Advisory Council on Intellectual Property

Patentable Subject Matter Report
Patentable Subject Matter

Report delivered to the Minister in December 2010 and publically released 16 February 2011

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Background and related enquiries

What were they thinking?
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What is ACIP?

Independent body appointed by the government to advise the Federal Minister for Innovation,

Industry, Science and Research on intellectual property matters and the strategic administration

of IP Australia.

Its membership reflects a cross section of industry involved with the intellectual property system,

and includes individuals from both large and small businesses, the legal and patent attorney professions and academia.
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Origin of the Review

ALRC 2004 “Report 99 Genes and Ingenuity: Gene Patenting and Human Health” considered that the existing manner of manufacture test for patentable subject matter was obscure and difficult to understand.

The ALRC also found it was unclear whether the test had the ability to consider social and ethical issues according to the traditional principle that an invention not be “generally inconvenient”
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Terms of reference

*Inquire, report and make recommendations to the Australian Government on patentable subject matter. The review will include the appropriateness and adequacy of the ‘manner of manufacture’ test as the threshold requirement for patentable subject matter under Australian law, and the historical requirement that an invention must not be ‘generally inconvenient’. 
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;

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.
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Major recommendations

Define patentable subject matter in the *Patents Act 1990* (Cth), for the purposes of both a standard patent and an innovation patent, using clear and contemporary language that embodies the principles of inherent patentability as developed by the High Court in the *NRDC* case and in subsequent Australian court decisions.

Amend the *Patents Act 1990* (Cth) so as to exclude from patentability an invention the commercial exploitation of which would be wholly offensive to the ordinary reasonable and fully informed member of the Australian public.
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Definition

‘Invention’ as defined as ‘manner of manufacture’, which relies on a definition from the English Statute of Monopolies 1623. The Statute of Monopolies 1623 provides that patents are only available for manners of new manufacture that are ‘not contrary to law or mischievous to the state by raising prices of commodities at home or hurt of trade or generally inconvenient’.

The manner of manufacture test can only be understood by reference to a substantial body of subsequent case law.

This leads to a mismatch between the words of the legislation and the principles developed by the courts. For a person reading the legislation, there is no transparency or guidance about the nature of the test. While the legislation tends to lead the reader to the literal words of section 6 of the Statute of Monopolies 1623, the courts have indicated that this the wrong approach.
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Definition

The courts have repeatedly acknowledged that an invention does not have to be either a ‘manufacture’ or a ‘manner of manufacture’ to be patentable.

The principles of inherent patentability used by the High Court in the National Research Development Corporation v Commissioner of Patents (NRDC) decision of 1959, and subsequently followed, are that an invention should be an artificially created state of affairs in the field of economic endeavour.

These principles have been consistently applied ever since, and there is now a large body of Australian case law illustrating their operation.

Corresponds with the ALRC view that while the threshold test of patentable subject matter should be flexible and capable of adapting to developments in technology as they arise, the terms of section 6 of the Statute of Monopolies 1623 are ambiguous and obscure.
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Exclusion

TRIPS Article 27(2)

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
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Exclusion

Desirable to use contemporary Australian language, rather than terminology that is not in common use in this country.

The United Kingdom adopted the phrase ‘public policy or morality’ as an alternative to the phrase ‘ordre public or morality’.

The wording in the TRIPS Agreement does not provide sufficient guidance about how to perform the assessment.

The reasonable person test is an objective concept that is commonly used in law.

Patent law uses a similar objective concept when considering inventiveness – by considering the views of the hypothetical person skilled in the art.
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Exclusion

Where there is an ethical concern about the invention itself (whether or not it is to be exploited commercially), it is more appropriate and more effective for other areas of the law to regulate and, if appropriate, prohibit use of the invention.

It would be inconsistent for the government to grant a patent for an invention the commercial exploitation of which was offensive to the Australian public. To do this would amount, in effect, to endorsing an activity that is offensive to the Australian public.

Society’s values change over time, and it is not for us to set rigid guidelines in this review. Recommending a framework that considers Australian values as they exist at the relevant time.
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Other Recommendations

Statement of Objectives

Remove overlap of the patentable subject matter provisions with the provisions on novelty, inventive step and usefulness.

Ensure the requirement of usefulness in paragraphs 18(1)(a) and 18(1A)(a) encompasses the requirement for utility that is currently an aspect of the manner of manufacture requirement.

Retain the exclusions in sub-sections 18(2) and 18(3)

Repeal section 50 and corresponding section 101B

Enable the Commissioner of Patents to seek advice in relation to the proposed general patentability exclusion.

Amend the standard for determining whether an invention satisfies the patentable subject requirements to ‘on the balance of probabilities’.