# **Senate Standing Committee on Community Affairs**

## ANSWERS TO QUESTIONS ON NOTICE

Public Hearing of 20 August 2009 Senate Inquiry into gene patents IP Australia

#### Question

Agency: IP Australia

Topic: Senate Inquiry into gene patents

Reference: Hansard, 20 August 2009, extract at CA34 and 35

**Senator HUMPHRIES**—You said that there are in force 202 Australian patents claiming an isolated human nucleic acid molecule. Can we find out a bit about those patents? What would the average age of them be, for example? You might have to take that on notice.

**Ms Press**—Most of those were granted before the publication of the human genome in 2003, so those 202 are the BRCA-style type of gene patent that claim over the normal or wild-type of gene, which is the reference type of gene, which is not associated with the disease phenotype. So it would include that and basically all uses of that gene sequence. So the majority of those had been granted before 2003.

**Senator HUMPHRIES**—Okay. Can you take on notice how many have been granted since 2003 and give us a breakdown of how many in each year since 2003 which claimed an isolated human nucleic acid molecule.

Ms Press—Yes.

### Answer:

The following table provides a breakdown of the patents granted each year from 2003 to 2008, which are currently in force and claim an isolated human nucleic acid molecule.

Year	Patents - granted and current
2003	15
2004	20
2005	19
2006	33
2007	22
2008	15

Source: IP Australia data current as at 3 September 2009

While these patents were granted after 2003, they all had a 'priority date' before publication of the human genome project in April 2003. This is

Priority dates are normally the date of filing an application (or a provisional application if any) in Australia, or the date of the earliest filing in a foreign intellectual property office for the invention (provided there is an equivalent application also filed in Australia within 12 months of that date).

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significant because novelty and inventive step are assessed based on what is known at the priority date.

Information which is not publicly available at the priority date is not taken into consideration in assessments of novelty and inventive step as part of the 'prior art base'. <sup>3</sup>

Priority dates can precede grant dates by many years due to:

- the time lag between filing applications and grant; and,
- divisional applications that take the priority date of the original parent application<sup>4</sup>.

These time lags are typical of patent systems worldwide and due to the many stages leading up to a grant.

IP Australia has used the 14<sup>th</sup> April 2003 as the cut-off date for publication of the human genome project on the basis of a media release (available at <a href="http://www.genome.gov/11006929">http://www.genome.gov/11006929</a>) announcing the project's completion on the 14<sup>th</sup>.

Prior art base refer to the types of information that can be considered in deciding whether an invention meets the requirements of novelty and inventive step.

<sup>&</sup>lt;sup>4</sup> Patent applications are meant to claim protection for only a single invention. Divisional applications allow applicants to elect to file a divisional application where they have claimed more than one invention in the application in certain circumstances.