

i) Certain aspects of the applicable national or regional patent law

<p>1. Prior Art</p>	<p>1. Information from documents made publicly available or information made publicly available through doing an act before the filing date (priority date), whether in Australia or elsewhere.</p> <p>2. For deciding whether an invention is novel, information contained in an Australian patent application (including all PCT applications designating Australia) published on or after the priority date with an earlier filing date (priority date), if the information was contained in the application at its filing date.</p>
<p>2. Novelty</p>	<p>The invention does not form part of the prior art. The prior art consists of information from documents or acts publicly available before the filing date (priority date), whether in Australia or elsewhere and information contained in an Australian patent application (including all PCT applications designating Australia) published on or after the priority date with an earlier filing date (priority date), if the information was contained in the application at its filing date.</p>
<p>3. Inventive Step (Obviousness)</p>	<p>The invention is not obvious to a person skilled in the relevant art in the light of the common general knowledge in Australia or elsewhere alone, or when combined with the prior art. The prior art consists of information from documents and acts publicly available before the filing date (priority date), whether in Australia or elsewhere, and includes combinations of any 2 or more pieces of prior art that the skilled person could, before the priority date of the relevant claim, be reasonably expected to have combined.</p>
<p>4. Grace Period</p>	<p>1. Disclosure not to be taken into consideration in determining novelty and inventive step if it occurred:</p> <p>(a) within six months before the filing of a provisional or basic application (provided a complete application is filed within 12 months from filing of the provisional or basic application), or otherwise within 12 months before the filing of a complete application;</p> <p>(i) by showing, use or publication of the invention at a recognized exhibition;</p> <p>(ii) in a paper written by the inventor and read before, or published with the inventor's consent by or on behalf of, a learned society;</p> <p>(b) within 12 months before the filing of a provisional or basic application (provided a complete application is filed within 12 months from the filing of the provisional or basic application), or otherwise within 12 months before the filing of a complete application by working the invention in public for the purposes of reasonable trial due to the nature of the invention;</p> <p>(c) within 12 months before the filing of a complete application in Australia, where disclosure was (i) with the consent of the nominated person, patentee or predecessor in title or (ii) without consent and the information disclosed was derived from the patentee or predecessor in title;</p> <p>(d) at any time before the filing date, if the information disclosed was given by or with the consent of the patentee or predecessor in title, to the Commonwealth or a State or Territory, an authority thereof or person authorized thereby, to investigate the invention; and anything done for the purpose of such investigation.</p> <p>2. In the cases of 1.a.(i), the applicant shall:</p> <p>(a) when filing the application, state that the invention has been disclosed at the exhibition;</p>

	(b) before the publication of the application, file a statement issued by the exhibition authority.
5. Sufficiency of Disclosure	An application shall: <ol style="list-style-type: none"> disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the relevant art; include the best method known to the applicant of performing the invention
6. Exclusions from Patentable Subject Matter	<ol style="list-style-type: none"> Matter that is not a “manner of manufacture” <u>where consideration is made as a matter of substance and not form</u>. This generally includes: <ol style="list-style-type: none"> Discoveries, abstract ideas, scientific theories and principles, mathematical algorithms without material effect Aesthetic creations; Schemes, rules and plans; Genetic information where the information is not made; Presentation of information characterized solely by its content without a material advantage; Mere working directions for using an existing apparatus or process to produce an identical product; Collocations or kits of known integers where is no actual or potential working interrelationship; mere admixtures of food or medicine without synergistic effect; New uses of a known substance for a purpose for which the substance’s known properties make it suitable; new uses of an old contrivance without ingenuity in analogous manner and purpose to the old use; analogous uses of a known device for its ordinary purpose. Applications where the only disclosed uses of the patent are illegal. Matter that lacks utility due to a failure to achieve the promised benefit, or a lack of a specific, substantial and credible use. Human beings and the biological processes for their generation. Inventions secretly used in the patent area before the priority date of a claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee’s or nominated person’s predecessor in title to the invention. A substance that is capable of being used as food or medicine (whether for human beings or animals and whether for internal or external use) and is a mere admixture of known ingredients; or a process producing such a substance by mere admixture.
7. Exceptions and Limitations of the Rights	<ol style="list-style-type: none"> Certain uses concerning foreign vessels, aircraft and land vehicles which temporarily or accidentally enter national territory. Continued prior use by person who, at the filing date (priority date), was using the invention in Australia independently of the patent owner or his predecessor in title, or was taking definite steps for that purpose. Acts for obtaining regulatory approval for pharmaceuticals and non-pharmaceuticals. Acts for experimental purposes. Compulsory licenses where necessary for the public interest or to remedy other anti-competitive practices, subject to remuneration. Compulsory licenses for patented pharmaceutical products for manufacture and export to developing countries which are experiencing a public health crisis, subject to remuneration.

	7. Exploitation or acquisition by the Commonwealth, State or Territory Governments, where necessary for the proper provision of services or in the interest of national security, subject to remuneration.
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ii) National and regional laws on opposition systems and other administrative revocation and invalidation mechanisms

Opposition

Australia

There are two types of patents in Australia, the 'standard' patent and the 'innovation' patent (similar to a utility model).¹ Australia operates a pre-grant opposition system for standard patent applications.² Any person may oppose the granting of a patent by filing a Notice of Opposition within three months of acceptance of the application being advertised in the Official Journal of Patents.³ Oppositions to innovation patents can only be initiated after the patent has been granted and then certified.⁴

According to Section 59 of the Patents Act 1990 (Cth) (*'Patents Act'*), the Minister or any other person may, in accordance with the Regulations, oppose the grant of a standard patent on one or more of the following grounds, but on no other ground:⁵

- (a) that the nominated person is either:⁶
 - (i) not entitled to the grant of a patent for the invention; or
 - (ii) entitled to the grant of a patent for the invention, but only in conjunction with some other person;
- (b) that the invention is not a patentable invention;⁷

¹ It is no longer possible to file a new application for an innovation patent. However, an applicant who has filed a patent application before 26 August 2021 (the effective date of Sch 1 Pt 2 of the *Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Act 2020* (Cth)) may file an amendment to convert that application to an application for an innovation patent or use that application to file a divisional application for an innovation patent.

² There are two types of patents in Australia, the 'standard' patent and the 'innovation' patent (similar to a utility model). Oppositions to innovation patents can only be initiated after the patent has been granted and then certified. Note: although the innovation patent is being phased out, opposition to innovation patents could still occur until at least 2029. It is no longer possible to apply for an innovation patent, although existing patent applications filed prior to 26 August 2021 (the effective date of Sch 1 Pt 2 of the *Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Act 2020* (Cth)) may allow the applicant to amend an existing application or file a divisional application for an innovation patent.

³ Subsection 49(1) of the *Patents Act* provides that, subject to Section 50, the Commissioner must accept a patent request and complete specification relating to an application for a standard patent, if the Commissioner is satisfied, on the balance of probabilities: (a) that the specification complies with subsections 40(2) to 40(4), i.e. disclosure, clarity, support and unity; (b) that the invention satisfies the criteria mentioned in paragraphs 18(1)(a), (b) and (c), i.e. manner of manufacture, novelty, inventive step and usefulness; and (c) that the invention is a patentable invention under Subsection 18(2) (human beings, and biological processes for their generation, are not patentable inventions).

⁴ Although the innovation patent is being phased out, opposition to innovation patents could still occur until at least 2029.

⁵ Section 101M of the *Patents Act* allows for opposition under analogous grounds for certified innovation patents, with an innovative step instead of an inventive step.

⁶ The applicant is taken to be the nominated person for the grant of the patent (Regulation 3.1A), and in this context the term 'person' means a legal person and includes a body politic (e.g. Commonwealth of Australia, French Republic) and a body corporate (e.g. a company incorporated under the laws of the State of Victoria), as well as a natural person.

⁷ Under Subsection 18(1), this includes a lack of novelty or inventive step, manner of manufacture or utility.

- (c) that the specification filed in respect of the complete application does not comply with Subsection 40(2), (3) or (3A).⁸

Under Section 60 of the *Patents Act*, the opposition is heard by the Commissioner who must, on the balance of probabilities, decide the case in accordance with the Regulations. The Commissioner must give the applicant and the opponent a reasonable opportunity to be heard before deciding the case. The Commissioner may, in deciding the case, take into account any ground on which the grant of a standard patent may be opposed, whether relied upon by the opponent or not. The applicant, and any opponent, may appeal to the Federal Court against a decision of the Commissioner under this Section.

Oppositions can also arise with regard to procedural matters including:

- (a) amendments: under Subsection 104(4) of the *Patents Act*, the Minister or any other person may oppose the allowance of an amendment. Section 102 of the *Patents Act* provides that amendment of the complete specification is not allowable if, as a result of the amendment, the amended specification would claim or disclose matter that extends beyond that disclosed in the specification as filed, together with other prescribed documents (if any);
- ~~(a)~~(b) extensions of time: under Subsection 223(6) of the *Patents Act*, any person may oppose the granting of an extension of time;
- ~~(b)~~(c) extensions of term for a pharmaceutical patent: under Section 75 of the *Patents Act*, any person may oppose the grant of an extension of term under Section 70 but only on the ground that one or more of the requirements specified in Section 70 (defining what subject matter is available for extension of term) and Section 71 (relating to the form and timing of an application) are not met;
- ~~(c)~~(d) grant of a licence to exploit an invention: under Regulation 22.21(4) of the *Patents Regulations 1991* (Cth), a person who receives a copy of an application for a licence can oppose the granting of that licence.

⁸ Subsection 40(2) of the *Patents Act* provides that a complete specification must disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the relevant art, disclose the best method known to the applicant of performing the invention, and end with a claim or claims defining the invention. Subsection 40(3) states that the claims or claim must be clear and succinct and supported by matter disclosed in the specification. Subsection 40(3A) states The claim or claims must not rely on references to descriptions, drawings, graphics or photographs unless absolutely necessary to define the invention.