QUESTIONS ON NOTICE following Gene Patent Hearing on Thursday, 19 March 2009 from Senator the Hon Bill Heffernan

to

Dr Luigi Palombi
Centre for the Governance of Knowledge and Development
The Australian National University

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1. In her evidence to the Committee (Hansard page 4 para 3) Mrs Beattie, the Commissioner of Patents, said: 'for for a patent to be granted over a gene sequence, the applicant must disclose a new and practical use for the sequence. Typically, this will include evidence of the association of the sequence with a particular disease and its use as a diagnostic or therapeutic'. What do you say in response?

ANSWER:

Mrs Beattie's evidence is contextually misleading.

First, even if, as Mrs Beattie says, a patent applicant 'must disclose a new and practical use for a gene sequence' a typical gene patent is *not* limited to that use, but typically will contain claims (which also define the scope of the patent monopoly) that cover the isolated gene and *all* its uses, actual or theoretical. For instance gene patents usually contains claims to the following:

(a) the genetic material (defined by a genetic sequence) which has been isolated, purified or synthesised. This isolated or purified genetic material is identical or substantially identical to the genetic material in its natural environment;

(b) proteins that are coded by that isolated genetic material (defined by an amino acid sequence);

(c) the production of either of the abovementioned biological materials in a process;

(d) the use of those biological materials in diagnostics;

(e) the use of those biological materials in therapeutics;

(f) the use of those materials in possible (not necessarily actual) treatments, vaccines and cures; and,

(g) other biological materials which are associated with either of the biological materials defined in (a) and (b), such as antibodies, and the production and use of these biological materials.

Secondly, the 'evidence' of use required by IP Australia is *not* evidence at all. This so called 'evidence' usually consists of nothing more than mere assertions made by the patent applicant in a document that is prepared by a patent attorney. If there is scientific data, in the context of gene patents that data usually comes from animal experiments. Certainly, while this kind of data is useful for further research and development, it does not necessarily mean that the data proves efficacy in humans.

Here are two examples:

The first is now of historical interest since the patent expired in November 2008, but it makes the point well. The patent is AU 624,105 and it concerns the hepatitis C virus. When IP Australian granted the patent it gave Chiron Corporation, the patent owner, a patent monopoly over virtually any biological material that was derived from a virus that was causative of hepatitis C. In addition it gave a patent monopoly over all possible and speculative uses of that material including in vaccines. The data that

Chiron produced to support its claim to the use of hepatitis C virus biological materials in vaccines consisted of animal experiments. That data was, however, useless in the context of humans. A patent judge in England came to the conclusion that the data in the Chiron patent that had been granted in the UK (which was identical to the data in the Australian patent) would not have removed the need for other research teams to expend the equivalent of another 30 man years of research in developing a vaccine that would immunise a human. Nonetheless, IP Australia (as did the British Patent Office and the European Patent Office) accepted this data as adequate evidence to justify the grant of the patent. This begs the question: what is the proper quality of that evidence?

The second example is current and expires in 2018. The patent, AU 2002048844 concerns a gene therapy for the treatment of haemophilia in humans. The principal patent claim is over a specific method that the patentee maintains actually treats a human medical condition, known as haemophilia, by transferring genetic material using a virus as the delivery mechanism (the vector). The data provided by the inventors in the patent application consisted of data coming from animal experiments. There was no data to show that this idea or concept or prototype treatment would work in humans. This was mere speculation on the part of the inventors. So convinced were they that in 2001 one of the inventors, Dr High, wrote in a peer-reviewed scientific paper that: 'data derived from animal studies will serve as a reliable guide to results in humans'. By 2005, however, it was clear that their hypothesis was incorrect and she conceded this in a paper which was published in August 2005 [High K (2005), *Journal of Thrombosis and Haemostais*, **3**, 1682-1691]. Nonetheless, in that same year IP Australian granted her institution, the Children's Hospital of Philadelphia, a patent.

Finally, often the *new* and practical use of the genetic or protein materials which Mrs Beattie speaks of is not inventive at all. In practice all that a patentee has to show is that the genetic material can be used in some elementary way, such as in a diagnostic assay.

Thus not only are the biological materials not inventions, but the use of those materials in diagnostics is not inventive.

Even twenty years ago the use of biological material in a diagnostic test was an elementary and non-inventive application. Typically, if there is anything that distinguishes one diagnostic assay from another it is the biological materials which they contain or that they are designed to detect. Otherwise, diagnostic tests use underlying technological platforms that are well known by persons of ordinary skill in the making of genetic tests.

An example of what I mean is found in a current patent which expires in 2024. Patent AU 2004200978 concerns a diagnostic method for *severe myoclonic epilepsy of infancy* (SMEI) in a child. This form of epilepsy is caused by a genetic malfunction to the SCN1A gene which means that children that carry this genetic malfunction have faulty nerve receptors and this contributes to them suffering seizures. The SME1 gene test is useful in so much as it enables clinicians who are assessing infants for epilepsy with information that will assist them in devising a form of treatment.

Clearly, the *key* to this particular diagnostic test for SMEI is the SCN1A genetic material used as components in the test and not the test's underlying technical platform. That this is so is reinforced by three things. First is a disclaimer in the patent that 'there exists a number of assay systems that can be used to test for the existence of an SCN1A alteration'. Secondly is an assertion made in the patent that 'the invention is not limited by the examples [of the diagnostic technologies] that are provided' therein. Finally, and perhaps more tellingly, the patent states that 'the specific method … is not critical and may include enzyme-linked immunosorbent assays (ELISA)…fluorescent enzyme immunoassays (FEIA or ELFA) … and radioimmunoassay (RIA).'

The patent specification also explains how the 'SCN1A alterations' are central to the test's performance by pointing out that the 'utility of the diagnostic assay in providing a likelihood that an individual may be affected with SMEI' are the 'mutations in the SCN1A gene in individuals that have been clinically diagnosed with SMEI'. These specific mutations are then defined in various sequence data tables which are referenced as SEQ ID NOS: 1-25; 26-48; 49-53 and 54-58. *These are so voluminous that they make up 458 pages of the total patent document which consists of 521 pages, thus 88% of the patent specification is simply made up of the sequence data of the SCN1A gene mutations.*

Needless to say, although the patent commences with claims that define the invention to be 'a method for determining the likelihood that a patient suspected of SMEI does or does not have SMEI' with some 26 claims to this effect, claims 27 to 30 are ultimately directed at the SNC1A DNA, the sequence of which is contained in the tables already mentioned. Furthermore, claims 35 to 38 are claims to proteins coded by the genetic sequences in those tables. Then there are claims to antibodies as well as the uses of these biological materials in various treatments, therapies and medicaments.

That the *key* to the invention is little more than the SCN1A mutations is further emphasized by the patent, providing virtually no instruction to the skilled addressee as to how to use that data to treat SMEI in the specification, while covering all possible uses of the biological materials (as defined by or derived from the DNA sequence data) in the claims.

In so far as the patent does contain information that a skilled addressee would find useful in producing a diagnostic assay, apart from the DNA sequence data there is nothing new or inventive disclosed. In fact, it would be fair to say that the use of the application of that data in various diagnostic assays was obvious to the skilled addressee.

2. In her evidence to the Committee (Hansard Page 4 para 4) Mrs Beattie said: 'Australia's current patents law does not give IP Australia any clear basis in law to refuse to patent gene sequences solely because the patent relates to these areas of technology'. What do you say in response?

ANSWER

Mrs Beattie is wrong.

Isolated biological materials are not 'manners of new manufacture' within the meaning of section 18(1)(a) *Patents Act, 1990*. As such they are not 'inventions'. The fact that these materials are isolated from their natural environments does not change what they are, it merely changes their *state*. For instance, a human gene remains a human gene even if it is removed from the human body. It contains the same, or virtually the same, genetic sequence regardless of its state. It is therefore nothing more than a natural phenomenon. There is no Australian court authority that has sanctioned the practice, adopted by IP Australia in the late 1980s, to grant patent monopolies over isolated biological materials.

Moreover, an isolated gene contains the same, or virtually the same, genetic information as does the gene in its natural state. It is this genetic information, which is not conceived, devised or created by anyone, that makes the gene useful - in its natural state it is a functioning part of the human body and in its isolated state its parity of information makes it predictable and reliable for the researcher.

Unfortunately, in neither the U.S. nor Australia have the highest appellate courts been given the opportunity to rule on the practice which the major patent offices around the world adopted in 1988 and which has led to the grant of gene patents.

However, Mrs Beattie could have been guided in her interpretation of patent law by the decision of the UK Court of Appeal in the case decided in 1989 called in *Genentech's Patent*. The Court held that the claims to isolated biological materials were *not* inventions because the process of the *isolation* of t-PA (which were the materials in issue in that case) did not change what it was, namely, the same as the t-PA that existed in nature. This Mustill LJ made clear in the following passage from his decision:

> It is true that the word "recombinant tissue plasminogen activator" may be a useful turn of phrase, but this should not be allowed to disguise the fact that "recombinant" describes, not the product itself, but its history. It is I believe, a failure to acknowledge this which has compounded the already substantial difficulties of relating these unusual claims to the framework of patent law, and which have diverted attention away from the fact that the success of Genentech lay, not in the invention of a new substance -- for protein molecules with the amino acid sequences shown in figure 5 and the functional characteristics set out in the specification have existed since far into the distant past -- but in the accomplishment for the first time of a method of creating that substance. Wrapped

up as it may be in the product claims, I believe that in truth what Genentech have invented (if they have invented anything at all) is a process.

3. In her evidence to the Committee (Hansard Page 4 para 4) Mrs Beattie said: 'Gene related inventions are not made unlawful under any existing Australian regulations, and courts have been reluctant to refuse patentability on the ground of generally inconvenient, believing it is best left to parliament to decide whether matters of ethics or social policy are to have any impact on what is patentable'. What do you say in response?

ANSWER

First, the term 'gene related inventions' is, itself, confusing. While a gene, even one that is isolated from its natural environment, is not an invention there are uses that a gene or genetic sequence can be put to in technologies that are themselves capable of being inventions but which are *not inventive*. An example of this kind of use is the application of a gene or its genetic sequence in a diagnostic test. This kind of technology, a genetic test, is hardly what one would consider to be 'inventive'. Apart from being commonplace, it is well within the competency of someone that knows how to make gene tests to use a gene or gene sequence in such a manner. So what does she mean by 'gene related inventions'? One can only speculate, but a reasonable interpretation might be technologies that use genes and genetic sequence information in new, inventive and practical ways. An example of this could be a gene therapy that has been shown to be efficacious in humans, that is it actually treats the genetic cause of the human illness by correcting the genetic malfunction.

Secondly, it *is* possible for a technology that uses genetic materials or information in a way that would be contrary to law to be unlawful (and therefore unpatentable). Even if that technology was new, inventive and practical, so that it could be described as a 'gene related invention', the potential to cause harm to human society could result in that invention falling outside of the limits of legality. The potential harm need not be physical. It could be mental. Indeed, the harm could be moral or ethical. It is for this reason that s.18(2) *Patents Act, 1990* expressly excludes from patentability "[h]uman beings, and the biological processes for their generation", but it is a mistake to think that this kind of exclusion is a matter only for parliament.

In *Anaesthetic Supplies Pty Limited v Rescare Limited* (1994) Lockhart and Wilcox JJ held that a method for the treatment of sleep apnoea, a human medical condition, was patentable subject matter because they interpreted the failure of the Australian Parliament to expressly exclude such methods from patentability, as had been done in s.18(2) in respect of biological processes for human reproduction, as indicative of a Parliamentary intention to permit patents with respect to methods of human treatment. Sheppard J, however, dissented. While he accepted that there was no binding authority in Australia to the effect that 'there cannot be a valid grant of a patent in respect of a method of treatment of the human body', he believed that the High Court in *Commission of Patents v NRDC* (1959), on which sat 'judges of great distinction', had held that whether such methods were patentable was a matter for a court 'to decide'. The fact that Parliament had not, in the 1990 patents legislation, expressly prohibited patents over such methods was not indicative of an intent to restrict the court's ability to assess inherent patentable subject matter nor was it indicative of permitting such patents. Sheppard J explained that it was 'not going too far' for a court to consider whether the grant of a patent was appropriate in circumstances where the exercise of a patent owner's exclusive patent rights over the use of an invention 'might mean the death or unnecessary suffering of countless people'. Having examined the technology and the human disease, which he described as 'life-threatening', he held that the patent claims to the treatment of this disease were invalid because they violated the proviso in s.6, *Statute of Monopolies, 1623*.

Thirdly, Mrs Beattie's reference to the term 'generally inconvenient' is to s.18(1)(a) *Patents Act, 1990* and to the definition of 'invention' in the Schedule 1 of the Act which itself refers to s.6 of the *Statute of Monopolies, 1623*. Under section 6 only if a 'manner of new manufacture' is 'not contrary to the law nor mischievous to the state by raising prices or commodities at home, or hurt of trade, or *generally inconvenient*' is it the proper subject of letters patent, that is, a patent monopoly.

There are many judicial decisions in both the UK and Australia as to what the words 'generally

inconvenient' mean and while one judge (Justice Finkelstein) has recently expressed the view, as Mrs Beattie says, that 'it is best left to parliament to decide whether matters of ethics or social policy are to have any impact on what is patentable', this view is by no means binding authority nor does it represent the views of other judges.

4. In her evidence to the Committee (Hansard Page 4 para 6) Mrs Beattie said: 'A patent over a gene sequence does not equate to ownership of that sequence'. What do you say in response?

ANSWER

Her answer is disingenuous. Clearly the issue is not ownership in the sense of physical ownership. Everyone owns their own genes that are in their own bodies.

The issue, however, is about who can control what people can do with those genes outside of their bodies.

A patent monopoly over an isolated gene and its genetic information means that anyone that does anything that comes within the scope of that patent monopoly has infringed the patent and is liable to the patentee for damages or an account of profits and can be enjoined from continuing to infringe by the grant of an injunction.

That kind of power, which a patentee possesses exclusively, is significant legally, economically and ethically. Legally because it provides the patentee with the right to sue with respect to the unauthorised use for damages, an account of profits and to seek an injunction. Economically because it enables the patentee to control access, use and price, in the exercise of their legal rights as a monopolist. Ethically because how the patentee exercises those rights can impact upon how society functions.

5. In her evidence to the Committee (Hansard Page 4 para 7) Mrs Beattie said: 'IP Australia's data indicates that the number of granted patents that assert rights over an isolated human gene is less than 400 in total to date. The data also indicates that patent applications for methods or processes of using gene sequences are increasing relative to patent applications for isolated gene sequences themselves. This indicates that innovation efforts have shifted to downstream applications of gene sequences.' What do you say in response?

ANSWER

1. The figure that Mrs Beattie quotes is unlikely to be accurate. Given that approximately 92% of Australian patents are granted to foreigners, a U.S. study published in *Science* in 2005 which showed that even by that time 'nearly 20%' of the 23,688 human genes had been patented as 'U.S. IP', suggests that the number in Australia must be much higher. According to this study nearly 4,300 U.S. patents over human genes had been granted by 2005 and that figure is most likely to be higher today. [*Science*, **310**, 239-240, 14 October 2005].

2. Again it is difficult to verify if what Mrs Beattie asserts about the changing nature of patents moving away from isolated genes and gene sequences to methods or processes is an accurate summary. But even if it were, an examination of these method or process patents reveals that although couched in language that uses the words 'method' or 'processes' instead of 'isolated', the scope of the patent monopoly extends to the biological material itself and to uses that are non-inventive. Like the example which I gave in an earlier answer regarding the use of biological materials in diagnostic assays, the 'methods' or 'processes' themselves may, and probably are, obvious and uninventive.

To illustrate what I mean let us return to the Australian patent over the diagnostic test for epilepsy. In AU 2004200978 (granted 4 June 2006; patent monopoly commenced 4 June 2004 and expires 4 October 2024) it is correct to say that claims 1 to 26 commence with the words 'a method'. From these words it would be fair to assume that the claims describe methods. However, that assumption would be wrong. The claims are actually to diagnostic tests capable of detecting gene mutations 'in the SCN1A gene', and are therefore claims to products. After all, a method to test for gene mutations is another way of defining a product that does just that. This kind of wordsmithing is what patent

attorneys are expert at, but it doesn't actually make any practical difference to the scope of the patent monopoly. The objective is to *maximise* the scope of the patent monopoly.

Let us now look at claim 1 of this patent. Claim 1 reads as follows:

> A *method* for determining the likelihood that a patient suspected of SMEI does or does not have SMEI, comprising
>
> (1) testing a patient sample for the existence of an alteration in the SCN1A gene of the patient, including in a regulatory region of the gene;
>
> (2) (a) terminating the process with an inconclusive diagnosis if no alteration is found; or (b) identifying the alteration;
>
> (3) ascertaining whether the alteration, when one is detected, is known to be SMEI associated or non-SMEI associated or is not known to be either;
>
> wherein (a) a diagnosis which will indicate a high probability of SMEI is made where the alteration is known to be SMEI associated; (b) a diagnosis which will indicate a low probability of SMEI is made where the alteration is non-SMEI associated; or (c) further analysis is undertaken to establish whether the alteration is a SMEI associated or a non-SMEI associated alteration.

The effect of this claim is to capture *any* diagnostic test that tests for 'for the existence of an alteration in the SCN1A gene of the patient'. The underlying technological platform is irrelevant. The feature that distinguishes this diagnostic test from another one is the specific genetic components that detect the gene mutations to the SCN1A gene. The same is true of the other method claims, namely 2 to 26.

However, the scope of the patent monopoly does not stop there. Claims 27 to 30 extend that scope to include 'isolated nucleic acid molecules', that is, the SCN1A gene mutations themselves. These are the very claims that Mrs Beattie asserts are less prevalent. Yet, clearly, they are not. All that's changed is that they are further down the list.

Then claims 35 to 38 extend the patent monopoly to the 'isolated' proteins that the SCN1A gene mutations code for, that is the proteins that relate to the defected nerve receptor that triggers epileptic seizures in the infant.

Finally, even 'a method of treating epilepsy' (claims 47, 49, 51 and 53) is claimed as an invention. Unfortunately the patent fails to provide any credible scientific data to support them.

3. Mrs Beattie's statement that this change 'indicates that innovation efforts have shifted to downstream applications of gene sequences' is a complete fabrication. While it is true that patent attorneys have changed the way that they structure the patent claims in such a way as to give that impression, in practical terms nothing has changed. The scope of the patent monopolies for gene patents, as this example shows, is not shifting to downstream applications. It is as broad as it has always been.

6. In her evidence to the Committee (Hansard Page 9 para 15) Mrs Beattie said:' if Myriad did not go to the trouble of defining the BRCA gene, where would we be now in relation to breast cancer tests?' How would you answer her question?

ANSWER

Her answer suggests that Myriad, a U.S. corporation was the only organisation that was researching breast and ovarian cancer in the early 1990s. It was not. There were others. They were participants in a competitive scientific race to where scientists who had come from various publicly funded universities and institutions (and who brought with them the knowledge which they gained at those universities) around the world came to collaborate with Myriad; they published their results before any of the other competing scientific teams, and therefore 'won the race', and effectively put a halt to the other researchers continuing their valuable work elsewhere in the world. That the Myriad team was the first to identify some (not all) of the gene mutations on the BRCA1 gene (located on human chromosome

17, itself identified by Prof Mary-Claire King in 1990 after 16 years of publicly funded research), and on that basis claimed all BRCA1 gene mutations as their 'invention', is another thing entirely.

Had these scientists undertaken their research completely within the public arena, as would have happened before gene patents became *de rigueur*, they would have made the same discovery. It was merely a matter of time.

7. In her evidence to the Committee (Hansard Page 14 para 9) Mrs Beattie said: 'I would dispute the 15,000 figure' in response to a question from Senator Heffernan about the number of gene patents in Australia. What do you say in response?

ANSWER

This figure comes from IP Australia's own patent database, AUSPAT.

8. In her evidence to the Committee (Hansard Page 14 para 13) Mrs Beattie said: 'The patent system is based on the benefits derived from the disclosure of information that could otherwise be kept secret. Therefore, you would not know that that invention was there. Therefore, you would not be adding to public knowledge of that. It also has benefits derived from facilitating international collaboration in research. It also has benefits in terms of facilitating access to technology that we may not necessarily achieve if we did not have a patent system because inventors from overseas would be reluctant to transfer that technology into our economy or our marketplace.' What do you say in response?

ANSWER

The patent system does facilitate the dissemination of technical information, but the quality of that information is not necessarily very high.

Often the information contained in a patent is nothing more than a summary of the existing knowledge base. To the extent that new and useful knowledge is added to the public domain through the publication of a patent application, whether that knowledge is of merit and practically useful is not measured. Therefore it is not possible to make a sweeping generalisation that the patent system facilitates 'international collaboration in research'.

The moment that a new product is made available to the public the process of imitation commences. It usually takes imitators some time before their versions are available. Thus a new product usually enjoys a period of exclusivity which comes from being the first on the market. Therefore it is nonsense to suggest that without the patent system new knowledge would be 'kept secret' or that 'you would not know that the invention is there' or that 'inventors from overseas would be reluctant to transfer that technology into our economy or our marketplace'.

In time all products are copied and their 'secrets' revealed through reverse engineering or other research and development. That is the nature of free competition. Indeed, if Australia did not have a patent system anyone could imitate and copy any technology.

The patent, however, interferes with the free competition process by creating a legal prohibition on the imitative process. Thus the patent owner is able to control the exploitation of the 'invention' disclosed by the patent by restricting its reproduction. And while this provides an immediate benefit to the patent owner, unless the information disclosed in the patent is able to be easily applied when the patent expires, the patent owner receives an economic benefit for the life of the patent monopoly, which is 20 years, while society pays a higher than normal price for the product, not only during the life of the patent but in some cases even afterwards.

An example of this is what has occurred in Australia over the biopharmaceutical version of erythropoietin, a naturally occurring human hormone. After a patent monopoly of nearly 22 years (it was extended by about 2 years), in 2006 the patent granted to Amgen, a U.S. corporation, over 'isolated' erythropoietin expired. At the same time scientists whose research was funded by Amgen began to suggest that generic versions of the biopharmaceutical erythropoietin were not bioequivalent

to the patented version and that generic manufacturers would need to undertake clinical studies to demonstrate to the regulatory authorities that there was bioequivalence. But how could this be so? To obtain a patent, an applicant is legally required to furnish sufficient detail in the patent itself to enable the patent to be replicated by someone skilled in the art. Surely, the information that Amgen disclosed in its patent would have been sufficient to enable a generic manufacturer to produce a bioequivalent generic erythropoietin biopharmaceutical without the need to undergo further clinical studies on humans. Apparently this is not what has happened. In an article authored by Dr Simon Roger, then with the Renal Unit of the Gosford Hospital at Gosford in NSW, and published in the Australian medical journal *Nephrology* [*Nephrology* (2006) **11**, 341-346], it was pointed out that although the European market alone in 2004 was estimated to be worth $US2.3 billion:

> … an Australian-based pharmaceutical company, Mayne Pharma, reported that it would not continue development of a biosimilar epoetin alfa with its Croatian collaborator Pliva, due to increasing clinical program costs, although the biosimilar had shown encouraging phase I results and substantial progress had been made.

For further information see Mandel, G. N. (2006) 'The Generic Biologics Debate: Industry's Unintended Admission that Biotech Patents Fail Enablement', **11** 8, *Virginia Journal of Law & Technology*.

Online: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=889326.

9. In her evidence to the Committee (Hansard Page 15 para 4) Mrs Beattie said: 'Provided that that isolated gene has a particular function identified and that it relates as a diagnostic or a therapeutic' it is an invention. What do you say in response?

ANSWER

An isolated gene, even if its function has been identified, is not capable of being an 'invention' because it is a natural phenomenon. Thus identifying a gene and linking it to a specific human illness or function is a discovery about something that occurs in nature. In any event, most scientists go 'looking for' the genes responsible for various functions so will always be able to 'identify' the gene's function once they find it.

That a gene, which contains information stored in a biological form, may be isolated and in that form used in a diagnostic or a therapeutic does not transform the gene itself, nor the information that it carries, into an invention.

Whether a patent that claims a diagnostic or therapeutic as an invention is a patentable invention will depend on whether the application of that gene and the information which it carries meets the patentability thresholds of novelty, inventive step and industrial applicability.

That is a separate issue which is quite irrelevant to whether it is possible to claim, as an invention, the gene in an isolated form.

10. In her evidence to the Committee (Hansard page 17 para 2) Ms Press, in answer to a question from Senator Heffernan: 'So can you explain to the committee how exactly an isolated and purified gene differs from the same gene in the human body?' said: 'A gene as exists in the human body exists not as a discrete entity like a blood cell or even, in effect, a micro-organism in the human body. It is part of a long sequence of DNA, which is assembled into our chromosomes.' What do you say in response?

ANSWER

When comparing a gene, both when within and without of the human body, it will always perform the same function since the information contained within it in both states is unchanged. Unless a gene has been 'genetically modified' to perform a different function, this will always be the case, and it is this predictability of outcome that makes the research into isolating genetic material so appealing. To suggest that, bodily, it is a link in a chain, not a discrete entity lying in a Petri dish, is not answering

Senator Heffernan's question, which was obviously directed to a gene's function not its physical state.

11. In his evidence to the Committee (Hansard page 21 para 3) Prof. Anderson said: 'we would not have Gardasil without a patent system'. Relating your answer to the terms of reference, what do you say in response? Can you give the Committee an example of any major medical advances that have not involved the grant of a patent? Is there a difference between a patent that claims an isolated gene as an invention and a patent that claims the use of that isolated gene in a product, such as a vaccine? If so, what is the difference and explain that difference in the context of the Inquiry's terms of reference?

ANSWER

In dealing with an example first, probably one of the world's greatest medical advances of the 20th century achieved without a patent was the development of penicillin, the world's first antibiotic. The inventors were Howard Florey, an Australian scientist and team leader, Ernst Chain, a German scientist, and Norman Heatley, a British scientist. When Howard Florey was interviewed just before he died he was asked about what motivated him to do the research. He replied by saying that it had been nothing more than satisfying a scientific curiosity. Chain's idea of seeking a patent was rejected out of hand by Sir Edward Mellenby, the Secretary of the UK's Medical Research Council.

The same was true in the 19th century with Louis Pasteur. He developed vaccines against anthrax, rabies and cholera. Towards the very end of the 18th century Edward Jenner, a British scientist, developed the science of vaccination with his experiments with cowpox. Jenner's work led to a vaccine for smallpox. Neither Pasteur nor Jenner sought to patent their vaccines.

It must also be noted that until 1978 most European countries excluded medicines as patentable subject matter. Between 1877 and 1968 Germany prohibited patents over chemical substances per se, only permitting patents over processes for their manufacture. Even the UK prohibited patents over chemicals between 1919 and 1949 and only removed that prohibition in 1949 by substantially strengthening the power of the Comptroller of Patents to grant compulsory licenses over the manufacture of medicines. That remained the law in the UK until 1978 when a new patents law became operational after the UK joined the EEC in 1973.

With regard to the last two questions, there is a world of difference between patent monopolies over isolated genes and other biological materials and those over the *use* of those materials in ways that are new, inventive and which have an industrial application. The difference is that the former enables a patent owner to control the fundamental raw data that is contained within a gene, whereas the later enables a patent owner to control only the specific application of that data in something that is an 'invention'. A vaccine, such as Gardasil, is one example of an invention. An isolated biological material that is identical or substantially identical to a naturally occurring thing is an example of what is not.

As to Prof Andersons' statement that without a patent system there would be no Gardasil I say that it is mere speculation on his part. History, scientific curiosity and the human desire to save lives suggest otherwise.

Moreover what the patent system has contributed to is controversy and litigation. Apart from the fact that there is not one (Gardasil manufactured under license by Merck), but two vaccines (Cerarix manufactured under license by GlaxoSmithKline) to treat specific strains of human papilloma virus (HPV), there is some disquiet among scientists as to who deserves the scientific credit. True it may be that a considerable amount of worthy praise has been earned by Prof Ian Frazer and the late Dr Jian Zhou for their research at the University of Queensland, but it is also true that scientists from the University of Rochester, the National Cancer Institute and Georgetown University in the U.S. played important roles as well. And as Dr Mathew Rimmer, a lecturer in intellectual property law has noted, the litigation between the University of Queensland and CSL Limited (who licensed Merck) and the University of Rochester (which licensed GlaxoSmithKline) has resulted in a 'three-way battle' between themselves and the National Institutes of Health.

The truth is that there are a number of patents around the world that relate to Gardasil and Cerarix and

as Prof Frazer has said: 'Patents are all to do with licenses and making money and selling vaccines which is quite a different business to scientific inventorship.'

12. In Part 2 of your submission you give six examples of patents that you say should interest this Committee. In those examples, has public moneys played a role in achieving what the patent owners claim to be the 'invention'? To what extent have or are these patents hindering doctors, scientists, laboratories and public hospitals from providing diagnostics and/or medical treatment to Australians?

ANSWER

In each example significant amounts of public money was used in the research that led to the identification of the genetic or biological materials.

Patents over these biological materials prevent scientists and doctors from making those materials for any use, whether experimental or clinical. These patents assume that knowledge of the genetic sequence of the gene or the amino acid sequence of the protein and their respective functions are all that scientists need to know to make all manner of medical and scientific use of those materials. Unfortunately, this assumption is wrong. Not only that, we now understand that the cause of human illness can be linked to many genes and how they interact within the human body. It has been suggested that in order to properly investigate human illness, a whole suite of genes must be investigated simultaneously. If one or any of these genes are the subject of a patent then the research avenue could be potentially barred.

Thus patents over isolated biological materials or over non-inventive uses of those materials, such as in diagnostics, are problematic because they quarantine those materials away from scientists and doctors who need to access and use them freely and without fear of litigation.

13. In Part 1 of your Submission you tell us about the European Commission's antitrust investigation into the pharmaceutical industry. Why is this investigation relevant to this Inquiry?

ANSWER

The European Commission's investigation into the pharmaceutical industry's attempts to block the entry of generic medicines by using the patent system is relevant to this inquiry because it demonstrates the propensity of this industry, which either controls or has significant interests in the biotechnology industry, to use monopoly power illegally.

While the patent system can be used for legitimate purposes, it can also be used for illegal purposes. Unfortunately, as a result of the significant increase in the number of patent applications that have been filed in the past ten years, the ability of patent offices to scrutinise them prior to grant has been reduced. As a result the quality of patents has fallen. The incapacity of the world's major patent offices to cope with the massive rise in patenting, caused mainly by gene, software and IT related patent applications being filed in ever increasing numbers, has created a loophole that is being exploited by multinational companies that seek to hide their anticompetitive practices behind patents, many of which would, if tested in the courts, be found to be invalid.

The difficulty with using the courts to invalidate patents is the enormous cost of patent litigation, which provides the pharmaceutical industry with an unfair advantage. Not only does the pharmaceutical industry employ many patent lawyers, but it can afford to employ scientists and other experts to support their litigation strategies.

On 28 November 2008 the European Commission's Competition Commissioner, Mrs Neelie Kroes, held a press conference in Brussels in which she outlined the preliminary findings of a year long investigation. The Commission identified various anticompetitive practices:

(a) generic manufacturers withdrawing their challenges to patent validity in return for making a deal with the patent owners which saw them receiving some US$200 million from pharmaceutical companies for agreeing to withhold production of generic medicines as part of

out-of-court patent litigation settlements;

(b) 'Patent clustering' as another tactic to create barriers to entry for generic manufacturers. In her statement, Mrs Kroes said: 'The worst example we found of this method was 1,300 separate patent filings, across the EU, for a single medicine'; and,

(c) The use of extensive patent litigation by patent owners to thwart the entry of generic versions of patented medicines when the patents were of questionable validity. In this regard, the Commission found that if the patent litigation was resolved, the decision usually went against the patentee, meaning that the patent, as granted by the EPO, was invalid in the first place. Consequently, even during the course of the patent litigation, which on average took three years, the patentee received an economic benefit that it was not entitled to receive.

According to Mrs Kroes, the alleged illegal antitrust activity has cost EU governments about US$3,800 million to date. The investigation is continuing.

However, the European Commission is not alone. On 27 January 2009 the US Federal Trade Commission and The State of California filed a complaint in the US Federal District Court for the Central District of California against three generic pharmaceutical manufacturers and Solvay Pharmaceuticals, Inc, the US subsidiary of the Belgium based Solvay SA. The complaint alleges that the generic manufacturers have violated the *Sherman* (anti-trust) *Act* by agreeing to 'delay until 2015 the sale of the low-cost generic versions of AndroGel, a widely prescribed branded testosterone replacement drug, in exchange for substantial payments from Solvay'. The charges made in the Complaint arise from the agreement to settle patent litigation which Solvay had brought against the generic manufacturers for patent infringement and, in response to which, the generic manufacturers had cross-claimed to revoke the relevant Solvay patent (which was due to expire in 2020) on various grounds. The Complaint describes the impact to the economy and to the cost of healthcare in the US in these terms:

> Significant consumer savings can result when generic companies successfully challenge patents and enter [the market] prior to patent expiration. For example, a generic company's successful challenge invalidating a patent covering the **antidepressant drug Prozac resulted in generic entry 2 1/2 years before patent expiry and about $2.5 billion in estimated consumer savings**. Another successful challenge invalidating patents covering the cancer drug **Taxol resulted in generic entry over 18 years before patent expiry and estimated consumer savings of more than $3.5 billion**.

The main message for this Inquiry is that patents are not necessarily contributors to innovation. Patents can be and are being used to suppress competition and innovation. Unless the system is carefully calibrated, monitored and the regulatory agencies are able to effectively police it, the kind of abuse which the European Commission's preliminary findings have described in the context of the EU will continue, not just in the EU, but elsewhere including in Australia.

14. Would a legislative ban on the patenting of isolated biological materials contravene any international agreement or treaty that applies to Australia?

ANSWER

No it would not. Article 27.1 TRIPS requires that patents be granted only over 'inventions'. Not only that Article 27.3(a) TRIPS enables WTO member countries to 'exclude from patentability … diagnostic, therapeutic and surgical methods for the treatment of human beings'. The US Australia Free Trade Agreement is consistent with TRIPS.