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## Follow-on innovation relating to block-buster drugs – innovators, timing, and private value

Statement of the Problem: The majority of patents associated with high-cost drugs are "secondary patents" - i.e. patents not for the Active Pharmaceutical Ingredient (API), but for follow-on innovation regarding the API, such as means for formulating the API, mechanisms for delivering the API, and methods of medical treatment using the API. Concern has been expressed about the potential for secondary patents to increase the cost of drugs, by extending ("evergreening") the API originator's monopoly over the drug. The purpose of this study is to determine whether these concerns are valid.

Methodology & Theoretical Orientation: For a sample of the 13 most costly drugs in Australia over a decade, we identify all the secondary patents granted in Australia for that drug (of which there are 636). We analyze those patents to determine by whom and when they were sought, for what type of innovation they were granted, and for how long they lasted.

Findings: Nearly three-quarters of all the secondary patents are owned by an entity other than the originator of the API of the drug. The patents were sought throughout the life of the original patent on the drug's API. Patents for delivery mechanisms or formulations of the API have a greater private value than patents for other types of innovations relating to the API.

Conclusion & Significance: The vast majority of follow-on innovation over blockbuster drugs is undertaken by competitors of the drug's originator, and occurs well before (in addition to well after) the expiry of the API patent. This is of significance to policy-makers, as it suggests that any concern that the grant of the API patent over a blockbuster drug will preclude follow-on innovation by competitors is not well founded.



## **Biography**

Andrew F Christie was appointed as the inaugural Chair of Intellectual Property at Melbourne Law School, University of Melbourne, in 2002. A former Fulbright Senior Scholar, he has held appointments at the University of Cambridge, Duke University, the National University of Singapore, and the University of Toronto. He is admitted to legal practice in Australia and England, and worked for many years in the intellectual property departments of law firms in Melbourne and London. He is an active Adviser to the Australian Government and to the World Intellectual Property Organization on Intellectual Property Law and Policy. He has been identified by the international magazine Managing IP as one of the world's 50 most influential people in intellectual property.

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