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2016 – Study Question (Patents)

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Added matter: the standard for determining adequate support for amendments

Responsible Reporter: Ari LAAKKONEN

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I. Current law and practice

You are reminded that a reference to patent in the following questions refers to both a granted patent and an application for a patent.

If your answer differs depending on the distinction between a granted patent and an application for a patent, please answer the questions for each, as applicable.

1) Under your Group's current law, are amendments to the description and/or figures of a patent possible?

Yes. A patent specification and figures can be amended in the Patent Office if no litigation is on foot, under s 104 of the *Patents Act 1990* (Cth) (**Patents Act**) or in the Court if litigation is on foot, under s 105 of the *Patents Act* (It should be noted that it is desirable to amend under s 104 where possible, since the court has a discretion as to whether to allow amendments under s 105, even if those amendments are otherwise permissible under the *Patents Act*, as set out further below).

However, some amendments will not be allowable (s 102 of the *Patents Act*). The limitations on amendment will depend on the legislative regime applicable to the patent:

- For complete patent applications filed before 15 April 2013 for which examination had been requested before 15 April 2013, and for innovation patents granted before 15 April 2013 for which examination had been requested before 15 April 2013 (**Pre Raising the Bar Patents**):
 - amendments are not allowable if the amended specification would claim matter not in substance disclosed in the specification as filed.
 - amendments which convert divisional applications for innovation patents (similar to utility patents) into standard patents are not allowable; and
 - amendments which seek to remove lawful grounds of objection to the validity of the patent in circumstances where the patentee had not furnished prior art searches for corresponding applications to the Patent Office are not allowable.
 - Further, amendments after:

- the acceptance of a standard patent or
- the examination of an innovation patent

are not allowable if a claim of the amended specification would not in substance fall within the scope of the unamended claims; or the specification would not comply with the old fair basis and sufficiency requirements (it should be noted that these requirements have been replaced in the Post Raising the Bar Regime by support and enablement requirements, which are intended to be more onerous, although they have not yet been tested).

Section 102 does not prevent amendments for the purpose of correcting a clerical error or obvious mistake.

(It should be noted that many Australian patents are still under the Pre Raising the Bar Regime)

- For complete standard patent applications filed on or after 15 April 2013, standard patent applications for which examination had not been requested before 15 April 2013, innovation patents granted after 15 April 2013 or innovation patents for which examination had not been requested for before 15 April 2013 (**Post Raising the Bar Patents**), a different regime applies. For these patents:
 - amendments are not allowable if the amendment would result in the specification claiming or disclosing matter which extends beyond that disclosed in the complete specification as filed and other prescribed documents (Prescribed documents is defined to include an abstract that was filed with the complete specification; a missing part or element of a complete specification that was incorporated into the specification, in accordance with the regulations or the PCT; or an amendment that has been made to the complete specification after filing, for the purpose of correcting a clerical error or obvious mistake or complying with the deposit requirements applicable to micro-organisms).
 - Amendments which convert divisional applications for innovation patents into standard patents are not allowable; and
 - Amendments after acceptance of a standard patent or the examination of an innovation patent are not allowable if a claim of the amended specification would not in substance fall within the scope of the claims of the specification before amendment; or the specification would not comply with the new enablement and support requirements (the new enablement and support requirements are intended to be consistent with the standards applied in European jurisprudence, although the requirements have not yet been tested by Australian courts).

The regulations place some further restrictions on amendments which:

- would convert standard patent applications into innovation patent applications and vice versa or
- would convert an accepted complete application into a divisional patent, or would convert an application into a divisional application after the time for filing a divisional, or
- would amend a patent request after grant, or
- would mean that the micro-organism deposit requirements are not met, or
- are made before an opponent can be heard, or
- would amend an innovation patent before grant, or
- would result in an innovation patent claiming excluded subject matter, or
- are made by the Patent Office while proceedings are on foot in relation to the Patent (including appeals from oppositions). Section 102 does not prevent amendments for the purpose of correcting a clerical error or obvious mistake.

For the sake of brevity, the remainder of this response only deals with Post Raising the Bar patents, unless it is necessary to refer to the Pre Raising the Bar regime to explain the changes to the law. Any questions about the operation of the pre-Raising the Bar regime, which worked quite differently, should be directed to the author.

2) Under your Group's current law, are amendments to the claims of a patent possible?

Yes, subject to the limits set out above. Most relevantly for Post Raising the Bar Patents, amendments are not allowable if:

- the amended specification would claim or disclose matter that extends beyond that disclosed in the complete specification as filed and prescribed documents, or
- for standard patents which have been accepted or innovation patents which have been examined, a claim of the amended specification would not in substance fall within the scope of the unamended claims, or the amended specification would not comply with the new enablement and support requirements.

The Court will also have a discretion as to whether to allow amendments if amendments are made during the course of litigation under s 105.

3) Further to your answers to questions 1) and 2), please indicate:

a) the standard for determining whether such amendments are permissible and indicate whether this standard exists in statutes, regulations, patent office guidelines, and/or in case law.

Prior to 15 April 2013, the position was that an invention need only be fully described (disclosed) at the date of grant. This was the result of a decision of the Full Federal Court, in *Pfizer Overseas Pharmaceuticals v Eli Lilly and Company* [2005] FCAFC 224, that a filed specification could disclose a claimed invention 'in substance' without necessarily satisfying the requirements under s 40 for the invention to be described fully, including the best method known to the applicant, at the time of filing, for performing the invention.

This meant that it was possible for a patentee to file an inadequate description that could be subsequently remedied by amendment in order to meet the full description requirements before the date of grant.

The legislature considered that this was problematic because:

- it meant that a patentee could gain protection for the period before it had adequately met its obligation to provide the public with a complete disclosure of the invention; and
- it created uncertainty for the public and competitors in the period between publication of the patent specification and grant, because the public and competitors may not be able to determine their freedom to operate.

Accordingly, although the new sections have not yet been tested, the intention of the amendments is that an applicant will not be able to amend a Post Raising the Bar patent to remedy inadequate disclosure, so that a patent cannot be amended to disclose new matter.

Amendments which affect claim scope

Amendments will have the effect that a claim of the amended specification would not in substance fall within the scope of the unamended claims if a proposed new claim would extend the patent monopoly in the sense that it would make something an infringement which was not an infringement already: *AMP Incorporated v Commissioner of Patents* (1974) AOJP 322-4 at page 322 (High Court). Such amendments are not allowed after acceptance/examination. This test is applicable to both Pre Raising the Bar Patents and Post Raising the Bar Patents.

b) whether there are the differences between the substantive standards for amendments under 1) and 2) above. If so, what?

There are no differences between the substantive standards for amendment to a specification and amendments to claims, although particular considerations apply to amendments which affect claim scope after acceptance (in the case of standard patents) or examination (in the case of innovation patents). Amendments which affect claim scope so that matter which was not previously claimed is claimed are prohibited.

It should be noted that these considerations apply whether the amendment which affects claim scope is to the specification (for example, by changing the definitions of terms subsequently used in the claims which change the claim scope, or by adding or removing limitations to the description) or to the claims.

- 4) To the extent your answer to question 3) depends on timing (e.g. after filing but before examination, after allowance but before grant, and after grant), please explain how the standard changes and during which time periods.

As set out above, after acceptance of a standard patent or examination of an innovation patent it is not possible to amend the patent in a way which would make something an infringement which was not an infringement already.

- 5) Further to your answer to question 3), if impermissible added matter is a ground for refusing an amendment, please explain how impermissible added matter is defined.

For Post Raising the Bar Patents, impermissible added matter is

- matter which means that the specification claims or discloses matter that extends beyond that disclosed in the complete specification as filed (and prescribed documents), or
- (after acceptance/examination), matter which means that a claim of the amended specification would not in substance fall within the scope of the unamended claims, or the amended specification would not comply with the new enablement and support requirements.

The case law provides that in identifying added matter, the Patent Office or the Court should engage in a two stage process:

1. identifying the precise nature of the proposed amendment - what is it that is changed? This requires a comparison between the specification before amendment and after amendment, and enables the identification of what matter results from the amendment.
2. Determining whether that matter is disclosed by the specification as filed (See *RGC Mineral Sands Limited v Wimmera Industrial Minerals Pty Ltd* (1998) 89 FCR 458).

As noted above, it may be the case that the scope of the claims is affected by a change to the specification.

- 6) In any assessment of impermissible added matter under your Group's current law, please explain:

- a) how the patent application as filed is interpreted;

- In order to ascertain the invention "*described and claimed*", it is necessary to refer to the specification as a whole: *Welch Perrin & Co Pty Ltd v Worrel* [1961] HCA 91; (1961) 106 CLR 588 at p 610 per Dixon CJ, Kitto and Windeyer JJ.
- The complete specification, which includes both the body and the claims (see *Kimberley-Clark Australia Pty Limited v Arico Trading International Pty Limited and Others* [2001] HCA 8; (2001) 207

CLR 1 at [14], per Gleeson CJ, McHugh, Gummow, Hayne and Callinan JJ), must be construed in the light of the common knowledge in the art before the priority date and must not be read in the abstract.

- The Court must place itself in the position of some person acquainted with the surrounding circumstances as to the state of the art and manufacture at the relevant time (being the priority date): *Kimberley-Clark Australia Pty Limited v Arico Trading International Pty Limited and Others* at [24], per Gleeson CJ, McHugh, Gummow, Hayne and Callinan JJ.
- Because the patent instrument is not a document operating *inter partes*, but rather a public instrument, it must define the monopoly in such a way that it is not reasonably capable of being misunderstood.
- Even though the specification must be read as a whole, it is necessarily made up of parts which have different functions. It is not legitimate to narrow or expand the boundaries of the monopoly, as defined by the claims, by adding to the language of the claims, glosses drawn from other parts of the specification. Further, if the language of a claim is clear, it is not to be rendered obscure simply because obscurities can be found in particular sentences in parts of the specification: *Welch Perrin v Worrel* at p 610, Dixon CJ, Kitto and Windeyer JJ.
- A proper analysis of the specification may show that references to a particular embodiment are by way of “*illustration and explanation of the invention*” rather than a “*definition of it*”: *Welch Perrin v Worrel* at p 612, Dixon CJ, Kitto and Windeyer JJ.
- The rational starting point is not to simply turn to the language of the claims and seek to attribute meaning to those words in the abstract. The body of the specification and the claims must be read together as a whole in an attempt to identify the invention and determine whether the meaning of the words used in the claim (that is, the construction of the claim in question) is truly “*plain and unambiguous*”. If, having examined the description of the invention in the body of the specification and the definition of the claims, an expression used in the claims is not clear, it is then permissible to return to the body of the specification to either “*define or clarify*” the meaning of words used in the claim (see *Interlego A.G. v Toltoys Pty Ltd*, p 479 per Barwick CJ and Mason J) without infringing the rule that clear and unambiguous words in the claim cannot be varied or qualified by reference to the body of the specification. See also, to the same effect, *Kimberley-Clark Australia Pty Limited v Arico Trading International Pty Limited and Others* at [15], per Gleeson CJ, McHugh, Gummow, Hayne and Callinan JJ.

(Principles taken from *Artcraft Urban Group Pty Ltd v Streetworx Pty Ltd* [2016] FCAFC 29 at [72] to [79] per Greenwood J, Rares J generally concurring at [142]).

Two specific observations should be made in relation to best method and sufficiency (now enablement):

- First, best method and sufficiency under the Pre Raising the Bar regime require the patentee to disclose the best method known to the patentee at the filing date of the patent (not the priority date): *Pfizer Overseas Pharmaceuticals v Eli Lilly and Company* [2005] FCAFC 224 (31 October 2005) at [375]. This probably also applies to enablement and support under the Post Raising the Bar regime (although there is no case law on the issue yet).
- Second, recent case law suggests that a rigorous standard applies to the best method requirement, so that the requirement to disclose best method is not satisfied simply because there is sufficiency of description (or enablement, under the law applicable to Post Raising the Bar Patents). There is a residual requirement to identify the best method of performing the invention. See *Les Laboratoires Servier v Apotex Pty Ltd* [2016] FCAFC 27.

b) if interpreted as the notional skilled person would understand the patent application as filed, what is the relevant date of knowledge of the notional skilled person?

Patents are to be construed in light of common general knowledge at the priority date. See *Kimberly-Clark Australia Pty Ltd v Arico Trading International Pty Ltd* [2001] HCA 8 at [24].

7) If an amendment that was made to a patent application prior to grant is later reviewed by your patent office or a court in a post-grant proceeding and determined to contain impermissible added matter, is there a mechanism for the patentee to remedy the defect, for example by removing portions of the amendment found to be impermissible?

yes

Please explain:

If a patent has been amended in a way which is impermissible, the claim will lose its priority date: s 114 of the *Patents Act*.

Although it is theoretically possible to amend at a later stage to remove the objectionable matter, where there is litigation on foot and an application is made under s 105 (whether for before Pre and Raising the Bar patents), the Court has a discretion as to whether to allow the amendment. In recent years this discretion has been exercised against the patentee where the Court forms the view that the patentee's conduct is disentitling (for example, because the patentee should have been aware that the claims were invalid at an earlier point).

There may also be a limitation on a patentee's right to recover damages where a complete specification is amended after becoming open to public inspection and where the court is not satisfied that the specification without the amendment was framed in good faith and with reasonable skill and knowledge (s 115 of the *Patents Act 1990* (Cth)).

II. Policy considerations and possible improvements to your current law

8) How does your Group's current law strike a balance between allowing a patent applicant to make appropriate amendments during the examination process and preventing the applicant from adding impermissible matter?

As set out above, there are two regimes which are currently in place under Australian law. The previous regime (applicable to Pre Raising the Bar Patents) allowed the patentee to make amendments to add matter during the examination process and after grant, provided that the added matter does not have the effect of:

- claiming matter that was not disclosed in the application as filed; or
- claiming matter after acceptance/examination which was not previously claimed.

This regime (which is still applicable to many Australian patents) took a liberal approach to amendment, on the basis that "there is a strong public interest that inventive genius should be encouraged" (*Ethyl Corporation's Patent* [1972] RPC 169). As set out above, the exercise of the Court's discretion under s 105 places some limitations on a patentee's power to amend where a court considers that a patentee had acted in an unreasonable way (such as delaying in making amendments).

However, the legislature was concerned that the law was too liberal and allowed patentees to remedy inadequate disclosure at a later date. In light of that concern, the regime applicable to Post Raising the Bar Patents was introduced. Broadly speaking, this regime, which has not yet been tested by the Courts, does not allow patentees to add matter that would have the effect of disclosing matter that extends beyond that disclosed at filing.

9) Are there aspects of these laws that could be improved?

no

Please explain:

The view of the Australian legislature was that the Pre Raising the Bar regime needed to be improved to ensure that patentees could not supplement inadequate disclosure at a later stage.

This is reflected in the (as yet untested) Post Raising the Bar regime. The Post Raising the Bar regime also replaced the requirements of sufficiency and fair basis with those of enablement and support, to make Australian law more consistent with European law.

It should be noted that Australia has particular requirements in relation to the disclosure of best method. These requirements are not satisfied merely because the sufficiency requirements (under the old law) are met: see *Les Laboratoires Servier v Apotex Pty Ltd* [2016] FCAFC 27.

These requirements are onerous and somewhat subjective (they are assessed by reference to the particular invention claimed), and they apply even where a patentee does not know that alternative methods produce a worse result. Following the Raising the Bar amendments, which prohibit the introduction of matter not disclosed in the specification as filed, it will be impossible to amend a patent to address a failure to comply with best method, which may result in some unfairness to patentees who do not appreciate the nature of the Australian best method requirement.

In light of the recent decisions on the best method requirement, the Intellectual Property Law section of the Law Council of Australia recently recommended that the requirement be abolished.

10) Does your Group's current law allow amendments post grant? If so, how does your Group's current law strike a balance between allowing a patentee to make appropriate amendments to a granted patent (such as amendments necessary to sustain its validity) and preventing the patentee adding impermissible matter?

As set out above, the law does allow amendments post grant, but there are limitations for Pre and Post Raising the Bar Patents. For Post Raising the Bar Patents, there are limits on:

- amendments at any stage which would disclose or claim matter which was not disclosed at filing and
- amendments after acceptance (for standard patents) or examination (for innovation patents) which would claim matter which was not previously claimed (for Post Raising the Bar Patents).

Where there are court proceedings on foot, amendments after grant can only be made under s 105 of the *Patents Act*. Because this section gives the court a discretion, the court will consider the patentee's conduct in deciding whether to allow the amendment.

Generally speaking, the Post Raising the Bar amendments were intended to strike a better balance to avoid the addition of impermissible matter, and it seems likely that they will do so. Section 105 also provides some protection where proceedings are on foot.

11) Are there aspects of these laws that could be improved?

yes

Please explain:

The retention of the best method requirement (at least in its present form), together with the amendments to s 102 which apply to Post Raising the Bar Patents, provides difficulties for patentees, since an inadvertent failure to comply with the best method requirement cannot be fixed at a later date even where the patentee is not consciously holding back the best method of working the invention and where the skilled addressee is able to work the invention across the scope of the claim on the basis of the specification as filed.

The Australian Group is of the view that the best method requirement is otiose in light of the new enablement and support requirements. The Law Council's recommendation that it be abolished should be adopted.

- 12) If your Group's current law uses, at least in part, the notional person skilled in the art to determine the permissibility of amendments, is this approach effective? Are there aspects of this that could be improved?

The skilled addressee approach is effective.

III. Proposals for harmonisation

- 13) Is harmonisation of the definition of impermissible added matter desirable?
- If yes, please respond to the following questions without regard to your Group's current law. Even if no, please address the following questions to the extent your Group considers your Group's laws could be improved.

yes

Please explain:

see below

- 14) If yes, please propose a definition of impermissible added matter that you believe is appropriate.

- Pre and post grant: Matter which would disclose or claim matter which was not present in the application as filed.
- Post grant: Matter which would claim matter which was previously claimed.

The issue of what is disclosed should be judged by reference to the common general knowledge of the skilled addressee.

- 15) Should this definition depend on when an amendment is made (for example, after filing but before examination, after allowance but before grant, and after grant)?

yes

Please explain:

Amendments to claim scope after grant should be restricted, to preclude amendments which make something was an infringement which was not an infringement before.

- 16) Should rules against impermissible added matter prohibit the addition of claims per se, as opposed to adding limitations to claims?

No

- 17) Should rules against impermissible added matter prohibit the removal of claims per se, as opposed to removing limitations from claims?

no

Please explain:

No, unless the removal of the claims after the grant of the patent has the effect of broadening the remaining claims.

18) Should the definition of impermissible added matter be the same when applied by a patent office as when applied by a court?

yes

Please explain:

19) If your proposed definition refers to the notional skilled person, what should be the relevant date of knowledge for the notional skilled person in evaluating the permissibility of an amendment?

The priority date of the relevant claims.

20) If the deletion of impermissible added matter by amendment would result in an impermissible extension of scope, how should the impermissible added matter defect be remedied in these circumstances?

The claim should be invalid.

21) Please comment on any additional issues concerning any aspect of impermissible added matter you consider relevant to this Study Question.

There should be a provision in any harmonised law which allows for patentees to fix clerical or obvious errors.

Please indicate which industry sector views are included in part “**III. Proposals for harmonization**” of this form:

No industry sector views were included.

Summary

In Australia, patents can be amended (although during litigation, the court has a discretion as to whether to allow amendments). Some amendments are not allowable. The limitations on amendment will depend on the applicable legislative regime. Under the new regime, amendments are not allowable:

- if the amendment would result in the specification claiming or disclosing matter extending beyond that in the complete specification as filed; and
- after acceptance of a standard patent or the examination of an innovation patent, if:
 - a claim of the amended specification would not in substance fall within the scope of the unamended claims; or
 - the specification would not comply with the new enablement and support requirements (intended to be consistent with European standards).

Amendments to correct clerical errors or obvious mistake are allowable.

Previously, it was possible to file an inadequate description and then amend. The law was changed to prevent this practice.

There are no differences between the substantive standards for amendment to a specification and claims. After acceptance/examination, it is not possible to amend the patent in a way which would make something an infringement which was not one before.

If a patent has been amended impermissibly, the claim will lose its priority and damages may be restricted.

Australia retains a best method requirement.

Harmonisation is desirable. The harmonised position should be that specifications can never be amended to add matter, and after grant should not be amended to claim new matter.