



IPTA

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

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

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

Dear Brendan,

Re: Issues Paper – July 2008 - 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 *Issues Paper – Patentable Subject Matter – July 2008*.

Kind regards,

Yours sincerely



Michael J Caine

Convenor - Legislation Committee
Institute of Patent & Trademark Attorneys of Australia

cc: Linda Tocchet, The Institute of Patent and Trade Mark Attorneys of Australia, Level 2, 302 Burwood Road, Hawthorn, Victoria 3122 – by email linda@ipta.org.au

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**The Advisory Council on Intellectual Property (ACIP)
Patentable subject matter - Issues Paper, July 2008**

**Comments on behalf of
The Institute of Patent and Trade Mark Attorneys of Australia (IPTA)**

Introduction

1. IPTA is the representative body for Australian patent and trade mark attorneys. Its aims include promoting improvements in patent laws and regulations.
2. In general, IPTA's position is that there should be no change to current Australian law on patentable subject matter. There is no perfect approach for distinguishing between patentable and unpatentable subject matter. The existing approach of interpreting "manner of manufacture" using the approach in *NRDC*¹ is the best available formula and should be retained.
3. None of the imperfections or perceived problems of the existing approach identified in the ACIP Issues Paper provides sufficient grounds for its rejection. The alternatives identified in the ACIP Issues Paper are more imperfect and problematic. Rejecting the existing approach to patentable subject matter is a radical step that carries with it drastic and far-reaching consequences. The ACIP Issues Paper does not provide any justification for making such radical and drastic change to the Australian patent system.
4. It is convenient to first comment on the issues raised by the ACIP Issues Paper, before commenting on its broad alternatives and specific questions.

Issues

Rationale of patent system, and objective of approach to patentable subject matter

5. There is no single socio-economic rationale for the patent system – rationales have varied over its 400-year history. One commonly-accepted rationale is that patents encourage innovation that benefits society. There is no empirical basis for rejecting this rationale. It follows that denying patents in a subject matter-specific manner discourages certain forms of innovation that would benefit society.
6. The objective of the Australian approach to patentable subject matter should therefore be to allow conceptions of patentable subject matter to evolve in response to changing conditions so as to maximise the benefits Australians can achieve through patents.
7. This is consistent with the correct policy approach to Australian patent reform under which "review and change should seek to optimise the net benefits arising from the operation of the patent system in the national interest to the extent possible consistent with international conventions".²
8. When interpreted using the *NRDC* approach, "manner of manufacture" clearly gives the measure of flexibility required by the above objective to satisfy the above policy approach.

"Manner of manufacture" and NRDC

9. The position of some law reviews and commentators on "manner of manufacture" and the case law that has evolved around it is inconsistent and illogical. On the one hand, "manner of manufacture" is praised for the breadth and flexibility it gives to conceptions of patentable subject matter. On the other hand, the case law, including the leading case of *NRDC*, is criticised for failing to provide definitive certainty about the scope of "manner of manufacture", and hence patentable subject matter.
10. *NRDC* plainly rejected rigid, definitive certainty in favour of broad flexibility. It nevertheless provided a clear approach to deciding between patentable and unpatentable subject matter.

¹ *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252

² Industrial Property Advisory Committee (IPAC), Parliament of Australia, *Patents, innovation and Competition in Australia* (1984) [1]-[2].

11. The *NRDC* approach starts by asking the "right question" - "[i]s this a proper subject of letters patent according to the principles which have been developed for the application of s 6 of the Statute of Monopolies?"³ This question is answered by looking to see whether the subject matter under consideration lies inside or outside the limits of patentability established by the history of patentable inventions in decided cases. For most subject matter, the answer is self-evident and the inquiry ends here. For example, industrial products and processes for making them have always been considered to be patentable.

12. For subject matter at the margins, such as a process without a tangible end product, *NRDC* provided some clear principles to help further the inquiry. They include:
 - a patentable process must belong to a "useful art as distinct from a fine art"; it must have an "industrial or commercial or trading character";⁴
 - a product, in relation to a patentable process, is "only something in which the new and useful effect may be observed"; that "something" need not be a "thing" in the sense of an article; it may be any "physical phenomenon in which the effect, be it creation or merely alteration, may be observed".⁵
 - in the context of the agricultural process under consideration in *NRDC*, the method had as its end result an "artificial effect" and thus was within the true concept of what must be produced by a process if it is to be held patentable;⁶
 - in the context of the agricultural process under consideration, the effect of the method is a "product" because it consists in "an artificially created state of affairs".⁷

13. Properly understood, *NRDC* clearly provides a broad, flexible approach which enables decision makers to clearly distinguish between patentable and unpatentable subject matter in most cases. It also provides some clear principles to assist in hard cases at the margins of established patentability.

Grant v Commissioner of Patents

³ *NRDC* at 269.

⁴ *Ibid* at 275.

⁵ *Ibid* at 276.

⁶ *Ibid* at 277.

⁷ *Ibid* at 277.

14. The decision of the Full Federal Court in *Grant*⁸ is clear authority for the proposition that legal discoveries, such as Grant's asset protection scheme, are not patentable inventions because, in the words of *NRDC*, they lack "an industrial or commercial or trading character".⁹
15. In reaching its decision, the Full Court corrected three misstatements made during the litigation. First, it stated that Grant's asset protection scheme was not unpatentable simply because it was a business method.¹⁰ Second, it rejected the proposition that patentable subject matter must be within an area of science or technology.¹¹ Finally, it rejected Justice Branson's "social balancing" approach to patentable subject matter by stating that the judiciary is not in a position to determine the balance between social cost and public benefit for specific subject matter.¹²

Combination of flexible and proscriptive tests

16. The current combination of the broad, flexible "manner of manufacture"/*NRDC* approach to patentability and the statutory exclusions from patentability does raise a question about the consistency and logicity of current Australian patent law. The justification for the contrary to law exclusion, as well as the exclusion of human beings and biological processes for their generation, is public policy. However, the justifications for the other existing statutory exclusions are questionable.
17. The rationale and applicability of the person's name exclusion is unclear. The rationale of the mere admixtures of food and medicine exclusion is also unclear. The use of the word "mere" suggests that the exclusion is based on lack of inventiveness. If so, the exclusion may be redundant in light of the requirement of inventive step in subsection 18(b)(ii) of the *Patents Act 1990*. The plant and animal exclusion appears to be an arbitrary exclusion justified on a perception that innovation patents somehow interfere with Plant Breeder's Rights.

Value of existing body of case law

⁸ *Grant v Commissioner of Patents* [2006] FCAFC 120.

⁹ *Ibid* [34].

¹⁰ *Ibid* [47].

¹¹ *Ibid* [38].

¹² *Ibid* [45].

18. The existing body of case law on patentable inventions and "manner of manufacture" is invaluable because it attests to experience of considering so many different things over the course of almost 400 years of technological development. Almost everything developed over that time has been tried to be patented at one time or another.

Archaic language

19. The existing "manner of manufacture"/*NRDC* approach is not ambiguous and obscure due to the archaic language of section 6 of the *Statute of Monopolies 1623*. The phrase "manner of manufacture" is all that subsection 18(1)(a) of the present Act takes over from section 6, and the phrase can be clearly interpreted using the *NRDC* approach discussed above.

General inconvenience

20. There is clear authority that the generally inconvenient exclusion from patentability remains available under the present Act.¹³ The basis for its continuing availability seems to be the original statutory context of section 6 which is carried over to the present Act by the language "within the meaning of section 6 of the Statute of Monopolies" in subsection 18(1)(a) and the definition of "invention".
21. The generally inconvenient exclusion is a valuable measure of last resort which gives the judiciary an important opportunity to disallow specific subject matter under consideration based on a specific judicial interpretation of the public interest. There is clear authority for the proposition that the judiciary should not use general inconvenience to place blanket bans on patents across broad categories of subject matter, such as methods of treatment.¹⁴ This is because judicial perspectives of the public interest are inherently subjective.
22. Although rarely used, application of the generally inconvenient exclusion is clear and straightforward as shown by the leading cases of *Rolls-Royce Ltd's Application*¹⁵ and

¹³ *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 28 IPR 383.

¹⁴ *Bristol –Meyers Squibb Co v FH Faulding & Co Ltd* (2000) 46 IPR 553.

¹⁵ *Rolls-Royce Ltd's Application* [1963] RPC 251.

Hillier's Application.¹⁶ A noteworthy but almost always overlooked fact is that the generally inconvenient exclusion was not necessary for the decisions in these cases. In both cases, the subject matter under consideration had already been found to be outside the useful arts and hence not a "manner of manufacture". The statements about general inconvenience in both cases were therefore strictly obiter to discourage appeals. It is nevertheless clear from both decisions that general inconvenience is based on a specific judicial perspective that the granting a patent for the specific subject matter under consideration would create a burden that is not in the public interest.

23. That general inconvenience is almost never used by individual decision makers as the basis for excluding specific subject matter attests to the fact that the primary "manner of manufacture"/*NRDC* approach works well in almost every case. The infrequent use of the generally inconvenient exclusion attests to its status as an important measure of last resort, it does not attest to its modern irrelevance or dormancy due to uncertainty.

Threshold of inventiveness

24. The assessment of inventiveness has historically been removed from the question of patentability by legislative changes, and is dealt with separately by subsection 18(b)(ii) of the present Act. Subsection 18(1)(a) of the 1990 Act refers to "manner of manufacture" instead of "manner of new manufacture". The clear intention of this legislative change was to clarify that the definition of patentable invention in the present Act does not contain any residual requirements of newness or inventiveness from the original statutory context of section 6. This creates a presumption that Parliament meant to remove any threshold requirement of inventiveness from the present Act. Any contrary interpretation violates subsection 15AA(1) of the *Acts Interpretation Act 1901* (Cth).
25. The High Court decision in *Lockwood v Doric*¹⁷ did not reopen the existence of a discrete "threshold" test of inventiveness. Instead, it simply affirmed the narrow proposition from *Microcell*¹⁸ that the Commissioner of Patents may refuse a patent

¹⁶ *Hillier's Application* [1969] RPC 267.

¹⁷ *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd* (2007) 235 ALR 202.

¹⁸ *Commissioner of Patents v Microcell Ltd* (1959) 102 CLR 232.

application where a specification "on its face" shows the invention claimed is not a manner of manufacture.¹⁹ The continuing value of this narrow proposition was demonstrated by the recent decision in *Milton Edgar Anderson*²⁰ where the Deputy Commissioner of Patents disallowed a patent application for "a new law of electric induction" because the specification as a whole did not disclose a specific practical and useful application of the law that could be termed a "manner of manufacture".²¹

Threshold of utility

26. The assessment of utility has historically been removed from the question of patentability by legislative changes, and is dealt with separately by subsection 18(c) of the present Act. The quantum of utility required to support a patent is very small.
27. Requiring a patent to have some threshold quantum of utility must be rejected as a matter of principle. There is no theoretical or empirical basis for specifically saying what amount of utility should be provided by any specific invention. Neither the judiciary nor patent examiners are in any position to assess the actual or potential utility of specific inventions.

Scope of rights awarded

28. The question of whether a patent claim is wider than what is useful is strictly irrelevant to the question of patentable subject matter, and is dealt with by the separate but often overlapping requirements of usefulness, full description and fair basis in subsections 18(c), 40(2)(a) and 40(3) of the present Act.
29. It is a fallacy to say that a claim to a class of chemical compounds or genetic material is bad merely because the class is large. Such a claim should only be found invalid if it is proved that the class is infinite, or if any of the class is proved to lack utility.

¹⁹ *Lockwood* [106].

²⁰ *Milton Edgar Anderson* [2008] APO 19 (11 August 2008).

²¹ *Ibid* [13].

Requirement for grant

30. Dispensing with pre-grant assessment of the question of patentability raises fundamental questions about the consistency and logicity of Australian patent law. It would inevitably lead to the illogical end of patents being granted for subject matter which has always been considered outside the established limits of patentability. This is a radical change with drastic and far-reaching consequences. Such a change can in no way be justified on the ground of patent examiner resources. Removing patentability as a requirement for grant would only create an unmanageable flood of patent applications and granted patents for clearly unpatentable subject matter.

Overseas approaches

31. The existing "manner of manufacture"/*NRDC* approach substantially overlaps with overseas approaches, such as those in Europe, the US, Japan and New Zealand. The perception that New Zealand wishes to more closely align its approach to the existing Australian approach suggests that it is world's best practice, at least in our part of the world.
32. The existing Australian approach sits somewhere in the safe middle ground between the European and US approaches. The European approach features subject matter exclusions combined with a requirement of technical contribution. Subject matter-specific exclusions, as well as inclusions, must be rejected as a matter of principle because there is no theoretical or empirical basis for saying specifically how patent treatment should differ across specific technologies. Excluding patent rights in a technology- or industry-specific manner risks dramatically reducing or eliminating important incentives to innovate in excluded technologies and industries. The precise scope of the European requirement of technical contribution is unclear, although the use of the word "technical" suggests that patentable subject matter must lie in some area of technology. This suggests that the European approach is relatively more restrictive than the existing Australian approach.

33. The US defines patentable subject matter as "any new and useful process, machine, manufacture, or composition of matter".²² This language was interpreted by the US Supreme Court as making patents available for "anything under the sun that is made by man".²³ It is self-evident that this expansive definition of patentable subject matter is relatively more permissive than the existing Australian "manner of manufacture"/*NRDC* approach. That is not to say that there are no restrictions on, or problems at the margins of, patentability in the US, as demonstrated by the recent cases of *In re Comiskey*²⁴ and *In re Nuijten*²⁵.

International harmonisation

34. The perceived need for greater international patent law harmonisation should not automatically lead to the conclusion that the Australian patent system must adopt any particular overseas approach to patentable subject matter, such as the US approach. The existing Australian approach already substantially overlaps the US approach to the extent necessary to readily facilitate reciprocal processing of US- and Australian-sourced patent applications.
35. Conforming Australian patent law to that of the US raises fundamental questions of Australia's sovereignty and national interest. As with the Foreign Examination Reports (FER) procedure that has been unilaterally adopted by patent examiners without public consultation with users of the Australian patent system, there is no basis whatsoever in Australian constitutional, administrative, or patent law for automatically deferring to the patent law of another country.
36. The abovementioned IPAC policy approach to Australian patent law reform clearly states that any changes must optimise Australia's national interest. There is nothing about the ideal of global patent harmonisation which alone makes it right to reject long-established national or cultural approaches to patentable subject matter such as the Australian *NRDC* approach. There are no grounds at all to suggest that Australia's national interest is optimised by slavishly following the US approach.

²² 35 USC 101.

²³ *Diamond v Chakrabarty* 447 US 303, 309 (1980).

²⁴ *In re Comiskey* (CAFC 2006-1286).

²⁵ *In re Nuijten* (CAFC 2006-1371).

Ethical constraints

36. The existing contrary to law exclusion is justified on broad public policy grounds which presumably encompass ethical considerations. Parliament has already made the judgment that the human beings exclusion is justified on public policy grounds which also presumably encompass ethical considerations.

International obligations

37. The existing "manner of manufacture"/*NRDC* approach complies with Australia's international obligations under Article 27 of TRIPS by avoiding technology-specific limitations on patentable subject matter. The existing contrary to law, human being and generally inconvenient exclusions are encompassed by the broad exclusions permitted by Article 27.2. The other existing exclusions appear to violate Article 27.2.

Broad alternatives

All subject matters are patentable

38. Patents are property rights which must have legal boundaries. It follows that there must be some restrictions on what subject matter is patentable. It is wrong to say that there are no restrictions on patentability in the US. The limitations of the permissive US approach are clearly demonstrated by the recent cases of *In re Comiskey* and *In re Nuijten* referred to in the ACIP Issues Paper.

A narrow or definable range of subject matters is patentable

39. There is no theoretical or empirical basis for specifically saying how patentability should differ across specific types of subject matter. Prescriptive lists of subject matter-specific inclusions to patentability should be rejected as a matter of principle.

All subject matters, except for a narrow or definable range, are patentable

40. There is no theoretical or empirical basis for specifically saying how patentability should differ across specific types of subject matter. Proscriptive lists of subject matter-specific exclusions from patentability should be rejected as a matter of principle.

A wide range of subject matters that are difficult to define is patentable

41. *NRDC* provides a clear approach to interpreting "manner of manufacture" in a broad and flexible way to easily identify a wide range of patentable subject matters.

Questions

Question 1 - Economic objectives of limiting patentable subject matter

Can placing limits on inherently patentable subject matter be justified on economic grounds? Should the subject matter of each individual invention be assessed to determine whether a patent is necessary to encourage innovation, or should such an assessment be done for entire fields of technology?

42. No. There is no theoretical or empirical basis for assessing specifically the economic benefits or costs of specific inventions or specific technologies.

Question 2 – Economic effect of inherent patentability test

What would be the consequences on innovation of imposing or removing limits on patentable subject matter? Are you aware of any empirical data on such consequences?

43. Excluding patent rights in a technology- or industry-specific manner risks dramatically reducing or eliminating important incentives to innovate in the excluded technologies and industries. IPTA is not aware of any empirical data conclusively demonstrating positive or negative effects on innovation of imposing or removing limits on patentable subject matter. Empirical data on patenting activity in specific technologies is irrelevant to this question.

Question 3 – Ethical reasons for limiting patentable subject matter

Can placing limits on inherently patentable subject matter be justified on ethical grounds? Is it appropriate for legislation to predetermine ethical limitations on patentable subject matter, or is it more appropriate for courts to determine such limitations on a case-by-case basis? Is patent law an appropriate avenue for dealing with ethical issues? If not, what is an appropriate avenue?

44. Ethical considerations are encompassed by public policy which changes over time and must be left to Parliament. Judicial perspectives of the public interest are inherently subjective. The judiciary is in no position to determine the social cost and public benefit, including ethical limits, of specific inventions or specific technologies.

Question 4 – Ethical effect of inherent patentability test

What would be the ethical consequences of imposing or removing limits on patentable subject matter? Are you aware of any examples of such consequences?

45. Subject matter-specific exclusions from patentability are ethically unacceptable in principle if they discourage innovation in areas that would benefit society, such as innovation in technologies to solve important problems, alleviate suffering or save lives.

Question 5 – Other reasons for limiting patentable subject matter

Other than economics, ethics and national security, can placing limits on inherently patentable subject matter be justified on any other grounds?

46. No.

Question 6 – Content and structure of current Australian law

Does the content of current Australian law meet the objectives of the system? Are decision makers focusing on the appropriate principles? Is the legislative structure of current law appropriate for the content? Is the current law clear to decision makers and users of the system? Does the content or structure of the current test cause you any significant problems?

47. Yes. The Full Court decision in the *Grant* litigation clarified a number of misstatements and refocused decision makers on the appropriate *NRDC* principles. Some of the current statutory exclusions from patentability raise questions of consistency and logic.

Question 7 – Issues with current Australian law

Do you have any comments on issues A to H identified in Part 11.3.1?

- *combination of flexible and proscriptive tests*
- *value of existing body of case law*
- *general inconvenience, mischievous to the state and hurt of trade*
- *archaic language*
- *threshold of inventiveness*
- *threshold of utility*
- *scope of rights awarded*
- *requirement for grant*

48. IPTA specific comments on these issues are set out above and defy paraphrasing. Suffice it to say that none of the issues identified in the ACIP Issues Paper provides sufficient grounds for rejecting the existing "manner of manufacture"/*NRDC* approach.

Question 8 – International integration

Is it more important to achieve best practice or to harmonise with a major jurisdiction? Are any jurisdictions preferable over others?

49. It is important to have the best available approach to patentable subject matter so as to optimise the net benefits arising from the operation of the patent system in the national interest to the extent possible consistent with international conventions. The approaches of other jurisdictions are no more perfect or less problematic, so none of them should be preferred over the existing Australian approach.

Question 9 – International compliance of current Australian law

Is current Australian law compliant with our international obligations?

50. The existing "manner of manufacture"/*NRDC* approach complies with Australia's international obligations under Article 27 of TRIPS by avoiding technology-specific

limitations on patentable subject matter. The existing contrary to law, human being and generally inconvenient exclusions are encompassed by the broad exclusions permitted by Article 27.2. The other existing exclusions appear to violate Article 27.

Question 10 – Preferred patentable subject matter

According to what you believe are the appropriate objectives and constraints of the patent system, what sorts of subject matters do you think should be inherently patentable and what should not? Would your preferred content be compliant with Australia's international obligations?

51. The objective of the Australian approach to patentable subject matter should be to allow conceptions of patentable subject matter to evolve in response to changing conditions so as to maximise the benefits Australians can achieve through the operation of the Australian patent system. This objective is met by the existing "manner of manufacture"/*NRDC* approach because it enables a wide range of patentable subject matter to be clearly identified. The existing approach complies with international obligations to the extent possible.

Question 11 – Legislative structure

What sort of legislative structure would be appropriate to achieve your preferred content identified in Question 10? Are any foreign structures preferred? In principle, when should statutory provisions excluding specific subject matters be used? Should such provisions be expanded, such as by including the exceptions from patentability allowed under TRIPS?

52. The existing legislative structure is appropriate and should be retained. No foreign structures should be preferred. Subject matter-specific exclusions should be rejected in principle. There should be no further exclusions from patentability.

Question 12

Do you have any other comments?

53. No, but IPTA welcomes the opportunity to provide further explanation of its comments above if necessary.