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Senate Community Affairs Committee Inquiry into Gene Patents

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Disclosure

This submission has been prepared by Pfizer Australia—a wholly owned subsidiary of Pfizer Inc., based in New York. Pfizer Australia is this country's largest manufacturer of prescription medicines. We produce 452 products, with sales exceeding $1.2 billion and exports worth $835 million a year. We employ 1,200 people around Australia. In 2008, we invested approximately $50 million in Australian R&D.

The bulk of our medicines are reimbursed by the Australian Government through the Pharmaceutical Benefits Scheme (PBS).

Pfizer Australia is a member of Medicines Australia—the peak industry body for the innovative medicines industry in Australia.

Pfizer Inc. has five licensees for gene patents in Australia. We own no gene patents in Australia.

Our interest

Pfizer is one of the world's largest developers of pharmaceutical and veterinary products.

In these fields, genetics plays an increasing role. Worldwide, there are over 300 pharmaceutical products that use gene technology and, we understand, there are at least this many again in development.

Our reason for preparing this submission is to urge the Australian Government to retain and strengthen this country's intellectual property environment, so that it balances the need to:

- create incentives to use genetic discoveries and create new medicines (as well as repay the investment of time and resources) and
- ensure that the products developed using genetic material benefit the Australian people.

Summary

We do not believe that there are fundamental problems with Australia's patents system covering gene technology. Although there have been a small number of high-profile cases concerning gene patents, these need to be balanced against the large number of cases where patents are working as they are intended to – creating incentives to harness knowledge of genetic science and improve human health. Our advice to the Senate Committee is that Australia's patent laws – and IP Australia – work well for the Australian community, the research community, and for investors.

As knowledge of genetics has grown – particularly with the publication of the Human Genome in 2001 – the number of patents on individual genes has dropped sharply. This is because the threshold for 'novelty' and 'inventiveness' at the heart of the patent system is now very much higher than it was when the first gene patents were issued. Also, as patent offices worldwide have gained experience with genetic technologies, the patents now granted are much more specific than the early gene patents, and they are increasingly granted to biotechnologies rather than on isolated genes themselves. Since the patent term

is 20 years from the date when the priority application is filed, many of the early, broad patents are nearing the end of their patent life.

As licensees of various gene patents, we do not believe that the existence of gene patents creates a barrier to the research and development of new medicines or healthcare treatments. Indeed, the patent system creates the certainty and incentives needed to invest the resources that are required to create new medicines. We firmly believe that the patent system balances community and individual interests: creating a system that achieves public good through private activity.

Investment by pharmaceutical companies in research is premised on strong protection of intellectual property. Weakening of this protection could have a significant impact on international investment in Australian research. In 2006-07, the pharmaceutical industry alone invested $540 million in R&D; by contrast, the entire NHMRC budget for the same year was $712 million.

A ban on patents for "microbial genes, … proteins and their derivatives" suggested in the Senate Committee's terms of references could have a particularly damaging effect on Australia's biotechnology industry, as microbial genes are at the heart of all genetic technologies. Banning patents on derivatives could see the withdrawal of some medicines from Australia. All insulin used in Australia, for example, is based on recombinant gene technology.

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Twenty years of gene patents

The most far-reaching of the Inquiry's three questions is "whether the *Patents Act 1990* should be amended so as to expressly prohibit the grant of patent monopolies over [human and microbial genes and non-coding sequences, proteins, and their derivatives]".

In many ways, the time for asking "should patents be permitted on genes?" has now passed. Gene patents have been a fact in research, industry and intellectual property law worldwide for nearly twenty years. Furthermore, genetic patent law and its practice have evolved in these twenty years.

We do recognise that, early in the development of patent law in this area, there were some broad patents granted – and these have created persistent fears about gene patents ever since. However, we would remind the Senate Committee that the term of a patent is twenty years from the date the patent application is filed and, therefore, many of these early patents are at the point of expiry.

Research in genetic science has also advanced enormously in these last twenty years. Gene technology has now become commonplace in research institutes, biotechnology companies, pathology laboratories and hospitals. This means that the baseline of knowledge about genes in the public domain is significantly higher than it was twenty years ago. Consequently, new applications for gene patents have to meet substantially higher standards of 'novelty' and 'inventiveness' than the early gene patents. The practical result is that the number of new gene patents has been falling over the last decade – particularly since the publication of the Human Genome in 2001.

Another result of the growing knowledge of gene technology is that, as both applicants and patent authorities have learnt more about effective gene patents, newer patents have become much more defined and specific.

Myriad Genetics, and the BRCA1 and BRCA2 tests

A good example of how the scope of patents on genetic material has have become narrower is the history of the BCRA1 and BCRA2 gene patents.

(Before we outline our understanding of this case, we want to note that Pfizer is not a party to any disputes involving Myriad, the University of Utah Research Foundation, Genetic Technologies Limited, or any of those European organisations that have challenged the BRCA patents. We report the following as observers, not as participants. The following comments are not intended to judge the rights or wrongs of the case, but rather to illustrate progress in regulation around genetic material.)

In 1994, Myriad Genetics first patented the gene BCRA1, and, in 2000, patented a second gene BCRA2 (It subsequently licensed them to the University of Utah Research Foundation in the USA and Genetic Technologies in Australia.) Mutated versions of these two genes were known to be present in 5-10% of women who develop breast cancer. Myriad's patents

also covered the BRCA1 protein, as well as a test (known commercially as BRCAnalysis) to identify the genes and variations in them.

BRCAnalysis was not the only test for these genes. European laboratories developed a number of other assays, and these were reported in the medical literature to be just as effective as the BRCAnalysis. They became widely used in Europe.

In response to the use of these other diagnostic tests, Myriad asserted its patent rights over the isolated gene, and also required that: (1) all tests for the two genes be conducted using BRCAnalysis, and (2) that all testing be conducted in Utah. (We understand that the reason for the second requirement was that Myriad Genetics and the University of Utah Research Foundation had the goal of developing an exclusive global database on breast cancer.)

Researchers and clinicians became concerned that, if Myriad's patents were upheld, the result would be sole control over the isolated gene, and a stifling of research – and that, potentially, women with the genes might go undiagnosed. We believe it is similar concerns that lie behind the third of the Senate Committee's terms of reference.

We would urge the Senate Committee to explore in detail the subsequent history of Myriad's patents in Europe, and seek expert advice on them. Since 2001, there has been a significant narrowing of its patent scope. Furthermore, this was achieved through the application of European patent law – not a change in the law, as is suggested in the Senate Committee's terms of reference.

What follows is necessarily a summary of a complicated series of challenges, but detailed information is available from the European Patent Office (EPO) website[1].

In 2002, nine European groups – including the Government of the Netherlands, French and Belgian research organisations, and the Swiss Social Democratic Party – filed an objection to the Myriad patents with the EPO. As a result, the EPO revoked Myriad's patents, and also rejected a subsequent appeal by Myriad.

In 2005, the EPO granted a new, severely-restricted patent to Myriad, limited to a specified gene probe, and which no longer included the BCRA1 gene, or the earlier diagnostic and therapeutic methods. The new patent was limited to very specific mutated sequences of the gene – and so allowed researchers and clinicians to test for other mutations to the BCRA genes outside the scope of Myriad's patent and without using either BCRAnalysis or Myriad's laboratories.

In 2007, Myriad lost an appeal on the revocation of its earlier patent, and the EPO upheld the much more limited 2005 patent.

The point that we want to draw attention to is that restrictions on the patents were achieved through normal patent office and legal processes – there was no need to change European patent law. Even with the new, restricted patents in place, hospitals and universities are still able to conduct cancer research into the BRCA gene, and cancer specialists have access a range of diagnostic tests to check for the BRCA genes. In short: we do not believe that the international system for patenting genetic

[1] http://www.epo.org/index.html. The relevant patents are EP 699754 and EP 705903. The most recent EPO press releases on the issue are at http://www.epo.org/about-us/press/releases/archive/2008/20081119.html

materials or technologies is fundamentally broken. There is no need for wholesale banning of gene patents. And we believe that problems in individual patents can be resolved through normal patent office processes.

BRCA1/BRCA2 patents and Australia

In Australia, the BRCA gene patent has been held by Genetic Technologies Limited (GTL) since 2002. While GTL initially allowed Australian public laboratories to use the patents for free, in July last year, it changed its position and announced that it intended to enforce its patent rights. The major complaints that we have seen about this are: (1) the cost of the GTL test; (2) the requirement that all BRCA tests had to be processed in Melbourne, and the consequent cessation of testing in other cities; and (3) the potential loss of access to research data. Without judging the merits of this case, we want to note that **the fact of holding a patent on genetic material is unrelated to either the fees charged for use of the patent or where the tests are conducted** – these are marketing decisions, not patent law in action. As the European experience shows, the fact that a gene patent is involved in this dispute does not imply that the fundamental problem is the patenting of either genes or genetic tests. (We would also note that Genetic Technologies replaced most of its Board on 19 November 2008, and the next day launched a review of its BRCA decision. On 2 December 2008, the company reverted to its earlier position of allowing other laboratories free use of its BRCA patents in Australia. The net result for clinicians, patients and researchers was that their concerns were all addressed through business means, and without the revocation of the patent.)

We want to stress that, **a business decision by a single patent holder should not be interpreted to mean that Australia's entire gene patent system is fundamentally flawed**. We urge the Senate Committee to consider the many other patents on genetic material and technology that are at work in Australia, which have not limited research or access to healthcare.

The role of patent offices

At the level of practice, the strength of patent law depends in large part in the experience and judgement of the patent assessors – and, in the case of gene technologies over the last 20 years, this has developed substantially. In this respect, **Australia has been well-served by IP Australia**. We strongly believe that, where researchers, clinicians and institutions have concerns about gene patents in Australia, the proper first response should be to work with IP Australia within the framework of Australia's robust patent system.

Researchers and clinicians also need to better understand how the patent system works. We know that IP Australia has conducted educational programs, and we hope that they will continue to do so.

Also, we hope that IP Australia continue to liaise with other patent offices around the world. Australia needs to have consistency with practices in other countries around the world, as well as a detailed understanding of new developments.

The ethical dimension

We appreciate that many see a strong ethical dimension to all aspects of genetics – and therefore, people have strong feelings on the subject. Ethical debate is vital in medical research. However, there have been a number of arguments put forward about gene patents under the title of 'ethical concerns' which simply confuse the issue or delay decision-making.

We want to distinguish between two main lines of argument.

The first is an older group of questions, dating from when the notion of gene patents first arose twenty years ago. They are concerned effectively with the question "should genes be patented?". A typical argument runs something like: "our genetic material is integral to who we are as individuals, and therefore patenting our genetic material is a violation of who we are as individuals or our identity." The problem with this argument is, although genes are certainly an essential part of our biological make-up, they are not an essential part of our identity – of our sense of ourselves as individuals. When the Human Genome project published its results in 2001, people around the world did not fundamentally change their identity. Similarly, people had well-formed identities before the discovery of the structure and function of DNA in 1953. In short, knowledge of genetic science is not actually a part of people's individuality or identity – and, therefore, the patenting of individual genes does not violate their individuality or identity. Such arguments – and the responses to them – were made two decades ago. Although they continue to be made, the time when they could have substantially influenced the direction of international genetic science and law has now passed.

What is much more relevant to both the current Senate Inquiry, and to the development of genetic technology, are arguments of a second type, which remain current. An example is: "genetic heritage is part of the common inheritance of all humankind, and therefore patenting a gene is effectively the privatisation of what should, in fact, be common." This is a broad question, and here we want to address just one portion of it, concerned with the development of new medicines.

To address this, we would take one step back, and pose the question: why is this genetic material important in the first place? The answer is: Researchers have discovered features in the genetic code that affect human health. With this knowledge, it is possible to develop tests and medicines to treat disease. Having the potential to cure disease then poses a new question: "what is the best way to harness this knowledge in order to benefit human health?" Answering this question has to acknowledge the basic economics of creating medicines: the time taken to develop a new medicine is now averages 12 years and costs about US$1 billion. These are not the kind of resources that most research or healthcare institutions can invest – and historically the task has fallen to private investors. For private investors to make investments on this scale requires confidence that they will be able to, minimally, recover the costs of development, as well as generate a reasonable return for such a large and risky investment. Combining this problem of achieving outcomes with the ethical question about the ownership of genetic material, the ethical question is transformed into "how does society balance the goals of (1) encouraging investment in the development

of effective medicines, while at the same time (2) ensuring that the community benefits from the use of its common genetic heritage." The in-principle answer to this question is: the patent system. That is: the community grants inventors exclusive rights to a domain in return for innovations which benefit the community. While critics of the patent system argue that it limits public access, they tend to overlook the 'public good' aspects of the patent system that are fundamental to its operation: for example, the limit of exclusivity to 20 years; the scrutiny of patent applications by public officials on behalf of the community; the maintenance of public registries of patents; publication of inventions, and the public right to review and challenge patents. All such features are specifically included in the patent system to ensure that it delivers a 'social dividend'.

When the Senate Committee asks whether there should be "measures that would ameliorate any adverse impacts arising from the granting of patents over [genetic material]", our answer is: that the system is actually already well balanced. There are high risks in developing medicines and diagnostic tool based on genetic material; but they deliver increasing targeted and effective treatments.

Pfizer's view is that, in the area of pharmaceutical development, the current trade-off – embodied in the patent system – benefits the community greatly. While genetic information may be part of the common inheritance of humanity, it is not information that can be accessed or used by individuals without sophisticated technology, highly trained researchers, and large investments in equipment and training. It was not knowledge that humanity held fifty years ago. By contrast, we hold that the benefits that humanity has gained through use of this knowledge – and this investment – is substantial: early detection of many diseases such as cancer; more targeted therapies; whole new classes of medicines. Therefore, we argue that the granting of exclusive licenses to develop new medicines and diagnostic tests is more than offset by the benefits that these technologies have delivered to the community.

We also need to be clear about the just how much the community is being asked to place – temporarily – in private hands. In Australia, there are around 400 gene patents in total. As the Myriad case illustrates, some of the newer ones are for mutations on genes – not even for whole genes. By contrast, the number of protein-coding genes in a human is estimated to be around 20,000-25,000 out of a total of maybe 150,000 genes.

Ramifications of prohibition

We wish to remind the Senate Committee that there is also a larger issue at stake. Changes to genetic patents could not be limited to that domain: they would affect the entire patent system. Changing patent law in one area changes the ethical basis upon which the whole patent system is based – the balance between public good and private incentive. Changes in that balance would be hard to contain just to genetic technology, and might potentially upset the investment that the patent system is designed to encourage.

Patents on microbial genes, proteins and their derivatives

Part of the Senate Committee's Terms of Reference refers to, "the impact of the granting of patents in Australia over … microbial genes … proteins, and their derivatives, including those materials in an isolated form, with particular reference to …(c) whether the *Patents Act 1990* should be amended so as to expressly prohibit the grant of patent monopolies over such materials."

This is a large question, and can be interpreted in a number of ways. However, prohibiting *all* patents on microbial genes and their derivatives would have a major impact on all aspects of biotechnology in Australia: in research, in biotechnology, and on products developed using any type of genetic material. At the most basic level, every part of genetic science depends upon microbial genetics: viral vectors are the way that new genes are introduced into the genetic material of other organisms.

In the pharmaceutical sector, a broad ban could have profound consequences for treatment of some diseases. Insulin is good example. When insulin was first developed to treat diabetes, it was extracted from a variety of animal sources, mostly pigs and horses. However, because this insulin was from a non-human source, after about a year, people's bodies began to reject this life-saving medicine. Around twenty years ago, gene technology allowed the gene for human insulin to be inserted into a bacterial plasmid, so creating an artificial insulin which the human body would not reject. Today, all insulin used in people is recombinant insulin produced by microorganisms. Pfizer does not supply insulin, and consequently we do not know what patents cover it internationally but, *in principle*, if there was a ban on "microbial genes … and their derivatives", it might feasibly affect the supply of all insulin in Australia. The same is true of many other types of medicines. The final report of the Pharmaceuticals Industry Strategy Group to the Minister for Innovation reported that, "The percentage of medicines made from biologics is set to increase, with some estimates indicating a rise from 18 per cent in 2006 to 27 per cent in 2012"[2]. A ban on medicines derived from patented microbial genes or their derivatives could significantly reduce Australia's access to innovative medicines.

The international dimension

Gene patents have become a fact of international protection of intellectual property rights.

While we appreciate some people still wish to raise the question "should patents be permitted on genes?", we believe that banning gene patents in Australia would create large inconsistencies between this country and other signatories to international covenants protecting intellectual property.

Australia has a prominent and honourable position in the protection of intellectual property rights. It is a signatory of the TRIPS Agreement (Agreement on Trade Related Aspects of Intellectual Property Rights), as well as a member of the World Intellectual Property Organisation (WIPO). We urge the Australian Government to approach any changes to

[2] PISG (2009) *Final report. December 2008*: Canberra: DIISR. Page 22.

gene patents within the framework of such international agreements about patent protection.

Substantial changes to gene patents could affect Australia's reputation for IP protection in fields far beyond genetics. In 2006-07, the international pharmaceutical industry alone invested $540 million in Australian research in 2006-07 (compared with the NHMRC's total research budget of $712 million in the same year). Such large amounts of private investment are premised on a strong, predictable and effective IP environment. With the number of medicines based on genetic technology predicted to grow strongly in the next twenty years, changes to gene patents could seriously affect Australia's capacity to attract this investment.

We are also not clear what positive practical outcomes would result from radical changes to Australia's IP laws. Even if Australia banned gene patents, they would remain in force in all other developed nations. The main consequences we foresee in our own field might be:

- loss of international research investment
- losses and closures amongst Australia's 470 biotechnology companies
- possible withdrawal of biologic medicines and gene technologies.

With only about 400 gene patents in Australia, we sincerely believe that, whatever gains there might be in early-stage research, these would be more than offset by the losses of research investment and medicines.

Progress in medical research

One of the other questions that the Senate Committee poses in its terms of references is "the impact which the granting of patent monopolies over such materials has had, is having, and may have had on … the progress in medical research." This is not a question we can answer for others. However, our own policy is explicit that gene patents must not impede research:

> … gene inventions and, in particular, research tools should be readily available for non-commercial purposes consistent with the advancement of biomedical research. This may be achieved through scientific publications or patent licensing. In the latter case, patents should be available for licensing on a voluntary basis for non-commercial purposes. Such licenses should be available on a non-exclusive and non-discriminatory basis and under fair terms consistent with the advancement of biomedical research.

We hope that, as one of the world's largest pharmaceutical companies, our position has some influence amongst others in the biomedical community.

Provision and costs of healthcare

The final question posed by the Senate Committee that we wish to address is the impact of gene patents on the provision and cost of healthcare in Australia.

Medicines are obviously one important line of treatment for many illnesses. The question for Pfizer, as a developer of medicines, is whether gene patents create a barrier to the

development of medicines that are effective and can be reasonably afforded by the community. Our experience is that they do not.

Pfizer does license use of gene patents in the development of new medicines. We regard the licensing fees as part of normal business costs. Our experience is that these costs have not been a barrier to the development of new medicines.