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Dear Commissioners

Thank you for providing Civil Liberties Australia with the opportunity to comment on the Productivity Commission's Issues Paper, part of the Commission's inquiry into the compulsory licensing provisions in the *Patents Act 1990*.

Civil Liberties Australia (CLA) is a national organisation based in Canberra. CLA stands for people's rights and advocates in favour of policies that advance human rights and civil liberties. CLA is non-party political and independent of other organisations. It is funded by its members and donations and does not receive funding from other sources. CLA monitors police and security forces, and the actions and inaction of politicians. It reviews proposed legislation to make it better, and keeps watch on government departments and agencies.

By way of background, CLA is supportive of current efforts to amend the *Patents Act 1990* to prohibit the patenting of genetic information, believing this practice to be contrary to law and restrictive of the rights of patients, doctors and researchers.[1] The question of whether genes constitute a patentable invention under section 18 of the *Patents Act 1990* is outside the scope of this inquiry; however, it is alluded to in the inquiry's terms of reference.

While this submission proceeds on the basis that compulsory licensing will be considered as one option to mitigate the adverse impacts of gene patents, CLA does not accept the reasoning of IP Australia that isolated or purified genes constitute patentable inventions under the current *Patents Act 1990*. Whether genes are inventions under the *Patents Act* is being tested for the first time in Australia and remains an open question.[2] As a matter of logic, CLA believes that compulsory licensing cannot be the solution to wrongfully-granted patents.

Patents and Current Compulsory Licensing Provisions

Questions addressed

- Are there any problems with the current system of patent licensing in Australia and how might they be solved?
- Are compulsory licensing provisions part of the problem?
- How effective are the compulsory licensing provisions as a safeguard to deal with cases where the reasonable requirements of the public are not being met…
- What aspects of the provisions, if any, cause them to be less effective than they could be?

[1] See for example: *You are not a drug* (New Matilda) (5 July 2012) available at http://newmatilda.com/2012/07/05/you-are-not-drug (accessed 26 September 2012).
[2] *Cancer Voices Australia (ABN 93 322 703 427) & Anor v Myriad Genetics Inc & Ors* (decision reserved 24 February 2012).

A patent is a time-limited monopoly that grants the inventor the exclusive right to 'exploit' their invention or to authorise another person to exploit the invention, usually under a licence.[3] In exchange for this monopoly, the patentee is required to describe their invention 'fully, including the best method known [to the patentee] of performing the invention'.[4] Standard patents are granted for a term of 20 years, with some pharmaceutical products eligible for a five-year extension.[5]

CLA contends that use of the term 'right' (as in 'Intellectual Property Right') provides an unnecessary ideological colour to the debate over patents. Because a free, competitive marketplace is the default position for the Australian economy there can be no 'right' to a monopoly. Rather, patent monopolies should be considered *privileges*, granted by the State on such terms and conditions it thinks just and reasonable, having due regard to the needs of the inventor and community.

A common justification for the patent system is that it rewards, promotes and 'supports' innovation;[6] however, the *Patents Act 1990* acknowledges that, in some cases,[7] the public interest in accessing an invention outweighs the right of the patentee to exclude others.[8] This may be where, in the words of the Productivity Commission, 'the diffusion and use of new ideas [is] below the socially optimal level'.[9] Compulsory licences are, in theory, one way to ensure 'socially optimal' use of patented inventions.

Does Australia's compulsory licence regime work? Academics,[10] the Productivity Commission,[11] Australian Law Reform Commission,[12] and judicial officers have all identified the weaknesses in Australia's compulsory licence provisions, namely that they are 'cumbersome and expensive to apply'.[13] There is a view that the compulsory licence provisions do not need to be used to be effective; rather, the threat of them is enough to achieve a positive outcome for ensuring access to patented inventions.[14] This argument has

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[3] s 13, *Patents Act 1990* (Cth).
[4] s 40(2)(a) *Patents Act 1990* (Cth).
[5] s 67 *Patents Act 1990* (Cth); cf. ss 71-77 *Patents Act 1990* (Cth).
[6] See, for example, IP Australia, Intellectual Property Laws Amendment Bill 2012 [Explanatory Memorandum] [exposure draft] p 3 available at http://www.ipaustralia.gov.au/46106/EM_for_Exposure_draft_of_Intellectual_Property_Laws_Amendment_Bill_2012.pdf (accessed 24 August 2012); cf. Dianne Nicol, John Liddicoat, 'Do Patents Promote Innovation' (21 February 2012) (*The Conversation)* available at http://theconversation.edu.au/do-patents-promote-innovation-5443 (accessed 24 August 2012).
[7] The *Patents Act 1990* (Cth) includes a range of measures whereby the Crown can acquire or exploit a patent without the consent of the patentee. For example, s 163 and s 171 *Patents Act 1990* (Cth).
[8] See, for example, Jane Nielsen, Dianne Nicol, 'Whither Patent Use Without Authorisation in Australia?' (2008) 36 (3) *Federal Law Review* 331, available at: http://www.austlii.edu.au/cgi-bin/sinodisp/au/journals/FedLawRw/2008/14.html (accessed 24 August 2012); Charles Lawson, 'Patenting Genes and Gene Sequences and Competition: Patenting at the Expense of Competition" (2002) 30 Federal Law Review 97 available at http://www.austlii.edu.au/cgi-bin/sinodisp/au/journals/FedLawRw/2002/4.html (accessed 23 August 2012).
[9] Productivity Commission, Compulsory Licensing of Patents - Issues Paper (August 2012) available at: http://www.pc.gov.au/__data/assets/pdf_file/0018/119061/patents-issues.pdf (accessed 21 August 2012).
[10] Nielsen, Nicol, above n 8.
[11] Productivity Commission, above n 8.
[12] The Australian Law Reform Commission was unaware of any compulsory licences that had been granted since federation: Australian Law Reform Commission (ALRC), *Genes and Ingenuity* (2004) at [27.10] available at http://www.alrc.gov.au/publications/27-compulsory-licensing/compulsory-licensing (accessed 26 August 2012).
[13] Per Finkelstein J, *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* [2000] FCA 316 at [137]
[14] ALRC, above n 91 at [27.11, fn 15].

been challenged on the basis that, because compulsory licence provisions have never been successfully invoked in Australia (and rarely in comparable jurisdictions)[15] the threat they represent is illusionary.[16]

CLA is of the view that a company devising its IP strategy will consider the costs and benefits of defending each patent in its portfolio or when entering into licensing arrangements. Part of this strategy would include a legal/risk assessment of each patent and how likely a competitor would be to challenge the patent or submit to a cease-and-desist notice. A company with a strong patent (or significant financial resources, such as a major pharmaceutical company) would consider the non-use of compulsory licence provisions in Australia as a factor in support of negotiating only on its terms – i.e. it would not reduce its profit expectations on the basis that a hypothetical compulsory licence could be sought and granted.

In Australia, a 'person' can apply to the Federal Court for an 'order requiring the patentee to grant the applicant a licence to 'work' the patented invention.'[17] This 'person' would, almost always, be the company seeking to exploit a product under a compulsory licence. This is the case irrespective of whether the invention had only a private, commercial function (e.g. a smartphone) or one directed towards a community outcome (e.g. a diagnostic tool or pharmaceutical).

CLA proposes that, where an applicant is seeking a compulsory licence to exploit an invention in the public interest, the Crown or a Department of State, whether at state or national level, should have the ability to intervene on behalf of the applicant. A similar model is proposed in the Intellectual Property Laws Amendment Bill 2012,[18] which would allow an NGO to work with a foreign government and/or manufacturer to seek a compulsory licence to export a patented pharmaceutical invention to a least-developed country suffering a public health crisis.

If the 'threat' of compulsory licences is considered sufficient to maintain the regime, then the involvement of a big player (i.e. Government) would give that threat more bite. In a different field, the Human Rights Commissioner has a standing right to intervene in a federal court hearing into an alleged human rights violation.[19]

The Commission may wish to examine other options for improving the effectiveness of compulsory licence including:

- Transferring jurisdiction to issue compulsory licences to the Administrative Appeals Tribunal or the Federal Circuit Court (*neé* Federal Magistrates Court) of Australia. Appeals could be limited to questions of law. However, it is important to recognise that many questions arising under the compulsory licence regime may constitute 'questions of law', and that decisions of administrative bodies (and lower courts) cannot be 'immunised' against review by the High Court under section 75(v) of the *Constitution*.[20]

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[15] ALRC, above n 91 at [27.18].
[16] ALRC, above n 91 at [27.12].
[17] s 133(1) *Patents Act 1990* (Cth).
[18] Intellectual Property Laws Amendment Bill 2012 [exposure draft] available at http://www.ipaustralia.gov.au/about-us/public-consultations/ip-laws-amendment-bill/ (accessed 23 August 2012).
[19] s 1(o) *Human Rights and Equal Opportunity Commission Act 1986* (Cth).
[20] *Kirk v Industrial Relations Commission of New South Wales*; *Kirk Group Holdings Pty Ltd v WorkCover Authority of New South Wales (Inspector Childs)* [2010] HCA 1.

- Providing for mandatory arbitration before proceeding to a judicial determination on whether a compulsory licence could be issued. In line with recent reforms to defamation law,[21] evidence that a reasonable licencing offer was made during arbitration could be used as evidence in Court and the Court could consider the conduct of both parties in awarding costs.

- A provision modelled on sections 26B and 26C of the *Therapeutic Goods Act 1989* which imposes certain requirements on patent holders prior to the commencement of infringement proceedings. This requirement could be modified so that a patentee had to lodge a certificate with the court (or commissioner for patents) stating that proceedings:
    - are to be commenced in good faith; and
    - have reasonable prospects of success; and
    - will be conducted without unreasonable delay.[22]

  Factors going to 'Good faith' could include whether the patentee adopted a reasonable course of action in any prior negotiations over licence and/or royalty fees. False and misleading certificates, or a breach of an undertaking given in a certificate, could be punishable by a pecuniary penalty.[23]

Research and the Experimental Use Defence

Questions addressed
• To what extent do the research and regulatory use exemptions solve the problem of access to patents for the purposes of …undertaking research? • Is there any need to invoke compulsory licensing in these cases? • If further reform is required, what should be done?

CLA welcomes the 'Raising the Bar' reforms, enacted in April 2012. The new experimental use exemption represents an important safeguard against corporate efforts to stifle researcher freedom.

However CLA is not convinced that 'Raising the Bar' eliminated all threats to academic speech. In this we share the concerns of Professor Ian Olver,[24] from the Cancer Council of Australia, and Melissa Parke MHR (Fremantle).[25] Their concern (and ours) is that the exemption may only cover 'blue-sky' or basic research. It might not cover applied research, especially where that research has a commercial goal.

For example, CLA considers that the following gene-patent examples may not be protected by the new section 119C:

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[21] See, for example, s 40 and s 38 *Defamation Act 2005* (NSW).
[22] s 26(C)(3), *Therapeutic Goods Act 1989*.
[23] s 26(C)(5A), *Therapeutic Goods Act 1989* allows a Court to award a fine of up to $10 million.
[24] See, for example: ABC, 'Push for ban on gene patents' available at http://www.abc.net.au/lateline/content/2012/s3502732.htm (accessed 22 September 2012).
[25] Melissa Parke (MP), 2nd Reading Speech (House of Representatives) (Monday 19 March 2012) available at http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22chamber%2Fhansardr%2F451460c0-4232-4947-a01e-30cf827a8e30%2F0346%22 (accessed 22 September 2012); Melissa Parke (MP), Grievance Debate (House of Representatives) (Monday 21 May 2012) available at http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22chamber%2Fhansardr%2Fabc2c0c8-7187-4566-b4d3-a8f9194f0813%2F0345%22 (accessed 22 September 2012).

A researcher is developing a new multi-gene screening tool, which she hopes to commercialise. To test the effectiveness of her tool, she runs a test on several gene sequences, included a patented genetic sequence. Because her intention is to commercialise her own product, her research might not be 'experimental'.

OR

A researcher, working at University A, sends genetic samples to a fellow researcher at University B, because University B has a better and more efficient set up for sequencing lots of genes. Both researchers may be experimenting but is University B experimenting or is it offering a 'service' – i.e. large scale, but not for profit, genetic testing? If so, would it be infringing the patent or authorising patent infringement?

OR

You or your family members enrol in a study that is exploring the role of particular genes in certain cancers. Some of those genetic mutations have patents over them. The researcher takes your DNA, sequences it, and analyses the results. So far, their activity is probably covered by the new exemption. But what if they discover, in the course of their research, that you had a genetic mutation that put you at risk of developing cancer. Under Australia's guidelines for ethical research[1] *they should offer you the choice to be told about the results – but now are they researching, or offering a screening service?*

OR

A university runs a Masters program in molecular biochemistry. As part of that course, students have an assignment to test for genetic mutations present in a tumour held by a Biobank.[2] *There is a patent over the particular gene being tested for. Are the university or students engaged in the 'experimental use' of a patented product? No, the university is providing a service – teaching. So is it infringing the patent? The defence in section 119C wouldn't cover this kind of activity. Going further, would the Biobank, in making patented products (genes) available, be liable for authorising the infringement, just like Napster was liable for authorising copyright infringement?*

1. Chapter 3.5 of the NHMRC/ARC/AVCC *National Statement on Ethical Conduct in Human Research* (2007): available at http://www.nhmrc.gov.au/book/chapter-3-5-human-genetics (accessed 22 September 2012).
2. http://en.wikipedia.org/wiki/Biobank

These examples are not far-fetched. In the US, which has had a research exemption in some form since 1831:

- a survey of laboratory directors in the United States conducted by Dr. Mildred Cho found that 53% decided not to develop a new clinical test because of a gene patent or licence, and 67% believed that gene patents decreased their ability to conduct research.
- American Society of Human Genetics... [reported] that 46% of respondents felt that patents had delayed or limited their research.
- a purportedly valid scientific survey of labs in the United States found a 26% drop in the number of labs performing testing for hemochromatosis as a result of gene patents.
- Cho's study also found that nine labs had ceased performing BRCA1/2 genetic testing as a result of Myriad's patents; and
- Myriad has prohibited researchers telling patients involved in research the results of their BRCA1/2 testing.[26]

[26] http://www.patentlyo.com/files/myriad-opinion.pdf

Other concerns with the exemption include the cost of defending your actions against an expensive IP lawsuit. Industry allegedly budgets $3-5 *million* for a pharmaceutical patent dispute case. Even if the law is on your side, you will need money to run the case and time to turn up in court or work with lawyers. Many small research institutions cannot afford this and will simply fold in the face of a 'cease-and-desist' letter. Moreover, these organisations depend on gifts, bequest and donations. CLA would prefer these organisations to spend their money on research, not lawyers' fees.

This fear will mean that the direction of future research may be influenced by the existence of a patent.

Finally, the exemption only applies to acts done after the enactment of 'Raising the Bar' – 16 April 2012. Patentees could still sue a person for historical experimental use as far back as September 2006, even if that research, today, would be protected.

Would compulsory licences assist researchers? CLA believes that, with the exception of the largest research institutions or universities, compulsory licensing will not be a viable option (see our concerns above). Of course, potentially infringing conduct occurred before the introduction of section 119C of the *Patents Act 1990* and wilful or ignorant non-compliance with the *Patents Act 1990* may continue to be common practice.

Crown Use, which allows the Crown to authorise exploitation of a patented invention by its own agencies or a third-party, may be an appropriate mechanism, although this would require a willing Government and could only occur where the exploitation of the invention was for the 'services of the Commonwealth or the State.'[27] Moreover, questions exist over *which* Crown must authorise the use. For example, the NSW 'Crown' may have to authorise Sydney University to exploit a patented invention, and the Queensland Government authorise exploitation by UQ. Any solution that relies on the lobbying skill of a research institute and the discretion of Government to grant or refuse an entreaty runs the risk of introducing unwanted inequities into the Australian marketplace or education system.

Healthcare and Crown Use

Question addressed
• In areas where governments are responsible for service provision, such as healthcare, do the Crown use provisions in the Patents Act provide a means of overcoming concerns about the effectiveness and efficiency of compulsory licensing?

CLA adopts the analysis of this issue outlined in paragraphs 26.33 – 26.40 of the 2004 Australian Law Reform Commission (ALRC) report *Genes and Ingenuity*.[28] CLA shares the concern of the ALRC that, under existing law, the delivery of healthcare to the public may not be considered a 'service' of the Commonwealth or a State.

The ability of the Government to respond to a domestic, or international, healthcare emergency – for example pandemic influenza – should not be compromised by the removal of Crown Use provisions.

[27] s 163 *Patents Act 1990*.
[28] http://www.alrc.gov.au/publications/26-crown-use-and-acquisition/crown-use-research-and-healthcare (accessed 22 September 2012).

While reiterating our earlier position that isolated or purified genes should not be considered patentable inventions, CLA endorses the view of the ALRC outlined in paragraphs 26.51 – 26.61 of its report, specifically recommendation 26-2:[29]

> **Recommendation 26–2** The Commonwealth should amend the *Patents Act* to clarify that, for the purposes of the Crown use provisions, an invention is exploited 'for the services of the Commonwealth or of a State' if the exploitation of the invention by a Commonwealth or State authority (or by an authorised person) is for the provision of healthcare services or products to members of the public.
>
> ALRC *Genes and Ingenuity* (2004)

International Treaties and Compulsory Licensing

Questions addressed

- What contentious treaty interpretation issues have the potential to increase the time and cost of an application for a compulsory licence order?

Contentious, international treaties, including the proposed Trans-Pacific Partnership Agreement (TPPA) have the potential to further restrict the usefulness of Australia's compulsory licensing provisions. We believe the Commission should recommend that Australia's trade negotiators not undermine the work of the Commission and Australia's health policy by pursing one-sided agreements that further tip the IP balance in favour of patent holders.

CLA recognises that Australia's IP policy space is not unconstricted. International trade agreements, including the *Marrakesh Agreement establishing the World Trade Organization* (WTO Agreement)[30] and the Agreement on Trade Related Aspects of Intellectual Property (TRIPS), have put in place restrictions on the ability of countries to grant compulsory licences or exclude certain subject matter from patentability.[31]

The Australia-US Free Trade Agreement (AUSFTA)[32] further restricted Australia's ability to exclude certain subject matter from patentability and, arguably, narrowed the TRIPS 'flexibilities' that supported Australia's 'public interest' ground for granting compulsory licences.[33]

However, we note that international law also supports a flexible approach to patent monopolies. For example, the 2001 *Doha Declaration on the TRIPS Agreement and Public Health* ('Doha Declaration') recognised that the TRIPS Agreement: 'does not and should not prevent members from taking measures to protect public health.'[34]

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[29] http://www.alrc.gov.au/publications/26-crown-use-and-acquisition/alrc%E2%80%99s-views (accessed 22 September 2012).
[30] *Marrakesh Agreement establishing the World Trade Organization* ('WTO Agreement') done at Marrakesh 1994 (entered into force in Australia 1 January 1995) [1995] ATS 8.
[31] For example, Article 31, *Annex 1C to the WTO Agreement – Agreement on Trade Related Aspects of Intellectual Property Rights* [1995] ATS 8 (hereafter 'TRIPS').
[32] Australia-US Free Trade Agreement done at Washington, 18 May 2004 (entered into force in Australia 1 January 2005) [2005] ATS 1.
[33] ALRC, *Genes and Ingenuity* (2004) [27.21 – 27.22] http://www.alrc.gov.au/publications/27-compulsory-licensing/compulsory-licensing (accessed 22 September 2012).
[34] WTO, *Declaration on the TRIPS Agreement and Public Health,* Ministerial Conference 4th Session, November 2001, WT/MIN(01)/DEC/2 available at:

Article 4 of the Doha Declaration

We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

International treaties not only constrain the legislative process, but also impact directly on the ability of a court to grant a compulsory licence. For example, section 136 of the *Patents Act 1990* states that an order of a court must not be 'inconsistent with a treaty between the Commonwealth and a foreign country.' The flexibilities of TRIPS and the principles stated in the Doha Declaration are being undermined by Australia's determination to sign the TPPA.[35] Sadly, CLA's ability to comment on the possible impacts of the TPPA is hampered by the secrecy that surround negotiations, despite the Australian Government stating: 'The public will be well informed about negotiations for, and the content of, proposed trade agreements and have an opportunity for input.'[36]

However, text purporting to be a draft IP and Investment Chapter was leaked in late 2011[37] and includes worrying provisions that would impact the ability of an Australian Court to issue a compulsory licence.[38] Most concerning, a proposed investor-state dispute settlement (ISDS) provision threatens to allow foreign companies to challenge a decision of an Australian Court (including the High Court) to grant a compulsory licence, or a Crown Use authorisation, or even policy change on IP matters, before foreign arbitration panels.[39] These panels can award unlimited damages against nation states and are not accountable to the Australian people.[40]

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http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (accessed 25 August 2012); see also, WTO, 'Ministerial Declaration', Ministerial Conference 4th session, Adopted 13 November 2001 WT/MIN(01)/DEC/1. Available at: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.pdf (accessed 24 August 2012).

[35] The Australian Government considers that 'Australia's highest trade priority at the moment is to conclude a Tans-pacific Partnership Agreement': Commonwealth of Australia, 'Gillard Government Trade Policy Statement' (April 2011) available at http://www.dfat.gov.au/publications/trade/trading-our-way-to-more-jobs-and-prosperity.html (accessed 22 September 2012).

[36] Commonwealth of Australia, 'Gillard Government Trade Policy Statement' (April 2011) available at http://www.dfat.gov.au/publications/trade/trading-our-way-to-more-jobs-and-prosperity.html (accessed 22 September 2012).

[37] Text purporting to be the draft IP Chapter can be found at http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificIP1.pdf while the purported draft Investment Chapter can be found at http://www.citizenstrade.org/ctc/wp-content/uploads/2012/06/tppinvestment.pdf accessed (22 September 2012).

[38] Thomas A Faunce and Ruth Townsend, 'The Trans-Pacific Partnership Agreement: challenges for Australian health and medicine policies' (2011) 194(2) *Med J Aust* 83-86.

[39] We note that Australia is resisting efforts to include a mandatory ISDS clause in the TPPA: 'Gillard Government Trade Policy Statement' (April 2011) available at http://www.dfat.gov.au/publications/trade/trading-our-way-to-more-jobs-and-prosperity.html (accessed 22 September 2012).

[40] Matthew Rimmer, 'A mercurial treaty: the Trans-Pacific Partnership and the United States' (15 June 2012) (*The Conversation)* available at: http://theconversation.edu.au/a-mercurial-treaty-the-trans-pacific-partnership-and-the-united-states-7471 (accessed 22 September 2012); Thomas Faunce, 'An affront to the rule of law: international tribunals to decide on plain packaging' (29 August 2012) (*The*

The impact of the TPPA will flow through the ability of a court to issue a compulsory licence per force of section 136 of the *Patents Act*.

CLA recommends the Productivity Commission reminds the Australian Government of its recommendations in its 2010 report: *Bilateral and Regional Trade Agreements* concerning the risks of including IP Chapters in bilateral and regional trade agreements[41] and its finding that:

> 'The Commission is not convinced, however, that the approach adopted by Australia in relation to IP in trade agreements has always been in the best interests of either Australia or (most of) its trading partners.'[42]

Compulsory Licensing and Gene Patents

Questions addressed
• How might compulsory licensing be utilised to address the specific concerns related to genes? Is compulsory licensing the most effective means to address these concerns…?
• Should the compulsory licensing provisions be altered to specifically address issues related to genes…? Would maintaining a more general (technology neutral) approach be preferable?

CLA has expressed its concerns over the effectiveness of Australia's Compulsory Licensing provisions in addressing *any* contentious patent dispute and its belief that, because isolate and purified genes are not patentable inventions, compulsory licences are an inappropriate remedy for gene patents.[43]

A technology-neutral approach to IP is mandated by the TRIPS Agreement and would extend to the application of compulsory licensing provisions. However Australia could still exclude the following subject matter from patentability:

> *diagnostic, therapeutic and surgical methods for the treatment of humans or animals*[44]

Whether this exemption was introduced in full or partially, it would largely address the problems of genetic diagnostic tests. While the ALRC rejected the introduction of this exemption in its 2004 report, the rejection was prior to further discussion over the impact of gene patents. Locally, New Zealand is currently debating a new Patents Act which would exempt *diagnostic and surgical methods performed on a human* from patentability.[45] Notably, in NZ this is an uncontroversial aspect of the Bill (so far as parliamentary debate goes) and is almost certain to be included in the final law. Importantly, the exemption formed part of the Government-supported draft.

Conversation) available at http://theconversation.edu.au/an-affront-to-the-rule-of-law-international-tribunals-to-decide-on-plain-packaging-8968 (accessed 22 September 2012).

[41] Productivity Commission, *Bilateral and Regional Trade Agreements* (2010) pp 262-264.

[42] Productivity Commission, *Bilateral and Regional Trade Agreements* (2010) p. 263.

[43] See above; see further, Don't Patent Me, 'Busting Myths about Gene Patents' available at https://www.facebook.com/notes/dont-patent-me/busting-myths-about-gene-patents/467743923253347 (accessed 22 September 2012).

[44] Art. 27(3)(a), TRIPS Agreement. Art. 17.9(2)(b) of AUSFTA also allows Australia to exclude this subject matter.

[45] s 15 Patents Bill 2010 (NZ) available at http://www.legislation.govt.nz/bill/government/2008/0235/14.0/DLM1419230.html

Finally, we note that countries which have exercised their right under international law to issue a compulsory licence to ensure their populations can access life-saving medicines (for example HIV anti-retrovirals) have had significant pressure applied to them by the United States (acting on behalf of its Pharmaceutical industry).[46][3]

Clearly, the Compulsory Licence system is broken. Far from being the solution to the problem of gene patents (or access to medicine) in Australia, it is a problem waiting for a worldwide solution of its own.

A Statement of Objects for the Patents Act

Questions addressed
• Should the Patents Act be amended to include a statement of objectives?
• What are the main objectives that should be included in this statement?

Several inquiries have supported the introduction of a statement of objectives for the *Patents Act 1990*.[47] Suffice to say, CLA believes it is time to get on with it!

Patents are a social contract: between the Government, Community and Inventor.

A patent is a time-limited reward (a monopoly privilege) conferred by the Government on an inventor in recognition of their novel and inventive contribution. In exchange the inventor promises to make the details of their invention public and to 'work' the invention locally.[48] This foundational principle should be recognised in any statement of objectives.

Likewise, the rights of the community should not be forgotten.

Any statement of objectives should state that decisions about the grant, enforcement and acquisition (via Crown Use or Compulsory Licence) should consider:

1. The impact of the proposed monopoly on competition (this could be a reformulation of the anti-competitive conduct ground for the grant of a compulsory licence);
2. The impact of the proposed monopoly on access to and delivery of healthcare; and
3. The goal to the patent system to promote innovation via the eventual transfer of ideas and technical know-how into the public domain.

Finally, the objectives clause(s) should reflect *all* of Australia's international treaty obligations including:

[46] RD Smith, C Correa & C Oh, 'Trade, TRIPS, and pharmaceuticals' [2009] 373 *Lancet* 684–691; Hans Lofgren, 'Big Pharma in legal battles for monopoly prices in India' (*The Conversation)* (5 June 2012) at http://theconversation.edu.au/big-pharma-in-legal-battles-for-monopoly-prices-in-india-4472 (accessed 27 September 2012).

[47] For example, ALRC, *Genes and Ingenuity* (2004); Advisory Council on Intellectual Property, Patentable Subject Matter (2011); Senate Community Affairs References Committee, Gene Patents [Final Report] (2010).

[48] The 'work' requirement could be satisfied by making the product available to the Australian community, whether or not it was manufactured here, provided price differences between countries did not amount to an obstacle to competition.

1. TRIPS, but also including
    a. the 2003 WTO Ministerial Council Decision on the implementation of Paragraph 6 of the Doha Declaration;[49] and
    b. the 2005 Protocol Amending the TRIPS Agreement.[50]
2. The 2001 Doha Declaration on TRIPS and Public Health
3. AUSFTA
4. Articles 11, 12, 13 and 15 of the *International Convention on Economic, Social and Cultural Rights*.
5. Articles 17(1), 19(2) and the second sentence of Article 7 of the *International Convention on Civil and Political Rights*.
6. The UNESCO *Universal Declaration on the Human Genome and Human Rights*.

Conclusion

Civil Liberties Australia thanks the Commission for considering our submission. We look forward to engaging further with the Commission over the course of its inquiry.

Yours sincerely

(signed)

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[49] *General Council Decision of 30 August 2003 on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health*, WT/L/540 and Corr.1 available at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (accessed 16 August 2012).
[50] Protocol Amending the TRIPS Agreement, WT/L/641, 8 December 2005 available at http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm (accessed 16 August 2012).