



*Generic Medicines Industry
Association Pty Ltd*

ABN 19 096 009 540

PO Box 222

Pymble BC

NSW 2073

Generic Medicines Industry Association

**Submissions to ACIP's options paper
"Patentable subject matter"**

December 2009

**For further details
Please contact
Kate Lynch, CEO
kate.lynch@gmia.com.au**

Submission to ACIP's options paper "Patentable subject matter"
By Generic Medicines Industry Association

Submissions to ACIP's options paper
"Patentable subject matter"

Prepared by the Generics Medicines Industry Association ("GMIA")

The GMiA has prepared this submission in response to ACIP's call for submissions to its options paper on "Patentable subject matter". ACIP is seeking comments on reforms options relating to:

1. retaining, clarifying, replacing or deleting the current test of "*manner of manufacture*";
2. retaining and/or adding to the current exceptions and filters that exclude certain subject from being patentable; and
3. reforming the requirements for inventiveness, usefulness and/or establishing an advisory panel to advise the Commissioner of Patents on the applications of social filters to the patentability of inventions.

Members of GMiA support balanced intellectual property rights in the pharmaceutical sector. The issues raised in this paper are therefore of great interest to the members of GMiA, who support law reform that brings about greater clarity and certainty.

1. *Economic test - defining patentable subject matter*

Option A - Retain

Retain the current definition. 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'.

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'.

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'.

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'.

GMIA supports option A, as it provides the most appropriate and balanced approach for defining what should constitute patentable subject matter, and around which there is significant established case law which add to certainty.

GMIA considers that the changes proposed under options B, C and D are unlikely to bring about any greater clarity or certainty than the situation under the current common law, and therefore, does not see any practical justification for reform.

Option B is the best alternative to Option A, which involves codifying the existing common law tests for patentable subject matter (e.g. as set out in the *NRDC* and *Grant* decisions). However, the revised statutory test is unlikely to result in significant practical changes (or improvements) to current practice. Any new test will raise new issues of interpretation, which could initially result in a period of uncertainty. Also, ACIP's comment that "*an invention must have an industrial or commercial or trading character*" is much more restrictive than what is acceptable as patentable subject matter under current practice.

Option C raises issues of how the definition will ultimately be worded. For example, ACIP's proposal to restrict patents to inventions in "*a field of technology*" raises questions as to how a field of technology is defined. ACIP correctly acknowledges the problems associated with the European approach of excluding certain subject matter from being within a field of technology, and should ensure that this approach is not adopted in Australia. The need for a "*field of technology*" may suggest there can be an established research community in a specific technical area which is not appropriate in completely new areas of research. Accordingly, GMIA believes that option C is unlikely to bring about any greater clarity or certainty compared with the existing law, but rather, is likely to open up new areas of debate that will raise uncertainty for businesses.

Option D removes the need for a separate threshold test for patentable subject matter, and will rely on the test under section 18 of the Patents Act to determine patentability of an invention. While there seems to be merit in the simplicity of this approach, GMIA notes that it would be desirable to retain some form of threshold subject matter requirement for patentable inventions, such as to exclude specific types of research or innovation activity that is undesirable from an ethical or public policy perspective (see comments below).

2. *Social filters - exclusions to patentability*

2.1 Retain current exception and filters

Option E

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;*

Submission to ACIP's options paper "Patentable subject matter"
By Generic Medicines Industry Association

- *a person's name as the name of the invention in a claim.*

GMIA does not support this proposal. The problem with option E is that the current exclusions under sections 18 and 50 of the Patents Act are very limited and (arguably) do not provide a mechanism to effectively exclude technologies which society (and Parliament) might consider undesirable. The exclusions imported by the Statute of Monopolies (i.e. that patents do not extend to manners of new manufacture that are "*contrary to law nor mischievous to the state by raising prices of commodities at home or hurt trade or generally inconvenient*") are rarely applied in practice, possibly because they are too vague for application.

2.2 Specific exclusions

Option F

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'.

GMIA supports this proposal. GMIA supports the rationale that the exclusion only applies to specific subject matter which does not benefit society. The exclusions can be easily implemented by extending the existing exclusionary factors under section 50(1)(b) of the Patents Act.

2.3 General filters

Option G

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'.

GMIA does not support this proposal in its current form. It is unclear, from the proposal, what type of subject matter is intended to be excluded on the basis of contravention of public policy or morality. In the absence of clear guidelines, the current proposal is likely to give rise to further litigation as the courts work out what things would offend public policy or morality at any point in time. GMIA believes that issues of public policy and morality are more suitably addressed in parliament rather than in the courts.

3. Enhancements

3.1 Inventiveness

Option H

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.

GMIA does not support this proposal.

The "evergreening" of patents in the pharmaceutical industry is a key concern to GMIA members. The current requirement of threshold inventiveness under the current law (by requiring "*a manner of new manufacture*") provides an important basis for rejecting "evergreening" patents. The threshold inventiveness test is also important for ensuring that only innovations which provide a real improvement over the prior art should be entitled to patent protection.

The need to retain the threshold inventiveness requirement is highlighted by the fact that Australian courts have effectively reduced the requirement of inventive step to a very low threshold compared to other jurisdictions (such as Europe). Accordingly, currently it is extremely difficult to invalidate "evergreening" patents using arguments based merely on lack of inventive step.

3.2 Usefulness

Option I

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 may be specific, substantial and credible.

GMIA supports this proposal. However, GMIA notes that the three factors proposed for assessing usefulness of an invention are rather vague, and therefore would be difficult to apply in practice.

3.3 Advisory Panel

Option J

Establish an advisory panel to advise the Commissioner of patents on the application of social filters (such as a contrary to order public or morality filter, or a 'generally inconvenient' exclusion) to the patentability of inventions.

GMIA supports this proposal.