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Generic Medicines Industry Association

Submission to IP Australia

Consultation on an objects clause and an exclusion from patentability

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For further details
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1. Introduction

The Generic Medicines Industry Association (GMiA) acknowledges that IP Australia released “**Consultation on an objects clause and an exclusion from patentability**” in July 2013, inviting comments from stakeholders.

GMiA overview comment

A patent can be seen as social contract where a patentee discloses an invention to the public and in return receives a monopoly for a specified term to commercially exploit their invention. The patent system thus strives to achieve a balance between the competing requirements of having new technology disclosed to, and used by, the public, and the reward of term specific exclusive rights to patentees to solely benefit from their invention. The patent system has been referred to as a social contract between the patentee and society.¹ This has been expressed as follows:²

Patents are a form of social contract, where inventors receive an exclusive right for a twenty-year term to exploit their invention commercially in return for public disclosure of information about it.

Finding the right balance that appropriately encourages and rewards innovation whilst safeguarding the public interest is critical.

GMiA commends IP Australia on the production of its discussion paper proposing amendments to the Patents Act 1990 (the Patents Act) to introduce an Objects Clause and an exclusion from patentability for an invention the commercial exploitation of which would be wholly offensive to a reasonable and informed member of the public.

These are necessary amendments that have an important role to play in achieving the right balance between granting strong patents, stimulating research, the interests of patentees, and the interests of society.

¹ ACIP’s options paper on Patentable Subject Matter, pg 46.

² Allen, Andrew "Biotechnology, research and intellectual property law" (2002) 8 Canterbury Law Review 365.

2. GMiA

This submission has been prepared by the members of the Generic Medicines Industry (GMiA). GMiA is the national association representing companies that manufacture, supply and export generic medicines. The generic medicines sector is a high value-add sector delivering significant health and economic benefits to the Australian public.

The availability of generic medicines in this country helps to deliver:

- Timely access to affordable medicines;
- Substantial savings to the PBS;
- Thousands of highly skilled jobs; and
- Domestic manufacturing and exports of over \$300 million.

The generic medicines sector is currently delivering significant savings to the PBS. According to the Department of Health and Ageing Budget Statement - Outcome 2, Government expects cuts to PBS expenditure every year to 2016 resulting in a four year saving of \$2.5bn. When this is added to the original projected \$1.9bn saving in the 2010/10 Budget and the Budget adjustment of \$1.6bn in the 2012/13 Budget, **we see \$6 billion in savings since Extended and Accelerated Price Disclosure (EAPD) reforms commenced.**

A report by Centre for Strategic Economic Studies, released in May 2013, estimates that **savings to Government and general patients (non health-card holding patients) from EAPD will be up to \$18 billion dollars over eight years to 2017-18.**³

Generic medicines deliver exactly the same health benefit to all Australians as the original brand and they must meet the same strict Australian standards, including the same manufacturing requirements, as branded medicines.

Australians deserve access to affordable, high quality medicines regardless of their socioeconomic background or whether they live in metropolitan or rural areas.

A national survey of more than 1,000 respondents reveals that Australians are very positive about generic medicines with 89% of Australians rating generic prescription medicines as 'a product I know and trust'. Most people will trust their doctor (84%) and their pharmacist (86%) to help direct them regarding which medicine to purchase.

³ Centre for Strategic Economic Studies (CSES), Report commissioned by Medicines Australia, "The Impact of Further PBS Reform", May 2013, <http://medicinesaustralia.com.au/issues-information/publications/reports/>

3. Submission

Question 1:

Do you have a preference for either of the two options proposed for the Objects Clause?

GMiA recommends the adoption of the World Trade Organization Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS) description of the objectives of the intellectual property system which is worded as:

*The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.*⁴

GMiA has concerns with each of the alternative wordings proposed in the IP Australia discussion paper.

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.

GMiA recommends that any exclusions to patentability should be specifically listed in legislation. However, if it is determined that an overarching exception to patentability is necessary, then the following language should be adopted:

A patent shall not be granted for an invention the commercial exploitation of which would be contrary to public policy or morality.

The ACIP report recommended the following exclusion:⁵

... exclusion for an invention the commercial exploitation which would be wholly offensive to the ordinary reasonable and fully informed member of the Australian public.

GMiA appreciates the underlying intent of this exception and highlights ACIP's following statement that,

⁴ TRIPS Agreement Article 7.

⁵ Advisory Council on Intellectual Property ('ACIP'), *Patentable Subject Matter* (2010), page 17, paragraph 1.

[s]ociety's values change over time, and it is not for us to set rigid guidelines in this review. Instead, we are recommending a framework that considers Australian values as they exist at the relevant time⁶

GMiA has some concerns regarding the proposed wording of the exception. GMiA believes that the proposed wording would create uncertainty in the legislation. An inherent risk in refusing to allow some inventions to be patentable is that certain inventions which are not patentable at a particular time point would be viewed to be patentable at another time point. This would create uncertainty in the law.

GMiA believes that the exception would be applied subjectively, and that the meaning of the exception would not be clarified for many years and after much litigation in the courts. Ethical and moral issues are by nature unclear and there is rarely consensus on any such issues. Particular examiners, therefore, would be making decisions based on what they think is moral or ethical as it would be near to impossible for an examiner to know what the ordinary, reasonable and fully informed member of the Australian public considered to be wholly offensive.

This is also recognised by IP Australia who has previously submitted that examiners “*were not equipped to deal with ethical issues or that it was not appropriate for IP Australia to decide matters of social policy administratively*”.⁷

The words “*wholly offensive*” are also subjective and would be difficult to apply. GMiA appreciates the difficulties associated with drafting an overarching exclusion clause and the GMiA re-iterates that it believes that issues of public policy and morality are more suitably addressed in Parliament rather than by IP Australia or in the courts.⁸

However, if IP Australia determines that an overarching exception to patentability should be included in the legislation then GMiA recommends that wording based upon s 1(3) of the *Patents Act 1977* (UK) be adopted, namely:

A patent shall not be granted for an invention the commercial exploitation of which would be contrary to public policy or morality.

This is the UK enactment of the language of article 53(a) of the European Patent Convention, namely that patents should not be granted in respect of inventions the commercial exploitation of which would be contrary to “*ordre public*” or morality. Whilst still subjective and has been criticised in the ACIP report, this would at least have the advantage of an immediately accessible body of case law and other determinations to assist IP Australia and the courts in the application of the exception. This will add certainty to the users of the Australian patent system.

⁶ See ACIP’s report on Patentable Subject Matter, pg 18.

⁷ As reported in ACIP’s option paper on Patentable subject matter, pg 47.

⁸ See GMiA’s submissions to ACIP’s options paper “Patentable subject matter”.