Senate Standing Committee on Community Affairs
ANSWERS TO QUESTIONS ON NOTICE
Public Hearing of 19 March 2009
Senate Inquiry into gene patents
IP Australia

Nature of Question		**Senator**	**Hansard Reference**
1	Number of patents claiming a human gene sequence	Humphries	CA18
2	Australian Patent for Dravet syndrome	Bilyk	CA21
3	BRCA appeals in Europe	Heffernan	CA25
4	Use of compulsory licensing provisions available under the Patents Act	Boyce	CA25

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Question 1

Agency: IP Australia

Topic: Senate Inquiry into gene patents

Reference: Hansard Page: CA18 on 19 March 2009

Senator Humphries asked:

Do you know how approximately how many human gene patents would be registered worldwide, or could you guess at such a figure?

Answer:

Precise data on the number of granted patents claiming **human gene sequences** is difficult to obtain because there is no specific Patent Classification (international or national) that relates directly to human DNA sequences. [1]

Many early studies overestimate the number of human gene patents because often the analysis is based on the number of relevant patents filed rather than actual number granted. The focus of more recent studies is on granted patents but usually from a national rather than worldwide perspective.

It is estimated that up to the year 2005, 4,270 patents comprising claims associated with a human gene sequence had been granted in the US.[2] A different study indicates that to March 2005 the European Patent Office had granted 774 patents claiming human gene sequences.[3]

IP Australia records indicate that from 1990 to 2008, granted patents that claim a human gene sequence itself number 363. Over the same period 545 patents claiming methods of using a gene sequence and not the gene sequence itself were granted in Australia. The significant difference between the number of patents granted in the US and Australia is likely to be a reflection of more patent fillings in the US due to the size of the US market.

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1 An explanation of the Patent Classification System is provided at page 25 of the Department of Innovation Industry, Science and Research and IP Australia. Submission to the Gene Patent Senate Inquiry, March 2009.

2 Jensen & Murray, "Intellectual Property Landscape of the Human Genome", *Science*, 2005, Vol 310, number 5746, pp 239-240.

3 Science and Technology Policy Research, University of Sussex, UK, "The Patenting of Human DNA: Global Trends in Public and Private Sector Activity" (The PATGEN Project), November 2006 at page 9.

Once granted, not all patents are maintained for the full 20 year term. It is estimated that 30% of patents granted in the US in the 1990s had been abandoned by 2005.[4] Of the 363 granted patents in Australia claiming a human gene sequence itself, 202 remain current.

There is no consensus regarding the number of patents claiming a gene sequence granted worldwide or indeed in Australia. Submissions to the present inquiry suggest that in Australia around 14,000 to 15,000 'gene patents' have been granted.[5,6] These estimates include many biotechnological inventions which do not fall within the definition of gene patent[7], for example patents for methods for isolating DNA. They also include patents that relate to plant and animal gene sequences as well as microbial sequence patents related to the food and brewing technologies rather than human gene sequences.

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4 See The PATGEN Project, November 2006, at page vii.

5 Centre for Governance of Knowledge and Development, Part 2. Submission to the Gene Patent Senate Inquiry, March 2009.

6 Dr Hazel Moir. Submission to the Gene Patent Senate Inquiry, March 2009.

7 Department of Innovation Industry, Science and Research and IP Australia, p6. Submission to the Gene Patent Senate Inquiry, March 2009.

Question 2

Agency: IP Australia

Topic: Senate Inquiry into gene patents

Reference: Hansard Page: CA21 on 19 March 2009

Senator Bilyk asked:

Can you explain to me how it benefits the public to have that sort of patent put in place? I refer specifically to the one I have been reading about – the SCN1A gene with regard to epilepsy and Dravet's Syndrome. Does anyone know anything?

Answer:

Mutations in the SCN1A gene are associated with a number of different epilepsy syndromes. Some mutations are associated with Dravet Syndrome which is also known as severe myoclonic epilepsy of infancy (SMEI), whereas other SCN1A mutations have been identified in children with other types of epilepsy.

A comprehensive analysis of the SCN1A gene might assist a clinician in making an early and definitive diagnosis of the particular epilepsy syndrome afflicting an infant.

Screening for the presence of mutations or abnormalities in the SCN1A gene is complex and requires access to gene sequencing capability. In addition to sequencing, a molecular analysis known as multiplex ligation-dependent probe amplification (MLPA) is often undertaken to determine the presence of structural rearrangements within the SCN1A gene.

IP Australia understands that in Australia, Genetic Technologies Limited offers an accredited and comprehensive SCN1A testing service based on patented methodology licensed from the Australian company, Bionomics Limited.

The Australian patent[1] relates to a method for determining the likelihood or probability that a patient suspected of SMEI does or does not have SMEI. IP Australia granted the patent in April 2006 following comprehensive examination.

[1] Patent AU 2004200978, "A diagnostic method for epilepsy".

The claimed diagnostic method involves identifying an alteration in the SCN1A gene and determining if the alteration is known or not known to be associated with SMEI. In instances where the mutation has not previously been known to be associated with SMEI a further analysis is undertaken to assess the likelihood that the mutation is or is not SMEI related. The patent also claims 24 sequences comprising mutations in the SCN1A gene that have not been previously isolated and associated with SMEI and 5 previously unknown SCN1A mutations that do not give rise to SMEI. The isolated SCN1A gene sequence itself is not claimed by the patent.

Corresponding patent applications are currently being examined by the European Patent Office and the United States Patent Office. [2]

The purpose of the Australian patent system is to benefit Australia by stimulating industrial innovation, and encouraging technology access and transfer. The system rewards inventors with a period of exclusivity to prevent others from exploiting their invention, in return for disclosing their invention to the public. Diffusion of knowledge in the public domain helps to facilitate research in emerging fields of the patented invention. The incentive provided through the patent system is considered essential by innovators to obtaining commercialisation capital to bring therapeutics and diagnostics into medical practice.

[2] Application EP1606418 is before the European Patent Office and application US 2004229257 is before the United States Patent Office.

Question 3

Agency: IP Australia

Topic: Senate Inquiry into gene patents

Reference: Hansard Page: CA25 on 19 March 2009

Senator Heffernan asked:

Detail the appeals process of the BRCA patents in Europe?

Answer:

The European Patent Office Opposition and Appeals Process

The Examining Division of the European Patent Office (EPO) examines patent applications. Where a decision is made to not grant a patent the Applicant may be heard through oral proceedings conducted by the Examining Division. Where the Applicant is not satisfied with the decision of the Examining Division they may appeal to the Technical Board of Appeal (TBA).

European patents granted by the Examining Division of the EPO may be opposed by any person or party or multiple parties, on grounds set down in Article 100 of the European Patent Convention. The Opposition Division of the EPO hears submissions from opponents and decides either that revocation of the patent is warranted or that the granted patent should be maintained as originally filed or in an amended form. Decisions of the Opposition Division can be appealed before the TBA of the EPO.

The TBA have final jurisdiction over the granting and opposition procedures in the EPO. A TBA decision is final and no further challenge to the patent can be made in the EPO context following a decision, although it remains possible to contest patents in national jurisdictions.

The EPO also includes an Enlarged Board of Appeal which usually only considers points of law. Only the TBA or the President of the EPO can refer matters to the Enlarged Board of Appeal.

All opposition and appeal actions relating to the three European BRCA1 patents concluded in November 2008. All three patents resulted in amendments. The decisions are final and no further challenge to the patents is possible at the

European level. However, revocation options are available at the individual national jurisdiction level. IP Australia is not aware of any such actions.

One European granted patent that relates to BRCA2 stands in amended form. In 2007 a related divisional patent application was refused grant by the Examining Division of the EPO. The Applicant has appealed this decision and the matter is yet to be heard in the EPO.

The European BRCA1 patents

Three patents relating to BRCA1 were granted by the EPO during 2001:

- EP 699754, "Method for diagnosing a predisposition for breast and ovarian cancer".
- EP 705902, "17 q-linked breast and ovarian cancer susceptibility gene".
- EP 705903, "Mutations in the 17 q-linked breast and ovarian cancer susceptibility gene".

Various consortia of European research laboratories, researchers, hospitals, scientists and humanitarian organisations opposed the grant of the patents on the basis that they did not meet many of the patentability requirements. Morality and ethical objections were also raised by some opponents.[1]

EP 699754. In 2004 patent EP 699754 was revoked by the Opposition Division and this decision was appealed to the TBA. In November 2008 the TBA decided that the patent was to be reinstated in an amended form. The patent claims now encompass methods for diagnosing a predisposition to breast and ovarian cancer due to frameshift mutations in the sequence of the BRCA1 gene.[2] In its current form the patent does not claim the BRCA1 gene itself.

EP 705902. In 2007, the TBA confirmed the Opposition Division's earlier decision that EP 705902 be maintained in an amended form. The amended patent comprises a claim relating to particular nucleic acid probes and claims to vectors and host cells comprising the nucleic acid probes. Original claims to the BRCA1 gene and protein sequence and diagnostic methods were not allowed on the basis of want of novelty because they were not entitled to the claimed priority

[1] Opposition was based on Article 53(b) EPC (ordre public and morality)

[2] A frameshift mutation in a gene results in a change to the amino acid sequence encoded by the gene.

date.[3] In the earliest priority documents the BRCA1 sequence differed in 15 nucleotides from the BRCA1 sequence in the application as filed. The correct sequence of the BRCA1 gene was submitted to a public database shortly after the earliest priority date and therefore the submission was considered by the TBA to be prejudicial to the novelty of the BRCA1 gene sequence. The TBA did not find that the invention which was subject of the patent contravened public morality or was unethical.

EP 705903. In November 2008, the TBA decided that EP 705903 could be maintained in a broader form than as originally determined by the Examining Division. The claims now cover methods for diagnosing a predisposition for breast and ovarian cancer based on detection of one particular mutation in the BRCA1 gene. Nucleic acid probes comprising the particular mutation are also claimed.

The European BRCA2 patents

Two patent applications relating to BRCA2 have been considered by the EPO:

- EP 785216, “Chromosome 13-linked breast cancer susceptibility gene BRCA2”.
- EP 02006768 “Chromosome 13-linked breast cancer susceptibility gene”.

EP 785216. The grant in January 2003 of patent EP 785216 was opposed by the Belgian Society of Human Genetics and the Institut Curie. Both opponents sought revocation of the patent. Third party observations were also submitted by interested parties including the European Society of Human Genetics. In June 2005, the EPO Opposition Division determined the patent be maintained in amended form. This decision was not appealed to the TBA. The amended patent contains a single claim over the *in vitro* use of the BRCA2 nucleotide sequence comprising a particular mutation, for diagnosing a predisposition to breast cancer in Ashkenazi-Jewish women.

EP 02006768. Patent application EP 02006768 is a divisional application derived from the original application which resulted in the grant of EP 785216.[4] In 2003, the EPO Examining Division raised objections which were subject of oral proceedings in July 2005. Through oral proceedings the Examining Division considered three separate amendment requests put forward by the Applicant and

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[3] An explanation of priority date is provided at page 11 of the Department of Innovation Industry, Science and Research and IP Australia. Submission to the Gene Patent Senate Inquiry, March 2009.

[4] A divisional patent application claims matter first filed in earlier parent application. The divisional application is accorded the same filing date priority from the parent application.

announced its intention to grant a patent based on the amended claims of the third request. Following the receipt of third party submissions on 4 October 2005, the Examining Division withdrew its intention to grant the patent. In October 2006 the Examining Division issued a notice of intention to grant the patent on the basis of the third amendment request submitted by the Applicant.

In February 2007 the Applicant disapproved of the basis of the grant and maintained the first two amendment requests which propose claims that do not restrict the *in vitro* BRCA2 diagnostic method to Ashkenazi-Jewish women. In June 2007 the examining division refused the application. The Applicant has appealed this decision to the TBA. The matter is yet to be heard.

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Question 4

Agency: IP Australia

Topic: Senate Inquiry into gene patents

Reference: Hansard Page: CA25 on 19 March 2009

Senator Boyce asked:

Who (if anyone) has used the compulsory licensing provisions available in the Act, and for what purposes? Have they been used by private companies or by institutions and organisations?

Answer:
IP Australia has only been able to identify three applications for compulsory licences in Australia since 1903; none under the *Patents Act 1903,* two under the *Patents Act 1952* and one under the *Patents Act 1990*.[1] The three cases are:

- *Patents Act 1952*:
  - Fastening Supplies Pty Ltd seeking a compulsory licence from Olin Mathieson Chemical Corporation; and
  - Mr Kenneth Mervyn Lown seeking a compulsory licence from Wissen Pty. Ltd.; and

- *Patents Act 1990*:
  - Amrad Operations Pty. Ltd. seeking a compulsory licence from Genelabs Technologies Inc.

In each case a compulsory licence was sought to enable use of a patentee's invention in order to satisfy perceived unmet "*reasonable requirements of the public*" for the patented invention. No compulsory licenses were granted.

Case 1: *Fastening Supplies Proprietary Limited v Olin Mathieson Chemical Corporation (**1969**) 119 CLR 572*

The first application was made under *Section 108* of the *Patents Act 1952.* Under *Section 108(1)* an interested party may (after the expiration of three years from the date of sealing of a patent) present a petition to the Commissioner of Patents alleging that the '*reasonable requirements of the public'* with respect to

[1] The registries of both the Federal Court of Australia and the High Court of Australia were contacted by IP Australia in preparing this response.

the patented invention have not been satisfied and seek the grant of a compulsory licence. Under *Section 108(2)* of the Act, where the Commissioner of Patents is satisfied that a prima facie case has been made out they must refer the petition to the High Court of Australia or otherwise dismiss the petition.

In this case, a petition was referred to the High Court. The petitioner, Fastening Supplies Pty. Ltd. sought a compulsory licence from the patentee, Olin Mathieson Chemical Corporation on the basis that its licensee, Ramset Fasteners (Aust.), was not meeting the '*reasonable requirements of the public*' for the invention, a captive-bolt gun. Fastening Supplies submitted that a compulsory licence should be granted due to Ramset's difficulty in designing a cost effective captive-bolt gun in Australia. In its decision on December 1968, the High Court found that the '*reasonable requirements of the public*' had not been satisfied. However, in a subsequent judgment on 8 December 1969, it determined that production established by Ramset did meet '*reasonable requirements of the public*' and dismissed the petition for a compulsory licence.

Case 2: *Wissen Pty Ltd v Kenneth Mervyn Lown* (**1987**) 9 IRP 124

The second application was also made under *Section 108* of the *Patents Act 1952*. Kenneth Mervyn Lown submitted a petition to the Commissioner of Patents for a compulsory licence from the patentee Wissen Pty Ltd to manufacture in Australia the invention for preventing birds roosting. The Commissioner of Patents determined that since Wissen Pty Ltd was marketing the invention in Australia a prima facie case of '*reasonable requirements of the public had not been met*' was not made out and dismissed the petition.

Case 3: *Amrad Operations Pty Ltd v Genelabs Technologies Inc and Others* (**1999**) 45 IPR 447.

The third application was made under *Section 133* of the *Patents Act 1990*. Under *Section 133(1)* a person may apply to the Federal Court for an order requiring the patentee to grant the applicant a licence to work the patented invention. Furthermore under *Section 133(2)(a)(ii)* (a similar provision to *Section 108(1)* of the *Patents Act 1952*) the court may make an order if satisfied that, *inter alia*, '*the reasonable requirements of the public with respect to the patented invention have not been satisfied*'.

In this case, the applicant Amrad Operations Pty Ltd applied for an order compelling the patentee, Genelabs Technologies Inc to grant it a licence to manufacture a Hepatitis E Virus diagnostic assay in Australia. As the respondent was incorporated outside Australia, the applicant also applied under Order 8 of the Federal Court Rules 1979 No. 140 (Cwlth) for leave to serve the application

outside Australia in the United States of America. The Court granted leave to the applicant under Order 8 rule 2(2) to serve the application in the United States. However, no judgment was ever made in regard to the compulsory licence. [2]

[2] A further directions hearing was heard on 7 June 2000 followed by another hearing on 5 September 2000, neither of which resulted in a judgment. IP Australia made inquiries about access to the relevant file held by the Victorian Registry of the Federal Court (file VID124/1999, Amrad Operations Pty Ltd v Genelabs Technologies) but did not pursue further as leave of the Court (Order 46 rule 6 of the Federal Court Rules) was necessary for access.