Question Q209

National Group: Australia

Title: Selection Inventions – the Inventive Step Requirement, other Patentability Criteria and Scope of Protection

Contributors:

Date: April 27, 2009

Question

1. Legal developments on selection inventions

1) What specific types of inventions are recognized under the concept of selection invention and are patentable in your jurisdiction? Do you have any examples of selection inventions in a field other than chemical, pharmaceutical or material science fields?

Selection inventions are not legislatively recognised in Australian law. Whilst the Australian Patent Examiner’s manual discusses selection inventions as a species and case law considers them, they are not specifically discussed or defined in the Commonwealth Patents Act 1990.

The criteria for a valid selection patent in Australia come from the English case of IG Farbenindustrie AG’s Patents¹ (IG Farbenindustrie):

- the selection must be based on some substantial advantage gained or some substantial disadvantage avoided;
- the whole of the selected members must possess the advantage in question; and
- the selection must be in respect of a quality or a special character which may fairly be said to be peculiar to the selected group.

Item (c) above essentially requires that the advantage must be in respect of some non-obvious quality of special character.

These criteria were recently discussed by the full bench of the Federal Court of Australia in Ranbaxy Australia Pty Ltd v Warner-Lambert Company LLC (Ranbaxy) which stated that:

‘A patent application will overcome a prior publication, as a selection patent, if the following criteria are met:

- there must be some substantial advantage to be secured by the use of the selected members;
- the whole of the selected members must possess the advantage in question;
- the selection must be in respect of a quality or a special character, which can fairly be said to be peculiar to the group; and

¹ 1930 47 RPC 289.
• the advantage possessed by the selected members must be clearly
disclosed in the specification.²

The discussion in the Ranbaxy case appears to confirm the IG Farbenindustrie
criteria and also specifically refers to the suggestion in IG Farbenindustrie (at page
323, lines 29 – 41) that there must be disclosure in the patent specification of the
advantages provided by the selected members (see question 4).

Selection inventions were recently considered by the Federal Court in the Australian
Plavix litigation³. In applying the IG Farbenindustrie principles, including as set out in
the Ranbaxy case, the Federal Court held that the claimed enantiomer was not a
valid selection from the compounds disclosed in the earlier racemic patents. The
Court did not accept the advantages in the claimed enantiomer were unexpected over
those described in the racemic patents (ie lack of novelty), and further, that isolating
the enantiomer from the racemic mixture was obvious as it involved a classic process
being applied to a known compound to produce the desired result (ie lack of inventive
step). The decision is on appeal.

Whilst most selection inventions in Australia are directed to chemical,
pharmaceutical and material science inventions, the issue is not confined to
these types of inventions. There is very little Australian court case law on
selection inventions other than chemical or pharmaceutical inventions but the
following English cases are considered to be part of Australian legal
precedence.

1. Clyde Nail Co Ld v Russell⁴ is a case about a patent entitled
‘Improvements in the manufacture of holdfasts, dog spikes and the like’. Prior
to the date of the patent, the method of manufacturing these
articles from blanks cut from plain plates or strips and headed by
heading devices in a nail cutting machine was well known. The
specification explained that where blanks had formerly been cut from
plain strips, the shape had not been so arranged as to prevent waste,
and that the invention might be regarded as the selection of a particular
shape of blank which was cut from a plain unribbed shape without
waste. Lord Parker, in considering the novelty of the claims stated:
A mere selection among possible alternatives is not subject matter. A selection
to be patentable must be a selection in order to secure some advantage or
avoid some disadvantage. It must be an adaptation of means to ends
impossible without exercise of the inventive faculty. It follows that in describing
and ascertaining the nature of an invention consisting in the selection between
possible alternatives, the advantages to be gained, or the disadvantages to be
avoided ought to be referred to.

2. Bosch’s Application⁵ refers to a patent directed to “Improvements
relating to shuttle armatures for dynamo electric machines”, the
improvement claimed being the making of each coverpiece and spindle
in one piece of non-magnetisable steel. Evans SG stated:

³ Apotex Pty Ltd (formerly GenRx Pty Ltd) v Sanofi Aventis and Spirit Pharmaceuticals Pty Ltd v Sanofi Aventis
[2008] FCA 1194.
⁴ (1916) 33 RPC 291.
⁵ (1909) 26 RPC 710.
A patent may, however, be granted for selecting the best material, the suitability of which was not previously known, for a particular purpose… The test is whether the selection involves invention…

There are a number of patents directed to different technologies that have been considered by the Australian Patent Office.

(a) Optical fibre cable
This decision of the Commissioner of Patents following a hearing in May 1995 (relatively unusual in Australia) related to an optical fibre cable of generally known construction, characterised by a certain range of dimensions (Australian patent number 597151). The hearing officer initially found that the reported test results in the specification showed that one of the test cables was within the claimed range of dimension, but failed to exhibit the improved performance alleged for the selection. Also, another of the test cables, which was outside the claimed range, was reported as exhibiting the improved performance. The invention claimed was also anticipated by the prior disclosure of a specific working example of such a cable with dimensions placing it within the claimed range. The claims were amended to avoid the prior disclosure and the patent was granted as a selection patent. The hearing officer made it clear that he doubted whether it was a proper selection but gave the applicant the benefit of the doubt.

(b) Soft tissue product and method
The decision of the Commissioner of Patents considered whether a soft tissue product and a method of making a soft tissue product constitute selection inventions. The soft tissue product had one or both external surfaces coated in a uniformly distributed solidified deposit of wax and oil. The relevant claims were not excluded from being considered as selection inventions, however, the delegate determined that the claims did not possess the advantages described. He also commented that the claims did not uniquely identify the class of materials or properties that would give rise to a proper selection.

(c) Method of killing or controlling weeds
The decision of the Commissioner of Patents found a valid selection in a petty patent directed to:

'A method of killing or controlling weeds, comprising applying to the weeds pressurised hot water at a temperature substantially 75°C or above, wherein the pressurised hot water is delivered at a pump pressure in excess of 200 psi and at a flow rate in excess of 4 litres per minute.'

The delegate stated:

'in my view, the claims are directed to a patentable selection and are therefore not a mere working direction or mere use of a known process. The claims are patentable firstly because the prior art is generic and vague compared to the specific parameters set out in the claims…. The claims are patentable secondly because there appears to be some merit in the invention…Generally in my view, none of the informant’s evidence indicates that it was known at the priority date that the particular selection of features as claimed in the petty patent would have the beneficial effects described in the specification and in the patentees evidence.'

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2. **Novelty**

2) Groups are asked to discuss any issues that should be considered with respect to the novelty of selection inventions. For example, is merely carving a range out of a broad prior art disclosure sufficient to make a selection invention novel? Is a different advantage or use, or the same advantage with an unpredictable improvement required for a selection invention to be novel? Considerations of novelty for selection inventions are no different to novelty considerations for any other type of invention. Thus, selection invention will lack novelty if anticipated by the prior art.

To anticipate the patentee’s claim, the prior publication must contain clear and unmistakable directions to do what the patentee claims to have invented... A signpost, however clear, upon the road to the patentee’s invention will not suffice. The prior inventor must be clearly shown to have planted his flag at the precise destination before the patentee.8

This is confirmed in the Australian Examiners Manual, which states that the basic level of disclosure required to anticipate a claim to a selection is the same as for any other claim. It suggests that the law of selection operates to exclude an objection to lack of novelty in those circumstances where a class of compounds or things in a citation has not been made – and thus their properties not known.

Thus:
(a) if the citation does not provide an enabling disclosure, there is no anticipation; and
(b) if any of the selected compounds have actually been made previously, a claim to that selection lacks novelty.

It is understood that if a generic disclosure is broad, vague and/or speculative, then that disclosure will not deprive a later claim of its novelty. Thus, a generic formula which describes countless permutations and combinations of chemical formulae does not constitute a disclosure of any particular chemical within the generic formula9.

(a) Where a specification gives instructions on making a compound, together with an indication that it has been made (such as by indicating the melting temperature), there is a high presumption that the disclosure of the compound is an enabling disclosure which can deprive a later claim to that compound of novelty; and

(b) The disclosure of a named chemical compound with no indication of it having been made, is nevertheless an enabling disclosure which can deprive a later claim to that compound of novelty – if it can be said that the production of that compound can be effected by any skilled chemist following the indications given; but

(c) If the disclosure of a named chemical compound is not an enabling disclosure, it cannot deprive a later claim to that compound of novelty.

The court in *El Du Pont de Nemours (Witsiepe’s) Application* also recognized the problem that some of the broadly claimed chemicals might have unexpected properties which a later researcher discovers and would want to patent10. The court suggested that the law regarding selection patents has been developed to deal with that problem:

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8 General Tire & Rubber Co v Firestone Tyre & Rubber Co Ltd, (1972) RPC 457 at pages 485, 486.

9 Beecham Group Ltd v Bristol Myers Co 1 NZLR 192 at page 218.

It has done so in the direction of recognising two objectives, first to protect the original inventor, as regards the invention which he has made, but secondly to encourage other researchers in the field to use their inventive powers so as to discover fresh advantages and to treat the discovery of such advantages as inherent in selected members of the group or class as a patentable invention.

Australian courts have recognised that selection patents might need special attention in relation to novelty, however, they have not had the need to consider the issue. Instead, Australian practice relies on the English law which can be summarised as follows:

The question of 'selection' arises when the invention claimed lies within a known field. Before an invention may be regarded as a selection, there must exist a single prior disclosure against which the claimed invention is compared. It is not necessary for the prior disclosure to encompass all of the claim under consideration. Only that portion of the claim which falls within the prior disclosure can have the selection test applied to it. Any portion of the claim which falls outside the prior disclosure is subject to the normal tests for lack of novelty and inventive step.

Australian case law on this point is restricted to chemical inventions such as *Pfizer Inc v Commissioner of Patents* in which Pfizer’s application for an extension of term for a patent was considered. Claim 1 of the parent patent encompassed some $10^7$ to $10^9$ compounds. The compound on which the extension of term application was based is voriconazole which is within the scope of the claims, but is not exemplified. Pfizer also filed and was granted a 'selection patent' which has claims specifically to voriconazole.

To obtain an extension of term of a patent:

- one or more pharmaceutical substances per se must in substance be disclosed in the complete specification of the patent and in substance fall within the scope of the claim or claims of that specification

The question before the court was whether voriconazole was 'in substance disclosed' and 'within the scope of the claims' of the parent patent. There was no dispute regarding 'within the scope of the claims', however, the Commissioner of Patents asserted that if the selection patent was valid (ie involved an inventive step), the parent patent could not have had voriconazole 'in substance disclosed'.

The court held that the existence of the selection patent was irrelevant to the determination of whether voriconazole was 'in substance disclosed' in the parent patent, voriconazole was in substance disclosed and the extension of term was therefore granted.

This is perhaps contrary to the later discussion in *Alphapharm Pty Ltd v H Lundbeck A/S* [2008] FCA 559 in which a patent directed to citalopram was found not to disclose the specific (+)-enantiomer which was claimed in a later patent.

### 3. Inventive step or non-obviousness

3) *Groups are asked to discuss the inventive step or non-obviousness requirements in their jurisdiction. If experimental data is used to back up the inventive step or non-obviousness requirement can it be submitted after initial patent filing? Are there any prerequisites or limitations on the late submission of data?*

For a claim to be a valid selection it will be novel over the relevant prior art. However, the mere fact that it is a selection does not render the claim inventive.

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11 [2005] FCA 137.
Kimberley-Clark World-Wide Inc v Arico Trading Australia Pty Ltd\textsuperscript{12} discussed inventive step in relation to selection inventions. The invention was directed to overcoming or substantially ameliorating the disadvantages of earlier nonwoven laminates in personal care articles such as disposable diapers, training pants, incontinent wear and feminine hygiene products. The claims were found to be novel. It was argued that the invention lacked inventive step because it merely described what those of ordinary skill in the art do conventionally. It was also argued that the invention is, in effect, a selection from a known range of laminates. The delegate of the Commissioner of Patents found that all the claims except one lacked inventive step and he then commented:

'The opponent also made submissions that the application was in substance, if not in form, a selection from a known range of products, i.e. those disclosed by Brock or Timmons (the prior art), but that it was not a valid selection. I think it is appropriate in this context to apply the statement of the delegate in American Home Products Corporation (unreported Patent Office decision on patent application number 16397/92, issued 28 September 2004):

- If a citation contains clear and unmistakable directions and an enabling disclosure, then the application will prima facie lack novelty. Then, and only then, will it be necessary to consider the question of selection. As I have already found that the claims are novel over Brock, as well as Timmons, there is no need for me to determine whether or not any such selection is valid, and I will not do so.'

Experimental data is often used to support a claim to inventiveness or non-obviousness. Australian law on amendment after filing allows any amendment so long as the specification will not then claim matter not in substance disclosed in the specification as filed. So, theoretically, it is possible to submit or insert experimental data after the filing date of a patent specification in Australia. It is highly likely that the Australian Patent Office would allow such an amendment. The lack of experimental data at filing would not be likely to affect the novelty or inventive step aspects of the invention.

However, if a patent amended in this way were to be challenged before the court system, it would be expected that the patent’s validity may be questionable in terms of sufficiency and enablement.

4. **Sufficiency and/or written description requirements**

4) Groups are asked to discuss the sufficiency or written description requirements in their jurisdiction. There may be several aspects to this question:

1) the threshold for sufficiency;
2) the allowable timing for submission of experimental data;
3) the time frame within which sufficiency or written description requirements must be satisfied; and
4) the breadth of claim scope that can be supported by a limited number of examples of asserted or proven advantages.

\textsuperscript{12} [2000] APO 15 (18 February 2000).
With respect to item 1), please discuss to what extent all members of the class selected by the patentee are required to possess the requisite advantage in your jurisdiction. Is there an absolute requirement that all of the selected class possess the relevant advantage, or is the patentee excused if one or two examples fall short? Also, with respect to item 4) above, if a new utility is asserted as a selection invention, would it suffice to claim a particular range or selection of components which have been found to be associated with such a new utility or would it be necessary to recite such a new utility in the claims?

Australian patent legislation requires that a patent specification must 'describe the invention fully, including the best method known to the applicant of performing the invention'. The 'full description' and 'best method' requirements are generally treated as separate requirements.

The current test for whether an invention is fully described is whether the disclosure will enable the addressee of the specification to produce something within each claim without new inventions or additions or prolonged study of matters presenting initial difficulty. The 'addressee of the specification' is taken to be an informed reader with reasonable skill in the trade. The specification is to be construed in light of the common general knowledge in the field as at the priority date.

In the case of a selection patent, the specification must describe the advantage possessed or disadvantage avoided by the selected members. As described in question 1, generally, the whole of the selected members must possess the advantage or avoid the disadvantage in question. However, in the IG Farbenindustrie case (see question 1 above) it was suggested in dicta that 'one or two exceptions' would be permitted. A 'best method of performance' need not be a specific exemplification of an invention, simply enough instructions for the skilled worker to put the invention into effect (enable) the claimed invention. There is no express requirement that experimental data be submitted with a patent application in order to meet the test of full description.

The requirement of fully describing an invention must be satisfied when the patent is examined by the Australian Patent Office. A lack of full description may be grounds for a third party to oppose the patent application or have the patent revoked. However, a lack of sufficiency may potentially be remedied at any time by amending the specification.

Each claim is separately considered for the purposes of full description but there is no current requirement under Australian law that a claim has to be enabled over its full scope nor that every possible application of the invention has to work or to have been demonstrated to work. Where the claim is extremely broad but the specification has still enabled one specific

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13 Patents Act 1990 (Cth) s40(2)(a).
15 Patent Examiners Manual, [2.4.6.6.2].
16 IG Farbenindustrie at page 322-3; Ranbaxy at page 473.
17 IG Farbenindustrie at page 322-3.
18 Patent Examiners Manual, [2.11.3.3].
19 Lockwood v Doric [2004] HCA 58 at 83; Kimberly-Clark Australia Pty Ltd v Arico Trading International Pty Ltd (2001) 207 CLR 1 at [25].
20 Photocure v Queen's University 64 IPR 314 at [107] and [109]; Bristol-Myers Squibb Co v F H Faulding & Co [2000] FCA 316 at [77].
embodiment, the examiner could not object to the claim under full description in national examination.\textsuperscript{21}

However, if a new utility is asserted as a selection invention, it is not sufficient simply to cite examples found to be associated with a new utility. The advantage of the selection must be clearly stated in the specification. This requirement was posited by Maugham J in \textit{IG Farbenindustrie} where his honour stated:

'I must add a word on the subject of the drafting of the specification of such a patent. It should be obvious, after what I have said as to the essence of the inventive step, that it is necessary for the patentee to define in clear terms the nature of the characteristic which he alleges to be possessed by the selection for which he claims a monopoly. He has in truth disclosed no invention whatever if he merely says that the selected group possesses advantages. Apart altogether from the questions of what is called sufficiency, he must disclose an invention; he fails to do this in the case of a selection for special characteristics, if he does not adequately define them. The cautions repeatedly expressed in the House of Lords as regards ambiguity have, I think, special weight in relation to selection patents.' [footnotes omitted]\textsuperscript{22}

While the 3 main principles laid down in \textit{IG Farbenindustrie} (described in question 1) appear to reflect the law in Australia with respect to selection patents, the additional requirement that the advantage of the selection be clearly stated in the specification (the 'fourth requirement') is less certain, but there are strong grounds for arguing that it applies in Australia.

In the first instance of the Federal Court case \textit{Ranbaxy Australia Pty Ltd v Warner-Lambert Co LLC}\textsuperscript{23}, Justice Young explicitly recognised, in the context of utility considerations, the stringent requirements for a selection patent established in \textit{IG Farbenindustrie}. He also cited and appeared to endorse the 'fourth requirement' that the advantages gained, or disadvantages avoided, by the selection must be expressly identified in the body of the specification:

'Where the patent is a “selection patent,” there is an additional requirement for sufficiency that the special advantage obtained from the selection must be stated in the specification. More generally, the advantage resulting from the invention must be stated whenever failure to do so leaves the invention inadequately defined.'\textsuperscript{24}

5. Infringement

\textbf{5) If a certain advantage or superior results were the reasons for the grant of a patent on a selection invention, does such advantage or superior result have to be implicitly or explicitly utilised by a third party for an infringement to be established?}

Australian patent legislation gives the patentee the exclusive right to exploit or authorise others to exploit the patented invention.\textsuperscript{25} The meaning of exploit, with respect to a patented product, includes making, selling or using the product, or keeping the product for any of those things. If the selection patent claims a product,
then exploiting the product in any way referred to in the definition of 'exploit' is likely to constitute infringement, regardless of whether the advantage or superior result which formed the reason for the grant is utilised.

If a selection invention is claimed as a new use, what are the requirements to establish infringement?

If a selection is claimed as a new use, the invention must be limited to that use in the claim. This 'use' claimed would be treated as an essential 'integer' of the claim. To establish infringement under Australian law, the patentee must show that the infringer has taken each and every essential integer of the claim. If they have, then there is infringement, but if not all of the essential elements have been taken, then there is no infringement. Further, one cannot avoid infringement by:

- taking not only all of the essential integers of the claim but adding additional elements to the allegedly infringing product or process; or
- using a mechanical equivalent for any of the essential integers of the claim.

In examining the essential elements of a claim to determine if there has been an infringement, what is done is to determine the 'pith and marrow' of the claims. This has been described as taking the 'essence of substance of the invention underlying the mere accident of form'. Finally, in construing the claims, the scope of a claim is not determined merely by the literal words of a claim. Rather, a purposive or common sense approach should be applied, that is:

'...whether persons with practical knowledge and experience in a kind of work in which the invention was intended to be used, would understand the strict compliance with the particular descriptive word or phrase appearing in a claim was intended by the patentee to be an essential requirement of the invention so that any variant would fall outside the monopoly claimed, even though it could have no material effect upon the way the invention worked.'

Would a manufacturer of a product that may be used for the new use infringe the patent?

For the reasons outlined above, mere manufacture of a product may not directly infringe a claim for a new use of that product. However, Australian patent law provides that if the 'use of a product' would infringe the patent, supply of that product would amount to contributory infringement. Unless the manufacturer is the patentee or licensee of the patent, the act of supply will constitute patent infringement if use of the product supplied would infringe the patent. 'Use of a product' means:

(a) if the product is only capable of one reasonable use, having regard to its nature of design – that use;

26 Lahore, Patents, Trade Marks and Related Rights, [15,165].
29 Patents Act 1990 (Cth) s117(1).
(b) if the product is not a staple commercial product – any use of the product, if the supplier had reason to believe that the person would put it to that use; or

(c) in any case – the use of the product in accordance with any instructions given for the use of the product, or any inducement to use the product given to the person by the supplier or contained in an advertisement published by or with the authority of the supplier.  

Case law on what constitutes the 'use of a product' for the purposes of contributory infringement remains somewhat scarce. A supply of a product by a manufacturer would be an infringement if supplied with instructions to use the product in a way that would constitute patent infringement. If the product is not a 'staple commercial product', the supply of that product would be an infringement if the supplier had reason to believe that the person would put it to the infringing use.

The recent decision of the High Court of Australia in Northern Territory v Collins provides some guidance on the meaning of the word phrase 'staple commercial product' in contributory patent infringement proceedings. As Justice Hayne stated:

'If [a product] is in fact supplied commercially for various uses, it is a staple commercial product and the supplier of such a product is not to be held liable as an infringer because the person to whom the product is supplied uses it in a way that infringes, even if the supplier has reason to believe that it may be used in that way.'

The High Court refused to interpret the test for contributory infringement in a way that would expand a patentee’s rights where the act of supply is not otherwise an infringement. It seemed concerned to avoid tipping the balance in favour of patentees at the expense of the right of a supplier of goods to freely trade in goods which have a variety of lawful commercial uses. A person that supplies a commercial product that has a variety of uses is unlikely to infringe, except where the supplier either instructs or induces the infringing use, or advertises the product with such instructions or inducement.

Does the intention of an alleged infringer play any role in the determination of infringement?

The intention of the alleged infringer is not usually an element to be considered in the determination of infringement. As noted above, infringement occurs where a patented invention has been exploited, and in the cases of making, selling or using a claimed product, intention does not play a role.

Intention has at least a theoretical role to play in considering aspects of contributory infringement. Where use of a product would infringe, supply of that product will also infringe in the circumstances described above. Where the product supplied is not a 'staple commercial product', the state of mind of the supplier is stated to be relevant in the second limb of the test for contributory infringement. That is, the supplier's belief as to the use that the infringing product will be put to is relevant to a finding of contributory infringement in relation to a 'non-staple' commercial product. However,

30 Patents Act s117(2).
31 Northern Territory v Collins [2008] HCA 49 (Unreported, 16 October 2008).
given the High Court's broad interpretation of ‘staple commercial product’ in *Northern Territory v Collins*, these seem little scope for a finding of contributory infringement based on this limb.

Intention may be important when considering certain defences, for example, the springboarding exemptions for otherwise infringing acts done solely for the purpose of obtaining regulatory approval. While ignorance of the existence of the patent is not a defence to infringement, it will have an impact on the liability as to damages. The court may refuse damages where it is satisfied that the respondent was not aware and had no reason to believe, at the date of the infringement, that a patent for the invention existed.32

6. Policy

6) Groups are asked to give a short commentary as to the policy that lies behind the law on selection inventions in their jurisdictions, and then to consider whether or not such policy considerations are still valid today as technology continues to advance.

There has been little discussion of selection inventions in Australian cases and they are not referred to in the patent legislation. As such, there is little discussion of the policy behind selection inventions which is peculiar to Australia, and that discussion which does take place usually makes reference to UK authorities. The Australian Federal Court,33 and the Australian Patent Examiners Manual,34 each quoting a different UK case, suggest that the law of selection inventions has developed to recognise two objectives: maintaining the protection of the original inventor, and encouraging other researchers in the field to discover fresh advantages. The Australian group considers both objectives are desirable and remain valid as the underlying rationale for granting selection patents. The Australian group considers that the conventional law in force in Australia adequately provides for selection patents.

With Reference to the Examples

7. Novelty

7) *In example 1 would the prior disclosure of the compounds containing the generic class of radicals anticipate any claim to a specific compound having a particular radical, or group of specific compounds having a selection of particular radicals in your jurisdiction?*

A claim to a specific compound will not have been anticipated by the prior disclosure of the generic class of radicals, unless the specific compound had been previously disclosed by way of identification or example. Furthermore a group of specific compounds having a selection of particular radicals would not be anticipated if the following criteria for a selection invention were satisfied:

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32 *Patents Act* s 123(1).

33 *Apotex Pty Ltd (formerly GenRx Pty Ltd) v Sanofi-Aventis* [2008] FCA 1194 (Unreported, Gyles J, 12 August 2008), [77].

34 *Patent Examiners Manual*, [2.4.6.6].
(a) the selection must be based on some substantial advantage gained or some substantial disadvantage avoided;

(b) the whole of the selected members must possess the advantage in question; and

(c) the selection must be in respect of a quality of a special character which may fairly be said to be peculiar to the selected group.

In the analysis, does it matter how wide the prior disclosed generic class of compounds is – ie. Would the analysis be different if the prior disclosed generic class consisted of 1,000,000 possible compounds (very few of which were specifically disclosed) as opposed to merely, say, 10? In relation to a claim to a specific compound which is anticipated by the prior disclosure of the generic class, the number of members of the prior disclosed generic class would be irrelevant. This would also be the case for a group of specific compounds, although inevitably the selected group would need to be greater than 1 and smaller than 10 if the prior disclosed generic class had only 10 members.

8. Inventive step or non-obviousness

8) In example 2 would any of the three possibilities constitute an inventive step over the prior art in your jurisdiction? Possibility (i) would not constitute an inventive step over the prior art. Possibility (ii) would not constitute an inventive step over the prior art, but it would be a matter of evidence of the skilled person’s expertise. Possibility (iii) would constitute an inventive step over the prior art. Further, if, say, scenario (iii) does constitute an inventive step over the prior art, what scope of protection should the inventor be able to obtain? Should the inventor be able to obtain protection for the products per se (that happen to have this advantageous property), or should any patent protection available be limited to the use of the products for the advantageous property (as an adhesive) not possessed by, and not obvious over, the prior art? Under Australian law where scenario (iii) does constitute an inventive step, the practice is to allow the patentee of the selection protection for the products per se. This leads to the potential need for cross-licensing between the patentee of the generic compounds and the patentee of the selected compounds.

9. Sufficiency and/or written description requirements

9) To what extent are all members of the class selected by the patentee required to possess the requisite advantage in your jurisdiction? Is there an absolute requirement that all of the selected class possess the relevant advantage, or is the patentee excused if one or two examples fall short? All members of the class selected must possess the advantage. While the IG Farbenindustrie case suggests that ‘one or two’ exceptions would be permitted, this was dicta and does not represent the law in Australia as recently restated in Ranbaxy.

35 IG Farbenindustrie, Ranbaxy.
10. Infringement

10) By reference to example 3 to what extent is evidence of the knowledge of the advantageous property of the selection, or intention of the infringer as to its supply, required to find infringement in your jurisdiction?

A finding of infringement is not dependent on knowledge of the advantageous property of the selection. ‘Exploitation’ in the sense described in question 4 supports a finding of infringement. If the compound in Example 3 is the subject of a claim of a granted patent, use of the claimed compound will infringe the patent. The competitor who manufactures the claimed compound may therefore be open to an allegation of contributory infringement. The intention of the competitor is unlikely to be relevant. The competitor may avoid a finding of contributory infringement if the claimed compound has more than one reasonable use or is supplied commercially for various uses, provided that, in addition to an absence of instruction as to its use, there is no inducement to use the product whether given directly to the person(s) supplied or contained in the competitor’s advertising.

11. Policy

11) Groups are asked to consider, in respect of examples 1 and 2, whether it matters how much effort the inventor has invested in arriving at his selection in order to found a valid selection patent. The answer to this question is closely related to the policy consideration that underpins the grant of selection patents and the incentive/reward equation involved. The inventor may have expended considerable time and money in trawling through the whole host of possible compounds encompassed by the prior disclosed generic class, and the particular selection that he has made may constitute a leap forward on the field. Surely the inventor should be rewarded for his efforts and obtain protection? On the other hand, it could be argued that such considerations may have been relevant in an age when the inventor’s efforts actually involved many man-years of careful and painstaking laboratory work, but are now increasingly irrelevant in an age of combinatorial synthesis when large varieties of different compounds can be manufactured in a fraction of the time. Are such considerations relevant?

It is irrelevant how much effort has been invested by the inventor to arrive at a selection when determining whether a valid selection patent should be granted. The Australian group considers that the considerations relevant to the grant of any patent should depend on the traditional criteria, such as novelty and inventive step, which have equal application today as they have previously. A selection patent must satisfy the same criteria that all other valid patents must satisfy including novelty (subject to comments made above), inventive step, manner of manufacture, utility, fair basis, sufficiency and enablement. The degree of effort involved, and to what end that effort is deployed, to define the selection may be relevant to considerations of inventive step. Otherwise, the degree of effort is irrelevant to the determination of validity of a selection patent.
Harmonisation

12) Groups are asked to analyse what should be the harmonised standards for the patentability of selection inventions. In particular, the items discussed in Q1-Q6 and the examples discussed in Q7-Q10 above should be referred to.

13) Groups are also asked to recommend any issues for harmonisation not referred to in Q11 above.

14) Groups are asked to outline any other potential issues that merit discussion within AIPPI as regards selection inventions.

The Australian group considers that it is not necessary to treat selection inventions as a separate class of inventions that require a specific set of rules or different application of generally applicable legal principles. The Australian group considers that the matters set out in question 11 above are the appropriate criteria to the grant of any patent. While there may be a case for harmonisation, it is in relation to more fundamental criteria, such as, and for example, the concepts of novelty and inventive step, rather than selection inventions as a *sui generis* class of inventions.