D International agreements

Australia is a party to several international agreements relating to intellectual property, which among other things, require harmonisation of certain aspects of Australia’s patents system with those in other countries. This appendix presents a brief overview of the agreements that explicitly address non‑voluntary access to patents (including the use of compulsory licensing arrangements). These are the:

* Paris Convention for the Protection of Industrial Property 1883 (Paris Convention)
* Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS agreement)
* Australia-United States Free Trade Agreement (AUSFTA).

Australia is also a party to several other treaties relating to intellectual property which do not mention non‑voluntary access to patents. These are the Patent Cooperation Treaty 1970, the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure 1977, the Patent Law Treaty 2000, and the Australia‑Chile Free Trade Agreement.

## D.1 Paris Convention

The Paris Convention dates back to 1883 and has undergone several changes since then. In 1925, an amendment was made to Article 5(A), allowing countries to issue compulsory licences. This provided an alternative to forfeiture of patents to prevent abuses that might arise from the exclusive rights conferred by a patent, including non-working of a patented invention. Article 5(A)(2) of the Paris Convention states:

Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.

In addition to providing for compulsory licensing, the Paris Convention also established the concept of national treatment with regards to intellectual property and minimum thresholds for patent eligibility.

## D.2 TRIPS Agreement

The TRIPS agreement was negotiated as part of the Uruguay Round, and came into effect in 1995. The agreement is administered by the World Trade Organisation (WTO), and being a signatory to the agreement is mandatory for WTO members. The aim of the agreement is to reduce distortions and impediments to international trade and ensure that intellectual property laws are not trade barriers themselves.

### Patentable subject matter

Article 27 of the TRIPS agreement states that patents will generally be made available for any inventions, in all fields of technology, provided they are novel, useful and involve an inventive step. However, Article 27 also gives members the option to exclude particular inventions from patentability such as:

* inventions where preventing commercial exploitation is necessary to protect public order or morality
* diagnostic, therapeutic or surgical methods for treating humans or animals
* plants and animals, other than microorganisms, and the biological processes for their generation (other than non‑biological and microbiological processes).

Where a decision has been made to forfeit or revoke a patent, the TRIPS agreement requires that judicial review of the decision is available.

### Non-voluntary access to patents

Article 30 of the TRIPS agreement allows members to provide limited exceptions to the exclusive rights conferred by a patent. However, such exceptions are only permissible if they ‘do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the interests of third parties’.

Other use without the authorisation of a patent owner is allowed under Article 31 of the TRIPS agreement. In the Australian context, this includes compulsory licensing and Crown use. Article 31 states that, where a member’s laws allow for use of a patented invention (by the government or a third party authorised by the government) without the authorisation of the patent holder, the following provisions shall be respected.

* Authorisation shall be considered on its individual merits (Article 31(a)).
* The proposed user has made efforts to obtain authorisation from the patent holder on reasonable commercial terms and for a reasonable period of time (waived during times of national emergency or other circumstances of extreme urgency) (Article 31(b)).
* The scope and duration of use will be limited to the purpose for which it was authorised (Article 31(c)).
* Such use is non-exclusive and non-assignable (Articles 31(d) and 31(e)).
* Such use is to be predominately for supply of the domestic market (Article 31(f)).
* The authorisation will be terminated if the circumstances that led to the initial authorisation of non-voluntary access cease to exist (Article 31(g)).
* The patent holder is paid adequate compensation (Article 31(h)).
* Decisions related to use and compensation are subject to judicial review (Articles 31(i) and 31(j)).
* Members are not obliged to apply Articles 31(b) and 31(g) when such use is intended to remedy anticompetitive behaviour by the patent holder (Article 31(k)).
* Where such use of an existing patent is for the purpose of registering a new patent, the following conditions apply.
* The invention claimed in the new patent will represent an important technical advance, of economic significance, on the existing patented invention.
* The holder of the existing patent will be entitled to a cross‑licence, on reasonable terms, to the invention claimed in the new patent.
* Such use of the existing patent will be non‑assignable, except where the new patent is assigned to a third‑party (Article 31(l)).

While Article 31 of the TRIPS agreement imposes conditions on how to implement the non-voluntary use of patents, it does not specify the grounds for allowing such use (Lawson 2008; Van Zimmeren and Van Overwalle 2011).

### Access to pharmaceuticals

In 2001, the WTO Ministerial Conference published the ‘Declaration on the TRIPS agreement and public health’ (WTO 2001), in which it noted the gravity of a range of public health problems experienced in many countries (particularly developing countries). It also noted that intellectual property rights are likely to result in higher prices for patented goods. In the context of public health, patent rights are likely to increase the costs of pharmaceutical products and might impair access to medicines (particularly in poorer countries). The declaration also affirmed the:

* right of member countries to determine the circumstances that constitute a national emergency
* right of member countries to determine the grounds on which a compulsory licence may be granted
* commitment of developed countries to encourage technology transfer to least‑developed countries.

The declaration stated that, with respect to pharmaceutical products, the least‑developed countries are not obliged, at least until 2016, to implement or apply sections 5 or 7 of Part II of the TRIPS agreement or enforce rights accorded under those sections.[[1]](#footnote-1)

The Ministerial Conference also noted that countries with insufficient manufacturing facilities might face difficulties in effectively exploiting a compulsory licence over a pharmaceutical product. The Council for TRIPS was directed to find a solution to this and report to the WTO General Council in 2002.

A temporary response to this issue was adopted by the WTO in an August 2003 decision of the General Council (WTO 2003). The General Council recognised ongoing exceptional circumstances justifying the waiving of Articles 31(f) and 31(h) of the TRIPS agreement for situations where a developed (exporting) country produces and exports pharmaceutical products to a least-developed (eligible importing) country.

The obligations associated with Article 31(f) (production primarily used for supply of domestic market) were waived for an exporting country, upon compliance with the following conditions.

* A notification has been made to the Council for TRIPS by the eligible importing country that:
* specifies the name and quantity of the pharmaceutical product
* confirms that it does not have the capacity to manufacture the product itself
* confirms that a compulsory licence for the product has been granted (if the product is patented in that country).
* The exporting country has granted a compulsory licence with the following conditions.
* Production is limited to the amount needed by the eligible importing country.
* Products produced by the exporting country shall be clearly identified as such through the use of specific marking or labelling, special packaging and/or special colouring/shaping of the products if it is feasible and does not have a significant impact on price.
* Prior to export, the licenced manufacturer will publish on a website details of the quantity supplied and destination country, and the distinguishing features as detailed above.
* The exporting country shall notify the Council for TRIPS of the issue of a compulsory licence, providing relevant information about the conditions attached to that licence.

A developed country that issues a compulsory licence in order to export pharmaceuticals is still obligated to provide reasonable compensation to the patent holders (as stated in Article 31(h)). However, this obligation is waived for an eligible importing country that issues a compulsory licence, conditional on remuneration having been paid by the exporting country.

In 2005, a protocol to amend the TRIPS agreement was adopted by the WTO General Council (WTO 2005), and submitted to WTO members for approval. The amendments are intended to provide a permanent solution to the issue of access to medicines and once accepted, replace the temporary solution provided by WTO (2003). Acceptance of the amendments requires approval by two-thirds of WTO members, and at present has not been accepted. Upon acceptance, the TRIPS agreement will be amended by inserting a new article, Article 31(bis), and a new annex to the TRIPS agreement.

Article 31(bis) would establish the right of a developed country to grant a compulsory licence in order to export a pharmaceutical product to an eligible importing country, and obligate the exporting country to provide reasonable remuneration to the patent holder. It would also allow the eligible importing country to export the pharmaceutical product to other developing countries that:

* share the health problem in question
* are party to a regional trade agreement with the eligible importing country.

The Annex to the TRIPS agreement would establish conditions for the grant of a compulsory licence.

The combined effect of Article 31(bis) and the Annex appears to provide at least the same rights and obligations as the temporary solution embodied in the decision of the General Council (WTO 2003).

In 2011, the Australian Government announced its intention to introduce legislation allowing Australian Courts to issue compulsory licences for the purposes of exporting pharmaceuticals to developing countries (Carr and Emerson 2011). A draft Bill was released in August 2012 (IP Australia 2012c).

## D.3 Australia-United States Free Trade Agreement

The AUSFTA entered into force on 1 January 2005 and among other things, established Australia’s obligations to the United States (and vice-versa) with respect to intellectual property. AUSFTA also establishes patentability criteria and minimum standards of patent protection which are in line with the TRIPS agreement.

Like the TRIPS agreement, AUSFTA allows either country to implement patentability exclusions where necessary to maintain public order or for diagnostic, therapeutic and surgical methods for the treatment of humans and animals. It also restricts the grounds on which a patent may be revoked to those that would have justified a refusal to grant a patent, or instances of fraud, misrepresentation or inequitable conduct.

### Non-voluntary access to patents

Under Article 17.9(7) of AUSFTA, a patented invention can only be used without the owner’s authorisation if it is to remedy a practice determined as anticompetitive by a judicial or administrative process, or in situations of public non-commercial use, national emergency or other circumstances of extreme urgency. This appears to be more restrictive than the Paris Convention and TRIPS agreement.

1. Section 5 relates to patents and section 7 relates to protection of undisclosed information. [↑](#footnote-ref-1)