



**The Institute of
Patent and Trade Mark
Attorneys of Australia**

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By E-mail ONLY
Brendan.Bourke@ipaaustralia.gov.au

Brendan Bourke
Secretariat
Advisory Council on Intellectual Property
PO Box 200
WODEN ACT 2606

Dear Brendan,

Re: Options Paper – September 2009 - Patentable subject matter

Please find enclosed a submission on behalf of the Institute of Patent and Trademark Attorneys of Australia (IPTA) in relation to the *Options Paper – Patentable Subject Matter – September 2009*.

Kind regards,

Yours sincerely

Michael J Caine
Convenor - Legislation Committee
Institute of Patent & Trademark Attorneys of Australia

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**Comments on the September 2009 Patentable Subject Matter Options Paper
of the Advisory Council on Intellectual Property (ACIP)
by the Institute of Patent and Trade Mark Attorneys of Australia (IPTA)
November 2009**

General comments

The proposals in the options paper to 'clarify' (or more correctly, 'codify'), 'replace', 'delete', or 'enhance' current Australian law on patentable subject matter are based upon a weak argument sustained by a handful of red herrings. The red herrings divert attention away from the weak argument, and overcomplicate what should be an essentially simple question of whether particular subject matter may be patented in Australia.

The weak argument is that the current 'manner of manufacture' (MoM) test is 'obscure' due to 'archaic language'. This argument is weak because the idealised view that citizens should be able to discover the law from plain words in legislation has long been rejected even in civil law systems where it recognised that "there is an overlying patina of judicial decisions that must be known if the law is to be comprehended".¹ The 'patina' of modern case law overlying the current MoM test and its 'generally inconvenient' exception provides clear, flexible, and predictable criteria for answering the simple question above. Legislative change therefore cannot be justified on 'access to law' grounds.

The first red herring in the options paper is economic theory and evidence on patents.² The options paper cites a recent analysis of international economic literature on patents but overlooks its self-defeating conclusion that it is doubtful whether existing economic research

¹D C Pearce & R S Geddes, *Statutory Interpretation in Australia* (6th ed, 2006) 277.

²Advisory Council on Intellectual Property (ACIP), *Patentable Subject Matter*, Options Paper (September 2009) 31-34.

on patents can be used “for drawing clear policy conclusions or answering particular questions”.³ Legislative change therefore cannot be justified on economic grounds.

The next red herring in the options paper is the socio-legal theory of patent law as a ‘social filter’ through which particular inventions can pass if they are socially valuable. The options paper makes the trite point that the patent system is not socially ‘agnostic’. Indeed, the existing ‘contrary to law’ statutory exception clearly shows that patent law is expressly subject to social, ethical and moral considerations. Furthermore, the existing ‘general inconvenience’ exception to the MoM test also clearly shows that the patent law is subject to broader considerations of public policy which encapsulate prevailing social values, ethics and morality. The options paper discusses the theory of ‘social filtering’ extensively but gives no practical means for measuring how valuable any particular invention is to society at large. Legislative change to introduce ‘social filtering’ is unnecessary in view of the existing ‘contrary to law’ and ‘general inconvenience’ exceptions.

The issue of ‘threshold inventiveness’ is a further red herring. From a practical ‘real world’ point of view, ‘threshold inventiveness’ is an ‘ant-sized’ issue to users of Australia’s patent system rather than the ever-growing ‘elephant-sized’ problem that the options paper views it to be. Removing the definition of invention from schedule 1 of the *Patents Act*, or removing MoM altogether, are fundamental changes that could potentially create serious unintended consequences. Making fundamental legislative change to deal with an abstruse legal issue is equivalent to trying to kill an ant with an elephant gun. Instead, what is needed is a clear and unambiguous statement by a majority of the High Court along the lines of Lord Hoffmann's instruction that judges should “put on one side their intuitive sense of what constitutes an invention until they have considered the questions of novelty, inventiveness and so forth”.⁴

The final red herring is the proposal that an invention be required to have ‘specific, substantial and credible’ usefulness. ‘Usefulness’ is a discrete statutory requirement that should be assessed at the level of ‘sound prediction’ or ‘plausibility’, not ‘specific and substantial credibility’.

³Bronwyn Hall, *The Use and Value of Patent Rights*, Prepared for the UK IP Ministerial Forum on the Economic Value of Intellectual property (10 June 2009) 23.

⁴*Biogen Inc v Medeva PLC* [1996] UKHL 18 at [42]–[46].

To sum up, neither the weak argument of ‘archaic language’ nor any of the red herrings in the options paper justify legislative change. The only option clearly in Australia’s national interest is to retain the current law on patentable subject matter.

Part 1 Economic Test

Option A Retain

Retain the current definition of invention. This option retains the requirement that an invention must be ‘a manner of manufacture within the meaning of section 6 of the *Statute of Monopolies*’.

This option should be preferred. The MoM test provides clear, flexible, and predictable criteria for answering questions of whether particular subject matter may be patented in Australia.

From the decisions of the High Court in *NRDC*,⁵ and the Full Federal Court in *Grant v Commissioner of Patents*,⁶ the MoM test clearly requires that a patentable invention must result in ‘an artificial effect’. This normally involves ‘a physical effect in the sense of a concrete effect or phenomenon or manifestation or transformation’. A patentable invention also must belong to a ‘useful art as distinct from a fine art’ by having an ‘industrial or commercial or trading character’.

The ‘generally inconvenient’ exception to the MoM test clearly exists under the *Patents Act 1990*.⁷ Applying this exception clearly involves asking whether granting a patent for a particular invention would unfairly and unreasonably limit the freedom of public service providers by requiring them to avoid infringing the patent.⁸ If so, patent grant should be refused.

⁵ *National Research Development Corporation v The Commissioner of Patents* (1959) 102 CLR 252.

⁶ *Grant v Commissioner of Patents* [2006] FCAFC 120.

⁷ *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* [2000] FCA 316 [7]-[18].

⁸ *Rolls-Royce Ltd's Application* [1963] RPC 255; *Hiller's Application* [1969] RPC 267.

Option B Clarify

Clarify the language used to define an invention by replacing the reference to the language of the *Statute of Monopolies* with a modern interpretation. For example, provide that an invention is 'an artificially created state of affairs in a field of economic endeavour'.

This option should be rejected. It would codify, not clarify, the test for patentable subject matter by enacting a version of the 'CCOM Rule' – 'an artificially created state of affairs ... in the field of economic endeavour'.⁹

Doubts have been cast about the correctness and value of the CCOM Rule because it is a mosaic of two isolated passages in the High Court judgment in *NRDC*.¹⁰ Doubts also exist when interpreting codifying language about the extent to which it is permissible to have regard to the case law that has been superseded by the code.¹¹ It is uncertain whether courts would follow case law on the superseded MoM test. This could potentially lead to the complete loss of invaluable case law on the MoM test thereby allowing the codified CCOM Rule to be used as a proxy to introduce a completely new test by stealth. The codified CCOM Rule would increase uncertainty about what subject matter is patentable in Australia until it was considered by the High Court.

Option C Replace

Replace 'manner of manufacture' with an alternative test. For example, provide that patents are available for 'any invention in a field of technology'.

This option should be rejected. The options paper admits any new test would increase uncertainty about patentable subject matter until the new test was interpreted by the High Court.¹² A new test making patent protection available for 'any field of technology' would

⁹ *CCOM Pty Ltd v Jiejing Pty Ltd* (1994) 51 FCR 260, 295.

¹⁰ Ann Monotti, 'The Scope of 'Manner of Manufacture' under the Patents Act 1990 (Cth) after Grant v Commissioner of Patents' (2006) 34 *Federal Law Review* 461-479.

¹¹ D C Pearce & R S Geddes, *Statutory Interpretation in Australia* (6th ed, 2006) 273.

¹² ACIP, above n 2, 12.

increase uncertainty and costly disputes about "what is or is not to be described as ... technology".¹³

Option D Delete

Delete the requirement for an invention. Remove all references to 'manner of manufacture' and section 6 of the *Statute of Monopolies* from the *Patents Act 1990*, by deleting section 18(1)(a) and the Schedule 1 definition of 'invention'.

This option should be rejected. Deleting all references to the MoM test would provide an incentive for a flood of patent applications for things that have never been considered proper subject matter for patent protection.

Part 2 Social Filters

Option E Retain current exceptions and filters

Retain the current exceptions:

- Patents are not available for inventions that are generally inconvenient.
- Human beings, and the biological processes for their generation, are not patentable inventions.
- For the purposes of an innovation patent, plants and animals, and the biological processes for the generation of plants and animals, are not patentable inventions.

In addition, retain the current discretion for the Commissioner of Patents to refuse patents for:

- an invention the use of which would be contrary to law;
- a substance that is capable of being used as a food or medicine (for humans or animals) and that is a mere admixture of known ingredients;
- a process for producing such a substance by mere admixture;
- a person's name as the name of the invention in a claim.

This option should be preferred. The current exceptions are necessarily a melange that has evolved to reflect the complex and ever-changing and often conflicting technological, economic, social, ethical, moral and political conditions existing in Australia. The absence of

¹³ *Grant v Commissioner of Patents* [2006] FCAFC 120 [38].

any specific examples of any anti-social, unethical, or immoral patents in the options paper is clear evidence that the current exceptions are working.

Option F Specific exclusions

Provide a list of specific subject matters that are not patentable. Under this option, the legislation would list specific subject matters that are not considered to be patentable. One such possible exclusion is ‘a mere discovery’.

This option should be rejected. Subject matter exclusions invariably lead to increased uncertainty and costly disputes over the limits of the excluded subject matter. For example, trying to draw the line between ‘mere discovery’ and invention is a non-trivial issue.

Option G General filters

Provide a general social filter in the legislation to exclude patents for inventions that would be contrary to public policy or morality. For example, the legislation would exclude inventions from being patentable where the use of the invention would be ‘contrary to *ordre public* or morality or generally inconvenient’.

This option should be rejected. It is unnecessary to explicitly provide any ‘general social filter’. The existing ‘contrary to law’ statutory exception clearly shows that patent law is clearly grounded in social, ethical and moral considerations. The current ‘general inconvenient’ exception clearly accommodates general public policy considerations.

Part 3 Enhancements

Option H Inventiveness

Ensure that the legislation explicitly deals with inventiveness under the requirement that a patentable invention involves an inventive step. For example, remove the reference to the *Statute of Monopolies* in the definition of ‘invention’ in schedule 1. Alternatively, adopt a different subject matter test to the manner of manufacture test as discussed in Options B to D of this paper.

This option should be rejected. Since the High Court decision in *Lockwood v Doric*, 'threshold inventiveness' has essentially been confined to rare cases where a specification shows 'on its face' that an invention does not involve an inventive step.¹⁴ Although the Federal Court has referred to 'threshold inventiveness' on a number of occasions since *Lockwood v Doric*, it does not appear to have been a decisive ground of invalidity in any case. That is not to say that 'threshold inventiveness' does not continue to be a problem in invalidity proceedings by increasing uncertainty and costs.

It is impossible to completely excise the concept of 'threshold inventiveness' from questions of patentable subject matter because, as noted by Lord Hoffmann, it is a basic human temptation to "take an axe to the problem by dismissing [an invention] without inquiring too closely".¹⁵ It is naïve to think the natural temptation to oversimplify what is essentially a complex task would be extinguished by legislative change such as removing the definition of invention from schedule 1 of the *Patents Act*, or removing MoM altogether. Instead, what is needed is a clear and unambiguous endorsement by a majority of the High Court of Lord Hoffmann's instruction that judges should "put on one side their intuitive sense of what constitutes an invention until they have considered the questions of novelty, inventiveness and so forth".¹⁶

Option I Usefulness

Implement the ALRC recommendations on usefulness. The ALRC recommended that IP Australia examine and report on the usefulness of an invention as a separate requirement, and that such use must be specific, substantial and credible.

'Usefulness' is a discrete statutory requirement for a patentable invention that should be included as a ground to be considered during examination and re-examination. However, legislative change to "clarify that the requirement for usefulness is only satisfied if the patent specification discloses "a specific, substantial and credible use for the invention" cannot be justified for the following reasons.

¹⁴ *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd [No 2]* [2007] HCA 21, [106]-[107].

¹⁵ *Biogen Inc v Medeva PLC* [1996] UKHL 18 at [42]-[46].

¹⁶ *Biogen Inc v Medeva PLC* [1996] UKHL 18 at [42]-[46].

It is notable that while, for example, the US,¹⁷ the EPC¹⁸ (and therefore the UK Patents Act) and Japan¹⁹ provide for patents to be granted for inventions which are, inter alia, useful or, as it is also worded, industrially applicable, there is no provision in any of their Acts to govern what must be included in the patent specification in order to satisfy the requirement for usefulness. Instead, in these jurisdictions, guidelines are provided to Examiners for examination of patent applications to ensure they meet the required threshold of usefulness.

In the US, Code 35 provides conditions for patentability in respect of novelty and inventive step, 35 U.S.C. 102 and 35 U.S.C. 103 respectively, but there are no conditions for patentability in respect of usefulness enshrined in the Code. The US Patent Rules too do not descend into detailed discussion about the treatment of usefulness in examination. Thus 37 CFR §1.104 entitled "Nature of Examination" is silent as to the treatment of usefulness but deals with the rejection of claims for want of novelty or obviousness.²⁰ Instead, the issue of utility (usefulness) is dealt with in the Manual of Patent Examining Procedure (MPEP).²¹ §§2107.01-2107.03 of the MPEP sets out the guidelines to be followed by Examiners in making a rejection based on lack of utility.

Hence, if the Australian Patents Act and/or Regulations were to be amended to include the requirement that the patent specification discloses "a specific, substantial and credible use for the invention", it would result in a divergence in practice between Australia and the US.

With regard to Europe, Article 57 of the EPC governs industrial applicability but the Article merely provides that: [a]n invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture. There is therefore no requirement in Europe for the patent specification to disclose a "specific, substantial and credible use for the invention". Likewise, the Regulations do not require that the patent specification disclose "a specific, substantial and credible use for the invention".

¹⁷35 U.S.C. §101: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title".

¹⁸ Article 52 of the EPC: "European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application." Similarly Section 1 of the UK Patents Act: "A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say - (a) the invention is new; (b) it involves an inventive step; (c) it is capable of industrial application ..."

¹⁹ Article 29 of the Japanese Patents Act - "(1) An inventor of an invention that is industrially applicable may be entitled to obtain a patent for the said invention ..."

²⁰ 37 CFR §1.104(c)(2).

²¹ 37 CFR §706.03(a) II & 37 CFR §§2107.01-2107.03.

Rule 42(1)(f) of the EPC Regulations specifies that the description shall "indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is industrially applicable". Hence, it is only in the specific circumstances set out in Rule 42 that it is necessary to specify the industrial applicability of the invention.

Similarly to the US MPEP, the Guidelines for Examination in the European Patent Office²² contain information to assist an Examiner in examining for industrial applicability. There is also no requirement in the Guidelines that the Examiner must examine for a "specific, substantial and credible use for the invention".

Once again, if the Patents Act or Regulations was amended as proposed, it would result in a divergence between the way usefulness/industrial applicability is assessed in Europe and in Australia. Even adoption of a "specific, substantial and credible" test in assessing usefulness during examination/re-examination would impose a far higher threshold of usefulness on Australian applicants than applies in Europe.

Article 29 of the Japanese Patents Act does not seek to limit how industrial applicability must be set out in the patent specification. Moreover, the Examination Guidelines for Patent and Utility Model (sic) in Japan are silent as to a generic test for assessing industrial applicability.²³ Instead, the Guidelines list specific examples of matters which are regarded as not being industrially applicable.

In summary, none of Australia's major trading partners has any specific requirement enshrined in its legislation or regulations governing how usefulness/industrial applicability is to be assessed. In the case of the three major trading partners referred to above, the manner in which usefulness/industrial applicability is assessed is set out in guidelines for Examiners.

The proposal that usefulness be examined during examination and re-examination is supported, but specific requirements for assessing usefulness should not be enshrined in the Act and/or Regulations. As is the case in other jurisdictions, the Examiner's Manual is the appropriate place for guidelines for examining for usefulness.

²² Guidelines: Part C, Chapter IV - Patentability - 5. Industrial Application.

²³ Examination Guidelines for Patent and Utility Model in Japan - Part II - Requirements for patentability - Chapter 1 - Industrially Applicable Inventions.

It is noted that the USPTO Revised Interim Utility Training Materials²⁴ direct Examiners to assess whether any asserted utility is specific and substantial and, if so, to then determine whether such asserted utility is credible. It appears that these Training Materials were established to deal with issues which are specific to biotechnology and chemical compound matters. Such a test is therefore inappropriate for all technologies. Such a test could have adverse, unintended consequences. For example, what would be the case if a use is asserted in the specification which is not met by the invention as claimed but the invention as claimed has another use? Such a new use may not meet the "specific" leg of the test as contemplated.

The words "specific, substantial and "credible" are of uncertain scope. For example, does "substantial" mean very significant or simply non-trivial? Does "credible" mean something more than simply plausible? How specific does a utility have to be? There is also the danger that, even if these terms are defined, for example, as set out in the USPTO Training Materials referenced above, Examiners may place too high a threshold on the terms "specific" and "substantial". Not only would this impose a usefulness threshold in Australia which is higher than in the other jurisdictions, it would also place a greater evidentiary burden on an Australian patent applicant than an applicant in those jurisdictions. Including a test requiring a "specific, substantial and credible" use would result in greater uncertainty for patent applicants and the loss of an entire body of jurisprudence relating to the present test for "usefulness". It is noteworthy that neither TRIPS nor the AUSFTA requires such a test.

The present test for usefulness, i.e. whether or not the invention as claimed fulfils its promise, should be retained, and the Examiner's Manual be updated to assist Examiners in examining for usefulness based on the existing test. Examination of the utility requirement could take into account concepts such as "sound prediction" or "plausibility". Such an approach has been adopted in Canada.²⁵

Option J Advisory Panel

Establish an advisory panel to advise the Commissioner of Patents on the application of social filters (such as a contrary to <i>ordre public</i> or morality filter, or a 'generally

²⁴ Accessible at: www.uspto.gov/web/menu/utility.pdf.

²⁵ *Apotex Inc v Wellcome Foundation Ltd* [2002] 4 SCR 153.

inconvenient' exclusion) to the patentability of inventions.

This option should be rejected. The social value, ethics and morality of a particular invention should not be decided *ex novo* by a central authority. An explicit 'general social filter' is unnecessary (see Option G above). It follows that there is no need for a central committee to perform 'social filtering' of individual inventions. As noted by the options paper, an advisory panel would only increase uncertainty, complexity, cost, and delay in the patent system. The options paper also admits that an advisory panel is vague and uncertain even at the logistical level of implementing, staffing and running it. The case law on the existing 'contrary to law' and 'general inconvenience' exceptions shows that they can readily be applied by decision makers without expert evidence on social policy, ethics or morality.