

AusBiotech Response to the IP Australia "Exemptions to Patent Infringement"

AusBiotech
May 2009

AusBiotech Ltd
ABN 87 006 509 726
Level 1, 322 Glenferrie Road
Malvern Vic 3144 Australia
Telephone: (03) 9828 1400
Fax: (03) 9824 5188
Email: admin@ausbiotech.org
Website: www.ausbiotech.org

Table of contents

Introduction	3
1. Proposed change	5
2. Do you agree in principle with IP Australia's proposal?	5
3. Do you think that IP Australia's formulations are the best solution?	6
Summary.....	7

Introduction

AusBiotech is the national industry organisation that represents one of the key industries of the future: biotechnology.

It is through a properly supported biotechnology industry that we will see solutions emerge to confronting global issues – whether they are in health, climate change, food or fuel supply. Biotechnology will be the ‘enabler’ to assist achievement of breakthroughs and drive wealth creation in Australia.

AusBiotech is Australia’s only national biotechnology organisation and represents more than 3,000 members covering the human health, agricultural, medical device, environmental and industrial sectors in biotechnology. AusBiotech is dedicated to the development, expansion and prosperity of the Australian biotechnology industry by providing initiatives to drive sustainability and growth, outreach and access to markets, and representation and support for members nationally and around the world.

AusBiotech welcomes the opportunity to comment on the proposed changes from IP Australia. Currently there are no provisions in Australian Patent Law that provide clear guidance on experimental research to determine how existing intellectual property (IP) “works”, without the need for an agreement with the owner of the IP. Research exemption provisions exist in Patent Law in other countries and any such exemption under Australian Patent Law will need to be consistent with the Trade-Related Intellectual Property Rights agreement (TRIPS). The aim of research exemptions is to allow examination of a patented product or process; to ensure patents do not impede research and development; allow for validity testing and scope assessment; facilitate undertaking comparisons with other patents; and to allow for the obtaining of regulatory information.

It should be noted that it is not the intent of the exemption to allow use of the patented invention in a process that is not an experiment (situations where the user will profit from the use of the invention).

It is the opinion of AusBiotech that the changes to the Patents Act will provide clarity to researchers; however the boundary between research and commercial exploitation of a patent will need to be clear.

1. Proposed change

IP Australia has proposed to amend Part 1 of Chapter 11 of the Patents Act to include the following statutory exemption:

A person may, without infringing a patent, do any act on a patented invention which is solely for the purpose of:

- *determining how the invention works;*
- *seeking an improvement to the invention;*
- *testing the validity of a patent;*
- *determining the scope of the patent claims;*
- *determining whether an act or product infringes a patent;*

or

- *obtaining the information required for regulatory approval under Australian law or the law of any other country that regulates the manufacture, construction, use or sale of the patented invention.*

The statutory exemption will not apply where the invention is used in, but is not the subject of, an experiment.

From the above change, it is clear that the intent is to permit research so long as the activity is not commercial in nature. As commented in the introduction, the exact boundary of what is and what is not commercial will need to be explored at some point in the future. AusBiotech suggests that any onus on demonstrating that experimental use is not commercial should be on the experimenter, rather than requiring the owner of the patent to demonstrate that the intention of the experimental use was to benefit from the patent.

IP Australia has asked the following questions regarding the proposed change.

2. Do you agree in principle with IP Australia's proposal?

In principle, the proposed changes provide increased certainty to researchers in Australia, providing clarity on activities that can be undertaken while protecting the value of the IP. For example, it allows the following situation to occur:

Researchers wish to compare introduced genetic traits contained in transgenic plant A developed internally to that contained within transgenic plant B, a variety containing a commercial trait. The purpose of the research is to assess the mode of action of each trait in each plant for the purpose of comparisons that are provided to a regulatory agency.

In a similar vein, researchers wishing to compare two biologically active compounds for clinical and efficacy trials should not be in breach of patent rights.

However, if in either situation, patented technology was used to produce the final product for sale, then it is necessary to have an agreement with the patent owner. If there is not an agreement, then the patent rights have been effectively breached.

Regarding the PCR example provided by IP Australia, the difficulty will occur where optimisation of a PCR protocol occurs using temperature and cycle number. The optimised protocol for commercial purposes is very specific and may fall within the boundary of a broader existing patent, a situation. As such, where the distinction between research and commercial use occurs, may not be clear for some time.

3. Do you think that IP Australia's formulations are the best solution?

The current formulation still restricts the use of patent technologies for generating ideas. From reading the formulation, copying a patented invention and using it in an experiment breaches patent rights. The proposed change supports the intention of patents to provide information to the community while protecting the value of the patent.

The proposed amendment is simple to implement legislatively. It is important that the exact wording used is robustly reviewed to ensure that it reflects the intent of the change. AusBiotech would welcome any opportunity to review the proposed wording.

Summary

AusBiotech welcomes the opportunity to comment on the proposed amendment to the Patents Act. The amendment will provide clarity to Australian researchers using intellectual property for research purposes and encourage innovation across industries, including biotechnology.

AusBiotech would welcome the opportunity to review any proposed wording prior to the legislative process.