



Law Council  
OF AUSTRALIA

*Business Law Section*

Intellectual Property Arrangements  
Productivity Commission  
GPO Box 1428  
Canberra City ACT 2601  
**Via email: [intellectual.property@gov.au](mailto:intellectual.property@gov.au)**

28 July 2016

Dear Sir or Madam,

### **Intellectual Property Arrangements**

As requested at the public hearing held by the Productivity Commission in Melbourne on 24 June 2016, the Intellectual Property Committee of the Business Law Section of the Law Council of Australia (*IPC*) provides the following answers to the questions raised. The questions, and the IPC's answers, are provided below.

#### **1 Obviousness test here and elsewhere**

At the public hearing, the Productivity Commission asked if the IPC's comments on Draft Recommendation 6.1 were consistent with the information provided by Professor Andrew Christie of the University of Melbourne on 22 June 2016 (see transcript of hearing 24/06/16 at p650 – 652).

The IPC's submission is that the test for obviousness is, substantively, now consistent with our trading partners, specifically Europe, and it should not be amended again.

Prof Christie's analysis is not inconsistent with the IPC's submission. His analysis relates to a different issue, namely the effectiveness of patent examination in Australia as compared to examination in the United States and Europe, as assessed by reference to the scope of claims of patents granted in the three jurisdictions. Importantly the data set used for his analysis relates only to patents granted historically, rather than patents granted today. The criteria for the refusal of a patent application under the *Patents Act 1990* (Cth) (***Patents Act***) has undergone a number of revisions, spelt out in more detail below, including those most recently introduced by the Raising the Bar amendments, which took effect for patent applications for which examination was requested after 15 April 2013 (see page 9 of the IPC's submissions on the Draft Report dated 3 June 2016). The amendments have had the effect that the threshold for acceptance of a patent application has been increased over time. Notably, the sample patents studied by Prof Christie were granted before the Raising the Bar amendments and some<sup>1</sup> may pre-date earlier

<sup>1</sup> Where the US application is a continuation.

GPO Box 1989, Canberra  
ACT 2601, DX 5719 Canberra  
19 Torrens St Braddon ACT 2612

Telephone +61 2 6246 3788  
Facsimile +61 2 6248 0639

Law Council of Australia Limited  
ABN 85 005 260 622  
[www.lawcouncil.asn.au](http://www.lawcouncil.asn.au)

**BLS**

important amendments in 2001. Changes to patent law have not been applied retrospectively. The Raising the Bar amendments only affect the quality of patents for which examination was requested after 15 April 2013. Patents examined based on requests before that date will validly remain on the register under the lower patentability thresholds.

The IPC has historically supported an increase in examination standards, including supporting the changes to examination standard and obviousness test implemented by the Raising the Bar amendments in 2013. However the suggestion now that there is a substantive difference in the obviousness test between Australia and Europe in particular, is wrong for the reasons identified in section 6.1 of the IPC's submission to the Productivity Commission on the Draft Report and the suggestion, put by way of a question, that Professors Christie's data relate to patents currently being accepted Australia is also wrong.

For pre-Raising the Bar patents, the criteria which the Commissioner applied to the decision as to whether or not to refuse a patent application differed depending on the date on which the application was filed and/or ground on which refusal might be based. For patents examined prior to the amendments introduced by the *Patents Amendment Act 2001* (Cth) (which took effect from 1 April 2002), once the Commissioner considered that there was no lawful ground of objection, he or she had to "accept" the request and specification.<sup>2</sup> The High Court in *Commissioner of Patents v Microcell Ltd and Others* (1959) 1A IPR 52 said (at 58) that the words "any other lawful ground of objection" are very wide, but that it was well settled that the Commissioner ought not to refuse acceptance of an application and specification unless it appeared practically certain that the patent would be held invalid.

Accordingly, any reasonable doubt on the part of the Commissioner was to be exercised in the patent applicant's favour and this approach was made clear to patent examiners in the Australian Patent Office Manual of Practice and Procedure.<sup>3</sup> This was not an irrational approach. An invalid patent could always be challenged in Court. However the approach placed higher value on the administrative efficiency of the patent application process than on disadvantages associated with the grant of potentially invalid patents, notwithstanding that their validity remained subject to challenge.

Following the amendments introduced by the *Patents Amendment Act 2001* (Cth), the threshold for acceptance of a patent application was raised, but only in relation to novelty and inventive step, such that:

- where the ground was lack of novelty or lack of inventive step, the Commissioner was required to be "satisfied" that the invention satisfied the relevant criteria; and
- for all other grounds, the Commissioner was to accept the application if he or she "considered" that none of them was a lawful ground of objection to the application.

As Gummow J explained in *Imperial Chemicals Industries Pty Ltd v Commissioner of Patents* (2005) 213 ALR 399, the intention behind these amendments was to

---

<sup>2</sup> Section 49 of the Patents Act.

<sup>3</sup> Section 1.2.1, APO Manual of Practice and Procedure - Oppositions, Courts, Extensions and Disputes (as at June 2002).

remove the so-called "benefit of the doubt" approach which had been applied under s 49 and earlier provisions (at least for the purposes of novelty and inventive step).

For post-Raising the Bar patents, the test has been raised again. Now, the Commissioner is required to be "satisfied" on the "balance of probabilities" that the application complies with the criteria set out in s 49(1) (ie, patentable subject matter, novelty, inventive step, sufficiency, support and clarity requirements). The *Microcell* test, requiring the examiner to accept the patent unless it was practically certain it was invalid, is now buried for patents subject to the Raising the Bar regime.<sup>4</sup>

Having regard to these changes, there is no evidence that there is now a substantive difference in examination standards between Australia and Europe. Given the legislative changes there is no reason why there should now be a substantive difference. The IPC is not aware of any empirical data relating to the current position.

At the public hearing Ms Chester said that "where we felt that there was still a disparity is that even with the raising of the bar, we can still grant inventions of patent here when the innovator is led directly as a matter of course which is disparate to what's required in Europe, as we understand it." This statement also appears in the presentation for the roundtable discussion, which says that the patent system should "[n]o longer award patents ... where applicants were 'led directly as a matter of course'". Such a finding would, to the contrary, *support* an obviousness allegation and render a patent invalid: *Aktiebolaget Hässle v Alphapharm Pty Ltd* [2002] HCA 59 at [53].

## 2 Objects clauses

At the public hearing, the Productivity Commission asked if the IPC has a general objection to objects clauses, or whether the objection is specific to Draft Recommendation 6.2 (see transcript of hearing 24/06/16 at p652 – 653).

As a general principle the IPC considers that operative provisions should be drafted clearly and that it should not be necessary, nor is it generally desirable, to rely on objects clauses to direct the construction of the provisions.

Secondly, the IPC considers that the specific objects clause proposed by Draft Recommendation 6.2 is problematic.

The Draft Report suggests that an objects clause would (to some extent) 'address low-quality patents' (see pages 8, 178) and 'guide decision making' (see page 186). The Productivity Commission has said that an objects clause would 'influence the granting of patents through the interpretation of patent criteria' (page 187), and provide 'specific guidance on whether to grant or revoke a patent' which 'would help to ensure that patents are only awarded when doing so provides net benefits to the community' (page 189), which suggests that the Productivity Commission is recommending that the assessment of whether the invention is 'socially valuable' be made at both the examination stage (ie pre-grant) and in a revocation action (post-grant). There are problems with this proposal. Some examples are as follows.

---

<sup>4</sup> Colin Bodkin, *Patent Law in Australia* (2<sup>nd</sup> ed, 2014), [1670].

First, if it is assessed at the examination stage, Patent Office examiners would be required to make a subjective assessment of the social value of a patent application before it has been commercialised and its full value realised, and – at least at the initial stages of implementation – before judicial consideration has been given to the operation and meaning of the objects clause.

Secondly, if it is assessed by a Court post-grant, the patentee is likely to have made numerous commercial decisions and invested further funds in the development of the invention, only to have the otherwise valid patent revoked due to a subjective assessment of what is 'socially valuable'.

Thirdly, the examiner and the Court may come to different conclusions based on the circumstances at the time the decision is made, leading to further uncertainty for the patentee and for potential users who are considering whether the patent is valid.

Fourthly, such an objects clause is either to be assessed in a subjective way – which may depend on personal views of the judge or examiner as to what is a benefit, or may alternatively, or in addition, require expensive and time consuming economic evidence to demonstrate net benefit to the community.

Fifthly, the assessment as to whether the invention is 'socially valuable' in the circumstances at the time may change with social views over the term of the patent.

Finally, such a clause appears to be contrary to international requirements for the reasons previously identified in the IPC's submissions on the Draft Report.

### **3 Section 51(3) – examples of licence provisions caught but for the exemption**

The Productivity Commission asked the IPC to provide examples of intellectual property agreements that would be caught by Part IV of the *Competition and Consumer Act 2010* (Cth) but for the exemption provided by s 51(3) (see transcript of hearing 24/06/16 at p655).

The following are specific examples of arrangements that are currently exempted from Part IV by s 51(3) of the CCA.

- Appointing an exclusive licensee.
- Appointing a sole licensee.
- Imposing obligations on a licensee not to acquire competing technologies.
- Cross-licensing competing technologies, where the parties agree not to sell products in each other's geographical areas.
- Imposing quantity restrictions on the licensee.
- Allocating geographic areas, or customer or supplier bases.
- Requiring a licensee to use a specific supplier of products, ingredients or components.
- Requiring the licensee to cooperate in infringement proceedings against third parties.

Such arrangements would not, but for s 51(3), necessarily contravene Part IV in any individual case. The IPC's concern is that repealing s 51(3) would, in every individual case,

require a debate including, in many cases, assessment of the subjective intention or of the effect of the arrangement in order to determine whether any of the provisions of Part IV of the CCA (including the cartel conduct provisions and ss 45 and 47) apply to the specific case. This is in circumstances where other jurisdictions provide specific exemptions on the basis that conditions of this kind are normal and not offensive, irrespective of the subjective intention of the parties.

By way of example, the position in Europe, which has been referred to previously, is discussed in more detail. The Commission Regulation (EU) No 316/2014 of 21 March 2014 on the application of Article 101(3) of the Treaty on the Functioning of the European Union (*Treaty*) to categories of technology transfer agreements (the *TTBER*)<sup>5</sup> provides that the provisions of Article 101 of the Treaty shall not apply to technology transfer agreements. A technology transfer agreement is a technology rights licensing agreement entered into between two undertakings for the purpose of the production of contract products (ie, goods or a service, including both intermediary goods and services and final goods and services produced, directly or indirectly, on the basis of the licensed technology) produced by the licensee or sub-licensee. The exemption provided for in the TTBER applies to provisions, in technology transfer agreements, which relate to the purchase of products by the licensee or which relate to the licensing or assignment of other intellectual property rights or know-how to the licensee, if, and to the extent that, those provisions are directly related to the production or sale of the contract products. Therefore, the TTBER does not apply to those parts of a technology transfer agreement relating to input and/or equipment that are used for other purposes than the production of the contract products.

The TTBER provides a list of 'hardcore restrictions' and where these apply, the agreement as a whole falls outside the scope of the block exemption. For competing undertakings, those restrictions include agreements which have as their object any of the following: the restriction of a party's ability to determine its prices when selling products to third parties; the limitation of output, except limitations on the output of contract products imposed on the licensee in a non-reciprocal agreement or imposed on only one of the licensees in a reciprocal agreement; the allocation of markets or customers (subject to a set of exceptions); and unrestricted in the use of its own competing technology rights provided that in doing so it does not make use of the technology rights licensed from the licensor.

The TTBER excludes agreements which have the object of restricting a party's ability to determine its prices when selling products to third parties (ie, resale price maintenance). Similarly, s 51(3) of the CCA does not provide an exception for conduct which contravenes the resale price maintenance provisions of the CCA.

Further, the Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements (*Guidelines*)<sup>6</sup> state that it is not a hardcore restriction:

- for the agreement to provide for output limitations on the licensee in a non-reciprocal agreement or output limitations on one of the licensees in a reciprocal agreement provided that the output limitation only concerns products produced with the licensed technology (paragraph 103);

---

<sup>5</sup> A copy of the TTBER can be accessed [here](#).

<sup>6</sup> A copy of the Guidelines can be accessed [here](#).

- for the licensor to grant the licensee an exclusive licence to produce on the basis of the licensed technology in a particular territory and thus agree not to produce itself the contract products in or provide the contract products from that territory (paragraph 107);
- for a non-reciprocal agreement, where the parties agree not to sell actively or passively into an exclusive territory or to an exclusive customer group reserved for the other party (paragraph 108); or
- for a licensor to appoint a sole licensee in a particular territory (paragraph 109).

Accordingly, the TTBER exempts conduct that is akin to cartel conduct under the CCA, which is also exempted under s51(3) of the CCA.

The TTBER also contains a list of 'excluded restrictions'. Where an agreement contains an excluded restriction, only the excluded restriction (as opposed to the entire agreement) will not fall within the block exemption. An excluded restriction is:

- any direct or indirect obligation on the licensee to grant an exclusive licence or to assign rights, in whole or in part, to the licensor or to a third party designated by the licensor in respect of its own improvements to, or its own new applications of, the licensed technology;
- any direct or indirect obligation on a party not to challenge the validity of intellectual property rights which the other party holds in the European Union, without prejudice to the possibility, in the case of an exclusive licence, of providing for termination of the technology transfer agreement in the event that the licensee challenges the validity of any of the licensed technology rights.

#### **4 Pay for delay – what issues should Guidelines cover?**

The Productivity Commission asked the IPC to outline the issues that guidelines for settlement agreements should cover, in the event draft recommendation 9.4 is implemented (see transcript of hearing 24/06/16 at p654).

The IPC does not support draft recommendation 9.4. The IPC's previous submission is that pay-for-delay agreements do not appear to be prevalent in Australia and that the structure which makes pay-for-delay particularly valuable in the US (the Hatch-Waxman legislation)<sup>7</sup> is not relevant in Australia. It is in principle desirable that litigation should be capable of settlement and unnecessary barriers should not be raised. The ACCC already has substantial powers to investigate and obtain documents and information.

However, to the extent it may be of assistance, some guidance on the issues which are relevant to any proposed guidelines follow. In particular, the international context may provide guidance.

In 2009, the European Commission (**EC**) published a report on the pharmaceutical sector in which it examined a number of strategies employed by originator

---

<sup>7</sup> The Hatch-Waxman legislation provides an incentive of 180 days of market exclusivity to the "first" generic ANDA applicant who challenges a listed patent by filing a paragraph IV certification and running the risk of having to defend a patent infringement suit. This provides an obvious incentive to pay the "first" generic for delay. In Australia there is nothing to prevent multiple generic entrants and far less incentive to pay one not to enter the market.

companies that could potentially delay the market entry of generic companies. Following the report, the EC has monitored patent settlements to better understand the use of this type of agreement and to identify those settlements that delay generic market entry possibly in contravention of the competition law. The EC published the *6<sup>th</sup> Report on the Monitoring of Patent Settlements (period: January-December 2014)* on 2 December 2015 (which can be accessed [here](#)). Whilst the EC notes that any concrete case will have to be examined under its own individual circumstances and merits, it acknowledges that the classification of settlements is aimed at giving an indication on which kinds of settlements may merit further competition rules scrutiny (including whether enforcement action may be necessary) and their relative importance.

The EC categorises patent settlement agreements as follows.

- Category A: agreements that do not restrict the generic company's ability to market its own product.
- Category B.I: agreements that do limit generic entry but where no value transfer from the originator to the generic company takes place.
- Category B.II: agreements that do limit generic entry and which foresee a value transfer from the originator to the generic company.

The EC observes that a generic company's ability to enter the market can be limited in several ways:

- the settlement agreement contains a clause explicitly stating that the generic company will refrain from challenging the validity of the originator company's patent and/or refrains from entering the market until the patent has expired;
- the settlement agreement contains a clause granting a licence by the originator company allowing market presence of the generic company, in circumstances where the generic company cannot enter the market with its own product or where the generic company cannot set the conditions for the commercialisation of its product freely;
- the parties agree that the generic company will be a distributor of the originator product concerned or if the generic company will source its supplies of the active pharmaceutical ingredient from the originator company; or
- the settlement agreement provides for an early entry of a generic medicine where entry is not immediate.

The EC also notes that the value transfer from the originator company to the generic company can take different forms:

- direct monetary transfer from the originator company to the generic company (which may have more than one purpose);
- distribution agreements in which the originator company grants a commercial benefit to the generic company; or
- the grant of a licence enabling the generic company to enter the market.

The US Federal Trade Commission also observed in the FTC staff study titled 'Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions' (which can be

accessed here) that pay-for-delay agreements do not necessarily involve payment from the originator company to a generic company and that there are a wide variety of techniques through which to compensate generic companies for delaying their entry, including for example, an agreement not to compete with the generic company through an authorised generic.

The EC states that Category A settlements should normally be 'unproblematic' from a competition law perspective, as they allow immediate market entry by the generic company with its own product. The EC states that some Category B.I settlements may attract competition law scrutiny, particularly those for which the settlement is concluded outside the scope of the patent and/or agreements made in relation to patents for which the patentee knows that it does not meet the patentability criteria. The EC notes that whilst Category B.II agreements are not necessarily incompatible with the competition laws, they will attract the highest degree of competition law scrutiny since they limit access to the market and contain a value transfer from the originator to the generic. The EC says that, where a Category B.II agreement is examined, an assessment of the particular facts would have to be undertaken and that the EC will consider arguments raised by the parties pointing to any potential pro-competitive effects of the agreement.

A pay-for-delay settlement agreement could potentially come under scrutiny in Australia on the basis that it is cartel conduct (ie, the originator company and generic company have reached an agreement that restricts the supply of goods by the generic company) or because it amounts to a misuse of market power by the originator company. As noted above, the exemption in s51(3) of the CCA will not exempt patent licences (and therefore pay-for-delay settlement agreements that take the form of a licence agreement), from the misuse of market power provisions.

It is not yet clear how pay-for-delay settlements would be treated by Australian courts. The lack of authority is not surprising given such agreements are not prevalent. It is also not clear to what extent Australian courts would be influenced by the positions taken by the US Supreme Court and the EC. In any examination of a patent settlement agreement that limits generic entry and which also provides for value transfer, the following considerations will be relevant.

- Whether there is a justification for the value transfer to the generic company. For example, in *FTC v. Actavis, Inc.*, 570 U. S. \_\_, \_\_ (2013) (**Actavis**), the US Supreme Court said *'[w]here a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement'*.<sup>8</sup> Further, the Supreme Court said that the reverse payment may amount to no more than a rough estimation of the litigation expenses saved through the settlement or it may reflect compensation for other services that the generic company has promised to perform (eg, distributing the patented item or helping to develop a market for that item).<sup>9</sup>
- The size of any payment from the originator to the generic company. The US Supreme Court, in *Actavis*, said that the size of the payment is itself a strong indicator of market power and suggested that an *'unexplained large reverse*

---

<sup>8</sup> *FTC v. Actavis, Inc.*, 570 U. S. \_\_, \_\_ (2013) (slip op., at 17).

<sup>9</sup> *FTC v. Actavis, Inc.*, 570 U. S. \_\_, \_\_ (2013) (slip op., at 17).

*payment itself would normally suggest that the patentee has serious doubts about the patent's survival'.<sup>10</sup> Further, a large unexplained payment in turn suggests that the payment's objective is to 'maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market'.<sup>11</sup>*

- Whether the agreement goes beyond the scope of the patent. For example, if the agreement prevents the generic company from marketing products not covered by the patent, this may go to establishing that the originator company has a substantial degree of market power.

The IPC considers that the approach adopted by the EC to the categorisation and assessment of pay-for-delay settlement agreements should inform the approach, and any guidelines, of the ACCC in Australia. In particular, the guidelines should ensure that an arrangements is **not** captured where the arrangement foresees the transfer of value from the patent holder to the alleged infringer but the value reflects:

- the benefit of permitting early entry; or
- a licence or supply arrangement on ordinary commercial terms; or
- a payment of the reasonable costs of resolving the dispute through court proceedings.

## 5 Grace period for design registrations

At the hearing, the Productivity Commission asked why the IPC does not endorse the introduction of a grace period for designs registrations (see transcript of hearing 24/06/16 at p657 - 658).

The IPC has previously made submissions regarding the introduction of a grace period for design registrations in Australia.

The introduction of a grace period for design registrations is not without its difficulties, and the IPC has generally not supported its introduction because it undermines the reliability of the Designs Register in favour of the design owner. An unregistered design right is a better option and solution.

However, the IPC notes that a grace period has now been recommended by ACIP and the recommendation has been accepted by the government. If the proposal is to be adopted it will be critical to include a prior user defence.

Please see the IPC's ['Submission in Response to the ACIP Review of the Designs System Options Paper'](#) dated 23 January 2015, section 3.3, and the IPC's ['Submission in Response to the ACIP Review of the Designs System'](#) dated 31 October 2013, page 2.

---

<sup>10</sup> *FTC v. Actavis, Inc.*, 570 U. S. \_\_, \_\_ (2013) (slip op., at 18).

<sup>11</sup> *FTC v. Actavis, Inc.*, 570 U. S. \_\_, \_\_ (2013) (slip op., at 19).

If you wish to discuss any aspect of this submission, in the first instance please contact the Committee Chair, Sue Gilchrist, on (02) 9225 5221 or via email: [sue.gilchrist@hsf.com](mailto:sue.gilchrist@hsf.com).

Yours faithfully,

A handwritten signature in black ink, appearing to read 'Teresa Dyson', written in a cursive style.

**Teresa Dyson, Chair**  
Business Law Section