



RESPONSE TO IP AUSTRALIA CONSULTATION ON PROPOSED OBJECT CLAUSE AND PATENTABILITY EXCLUSION

INTRODUCTION

On 26 July 2013 IP Australia release a consultation paper entitled "[Patentable Subject Matter: Consultation on an objects clause and an exclusion from patentability](#)". Comments were sought from the public on three specific questions in Section 4 of that paper. Questions 2 and 3 were as follows:

2. Do you agree with the wording proposed by ACIP for the patentability exclusion? If you disagree with the wording, please explain which elements you disagree with and why.

3. Do you agree with amending the Patents Act to explicitly provide the Commissioner of Patents with powers to seek advice on ethical matters? If you disagree please explain why.

Below is a response from ResMed Limited to Questions 2 and 3.

SUMMARY

2. We agree with the proposed repeal of section 50 of the *Patents Act*. We do not agree with replacing it with a general patentability exclusion on ethical grounds, however worded. However, if such a general exclusion were to be enacted, we are not in favour of the proposed wording. We would prefer the wording "the commercial exploitation of which would be contrary to public policy".

3. It is impractical to place the burden for making decisions about whether a general ethical exclusion, however worded, is applicable with a patent examiner. Such an exclusion should only be applicable during revocation and (perhaps) opposition proceedings rather than at examination or re-examination stages, to allow advice from a specialist individual or body appointed by Parliament to that task.

Our detailed reasons for these answers now follow.

REASONING

INTRODUCTION

In ACIP's Final Report on Patentable Subject Matter¹ (December 2010) (the ACIP report), recommendations 7 to 10 recommended repealing Section 50 of the *Patents Act 1990* and replacing it with a general patentability exclusion:

Amend the *Patents Act 1990* (Cth) so as to exclude from patentability an invention the commercial exploitation of which would be wholly offensive to the ordinary reasonable and fully informed member of the Australian public.

This is taken to be the "wording proposed by ACIP for the patentability exclusion" referred to in Question 2. It is not clear from the terms of the consultation paper whether comment is sought on Recommendation 7 (to repeal section 50), but our assumption is that this repeal would be part of any "general exclusion on ethical grounds" reform, and we therefore include this recommendation in the discussion below.

DEFINITIONS

There may be considered two categories with respect to the ethics of patenting a given invention:

(i) The invention itself, its publication, or its exploitation², may be considered "unethical". Unethical technology areas might be those for example relating to nuclear weapons, instruments of torture, certain forms of medical intervention, methods for genetically modifying disease to make them more virulent.

(ii) The invention itself, or its exploitation, is beneficial, in that it brings benefit to the end user, and there is a need for it to be disseminated as quickly and as widely as possible. Examples of such a technology may be those where the technology is needed to overcome a medical emergency, medications to treat a life-threatening condition with no practical alternative, or some form of safety procedure – e.g. a method of landing an aeroplane, or a safety belt.

DISCUSSION

The ACIP Report's Recommendation 7 is that Section 50 of the *Patents Act* be repealed. The present Section 50(1)(a) allows the Commissioner to refuse an application for an invention "the use of which would be contrary to law". This allows the Government to enact specific exclusions from patentability on any technology without amending the *Patents Act*, merely by passing a law banning the use of the technology. Anticipating the arbitrary nature of such exclusions, Article 4*quater* of the Paris Convention stated:

¹ http://www.acip.gov.au/pdfs/ACIP_Final_Report_Patentable_Subject_Matter_Archived.pdf

² Schedule 1 of the *Patents Act 1990* (Cth) defines "exploit" in relation to an invention as: "(a) where the invention is a product—make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things; or (b) where the invention is a method or process—use the method or process or do any act mentioned in paragraph (a) in respect of a product resulting from such use."

The grant of a patent shall not be refused and a patent shall not be invalidated on the ground that the sale of the patented product or of a product obtained by means of a patented process is subject to restrictions or limitations resulting from the domestic law.

Echoing the Paris Convention, Article 27(2) of the TRIPS agreement to which Australia is a signatory forbids countries from enacting patentability exclusions “merely because the exploitation is prohibited by their law”. Section 50(1)(a) is therefore arguably contrary to TRIPS Article 27(2). We are consequently in favour of the repeal of at least subsection (1)(a) of Section 50, if not the whole of Section 50, to put beyond question Australia’s compliance with the Paris Convention and Article 27(2) of TRIPS in this respect.

The ACIP Report’s Recommendation 8 is that a general patentability exclusion as permitted by TRIPS Article 27(2) be inserted into the *Patents Act 1990*.

TRIPS Article 27(2) reads as follows:

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment ...

It is the prevention from exploitation that needs to be necessary to sustain an exclusion, not the exploitation itself that needs to be necessary. In other words, the patentability exclusion permitted by Article 27(2) is intended for inventions in the “unethical technology” category (whose exploitation it is necessary to prevent), not inventions in the second category (whose exploitation may be desirable).³ Any general patentability exclusion that explicitly targets such beneficial technologies would be inconsistent with TRIPS Article 27(2).

While the proposed wording of the general exclusion in Recommendation 9 (“an invention the commercial exploitation of which would be wholly offensive...”) is targeted to exclude only unethical inventions, not inventions in category (ii) above, we are concerned that some may attempt to apply it to such beneficial technologies. Hence we are not in favour of such an exclusion.

We think the main concern for unethical technologies is not their patenting, but the dissemination of the information. In other words it is the *publication* of the patent that is the issue, not the *grant* of the patent.

We think it unlikely that an applicant would attempt to obtain, let alone enforce, a patent for an unethical technology. Leaving aside the significant legal risk to the applicant that such a public advertisement of their dubious inclinations would entail, patents are expensive to obtain, maintain, and enforce, and the only justification for the expense of doing so is the economic return generated by the ability to exclude others from performing an activity for gain. If that activity is already prohibited by law or at least strongly discouraged by public attitudes, where is the return from obtaining a monopoly in the activity? A general patentability exclusion of unethical technologies would therefore have practically no beneficial effect on the economic life of this country, other than perhaps to discourage those misguided enough to want to file such applications from doing so and thereby publishing their unethical technology to

³ [Resource Book on TRIPS and Development](#): An authoritative and practical guide to the TRIPS Agreement, Chapter 19 Section 1: “This excludes the possibility of applying such exceptions when, for instance, it would be in the interest of public health to promote the diffusion of an invention (e.g., a medicinal product), since a Member cannot refuse a patent on *ordre public* or morality grounds and, at the same time, permit the commercialisation of the invention.”

the world. Its principal effect would be as a kind of public relations gesture to reassure the public. There may be some diffuse benefit in such a gesture⁴.

However, we believe that any such benefit would be outweighed by the significant risk that a general patentability exclusion on ethical grounds, however worded, and regardless of the intent of the exclusion, would be misused by opponents of the granting of patents in certain controversial but unquestionably beneficial technologies to challenge such patents.

As evidence for this belief, consider Article 53(a)⁵ of the European Patent Convention (EPC). This article contains a general exclusion from patentability of inventions whose commercial exploitation would be “contrary to ‘*ordre public*’ or morality”. TRIPS Article 27(2) was modelled on this article⁶. However, the clear intention of this article did not prevent an opposition being filed to a European patent for a gene sequence, i.e. a clearly beneficial technology, on the ground that the patent fell within the general exclusion of Article 53(a). The opposition was dismissed⁷ “because it [the technology] would not be universally regarded as outrageous”, reaffirming that the Article 53(a) exclusion was targeted at unethical technologies. However, the opponents, nothing daunted, appealed the decision on the same grounds⁸.

While the appeal was pending, a new Chapter VI⁹ was inserted into the Implementing Regulations of the EPC to clarify the Article 53(a) exclusion in relation to biotechnological inventions. Rule 23d¹⁰ of Chapter VI lists certain “biotechnological inventions” which are to be treated as excluded under Article 53(a):

- (a) processes for cloning human beings;
- (b) processes for modifying the germ line genetic identity of human beings;
- (c) uses of human embryos for industrial or commercial purposes;
- (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

⁴ In a [post](#) related to the present consultation, respected Australian patent attorney and commentator Mark Summerfield wrote “A general exclusion on ethical grounds may serve an important function in reassuring the wider public that the patent laws are not merely an amoral mechanism for placing monopoly powers in commercial hands.”

⁵ [European Patent Convention, Article 53\(a\)](#)

⁶ In its original (pre-2000) form (the [1973 European Patent Convention](#)), Article 53(a) excluded from patentability “the [publication or](#) exploitation of which would be contrary to “ordre public” or morality”. The TRIPS drafters originally included, but later deleted, the reference to “publication” in Article 27(2). The reason for this deletion is unclear, but the scope of the exclusion would have been considerably wider had “publication” remained.

⁷ OJ EPO, 1995, No. 388

⁸ A further ground of appeal was that “it constituted a fundamental violation of a person's rights if an invention was derived from his/her body and no consent had been obtained for the specific exploitation which was intended for the invention”.

⁹ [European Patent Convention, Implementing Regulations, Chapter VI – Biotechnological Inventions](#)

¹⁰ [European Patent Convention, Implementing Regulations, Rule 23d](#)

The Enlarged Board of Appeal in October 2002 dismissed the appeal¹¹, affirming that the claimed invention did not fall within the general exclusion of Article 53(a). However, the Board only reached this conclusion because the claimed invention was found to be within the scope of Rule 23e(2)¹² of Chapter VI, which states that “An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.”

This controversial case leads us to believe that a general exclusion from patentability on ethical grounds, however worded, would open the way to similar challenges to beneficial technologies (biotechnological and otherwise) in Australia, particularly if it is unaccompanied by any regulation comparable to Rule 23e(2). The ACIP Recommendations do not mention any such regulation.

In summary, a general exclusion from patentability of unethical technologies, while consistent with TRIPS Article 27(2), would be at best a harmless gesture with no measurable effect on Australia’s economy, and at worst an invitation to interest groups to challenge the grant of monopolies in controversial but unquestionably beneficial technologies. Such challenges, and the publicity they attract, would represent a serious threat to innovation, not just in those controversial technologies, but in many other beneficial technologies, within Australia.

The exploitation of technologies that are genuinely considered unethical may still be banned or regulated by law other than the *Patents Act 1990*¹³. Access to patented beneficial technologies may be improved by judicious use of the compulsory licensing or Crown use provisions in the Patents Act, particularly if the latter were to be amended along the lines of the recently proposed, now lapsed, Intellectual Property Laws Amendment Bill 2013¹⁴.

However, putting aside these objections, and assuming that a general patentability exclusion is to be enacted, we now address the substance of Question 2. Recommendation 9 of the ACIP Report was for the general patentability exclusion to be worded so as to exclude from patentability “an invention the commercial exploitation of which would be wholly offensive to the ordinary reasonable and fully informed member of the Australian public.”

We are unconvinced that a general patentability exclusion need deviate from the wording of TRIPS Article 27(2) which it is intended to emulate. We would prefer the wording considered, though rejected, by the ACIP Report¹⁵: “the commercial exploitation of which would be contrary to public policy” as a more direct translation of Article 27(2)’s “contrary to ordre public or morality”. The reasoning given by ACIP for rejecting this wording refers to a risk that patents for beneficial technology might be excluded by such wording. We believe it is less likely that the grant of patents for beneficial technology would be hindered under the wording “the commercial exploitation of which would be contrary to public policy” than under the proposed wording.

Regarding Question 3, Recommendation 10 of the ACIP Report proposed “Amend the *Patents Act 1990* (Cth) to provide the Commissioner of Patents with an explicit power to seek advice, from any person the Commissioner

¹¹ [Decision T 0272/95](#)

¹² [European Patent Convention, Implementing Regulations, Rule 23e](#)

¹³ The ACIP Report recognises this in Part C, Section 4.2.2, third paragraph: “where there is an ethical concern about the invention itself ..., it is more appropriate and more effective for other areas of the law to regulate and, if appropriate, prohibit use of the invention.”

¹⁴ <http://www.comlaw.gov.au/Details/C2013B00139/>

¹⁵ ACIP Report, Part C, Section 4.2.1, page 66.

considers appropriate, to assist the Commissioner in applying the general patentability exclusion proposed in Recommendation 8 and in Recommendation 9.”

As stated above, we are not in favour of the general patentability exclusion of Recommendations 8 and 9. We do not believe that patent law is the most appropriate forum to determine ethical issues. Crucially, we think issues about sufficient access to beneficial technologies arise long after examination. They may arise in the manner in which the invention is exploited, or the patent monopoly therefor is enforced. Any abuses may be addressed by application of competition law or compulsory licensing or Crown use provisions.

Therefore, if such a general exclusion were to be included in the *Patents Act*, it would be inappropriate to place the burden for making decisions about the exclusion with a patent examiner. During debate about the "Onco-mouse" patent application before the European Patent Office, there was reportedly much controversy. New Scientist magazine reported the following¹⁶:

Staff at the EPO are already tired of having to grapple with issues of public morality. 'We wish someone would invent a transgenic cat to eat this transgenic mouse,' said one exasperated patent officer in Munich last week. 'Then we could go back to ordinary work.'

Such an exclusion should only be applicable during revocation and (perhaps) opposition proceedings rather than at examination or re-examination stages, to allow input from a specialist individual or body appointed by Parliament to that task, perhaps similar to the Classification Review Board.

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¹⁶ Issue 1791 of New Scientist magazine, 19 October 1991, page 11