

**COMMENTS FROM THE AUSTRALIAN INSTITUTE OF MARINE SCIENCE**

The Australian Institute of Marine Science (AIMS) conducts a mix of strategic and basic research on a range of marine issues of national importance. The Institute supports a substantial Marine Biotechnology research group, which incorporates projects focused on aquaculture, discovery of bioactive molecules, chemical ecology, and molecular ecology. Because AIMS facilitates the commercial development and application of its research where possible and appropriate, it has considerable experience in the management of Intellectual Property involving marine biota including plants, animals and micro-organisms. AIMS does not have experience with the recently introduced Innovation Patent system, has never sought an Innovation Patent, and the Innovation Patent may not be suitable for discoveries made at AIMS in the future. Nevertheless, the following comments are made to contribute to discussion on the expansion of the Innovation Patent's scope to include biota, from a perspective of concern that such an expansion might impact AIMS ability to secure protection of its discoveries.

In general, AIMS patents involving biota are for a particular attribute of a species and a novel application or use for that attribute. Examples include chemical compounds that exhibit a particular pharmaceutical activity, and coral tissue for use in bone transplantation. AIMS does not seek a patent over compounds or attributes per se even if though in many cases they may be a novel discovery. The criteria for true invention and therefore standard patent protection are only satisfied by the combination of the attribute and a novel and useful application for it. There also needs to be a clear pathway to commercialisation.

**Is the current 'gap' in IP protection for inventions with a lower level of threshold, that involve plant and animal subject matter, seen as an existing or potential problem?**

Not from the perspective of inventions made at AIMS. The standard patent system is seen as the desirable level of protection now and into the future. Lower thresholds could mean that good opportunities are lost if not handled correctly and may lead to 'parking' or 'blocking' strategies as these options become affordable.

**Given the existence of the standard patent system and the PBR system, is there a need for those involved with plant and animal subject matter in R&D in Australia to be able to protect their research with the Innovation Patent?**

Not from the perspective of AIMS. As stated above, AIMS will continue to seek standard patent protection over its inventions involving marine biota.

**What, if any, are the national benefits of excluding plant and animal subject matter from the Innovation Patent?**

The major benefit of a continued exclusion of plant and animal subject matter from the Innovation Patent is the avoidance of potential pitfalls of inclusion of such matter. An Innovation Patent system that includes biota in its scope has the potential to allow protection of inventions that are closer to the 'discovery' end of the inventiveness spectrum, allow an unfocused breadth of scope, and confound standard patent protection of true biota related inventions such as those made at AIMS.

It is important to note that in the relatively unexplored marine realm, discoveries come easily. Vast areas of the marine sphere remain unexplored, and even in the relatively well studied marine habitats, such as shallow tropical reefs, the majority of biodiversity remains undescribed. These organisms and habitats in turn possess a plethora of undescribed chemical compounds, biomaterial types, and other attributes. Scientists working with marine material do not have to look far to make a 'discovery'.

If widened to include biota, the Innovation Patent's lower invention threshold and less rigorous examination and scrutiny process may promote a rash of cheap, easily obtained, poorly justified, and broad in scope 'discovery' patents which would prevent standard patent protection of a specific novel application of an attribute of that biota. The Innovation Patent would essentially 'park' potential inventions regarding as yet unidentified attributes. In AIMS view, such an Innovation Patent system would also provide an opportunity for unscrupulous operators to proactively park broad swathes of biota types and their attributes that showed commercial potential (and hence satisfying the lower thresholds), beyond their own R&D capability to progress the subject matter to commercialisation with the patent's life. While protecting their own efforts by eliminating R&D competition, this system would impede the full invention and commercial capacity of the subject material.

Further, for biodiscovery R&D (ie seeking attributes of biota with a commercial application), the time frame of 8 years for an Innovation Patent is completely unsuitable. For example, for drug discovery, the time line from lead discovery in the crude extract of the source organism to the pills available to the market (via in vitro research, in vivo animal model testing, and finally three phases of clinical trials), is typically at least 8 years. At AIMS, an important consideration in the patenting strategy is not to patent too early, so that once an invention progresses to a commercial reality, there is still sufficient life left in the standard patent for it to be an attractive investment option to industry. An Innovation Patent system that included biota would provide opportunity to patent too early and for too little time, and in reality impede commercial opportunities.

#### **What impact would the Innovation Patent have on non IP right holders were it to include plant and animal subject matter?**

In AIMS view, such a system would allow protection of research findings at the 'discovery' end of the inventiveness spectrum, with a lower requirement for examination and scrutiny. The resulting broad scope patents involving biota would have the potential to impede the application and even non-commercial use of biota by non IP right holders in the community.

#### *The case of microorganisms.*

Microorganisms have long been recognised as holding enormous potential for the production of natural products. Now there is unprecedented opportunity (due to presence and low cost of sophisticated tools) to identify unculturable types, manipulate DNA and culture previously unculturable organisms. Many antibiotics on the market today have their origins in bacteria, and microbes from extreme environments have yielded enzymes and other industrial products that are stable in extreme conditions (eg enzymes in cold water laundry detergent). The marine microbial collection at AIMS has huge potential in this regard. It is unique due to the efforts spent in culturing previously unculturable strains from a wide range of microhabitats including extreme environments. Thus, it contains strains that have never been screened against most commercial targets.

There is an important bonus advantage in the discovery of commercial products in culturable microorganisms – if you can culture them, you also have the means of economic, sustainable, large scale production.

It is of concern to AIMS that the Innovation Patent system currently specifically includes microbiological processes or products of those processes. The above discussion regarding time frames and concern over a system that allowed protection of IP that was too broad in scope and poorly justified (with respect to inventiveness) is equally applicable to macro-organisms and Australia's unique and endemic micro-organisms. AIMS therefore recommends that at least limited exclusion of micro-organisms from the Innovation Patent system be considered.

**For further information:**

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