

Freedom to Operate

While it is widely known that intellectual property may be used to claim rights in ‘inventions’ or new technologies that are the products of science, intellectual property also covers many of the tools or enabling technologies on which the research relies. Therefore, scientists need to know enough about intellectual property to be aware of the issues that may arise during the research process, and when to seek advice from research management experts.

In fields such as the biological and health sciences, patents are commonly used to claim exclusive rights in the utilisation of enabling technologies. Patents allow their owners to exclude others from making, using, selling, offering for sale, or importing the patented invention. In some countries, such as the United States, patent law does not recognise an explicit exemption for research use. In Australia, this changed in 2012, when an amendment to the Patents Act 1990 introduced a statutory exemption to patent infringement for use of the patented invention for experimental purposes, including improving or modifying the invention. Nevertheless, it is still important for researchers (and research managers) to ensure that products, processes, and services do not infringe the intellectual property rights of other parties.

Where researchers are unable to conduct research using enabling technologies without infringing the intellectual property rights of a third party, they do not have ‘freedom to operate’. A well-known example of a major research project that implicated the freedom to operate concept is ‘Golden Rice’, a genetically engineered rice that was developed to prevent vitamin-A deficiency. When research towards the development of Golden Rice began, experts soon realised that the intellectual property rights for 70 enabling technologies belonging to 32 different companies and universities had been infringed. Therefore, licences needed to be obtained for all of these technologies to secure freedom to operate to allow them to continue the research process.

What is freedom to operate?

Freedom to operate refers to the ability of a researcher to conduct research or to commercialise a research output without infringing the intellectual property owned by a third party. A major risk in the development of new products is that third parties may block exploitation because they hold patents for enabling technologies that a party needs to market their invention. This is common in fields where inventions are protected by patents and plant breeder’s rights, but issues also may arise in relation to other forms of intellectual property (e.g., trade marks).

It is important that researchers have a clear understanding of potential freedom to operate issues that may affect the production, marketing, and use of new products, processes, or services as early as possible in the research process. This will help to ensure that their work does not infringe the intellectual property of others. While an initial determination of freedom to operate at the start of a research

project is important, researchers and research managers should continue to assess freedom to operate throughout the duration of the project.

Determining freedom to operate

The best way to understand how third party intellectual property might affect research is to conduct a freedom to operate analysis. This is something that you might do yourself, or that a research manager or intellectual property specialist may conduct for you. A freedom to operate analysis identifies who owns the enabling technologies used in your research and who has the right to grant licenses or assignments for these technologies.

This information is essential to design a strategy for obtaining freedom to operate and to determine the risks associated with going forward. Some research funding agencies require the person seeking grant money to disclose freedom to operate as part of the application process. In this situation, the onus

is placed on the investigator to obtain freedom to operate.

If a patent search reveals that one or more patents (or other forms of intellectual property) do in fact limit your freedom to operate, you must decide how to proceed. There are various options for gaining access to proprietary technologies. Ultimately, selecting the best strategy will involve a cost/benefit analysis of the relevant merits of each option, including the possibility of abandoning the project for lack of freedom to operate. Alternatively, you may need to pursue several of the strategies described above to obtain freedom to operate for a given project. The various options include:

(1) Licences

Researchers may seek a licence from the owners of the intellectual property that covers each proprietary enabling technologies that the freedom to operate analysis reveals. A licence is an agreement involving the transfer of rights from one party ('the licensor') to another party ('the licensee'). Licences can be used to obtain usage rights for technologies protected by different forms of intellectual property, including patents, plant breeder's rights, and trade secrets.

Licences may be exclusive or non-exclusive, and they may contain different kinds of restrictions, which may limit the field of use or the territory (i.e., jurisdiction) in which the license applies. Another strategy involves 'cross-licensing', which may be an option if you have your own intellectual property portfolio. For example, X may enter a cross-licensing agreement with Y under which X receives access to Y's products. At the same time, Y gains access to X's technology.

(2) Collaborations

In academic research, collaborations may enable a researcher from one institution to access technologies owned by another institution. Sometimes, these arrangements take the form of 'patent pools' or other agreements to make intellectual property protected technologies openly available to all members of a network of researchers. In the commercial sector, mergers, acquisitions, and joint ventures are common strategies that are used to reduce transaction costs associated with obtaining third party intellectual property.

(3) Purchase the patent

If the patent is of great value to your project (or to projects that others may conduct in the future), you may seek to purchase the patent outright. Doing so will result in the 'assignment' of the patent from the previous owner to you. Obtaining an assignment of a patent allows you to exploit all of the exclusive rights that patent ownership entails, including restricting others from accessing the protected invention. However, one downside to patent assignment is that there may be a substantial cost involved with the purchase.

(4) Invent around

Researchers may attempt to find alternative ways to develop a desired product or process, effectively 'inventing around' the third party intellectual property that would otherwise limit their freedom to operate. Inventing around a proprietary enabling technology would mean that you do not need to acquire usage rights to the technology through assignment or licensing.

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