



Melbourne Law School

Productivity Commission
Review of Intellectual Property Arrangements

**Submission by Professor Andrew Christie
in response to its Draft Report**

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I confine my submission to some observations on patents, based on empirical evidence from two studies – one dealing with the effectiveness of patent examination in Australia, the other with secondary patents for high-cost pharmaceuticals in Australia.

1. EFFECTIVENESS OF PATENT EXAMINATION IN AUSTRALIA

I, Chris Dent and John Liddicoat are co-authors of an article entitled ‘The Examination Effect: A Comparison of the Outcome of Patent Examination in the US, Europe and Australia’ which is forthcoming in 16(1) *The John Marshall Review of Intellectual Property Law* (2016). A pre-publication version of the article is available at <http://bit.ly/28LkfvV>.

The article reports a study in which we undertook an empirical analysis that compared, for approximately 500 granted patents, the form of the first claim (“claim 1”) in the granted patent with claim 1 in the patent application as filed for examination. By comparing the form of claim 1 as granted with claim 1 in the patent application, we could identify whether there was any meaningful difference between the two – and, hence, the extent to which the examination process had a practical effect. We undertook this analysis separately for three patent offices: the United States Patent and Trademark Office (USPTO), the European Patent Office (EPO), and the Australian Patent Office (APO). Importantly, we assessed how each office examines *identical* claims – that is, filed patent applications in which claim 1 was in precisely the same form in each of the three offices. By using identical claims, we were able to compare the effect of the examination process in each office against the effect in the other offices.

Our analysis focused on three particular matters: (i) the *rates* at which the examination process produced “meaningful change” to (i.e. change to the scope of) claim 1; (ii) the *types* of meaningful change to claim 1 produced by the examination process; and (iii) the *factors* that were associated with the meaningful changes produced by examination. For all three matters, tests were conducted to determine which of the observed differences – both across and between offices – were statistically significant. As a result we were able to draw detailed conclusions about the practical effects of the patent examination process in the offices, the differences between the offices in those effects, and the consequences of those differences.

Our analysis of the **rates** of meaningful change produced by examination show that meaningful change to claim 1 resulted from examination nearly four-fifths (79%) of the time in the USPTO, more than two-thirds (68%) of the time in the EPO, and just over one-half (57%) of the time in the APO. Testing showed that each of these observed differences – that is, between the USPTO and the EPO, between the

USPTO and the APO, and between the EPO and the APO – was statistically significant.

We defined two **types** of meaningful change: “integral change”, being change that adds to or alters the elements, or integers, of the invention as claimed; and “fundamental change”, being change that alters the fundamental form of the invention, such as from a product to a process (or *vice versa*). Our analysis of the types of meaningful change produced by examination showed that where the examination resulted in meaningful change to claim 1, the vast bulk of that change in all three offices was “integral change”.

To identify the **factors** that were associated with meaningful change we ascertained the rates of meaningful change in all three offices by the field of the technology of the invention and by the country of origin of the patent application for the invention. We found that within each office there was *no* statistically significant difference in the rate at which inventions in different fields of technology underwent meaningful change as a result of examination. We further found (for reasons not clear to us) that patent applications originating in certain countries (namely Canada, Finland, Italy, Japan, Norway and Sweden – being half of the countries from which the most number of applications in our sample originated) underwent statistically significantly *less* meaningful change in the three offices than patent applications originating from the United States.

We make the following **observations** on these findings:

1. The typical effect of examination is to produce change in claim 1 of a patent application. This change is meaningful, in the sense that it changes the scope of the monopoly provided by the patent over the claimed invention, and it occurs by way of adding integers to the claim. Across the three offices under consideration, examination resulted in meaningful change much more often than not.
2. Across the three offices analysed in this study, almost all of the meaningful change to claim 1 that results from examination is integral change – that is, change that adds to or alters the integers of the claim. Because this type of change generally only occurs as a result of a novelty and/or an inventive step (non-obviousness) objection, it follows that almost all the meaningful change that occurs as a result of examination is due to the requirements of novelty and/or inventive step.
3. Claim 1 in US-originating applications underwent more meaningful change during examination than claim 1 in applications originating from many other countries. This suggests that US-originating applications are drafted more broadly than those from those other countries.

4. There is a statistically significant difference between the three offices in the frequency with which their examination results in meaningful change to claim 1. It is a fundamental principle of patent law that the effect of any changes made to a claim during examination cannot be to widen the scope of the claim. Thus, where a meaningful change occurs as a result of an integral change (which is the usual case), the effect of that change is to narrow the scope of the claim. Assuming that the frequency of claim narrowing is a measure of the effectiveness of the examination process, our findings indicate that the examination process in the APO is *less* effective than in the USPTO and in the EPO.
5. Given that each application claim 1 entering examination in the three offices is identical, the only part of the patent system that could impact on the form of the granted claim 1 is the examination process in the respective patent office. If the examination process in each office was the same, then it would be expected that the rate at which it produced meaningful change to application claim 1 would be the same. Given that we found that this was not the case, it follows that there must be a significant difference in the examination process that is adopted by each of the three offices.
6. Logically, any differences in the examination process adopted by the offices must one or both of two types: (i) a difference in the *law* being applied during examination; or (ii) a difference in the *practice* of applying the law during examination – which, in turn, could be a difference in either function (e.g. the comprehensiveness of prior art searching) or rigour (e.g. the “height of the bar” being applied).
7. Given that the rates of integral change in each of the three offices is significantly different, and that the most usual type of meaningful change made in all three offices is integral change, it follows that the most substantive difference in the examination process adopted by the three offices is in respect of the requirements that typically give rise to integral change – namely, the prior art-based requirements of novelty and non-obviousness. Thus, whether the difference in approach is due to a difference in the law or a difference in the practice (or a difference in both), it is clear that the difference is *about* the requirements of novelty and/or non-obviousness.

We draw the following **conclusions** from our analysis:

1. The practical effect of patent examination is that, more often than not, it results in a meaningful change to – and, in particular, in a narrowing of – the definition of the invention contained in claim 1 of the patent. Importantly, this effect of examination does not occur at the same rate in the different patent offices; rather, the effect occurs significantly more often in the USPTO than in the EPO, and significantly more often in both of those offices than in the APO.

2. Taken together, our findings can be seen to add to the debate on “patent quality”. While the literature in this area does not offer a unanimous definition of what is a quality patent, a common feature in most understandings is that a quality patent is one that meets the “statutory standards of patentability”. That patent examination in all three offices generally results in a narrowing of claim 1 shows that the statutory standards for patentability are impacting on the scope of the claims contained in granted patents. That the APO narrows claim 1 less often than does either of the other two offices suggests that the quality of granted Australian patents is lower than that of granted US and European patents – since the concern in the literature to date has been that granted patents are too wide, not too narrow.

2. SECONDARY PATENTS ASSOCIATED WITH HIGH-COST DRUGS IN AUSTRALIA

Chris Dent and I, with assistance from Simon Walter and David Studdert, are the lead researchers of a work-in-progress study that explores the characteristics of secondary patents associated with high-cost drugs in Australia. The study is a follow-up to our article “Patents Associated with High-Cost Drugs in Australia” published in (2013) *PLoS ONE* 8(4): e60812. doi:10.1371/journal.pone.0060812. A report of the study is not yet publically available, but a confidential copy of the draft working paper has been made available to the Commission.

The study concerns the same high-cost drugs that were the subject of our earlier paper, but focuses on the *secondary* patents associated with those drugs – that is, the patents that relate to one of the high-cost drugs but that is not the patent that covers the active pharmaceutical ingredient (API) of the drug. The inventions to which secondary patents relate are “follow-on” inventions, in the sense that they follow on from the primary inventions of the API of the high-cost drugs. Many of these follow-on inventions are owned by parties other than the inventor of the high-cost drug.

Our analysis focuses on two particular matters: (i) the *duration* of the granted secondary patents; and (ii) the *timing* of the application for the secondary patents. Data on patent duration is frequently used to estimate the private value of patents, with a longer duration regarded as a proxy for greater value – since it is assumed that patentees will only renew their patents if the private value of holding those patents over an additional year exceeds the cost of renewal. Thus, observing the durations for which high-cost drug secondary patents are held tells us about the relative private values of the various follow-on innovations relating to the drug. The timing of the application for the secondary patents for high cost drugs is also of interest, as it demonstrates when the relevant follow-on innovation took place. That a patent application has been filed may be regarded as evidence that an act of innovation has occurred. Thus, observing when applications for secondary patents are filed tells us at what stage in the high-cost drug’s life cycle follow-on innovation takes place.

Our analysis of the **duration** of the secondary patents shows that the median duration for these patents is 13 years. In terms of the type of invention protected by the secondary patents, only the category of delivery mechanism or formulation patents had a statistically significant different duration – these secondary patents lasted longer than the other categories of patents in the sample. There was a statistically significant difference in the duration of secondary patents when categorised by patent owner – secondary patents owned by both “other originator” and “non-originator” patentees had a shorter duration than the secondary patents owned by the “originator” patentees. The cumulative expenditure on an API drug, relative to the other drugs in the sample, did *not* impact on for how long the secondary patents were held.

To undertake our analysis of the **timing** of the application for the secondary patents, we plotted the application dates against two factors related to the APIs with which they are associated: (i) the expiration date of the API patent; and (ii) the date of regulatory approval to market the drug containing the API. Our plot against *expiration* date of the API patent shows that the company that owns the API patent applies for secondary patents at an early stage than the other two categories of secondary patent owner. However, companies that do not own the API patent apply for secondary patents well before the expiration of the API patent. Further, broadly speaking, the non-originator and other originator owners seek about as many secondary patents before the expiration of the API patent as after that date. It also appears that, overall, the owners of the API patent stop seeking secondary patents for a drug earlier than the other types of owners (though, they still innovate after the end of the API patent); and that non-originators seek secondary patents at a longer period of time after the expiration of the API patent than the other two categories of secondary patent owners.

When the application dates of the secondary patents are plotted against the date of *first registration* of the drug containing the API, a clearer picture emerges. Again, originator patentees seek secondary patents at an earlier stage than the other categories of secondary patent owners. It is also clear that the vast bulk of the secondary patents sought by the non-originator and other originator owners are applied for after the drug containing the API has been registered for sale in Australia. Also, the originator patentees stop seeking secondary patents at a point of time closer to the first date of registration, whereas there is a longer “tail” of secondary patent applications by non-originator patentees.

We make the following **observations** on these findings:

1. On the assumption that a longer-held patent has a private value greater than a shorter-held patent, the finding that secondary patents are not held for as long as patents over the API indicates that high-cost drug secondary patents are of less private value to the patentee than the patent for the API of the drug to which they relate.

2. Because the secondary patents owned by other originators and non-originators have a shorter life than secondary patents owned by the API originator, it appears that the API originator's secondary patents are of greater private value than those owned by the other two types of patent owner.
3. The fact that the secondary patents for inventions concerning delivery mechanisms or formulations of the API are kept for longer suggests that they are of greater private value than the secondary patents for other types of inventions relating to the API. This is consistent with our early finding that the largest category (by number) of secondary patents is for these types of invention, and suggests that these types of inventions are the most commercially valuable in the market place.
4. The apparent private value of secondary patents (as measured by the proxy of duration) relating to a high cost API drug is not associated with the actual value (as measured by average cumulative cost) of the API drug relative to the others in the sample. This suggests there is a threshold of success of the API drug to which it relates, above which the apparent private value of a secondary patent does not change – and that this threshold is exceeded by even the least successful of the top 15 selling drugs in Australia.
5. All categories of patent owner apply for secondary patents throughout the life of the API patent, as well as after the expiration of the API patent. On the assumption that the filing of a patent application for a secondary patent may be used as a proxy for when the act of innovation took place, it can be seen that even patentees who are not the owner of the API patent engage in follow-on innovation in relation to the API well before the expiration of the API patent. This means that, despite the API patent owner having a legal monopoly on the making and selling of the API drug itself, the owner does not have a practical monopoly on innovation around the drug. This is consistent with the existence of an experimental use exception to the exclusive rights of the patentee.
6. Entities other than the holder of the API patent seek secondary patents only when they know that the API drug has been registered in Australia. This behaviour makes commercial sense because, without registration, there will be no market for the drug in the country and, therefore, little or no reason for inventions relating to the API drug to be protected by patents in Australia.
7. Smaller innovating entities – as identified by the fact that they do not own patents over high-cost API drugs, either as originators or other originators – innovate later in the lifecycle of the API drug. This is seen in the long tail of registrations and patent applications – up to 30 years after the first registration of the API drug. This suggests that the smaller entities are innovating for reasons other than solely to participate in the market for that drug.

We draw the following **conclusions** from these findings:

1. The fact that competitors of the API originator undertake follow-on innovation well before (in addition to well after) the expiry of the API patent has significance for policy-makers. In particular, this finding suggests that there is little foundation for a concern that the grant of the API patent over a blockbuster drug, and/or the grant of secondary patents to the API originator (sometimes called “evergreening patents”), will preclude follow-on innovation by competitors.
2. The vast majority of the follow-on innovation over blockbuster drugs that is undertaken by competitors of the drug’s originator occurs only after regulatory approval to market the API has been granted. While this finding is not surprising, it does have significance for policy-makers. To the extent that policy-makers wish to increase the amount follow-on drug innovation by competitors of the drug’s originator, a solution is to expedite the granting of regulatory approval for the drug.