The pharmaceutical patent review in Australia

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Freehills Patent Attorneys - overview

- With over 80 staff we are capable of meeting all your patent needs.
- We have over 30 attorneys preparing and prosecuting patents directly in Australia and New Zealand and through our agent network in other countries.
- FPA works seamlessly with Herbert Smith Freehills (an international litigation practice) on patent disputes globally adding our knowledge of patent drafting and interpretation skills to the litigation team.
- Our Attorneys continue to attract international recognition for their excellence.
- We are proud to serve a large range of clients from small spin off companies, to university institutions and large multi-nationals.
**Background**

**Australian Pharmaceutical Market**
- Services 23 million people
- Projected value: $AU19.2 billion by 2015
- Dominated by offshore companies

**Pharmaceutical Patent Review**
- Implemented by Australian Government to look to address perceived imbalances in the patent system to the extent that it is directed to pharmaceuticals.
- A major concern is reducing the cost of pharmaceuticals to the health care system
- Was not directed to “gene patenting”
- Numerous issues raised in the course of the review. This talk will focus on the proposed changes to patent term extensions.

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**Some key terms**

**Therapeutic Goods Administration (TGA)**
- Body which regulates the sale of drugs in Australia
- Equivalent to FDA in US

**Australian Register of Therapeutic Goods (ARTG)**
- In order to sell a drug in Australia it must be registered on the ARTG which is administered by the TGA

**Pharmaceutical Benefits Scheme**
- Scheme by which prescription medicines are subsidised by the Australian Government - $AU 9.2 billion in 2012. The cost to government of the PBS is rapidly increasing.
Pharmaceutical Benefits Scheme

- Entry of a drug onto the PBS is a separate step from gaining regulatory approval and registering drug on the ARTG
- It is not mandatory to have your drug approved for entry onto the PBS. However, in practice, if the sale of a drug is not subsidised by the PBS then it is extremely difficult for it to compete with subsidised drugs for treating the same disease.
- PBS sets prices for drugs subsidised by the scheme (in practice, practically all prescription drugs are subject to the scheme)
  PBS subsidises both innovator and generic versions of a drug
- PBS applies automatic price reduction to price of a drug once a generic competitor enters the market. This price reduction can be up to 35% in a very short period of time

Pharmaceutical Benefits Scheme (cont)

- If a generic competitor applies for entry of their drug onto the PBS and is successful then the price reduction applies even if the competitor is later found to be infringing a valid patent and cannot sell the generic drug
- Innovators have a strong incentive to prevent generic competitors applying to the PBS for registration of a generic drug
- Innovators often seek preliminary injunctions to prevent PBS entry by generic competitors.
Extensions of patent term

- Australia has extensions of patent term for pharmaceutical patents.
- Maximum term of extension is 5 years - which is based on the delay between the filing date of the patent and the registration on the ARTG of the drug – similar to other jurisdictions such as US and Europe.
- Extension only applies to patents which have claims directed to a “pharmaceutical product per se” registered on the ARTG. This is a different regime to other jurisdictions.
- Extension therefore does not apply to patents directed to methods of treatment using a drug or processes for preparing a drug.
- However, certain formulations of a drug may be covered (law here is unclear).

Extensions of patent term (cont)

- In practice, pharma companies often seek regulatory approval in Australia after approval in larger jurisdictions, usually US and Europe as:
  (i) approval expedited in Australia if the drug is approved in a major overseas jurisdiction, and
  (ii) Australian market is not as high a priority as larger jurisdictions. Therefore, extensions of term are often longer in Australia than in other major jurisdictions for an equivalent patent.
- During the patent term, cannot manufacture drug in Australia for export to jurisdictions where the drug is not protected by patent.

- Draft report released April 2013 for public consultation.
- Final Report has been tabled with the Australian Government but not disclosed to the public.
- Draft report contained a number of recommendations directed to the patent system and its interaction with the regulatory framework for pharmaceuticals.
- There is considerable uncertainty as to how the Report and its recommendations will progress in the light of the upcoming election and a potential change of government.

Competing policy considerations

- Government wishes to reduce the cost of the PBS while still providing an incentive for new drugs to be registered in Australia.
- If new drugs are not registered then there will be no generic entry into the market either.
- Eliminating or reducing patent term extensions will significantly reduce cost to the system. However, there is an argument that patent term extensions compensate for reduced patent term due to regulatory delay and encourage research and development.
- Government wish to encourage research and development in Australia.
- Government wish to maintain Australia’s reputation in the world as an “innovative” country with a strong patent system.
- Governments need to comply with international obligations
Competing policy considerations (cont)

• Government wish to support manufacturing of pharmaceuticals in Australia.
• Preventing Australian companies from manufacturing patented drugs in Australia for export to countries in which the drug is not patented means that Australian companies are at a disadvantage relative to companies in jurisdictions where a corresponding patent has expired or has not been filed.
• The fact that patent term extensions in Australia are often longer than patent term extensions for corresponding patents in other jurisdictions means that Australian companies are further disadvantaged.

Patent term extensions - recommendations

Replace patent term extensions with direct R & D subsidies

• Panel recommended replacing extension of term regime with direct subsidies for R & D.
• Shifts policy from compensating companies for diminished patent life for drugs developed anywhere in the world to providing a specific incentive for conducting R & D in Australia.
• Amount to be calculated on basis of savings to the PBS made from eliminating patent term extensions
Patent term extensions - recommendations

Reduce the length of the extended patent term

• Panel recommends reducing the length of patent term extensions so the patent expires at a similar time to equivalent patents in other jurisdictions.
• Option 1: setting the first regulatory approval date to the date of approval in specified jurisdictions, eg US or Europe.
• Option 2: terminating an extension of term in Australia at the date it is terminated for equivalent patents in specified countries.
• The intention is to provide an incentive for pharma companies to register their products in Australia promptly.

Extension of term to be based on relevant registered product

• In some recent cases, patent terms have been calculated on the basis of ARTG registrations that are not directed to the pharmaceutical product per se.
• In one case, the court held that the correct regulatory approval date related to a product that included the patented substance only as an impurity.
• In another case, the court held that a patent term extension for an enantiomer should be based on upon the regulatory approval date of the racemic mixture.
• The panel recommends a clarification of the position so that the extension of term is based on the ARTG registration of the relevant product.
**Further recommendations**

**Limit contributory infringement**
- Panel recommended amending the contributory infringement provisions to make it clear that a pharma manufacturer does not contribute to infringement of a patent where the manufacturer has taken reasonable steps to avoid infringement.
- “Reasonable steps” include **not** including infringing indications on product labels.
- That is, it is contemplated that “carve-outs” on product labels would be permissible.

**Further recommendations**

**Manufacture for export exemption**
- Manufacture for export is presently an infringement even if export is to a jurisdiction which does not have patent protection for the relevant drug.
- Panel considers that this costs the Australian economy without providing any benefit.
- Panel also concluded that providing an exemption would be inconsistent with Australia’s international obligations.
- Panel recommends Australia seeks to alter these obligations.
- In the interim, Panel recommends that the government seek agreement from pharmaceutical companies that they will not enforce their patents against manufacturers who are manufacturing for export.
Website
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Any Questions?

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