

# SENATE COMMUNITY AFFAIRS ENQUIRY INTO GENE PATENTS

## Press Conference Briefing Document

*Imagine a world where the BRCA breast cancer diagnostic test was simply never developed and women were ignorant of the fact that they could have advance warning of their predisposition to the development of an aggressive form of breast and ovarian cancer. This is the likely outcome if the companies prepared to take the risk and invest the hundreds of millions of dollars required to bring a diagnostic or treatment to the market are not provided with a patent monopoly to enable them to recoup this investment and generate the profit which is invested into the next great finding. Without this investment, University research findings can never leave the laboratory. Imagine a world without Gardasil...*

In recent months there has occurred significant debate in relation to the issue of patenting “genes”. This debate has led to a Senate enquiry which is currently underway. The terms of reference of this enquiry are stated to be directed to:

“the impact of the granting of patents in Australia over human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form...”

This debate, and the subsequent Senate enquiry, was triggered by Genetic Technologies Limited (GTG) announcing that it proposed to control BRCA breast cancer screening test in Australia. This test is the subject of granted patents which are owned by Myriad Genetics Inc and its University partners. Myriad has licenced the Australian rights to this technology to GTG.

IPTA is very concerned about the significant level of misinformation which has been circulating in relation to this issue and it is seeking to place into perspective the matters which are under discussion. These matters are as follows:

### **(i) Patent Monopoly**

- A patent is a temporary monopoly which provides the owner of the patent a limited time period within which to exclude others from performing the technology covered by the patent.
- Although a 20 year monopoly may sound lengthy, it should be noted that patent applications are filed very early in a research program. It can take a further 10-15 years to bring a treatment or diagnostic to market. By the time the public is given access to such a development, there is often only a few years left on the patent. Once the patent has expired, the technology is available for any other party to exploit.

### **(ii) Discovery vs. invention**

A view has been expressed that allowing patenting of genes and proteins is equivalent to allowing a third party to own a part of your body. Still further, it has been stated that genes are a product of nature and thereby belong to humanity. Further views have been expressed that the identification of new genes and proteins is a matter of routine procedure and that identifying these molecules is therefore a mere discovery, much like discovering a new mineral.

IPTAs comments in relation to this issue are as follows:

- There seems to exist significant misunderstanding in relation to the issue of what amounts to a “gene”. A gene is made of DNA, exists in a chromosome and is inherited. It provides the means for a cell to produce a specific protein.
  - A gene comprises both protein coding and non-coding DNA regions. These molecules are therefore inherently very large. The molecules that researchers generally work with in the laboratory are usually DNA which is assembled such that it contains only the coding region and not the non-coding region. This molecule, often termed ‘copy DNA’, is therefore not a “gene” and has no natural form of existence in the human body. Proteins can be generated from either the gene in its full form or the cDNA.
  - In terms of isolated DNA and protein molecules, the purification of these molecules from the human body is generally not a feasible method for sourcing such molecules. Rather, once the structure of a molecule has been elucidated, DNA and protein molecules can be artificially produced in the laboratory. Often, the form of molecule produced in the laboratory is not identical to the naturally occurring form.
- The mere identification of the existence of a new gene or protein in the human body is not sufficient to secure a patent. It is the act of isolating that molecule and/or artificially reproducing that molecule in the laboratory and developing a use of the molecule that leads to the existence of an invention. The isolated molecule or artificially generated molecule and its use is the subject of the patent. The patent law does not allow the patent owner to have any rights in relation to these molecules while in the body.
- The issue of whether the technology required to isolate or to artificially reproduce a gene or protein is complex, or not, is irrelevant. The issue of patentability is governed by whether or not an invention is sufficiently new and useful, rather than the sophistication of the technology used to arrive at the invention.

### **(iii) Does the patent system stifle research?**

A view has been expressed that allowing the patenting of genes and protein molecules will inhibit research since a licence is required to use these molecules and this will “lock up” these technologies. It has also been stated that imposing payment of licence fees on research institutes increases research costs, that this contrary to the ethos of scientific innovation and that excluding genes and proteins from patentability is the best way to ensure that medical research is not compromised.

IPTAs comments in relation to this issue are as follows:

- There is no empirical evidence that research activity has been inhibited in Australia because of the existence of patents. Gene and protein patents are only a small proportion of the totality of technology patents which exist and which are used by laboratories. In a US analysis less than 1% of US scientists reported that their research activity had been impeded by patents. In their submission to the Senate enquiry, The Walter and Eliza Hall Institute of Medical Research indicated it has not experienced any patent-related difficulties in relation to performing its research.

- Universities and other public research institutes are not the sole bastions of research. High level research is performed in companies. However, scientists working in a company are often subject to confidentiality obligations. In the absence of patent protection, companies would likely maintain their research as a secret in order to protect the “edge” which they may have over rival companies. The patenting process, however, requires publication of the invention to occur 18 months after filing the application and limits the patent monopoly to 20 years. Keeping an invention secret is potentially indefinite.
- Government research grants are inadequate to support anything more than basic research/proof of principle and does not support further development such as product development and clinical trials. Accordingly:
  - (i) Licencing income is vital to research institutes. All research institutes are themselves owners of broad ranging patent portfolios which include patents across all technologies and from which they derive income.
  - (ii) Corporate money is also vital to institute-based research. Companies commonly have in place programs which provide money to laboratories to perform research. The provision of this money is, however, usually conditional on the recipient institute agreeing that any research generated is assessed in terms of whether it has commercial potential and is patentable. In the absence of agreement to this by the institutes these corporations would not invest this money into the research programs.

## Solution

- Up until 2004 it was generally believed that the Australian law provided an exemption from infringement for individuals whose use of an invention occurred in the context of non-commercial research. In 2004 an enquiry held that under a correct interpretation of the law no such research use exemption did truly exist. It was therefore proposed that such an exemption should be introduced to the law to clarify the situation. IP Australia is currently moving this proposal forward.
- Medical research is bigger than just gene and protein patents. If stifling research is a real problem, then this problem exists across all technologies and should be dealt with unilaterally. The most appropriate way to deal with this issue is to introduce a research use exemption into the law. This will then provide a research use exemption which benefits all and is not limited according to any particular technology.

### (iv) Is a patent risking public health and does it drive up costs?

A view has been expressed that the existence of patents increases the cost of products, such as genetic tests, which would benefit public healthcare. This increased cost is allegedly due to the patent monopoly eliminating competition. It also allegedly decreases the incentive for others to develop better and more affordable tests. Patents are therefore argued to reduce public access to beneficial technology, thereby creating a potential public health crisis. A particularly concerning view is that a patentee could refuse to make a test available to the public at all and that the current legal framework could not protect the community. Finally, it has been alleged that the BRCA test is free in Australia due to GTG now not enforcing its patent rights but that this test costs women in the United States \$3,000 due to the fact that the US patent rights are enforced.

IPTAs comments in relation to this issue are as follows:

- The BRCA test is not “free” in Australia and never could be. Although GTG may not be receiving a royalty from the tests performed by others in this country, the test is still charged for by its providers and it is paid for by the Australian government. Accordingly, the difference between the Australian system and the US system is that the Australian government subsidises payment of the cost of the test whereas in the US this does not occur.
- The licence fee is usually only one component of the cost of a given test. A submission to the current Senate enquiry notes that the cost of the BRCA test will come down once the cost of DNA sequencing is reduced. The cost of performing DNA sequencing is unrelated to the issue of the existence of the BRCA patents, as is the purchase of the other reagents which are required in order to perform the test.
- The existence of patents does not eliminate competition and decrease the incentive to find better and more affordable tests. Rather, the patent system encourages such research since any improvement on a test or technology may itself be patentable and enables a new party to secure a position in the market. This is a huge incentive to develop improved second generation tests.
- The discussion in relation to payment of licence fees seems to be quite vigorous. However, there appears to be no objection to purchasing products, for performing diagnostic tests or for therapeutics (e.g. chemotherapy drugs or antiviral drugs), off the shelf. These kits and reagents, where they are patented, include built in licence fees. Surgical instruments and other medical devices are also often the subject of patents and licence fees are built in at the point of purchase.

### **Solution**

- The legal framework as it exists in Australia does protect the community by providing for Crown use of an invention. Where it is necessary for the public good, such as if a patentee was to refuse to make a test available to the public, the government has the legal right to step in and access the technology irrespective of the wishes of the patentee. Accordingly, the patentee does not have the power to unilaterally prevent a necessary test or therapeutic being made available to the public. At the time that GTG had been indicating that it sought to assert its rights in relation to the BRCA tests, there was suggestion in the media that the government was considering the possibility of exercising this right in order to ensure that access to this test was maintained for the women in Australia.
- Where a patentee is not meeting the reasonable requirements of the public and refuses to make technology available on reasonable licencing terms, the law allows a third party to seek a compulsory licence. Such a licence, where granted, will force the patentee to grant a licence on reasonable terms.
- The problem with access to diagnostic tests and therapeutics, if one exists, is not limited only to technologies which involve genes or proteins. It may apply equally to other areas of biotechnology. The introduction of a PBS type system to keep costs down, as has worked well with the pharmaceutical industry (where many pharmaceutical drugs are the subject of patents), could potentially alleviate any such costs based problem.

A ban on patenting genes and proteins would not impact on the existence of the rights which exist in relation to the BRCA test. Since the BRCA test does not involve the use of a gene or protein, but is directed only to screening for the existence of a particular mutation, a ban on patents to genes and proteins would not affect ownership of a method of screening for a specific mutation. The solution to alleviating any perception of the existence of monopolies or high costs therefore cannot be dealt with by trying to specify what subject matter can or cannot be patented. Rather, the issue should be dealt with across all technologies by ensuring that the current protections which exist, being the existence of Crown use provisions and compulsory licence provisions, are maintained and exercised where necessary.

**(v) Who will invest in developing research findings into a product and bringing that product to market?**

IPTA would like to bring the following points to the media's attention:

- It costs hundreds of millions of dollars to bring a drug or diagnostic, such as the BRCA test, to market. The fact that there is huge expense in making these products available to the public is not linked to the patent system. It is the regulatory system which governments all around the world have put in place, to protect the public, which causes these costs. These tests take the form of clinical trials which occur subsequently to the completion of the basic research. They are extremely costly to run. In the absence of stringent regulatory requirements, events like the Thalidomide disaster of the 1960's can occur.
- Governments are not in the business of bringing products to market and never will be. Governments provide relatively small amounts of money, in the amount of tens or hundreds of thousands of dollars per project, in order to enable basic research. Governments rely on the corporate sector to invest the many millions of dollars which are required, per project, to bring diagnostics and therapeutics to market.
- Without the existence of a patent monopoly, no company will take the risk of investing millions of dollars to bring a product to market. These companies rely on the fact that although not all their leads will make it to market, where one does make it to market, the patent will enable costs to be recouped and profit to be generated. If these companies do not achieve a return on their investment, their research investment will cease.
- If companies cease to invest in clinical trials, medicines and diagnostic tests will not come to market and the public will suffer.

**(vi) International obligations**

Under TRIPS and, for example, the Australia/US free trade agreement, there exist obligations that a patent system is made available for inventions across all technologies. Australia is a party to these treaties. There has been a suggestion made that Australia should disregard these obligations, on the ground that Europe and the US differ to Australia due to their huge biotechnology sectors. In the first place, we would hope that Australia equally regards itself as a significant player in the biotechnology sector. Even if it does not, this is not a sufficient reason to ignore international obligations to which this country is committed.

## (vii) General Issues

- There has been a view expressed that “private companies should not make profits from Australian publicly funded research”. This criticism was directed to GTG by Senator Heffernan and Dr. Palombi. However, the BRCA developments, although stemming from basic research out of the University of Pennsylvania were funded by US private investment to take them from the initial laboratory finding to the market – an investment of millions of dollars. The current situation is, in fact, that Australian laboratories are making a profit from a US corporate investment.
- Dr. Palombi, who has been advising Senator Heffernan and Cancer Council Australia, has expressed the idealistic view that public money should not lead to private profit. However, this is an unrealistic view. Public funding of research is minimal. Many projects are funded from more than one source, with some of these sources invariably being commercial sources. Once proof of concept has been achieved, progress through the clinical trial phase in order to achieve registration is funded by commercial entities not governments. When one objectively views the contribution of government funding to a product which has reached the market, it is minimal. It is not reasonable to expect that investment made by third party commercial entities should not be recouped.
- There is a perception of risk which has never really played out. The ALRC has acknowledged that there is not much actual evidence of a problem. Rather, the same few names (e.g. GTG) come up time and again.

## Conclusion

Public discussion to date has focussed on the issue of patenting genes and proteins. However, Cancer Council Australia has in fact proposed an amendment to the Patents Act which would exclude from patentability all biological materials (not just genes and proteins). The commentary accompanying this proposal has also suggested that all “use of these materials in conventional, routine and standard methods and technologies” should not be patentable. This is a far more extreme proposal than that currently under discussion and would essentially ban all patents in relation to any cellular, protein or nucleic acid based material irrespective of its source, whether or not it can even be found in nature in that form.

By preventing patenting of all such materials and “use of these materials in conventional, routine and standard methods and technologies”, this would arguably effectively prevent patents in respect of almost all medical and biological research and would likely result in the withdrawal of investment by the corporate sector. In the absence of this source of funding, the consequence may be that the issue is not one of whether or not a test exists, the cost of that test or issues of monopolistic behaviour but the fact that the test may simply never be developed. In the absence of the investment of millions of dollars by Myriad, the BRCA test may not have been brought to market. Rather, the finding in relation to the link between the BRCA mutation and the onset of breast and ovarian cancer may have been relegated to the realms of an archived journal article and would have proceeded no further. However, Myriad and Eli Lilly were prepared to make the investment and take the risk of failure to take proof of principal all the way through to a product which was made available to the general public. Imagine a world where the BRCA test was simply never developed and women were ignorant of the fact that they could have advance warning of their predisposition to the development of a very aggressive form of breast and ovarian cancer.