

7 October 2008

Brendan Burke
Secretariat
Advisory Council on Intellectual Property
PO BOX 200
WODEN ACT 2606

Submission by Medicines Australia to the Australian Council on Intellectual Property on the Review of Patentable Subject Matter

Dear Mr Burke

Medicines Australia is pleased to have the opportunity to respond to the ACIP as part of its review of patentable subject matter in Australia. We also appreciate the extension of time granted to lodge this submission.

Below, Medicines Australia responds to questions 1, 2, 6, 8, and 10 in section 11 of the *Issues Paper*.

Medicines Australia represents the innovative medicines industry in Australia. Our member companies comprise more than 80 per cent of the prescription pharmaceuticals market and are engaged in the research, development, manufacture, supply and export of prescription medicines.

Medicines Australia believes that Australia needs a well-crafted, strong and progressive intellectual property framework to protect and promote innovation in not only the pharmaceutical and life sciences sectors but across the whole of the national innovation system.

This means enforcement of patent protection rules, effective data protection, a commitment to the concept of patent term restoration (in case of pharmaceuticals), and the willingness to quickly adapt existing frameworks to create appropriate protection for, and, concurrently, strong incentives for research and development of advanced and emerging technologies.

Medicines Australia looks forward to working with the ACIP as it conducts this review of patentable subject matter. If you have any questions about this submission, or if you would like further information, please do not hesitate to contact Deborah Monk, Director, Innovation and Industry Policy, at deborah.monk@medicinesaustralia.com.au or at 02 6122 8500.

Yours sincerely



Ian Chalmers
Chief Executive

11.1 OBJECTIVE OF THE TEST

Question 1 – Economic objectives of limiting patentable subject matter

Can placing limits on inherently patentable subject matter be justified on economic grounds?

The economic ground relied on in 11.1 of the Issues Paper to limit patentable subject matter, is that protection should be confined to areas where it is known that free-riding occurs and causes financial injury to inventors. Medicines Australia submits that generally such limitations cannot and should not be justified on economic grounds.

Medicines Australia accepts that it can be impractical to assess whether free-riding would be injurious to each individual innovation, but does not support:

- (a) the broad assessment of innovations according to their designated class; and
- (b) in particular, the classification of broad areas of innovation as non-patentable subject matter.

This is for 2 main reasons:

- (i) The formulation of proscriptive categories of subject matter which are to be excluded from patentability is, as described at 11.1 of the Issues Paper, a "crude on/off switch" which has the potential to stifle entire fields of innovation. This is particularly so for fields such as pharmaceuticals and other technologies which treat and/or prevent human disease, where the risks of failure are high and huge investments of resources are required to understand and then address scientific problems.
- (ii) Precluding an otherwise patentable invention from grant on the basis that its subject matter is deemed to fall within a proscribed category obviously adversely affects the desire to innovate within that field.

Therefore, Medicines Australia respectfully submits that, to the greatest possible extent, Australia should limit proscriptive exceptions to patentable subject matter (for example, contrary to law; and human beings, and the biological processes for their generation) and should avoid creating any new categories of exception, as these may have the undesirable effect of adversely affecting the incentives to invest in the development of existing and new technologies.

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?

As stated above, Medicines Australia is in favour of a liberal test on patentable subject matter. Accordingly, it does not support:

- (a) a "patentable subject matter" assessment test for each individual invention. However, the "patentability" should continue to be assessed on an individual basis according to the other criteria, for example, novelty, inventive step, utility, sufficiency etc. There are sufficient checks and balances in these criteria; and
- (b) an assessment being done for an entire field of technology.

Further to (b), because categories of exclusion are broad by definition, their scope is uncertain and innovators in fields which fall within "grey areas" cannot be confident as to whether the eventual product of their investment, research and development, which may be novel, inventive and useful, will nevertheless be proscribed from patentability. As technologies continue to advance, the nature and scope of "defined" categories of exclusion will inevitably change creating greater uncertainty.

As noted above, the only way to resolve such uncertainties is for Parliament to make it expressly clear that there are limited *per se* exceptions to patentable subject matter.

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?

Medicines Australia can confidently report that the potential economic benefits and rewards of a patent monopoly over an innovation is one of the most significant drivers in originator pharmaceutical companies undertaking research in that subject matter. These economic benefits help to underpin the entire research program. Imposing limits can therefore remove these benefits and removing limits can help to open up areas of research.

One example is the changing approach in relation to the patentability of methods of medical treatments of humans. Contrast the decision of the Honourable Justice Heerey in his first instance decision (not patentable) in *Bristol-Myers Squibb Company v FH Faulding & Co Ltd* with the Full Court on appeal (patentable).

There can be no logical distinction between the research required to develop a compound and a method of using that compound to treat an illness. It should be made clear in whatever test is adopted that such methods are patentable.

11.3 CONTENT AND STRUCTURE OF THE TEST

11.3.1 Current Australian Law

Question 6 – Content and structure of the current Australian law (Part 7)

Does the content of current Australian law meet the objectives of the system? Are decision makers focusing on the appropriate principles?

Medicines Australia is concerned that the content of the current Australian law is not sufficiently focused on providing incentives which foster innovation, which should be the paramount objective of patent law. For this reason, we propose below that the Australian law apply a flexible test for patentable subject matter and limit proscriptive exceptions to patentable subject matter as much as possible, similar to the US law.

Is the legislative structure of current law appropriate for the content?

Medicines Australia agrees with ACIP that removing proscriptive provisions, such as that relating to, for example, mere admixtures of food and medicine may help simplify administration of the law, as these are based on the concept of inventiveness and do not warrant separate treatment.

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?

As described above, Medicines Australia considers the current law, and in particular the prevailing categories of exception to patentability, to be unclear. Better clarity can be achieved by abolishing categories of exclusion to patentability (again subject to the limited cases described above).

11.3.2 International issues

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?

Medicines Australia believes that it is in Australia's best interests to apply a flexible test for patentable subject matter and limit proscriptive exceptions to patentable subject matter as much as possible, similar to the US law. This is also prudent in the light of the Australia and United States Free Trade Agreement 2004 (**AUSFTA**). Many significant changes to patent and other intellectual property laws, such as copyright, have already been made pursuant to AUSFTA, but not all of the agreed changes have yet been made. In particular, under the AUSFTA, Australia is required to make patent protection available to "new uses or methods of using a known product". By contrast, while the AUSFTA lists "diagnostic, therapeutic and surgical methods for the treatment of humans and animals" as essentially the only category of subject matter which Australia may exclude from patentability, for the

reasons outlined above Medicines Australia does not believe that Australia should do so.

11.3.3 Broad alternatives

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?

As described above, Medicines Australia does not believe that any subject matters should be deemed inherently patentable or, in particular, inherently un-patentable. As discussed above, the scope of any purported category of subject matter is generally unclear.

Would your preferred content be compliant with Australia's international obligations?

Yes, and in particular, Medicines Australia's suggestions that express provision be made to allow the patenting of new uses of known substances without limiting them to method or process claims are consonant with Australia's obligations under the AUSFTA. Further, Medicines Australia's suggestion to abolish all *per se* exceptions to patentability does not offend GATT, TRIPs or the AUSFTA, all of which permit the exclusion of some methods of medical treatment but do not mandate any exceptions.