

Innovation Patent Exclusion Round Table
18 June 2003
Stamford Plaza Hotel, Melbourne

ACIP Biotechnology Working Group — Membership

- Professor Paul Greenfield — Chair
- Professor Andrew Christie
- Mr Doug Carter
- Mr Keith Smith
- Dr Greg Smith (not present at meeting)
- Dr Stewart Washer (not present at meeting)

Introductions

Participants introduced themselves. A list of attendees is attached.

Prof. Greenfield — background to the innovation patent and the exclusion

- The Parliamentary Secretary to the Minister for Industry, Tourism and Resources, the Hon Warren Entsch MP has asked ACIP to consider the exclusion, particularly from the perspective of national interest issues.
- Received over 30 submissions — divergent views — purpose of today's round table is to discuss these and help ACIP in its deliberations.

Prof. Christie — rundown of the innovation patent, standard patent and plant breeders rights (PBR) systems. (see overheads on the website for details)

- subject matter protected
- requirements for protection
- examination and grant
- exclusive rights
- scope of rights
- exceptions to infringement
- duration

statistical information covering use of the innovation patent to date.

Prof. Greenfield

Questions asked in the issues paper

Went through the broad responses provided in the submissions

2 issues that ACIP would like more information on at this meeting

- nature of exemption itself
- is there sufficient reason to overturn the exemption

Discussion

Was a question regarding the Competition Principles Agreement and its role in the discussion.

ACIP — referred the group back to the terms of reference given to the Committee by the Hon Warren Entsch, MP, Parliamentary Secretary to the Minister for Industry, Tourism and Resources. In addition the Committee noted that the burden of proof is such that those that want to change the status quo (ie remove the exclusion) need to make their case. However at this stage ACIP want a full and broad discussion covering all sides, so they are not adopting too narrow and legalistic approach.

Question asking why the exclusion was introduced in the first place.

ACIP — not clear on the reasons that lie behind the exclusion. However, even if these were identified, still have the question of whether the exclusion should be retained. Would like to tease out from those that think exclusion should remain, why they think it is in Australia's national interests to have the exclusion.

Suggested that the exclusion is necessary because the petty patent system (which the innovation patent replaced), didn't undermine and undercut the PBR system as the innovation patent would because of the overlap issues it raises.

ACIP — want to discuss this — where is the problem of the overlap? What problems does this cause?

Discussion about the differences in the innovation patent system including no need for examination, the innovative threshold required for an innovation patent and whether or not this is higher, equal to or lower than that required under the PBR system. Also the lack of defences to infringement under the patent system, compared to those available under the PBR. Whether these would cut into the PBR system and undermine the advantages that the PBR system offers to the non right holders.

Question — if the exclusion is the result of an overlap with PBR why have the animal exclusion as well?

Protection of animal matter controversial. No equivalent to PBR for animal breeds.

ACIP — the implication is that innovative step and PBR are equivalent – still does not understand what the threat to PBR system is.

Response — what should be the proper relationship between different regimes. The current systems work quite well together and provide a good balance. Allowing duplication where IP rights will cover 2 systems will cannibalise each other. Breeders will be required to seek more than one type of IP protection.

ACIP — why is there no problem with the current system?

The exceptions in PBR — a clear research exemption and farm saved seed provision — are lost under the patents system.

ACIP – what is special about plant and animal area that these should not be protectable under the innovation patent system?

Much of the work done in plant breeding involves very small incremental changes. Are talking discoveries rather than inventive step. PBR sets up a balance of interests by keeping the wide exclusions in recognition that have small invention. For the innovation patent, don't understand the threshold level – not tested.

Others would see PBR and the innovation patent working together rather than against each other. Can't understand why the innovative step would allow incremental changes to be protected under the innovation patent system.

ACIP – if make assumption that incremental changes would be protectable under the innovation patent system then what would be the problem?

If it did, it would conflict with PBR and this would be bad. The innovation patent would be good for the area of essential derivation. This is a grey area of PBR.

ACIP – where are the points of conflict – what is problematic about this?

The value of PBR is that it allows exchange of material internationally so can have innovation. Need to ensure that the incremental changes are protected and that essential derivations are protectable. Standard patents are likely to be a difficult route. An innovation patent is shorter and would give a sustainable market share for essential derivations.

The great majority of grain research is done using overseas germplasm. The CGIAR centres have concerns about how germplasm can be used. PBR developed from a system which allows the exchange of material. If introduce patents, then this exchange is tied up. Centres may be reluctant to provide germplasm if they think it could be protected by an innovation patent.

Discussion of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture. This clearly says that where material accessed under the multilateral system goes into an IP regime where it is not available for further research royalties must be paid.

Regarding the issue of access to germplasm from overseas – requirement to benefit share only kicks in when commercialised product is not available for further R&D. There is a concern that the majority of varieties protectable under the PBR system would meet the lower threshold of the innovation patent, even though this is not the intention — the innovation patent system was written down from patents, rather than up from PBR.

Question as to whether there was any discussion about plants and animals during the original ACIP investigation (review of the petty patent system) and whether or not there was any comparison with existing 2nd tier patent systems in terms of the technologies that these covered.

Malcolm Royal (a member of the ACIP working group that did the review of the petty patent system) – an exclusion was not considered. However he notes that the committee's recommendation was that there should be examination prior to grant. Thinks that many of the incremental changes that are being discussed would not be granted if there was examination prior to grant.

It was suggested that perhaps the implications of the plants issues haven't been discussed widely enough. IP protection for plants has been considered for the last 25 years. The original ACIP report got cherry picked a little — lost the examination prior to grant and didn't consider flow on effects of that particular change.

Some thought it would be more appropriate to look at exclusion as part of general review of the innovation patent system. Only 10% are examined. Difficult to determine value of such patents if not examined.

Others reiterated that they don't want to see competition between PBR and patents. What they do want to see is a tiered system. There are times when they want to get broader protection than is available under PBR. PBR are hard to prosecute in the field. Essentially derived variety issues are also being discussed and considered internationally.

Suggestion that the corollary is to extend the essentially derived variety protection under the PBR system. Is this an alternative option?

PBR needs to be able to be enforced and seen to be able to be enforced. This is an advantage of the patent system — it is tested. At present, PBR are not providing sufficient deterrent.

Discussion about the need to 'subdivide' different types of plants eg need to split grains from tree fruits where they have commercial advantage in market place not in production levels. The standard patent system difficult to use for those without a good working knowledge of the system. Innovation patent is a midway step — it would be easy to get innovation patent protection using internal resources. Don't need competition, but want full range of IP rights available to protect as necessary.

ACIP — question regarding the challenge to prosecution of PBR. How serious is the issue from the breeder's perspective?

It is a problem in relation to grains. There is the sheer cost of going to court coupled with difficulties of getting sufficient information to prosecute. Is a monetary driver. No guaranteed outcome. If the variety was developed in public system, breeder unlikely to let commercial people prosecute any infringements. Want more certainty. See the innovation patent as providing protection for essentially derived varieties.

ACIP — would the short term of an innovation patent be a problem?

Innovation patent would allow sufficient protection so can draw in investors and do enough work to develop market position.

Challenge made to the statement that while companies don't have resources to prepare standard patent applications, they could prepare innovation patent documentation and this would provide increased certainty. Are you setting up for false degree of certainty because the innovation patent could get knocked off at examination stage?

Is not a question of putting together applications, but expertise to start. Lack of examination and degree of uncertainty. If using an innovation patent to attract investment, due diligence.

Question asked seeking more information as to why the exclusion was included in the first place — this will inform the debate significantly.

The decision to exclude plants and animals was made at the 11th hour. It was made primarily so that the innovation patent legislation could proceed allowing the system to be introduced for the bulk of technologies.

ACIP — have two themes — the nature of industry and the subject matter. The nature of the industry is such that this sort of right inappropriate — the nature of the subject matter itself has its own special characteristics. Need to work out now whether we can justify the existence of the exclusion or its removal.

It was stated that consideration of all the issues at the time that the government policy was being developed might not have been as extensive as would all like. Consistency with government policy and existing legislation was not an apparent feature of the environment at that time. We now have opportunity to go back to and consider. In considering the national interests, need to draw not only on economic interests but wider interests, including green issues.

ACIP — clear concern that users don't want competition with PBR and this comes to the innovative step threshold. For the innovation patent to be useful, it must form a specific subset or be used in combination with other types of IP rights. Lack of compulsory examination is an issue. Would like to explore some of these further, for example there was no pressure from pharmaceutical sector for a need to use the innovation patent system, but pharmaceuticals were not excluded from the innovation patent system. Is there anything else that is at issue?

It was suggested that non-examination has caused concern and a hesitation to invest. So it is an inhibitor to use the innovation patent in genetic research.

ACIP — is there a threshold problem with using the patent system rather than the innovation patent?

Industry specific regulations exist for animal breeding. Could impact on these if we remove the exclusions. Could upset the industry balance eg horse racing industry, kennel clubs etc.

It was suggested that there is no need for the innovation patent as can use the standard patent system. It was suggested that it makes more sense to use the standard patent system for transgenic animals, including because have pre grant examination. Don't need to patent the animal to protect the invention. This is true also for plants. It is possible to use all sorts of systems other than protecting the animal *per se*.

ACIP — is there a concern that if the innovation patent system is available that people will use this to prevent further research?

Reference to the big expansion of inventions in the biotech fields in the 80s. Use of these were regulated by market forces and licensing charges. Expect that it would be the same for animal models. It is unlikely to be in the interests of patent holder to prevent researchers using.

General discussion about licencing practices and possible restrictions imposed by their use.

Prof. Greenfield — post lunch would like to discuss the research issue. Is there evidence that the lack of innovation patents is hindering investment in research? Are there examples where are clearly seeing dis-benefits?

Lunch

Prof. Greenfield — before continuing the more general discussions, would like to address some of the perceptions regarding the innovation patent system and non-examination.

Concerns regarding uncertainty and to challenge is expensive. People do not know the difference between an examined and an unexamined patent.

Prof. Christie — general explanation of who can seek examination; 3rd party pays half the cost. Or patentee can request. Can't threaten to sue or sue until the patent has been examined and certified. Can't do anything positive with it until has been examined. Therefore is it a question of the examination system in practice or a perception? If educate the less educated users so is a reasonable standard of understanding, is there still a problem?

Some still believe there will still be a problem.

ACIP – heard this morning how the innovation patent might be used and examples of potential benefits if it was available. Interested in any thoughts of problems that have arisen through the exclusion or is it too soon. For example, the potential to slow research activity, is this a theory only?

Probably too soon to answer. But have researchers discussing what tools they will use. Particularly when have private sector funding interests that want protection for their investment. There is increasing activity for some areas in plant breeding and in some plant species and alternatives being investigated. For example, common law contracts — see a movement away from intellectual property protection.

Was a question as to whether the private sector will invest on the basis of an unexamined innovation patent.

Response was that if an innovation patent was taken out, that they would see no reason not to get it examined.

Statement made on behalf of the NHMRC that although they are arguing for removal of the exclusion, but would not want to encourage those who receive NHMRC funding to use it.

Question about whether the innovation patent is on the table for discussion of the AUSFTA?

Understanding is that the innovation patent has not come up as is a domestic issue. Some argued it is not a trade issue either.

Others were of the opinion that there are trade implications. Australia relies very heavily on improving varieties for export. Can't ignore the trade issues. PBR rely heavily on import of technologies, lose competitiveness.

Discussion about the nature of research that can be done when there is a patent, there is no explicit research exemption in the Patents Act. Having PBRs available for further R&D is in the national interest. The patents research exemption is however at best uncertain.

ACIP advised that they have another working group considering the relationship between public and private rights, which includes the issue of experimental use of patents.

ACIP – 90% of innovation patents are owned by domestic entities. Where are the trade issues?

Response is that we can't use data of current innovation patents to determine where plant innovations are going to come from. Data show for PBR that 60% come from overseas. Australia has consciously decided that we want to give access to our breeders to that material for further R&D to improve for our local conditions.

Others agree that a lot of germplasm comes from overseas, however still don't see any conflict in allowing innovation patents.

Response is that it is not a protection issue *per se*, but a cost one.

Others commented that the free availability of PBR for research and breeding is stopping some companies registering varieties under PBR and instead they are using commercial restrictions and secrecy. Australian interests are not getting access to this material. Are more likely to be able to negotiate access if have something other than trade secret to rely on.

Response to this was there was a conscious decision to provide reasonable public access under the PBR system as an immediate national benefit. Reasonable quantity, quality and price. If IP is protected under the PBR system there is access that patents and trade secrets don't provide.

There is no difference between a patent and a trade secret. Providing reasonable public access is in the national interest. If this is derogated in some way, need to make a conscious decision that this is what we want to do.

ACIP — how important is the farm saved seed provision?

At the political level is a real given - 80% of the market. Some commented that the major seed companies are likely to have arrangements in place that restrict access in other ways - for example, by contract. Farmers will revolt if the farm saved seed provisions are taken away from them. Contractual arrangements are also around. Farmers have insisted on having farm saved seed available. Strong historical support in UPOV by Australia during negotiations for farm saved seed provisions to be included.

Question — could use the innovation patent system to claim genetic material *per se*? Would this not be an unintended consequence of removing the exclusion?

Genetic material *per se* can be patented under the existing system. The AIMS submission asks whether the innovation patent permits protection of discoveries? The answer is no. Phenotypes could be protected with an innovation patent that would not be protectable under the PBR system.

ACIP — in this context, the question should be whether there are issues of a qualitative nature that are questions of innovative / inventive step. Manner of manufacture questions are not relevant to these discussions.

ACIP — in summary we run the risk of some technology being locked up and some research not occurring due to the current exclusion. However we can reasonably put to bed the question of ongoing research capabilities in Australia.

This understanding was questioned. The capacity for ongoing research is the reason why we are having an inquiry. We can't put the issue to bed because we need to discuss this in the light of the research exemption discussions.

ACIP — although this is a concern, it is not a burning issue at the moment.

ACIP would like to clarify that there is a difference between experimental use and the new variety exemption. If the innovation patent were to preclude commercial developmental work would this be a good thing?

Yes — it would be warmly welcomed by a sector of the community.

AFFA noted that the social / ethical issues surrounding this have not been covered off and that broader community consultations might be necessary.

ACIP — don't want to go into the discussion of the ethics of patenting in this area as it is beyond the current working group's remit. It was further noted that the original discussion paper was sent out to a broad group of people (about 150) and that AFFA were consulted on who should be included on the mailing list. Those who made submissions were invited to attend this meeting.

It was suggested that it might be worth noting how the ALRC inquiry into gene patenting would consider these issues.

ACIP – the ALRC want to focus on human health issues and therefore have a different focus. They are not primarily interested in plants and animals *per se*.

Future actions

ACIP will prepare a summary of the proceedings and send out. One party has asked whether they could provide an additional submission. This offer is available to anyone else who would like to make a further submission. Any further submissions are due by 18 July.

Copies of the overheads and a list of attendees will be posted on the website.

Attachment A

Attendees - Innovation patent round-table.

1. Mr David Adamthwaite Meat and Livestock Australia & the Sheepmeat Council of Australia
2. Mr Chris Adriaansen Department of Primary Industry, Queensland
3. Mr Stewart Anderson Department of Primary Industry, Victoria
4. Mr Geoff Budd GRDC
5. Mr Karl Divers AWB Limited
6. Dr John Golding University of Sydney
7. Ms Melanie Howlett Intellectual Property Research Institute of Australia
8. Mr Peter Huntsman FICPI
9. Dr Peter Janssen La Trobe University
10. Mr Peter Jones Meat and Livestock Australia Ltd & the Sheepmeat Council of Australia
11. Dr Charles Lawson Australian Centre for Intellectual Property in Agriculture
12. Mr David Liesegang Agriculture Victoria Services Pty Ltd
13. Mr Len Marsden Australian Research Council
14. Mr Chris Melham Seed Industry Association of Australia Ltd
15. Mr Bala Murali Department of Agriculture, WA
16. Mr Peter Neilson Seed Industry Association of Australia Ltd
17. Dr Mathew Rimmer Australian Centre for Intellectual Property in Agriculture
18. Mr Malcolm Royal Institute of Patent and Trade Mark Attorneys of Australia
19. Prof Brad Sherman Griffith University
20. Ms Karen Sinclair FICPI
21. Prof Mohan Singh The University of Melbourne
22. Dr Kamal Singhe Department of Industry, Tourism and Resources
23. Mr Doug Waterhouse Department of Agriculture, Fisheries and Forestry - Australia
24. Dr Elane Zelcer NHMRC