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23 February 2011

Ms Julie Dennett
Committee Secretary
Senate Standing Committee on Legal and Constitutional Affairs
Parliament House
CANBERRA 2600

Dear Ms Dennett

**INQUIRY INTO PATENT AMENDMENT (HUMAN GENES AND BIOLOGICAL MATERIALS) BILL 2010**

Thank you for your letter of 9 December 2010 inviting me to make a written submission to the abovementioned inquiry.

The essence of the Bill is to reinforce the important distinction between a non-patentable discovery and a patentable invention in the specific subject matter area of genetic material. As the Intellectual Property Competition Review Committee noted:

> "[p]roperty rights in discoveries … could give rise to unreasonable barriers to potential competitors or to those who wished to use the 'discovery' in other fields of endeavour"[1]

My submission covers two key issues that are important for considering enactment of this Bill. As the Committee has learned only too well during its deliberations, facts about how patents operate are scarce. I therefore draw together some key available facts on patenting. Secondly, I would like to summarise for the Committee the genuine evidence available about the alleged relationship between patent monopolies and the incentive to invest in new medical products and processes. This solid empirical information is a useful antidote to the subjective opinions of those benefiting from the current system. Access to affordable health care, at a reasonable cost to the Australian taxpayer, is too important an issue to leave to interest groups.

## Who Patents in Australia, particularly in biological and pharmaceutical areas?

Less than 10 per cent of standard patents granted in Australia are owned by Australians. This very long-standing fact is typical of nations without large and dominant technology-exporting sectors. In countries such as Australia the patent monopoly system is effectively designed for the benefit of foreign firms. Figure 1 in the

[1] IPCRC, (2000), *Review of Intellectual Property Legislation Under the Competition Principles Agreement: Final Report,* Canberra: (Intellectual Property and Competition Review Committee), Commonwealth of Australia: 152.

appendix shows the proportion of standard patents granted to Australian companies and individuals from 1990 to 2001. The percentage owned by Australians ranges from a low of 7 per cent to a high of 9 per cent. These "Australian" patents of course include the Australian-registered subsidiaries of firms with headquarters overseas.

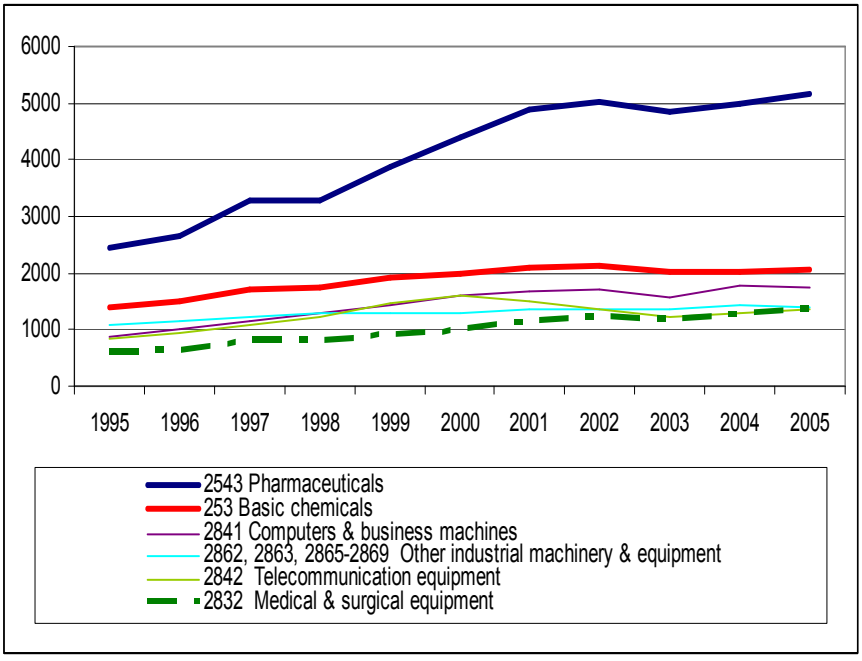
It is also well known that the principal nations benefiting from the global patent system are the USA, Japan and Germany, and to a lesser extent Korea, China, the UK and France. Between them these seven nations own 78 per cent of all patents filed through the International Patent Co-operation Treaty anywhere in the world.

Less frequently commented on is the fact that within each of these countries only a very small number of companies own very many of the granted patents. In Australia, 100 companies own 47,024 of the 141,584 standard patents granted to companies from applications filed between 1990 and 2001. Only one of these 100 companies is Australian.[2] Bessen and Meurer have drawn attention to the fact

> "that the economic benefits of patents are very highly concentrated among a small number of firms. Over one-half of the value of worldwide patents accrues to a small number of large pharmaceutical firms; over two-thirds accrues to firms in the chemical and pharmaceutical industries."[3]

Another well-known fact about the patent system is the "explosion" in the number of patent applications over the last few decades. Data on the major industry classes for Australian patent applications show that of the major patenting industries, it is the pharmaceutical sector which has massively increased its patent demands.

**Top 6 industry classes of Australian patents, 1995-2005 applications**




Source: http://www.ipaustralia.gov.au/pdfs/statistics/P66(mar06)%20Standard%20applications%20by%20Industry%20Codes.xls [accessed 20 February 2007]

In regard to the technology classes in which gene patents might be found, in my original submission I presented a table on the number of applications in IPC Class

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[2] See http://www.silverbrookresearch.com/l-en/index.html for information about this company and its patents.

[3] Bessen, J.E. and M.J. Meurer, (2008), *Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk*, Princeton and Oxford: Princeton University Press: 109.

C12N15. These data showed the volume of applications where claims might be being made over genetic material *per se*. In the two years since I presented those data, IPAustralia have granted a further 994 patents in this class. Altogether some 15,300 patents have ever been granted in this one technology sub-field. Of these some 7.600 are still operating, with an unknown range of effects.

Despite the clear recommendation of the 1984 Intellectual Property Advisory Committee that the government collect period data on the use to which patent monopolies are put, no government has yet collected data on the impact of the monopolies so frequently handed out.

**What evidence is there that investment in biotechnology would change if this bill were enacted?**

Despite the overwhelming evidence that patent systems, including that in Australia, largely benefit a fairly small number of foreign firms, there are frequent loud voices from patent owners, and others earning income from patent monopolies, arguing that if *any* changes are made *all* industrial innovation and scientific research will cease. There is no substantive evidence for this position – only the subjective views of those benefiting financially from the current system.

There is objective academic evidence to show that allowing patent monopolies over chemical compositions had large negative effects on the international competitiveness of a nation's chemical industry. This of course is directly relevant to today's biotechnology industry – the chemical composition of the late nineteenth century is to the chemical industry what genetic material is to the twenty-first century bio-technology industry.

The earliest evidence is from Germany where it has been clearly shown that the decision to allow patents for chemical processes, *but not for chemical products*, was integral to the ability of German chemical firms to become so competitive that they decimated the existing chemical industries in France, the UK and the USA. As Dutfield,[4] among others, has shown allowing monopolies on chemical compositions can lead to the death of an otherwise competitive chemical industry. Focusing monopoly grants on genuinely inventive areas – processes – provides a competitive incentive and assists in the development of globally competitive industries.

Fast forwarding to the modern world of pharmaceuticals, Italy had a thriving generic pharmaceutical industry in the post-World War II period, and included among its clients the US military. Unfortunately the lowest-common-denominator approach to the European Patent Convention meant the adoption of the policy that chemical compounds could be granted patents in all European countries from the 1970s. As Scherer and Weisburst have shown, this change in Italian policy lead to the death of its healthy generics industry – and there has been no replacement activity in terms of the development of new chemical entities.[5]

Despite the Italian evidence countries such as India were promised, during the TRIPS negotiations, that shifting policies to allow patents for chemical products as well as chemical processes would lead to a new flourishing industry focused on developing new pharmaceuticals to meet India's own health priorities. As Chaudhuri has shown, to date no such glowing future has emerged – R&D in pharmaceuticals has increased, but this is almost wholly directed to meeting the regulatory requirements of the US Food

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[4] Dutfield, G., (2003), *Intellectual Property Rights and the Life Science Industries: A 20th Century History*, Burlington: Ashgate.

[5] Scherer, F.M. and S. Weisburst, (1995), 'Economic Effects of Strengthening Pharmaceutical Patent Protection in Italy,' *International Review of Industrial Property and Copyright Law,* 26:6, 1009-1024.

and Drug Administration (i.e. to support the export of generic products to the lucrative US market).[6]

The available empirical evidence strongly supports the view that where an industry uses as a major ingredient things found in nature, granting monopolies over these natural substances is a sure-fire policy to produce a non-competitive industry. Eliminating patents for biological materials *per se* will free Australia's biotechnology industry to orient itself towards developing exciting new processes, unimpeded by legal costs and impediments due to the many patents over genetic material granted to foreign firms importing products into Australia.

I have noted before, in response to a Question on Notice from Senator Heffernan, that Australian courts have interpreted the introduction of Section 18(2) as implying a Parliamentary intent that *all traditional exclusions* from patentable subject matter be abandoned.[7] It would be useful for Parliament to take the opportunity when debating this Bill to disabuse the courts of this misinterpretation of Parliamentary intent.

As I have previously advised the committee, the views I present are my own and should not be taken to represent the views of any institution or organisation with which I may be associated.

If you require any further information please contact me at

Yours sincerely

Hazel V J Moir

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[6] Chaudhuri, S., (2007), *Is Product Patent Protection Necessary in Developing Countries for Innovation? R&D by Indian Pharmaceutical Companies after TRIPS,* Calcutta: Indian Institute of Management, , , Working paper Series No 614 (September).

[7] For example, the 1994 Federal Court decision to eliminate the exclusion for methods of medical treatment (clearly stated in *Joos v Commissioner of Patents* (1972) 126 CLR 611, 619 (ALRC 2004: 94)) was because "there was no reason in principle" for the exclusion and "Parliament had an opportunity to include an exception in the *Patents Act* when it was re-enacted in 1990, and had chosen not to" (Wilcox, J. cited in ALRC, (2004), *Genes and Ingenuity: Gene Patenting and Human Health* ALRC Report No. 99, (http://www.austlii.edu.au/au/other/alrc/publications/reports/99/, accessed 11 November 2007).: 95).

## Appendix. Who benefits from the current patent system? The data

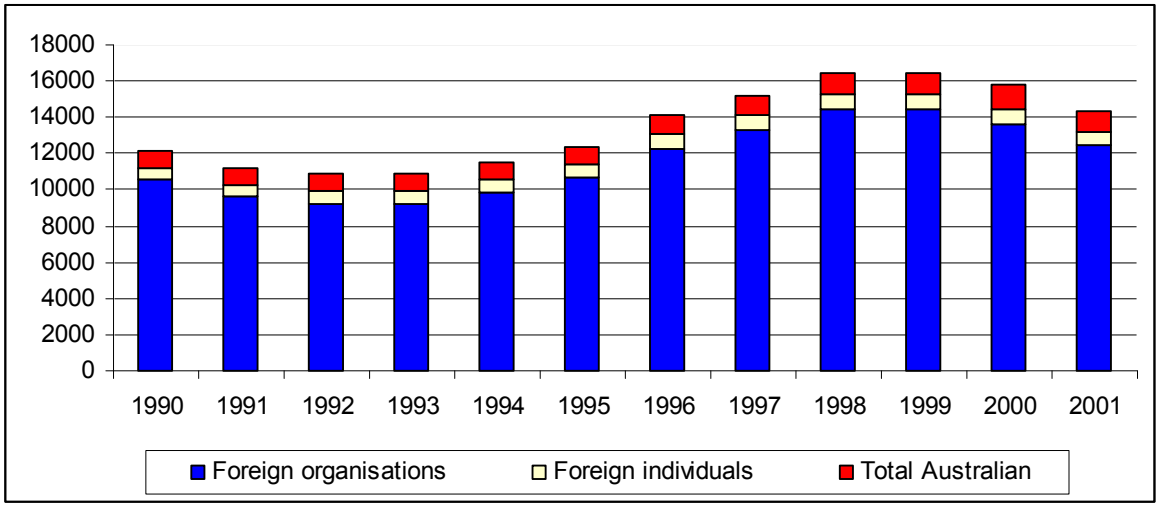
I planned to draw on up-to-date statistics from the IPAustralia website to summarise the current state-of-play for the Committee. Unfortunately, when I accessed the site on 22 February, I found that the longstanding series of very useful tables on patent applications and grants has disappeared. IP Australia appear to have ceased sharing with the public this useful information on the many thousands of monopolies they grant each year. The data below are slightly out-of-date. Nonetheless the overall pattern in the patent statistics is very stable over the years and these data provide striking evidence about the principal beneficiaries of the current patent system.

The data are not as out-of-date as they seem on first impression as it currently takes over 7 years for a cohort of patent applications to be completely processed by IPAustralia. A search of AusPat on 22 February 2011 for applications lodged in calendar year 2001 shows that of the 16,865 which were filed and entered National Phase, 9,898 have been sealed (with a further 8 accepted but not yet sealed), 9 are still pending and two have been refused. Of the remainder 3,692 were granted but have now ceased (probably due to non-payment of renewal fees), 5,590 have lapsed or been withdrawn (ie were never accepted).

The graph below shows the proportion of standard patents granted to Australian companies and individuals from standard applications filed in each year from 1990 to 2001. The percentage of granted standard patents owned by Australian companies or individuals ranges from a low of 6.7 per cent in 1997 to a high of 9.2 per cent in 1992.

Over this period of 12 years, 161,404 standard patent monopolies were granted, of which 148,554 went to foreign-based companies and organisations, 12,850 to foreign-based individuals and 12,665 to Australian organisations and individuals. The latter category of course includes the Australian-registered subsidiaries of firms with headquarters overseas.

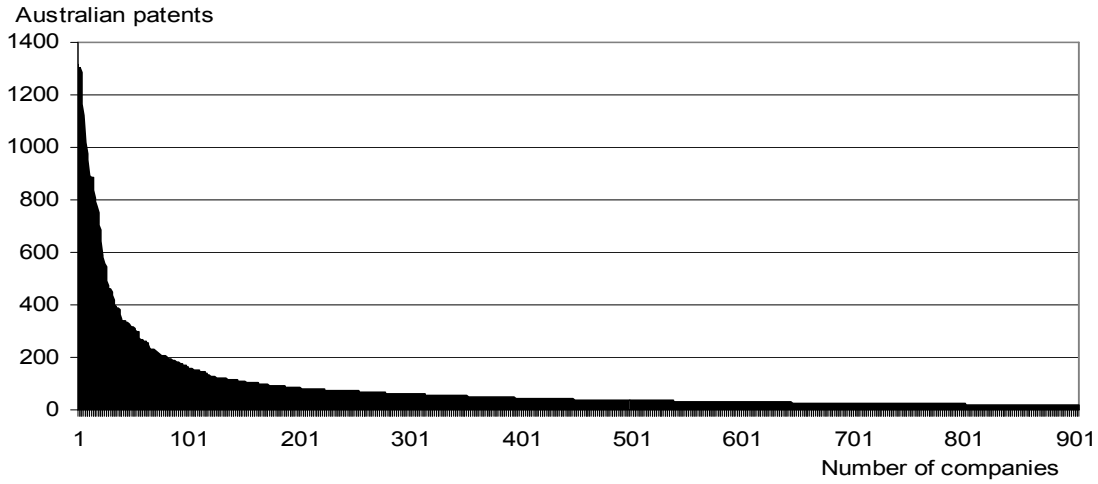
**Figure 1: Standard patent grants: ownership status, by date applications filed.**



The fact that the Australian patent system principally benefits foreign companies is no surprise – this aspect of patent systems has been known for many decades. It is also well known that a small number of countries are the principal beneficiaries of national patent systems throughout the world. The 2009 Report on the administration of the Patent Co-operation Treaty shows that for this large sub-set of global patent applications, 30 per cent of all applications were from the USA, 19 per cent from Japan, 11 per cent from Germany and 5 per cent from each of China and Korea – 70 per cent of the total.[8] If France and the UK are added, the total comes to 78 per cent.

Within these few countries, there is also a high degree of concentration of patent ownership, with just a few companies owning a very large share of all granted patents. For example, in the 1990-2001 period in Australia, 47,024 of the 141,584 standard patents granted to companies were owned by just 100. Of these, **one** has corporate headquarters in Australia – Silverbrook Research Pty Ltd which specialises in high-speed printers. Altogether 908 companies, each owning at least 19 patents filed in this period, together owned 64 per cent of the patents granted. This concentrated distribution is graphically displayed below. Figure 2 excludes the three companies owning most patents,[9] and the very many companies with less than 19 patents – if they were included the graph would be so close to the axes as to be almost invisible.

**Figure 2: Ownership distribution of Australian patents, 1990-2001**



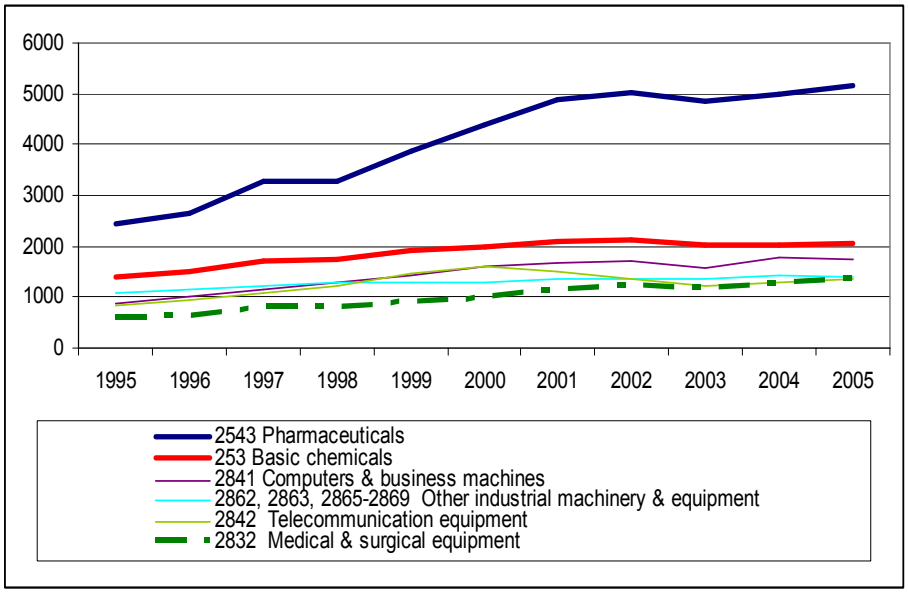

Note: excludes the 3 companies owning most patents (see endnote 3) and the many thousands of companies owning less than 19 patents filed in this period.

IPAustralia used to produce a useful series of statistics on the monopolies they grant, including a graph of the major industries in which patents were being granted. The 2007 version allows the main industries using the patent system to be identified. Of these, three of the top six are chemical or medical (see Figure 3). The biotechnology 'industry' was not identified separately from other chemical and pharmaceutical industries in this table. The very large increase in the volume of pharmaceutical patenting in Australia since the adoption of the TRIPS Treaty is clearly shown.

[8] World Intellectual Property Organisation, PCT: The International Patent System >> Yearly Review, 2009, p.14-15 (http://www.wipo.int/export/sites/www/ipstats/en/statistics/pct/pdf/901e_2009.pdf).

[9] Ericsson owned most (1,858) followed by Hoechst (Sanofi-Aventis) with 1,818 and then Proctor & Gamble with 1,526.

**Figure 3: Top 6 industry classes of Australian patents, 1995-2005 applications**




Source: http://www.ipaustralia.gov.au/pdfs/statistics/P66(mar06)%20Standard%20applications%20by%20Industry%20Codes.xls [accessed 20 February 2007]

Turning to the technology classes in which gene patents and monopolies over fragments of genetic material per se may be being granted, this is identified as International patent Classification Class C12N15. Not all applications in this class will claim genetic material *per se*, though an unknown proportion do.

In the two years since I lodged my first submission to this enquiry, the number of patents ever granted in this class has increased from 14,306 to 15,302 – nearly 500 further monopoly claims each year. This number is vastly greater than the number of significant breakthroughs in biotechnological research being announced – yet another indicator of the very low standard of "inventiveness" required for the grant of a patent monopoly. Data on applications in this class are presented in Table 1 below, together with summary results on the outcomes for each year. Currently some 7,600 granted patents in this class exist in Australia – a mind-boggling number compared to the number of useful medical breakthroughs.

**Table 1 Australian patent applications and grants in Class C12N15: 2003 to 2010**

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 2010 | 215 | 0 | 0 | 2 | 2 | 202 | 15302 | 1% | 0% | 7619 |
| 2009 | 581 | 0 | 0 | 8 | 8 | 540 | 15300 | 1% | 0% | 7617 |
| 2008 | 1035 | 0 | 0 | 54 | 54 | 924 | 15292 | 5% | 0% | 7609 |
| 2007 | 1058 | 1 | 0 | 140 | 141 | 751 | 15238 | 13% | 1% | 7555 |
| 2006 | 972 | 7 | 0 | 174 | 181 | 585 | 15097 | 18% | 4% | 7415 |
| 2005 | 994 | 23 | 0 | 338 | 361 | 374 | 14916 | 34% | 6% | 7241 |
| 2004 | 1098 | 48 | 0 | 516 | 564 | 121 | 14555 | 47% | 9% | 6903 |
| 2003 | 3784 | 117 | 1 | 725 | 843 | 27 | 13991 | 19% | 14% | 6387 |
| 2002 | 4774 | 224 | 1 | 839 | 1064 | | 13148 | 22% | 21% | 5662 |
| 2001 | 5955 | 371 | 1 | 841 | 1213 | | 12084 | 20% | 31% | 4823 |
| 2000 | 4487 | 334 | 1 | 779 | 1114 | | 10871 | 25% | 30% | 3982 |
| | | | | | | | | | | |
| 1995-9 | 12385 | 2434 | 1 | 2399 | 5501 | | 9757 | 44% | 44% | 3203 |
| 1990-4 | 4715 | 1523 | 20 | 792 | 2647 | | 4256 | 56% | 58% | 804 |
| 1985-9 | 1919 | 886 | 266 | 12 | 1323 | | 1609 | 69% | 67% | 12 |
| 1980-4 | 395 | 166 | 110 | 0 | 278 | | 286 | 70% | 60% | 2 |
| 1970s | 8 | 5 | 3 | | 8 | | 8 | 100% | | |
| **Total** | **42,326** | **5,552** | **402** | **8,352** | **14,306** | | | | | |

Source: AusPat, downloaded 12 February 2009. Years 2000-2010 updated 23 February 2011; currently operating grants data updated for all years.