

A blurred background image of a business meeting with several people in professional attire. In the foreground on the right, a man in a dark suit and a bright yellow striped tie is partially visible.

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# Interplay between patents and regulation

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# INTERPLAY BETWEEN PATENTS AND REGULATION <sup>2</sup>

## Speakers:

Lawrence T. WELCH

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Francis AHNER

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Conseils en Propriété Industrielle

# INTERPLAY BETWEEN PATENTS AND REGULATION <sup>3</sup>

## Topics for discussion include:

- Data exclusivity
- Patent term extensions
- Skinny labelling
- Scope of patent term extensions; covering drug itself or just approved indications
- Multiple patent term extensions covering different indications
- Patent linkage
- Price drops
- Prohibited Agreements
- Abuse of a dominant position

# AU - INTERPLAY BETWEEN REIMURSEMENT (PBS) AND PATENTS

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## Price disclosure and price drops

- 16% mandatory price drop from date of first generic product to be included in Pharmaceutical Benefit Scheme (PBS)
- Potential price drops every six months based on price disclosure
- Price drop will occur **even if generic product infringes valid claim in originator patent**
- Originator is forced to obtain preliminary injunction to prevent generic launch in order to maintain original price, while validity/infringement of patent is assessed (~2 years)
- The system works unfairly for innovator companies, and diminishes the value of an Australian pharmaceutical patent

## Why the system is unfair to originators

- Patentee does not get notified of application to register generic product until it is registered providing insufficient time to have patent validity/infringement assessed before generic launch
- This forces patentee to seek PI, and give undertaking as to damages, to avoid price drop
- Therapeutic Goods Act describes circumstances under which Government can claim losses resulting from litigation commenced by originator against a generic company
- Until recently, Government has not claimed under TGA provisions or undertaking as to damages

## Why the system is unfair to originators

- However, without prior warning Government indicated it would claim damages from Sanofi and Wyeth under the undertakings as to damages given in support of PI application after a finding of patent invalidity.
- Other originators have now found themselves in the same boat
- Before considering whether or not this is fair, consider what happens if no PI is obtained and generic activity results in substantial price drop
- Is the price restored following a finding that patent was valid and that the generic activity that caused the price drop was infringing activity?
- Although there is discretion to restore the price, this is not done in practice: low price remains for rest of patent term and no compensation from Government for losses sustained during period of infringing activity, even though Government benefited from and continues to benefit from low price

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