

EXPERIMENTAL AND REGULATORY USE EXEMPTIONS TO INFRINGEMENT OF PHARMACEUTICAL AND MEDICAL DEVICE PATENTS

GRACE O'CONNOR

DAVIES COLLISON CAVE LAW



DAVIES
COLLISON
CAVE LAW

INTELLECTUAL PROPERTY
TECHNOLOGY AND
COMMERCIAL LAW

dcc.com

WHAT IS INFRINGEMENT?

A patent gives the patentee the exclusive rights, during the term of the patent, to **exploit** the invention and to authorise another person to exploit the invention.

"exploit" , in relation to an invention, includes:

- a) where the invention is a product--**make, hire, sell or otherwise dispose** of the product, **offer** to make, sell, hire or otherwise dispose of it, **use or import it**, or **keep it for the purpose** of doing any of those things; or
- b) where the invention is a method or process--use the method or process or do any act mentioned in paragraph (a) in respect of a product resulting from such use.

WHAT ARE THE EXEMPTIONS?

Regulatory Use Exemptions

- S 119A - a patent will not be infringed by a person carrying out acts for obtaining regulatory approval of pharmaceuticals
- S 119B - a patent will not be infringed by a person carrying out acts for obtaining regulatory approval of non-pharmaceuticals (such as medical devices)

These exemptions apply whether the regulatory approval being sought is in Australia or overseas.

Experimental Use Exemption

- S 119C - a patent will not be infringed by acts done for experimental purposes relating to the subject matter of the invention

WHY ARE THE EXEMPTIONS IN PLACE?

Regulatory Approval Exemptions

- Approval from the Therapeutic Goods Administration (**TGA**) usually takes about 12 to 18 months following application.
- Application for regulatory approval often requires the carrying out of steps that might otherwise infringe a granted patent.
- Patent owners maintain market exclusivity whilst generic competitors participate in approval process.
- Other jurisdictions have “springboarding” provisions in place.

Experimental Use Exemptions

- address uncertainty

WHAT ACTIVITY IS COVERED BY THE EXEMPTIONS?

Regulatory Use Exemptions

“**solely for purposes connected with**” obtaining inclusion in the ARTG or obtaining approval required by law

Experimental Use Exemptions

“for **experimental purposes** relating to the subject matter of the invention”

EXPERIMENTAL USE INCLUSIONS

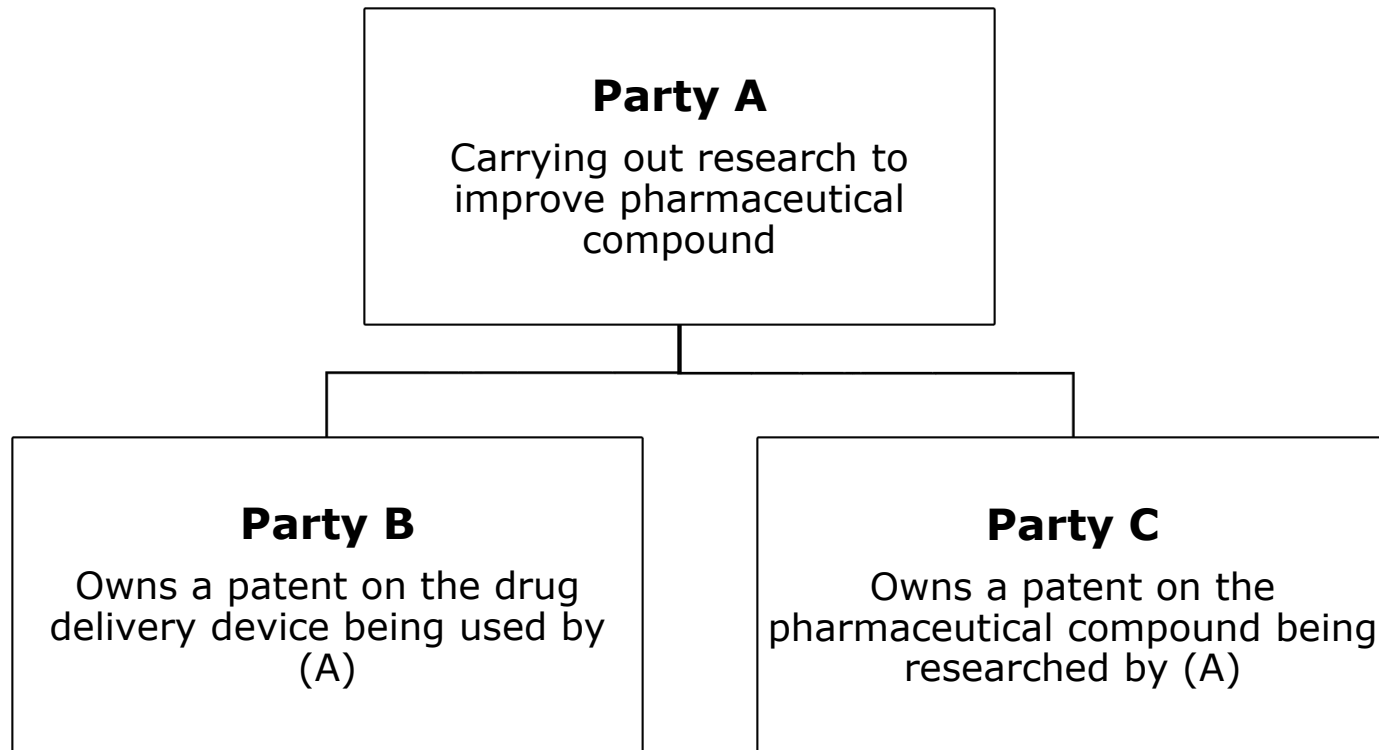
Non-exhaustive list included in the *Patents Act 1990* (Cth):

- a) determining the **properties** of the invention;
- b) determining the **scope of a claim** relating to the invention;
- c) improving or modifying the invention;
- d) determining the **validity** of the patent or of a claim relating to the invention;
- e) determining whether the patent for the invention would be, or has been, **infringed** by the doing of an act.

WHAT ACTIVITY IS EXCLUDED?

- where the **main purpose** of the research activity is to **commercialise** the patented invention, or to manufacture it for sale or use for commercial purposes
- “market research”
- “*research tools*”
 - something used to **facilitate** an experiment, rather than being the **subject** of the experiment.

CASE STUDY EXAMPLE



SUMMARY

The *Patents Act 1990* provides for exemptions to patent infringement in circumstances where:

- A person does an act which would infringe a patent, if that act is done solely for purposes connected with obtaining regulatory approval to exploit a product, method or process (s119A and s 119B); or
- where the act is done for experimental purposes relating to the subject matter of the invention (s 119C).