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The Productivity Commission

The Productivity Commission is the Australian Government’s independent research and advisory body on a range of economic, social and environmental issues affecting the welfare of Australians. Its role, expressed most simply, is to help governments make better policies, in the long term interest of the Australian community.

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The Hon David Bradbury MP  
Assistant Treasurer

Parliament House

CANBERRA ACT 2600

Dear Assistant Treasurer

In accordance with Section 11 of the *Productivity Commission Act 1998*, we have pleasure in submitting to you the Commission’s final report into Compulsory Licensing of Patents.

Yours sincerely

|  |  |
| --- | --- |
| Alison McClelland  Presiding Commissioner | Dr Warren Mundy  Commissioner |

# Terms of reference

I, David Bradbury, Assistant Treasurer, under part 3 of the *Productivity Commission Act 1998*, hereby request that the Productivity Commission undertake an inquiry into the compulsory licensing provisions in the Patents Act 1990.

**Background - balancing access to technology and innovation**

The compulsory licensing provisions in the *Patents Act 1990* are a key safeguard, which may be invoked where the exercise of the exclusive rights conferred by a patent are not meeting the reasonable requirements of the public or constitute anti-competitive conduct.

In Australia, these provisions are used rarely and there are opposing views on their effectiveness. Infrequent use is attributed to significant barriers to accessing the provisions, or as a result of the deterrent effect of the provisions, which induces patent holders to enter into voluntary licences for their patented inventions.

Australia is a net importer of technology. Of the 14,557 patents granted in 2010, 1,178 (8 per cent) were granted to Australian residents. Overall, the likely benefit of these provisions is their use as a deterrent in licensing negotiations between a foreign patent holder and potential licensee in Australia, in order to ensure domestic access to technology and technology diffusion.

In November 2011, the Government’s Response to recommendation 12 of the Senate Community Affairs References Committee’s *Gene Patents* Report November 2010 and recommendation 27-1 of the Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health* (ALRC 99, 2004) Report, endorsed a review of the operation of the compulsory licensing provisions in the *Patents Act 1990*, including measures to raise awareness of these provisions.

Compulsory licensing is an increasingly sensitive issue internationally, particularly in the context of access to affordable healthcare, and concerns that gene patents may prevent equitable access to medical advice that relies on the identification and use of gene sequences related to human health and disease. Other areas of sensitivity include climate change mitigation, food security and alternative energy technologies, and technical standards essential patents (e.g. in telecommunication technologies).

Compulsory licensing provisions are a feature of many patent laws around the world, and are included in international agreements to which Australia is a party.

**Scope of the inquiry**

The Commission is requested to review the operation of the compulsory licensing provisions in the *Patents Act 1990,* in particular:

1. Assess whether the current Australian provisions can be invoked efficiently and effectively to deal with circumstances where reasonable requirements of the public are not being met or where the patentee engages in anti-competitive conduct. This includes, but is not limited to, consideration of concerns that gene patents may hinder access to affordable healthcare, including access to medical advice that relies on the identification and use of gene sequences related to human health and disease.
2. Advise on the frequency, and impact, of the issue of compulsory licences in comparable markets and the common features in such compulsory licenses.
3. Recommend any measures that may be required to efficiently and effectively exercise these safeguard provisions and invoke their use in a manner consistent with Australia’s international obligations, without limiting access to overseas technologies, technology transfer, research and development investments or substantially reducing the patent incentive for innovation.
4. Recommend any alternative mechanisms deemed necessary to ensure that the balance between incentives to innovate and access to technology best reflect objectives of ensuring reasonable access to health care solutions, maximising economic growth and growing the Australian manufacturing industry.
5. Recommend measures to raise awareness of these provisions and their purpose, including the specific challenges of raising awareness among small businesses and the healthcare sector.

In conducting the inquiry, the Commission should have regard to:

* 1. the importance of incentives for industry and researchers to invest in research and development, and innovation;
  2. access to and transfer of technology, including climate change mitigation, food security, healthcare and alternative energy technologies, and standard essential patents in telecommunication technologies, particularly where multiple patentees are involved;
  3. affordable and equitable access to healthcare, including medical treatments and diagnostic tests in Australia;
  4. recent changes to the intellectual property system reflected in the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012*, including the research exemption;
  5. other relevant parts of the intellectual property system, such as crown use provisions; and
  6. the range of international approaches.

The Commission will report within nine months of receipt of this reference and will hold hearings for the purpose of this inquiry. The Commission is to provide both a draft and a final report, and the reports will be published. The Government will consider the Commission’s recommendations, and its response will be announced as soon as possible after the receipt of the Commission’s final report.

DAVID BRADBURY  
[Received 29 June 2012]

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# Abbreviations

Abbreviations

ABSDO Accreditation Board for Standards Development Organisations

ACCC Australian Competition and Consumer Commission

ACIP Advisory Council on Intellectual Property

ADR Alternative dispute resolution

AHMAC Australian Health Ministers Advisory Council

ALRC Australian Law Reform Commission

AUSFTA Australia-United States Free Trade Agreement

CAL Copyright Agency Limited

CCA *Competition and Consumer Act 2010* (Cwlth)

CIPO Canadian Intellectual Property Office

DOHA Department of Health and Ageing

EPC European Patent Convention

EPO European Patent Office

FICPI Australian Federation of Intellectual Property Attorneys

FRAND Fair, reasonable and non-discriminatory

FTC United States Federal Trade Commission

GTL Genetic Technologies Limited

IAC Industries Assistance Commission

IC Industry Commission

IP Intellectual property

IPCRC Intellectual Property and Competition Review Committee

IPTA Institute of Patent and Trade Mark Attorneys

JPO Japan Patent Office

KIPO Korean Intellectual Property Office

LOR Licence of right

MBS Medicare Benefits Schedule

MSAC Medical Services Advisory Committee

NGO Non-government organisation

NHMRC National Health and Medical Research Council

OECD Organisation for Economic Cooperation and Development

PBAC Pharmaceutical Benefits Advisory Committee

PBPA Pharmaceutical Benefits Pricing Authority

PBR Plant breeders right

PBS Pharmaceutical Benefits Scheme

PC Productivity Commission

PCT Patents Cooperation Treaty

PPH Patent Prosecution Highway

PPI Patented pharmaceutical invention

RCPA The Royal College of Pathologists of Australasia

RIS Regulation impact statement

SDO Standards development organisation

SCARC Senate Community Affairs and References Committee

SLCALC Senate Legal and Constitutional Affairs Legislation Committee

TRIPS Agreement on Trade-Related Aspects of Intellectual Property Rights

UK IPO United Kingdom Intellectual Property Office

UNFCCC United Nations Framework Convention on Climate Change

USPTO United States Patent and Trademark Office

WEHI Walter and Eliza Hall Institute of Medical Research

WHO World Health Organisation

WTO World Trade Organisation

WIPO World Intellectual Property Organisation

# Glossary

|  |  |
| --- | --- |
| Blocking/dependent patent | A patent owned by another party that prevents a patentee from exploiting its own invention without authorisation of the other party. |
| BRCA genes | A class of tumour suppressor genes. Mutations of these genes are associated with breast, ovarian and prostate cancer. |
| Compulsory licence | A government- or court-issued order for a patentee to grant a licence to another party (which allows that party to exploit the patented invention). |
| Crown acquisition | Acquisition of a patented invention by the Crown under s. 171 of the *Patents Act 1990* (Cwlth). |
| Crown use | Use of a patented invention by the Crown or another party authorised by the Crown under ss. 163–170 of the *Patents Act 1990* (Cwlth). |
| Injunctive relief | A court order instructing the defendant to cease a specific behaviour (for example, selling of a product that infringes an existing patent). |
| Innovation patent | An exclusive right to exploit an invention, granted for a term of eight years. To be eligible for an innovation patent, an invention must be novel, useful and involve an innovative step. |
| Isolated gene sequence | A free-standing portion of genetic material that is isolated from the larger natural DNA molecule. The process of isolating a gene involves chemically altering the DNA. However, the genetic information contained in the isolated gene is identical to that in the gene’s naturally occurring form. |

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| Licence of right | A legally enforceable mechanism by which a patent holder voluntarily chooses to provide access to a patented invention to anyone who is willing to accept the licence conditions. |
| Patent | A legally enforceable right to exclude others from exploiting an invention — a device, substance, method or process  — that is new, inventive, and useful at the time the patent is granted. |
| Patent holdup | Where a new technology unknowingly infringes a patent and is not made aware until large scale production has commenced or is about to commence. In such cases the patent holder can use its enhanced bargaining power to ‘hold up’ production and extract higher licensing fees. |
| Patent infringement | Use of a patented invention in a prohibited manner without the authorisation of the patent holder. |
| Patent thicket | An area of technology in which many overlapping patents exist. Commercialisation of new technology might require licence deals in relation to multiple patents and with multiple patent holders. |
| Patent troll (non‑practising entity) | A patentee who holds a patent with the intention of pursuing infringement claims but no intention of working the patent itself. |
| Prior art | All information relevant to a patent claim that is publicly available at the priority date. A patent might not be granted if the invention is described in the prior art. |
| Priority date | The date at which the invention is assessed and compared to the prior art. The priority date might differ from the patent application filing date. |
| Royalty stacking | Refers to a situation where a single product infringes multiple patents and is thus subject to multiple royalty burdens. Each royalty burden can be ‘stacked’ to determine the total royalty burden. |

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| Springboarding | Springboarding allows firms to use patented inventions prior to the patent expiration for the sole purpose of gaining regulatory approval. Pharmaceuticals are an example of a product that requires regulatory approval. |
| Standard essential patent | A standard essential patent is a patent on an invention that is required to practise an industry standard (for example, 3G mobile internet technology). |
| Standard patent | An exclusive right to exploit an invention, granted for a term of 20 years. To be eligible for a standard patent, an invention must be novel, useful and involve an inventive step. |
| Subject matter exclusions | Exclusion from patent eligibility for particular fields of technology. |