressly prohibit the grant of patent monopolies over such materials.²

Conduct of the inquiry

1.5 Information about the inquiry was advertised in *The Australian* and on the Committee's website, which included an invitation to make submissions on the terms of reference by 19 March 2009 (due to extensions to the reporting date, submissions were in fact accepted throughout the course of the inquiry). The Committee also wrote to relevant organisations and individuals to notify them of the inquiry and inviting submissions. The Committee received 78 public submissions. A list of the submissions authorised for publication by the Committee is provided in Appendix 1.

1.6 The Committee held eight public hearings for the inquiry. These took place in Canberra (19 March 2009, 20 August 2009, 14 September 2009, 18 May 2010 and 15 June 2010); Melbourne (3 & 4 August 2009); and Sydney (5 August 2009). Witnesses who appeared at the hearings are listed in Appendix 2.

The report

1.7 Chapter 2 of the report provides the background to the inquiry, and briefly outlines those aspects of the patent system, both in Australia and internationally, that are most relevant to the inquiry terms of reference. Chapter 3 considers the extent and impacts of the granting of patents over human genes and genetic material (term of reference (a)(i) to (iv)); Chapter 4 considers whether the *Patents Act 1990* should be amended so as to expressly prohibit the grant of patent monopolies over such materials (term of reference (c)); and Chapter 5 identifies measures to ameliorate any adverse impacts arising from the granting of patents over such materials, including whether the *Patents Act 1990* should be amended (term of reference (b)).

Terminology used in this report

1.8 The inquiry terms of reference directed the Committee to consider the impacts of granting patent monopolies over 'human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form'. As noted by IP Australia, there is no internationally recognised definition or common understanding of what is a 'gene patent' other than that they are a subset of

2 The terms of reference for the inquiry, as well as submissions and other information on the Committee, is available from the Committee's website at http://www.aph.gov.au/senate/committee/clac_ctte/gene_patents/index.htm.

biotechnology patents.³ The report uses the term 'gene patent' to refer to patents that specifically relate to gene sequences. More general references such as to 'human genes and genetic materials' may be understood as referring to all substances listed in the inquiry terms of reference.

1.9 The Committee notes that patent law, genetic science and health research are all areas which rely on specific and technical vocabularies, and the report seeks to avoid unnecessary use of technical terms wherever possible. The Committee wishes to acknowledge the patience and assistance of the many witnesses who assisted the Committee in developing an understanding of the complexities of patent law and genetic science.

3 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 5.

