

# Human gene patents: wrong in principle, wrong in practice

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# In Australia, a patented item must be

- **an invention** [but genes are natural chemicals]
- **a manner of manufacture** [but gene in tube = gene from body]
- **novel** [but people have isolated genes for decades]
- **inventive** [but test repeats process of discovery]
- **useful** [but tests are done one patient at a time].

Human genes do **not** meet these requirements.

**Gene patents are wrong in principle**

# IP Australia's submission to Inquiry

- Argues that genes are patentable.
- Corrects a “misunderstanding” about gene patents (p23): “*A patent over a gene sequence does not equate to ownership of that sequence*”.
- Next sentence captures crucial consequence of gene patents: “*A patent is a right to restrain others from using or exploiting the claimed invention without ... permission*”.

i.e. you need permission from a company to access your own genetic code.

- Patent holders may not own your genes, but **they control access to your genes**.
- This is an inappropriate restriction on personal freedom in Australian society.
- If the current patent legislation allows this state of affairs, then it must be changed.

**Gene patents are wrong in principle**

# A monopoly is the legitimate outcome of a gene patent

**Monopolies in medical testing can limit training for lab staff.**

- In 2006, 10 labs in Australia offered BRCA testing (~1,900 patients).
- Each patient requires analysis of 20,000 results. Skills apply to other genes.
- Delivery of these tests is major factor in training of staff.
- Monopolies result in fewer opportunities for training.

**Gene patents are wrong in practice**

# A monopoly is the legitimate outcome of a gene patent

Monopolies in medical testing can **preclude quality assurance.**

- Labs share problems, quality control samples, and solutions.
- Diversity of experience drives quality both informally and formally e.g. external quality assurance programs.
- Limited diversity or sharing = fewer drivers for quality.
- Monopoly labs can make mistakes, but how would they know?

**Gene patents are wrong in practice**

# A monopoly is the legitimate outcome of a gene patent

Monopolies in medical testing can **stop development of better tests.**

- Monopoly lab in US missed mutations in 12% of women tested for familial breast cancer.
- New method (“MLPA”) developed and provided in Europe in defiance of patent identified these mutations.
- Monopoly lab then implemented the new method.

**Gene patents are wrong in practice**

# A monopoly is the legitimate outcome of a gene patent

Monopolies in medical testing can **block access to genetic data.**

- Monopoly lab in the US holds all of the test data (20,000 records per patient) for breast cancer testing.
- Pharmaceutical companies value these data for drug development and testing.
- Monopoly lab decides fate of data.
- Limiting access limits quality assurance for other labs.

**Gene patents are wrong in practice**

# A monopoly is the legitimate outcome of a gene patent

**Monopolies in medical testing can dictate security of healthcare.**

- 60% of genetic labs operate in public sector with comparable funding and governance.
- 45% of tests are provided by 2 or more labs [other tests are for rare disorders] i.e. if one lab stops testing, there is backup.
- But no restriction on whether a monopoly lab can shift monopoly to another provider.
- If a monopoly lab goes under, no backup.

**Gene patents are wrong in practice**

# A monopoly is the legitimate outcome of a gene patent

**Monopolies in medical testing can dictate standards of care.**

- Patent enforcement in British Columbia lead to withdrawal of breast cancer genetic testing.
- Same threat in Australia in 2003 and 2008.
- In the US, the same patent holder encourages non-expert clinicians to request testing.

**Gene patents are wrong in practice**

# A monopoly is the legitimate outcome of a gene patent

**Monopolies in medical testing can **impede research.****

- In US, 20% of senior researchers delay publication of data to allow for patent applications and to protect scientific lead [JAMA 1997]
- 40% of genetic researchers withhold data from publication, usually for patent-related reasons [Acad Med 2006]
- 50% of trainee researchers feel that withholding of data compromises their research and that of their host laboratory [Acad Med 2006].

**Gene patents are wrong in practice**

# If gene patents can cause this...

- **limit training for lab staff**
- **preclude quality assurance**
- **stop development of better tests**
- **block access to genetic data**
- **dictate security of healthcare**
- **limit access to testing**
- **impede research**

**... why are they legitimate?**