EVIDENCE OF 'EVERGREENING' IN SECONDARY PATENTING OF BLOCKBUSTER DRUGS

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Secondary patents associated with blockbuster drugs are granted for follow-on innovations relating to the active pharmaceutical ingredient ('API') of the drug. Our analysis of all secondary patents for 13 top-selling drugs in Australia shows that, while the majority of follow-on innovations are made by entities other than the originator of the drug, the innovations with the highest private value are undertaken by the drug's originator and concern a delivery mechanism or an alternative formulation for the API. Since that is the type of follow-on innovation most commonly undertaken by drug originators, and considered most likely to result in a de facto extension of marketplace monopoly over the drug, we see in these findings evidence that the originators of blockbuster drugs engage in secondary patenting that has an 'evergreening' effect.

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I Introduction

The high and rapidly rising cost of pharmaceuticals is a phenomenon of concern in many countries.[1] In the search for cost drivers, the marketplace monopoly conferred by patents, particularly on high-cost, high-selling ('blockbuster') drugs, has been a popular target.[2] While there is substantial literature on pharmaceutical patenting strategies generally,[3] comparatively few studies have empirically analysed the actual patents granted in relation to specific drugs; of those that do, none of which we are aware have compared the characteristics of the patents granted to the inventors of blockbuster drugs with those granted to their competitors and third parties in relation to those drugs.[4]

[1] See, eg, National Academies of Sciences, Engineering, and Medicine, *Making Medicines Affordable: A National Imperative* (National Academies Press, 2018) 1.

[2] Recent studies looking at the effect of patents on drug prices include Hannah Brennan et al, 'A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health' (2017) 18(1) *Yale Journal of Law and Technology* 275, see especially at 284–6; Gerard T Vondeling et al, 'The Impact of Patent Expiry on Drug Prices: A Systematic Literature Review' (2018) 16(5) *Applied Health Economics and Health Policy* 653.

[3] See, eg, the literature discussed in Gideon O Ndubuisi, 'Strategic Patenting in the Pharmaceutical Industry' (Research Paper, Philipps-Universität Marburg, 15 February 2015) 1–3.

[4] Many of the empirical analyses of secondary patents are in relation to a single drug or a small number of related drugs: see, eg, Christian Sternitzke, 'An Exploratory Analysis of Patent Fencing in Pharmaceuticals: The Case of PDE5 Inhibitors' (2013) 42(2) *Research Policy* 542; Mike Lloyd, 'Evergreening by Whom? A Review of Secondary Patents for Omeprazole' (2013) 2(6) *Pharmaceutical Patent Analyst* 737; Tahir Amin and Aaron S Kesselheim, 'Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs Could Be Extended for Decades' (2012) 31(10) *Health Affairs* 2286. A smaller number of studies have considered a range of drugs: see, eg, María José Abud, Bronwyn Hall and Christian Helmers, 'An Empirical Analysis of Primary and Secondary Pharmaceutical Patents in Chile' (2015) 10(4) *PloS ONE* e0124257:1–17; Amy Kapczynski, Chan Park and Bhaven Sampat, 'Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents' (2012) 7(12) *PloS ONE* e49470:1–9; Robin Feldman, 'May Your Drug Price Be Evergreen' (2018) 5(3) *Journal of Law and the Biosciences* 590. However, none of these studies analyse the secondary patents granted to persons other than the originator of the blockbuster drug.

In an earlier study we sought to improve the baseline understanding of patenting behaviour by identifying and analysing all of the patents associated with the 15 drugs responsible for the largest cumulative expenditures in Australia over the last 20 years.[5] We found that there was a mean of 49 (median of 45) patents associated with each drug. Surprisingly, three-quarters of these patents were owned by an entity other than the originator of the drug. Almost all of the patents we identified were 'secondary patents'; that is, they related to the high-cost drug in the study sample, but did not claim the active pharmaceutical ingredient ('API') of the drug in their own right. Examples of the inventions covered by such secondary patents are means for formulating the API, mechanisms for delivering the API, and methods of medical treatment using the API (whether for the same or a different condition for which the API first received regulatory approval). Patents on such inventions are 'secondary' in the sense that they are granted subsequent to the grant of the primary patent over the drug's API,[6] and are for 'follow-on innovation' in the sense that they are for variations or applications of the API.

Understanding the nature of secondary patents has direct relevance to policy concerns over drug prices. Many commentators worry that producers of blockbuster drugs use secondary patents to obtain a de facto monopoly over the drug in the marketplace after the de jure monopoly conferred by the original patent over the API expires, thereby enabling them to keep prices high — one of the practices colloquially referred to as 'evergreening' of exclusivity.[7] In particular, there is concern that, towards the end of the life of the patent over the API, the drug originator introduces a new version of the drug (eg a slow-release formulation) which incorporates an innovation protected by a secondary patent, and encourages doctors to switch to prescribing the new version as being an improvement. By the time the API patent expires, the new version will have become the standard. Although competitors

[5] Andrew F Christie et al, 'Patents Associated with High-Cost Drugs in Australia' (2013) 8(4) *PloS ONE* e60812:1–7.

[6] We note that one article refers to patents for delivery mechanisms as 'tertiary patents': Reed F Beall and Aaron S Kesselheim, 'Tertiary Patenting on Drug–Device Combination Products in the United States' (2018) 36(2) *Nature Biotechnology* 142. However, we adopt the more common practice of calling such patents 'secondary'.

[7] The term 'evergreening' refers to a wide range of activities, of which the use of secondary patents is but one: National Academies of Sciences, Engineering, and Medicine (n 1) 37–8. See also Kristina ML Acri, Mark Schultz and David Lund, 'Evergreening of Pharmaceutical Exclusivity: Sorting Fact from Misunderstanding and Fiction' (Research Paper, 29 April 2018) pt I(B). For a discussion of some of the other activities which have been termed 'evergreening', see Gaurav Dwivedi, Sharanabasava Hallihosur and Latha Rangan, 'Evergreening: A Deceptive Device in Patent Rights' (2010) 32(4) *Technology in Society* 324, 325–8.

are free to make the API, the secondary patent precludes them from making the API with the improvement — with the result that the drug originator maintains exclusivity in the marketplace for supplying the drug.[8]

A recent report on drug costs from the National Academies of Sciences, Engineering, and Medicine in the United States ('US') determined that such evergreening of exclusivity through secondary patents adversely affects consumers, and recommended that the US Patent and Trademark Office 'identify specific means to reduce "evergreening" of drug exclusivity' via secondary patents.[9] The Australian government's independent economic research and advisory body, the Productivity Commission, has taken a similar view.[10]

A surprising finding from our previous study was that, of the large number of secondary patents granted for blockbuster drugs, the majority of them were granted to entities other than the originator of the drug.[11] That type of patenting activity does not fit the classic notion of evergreening through secondary patenting.[12] In this study, we delve more deeply into those secondary patents. Specifically, we examine by whom and when the applications for them were filed, and for how long these secondary patents were maintained. Unlike prior studies, we consider secondary patents granted to *any* person, not just to the originator of the API with which they are associated.[13] Knowing who owns secondary patents associated with high-cost drugs is important because the identity of the patent owner determines the potential for the secondary patents to have an evergreening effect. We are able to compare

[8] See, eg, Hazel VJ Moir, 'Exploring Evergreening: Insights from Two Medicines' (2016) 49(4) *Australian Economic Review* 413, 414.

[9] National Academies of Sciences, Engineering, and Medicine (n 1) 71 (finding 2-6), 127 (recommendation A-3).

[10] Productivity Commission, *Intellectual Property Arrangements* (Inquiry Report No 78, 23 September 2016) 322–4.

[11] Christie et al (n 5) 3.

[12] See, eg, National Academies of Sciences, Engineering, and Medicine (n 1) 38; Dwivedi, Hallihosur and Rangan (n 7) 325.

[13] Other studies considering secondary patents almost always concern United States ('US') patents identified using the US Food and Drug Administration, *Approved Drug Products with Therapeutic Equivalence Evaluations* (US Department of Health and Human Services, 40th ed, 2020) <https://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm>, archived at <https://perma.cc/9XSV-4G2D> ('*Orange Book*'). Patents listed in the *Orange Book* are those owned by the originator of the Active Pharmaceutical Ingredient ('API') to which they relate. In the rare case where the study concerned non-US patents, the initial source for identifying the secondary patents was still the *Orange Book*, and the patents identified were thus limited to those owned by the API originator: Abud, Hall and Helmers (n 4) 2.

characteristics of secondary patents that raise the spectre of evergreening because they are obtained by the originator of the API, with characteristics of secondary patents which cannot have this effect (under the conventional conception of evergreening) because they are obtained by others.

II Method

A *Identification of Drugs and Associated Secondary Patents*

We used the *Australian Statistics on Medicines* series[14] to identify a sample of the costliest drugs in Australia. Specifically, from among all drugs sold in Australia, we identified the 20 that accounted for the highest cumulative expenditures during the period 1990–2000. We chose high-cost drugs from an earlier period because patents for such drugs typically last for 20 years[15] (or even more),[16] and we wished to observe patenting behaviours that occurred well after the expiry of the original patent on those drugs. Using publicly accessible databases, including the Merck Index,[17] PATSTAT,[18] INPADOC,[19] and AusPat,[20] we identified for all but two of those drugs the patent on the

[14] Department of Health, Housing and Community Services, *Australian Statistics on Medicines* (Australian Government Publishing Service, 1992–8).

[15] Prior to the enactment of the *Patents (World Trade Organization Amendments) Act 1994* (Cth) ('*WTO Amendments Act*'), the maximum duration of Australian patents was 16 years. The maximum duration was increased to 20 years by virtue of those amendments: at s 4. This maximum duration applied to all standard patents granted on or after 1 July 1995, and to all standard patents granted prior to that date for a 16-year term that had not expired as of that date: at s 7.

[16] Patentees of certain pharmaceutical patents are entitled to apply for an extension of patent term (of up to five years) if specific conditions are satisfied. In general terms, those conditions are that the patent is for a 'pharmaceutical [substance] per se', and that the first regulatory approval for that pharmaceutical substance occurred more than five years after the patent commenced: *Patents Act 1990* (Cth) s 70 ('*Patents Act*').

[17] 'Merck Index Online', *Royal Society of Chemistry* (Database, 2020) <https://www.rsc.org/merck-index>, archived at <https://perma.cc/ELU9-KL9J> ('*Merck Index*').

[18] 'PATSTAT', *European Patent Office* (Database, 2 November 2020) <https://www.epo.org/searching-for-patents/business/patstat.html>, archived at <https://perma.cc/XRP6-LSZ3>.

[19] 'INPADOC Extended Patent Family', *European Patent Office* (Web Page, 3 August 2017) <https://www.epo.org/searching-for-patents/helpful-resources/first-time-here/patent-families/inpadoc.html>, archived at <https://perma.cc/2Q5R-9H4R> ('*INPADOC*').

[20] 'AusPat', *IP Australia* (Database) <http://www.ipaustralia.gov.au/auspat/index.htm>.

drug's API ('API patent') that was granted in Australia.[21] Of the remaining 18 drugs, we excluded five, the granted API patent of which had not expired by 31 December 2005 because there was insufficient time to observe post-expiration secondary patenting activity for those drugs. This left 13 drugs in our sample.

Our method for identifying the API patent for each drug, as well as all granted secondary patents associated with the drug, is described in detail in our earlier study.[22] Here, we recap the procedures for identifying and classifying the secondary patents. To determine which patents among the large number that named the APIs of interest were secondary patents, we obtained and examined the text of all published Australian patent specifications from public sources. Our examination focused on claim one in the patent specification. Claim one typically represents the broadest claim in a patent, and encompasses the fundamental concept of the invention. Thus, if claim one of a patent is not associated with a drug in our sample then it is almost certain that no other claim of that patent will be. We defined a patent as 'associated' with a sampled drug if claim one had an integer (ie an element of the claimed subject matter) that covered, or 'read onto', the API of the drug. Determining the subject matter that an integer of a claim covers is an objective assessment routinely undertaken by patent lawyers and patent attorneys (and our research team had one of each).

Table 1 lists the 13 drugs in our sample by their International Nonproprietary Name ('INN') and Anatomical Therapeutic Chemical ('ATC') classification.[23] The table also shows the total cumulative expenditure on each drug in Australia between 1991–2008, the owner of the drug's API patent, and the number of secondary patents granted on that drug in Australia up to August 2010. To facilitate subsequent analyses, we grouped the 13 drugs into categories based on their total cumulative expenditure. Four categories were determined, using the 'Jenks optimization' method to identify natural break points in the expenditure totals, and are shown in Table 1.[24]

[21] There were two drugs for which no API patent was granted in Australia: glyceryl trinitrate and beclomethasone.

[22] Christie et al (n 5) 2–3.

[23] The Anatomical Therapeutic Chemical for each drug was obtained from WHO Collaborating Centre for Drug Statistics Methodology, *ATC/DDD Index 2020* (Database, 16 December 2019) <http://www.whocc.no/atc_ddd_index/>, archived at <https://perma.cc/6EZG-FHDF>.

[24] For an explanation of the 'Jenks optimization' method, see generally George F Jenks and Fred C Caspall, 'Error on Choroplethic Maps: Definition, Measurement, Reduction' (1971) 61(2) *ANNALS of the Association of American Geographers* 217.

Table 1: Study Sample of High-Cost Drugs with a Patent Covering the API

Drug (INN)	ATC — Level 2	Cumulative expenditure 1991–2008 ($m)	Cost rank	API patent owner	Number of secondary patents
Simvastatin	Lipid modifying agents	4,350	1	Merck	70
Omeprazole	Drugs for acid-related disorders	2,917	1	AstraZeneca	119
Salbutamol	Drugs for obstructive airway diseases	1,289	2	GSK	42
Ranitidine	Drugs for acid-related disorders	1,239	2	GSK	52
Enalapril	Agents acting on the renin-angiotensin system	1,115	2	Merck	46
Sertraline	Psychoanaleptics	1,090	2	Pfizer	37
Ipratropium	Drugs for obstructive airway diseases	839	3	Boehringer	21

Drug (INN)	ATC — Level 2	Cumulative expenditure 1991–2008 ($m)	Cost rank	API patent owner	Number of secondary patents
Felodipine	Calcium channel blockers	726	3	AstraZeneca	25
Budesonide	Drugs for obstructive airway diseases	647	3	AstraZeneca	58
Captopril	Agents acting on the renin-angiotensin system	614	3	Bristol-Myers Squibb	49
Fluoxetine	Psychoanaleptics	583	3	Eli Lilly	32
Famotidine	Drugs for acid-related disorders	379	4	Merck	21
Cimetidine	Drugs for acid-related disorders	190	4	GSK	41

B *Classification of Secondary Patents*

The secondary patents for each drug in the sample were classified along two dimensions: the type of invention they protected and the nature of the company that owned them.

Determinations of the type of invention were based on the text of claim one of the secondary patent. As previously described, our final taxonomy consisted of six mutually exclusive categories:[25]

1 an intermediate or a different form of the API (eg an isomer, or a salt or crystalline form, of the drug's chemical compound);

2 a combination of the API, or an intermediate or a different form of it, with another drug (eg the drug's chemical compound combined with the chemical compound of another drug);

3 a delivery mechanism or a formulation for the API, or an intermediate or a different form of it (eg a transdermal patch containing, or a slow-release formulation of, the drug's chemical compound);

4 a process for making or formulating the API, or an intermediate or a different form of it (eg a method of preparing or purifying the drug's chemical compound);

5 a method of treatment using the API, or an intermediate or a different form of it, for an indication in an ATC class the same as the ATC class of the indication for which the relevant sample drug was listed for government subsidy (eg a method of treating asthma using a drug that was subsidised for treatment of obstructive airway disease); and

6 a method of treatment using the API, or an intermediate or a different form of it, for an indication in an ATC class different from the ATC class of the indication for which the relevant sample drug was listed for government subsidy (eg a method of treating obesity using a drug that was subsidised for treatment of depression).[26]

[25] Christie et al (n 5) 3. Those patents which were coded as 'other' in our earlier study — that is, which did not fall into any of these six categories (eg use of the API for a veterinary purpose) — were excluded from this study.

[26] Such an invention is commonly referred to as a second (or subsequent) medical use invention, and the patent for such an invention is correspondingly called a second (or subsequent) medical use patent. Such patents are within our definition of secondary patents because they are granted subsequent to the API patent and relate to the API, but do not claim per se the API.

Classifying the owners of the secondary patents involved a two-step process. First, we extracted the names of the owners from the databases used to identify the patents. We then checked for linkages between named patentees due, for example, to changes of company name, mergers and acquisitions, and holding company and subsidiary arrangements. Information to enable these checks came from the Mint Global and Mergent databases.[27] When different patentee names were identified as part of the same or a closely-linked entity, we collapsed them together under a common patentee name for classification purposes.

Second, after the disambiguation work was complete, we classified the resultant list of patent owners into three categories: API originator, other originators and non-originators. The API originator was the owner of the original API patent associated with the drug. Owners who held a patent on the API of *another* high-cost drug were classified as other originators. For the purposes of this classification, we defined 'another high-cost drug' as any of the 50 drugs associated with the largest cumulative expenditures in Australia over the period 1990–2000. All other owners of secondary patents in the sample were 'non-originators'. The goal of separating patentees in this way was to allow us to explore differences between follow-on innovators who also engage in the identification of new drugs (the API originator and other originators) and those who focus on other activities, such as upstream research, the manufacture of generic drugs, and the development of delivery mechanisms for existing drugs (non-originators).

C *Relative Timing of Secondary Patent Applications*

Using the AusPat database, we determined the filing dates of the applications for all granted patents in the sample: those on APIs and all secondary patents. We then classified the applications into eras, defined by the decade in which they were filed. Next, we determined two key dates in the life cycle of the sample drugs: (i) the date on which the API patent for the drug expired; and (ii) the date of registration of the drug with the Australian medicines safety and efficacy regulator, the Therapeutic Goods Administration ('TGA') or its

[27] 'Mint Global', *Bureau van Dijk* (Database) <https://www.bvdinfo.com/en-gb/our-products/data/international/mint-global>, archived at <https://perma.cc/9QP8-P7PG>; 'Mergent Online', *Mergent Online by FTSE Russell* (Database) <https://www.mergentonline.com/login.php>, archived at <https://perma.cc/4JFC-CUEY>.

predecessor.[28] The former date is the first point in time at which any person other than the API patentee or its licensee can (without risk of being sued for patent infringement) make the drug for commercial purposes, while the latter date is the first point in time at which any person, including the API patentee or its licensee, can sell the drug for therapeutic purposes. Dates for registrations with the medicines regulator made in 1991 or later were obtained from the TGA website;[29] earlier ones were obtained from the Supplements to the *Victoria Government Gazette*.

D *Analysis*

Our analysis focused on empirically describing the timing and the duration of the secondary patents. We had two main goals: to compare the secondary patenting activity of the three types of innovators (the API originator, other originators and non-originators), and to identify the characteristics of the longest-held secondary patents.

The fact that a patent is granted indicates that, according to the examining patent office, something new and inventive has been identified[30] — or, put another way, that an act of innovation has occurred.[31] To determine how much follow-on innovation was occurring, we calculated annual counts and rolling five-year period[32] counts of granted secondary patents, both by the year of their application and by their type of owner.

[28] It was only in 1989, under the *Therapeutic Goods Act 1989* (Cth), that the registration of drugs in Australia was centralised in a federal agency. Prior to this time, registrations occurred at the state level. For an account of the evolution of the national therapeutic goods framework, see John McEwen, *A History of Therapeutic Goods Regulation in Australia* (Report, September 2007) 51–62.

[29] 'Therapeutic Goods Administration', Department of Health (Cth) (Web Page, 2020) <http://www.tga.gov.au>, archived at <https://perma.cc/RU2B-RHRK>.

[30] This is because it is a requirement of all patent legislation that a patent only be granted for an invention which is both novel and non-obvious (ie involving an inventive step): see, eg, *Patents Act* (n 16) s 18(1)(b).

[31] See, eg, Zoltan J Acs and David B Audretsch, 'Patents as a Measure of Innovative Activity' (1989) 42(2) *Kyklos* 171, 177: 'The empirical evidence suggests that patents provide a fairly reliable measure of innovative activity.'

[32] The rolling five-year period counts are the sums of secondary patents the applications for which were filed within five consecutive years of each other. The first five-year period commenced in the year in which the first secondary patent application was filed. Each subsequent five-year period commenced in the year following the first year of the preceding period. The final five-year period commenced in the year that was five years before the last secondary patent application was filed.

The date of the filing of a patent application that proceeds to grant may be used as a lag indicator of the time when the innovation that led to the patented invention was undertaken.[33] It is a lag indicator because, self-evidently, the patent application can only be filed after the invention has been made — and, therefore, after the undertaking of the innovation that led to the invention. To place the timing of the follow-on innovation in a meaningful timeline, we examined the timing of the secondary patents' application dates in relation to two key life cycle dates of the drug with which they were associated: the expiration date of the patent on the API of the drug, and the date that the drug was approved for marketing.

The duration of a patent may be interpreted as an indicator of its private value — that is, of the commercial value of the patent to its owner — which is distinct from its public value.[34] Patent duration is related to private value because it is assumed that a rational patentee will only renew a patent if the expected private value of holding it over an additional year exceeds the cost of its renewal for that additional year.[35] Consequently, the longer a patent is maintained, the greater is its assumed private value.

To establish which secondary patents had greater private value, we determined for how long each secondary patent was held. Our analysis of patent duration was complicated by right-censoring.[36] Our sample included secondary patents granted up to August 2010, and these patents may be retained for up to 20 years (or, with extensions of term, for up to 25 years), rendering a simple comparison of means or medians potentially misleading. To address this problem, we used a time-to-event (or survival) analysis to measure and compare durations, and plotted them with a Kaplan-Meier curve.[37] This

[33] See Zvi Griliches, Ariel Pakes and Bronwyn H Hall, 'The Value of Patents as Indicators of Inventive Activity' in Partha Dasgupta and Paul Stoneman (eds), *Economic Policy and Technological Performance* (Cambridge University Press, 1987) 97, 104, 115.

[34] In simple terms, the public value of the innovation is determined by the degree of contribution, or improvement, made by the innovation to society; the greater is the contribution, the higher is the public value.

[35] For discussion of these underlying assumptions, see Ariel Pakes, 'Patents as Options: Some Estimates of the Value of Holding European Patent Stocks' (1986) 54(4) *Econometrica* 755, 755–6; Jean O Lanjouw, Ariel Pakes and Jonathan Putnam, 'How to Count Patents and Value Intellectual Property: The Uses of Patent Renewal and Application Data' (1998) 46(4) *Journal of Industrial Economics* 405, 406–9.

[36] For an explanation of right-censoring, see David G Kleinbaum and Mitchel Klein, *Survival Analysis: A Self-Learning Text* (Springer, 3rd ed, 2012) 5–7.

[37] For an explanation of the Kaplan-Meier method, see EL Kaplan and Paul Meier, 'Nonparametric Estimation from Incomplete Observations' (1958) 53(282) *Journal of the American Statistical Association* 457; Kleinbaum and Klein (n 36) 58–60.

analysis considered the duration of each secondary patent as being the interval between the commencement of exclusive rights and the termination of exclusive rights or the end of the observation period, whichever came first. We coded exclusive rights as commencing in the year in which the application for the patent was filed and terminating in either the year in which the patent ceased due to non-renewal or the year in which the patent reached its maximum duration and expired.

Finally, to investigate which characteristics of the secondary patents, or of the drugs to which they related, were significantly associated with differences in the duration of secondary patents, we fitted a Cox proportional hazard model.[38] This type of model — sometimes referred to as a survival model — estimates the likelihood of a patent ceasing in any particular year given that it was active in the prior year.[39] The outcome variable was the patent's duration, as defined above. The covariates were: the type of invention protected by the patent, per the six categories described above in Part II(B); the type of owner, per the three categories described above in Part II(B); the ATC class of the drug to which the patent related; the decade in which the patent application was filed (1981–90, 1991–2000 or 2001–10); and the total cumulative expenditure associated with the drug, grouped by the four ranked categories described above in Part II(A).

III Results

A *Numbers and Owners of Secondary Patents*

A total of 613 secondary patents were associated with the 13 high-cost drugs in our sample.[40] Approximately one-quarter (27%) of these secondary patents

[38] For an explanation of the Cox regression method, see DR Cox, 'Regression Models and Life-Tables' (1972) 34(2) *Journal of the Royal Statistical Society: Series B (Methodological)* 187, 189–90.

[39] The likelihood of a patent ceasing is measured by its hazard ratio. Hazard ratios greater than one indicate a shorter duration (or a higher probability of expiration) relative to the referent category, and the larger the hazard ratio, the shorter the duration in relative terms. Hazard ratios less than one indicate a longer duration (or a lower probability of expiration) relative to the referent category, and the smaller the hazard ratio, the longer the duration in relative terms. For further details on survival modelling, see generally Kleinbaum and Klein (n 36). For an example of the method being applied to the duration of patents, see Roger Svensson, 'Commercialization, Renewal, and Quality of Patents' (2012) 21(2) *Economics of Innovation and New Technology* 175, 183–4.

[40] This number of patents differs from the number of patents analysed in our earlier study for a number of reasons. First, our sample of drugs did not include the two drugs from our earlier study for which no API patent was granted in Australia, and hence for which there are no

were owned by the API originator, one-quarter (25%) were owned by other originators, and nearly half (48%) were owned by non-originators. The mean (and median) number of secondary patents per drug owned by the three categories of owner were — API originator: 12.9 (9.0); other originators: 11.5 (8.5); and non-originators: 22.7 (19.0).

B *Timing of Applications for Secondary Patents*

The histograms in Figure 1 below show the timing of secondary patent applications in relation to the date on which the API patent expired (t=0 in all panels, and indicated by the dashed vertical line). Considering all secondary patent applications (Panel A), applications were filed in the range from 20 years before to 23 years after expiration of the API patent, with a slight majority (54%) of them filed before expiration. The most intense period of filing — as determined by the rolling five-year period with the largest number of filings — occurred in the period from three years before to two years after expiration of the API patent, with filings in this period accounting for slightly more than one-quarter (27%) of all filings.

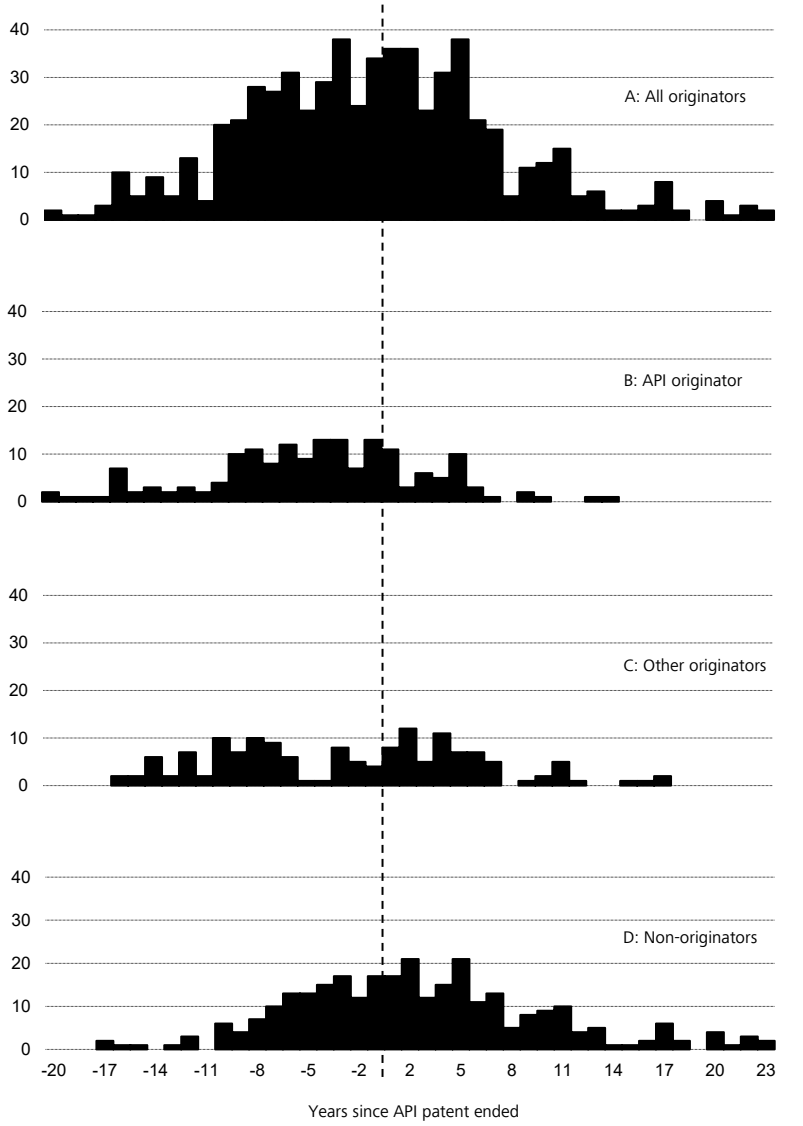
API originators (Panel B) filed secondary patent applications noticeably earlier than the other types of applicants. Their applications were filed in the range from 20 years before to 14 years after expiration of the API patent they owned, with a large majority (74%) being filed prior to expiration. The most intense five-year period of filing began four years before and ended a year after expiration of the API patent; in this period, one-third (34%) of all filings by API originators occurred.

Secondary patent applications filed by other originators (Panel C) were more evenly distributed around the date of expiration of the associated API patent. They were filed from 16 years before to 17 years after expiration of the API patent, with a slight majority (55%) of them being filed before expiration. The most intense five-year period of filing began in the year immediately after expiration of the API patent; 29% of all filings occurred in this period.

secondary patents according to our definition — meaning we excluded the patents for those drugs. Second, we excluded the patents that were for the API of the drugs in our sample, since those patents are, by definition, not secondary patents. Third, we excluded patents that had been revoked, since such patents were never valid. Fourth, we excluded patents that were either petty patents or innovation patents, since those patents have a much shorter maximum possible duration (six years and eight years, respectively) than does a standard patent (16 or 20 years, depending on the legislative provisions in force at the relevant time). Finally, we excluded 20 patents that were for a type of invention other than one of the six categories described above in Part II(B) (eg use of the API for a veterinary purpose).

The timing of secondary patent applications by non-originators (Panel D) was similar to that by other originators. Non-originators' applications were filed in the range from 17 years before to 23 years after expiration of the API patent, with a majority (59%) of them being filed after expiration. The most intense five-year period of filing was the same as for other originators — it began in the year immediately after expiration of the API patent, and encompassed 29% of all filings.

Figure 1: Timing of Secondary Patent Applications in Relation to Expiration Date of API Patent, by Type of Secondary Patent Owner



The histograms in Figure 2 below show the timing of secondary patent applications in relation to the date on which the API was registered as approved for marketing by the TGA (t=0 in all panels, and is indicated by the

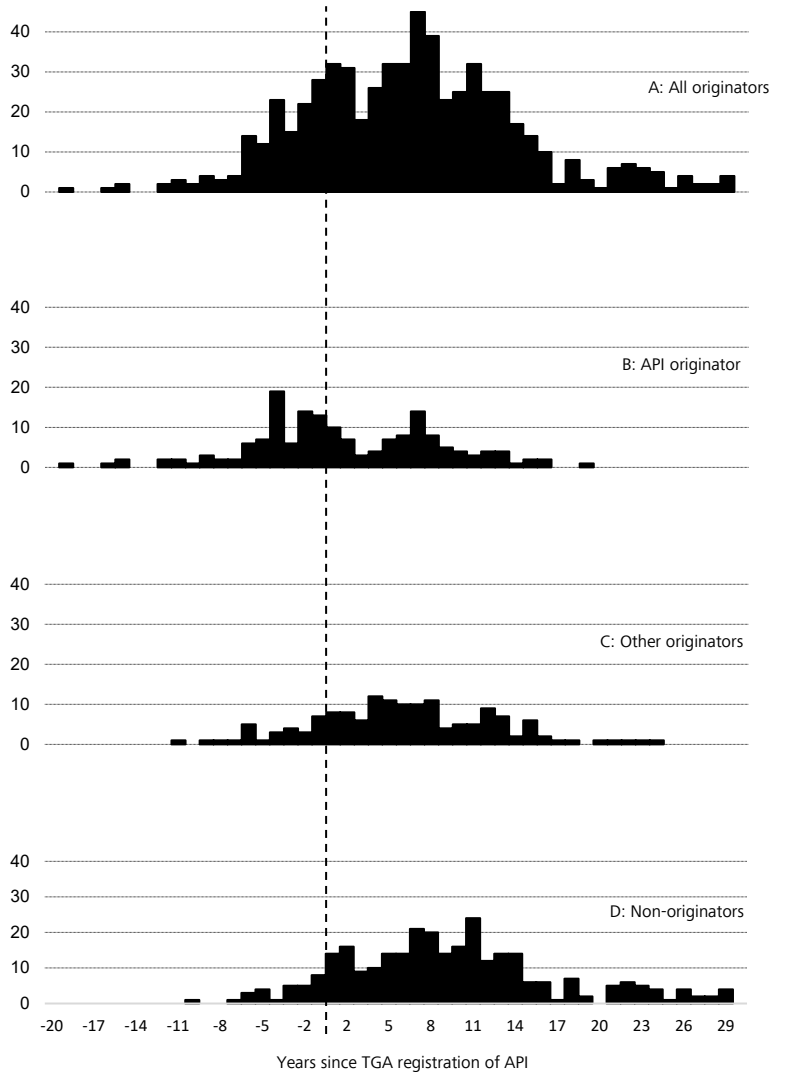
dashed vertical line). Considering all secondary patents (Panel A), applications were filed in the range from 19 years before to 29 years after TGA registration of the API, with a large majority (78%) filed after registration. The most intense period of filing — again, determined by the rolling five-year period with the largest number of filings — occurred in the period from four to eight years after TGA registration, with filings in this period accounting for more than one-quarter (28%) of all filings.

The API originator (Panel B) filed secondary patent applications in the range from 19 years before to 19 years after TGA registration of the API. Although a slight majority (52%) of all applications were filed after registration, the most intense five-year period of filing began four years before registration and accounted for more than one-third (37%) of all filings.

The timing of secondary patent applications filed by other originators (Panel C) was substantially more right-skewed than that of the API originator. Applications were filed in the range from 11 years before to 24 years after TGA registration of the API, with the substantial majority (82%) filed after registration. The most intense five-year period of filing began four years after registration, with 36% of all filings occurring in this period.

The timing of the secondary patent applications filed by non-originators (Panel D) was even more right-skewed. Applications were filed in the range from 10 years before to 29 years after TGA registration of the API, with the vast majority (91%) of the applications filed after registration. The most intense five-year period of filing began seven years after registration, accounting for 32% of all filings.

Figure 2: Timing of Secondary Patent Applications in Relation to Date of the TGA's Grant of Approval to Market API Drug, by Type of Secondary Patent Owner



C *Duration of Secondary Patents*

Our time-to-event analysis estimated that the secondary patents were maintained for a median of 13 years (with a 95% confidence interval of 12–14 years). This was less than the median duration (20 years) of the original API patents for the drugs in our sample; indeed, every one of these patents was maintained for its maximum standard term — either 16 years or 20 years, depending on the legislative provision governing it — and four of them were extended beyond the maximum term.[41]

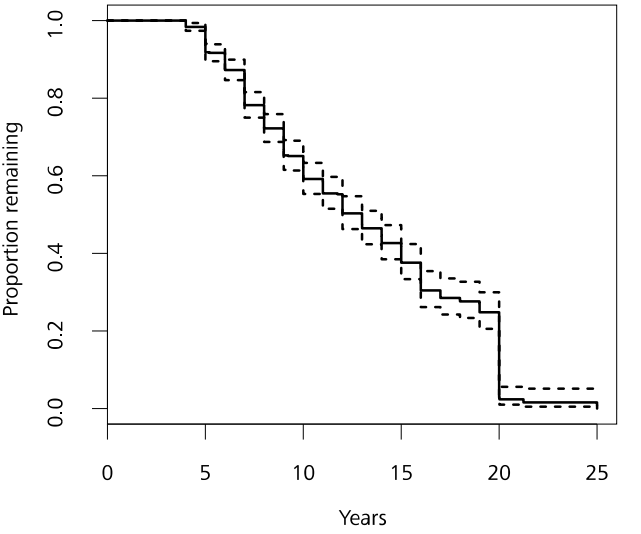
Figure 3 below presents a Kaplan-Meier plot of the estimated durations of all secondary patents in our sample (with 95% confidence intervals shown by dashed lines). The plot shows a steady rate of expirations over the observation period. The exceptions occur at the beginning and at the end of the patents' lives. The horizontal line in the upper left corner indicates that all patents had a minimum duration of either three or five years, depending on the year of application.[42] The vertical line near the lower right corner shows that all of the secondary patents that lasted for 20 years (the statutory maximum duration) then expired — except for five, which were granted extensions of term (as indicated by the horizontal line in the bottom right corner).[43]

[41] Of the 13 API patents in our sample, two (salbutamol and cimetidine) had a maximum standard term of 16 years; the others had a maximum standard term of 20 years. The four patents to receive an extension of term were enalapril (of 1.4 years), famotidine (3.4 years), simvastatin (4.5 years) and sertraline (5.0 years).

[42] This minimum period of protection is a result of the fact that, upon grant, a patent has an initial duration before a renewal is required. Depending on the legislative provision in effect at the relevant time, this initial duration was either three or five years from the commencement of protection.

[43] Of the six types of secondary patents classified by us, only two come within the concept of being for a 'pharmaceutical substance per se' and hence would be entitled to an extension of term (subject to the other conditions for an extension of term being satisfied): (i) an intermediate or different form of the API; and (ii) a combination of the API, or an intermediate or different form of it, with another drug. This means that no extension of patent term is possible for secondary patents that relate to an invention that is either a delivery mechanism for an API, the process of making or formulating an API, or a method of treatment using an API (whether the same or different ATC).

Figure 3: Plot of Kaplan-Meier Survival Probabilities for All Secondary Patents[*]



[*] *Dashed lines indicate 95% confidence intervals*

Table 2 below shows the results of the multivariate Cox regression model, which analyses characteristics associated with the duration of the secondary patents. Several characteristics of the secondary patents, or of the original API patent to which they related, were associated with significantly shorter or longer durations.

Compared with secondary patents owned by the API originator, secondary patents owned by other originators (hazard ratio ('HR') = 1.41) and by non-originators (HR = 1.55) had an approximately 50% higher risk of expiration at any given point during their allowable term. Secondary patents for drugs in the psychoanaleptic class were also at higher risk of expiration (HR = 1.80) compared with secondary patents for other types of drug. However, secondary patents relating to delivery mechanisms and formulations of the API were at lower risk of early expiration (HR = 0.70) than secondary patents for other types of inventions associated with the API.

Neither the total cumulative expenditure on the drug nor the decade in which the drug was first patented was an independent risk factor for expiration.

Table 2: Multivariate Predictors of Duration of Secondary Patents

	HR	*p*-value
Type of secondary patent		
Intermediate or different form (*reference value*)	1.00	
Combination	0.86	0.38
Delivery mechanism or formulation	0.70*	0.04
Process for making or formulating	1.00	0.99
Treatment method — same ATC	1.14	0.53
Treatment method — different ATC	1.09	0.67
Owner of secondary patent		
API originator (*reference value*)	1.00	
Other originator	1.41*	0.02
Non-originator	1.55**	<0.01
Period in which API patent commenced		
1971–80 (*reference value*)	1.00	
1981–90	0.97	0.94
1991–2000	1.55	0.31
2001–10	1.24	0.64
Type of drug — ATC level 2		
Renin-angiotensin system agent (*reference value*)	1.00	
Drug for acid-related disorders	1.02	0.90
Drug for obstructive airway diseases	0.81	0.26
Lipid modifying agent	1.01	0.96
Psychoanaleptic	1.80**	<0.01
Calcium channel blocker	0.61	0.08

Drug expenditure		
Expenditure rank 1 — higher total cost (*reference value*)	1.00	
Expenditure rank 2	1.27	0.08
Expenditure rank 3	0.89	0.40
Expenditure rank 4 — lower total cost	1.02	0.90

*Note: Statistical significance levels: ** p-val < 0.01; * p-val < 0.05.*

IV Discussion

A *Numbers and Owners of Secondary Patents*

It has long been recognised that a secondary patent owned by the originator of a drug has the potential to evergreen the originator's exclusivity over the drug, thereby adversely affecting consumers[44] and producing a net negative effect on social welfare.[45] However, evidence of this taking place — such as can be provided by a comparative analysis of the particular characteristics of such patents across a range of drugs — has been missing. As the Productivity Commission recently concluded: 'While it is clear that the *preconditions* for evergreening are present and examples of the practice can be identified, it is difficult to be definitive about the extent and impact of the practice.'[46] Our finding that the API originator owns more than one-quarter (27%) of all secondary patents associated with the high-cost drugs in our sample is an important contribution to the evergreening debate. If the API originator's secondary patents have an evergreening effect, then our finding shows that the extent of the practice — on average, 13 secondary patents per drug — is not insignificant.

The observation that nearly three-quarters of all secondary patents are owned by entities other than the originator of the drug's API illuminates a neglected side to the follow-on innovation story. It suggests that publication of

[44] National Academies of Sciences, Engineering, and Medicine (n 1) 71 (finding 2-6).

[45] Concern has been expressed that the innovation protected by secondary patents obtained by a drug's originator have little or no public value because these patents make limited contribution to patient welfare: Moir (n 8) 414. If the contribution of the innovation protected by a secondary patent is low or non-existent, the social welfare effect of the patent may be negative, as it may have the effect of suppressing competition.

[46] Productivity Commission (n 10) 322 (emphasis in original).

the patent for the drug's API encourages others to undertake follow-on innovation in relation to it, presumably with the hope and expectation that they will benefit from any subsequent success of the drug in the marketplace. Assuming that such follow-on innovation has social and public health value,[47] the significant extent of this practice — on average, 34 follow-on innovations per drug — suggests a substantial net positive effect on welfare.

B *Timing of Applications for Secondary Patents*

An act of follow-on innovation in relation to a drug's API invariably involves use of that API. Where that act is undertaken by someone other than the API patentee (ie the API originator), it will constitute an infringement of the API patent unless either the API originator has licensed the use, or an exception to infringement (eg for 'experimental use') applies. If we assume, as seems reasonable, that the API originator did not license the other originators and non-originators to use the API patent when they undertook their follow-on innovation, then our finding that other originators and non-originators apply for secondary patents during the life of the API patent is important. It indicates that the legal monopoly over use of the blockbuster drug does not equate to a practical monopoly over innovation in relation to it.

The question that then arises is: why does the API patent not provide a practical monopoly over innovation in relation to the drug? The answer seems to be that the other originators and non-originators who engaged in follow-on innovation either assumed that an exception to patent infringement applied to their activities, or alternatively did not consider or did not care whether such an exception applied. While a specific pharmaceutical patent exception was in force during the period of our study, it did not apply to the vast majority of follow-on innovations in our sample;[48] and the general 'experimental purpos-

[47] We recognise that this assumption is open to challenge. Just as the secondary patents obtained by the API originator may provide little or no public value, so too may the secondary patents of other originators and non-originators: see above n 45 and accompanying text.

[48] This particular exception was introduced as s 78(1) of the *Patents Act* (n 16) by the *Intellectual Property Laws Amendment Act 1998* (Cth) sch 1 item 3. The provision operated to save from infringement an act of exploitation of a patented pharmaceutical that did not constitute a therapeutic use of it — thus excepting acts of experimentation, so long as they did not involve administration of the pharmaceutical to patients. The exception took effect from 27 January 1999, but it applied only to pharmaceutical patents for which an extension of patent term had been granted. Only four of the 13 API patents to which our sample of secondary patents relate were granted an extension of term. The secondary patents related to these four API patents account for only 28% of all secondary patents in our sample — meaning that nearly three-quarters of the acts of follow-on innovation were ones to which the

es' infringement exception that now exists was not in force at the time the acts of follow-on innovation considered in this study took place.[49] Thus, if the other originators and non-originators were assuming that their acts of follow-on innovation were excepted from infringement, it must have been on the basis that a common law (non-statutory) exception applied.[50] However, the scope — and, indeed, the existence — of a common law experimental use exception in Australia was uncertain prior to the introduction of the general statutory exception.[51] It may be, therefore, that these other innovators simply did not consider, or did not care, whether their follow-on innovation constituted infringement.

This observation applies not only to the API patent but also to the *secondary* patents owned by the API originator. The API originator commenced its filing of secondary patent applications earlier than the other two categories of follow-on innovators. Since all of the secondary patents in our sample were held for a median of 13 years, we know that the API originator owned numerous secondary patents relating to the drug's API that were in force at the time that other originators and non-originators were undertaking their follow-on innovation. As with the API patent, it is clear that the secondary patents of the API originator did not have the practical effect of preventing other parties from engaging in follow-on innovation in relation to the drug.[52]

exception did not apply. The exception was later amended to operate as a regulatory review exception applicable to all pharmaceutical patents, whether or not their patent term had been extended: *Intellectual Property Laws Amendment Act 2006* (Cth) sch 7 item 3, inserting *Patents Act* (n 16) s 119A. However, that amendment did not take effect until 25 October 2006, by which time almost all (98%) of the secondary patents in our sample had been filed — meaning that this exception could not apply to the acts of follow-on innovation proxied by those patents.

49 The general exception saves from infringement an act done 'for experimental purposes relating to the subject matter of the invention': *Patents Act* (n 16) s 119C(1). We call this a general exception because its application is not limited to pharmaceutical patents; it applies to all patents. The provision took effect on 16 April 2012, well after the making of all innovations to which the secondary patents of this study relate: *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (Cth) sch 2 item 1.

50 An exception for an act done 'by way of *bona fide* experiment' arguably was recognised under the common law of the United Kingdom: *Frearson v Loe* (1878) 9 Ch D 48, 66 (Jessel MR). A similar exception has been recognised in US case law, beginning with *Whittemore v Cutter*, 29 F Cas 1120, 1121 (D Mass, 1813) (Story J), and most recently in *Madey v Duke University*, 307 F 3d 1351, 1361–2 (Fed Cir, 2002) (Gajarsa J), in which the exception was given limited scope.

51 *Patents Act* (n 16) s 119C. See also Advisory Council on Intellectual Property, *Patents and Experimental Use* (Report, October 2005) 28–9.

52 It might be thought that the secondary patents owned by the API originator would not, due to the nature of the claim in such a patent, have the legal effect of granting exclusivity over

It makes commercial sense that other originators and non-originators generally undertook follow-on innovation only after TGA registration of the drug, because without TGA registration there is no clear market for the drug — and therefore little or no reason to invest in innovation in relation to the drug. However, our finding that non-originators undertake follow-on innovation for a longer period over the life cycle of the drug than both the API originator and other originators — as seen in their long tail of secondary patent applications post-TGA registration — is surprising. Sales of the drug invariably will have diminished over time as new and improved drugs become available. If the market for the drug was still thriving 20 years after it was first approved for sale, one would expect that the API originator and other originators would also be actively innovating in relation to the drug at this time, but we detect little evidence of this.

It may be that non-originators seeking secondary patents up to 30 years after the first TGA registration of the drug are doing so for reasons other than, or in addition to, participation in the market for which that drug was first registered. These reasons include a desire to participate in a market for which the drug was *not* registered (ie an 'off label use' market) or in the market of *another* drug.[53] The data from our earlier study provide some support for this possibility. The two types of innovation most often patented by non-originators are a method of treatment using the drug's API for a disease in another ATC class (which, by definition, is a disease other than the one for which the drug first obtained TGA registration), and a delivery mechanism or formulation for the drug's API (which, in principle, can be a mechanism or formulation that may also be applied to the API of other drugs).[54]

experimenting with the API and, hence, could not be asserted against later follow-on innovators. While that may be true in some instances, it is not true in all instances. In particular, where another's follow-on innovation requires a comparative assessment against the API originator's follow-on innovation — eg a comparison of the safety and efficacy of an alternative delivery mechanism or dosing regimen for the API — the use of the embodiment of the API originator's follow-on innovation would be within a claim of the API originator's secondary patent. Thus, we consider it likely that at least some of the API originators' secondary patents in our study would, as a matter of law, have provided the API originator with exclusive rights in respect of the acts undertaken by some subsequent follow-on innovators.

[53] We recognise the validity of Granstrand's observation that there may be other, non-market, reasons for seeking these patents such as to motivate employees to invent, to provide a measure of research and development productivity, and to improve the corporate image: Ove Granstrand, *The Economics and Management of Intellectual Property: Towards Intellectual Capitalism* (Edward Elgar, 1999) 78.

[54] Christie et al (n 5) fig 3.

C *Duration of Secondary Patents*

The observation that the secondary patents relating to a high-cost drug are not held for as long as the patents over the API of that drug (a median of 13 years, compared with a median of 20 years) — and, hence, that follow-on innovation in relation to a high-cost drug has less private value than does the original innovation which led to the drug — is not surprising. It is the API which makes the original drug a commercial success, since it is the API which delivers the therapeutic effect. Follow-on innovations that are the subject of secondary patents are, in essence, 'applied to' the API of the drug (and, possibly, to the API of other drugs as well). Thus, the private value of a secondary patent is unlikely ever to exceed the private value of the patent over the API itself.

Less easily explained is our finding that the API originator's secondary patents were typically held for longer than those of other innovators. Our previous study showed that each category of innovator owns secondary patents for all types of invention, albeit with some systematically different preferences. Our finding in this study shows that, irrespective of the types of invention made, follow-on innovations by the API originator appear to have greater private value. Assuming that patent duration is a valid proxy for private value, it needs to be asked: from where does that greater private value derive? One plausible explanation is that it derives from the secondary patents' potential to have an evergreening effect in relation to the innovator's blockbuster drug.

Also of significance is our finding that secondary patents for a delivery mechanism or a formulation of the blockbuster drug's API were typically held for longer than were other types of secondary patent. In our earlier study, we found that this was the most common type of secondary patent owned by the API originator, accounting for 36% of all secondary patents it held — more than double the frequency of any other type of secondary patent.[55] This is also the type of secondary patent most often theorised to have an evergreening effect.[56] Our findings that secondary patents for a delivery mechanism or for a formulation of the blockbuster drug's API have greater private value than other types of secondary patent, and that this is the most common type of secondary patent owned by the API originator, are consistent with the theory

[55] Ibid 3.

[56] See, eg, Moir (n 8) 415; Sandeep Kanak Rathod, 'Ever-Greening: A Status Check in Selected Countries' (2010) 7(3) *Journal of Generic Medicines* 227, 227.

that API originators use secondary patenting to evergreen their marketplace exclusivity.

It is noteworthy that the expenditure rank of the drugs in our sample was not associated with a statistically significant difference in the duration of their associated secondary patents. This suggests that, even though the drugs in the highest expenditure rank had a cumulative cost 12 times greater than the drugs in the lowest expenditure rank, there is no difference in the private value of the follow-on innovations in respect of the most successful compared with the least successful of the blockbuster drugs in our sample. This observation indicates that there is a threshold of success of the original drug, above which the private value of a secondary patent relating to it does not change — and that this threshold was exceeded by even the least successful of the 13 top-selling drugs in Australia.

D *Limitations*

We recognise some potential limitations of our study. One is that we have assumed the validity of the assumption — adopted by economists — that the relative duration for which a patent is maintained is a valid proxy for its relative private value to the patentee. This proxy may be weak at distinguishing differences in private value across different categories of innovators. For example, while the absolute cost of renewing a patent for an additional year is the same for all patentees, the relative cost of doing so will vary according to the size (in terms of revenue) of the patentee. Thus, to the extent to which an API originator is a larger enterprise than the other types of secondary patent owner, the cost to it of maintaining any particular patent is relatively smaller — which may explain why it keeps its patents for longer. While we recognise the validity of this logic, we doubt that it invalidates the use of the duration proxy in this instance. First, it is not certain that other originators are smaller enterprises than API originators. We have defined other originators to be those that hold a patent on the API of another high-cost drug[57] — which suggests they are of similar size to API originators. Second, while it may be that non-originators are smaller enterprises than API originators, the fact that their relative cost of maintaining a patent is higher may be offset by the fact that their relative potential benefit of doing so is also higher.

[57] As explained above in Part II(B), we define 'another high-cost drug' to be any of the 50 drugs with the largest cumulative expenditure in Australia over the period 1990–2000.

Under this logic, all categories of secondary patent owner will have the same net incentive to maintain any particular secondary patent.

There may be reasons other than differences in private value that cause some patentees to maintain patents for longer than others. For example, because API originators seek their secondary patents earlier (relative to the date of TGA registration of the API) than do the other secondary patent owners, they will, in general, have to keep their secondary patents for longer before TGA registration for the drug is obtained and, hence, for longer until there is a market for the drug to which the follow-on innovation relates. Thus, the reason that API originator-owned secondary patents are kept for longer may be that they are applied for earlier in the life cycle of the drug. We acknowledge the plausibility of this point, but we do not consider it invalidates the proxy. The fact that API originators undertake follow-on innovation earlier than do other originators and non-originators may itself be a consequence of their secondary patents having greater private value.

Another potential limitation of our study is that the secondary patents we analyse are Australian patents. Patents are territorial by nature, meaning that the legal monopoly to which they give effect is limited to the jurisdiction in which they are granted. It follows that our study's findings are, strictly, of the patenting behaviour of API originators, other originators and non-originators in Australia. However, we do not think that this limitation is significant. Since Australia is a high-income, 'western' country, the demand side of its pharmaceutical market is like that in the US, Canada, the United Kingdom and much of Europe. Thus, most, if not all, of the blockbuster drugs in our study are likely to have been major drugs in those countries. Furthermore, the basic characteristics of Australia's patent law — including, in particular, the requirements that must be satisfied for the grant of a valid patent — are in essence the same as in those countries.[58] This means that there is no reason to

[58] We recognise that under the *Convention on the Grant of European Patents*, opened for signature 5 October 1973, 1065 UNTS 254 (entered into force 7 October 1977), as revised by *Act Revising the Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973*, OJ EPO 2001 Special Edition 4/1, 13 art 53(c) ('*EPC*'), 'methods for treatment of the human or animal body by surgery or therapy' are excluded from patenting. These methods equate to inventions in our categories of methods of medical treatment with either the same or a different ATC class as the relevant sample drug: see above Part II(B). However, the practice of the European Patent Office, when applying the *EPC*, is to permit claims to the use of pharmaceutical composition 'in the treatment of' the human body for a particular condition, thereby providing a means by which patent protection can be obtained in respect of a method of medical treatment (whether a first, a second, or a subsequent medical use) using an API: see *EP Enlarged Board of Appeal Patent Decision G0002/08*, decided on 19 February 2010, 27–30 [5.9.1]–[5.9.2.2].

think that the same types of patent, in the same types of numbers, will not have been granted for the drugs in those countries. We consider, therefore, that it is reasonable to believe that our findings will largely reflect the secondary patenting practices taking place in much of the developed world, and that the policy conclusions we draw below about those findings have application beyond Australia.

V Conclusion

It is reassuring that the majority of follow-on innovation associated with blockbuster drugs is undertaken by entities other than the drug's originator, and occurs both before and after expiry of the patent over the drug's API and the expiry of associated secondary patents held by the originator of the API. This shows that patents — both primary and secondary — which are owned by the originators of blockbuster drugs do not give them a monopoly over further innovation in relation to the drug. Thus, it appears that policymakers do not need to be concerned that drug originators' secondary patents stifle welfare-enhancing innovation by others.

The fact that most of the follow-on innovation by others occurs after the granting of regulatory approval to market the drug provides policymakers with a potentially valuable lever. It seems likely that any regulatory reforms which expedite the granting of drug approval will also expedite the commencement — and thus potentially increase the amount — of follow-on innovation that is undertaken by third parties. Since such follow-on innovation is generally regarded as socially desirable, policymakers should seek to identify mechanisms that speed up the assessment of drug approval without compromising the effectiveness of that assessment.

Although the majority of blockbuster drug follow-on innovation is undertaken by third parties, a substantial amount (27%) is undertaken by the originator of the drug — resulting in an average of 13 secondary patents per drug. These secondary patents have greater private value than those held by others, and their typology is consistent with the theorised evergreening behaviour of drug originators. Considered together with our earlier study's findings, these findings provide support for the view that secondary patenting by drug originators can have adverse welfare effects through extending the originator's marketplace exclusivity over the drug.

Policymakers must be alert to this possibility, and need to consider how to reduce its likelihood. We consider that those responsible for implementing, reviewing, validating and correcting patent examination practices — patent offices and, ultimately, courts — should ensure that the patentability require-

ments, especially those of inventive step (non-obviousness) and industrial application (utility), are applied rigorously to the types of follow-on innovation with the greatest potential to have an evergreening effect — namely, delivery mechanisms for, and formulations of, APIs.