Australian Government
Productivity Commission

Intellectual Property Arrangements

Roundtable on pharmaceutical patents

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Commissioners

About the inquiry

How did we go about this task?

- Asked to look at IP arrangements by government who want to make sure the IP system provides appropriate incentives, while not unreasonably impeding access.
- Sought evidence:
  - *Consultations*
  - *Roundtables*
  - *Submissions*
  - *Draft report for comment and feedback*

How did we go about this task?

- More consultations to come
  - *Hearings*
  - *Additional roundtables*
  - *Submissions on draft report*
  - *Final report to be delivered to government later this year*

About today

Purpose of roundtable

- Discuss draft recommendations affecting pharmaceutical patents
- Focus on areas of potential change: extensions of term, evergreening and pay-for-delay
- Seek further evidence on the magnitude of costs and benefits
  - *of the status quo*
  - *of potential policy changes*

Conduct of roundtable

- Discussions will occur under 'Chatham House' rules
- A copy of this presentation and a list of roundtable attendees will be made available on our webpage

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Pharmaceutical patents
What did we recommend and why?

Where are we coming from: The policy framework

Effective:
Does the IP system lead to additional IP being generated?

Is the IP system effective in disseminating IP?

Efficient:
Is the IP system getting the right balance between encouraging IP creation and costs that rights can cause?

Is the IP system ensuring IP is being generated at the lowest cost?

Is the IP system ensuring that IP is traded so that those that can use it most efficiently can do so?

Is the IP system appropriately balancing the long-term costs and benefits that stem from the system's effects on competition and innovation?

Adaptive:
Does the IP system adapt as the nature of innovation, competition and broader economic conditions change?

Accountable:
Are the policies and changes made to the IP system evidence based, transparent, and do they reflect community values?

An IP system that satisfies these 4 principles is well placed to improve community wellbeing

Assessment of the overall patent system

- Fails to meet the principles of a well-functioning IP system
  - *Many patented inventions do not benefit the community, reducing effectiveness*
  - *The excessive strength of rights and strategic use reduce efficiency*
- As a result, current arrangements frustrate follow-on innovators and raise the costs of innovation

Extensions of term: Why did we recommend policy change?

- EoTs argued to be: necessary compensation for regulatory delay; align with other technologies; and intended to encourage R&D
- However:
  - *No evidence provided that EoT encourage R&D*
  - *Extending exclusivity imposes significant costs on taxpayers and the broader community*

Extensions of term: What did we recommend?

- DR 10.1: target EoTs to genuine cases of regulatory delay
- DR 10.2 tailors to domestic market (allowing manufacture for export)

Extensions of term: Issues for discussion

- How large are the costs associated with extensions of term in Australia and who bears them?
- How freely and commonly are EoTs granted?
- How do the elements of patent filing, Australian clinical testing and TGA requirements contribute to time-to-market?
- Are there superior ways of targeting EoTs towards unnecessary regulatory delay/cost?

'Evergreening': Why did we recommend policy change?

- Follow-on patents building upon an original pharmaceutical can be:
  - *genuine innovations that improve consumer well-being*
  - *But also a 'technical' change as a legitimate response to financial incentives to extend protection*
- Evidence of examples amongst high-value PBS drugs, but hard to diagnose precise extent of strategic behaviour
- Similar to EoT, evergreening raises costs to community – drugs with higher costs give greater incentive to evergreen

'Evergreening': What did we recommend?

- No pharmaceutical specific measures were recommended
- However, changes to the inventive step (DR 6.1) should help the patent system focus on genuine invention
  - *Amend the law to 'having regard to the state of the art, it is not obvious to a person skilled in the art'*
  - *This would better align with the approach in Europe*
  - *No longer award patents for a 'scintilla' of invention, or where applicants were 'led directly as a matter of course'*
  - *Further reform may require international collaboration*

'Evergreening': Issues for discussion

- *Can advances be distinguished from strategy? How?*
- *What is the evidence of the extent and effect of evergreening?*
- *Is the inventive step the only lever to address evergreening? Is it working? What has been the effect of Raising the Bar?*

Pay-for-delay: Why did we recommend policy change?

- A known, and potentially costly, phenomenon overseas
- In Australia, there is scope to enforce under CCA.
- But, cartel-like behaviour is difficult to detect: both parties benefit, so have no incentive to disclose, yet the uninformed consumer loses.

Pay-for-delay: What did we recommend?

- DR 10.4: a 5 year monitoring program, administered by the ACCC

Pay-for-delay: Issues for discussion

- Studies focus on other jurisdictions such as the US. Are there any reasons it would not be occurring in Australia?
- Can existing regulation and data detect this behaviour?
- If not, how to best design processes that are effective but minimise compliance costs?
  - *Can the US FTC's monitoring be transplanted here, in whole or in part?*