Pharmaceutical Patents Review

Submission by:

**Professor Andrew Christie**
Chair of Intellectual Property
Melbourne Law School
University of Melbourne

**Dr Chris Dent**
Principal Research Fellow
Melbourne Law School and Intellectual Property Research Institute of Australia
University of Melbourne

**Profess Peter McIntyre**
Deputy Director
Health Innovations Research Institute
RMIT University

**Dr Lachlan Wilson**
Intellectual Property Manager
UoM Commercial Ltd
University of Melbourne

**Professor David Studdert**
ARC Laureate Fellow
Melbourne Law School and School of Population Health
University of Melbourne

30 April 2013
This submission is addressed towards **Question 8** posed in the Pharmaceutical Patents Review Background and Suggested Issues Paper: *Are follow-on patents being used to inappropriately extend protection for pharmaceuticals? If so, how? And, if they are, is this sound policy and what changes, if any, are needed?*

Our submission is based on empirical research undertaken by us as part of a major research project funded by the Australian Research Council (Discovery Project DP0987570). This submission sets out a précis of our method and findings, and the conclusions we draw therefrom of relevance to this Review. The published paper detailing our method and reporting our findings is published as Christie AF, Dent C, McIntyre P, Wilson L, Studdert DM (2013) ‘Patents Associated with High-Cost Drugs in Australia’ *PLoS ONE* 8(4): e60812.doi:10.1371/journal.pone.0060812 (available at [http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0060812](http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0060812)).

**Study Methodology**

- We analysed patenting activity around 15 of the costliest drugs in Australia over the last 20 years to determine the number, nature and ownership of these patents. The analysis included consideration of the patents granted to both the originator of the high-cost drugs under study and to other parties.

- To do this we searched various databases for all patents, granted anywhere in the world at the date of the search, that contained a reference to the API of the drugs in our sample. We extracted the Australian records, eliminated duplicates, and identified the status of the patent application (as at the date we made the extraction, between May and August 2010). We excluded all records for patent applications that had not proceeded to grant (i.e., that had not been examined and accepted by the APO).

- We evaluated claim 1 of each patent associated with each drug in our sample to identify its nature. In doing so we observed claims on seven types of inventions:

  1. the API of the drug (i.e. the drug’s chemical compound) – which we called the “original patent”;
  2. an intermediate or a different form of the API (e.g. an isomer, or a salt or crystalline form, of the drug’s chemical compound);
  3. a combination of the API with another drug (e.g. the drug’s chemical compound combined with the chemical compound of another drug);
  4. a delivery mechanism or a formulation for the API (e.g. a trans-dermal patch containing, or a slow-release formulation of, the drug’s chemical compound);
  5. a process for making or formulating the API (e.g. a method of preparing or purifying the drug’s chemical compound);
6. a method of treatment using the API in the same Anatomical Therapeutic Chemical (ATC) class (e.g. a method of treating asthma using a drug classified for treatment of obstructive airway disease); and
7. a method of treatment using the API in a different ATC class (e.g. a method of treating obesity using a drug classified for treatment of depression).

• We classified the original patent, and any other patents held by the patentee of the original patent, as owned by the “API originator”. Patentees other than the API originator were classified into one of two groups: “other originator”, being patentees who hold a patent on another high-cost drug (one of the 50 drugs associated with the largest cumulative expenditures in Australia over the period 1990-2000, but not necessarily one from our sample); and “non-originator”, being all the remaining patentees.

Study Results

• We found 593 granted Australian patents whose claim 1 read onto the API of one or more of the 15 high-cost drugs in our sample. These 593 unique patents had a total of 736 associations with drugs in our sample, producing a mean of 49 associated patents per drug (median 45). The number of associated patents per drug varied widely (standard deviation 24), ranging from 22 patents associated with Ipratropium and Famotidine to 121 patents associated with Omeprazole (Figure 1).

![Figure 1: Patent counts by high-cost drug (arranged in descending order of total cumulative cost 1991-08)](image-url)
• Two types of patents accounted for one half (360/736) of all associated patents: 29% (213/736) were for a delivery mechanism or a formulation for the API, and 20% (147/736) were for a combination including the API (Figure 2). An additional 15% (108/736) of all associated patents were for a new method of treatment (different ATC class) using the API.

• Patentees other than the API originator owned three-quarters (551/736) of all associated patents, and half of these patentees (367/736) were non-originators (i.e. entities that had not held patents on a top-50 high-cost drug in Australia from 1990-2000).

• API originators were particularly active in patenting two types of inventions, which together accounted for just over one half (98/185) of all patents they owned: a delivery mechanism or a formulation for the API (36%); and a process for making or formulating the API (17%). API originators were not, however, the dominant patentee for either of these types of inventions: they owned only 31% and 39%, respectively, of all associated patents in these categories.

• The patenting activities of other originators focused on combinations with the API; 41% of their associated patents were of this type. Other originators were the dominant patentee for this type of invention, owning 52% of all combination patents.

• Non-originators were active in patenting inventions across the board. Excluding the original API (which was, by definition, held by the API originator), non-originators held more associated patents than either of the other patentees in every category except combinations. In addition, non-originators held more associated patents than API originators and other originators combined in two categories: a method of treatment (different ATC class) using the API (held 69% of all patents), and an intermediate or a different form of the API (67%).

• The 371 non-originator patents were held by 161 separate entities. Of these entities, we classified 12% as “generic manufacturers”, on the basis of either public self-identification as such or listed membership of a generic pharmaceutical trade association. The bulk (66%) of the non-originator patentees were other pharmaceutical companies – that is, pharmaceutical companies not classifiable as a generic manufacturer. The remainder of the non-originator patentees were non-pharmaceutical organizations: universities (11%), government agencies (1%), hospitals (1%), and other entities (8%).
Conclusions

Examining patents associated with high-cost pharmaceuticals by type of invention sheds light on where the various industry participants have focused their investment in follow-on innovation. Our results show that the patents most commonly held by the API originator are for delivery mechanisms or formulations for the API, and for processes for making or formulating the API. The focus of API originators on these areas of innovation is probably not surprising, given that these areas are most closely connected with the original innovation, the API.

Patentees who were originators, but not the API originator, concentrated their patenting activity on medicines that combined the API with other compounds. A plausible explanation is that these companies are investing in follow-on innovation to combine their own drug compounds with the successful APIs of their competitors, although it was beyond the scope of our study to probe how often this explanation applied in the 75 combination patents owned by other originators.

Non-originators patented heavily in three areas: delivery mechanisms or formulations for the API; methods of treatment (different ATC class); and intermediates or different forms of the API. The focus of non-originators on intermediate and alternative forms is logical: they are likely to be exploring these compounds in preparation for manufacture of the API once the original patent on it expires. However, the reasons behind non-originators’ other areas of focus are less clear. The strategic value may be in providing leverage or bargaining power against the original patent holder should it seek to use its other associated patents to keep the non-originator out of the market after expiry of the original patent. The high levels of patenting activity we observed for both API originators and non-originators in the delivery mechanisms/formulations space, for example, points to this possibility.

Figure 2: Patent counts by type of patent and patentee
Commentary and policy discussions about inappropriate patenting behaviour by pharmaceutical companies, including follow-on patenting, have been centred on the originators of the drugs in question. Our findings suggest that this account of patenting practices around high-cost drugs is too simplistic. It overlooks the substantial patenting activity undertaken by companies other than the originator of the high-cost drug, including generic manufacturers, based on follow-on innovation.

The terms of reference for this Review require the Review to consider whether there is evidence that the patent system is being used to extend pharmaceutical patent monopolies at the expense of new market entrants and, if such evidence is found, to provide an assessment of the subsequent impact on competition, innovation and investment.

We consider that our data are relevant to this issue. A patent can only be validly granted for something that is new (novel), inventive (non-obvious) and useful (capable of application). This means that the existence of a patent (assuming it has been validly granted) is evidence of the occurrence of innovation – because a patent applicant’s claim to having produced something new, inventive and useful has been validated by the patent office that examined and granted the patent.

Our data show that follow-on patents are being granted to the API originator and to the competitors of the API originator (both other originators and non-originators). While our data cannot directly answer the question of whether the API originator’s follow-on patents are being used to inappropriately extend the API originator’s protection, it does show that the existence of the API originator’s follow-on patents does not prevent competitors from engaging in follow-on innovation (or from patenting the novel, inventive and useful outcomes of that follow-on innovation).