



# **Submission to the Senate Inquiry into Gene Patents**

By  
MADGE

MADGE is a network of people interested in food.

PO Box 10  
287 Brunswick St  
Fitzroy, 3065

Email: [info@madge.org.au](mailto:info@madge.org.au)

Website: [www.madge.org.au](http://www.madge.org.au)

## Index

1. Patents .....	3
2. Are the assumptions around patents, productivity and progress correct? .....	3
3. Who benefits from these patents? .....	4
4. What is happening with the patents already granted?.....	5
5. Users of the patented technology and innocent bystanders may be sued .....	6
6. The changing gene definition .....	7
7. Conclusion.....	8
8. References.....	8

# 1. Patents

Should patents have been granted over genes and gene sequences?

“John Barton, professor of law at Stanford University, described intellectual property protections as “a set of statutory exclusion rights.” In other words, the holder of a DNA patent does not own the gene sequence; he or she simply has the right, for a limited period of time, to prevent others from using it.” (1)

Since life, including human life, consists of genes and gene sequences, allowing patents over these calls into question several things:

- Who owns life? Do Patent Offices' actually have the power to pass control to anyone, any company or any other body, the common inheritance of all life?
- What genes belong where? Humans share many of their genes with worms, as well as with animals like chimpanzees. (2)
- Where do we begin and where do other organisms end? All life is interdependent. For example the human body consists of 1 trillion cells. Living on and around it are 10 trillion bacteria cells. Many of those cells live in our guts. Without their help we would be unable to digest food and would starve (3).
- Natural genes cannot be patented but isolated and identified genes can be. Is this distinction irrelevant? Patents confer a legal right to exclude others. This is a very powerful right. It can only be limited by governments deciding to restrain this right by licensing conditions. Governments may decide to limit rights due to the outrage of the general public. These limits to the legal patent rights are very weak and uncertain. Governments do not seem able to easily resist concerted pressure by large companies. Outrage cannot be generated by the general public unless they know and understand the issues. Most people do not know that patents have been granted over genes and gene sequences or what this means. (4)

## 2. Are the assumptions around patents, productivity and progress correct?

In theory patents are granted to encourage innovation and development of new products and processes.

In practice they can limit development of technology and alternatives to it. George Selden filed a patent on the internal combustion engine in the US in 1879. He was the son of a patent attorney. He had worked on developing an internal combustion engine with limited success. Instead he decided to file a technical patent claim that could be used to “extract tribute from others”. (5)

Selden's knowledge of the patent system allowed him to continually extend the deliberations over the validity of his patent. During this time he initiated expensive and draining litigation against small rival companies. This also had the effect of intimidating larger ones too.

The Selden patent inhibited the development of alternatives to the petrol-driven car. To avoid being caught by this patent car groups stopped trying to overturn this patent. Instead they formed a cartel to protect themselves via this patent and remove challengers. Henry Ford went to court over the Selden patent. After years of litigation Ford won on appeal in 1911. The Selden patent limited development and alternatives in this field for 32 years.

This shows that the link between the issue of a patent and the reward for creating a public good is not automatic.

It also shows the dangers where powerful people and companies link up to enforce patents, regardless of their merit. Ford was able to challenge the patent as he was manufacturing and selling cars while the court case proceeded.

Due to the nature of genes and gene processes it is highly unlikely that anyone would be able to mount a similar challenge in the genetic field.

### **3. Who benefits from these patents?**

In 2005 it was estimated that nearly 20% of the human genome had been patented. 63% of these patents were owned by private firms. (6)

Giant agricultural and chemical companies are making sweeping patent claims on plant genes thought to be useful in surviving climate change (7). BASF, Monsanto, Bayer, Syngenta and Du Pont are the main firms. All apart from BASF are part of the top 10 seed companies that now control 57% of the world market in commercial seed (8). They also have pharmaceutical industry subsidiaries and links.

Globally the World Trade Organisation created Trade Related Aspects of Intellectual Property (TRIPS) in 1995. They govern the international enforcement of patents. They were the result of successful lobbying by multinational companies. "Corporations in the rich world are the world's biggest owners of intellectual property. Industrialised countries hold over 97% of patents worldwide, and almost 90% of these are held by large corporations. The WTO's TRIPS agreement is essentially about extending these corporations' rights over the world's foods, medicines, and even our genes." (9)

"TRIPS also allows biotechnology companies to engage in "biopiracy": patenting indigenous knowledge which in many cases has been used for thousands of years, and ignoring millions of years of evolution that preceded the company's "invention". These patents allow a company to "own" the traditional knowledge of indigenous communities for use in developing new products such as medicines. "(9)

## 4. What is happening with the patents already granted?

### BRCA 1 and 2 (10)

Myriad owns the patents on two genes BRCA 1 and 2 that are associated with the development of breast cancer. These patent rights allow them to:

- Have exclusive rights to perform diagnostic testing on these genes
- Prevent any researcher even looking at these genes without first getting permission from Myriad
- Have rights over future mutations discovered on the BRCA2 gene

### Patents filed on beer, baby food and trees (11)

The European Patent Office is granting property rights on plants and seeds which have been conventionally grown. "Besides maize and lettuce, trees, baby food and beer are claimed in the 500 patent applications researched by the No Patents on Life organisation and in roughly 70 patents already issued. The organisations involved are calling for the flood of patents to be stopped by clear political guidelines. Only recently Greenpeace and Misereor filed an opposition to the breeding of pigs at the European Patent Office (EPO)."

The report, "The future of seeds and food under the growing threat of patents and market concentration", gives a comprehensive overview of the scale of the patenting of seed, plants and food in Europe. While patent applications for genetically modified plants have been on the decrease in the last few years, applications for plants that are conventionally grown are now booming. Should this practice be supported in an imminent decision by the EPO's Enlarged Board of Appeal, it is to be expected that farmers will be hugely impeded in their work in breeding in the future..."

### Patent for a pig (12)

Monsanto has applied for patents on a commonly occurring pig gene. If granted it will create rights over every pig and its offspring that has these genes. A documentary on this almost unbelievable patent claim can be viewed on You Tube.

### Limits access to drugs and destroys goodwill (13)

Companies who own patents for treatments for illnesses such as HIV/AIDS, TB and malaria are limiting the use of these generic drugs. This means people are dying because they cannot afford treatment.

Laboratories in developing countries affected by avian flu gave viral material to the World Health Organisation (WHO). They did this for the public good. This viral material was passed to private companies who took out patents and profited from this.

### Limits ability to challenge agronomic and scientific claims

#### ***Crop yields***

GM crop trials cannot go ahead without the agreement of the patent holder of the seed. This inhibits independent trials. For example the ex-WA State Premier wanted GM canola trials to go ahead to test agronomic performance. The patent holder decided not to supply seed for the

trials stating that the hostility of the State Government was to blame (14). Surely this is irrelevant.

The new WA State Government now supports the introduction of GM crops. GM canola trials will go ahead across the state (15). These trials are far larger than are required and no details have been given of how their performance will be monitored. Since GM canola is highly likely to cause widespread contamination it is feared that these trials will really be a contamination and commercialisation by stealth.

Interestingly trials conducted in the Eastern States showed that, contrary to claims, GM canola yielded less than non-GM canola. (16) A recent report "Failure to yield" reports on two dozen academic papers studying the yields of GM soy and corn. (17) It finds that conventional breeding is responsible for the vast majority of yield increase. GM crops mainly yield the same, or less than non-GM crops.

### ***Health testing***

Previously the WA Carpenter government commissioned a research group to investigate the health effects of GM. (18) This was done since there are scientific doubts about the adequacy of the tests done to date on GM foods. (19)

Since the food is patented permission is needed to test it. One company ignored the request for samples for experimentation. Others refused unless the researchers agreed to prohibitive conditions that undermined the research. (20)

## **5. Users of the patented technology and innocent bystanders may be sued**

"The contract between biotechnology firm Monsanto and GM canola growers bars farmers from selling their land to anyone without a Monsanto licensing agreement.....The contract, obtained by The Canberra Times, shows that if the land is sold up to two years after the agreement expires, contractual obligations are passed to the buyer, who could be liable for the former owner's contract breaches." (21)

Moe Parr, a seed cleaner from the US was sued by Monsanto (22). Seed is cleaned so that farmers can replant the seed they have grown. Monsanto contended that Parr was assisting farmers to break their patent by cleaning their GM seed. Parr's argument was that he had no idea if seed he was cleaning was GM or not. Since he did not have a direct contract with Monsanto Parr claimed he was not guilty of anything. Although advised that his case was strong he decided to settle as he did not have the money to run the court case. His business dropped by 90% and he now calls himself a patent enforcer for Monsanto.

There are many cases of farmers and others in rural America being sued by biotech companies. Vanity Fair wrote an article called "Monsanto's Harvest of Fear" that detailed the actions being taken by the company. (23) "As interviews and reams of court documents reveal, Monsanto relies on a shadowy army of private investigators and agents in the American heartland to strike fear into farm country. They fan out into fields and farm towns, where they secretly videotape and photograph farmers, store owners, and co-ops; infiltrate community meetings; and gather information from informants about farming activities.

Farmers say that some Monsanto agents pretend to be surveyors. Others confront farmers on their land and try to pressure them to sign papers giving Monsanto access to their private records. Farmers call them the “seed police” and use words such as “Gestapo” and “Mafia” to describe their tactics.”

## **6. The changing gene definition**

The first gene patent was granted in 1980. (24)

At that time it was assumed that each gene produced a protein. Then in 2003 the Human Genome project showed that this idea was wrong. In 2007, ENCODE, the 4 year investigation by 300 scientists into the genome, found that genes are not neatly identifiable items. “To their surprise, researchers found that the human genome might not be a “tidy collection of independent genes” after all, with each sequence of DNA linked to a single function, such as a predisposition to diabetes or heart disease.

Instead, genes appear to operate in a complex network, and interact and overlap with one another and with other components in ways not yet fully understood. According to the institute, these findings will challenge scientists “to rethink some long-held views about what genes are and what they do.” .....(25)

“In the context of the consortium’s findings, this definition now raises some fundamental questions about the defensibility of those patents.

If genes are only one component of how a genome functions, for example, will infringement claims be subject to dispute when another crucial component of the network is claimed by someone else? Might owners of gene patents also find themselves liable for unintended collateral damage caused by the network effects of the genes they own?

And, just as important, will these not-yet-understood components of gene function tarnish the appeal of the market for biotech investors, who prefer their intellectual property claims to be unambiguous and indisputable?” (25)

The picture has become more complex since the recent discovery of epigenetics. Researchers found that detrimental genes could be turned off if the mothers’ diet was high in beneficial compounds.(26) The genes were still inherited, they were just not expressed. It has since been discovered that genes are in constant conversation with the environment. Food, environmental quality, exercise and maternal treatment of their offspring can turn on and off genes. The effects of this can be inherited and passed for several generations.

This means that in future health problems may be able to be avoided, cured or alleviated by diet, exercise or other interventions. It may be that the use of pharmaceuticals will be a last resort for health rather than the first option for treatment.

Improvements in scientific understanding mean that neither genes nor what they do are simple, stable, industrial type items that can be easily patented. If no one understands how the gene functions or what other genes it is linked to or what it produces then what exactly is the patent for?

## 7. Conclusion

Currently the patenting of genes appears to be allowed because:

1. It confers a financial advantage for companies large enough to patent and defend the patent and to monopolise control over a naturally occurring area.
2. The current view of how the global economic system works supports this type of exploitation. The WTO and the TRIPS agreement have enormous power to enforce patents.
3. To challenge the patenting of genes and gene sequences is too expensive and overwhelming for any ordinary person, company or even most governments to contemplate.

Should the existing system of genes and gene patents constructed both by patent law and by TRIPS, enforced by the WTO, be continued?

It appears that:

- The whole basis of the patenting of genes and gene sequences is a scientific nonsense.
- The patents granted to date are causing damage to the public good and human rights abuses.
- It appears to be an abuse of power for Patent Offices, the WTO and multinational companies to grant and control exclusionary powers over the common inheritance of all life.

Therefore patents over genes and gene sequences should be scrapped.

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