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EDITORIAL 77

ARTICLES

Strategically Deterring Generic Entry Ahead of Patent Expiry: A Competition Law Antidote? Assessing Australian Pharmaceutical Antitrust Enforcement after ACCC v Pfizer – Colette Downie

The strategies employed by pharmaceutical patentees to deter generic entry ahead of patent expiry have been closely scrutinised by competition regulators in both the European Union (EU) and the United States (US). The decision in *ACCC v Pfizer*, marks the Australian Competition and Consumer Commission's first, albeit unsuccessful, attempt to test the competition law implications of a pharmaceutical patentee's tactics to minimise profit erosion before loss of exclusivity. This article critiques the *ACCC v Pfizer* decision, and discusses how the market structure of Australia's pharmaceutical and patent regimes provide potential incentives for anticompetitive conduct designed to deter generic entry. Drawing on antitrust enforcement trends in the EU and US, this article examines the likely competition law implications of "product hopping" and patent settlement agreements (PSAs) in Australia. In considering future trends in Australian pharmaceutical antitrust enforcement, this article concludes that whilst Australia's misuse of market power prohibitions may effectively curtail unilateral conduct such as product hopping, there is no clear competition law "antidote" to the anticompetitive concerns raised by PSAs, given the variability of such agreements.

80

Marine Insurance Law Reform in Australia – a Following Sea – Julie-Anne Tarr

The *Marine Insurance Act 1906* (UK) is perhaps one of the outstanding examples in the common-law world of a statute that has had major impact upon international commerce and a wide reach beyond its maritime focus. That said, since its inception more than a century ago international markets and practices have grown and evolved, and as such necessary reform to the Act was effected through the passing of the *Insurance Act 2015* (UK). For Australia and other countries that largely or totally replicated the original UK statute in their domestic laws, significant flow-on effects must now be addressed if, indeed, the determination to remain in step with the UK is prioritised. Prior to reform of the UK Act, the principal brake upon this task was a desire to preserve consistency in a strongly connected and international market with an epicentre and legacy in London. Hence these changes have opened the door to reform without creating unnecessary disharmony or inconsistency in international practice. This article examines the law reforms in the UK, parallel reform considerations and options in Australia, and recommends a way forward.

117

Registered Charities and Governance Standard 5: An Evaluation – Ian Ramsay and Miranda Webster

Most charities must comply with a set of five governance standards to be registered as a charity by the Australian Charities and Not-for-profits Commission (ACNC). The authors focus on governance standard 5, which outlines the duties of the individuals who govern registered charities – the “responsible entities” of the charities (typically directors or management committee members). The authors analyse the multiple obligations that now apply to those individuals deemed by the ACNC Act to be responsible entities. They also examine the remedies that are available for breaching these obligations, including highlighting how the ACNC governance framework has affected members’ remedies, the remedies available to regulators and to the charity itself. The authors argue that governance standard 5 has introduced increased complexity to the obligations of registered charities and to the duties of the individuals who are deemed to be responsible entities. They also argue that the ACNC governance framework has reduced the accountability of the individuals who work for registered charities that are incorporated under the *Corporations Act 2001* (Cth). 127

Australian Charities and Not-for-profits Commission: Enforcement Tools and Regulatory Approach – Marina Nehme

The Australian Charities and Not-for-profits Commission (ACNC) commenced operation on 3 December 2012 after a decade of inquiries and recommendations about the establishment of an independent “one-stop-shop” regulator for the charity sector. The introduction of this regulator is a move that recognises the unique and distinctive role that charities play in Australia. This article reviews the sanctions available to the ACNC. It considers some key aspects of the ACNC’s regulatory approach to date and discusses the benefits arising from this approach. The article then assesses whether the current enforcement regime available to the regulator supports the continued implementation of such a regulatory approach and empowers the ACNC to enforce the provisions in the legislation or whether some changes may be needed. 159

PRIVACY LAW – Normann Witzleb

“Personal information” under the Privacy Act 1988 (Cth) – Privacy Commissioner v Telstra Corporation Ltd [2017] FCAFC 4 188