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SENATE

STANDING COMMITTEE ON COMMUNITY AFFAIRS

Reference: Gene patents

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**SENATE STANDING COMMITTEE ON
COMMUNITY AFFAIRS
Thursday, 19 March 2009**

Members: Senator Moore (*Chair*), Senator Siewert (*Deputy Chair*), Senators Adams, Bilyk, Boyce, Carol Brown, Furner and Humphries

Substitute members: Senator Fifield for Senator Adams

Senators in attendance: Senators Bilyk, Boyce, Furner, Heffernan, Humphries, Fifield, Moore

Terms of reference for the inquiry:

To inquire into and report on:

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, with particular reference to:

- (a) the impact which the granting of patent monopolies over such materials has had, is having, and may have had on:
 - (i) the provision and costs of healthcare,
 - (ii) the provision of training and accreditation for healthcare professionals,
 - (iii) the progress in medical research, and
 - (iv) the health and wellbeing of the Australian people;
- (b) identifying measures that would ameliorate any adverse impacts arising from the granting of patents over such materials, including whether the *Patents Act 1990* should be amended, in light of the any matters identified by the inquiry; and
- (c) whether the *Patents Act 1990* should be amended so as to expressly prohibit the grant of patent monopolies over such materials.

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Committee met at 3.36 pm

CHAIR (Senator Moore)—I declare open this hearing of the Senate Standing Committee on Community Affairs. I apologise for the slightly late start. The Senate had a moment of silence for the soldier who was lost in Afghanistan, so we thought it was important that we had as many people there as possible. Welcome to our inquiry into gene patents. This is the commencement of our inquiry. The terms of reference of this inquiry involve a range of highly complex issues, many of which this committee has not previously considered. That is very real. This hearing is, in effect, a preliminary hearing and a briefing. The committee has invited departmental officers and other witnesses to give presentations to provide background information on the subject and issues within the terms of reference, which include human and microbial genes and non-coding sequences; their operations in the medical and research and health care systems; patent monopolies; and the operation of a patent system.

[3.37 pm]

ANDERSON, Professor Warwick Peter, Chief Executive Officer, National Health and Medical Research Council

BEATTIE, Mrs Fatima, Deputy Director-General, IP Australia

HUYNH, Ms Kristina, Policy Officer, IP Australia

MURNANE, Ms Mary Patricia, Deputy Secretary, Department of Health and Ageing

O'KEEFFE, Mr Leo, Director Domestic Policy, IP Australia

PRESS, Ms Lexie Leigh, Senior Examiner of Patents, IP Australia

REID, Mr Chris, General Counsel, Department of Health and Ageing

CHAIR—Welcome. Information on parliamentary privilege and the protection of witnesses and evidence has been provided to you. As departmental officers—and I think all of you know this from your very regular attendance at these things, but I will read it into the record—you will not be asked to give opinions on matters of policy, though this does not preclude questions asking for explanations of policy or factual questions about when and how policies were adopted. I am sure that you know most of us. While we have regular interaction with Health and Ageing, this committee has not had a lot to do with IP Australia. We will be expecting senators coming in and out during the process because we are having this hearing during a sitting of the Senate. So there could well be people moving in and out. It does not reflect on the interest in your evidence. I will invite each of you to make an opening statement. I am hoping you will because, weighing through the submissions, I know I need some help. Then we will go into questions after that. Have you worked out a batting order?

Ms Murnane—No, we were waiting for you to do that.

CHAIR—Ms Murnane, because you are such a regular contributor to our committee, I suggest that we start with you and Mr Reid from the department. Then we will work out from there, if that is okay. I take it that each of you do have an opening statement.

Ms Murnane—Well, not each. We will have one for the department.

CHAIR—Okay.

Ms Murnane—Thank you very much for inviting us to attend this hearing. We are pleased to be here. We recognise that these matters are very important. Genetics is a rapidly advancing scientific field that potentially offers important health benefits. There can also be far-reaching consequences of the applications of this knowledge and those consequences are not always immediately obvious and well-understood, especially by health consumers. In essence, numerous and complex issues surround genetic testing and services.

Genetic Technologies are involved in the development of new diagnostic tests. It was one of those tests that was an important spearhead for this committee. In addition, pharmaceuticals, vaccines and other genetic based biological therapies are being used for the targeted treatment of diseases and conditions. The inclusion of genetic tests and services in everyday practical use requires the same thoughtful and considered approach that informed the research that generated this new knowledge.

The science of genetics is now fairly well established, but its implications are still evolving. The pace of innovation often exceeds our capacity to manage the effects. These aspects require holistic policy considerations with the understanding that genetic knowledge impacts heavily on people's lives and their daily existence. There are financial, legal and medical decisions that have to be made as well as consequences to be assessed and discussed with families and carers. Therefore, it is of paramount importance that genetic testing and services take place in a therapeutic setting with careful pre and post counselling of the individual and significant others.

To date, the focus has been on diseases associated with single genes, but emerging trends suggest that many diseases are associated with changes in the expression of a number of genes. This complexity provides added challenges to the regulatory frameworks underpinning the technologies. Hence, careful and prudent and careful assessment of these technologies is needed within a framework that rigorously assesses the costs and benefits for both individuals and society.

To summarise, the department's view is that, for individuals, genetic testing and related clinical services can have significant financial, psychological, social and family impacts. Many of those are beneficial, but some of them need significant thought. These need to be appropriately managed. Therefore, where genetic testing and services are used for diagnosis and to assist with treatment, they should be carefully conducted in the clinical context with oversight by skilled clinicians and counsellors supported by a multidisciplinary health team. Thank you.

Mrs Beattie—IP Australia welcomes the invitation to attend today's background briefing and to support the Senate committee, as needed, on patent related issues raised by the inquiry. A joint submission from the Department of Innovation, Industry, Science and Research and IP Australia, which is a prescribed agency within the IISR portfolio, was submitted yesterday to the inquiry's secretariat. The purpose of our submission was to provide information on Australia's patent system; its objectives and patentability requirements as set out in legislation and case law, including how IP Australia assesses applications for gene patents; Australia's obligations under relevant international treaties and agreements; and data on the number and trends of gene patents filed and granted in Australia. We also propose a number of changes to the patent system applicable to all patentable technologies aimed at increasing the inherent quality of patents granted. These proposed changes are part of an IP rights reform package IP Australia is progressing this year.

The objective of Australia's patent system is to benefit Australia by stimulating industrial innovation and encouraging technology access and transfer. The system rewards inventors with a period of exclusivity to prevent others from exploiting their invention in return for disclosing their invention to the public. Diffusion of knowledge in the public domain helps to facilitate research in emerging fields of the patented invention. The grant of a patent does not give its owner a guaranteed right to exploit the patented technology in Australia. The use of the

invention may be regulated by other laws, international standards and guidelines. For example, for a new drug, its availability and cost may depend on whether it is determined to be safe by the Therapeutic Goods Administration and whether it demonstrates cost effectiveness to allow its listing on the Pharmaceutical Benefits Scheme.

In accordance with international obligations, Australia's patent system is technology neutral. Applications for gene patents are assessed by applying the same patentability criteria applicable to all other technologies. IP Australia is also bound by parliament enacted law and court decisions interpreting this law. What can be the subject matter of a patent has been interpreted broadly by the courts. This has enabled the law to keep pace with scientific and technological developments. As such, Australia has granted patents over substances and materials isolated from nature since at least 1924, where they have met other requirements for patentability.

The courts have also recognised that the distinction between discoveries, which are not patentable, and inventions can be extremely fine. However, if ingenuity has been applied to a discovery to produce a new and useful result, it is an invention and may be patentable. A practical application of information to a useful end translates a discovery into an invention because a step is taken from knowing to being able. For example, 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.

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. 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. Jurisdictions like the European Union have other exclusionary provisions based on protecting public order and morality, but these have not been used to exclude gene sequences from patentability.

As stated in our submission, we address a few apparent misunderstandings about patents and gene patents. For example, patents may be awarded to ground-breaking inventions as well as incremental advancements where they meet the requisite level of ingenuity required to be granted a patent—that is, the inventive step. The grant of a patent is awarded irrespective of the level of intellectual endeavour or effort exerted to achieve the invention. The validity of a patent cannot be judged on what is well-known or routine today but at the date the patent was filed—which could be many years in the past.

A patent over a gene sequence does not equate to ownership of that sequence. A patent to an isolated gene sequence does not impinge on the freedom of the individual to use their DNA.

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.

Other jurisdictions, in reviewing similar issues, have proposed measures that strike a balance between the need for genetic research, the prosperity of the biotechnology industry and access to new innovations in health care. Such measures include strong patentability criteria, public education, a statutory research exemption, access to compulsory licensing and guidelines for licensing of genetic inventions. IP Australia is currently progressing a patent reform package that seeks to strengthen Australia's patentability criteria to bring Australia into alignment with other jurisdictions. This includes a statutory research exemption that may help to address concerns by researchers regarding a lack of freedom to research. The changes will apply across all technologies, not just human gene technology.

In conclusion, IP Australia and the Department of Innovation, Industry, Science and Research are not aware of any reviews or evidence identifying a systemic problem with access to diagnostic genetic tests. Licensing issues are often resolved in the market through commercial negotiation. However, there are existing provisions within the patent system, such as crown use and compulsory licensing, that can be used to deal with any adverse impacts should problems arise. The data obtained by IP Australia so far indicates that genetic research appears to be continuing as downstream applications of gene sequences are being patented. My colleagues and I are happy to answer any questions that you may have regarding gene patents.

CHAIR—Thank you, Mrs Beattie. Senator Heffernan has been holding himself back.

Senator HEFFERNAN—Thank you very much. My congratulations not only to this committee but to the government for bringing on this inquiry. Obviously, besides being a disgrace, I am also just a wool classer and a welder, so technically this is going to be quite an endeavour for people like me who do not have the expertise that you people on that side of the room have. So I will apologise in advance for some of the lack of understanding of technology. Mrs Beattie, who was the author of your opening statement?

Mrs Beattie—The four of us.

Senator HEFFERNAN—Madam Chair, I would like to give a little colour and movement and then go to some pretty intense questions. The reason that this inquiry came about is we were made aware of the case of BRCA1 and 2, which predisposes in that gene sequence women to breast cancer and cervical cancer, I think. An arm of it goes to men's prostate cancer. The letter of demand by Genetic Technologies Australia used some pretty simple language to places like Westmead Hospital and the Peter MacCallum Cancer Centre et cetera. GTG, in their language, stated:

GTG also announced that the intellectual property rights it had obtained from Myriad for breast cancer susceptibility testing will not be enforced by GTG against other service providers in Australia ... and were a gift from GTG to the people of Australia ...

That was in 2003. They subsequently decided this year to enforce that patent right. When I rang them—I do not think they had ever had a call of the nature they got—they said, 'Well, Senator, we have the licence for Australia and we want to centralise from Westmead and all these other places the testing.' I then got a reaction from Professor Judy Kirk at Westmead Hospital. Her people were wondering who they could lobby because it seemed that they had to surrender a lot of their work that they had been doing since 1994. They were going back and testing those

samples when newer testing technology came along. So the outcome of that was that the people in Melbourne at Genetic Technologies Australia said, 'Well, we've got the licence and we've come to an arrangement', unlike a lot of other places in the world, like Japan. They used them as an instance. They said, 'Because we've discovered that Myriad in America are breaching one of our patents, we've have come to a commercial arrangement where the local testing for these BRCA1 and 2 could be done in Australia.' If you are in Japan, for instance, the samples have to be sent back to America. I think ordinary people relate to the cost of all that and the monopolisation of that. Hence we are here.

CHAIR—I think that is the colour and movement.

Senator HEFFERNAN—The Patents Act provides patents for inventions and not discoveries. Why, then, do you not find any basis in law, on page 3 of your submission, for refusing to give monopolies to materials that are identical to those found in the human body?

Mrs Beattie—As indicated in our submission, things found in nature that have been isolated and a specific function which has economic utility that has been identified for those materials are considered inventions. For example—

Senator HEFFERNAN—The isolation?

Mrs Beattie—No, not the isolation. The fact that you have found that this entity, this chemical composition, this molecule has a particular activity which has economic utility is an invention and the—

Senator HEFFERNAN—Not a discovery?

Mrs Beattie—It would be a discovery if all you did was identify, for example, the gene sequence. If all you did was say, 'This is the ATG-CG combination' and you left it at that, that would be a discovery, and that is it.

Senator HEFFERNAN—But it is my understanding—

CHAIR—Senator Heffernan, can we just let Mrs Beattie finish and then we will go further.

Mrs Beattie—So it is no different, for example, to taking a plant and finding that some extract, an active ingredient in that plant, provides a useable function. That has been the practice all along—that you can identify that. You have found a use for it, a practical use for it. Therefore, you have taken that knowledge and applied it and it becomes an invention.

Senator HEFFERNAN—Has that been tested at law, the difference between the invention—

Mrs Beattie—No.

Senator HEFFERNAN—Is it time that it was tested at law?

CHAIR—I think that is an opinion, Senator.

Senator HEFFERNAN—No. You do whatever you like in response. I am just someone trying to get my mind around how we can have companies that have taken out a whole range of patents on naturally occurring things in your body and then monopolising, not only in the case of BRCA1, the actual patent on the gene and the test. Do you agree that they have the patent on the gene as well as the test?

Mrs Beattie—Yes.

Senator HEFFERNAN—How the hell can they get a patent on a naturally occurring gene in my body? What is the status? This is one of the big questions that this inquiry has to go to. It took hundreds of years for people to figure out that slaves were not actually chattels. That makes the gene in my body a chattel.

Mrs Beattie—The gene that has been isolated does not actually exist in your body in that form.

Senator HEFFERNAN—It has been isolated.

Mrs Beattie—It has been isolated. It has been extracted. In your body it exists as a big long chain of all sorts of letters. What the particular inventor has done is identified a particular group of letters that have a particular function that is useful. They have been able to identify and extract that and define it as having a function.

Senator HEFFERNAN—And a lot of that research has been done with public money for the public good and then commercialised and monopolised. As you would be aware, since the challenge in Europe, where obviously the courts are about the law and not necessarily the truth, there is now a situation in Europe where people of a certain Jewish genetic background have to pay the full cost of €4,000 as compared to €900 if you are not of that genetic background. Do you really think that all makes sense?

Mrs Beattie—I am not sure I can answer that.

Senator HEFFERNAN—Madam Chair, it is going to take several goes to get our heads around this. You said in your submission that the current system for diagnostic genetic tests is functioning effectively. What data on costs and benefits have you used to draw that conclusion?

Mrs Beattie—We have not seen any evidence that we could find that suggested there was a problem. What we have done in our submission is refer to a number of studies that have been done into impacts of gene patenting. That includes the ALRC review. It also includes a study that was done in Canada and in the UK. They have all determined that there is no systemic problem with gene patenting and that, provided you have strong patentability criteria, you provide research type exemptions and you encourage good licensing practices, especially in relation to government funded research, those issues can be dealt with. Page 28 talks about the studies that we have identified and made use of in our submission.

Senator HEFFERNAN—So you do not think there is a problem?

Mrs Beattie—I have not seen evidence, based on the studies—

Senator HEFFERNAN—Can I just take you to the BRCA1 and 2 and Westmead. They obviously have been doing research at Westmead Hospital since 1994 and then, of course, the mapping of the genome came along. They are now going back with family histories to those original samples. Peter MacCallum, for instance, gets a letter dated 7 July last year. It states:

I am writing to notify you that Genetic Technologies Limited ... is seeking to enforce its intellectual property rights with regard to offering diagnostic testing of the BRCA1 and BRCA2 genes—

You have probably read the letter. Have you read the letter?

Mrs Beattie—No, I have not seen the letter.

Senator HEFFERNAN—I will table the letter. It continues:

for suspected cases of hereditary breast and ovarian cancer syndrome in Australia and New Zealand.

In the interests of avoiding costly and time consuming litigation, Genetic Technologies proposes a commercial solution whereby Genetic Technologies will perform all of Peter MacCallum Cancer Institute's future BRCA1 and BRCA2 testing requirements as settlement of all Peter MacCallum Cancer Institute's past and prospective infringement of our exclusive patent rights.

They earlier wrote in 2003 that they were going to give it as a gift to Australia. It continues:

Genetic Technologies has invested millions of dollars to both procure—

not do the testing; to procure the licence—

and to be in a position to exploit these exclusive rights.

I will table the letter. I will not burden you with it all. It continues:

However, in the event the Peter MacCallum Cancer Institute is not prepared to provide the requested undertaking in writing by Monday, 14th of July 2008—

and this was written on 7 July 2008; it would be a lawyer that wrote this—

Genetic Technologies will then immediately proceed with legal action without further notice. Our lawyers have prepared a detailed Statement of Claim and are ready to file an Application with the Federal Court if necessary.

I would have thought that is very unhelpful to the public good. As a consequence of that, we have all these alarmed families. These people are decent people. People like Professor Judith Kirk spend their waking hours trying to placate people who have all sorts of difficult decisions and histories of medical care to face up to. I would have thought that there is a problem. You say there is not. I would have thought there is a serious problem.

What they are proposing to do—my understanding from Westmead and Peter MacCallum and other places—is surrender the rights to their testing to a central laboratory in Australia. The

alleged benefit to Australia was that because Genetic Technologies Australia had found a breach by Myriad in America, they did not actually have to send the samples back to America to be tested. You have said that you think the business is functioning effectively. I do not think it is.

I will take you to an example of why I think it is not functioning effectively. Do you know Chiron?

Mrs Beattie—Yes.

Senator HEFFERNAN—Why was Chiron granted a patent for a hep C vaccine which did not exist? The patent number is 624105. Could you answer that?

Ms Press—That patent is quite old. It has now ceased.

Senator HEFFERNAN—But they were granted a patent for something that did not exist.

Ms Press—That is not my understanding of it.

Senator HEFFERNAN—Well, I will clarify that with other expert witnesses.

Ms Press—My understanding is—

CHAIR—Ms Press, what is your understanding of the Chiron situation?

Ms Press—At that time it met patentability requirements. The original claims that were granted were challenged and amended. There were amendments to the original claims. But they are to nucleotide sequences and epitopes from the hepatitis C virus, so they do represent patentable subject matter, although that was disputed; it has a history of litigation.

Senator HEFFERNAN—But nothing ever came out of it, yet you gave them a patent.

Ms Press—Senator Heffernan, that is often the case with many patents.

Senator HEFFERNAN—But you actually tie up research. Take that on notice or that can be your answer. Perhaps you have a more comprehensive answer. This is all new territory for us. I apologise for my crassness or whatever it is.

Mrs Beattie—Senator Heffernan, if Myriad did not go to the trouble of defining the BRCA gene, where would we be now in relation to breast cancer tests?

Senator HEFFERNAN—I will come to that and the public money and the public research that went into it before they—

Mrs Beattie—But it was not Australian public money; it was US money.

Senator HEFFERNAN—With great respect, can I explain what I understand. We accepted the patent right in America of Myriad by convention in Australia, not by law.

Mrs Beattie—No, it was examined in Australia. It was examined in Australia through Australian law.

Senator HEFFERNAN—It has never been tested at law.

Mrs Beattie—I am sorry, but no-one has opposed it. No-one has taken it to court.

Senator HEFFERNAN—Well, hopefully out of this hearing will come some clarification.

Mrs Beattie—But that is what I am trying to provide to you. I guess what I am trying to understand is if the gene sequence had not been sequenced and identified and linked to hereditary breast cancer by Myriad, where would we be now? We would not have a test. We would not have an understanding of the hereditary risk in relation to that gene.

Senator HEFFERNAN—You cannot say that, because a lot of good public laboratories do a lot of good public research.

Senator BOYCE—That is hypothetical.

Senator HEFFERNAN—You cannot say it would not have come along anyhow. But my point is that you then monopolise the test. We will get to it. This is going to take a month or two, Madam Chair. There has been millions of dollars of public research money spent which has then been commercialised and licensed and monopolised. There is billions of public health money spent on not only applying the tests but paying for the licence. We will give you examples of billions of dollars of licence fees as opposed to health care.

Senator BOYCE—I want to follow up on that. Mrs Beattie, would you expect that whoever had identified and described the BRCA phenotype in the way that you have mentioned would have sought to patent it?

Mrs Beattie—I would expect that they would have. I cannot say definitely that they would. But, as you know, all around the world public research institutions are encouraged to clearly identify their intellectual property that they create through the research that they undertake. They also encouraged to ensure that appropriate protection is taken for that intellectual property so that it can be commercialised and that the benefit can flow back to the economy that has spent the money in publicly funding that research. That is the model that all economies employ at present.

Senator BOYCE—Are you aware of any countries that use a public good type of patent, where it is not a privately owned patent but might be owned by an organisation that is going to make it freely available to anyone who wants to use it?

Mrs Beattie—Lots of companies with patents—

Senator BOYCE—I realise that lots of companies do that. But are you aware of any government move that would categorise patents into private and public good, so to speak?

Mrs Beattie—I cannot answer that specifically. What I am aware of is that companies and research institutions patent, but they do not then enforce the patent. They actually make it available. If they do licence, they licence very broadly.

CHAIR—So what is the intent of the patent when they actually do it? I think that is the core of Senator Heffernan's original issue. What is the intent of a patent, from your perspective, in the agency that actually does it? Do they have to put an argument up as to what their intent is?

Mrs Beattie—In terms of what are they trying to achieve by it?

CHAIR—Yes.

Mrs Beattie—Well, I would say that that would be determined. It would be to gain return on the research dollars that have been spent. It might be to gain some benefit and fund further research. It may be that they provide it to everybody for the benefit of humanity.

CHAIR—And do they have to provide that information to you when they are seeking a patent?

Mrs Beattie—No.

CHAIR—So what exactly do they have to provide to your agency? If someone is seeking a patent, exactly what do they have to provide?

Mrs Beattie—They have to define their invention. So they have to describe their invention. They have to explain what they are actually claiming in terms of the scope that they are claiming, so the application would contain claims to the invention and the description of the invention. We would assess it based on the patentability criteria within the legislation. We do not get information about what they intend to do with it—whether they intend to commercialise it or whether they intend to license it exclusively or widely. That is not a requirement for the patent application.

CHAIR—What they are going to do with it is not part of the requirement?

Mrs Beattie—No.

CHAIR—You said in your opening statement that one of the things you assess is the degree of ingenuity that it takes. Does that have to be defined when they are claiming the patent?

Mrs Beattie—We assess that. Of course, they would provide indications in their specification that their patent is inventive above the prior art that exists.

CHAIR—Is there a set form that they have to use?

Mrs Beattie—Not a set form, but there is a sort of set structure.

CHAIR—Format?

Mrs Beattie—Yes, format in terms of what—

CHAIR—And is that on your website?

Mrs Beattie—Yes. You will find the requirements online.

Senator BOYCE—I want to ask one technical question. All patents are subject to the same length of existence? Do they all last for what?

Mrs Beattie—Twenty years. Pharmaceutical patents do have an option for an extension up to five years. That is intended to compensate for the lengthy regulatory approval process that they have to go through.

Senator BOYCE—This does not matter if I have invented a new cistern for a toilet?

Mrs Beattie—No.

Ms Press—Many patents do cease or lapse before the 20-year term. Not all patents are maintained by the inventor or applicant for 20 years.

Senator BOYCE—If I pay my money, it will last 20 years?

Ms Press—Yes.

Senator BILYK—I have a question to follow on from Senator Moore's question. Is there an average timeframe that it takes for a patent to be finalised?

Mrs Beattie—There are a number of statutory timeframes within our legislation, but it can take up to five to six years from the date of filing to finalisation.

Senator BILYK—Have many gene patents been finalised in a shorter timeframe than that?

Mrs Beattie—Again, it depends on how quickly they want to prosecute the patent. I cannot answer that directly. I would have to maybe look at some information.

Senator BILYK—How many—it probably is in the submission, but I took in quite a lot trying to read all the submissions—patents have been finalised to date?

Mrs Beattie—On gene sequencing?

Senator BILYK—On gene patenting, yes.

Mrs Beattie—We believe, from the information that we have been able to extract from our systems, that up to 400 patents potentially claiming a human gene have been granted in Australia in the period 1983 to 2008. That information is on page 28 of our submission.

Senator HEFFERNAN—I have a series of questions. I want to follow on about hep C, where you granted a patent for something that does not exist. I am a layman. I do not quite get that. You granted a patent for gene therapy for haemophilia when no data was provided showing it worked in humans. With that in the background, an article in the *Sydney Morning Herald* states, ‘Women no longer will be able to go to a public hospital to find out whether they have inherited a genetic mutation that causes breast cancer, after the company that holds the licence to the gene patents set a deadline of November 6’.

Against that background, the objective of the competition principles agreement is the removal of anti-competitive elements in existing and proposed regulation clause 5(1). The agreement stipulates that legislation should not restrict competition unless it can be demonstrated that the benefits of the restriction to the community as a whole outweigh the costs and the objectives of the legislation can only be achieved by restricting competition. What data can you present to the committee that the benefits of allowing patent monopolies on human and microbial genes and non-coding sequences, proteins and their derivatives, including those materials in an isolated form, outweigh the costs?

Mrs Beattie—I do not have that information. I am not aware of any study that has done that sort of evaluation. Maybe my health colleagues have something that they can draw on.

Senator HEFFERNAN—So there has been no work done on anti-competitive behaviour?

Ms Murnane—Senator, we would agree with our colleagues on the fact that, other than the issues that came up on two occasions in 2003 and in 2008 in relation to the BRCA genes, there has not been any challenge to the delivery of genetic tests or any other sort of genetic medicine through patents. That does not mean the potential is not there. But they are the only two instances that have come up. On both occasions, our department did make contact with the company. What part that contact made and what we did have in them withdrawing claims on both occasions I cannot say. But that is what happened on both occasions.

Senator HEFFERNAN—Would it be fair to say that Genetic Technologies Australia have written to the people they put on notice to say there was an ACCC investigation? Have you got that letter? Are you aware of that?

Ms Murnane—Yes. We are aware—

Senator HEFFERNAN—Are you aware of the ACCC intrusion?

Mr Reid—Yes. The department had some discussions with the ACCC when the letter from GTL came to the department’s attention because it seemed to us that the letter itself might constitute breaches of the Trade Practices Act.

Senator HEFFERNAN—I do not want to interfere in any way, Madam Chair, with an ongoing investigation. What data can you present to the committee, given the previous answer—

Mrs Beattie—I want to add something to the issue about anti-competitive conduct. In the Patents Act, there is a provision for compulsory licences to be sought. One of the grounds for seeking a compulsory licence is anti-competitive conduct. We are not aware that such provisions have been invoked or sought by anyone.

CHAIR—Would they seek the licence from your organisation, Mrs Beattie?

Mrs Beattie—No. You would go to the Federal Court to seek an order for the issue.

CHAIR—There would be steps. You would not be aware of that. As an organisation would have had a patent through IP Australia, if there were action taken in the Federal Court, is there any reason that you would be advised of that?

Mrs Beattie—We are.

Mr O’Keeffe—We probably would be advised of a licence being granted because we would have to record that on the register.

CHAIR—I was just thinking of that communication link. So there would have to be some cross-referencing. So if a licence were granted, you would have to be advised for your records. If a licence were not granted, would there be any reason that you would be advised of that?

Mr O’Keeffe—Probably not formally. But we may become aware of it.

Senator HEFFERNAN—I will continue. I apologise for my inattentness. This is sort of new territory, certainly for us and it is probably for the wider Australian community, who are generally pretty horrified to discover that, like mineral exploration licences, there are a lot of patents out there on things that we have not even got to yet. Are there equal and offsetting examples of harm? Do you have any more substantial scientifically based data about the benefits and costs of the 15,000 or more granted patents?

Mrs Beattie—I guess I would dispute the 15,000 figure.

Senator HEFFERNAN—I guess we will drill down to that in due course. But I apologise. We are just at the start of the inquiry.

Mrs Beattie—But in terms of harm, I am not aware of any studies that have been done to reflect it.

Senator HEFFERNAN—Have any studies been done to show there is a benefit? There is no harm. Is there a benefit?

Mrs Beattie—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.

Senator HEFFERNAN—Later in the inquiry, we will be giving some examples of the licensing costs around the globe. Obviously, Madam Chair, there has to be a balance between an incentive to do the research and the reward, which is all part of what will be the deliberations of

this committee. But there are billions of dollars in the licensing fees. At page 7 of your submission, you give examples of two types of claims that are broadly covered by the term 'gene patents'. The first are examples of product claims and the second are examples of method claims. Do you mean to suggest that everything included in figure 1 on page 7 are inventions within the meaning of that word in the Patents Act 1990? Is that what you are telling us?

Mrs Beattie—Yes.

Senator HEFFERNAN—Taking the first one on the list—the product claims—can you explain to this committee how a gene that has been isolated from its natural environment, be that a human body or other some entity, can be an invention?

Mrs Beattie—Provided that that isolated gene has a particular function identified and that it relates as a diagnostic or a therapeutic.

Senator HEFFERNAN—Is not the gene sequence, whether the gene is isolated or not, identical or substantially identical to the gene in its natural environment?

Ms Press—No. That is not the case. Genes do not exist as discrete entities in the human body or in nature. As Mrs Beattie mentioned earlier, they are part of our entire complement of genomic DNA. In isolating a gene sequence, it becomes a discrete entity usually maintained in a vector, where it can be replicated easily and manipulated easily. So, in a sense, it may be analogous to what we have in our human body, but it is something quite different when it is in an isolated form.

Senator HEFFERNAN—So how do these variations to the isolated gene transform into something that is an invention?

Ms Press—Because they meet that patentability threshold. It becomes an invention and not a discovery as soon as it has an applicable use as a diagnostic, as a medication, as a therapeutic. DNA is often used as a bio-barcode, as a research tool. As soon as a use is found for a DNA molecule, it enters the realm of invention.

Mrs Beattie—Provided that use is novel and it is not obvious to a person skilled in the art.

Senator HEFFERNAN—I think ordinary people standing at the back of the room would think there is a fair enough case to be made out for the test from an isolated gene. But the patent on the actual naturally occurring gene in your body is a bit hard to come to terms with. Is it not the case that a gene is usually carried through a protein so that there is a relationship between the two biological materials?

Ms Press—Yes. One might say that.

Senator HEFFERNAN—So it follows if you know the amino acid sequence or if you have access to the protein, be that a hormone or erythropoietin or some other protein like tissue plasminogen activator, or TPA for short, that you can reduce or reverse engineer back to the gene?

Ms Press—It may or may not be the case. I think you are referring to litigated examples, litigated patents. It really depends on the case by case basis and the situation and the particular patent and what has exactly been occurring.

Senator HEFFERNAN—So it is neither yes nor no, the answer?

Ms Press—I do not think you can draw a general principle of application that broadly applies to each gene patent from specific cases litigated. The monopoly claimed by each patent is quite different. Generic principles are not always derived from specific litigated cases.

Senator HEFFERNAN—So is it neither yes nor no, or tending to no or tending to yes?

Ms Press—No. I reiterate that a generic or general principle of application cannot always be derived.

Senator HEFFERNAN—So the case for no, as opposed to the case for yes, is the answer. If you—

Ms Press—No. That is not what I said.

Senator HEFFERNAN—I will not use my colourful language. It is neither something nor your elbow. Just for the purposes of the first meeting, Madam Chair, because this is seriously technical and I apologise, I will just leave that aside. You will be back. Do not worry; you will be back.

Ms Press—I look forward to it.

Senator HEFFERNAN—With regard to the haemophilia, where no data was provided that it worked in humans, why did we grant a patent for that?

Ms Press—Well, I would have to actually review that case to see whether that was the case. One thing that I have noticed—

Senator HEFFERNAN—Do you want the patent number?

Ms Press—I will obtain it. We will look at that.

Senator HEFFERNAN—It is 2002048844.

Ms Press—May I just explain that sometimes the applicant in their patent does not always have to reduce to practise everything. So if there is a proof of principle that that protein works as a therapeutic in a mouse, within the art it may be a very reasonable extrapolation to say that that is going to work in a human. In fact, usually when new drugs or therapeutics are tested on humans, there needs to be a regulatory approval process and an ethical process for that. So a patent may very well be granted on the basis of that therapeutic or drug working in an animal model.

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?

Ms Press—I have just attempted to explain that before. 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.

Senator HEFFERNAN—I have some questions about why you granted patents. Why did you grant a patent for a method to treat epilepsy without requiring data to show that it worked in humans?

Mrs Beattie—Senator, patents are filed well and truly before clinical trials are undertaken for these inventions. So what I think you are suggesting is that we should not be contemplating granting patents until clinical trials have been done in humans, which would defeat the purpose of the patent in terms of seeking to protect the intellectual property in order to make it public and enable it to be used in clinical trials, which are very public processes.

Senator HEFFERNAN—We will come to the competition side of that question at another time. That will be a bit of work for the lawyer. I want to ask a couple of questions of the Department of Health and Ageing. Are you aware—I am aware—of any pressures on medical researchers, doctors or academics that would lead them to not make a submission to this inquiry?

Ms Murnane—We are not. I can say that we are not, no.

Senator HEFFERNAN—Would you be interested if people felt threatened with their future research grants et cetera?

Ms Murnane—I am sure we would. I think that Professor Anderson might like to speak to—

Senator HEFFERNAN—It might be that these people are imagining this. But this is another flow-on effect of what we are doing.

CHAIR—Professor, are you aware of any in your industry?

Prof. Anderson—No, I am not. But I think it is fair to say that the research community is aware of the uncertainty around this issue and around the research use of things that are under patents. There is no doubt that they would appreciate some clarity around that. I think that is fair to say.

Senator HEFFERNAN—I hope that is at the end of this journey. Have any employers, to your knowledge, of any state or federal department of health been encouraged to not make a submission to this inquiry?

Prof. Anderson—No. I am completely unaware of that, Senator. Can I just add that, of course, we have the Human Genetics Advisory Committee. It is the principal committee of the NHMRC. It has many researchers on it as well as laypeople, consumers and counsellors and so on. They have been very active in forming the NHMRC's thoughts and views on this. I am certainly not aware of any specific intimidation of the type that you mention.

Senator HEFFERNAN—I think I have had a pretty fair go, Madam Chair. I am grateful for the opportunity and I am grateful that all of you are here because this is obviously a pretty big question.

Senator HUMPHRIES—I have missed most of this afternoon's hearing. I have to confess that, with the pressure of this week's work, I have not yet read the submissions before us. So if I ask a question that has already been answered, do not hesitate to say, 'Go back and read the transcript.' Can anybody at the table tell me how many patents have been granted over genes in Australia at this time?

Mrs Beattie—In the IP Australia submission, we have provided a section on the data that we have been able to extract out of our systems. It starts on page 25. On page 28, you will note that our investigations have revealed that, in the period from 1983 to 2008, less than 400 patents were granted over an isolated human gene per se.

Senator HUMPHRIES—A human gene?

Mrs Beattie—Yes. That is to the best of our ability to determine that data.

Senator HUMPHRIES—Because you do not keep statistics on the number of patents that relate to human genes as opposed to animal genes?

Mrs Beattie—Because the particular classification system that is employed by the patent offices does not have a specific classification for human genes. It is in the animal gene realm.

Senator HUMPHRIES—Did you say that that number has been predominantly accumulated in recent years?

Mrs Beattie—That was from 1983 to 2008.

Senator HUMPHRIES—It is not likely there would be any genes before then?

Mrs Beattie—No.

Senator HUMPHRIES—I want to get an impression of whether the frequency of gene patent registration is likely to be increasing. Is it likely to become more common?

Mrs Beattie—Actually, on page 27 of our submission, we have provided figure 2, which shows a pattern of declining granting and filing of patents for gene sequences per se since publication of the human genome in 2001 because the novelty and inventive step thresholds are now different with that public knowledge.

Senator HUMPHRIES—Do you know approximately how many human gene patents would be registered worldwide, or could you guess at such a figure?

Mrs Beattie—I do not have that figure, but there is a study that was done in the US that suggests, I think, about 4,000 patents.

Senator HEFFERNAN—You might be able to take that on notice.

Prof. Anderson—Maybe I could add something. It reflects Senator Heffernan's comments about the complexity of this area, if you like. This is a very rapidly changing area of science, so 10 years ago and 20 years ago we really did isolate things gene by gene. We cut, bang and worked out what to do. With the technology that has been developing from the human genome, which cost billions, we can now run whole human genome sequences for about \$100,000. There is a very strong prediction that that is going to be about \$5,000 maybe later this year. So instead of—

Senator HUMPHRIES—So you can run the sequence?

Prof. Anderson—Well, it is a machine. You put the cell in and you get the sequence out at the end. So instead of gene by gene, many people, including many people we fund here in Australia, are able to do all the gene sequence in individual patients. Indeed, we have signed up to an international cancer genome consortium that is going to take 500 people suffering from cancer with the 50 most common cancers and do the complete sequence of those genes. It will be not only the DNA sequence but the changes around the gene that you heard about earlier. When the gene is in situ, it is affected by the chromosome itself. The technology is changing so fast that people can understand the gene sequence in a way that was just not possible. That is transforming, therefore, what people are patenting and so on.

I think the second thing that has changed is, for example, with that huge study, all the data acquired by agreement is going to be in the public domain immediately. So the ethos now around molecular genetics and human genetics is much more along the lines of putting the information out there for others to build application and knowledge and diagnosis on top of that. So we have been through several phases in terms of DNA sequencing and intellectual property protection. I am not surprised to see the figures going down on individual genes because I think we have moved into a phase where we can sequence all the genes with alacrity.

Senator HUMPHRIES—But is that process likely to lead to more applications for gene patent registration or less, do you think?

Prof. Anderson—This is really not my area. But the patents, I would have thought, will not be for the genes because they will be out there in the public domain. It will be for use of the genes for human purposes.

Senator HUMPHRIES—Well, that is still a patent, though, is it not?

Prof. Anderson—True.

Senator HUMPHRIES—To use the gene?

Prof. Anderson—True.

Senator HUMPHRIES—So, if that is the case, would we not expect an increase in gene patent registrations?

Mrs Beattie—In the method of use. The different diagnostic, the different methods, yes.

Senator HUMPHRIES—What is the situation in other comparable countries in terms of the way our law works? Are our laws about the registration of human gene patents effectively the same as they are in other OECD countries?

Mrs Beattie—They are effectively the same as in European Union countries. They are effectively the same as in the US, Japan, I think Korea as well and many others. There are exceptions. For example, Brazil excludes those types of things from patenting. I think Argentina or the Andean countries exclude gene sequences per se and other elements. So there are provisions in other countries for exclusions.

Senator HUMPHRIES—Are any of you able to tell me whether any of the organisations or client groups or stakeholders that you deal with have expressed concern about the state of Australian law in this area? Have they argued for changes in the way in which we either register or use human gene patents?

Ms Murnane—Senator, I think it is fair to say that when the issues around the BRCA genes surfaced again last year, yes, some organisations did raise concerns about what would happen if the BRCA genes were not able to be used in the way they were currently used both for research and diagnosis.

Senator HEFFERNAN—Subject to the ACCC inquiry, we may be in that position in due course.

Ms Murnane—It may not only be that, Senator. It may not only be that. Our colleagues from IP said that this has never been tested in law. We do not know what motivated Genetic Technologies to withdraw, but the fact is they did.

Senator HEFFERNAN—Was it called money? Are they going to go belly up?

CHAIR—Do you have many more questions, Senator?

Senator HUMPHRIES—No, I do not.

Senator BOYCE—Of the organisations you are speaking of, are you talking about government bodies who are concerned about the agreements or individual companies?

Ms Murnane—It was not companies. These would have been research organisations and clinical organisations.

Prof. Anderson—That is right. Bioresearch organisations want clarity around this and the use in research in particular. But, beyond that, it has been raised now over a number of years.

Senator BILYK—I am not quite sure who I am aiming these questions at. I cannot quite get my head around the fact that some of these patents seem to actually slow down or stop future research into areas because the patents can involve, as I understand, some speculation. They can be a patent for something that involves a potential new treatment. That is like a ‘how long is a

piece of string?’ type question to a layperson like me. Can you explain to me how it benefits the public to have that sort of patent put in place? I refer specifically to the one I have been reading about—the SCN1A gene with regard to epilepsy and Dravet’s Syndrome. Does anyone know anything?

Prof. Anderson—I suppose for some devastating diseases of the brain or anything else, in human medicine it costs maybe \$2 billion to develop that drug or the therapy or whatever it is. This is different to diagnostics, because that is not so expensive. But if somebody could isolate the genes, although it is very unlikely, that lead to multiple sclerosis or something like that, for the company to invest the \$1 billion or \$2 billion eventually to bring that finding to market, they need the protection of intellectual property so that they have a reason for investors to put all the money into that drug. So I think this was answered earlier. It is crucial but only a part of effectively developing therapeutics from medical research. But, like so many things, there is the other side, and that is what you are also implying.

It is very important that that process does not inhibit original discovery and original medical research itself. So, from a researcher’s perspective, the need to be able to undertake research freed from the threat of maybe transgressing some barrier and having to pay fees I think is a very important thing. Although it has been raised with me many times—‘We would like some more clarity about this, Professor Anderson’—we are not aware at the research end of cases that have been inhibited. So I guess what I am saying is that, on the one hand, we would not have Gardasil without a patent system so that Ian Fraser’s original discoveries could have been protected and developed by CSL and other pharmaceutical companies.

Senator BILYK—Well, we might have it if other researchers could have done the research. But once the speculative patent has been put in place, that basically stops other people doing the research. So you cannot say we would not have it, I do not think.

Prof. Anderson—No. With respect, that is not quite the point I was making. It is to do with there not being an investment into the original finding or research. Professor Fraser published the research and others have used that research in research and found many other discoveries which have gone on. I am just saying that the companies would not have been able to confidently invest in that original discovery if other companies could have gazumped them by having that knowledge in the public arena without the protection around patents. I thought you phrased it pretty well. It is this balance thing out of research. I want to let research rip without restrictions on it. So if patents get in the way, I think that is a bad thing. On the other hand, you also want humans to get the benefit out of research. Sometimes that requires intellectual protection so that investors will invest the many hundreds of millions, perhaps billions, of dollars so that the end product can then be marketed. It is so complicated, really.

Ms Murnane—It is a balance. I would like to add to what Professor Anderson said. The issue of Gardasil and the discovery of the human papillomavirus and its association with cervical cancer I think is a very good example of everything working well. As Professor Anderson said, Professor Fraser published his results. It has been used in diagnosis and in treatment regimes for many, many years. But once they had an idea for the drug, it was right that their idea for that drug and the final drug were patented. But the original research was also used by another company—Merck Sharp and Dohme—who very quickly after put their drug, a similar drug, on the market.

Senator BILYK—Is that not competition? Is that not acceptable?

Prof. Anderson—Yes, so we are really saying the system is working.

Ms Murnane—The system has worked there.

Senator BILYK—I want to go to another issue, which is the specific question about the speculative patent for areas such as newborn babies. The damage is done to them in the first 12 to 18 months of their life. They cannot have the tests done in a hospital. They have to have the tests done specifically. How is that in the public interest? To the parents of these young kids, who can end up with severe problems because they could not have the tests done to clarify whether it is Dravet's or epilepsy, how is that possibly in the public interest?

Ms Murnane—Is this related to the particular gene?

Senator BILYK—Yes.

Ms Murnane—I think, Senator, what we would like to do is to look at that and get more information and talk to some of the clinicians involved.

Senator BILYK—Can you take that on notice and make sure I get a response fairly soon?

Ms Murnane—Yes. We will do that.

Senator HEFFERNAN—I am worried about what we have just learnt in the banking world. Extending credit to 100 times your capital base produced greed and a river of gold that has all blown up. We do not want this to turn into a river of gold. If there is no balance, this will turn into a river of gold. Can you tell me if what I am about to read out is wrong. Before I do that, I just want to say that the US free trade agreement and the TRIPS document state:

Each Party shall make patents available for any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step and are capable of industrial application.

It says that in both documents. It continues:

A Party may exclude from patentability—

And it goes through that. This is what they may exclude from patentability in both the free trade agreement and the TRIPS document:

(b) diagnostic, therapeutic, and surgical methods for the treatment of humans and animals.

It says it in both documents. So if we want to, we can actually exclude the patents. Do you agree?

Ms Murnane—Dr Lopert—

Senator HEFFERNAN—This is just a little warm-up. You can bring the paperwork next time.

CHAIR—I think we will put that on notice. We want to wrap up.

Ms Murnane—Dr Lopert was very engaged in the development of the agreement. But we would need to have the agreement with us, I think.

Senator HEFFERNAN—This is just a little warm-up. I just want to pick up a senator's prior remarks. This is a little synopsis of the commercial monopoly of cancer susceptibility genes BRCA1 and 2 that now can exist. Current clinical services and testing in public laboratories in Australia has been in place since 1994. Would you agree with that? If you disagree, yell out. The remarks continue:

In 2003, GT made a statement to the ASX stating that although GT would be offering testing, the IP rights (from Myriad)—

he did not say licence for—

would not be enforced by GT against other service providers—

which goes to the public benefit. It continues:

Public labs and infrastructure have been further developed since then on this basis, using a co-operative team of expert Australian senior scientists in NATA accredited public labs in most states.

GT—

in 2008—

demands public labs cease testing.

That was 6 November and it is now held off because of the ACCC. If that occurs, when that process is over, a monopoly will almost certainly exist, as it does in Canada, where costs just went like that—the river of gold turns up. It continues:

Samples sent to a private lab are lost for the future ...

I have been out to Westmead to the familial cancer centre. Sometimes it is fairly traumatic but at other times there is great relief in a generation of girls in a family that find out what the score is. It continues:

samples held in public labs can be used to test new genes (not patented) that may be identified in research OR to apply new improved technology for gene mutation detection.

What happens to those samples if under what is proposed they are sent to a central laboratory and the company goes belly up?

CHAIR—Senator Heffernan, I think we should put that on notice. That is a threshold situation.

Ms Murnane—It is hypothetical, Senator. It did not happen. I hope this is helpful. I think there are really two issues in relation to the BRCA genes. One is the insistence—as I said, it was later withdrawn—on holding a patent that made it necessary for other users to provide a licence fee. That is one. The further position is that only their laboratory could actually undertake the tests. That is a further step. As it happens, neither of those was tested in court, so I do not really know that we are going to be able to say much more about it.

Senator HEFFERNAN—This is preliminary. Genetic Technologies in good faith have told me the only reason they can test in Australia is because they were caught out busting one of their patents, so they came to a commercial arrangement. In the US, Myriad have used direct to consumer marketing—this is about getting the maximum out of what you have got—resulting in inappropriate testing of low risk women and a loss of the vital link to thorough and expert genetic counselling available obviously in familial cancer centres prior to consideration of genetic testing. It just becomes another river of gold. Would you agree with that, Professor?

Prof. Anderson—Certainly the NHMRC has some concern about direct marketing to consumers, including for the reasons you have mentioned. We have held a public forum on this. Our Human Genetics Advisory Committee is actively working on it. There is no doubt that there is an important issue to be resolved there. This, again, is part of what has come out of the new technology here. So I think that is certainly an issue of concern for our organisation.

Senator HEFFERNAN—Finally, would you like to comment on what is happening in Europe, where it has gone back to appeal, that test case? Are you familiar with that?

Prof. Anderson—No, I am just a scientist.

Ms Press—That is the BRCA test?

Senator HEFFERNAN—Yes.

Ms Press—No, that has been settled. It is not on appeal any more.

Senator HEFFERNAN—So who is in and who is out now in Europe? Would the licence prevail or did the licence not prevail?

Ms Press—The BRCA patents have not been honoured in Europe. People infringe and have been for a long time. The BRCA patents stand in Europe but their claims have been amended. It cannot be heard in the European patent office. It is finalised.

Senator HEFFERNAN—That is an indication that not only has this become a lawyer's feast but a banker's trust. We are in serious trouble. This inquiry is about to ask questions—

Ms Press—My understanding is that the public in Europe did not provide any moneys to the legal prosecution of that case. It would have been Myriad itself.

CHAIR—Senator Heffernan, I think the appeal process will be of interest and what happened in the end in that case. It has been identified. We have run out of time.

Senator BOYCE—I want to put one question on notice. You have commented on the compulsory licensing provisions that are available and said that they have been very rarely used. Are you able to tell us who has used them and for what purpose? I am more interested in whether they have been used by private companies or by institutions and organisations.

CHAIR—Is that something you would know?

Mrs Beattie—I will have a look. I am not sure.

Senator BOYCE—That is why I am asking. There is no-one else here, I think, who can give me that. If the department were able to provide it, that would be good.

CHAIR—I thank very much the officers from IP Australia, Health and Ageing and the National Health and Medical Research Council. I think Senator Heffernan has made it clear that you will be required in the future again. Thank you for coming this afternoon for the preliminary hearing.

[4.56 pm]

MOIR, Dr Hazel Veronica Jane, Private capacity

PALOMBI, Dr Luigi, Private capacity

CHAIR—Good afternoon. This hearing is very much a preliminary process in this exercise. We only have half an hour this afternoon. I do appreciate your patience in waiting. Information on parliamentary privilege and the protection of witnesses has been provided to you. This afternoon is the form of a briefing. Perhaps either or both of you would like to make a presentation. We will get into some very early questions. We have your submissions. They are significant submissions. Thank you very much. Is there anything you want to get on record or give to us this afternoon? Then we will go to questions in the half hour we have.

Dr Moir—I might go first, Senator. I am sorry my submission was lodged so late—just this morning—but I would like to make four points. I would like to preface that by saying that I am an economist. I am not a scientist. I am not a lawyer. I have been intensively studying the patents system for the last four years, particularly the issue of how inventive something has to be before it is granted a monopoly.

The four points I would like to make are, firstly, that the objective of patent policy is economic. The objective is to induce additional investment in research and development. If that additional investment is not induced, it is ineffective policy. There is no evidence on this point. The second point is that complexity is a ploy that is regularly used to try to prevent sensible questions being asked about the patent monopoly system. But, in its essence, the patent monopoly system is very, very simple. It is an exchange. It is an exchange of a monopoly for an induced innovation for the benefit of either new knowledge or new artefacts. It is the balance of these costs and benefits that determines if the patent system overall is good or bad for Australia.

In that regard, the most overarching principle is, as Senator Heffernan said earlier, the competition principles agreement. That is about legislation that restricts competition. Handing out monopolies is a restriction of competition. The competition principles agreement between the Commonwealth of Australia and all the states and territories requires that legislation which restricts competition should be reviewed to make sure that the benefits to the community as a whole outweigh the cost. This has not been done either for the patent system in general or for gene and related patents in particular.

There are no court decisions in Australia on granting monopolies for isolated and purified genes. There are no impediments under either TRIPS or the US FTA for refusing to grant a patent for discoveries—that is, isolated and purified genes—or for methods of medical treatment. Thank you.

Dr Palombi—Nearly 20 years ago, in this very building, the Hon. Barry Jones, as the Minister for Science, Customs and Technology, laid out the objectives of the current patents legislation, the Patents Act, 1990. Those objectives are to foster indigenous innovation;

to reduce unnecessary social costs; to improve the efficiency of the administration of the patent system; and to make it harder to get a patent by strengthening the standards of novelty and inventiveness. Twenty years later we know that these objectives have failed to materialise.

Ninety-two per cent of all patents granted in Australia go to foreign organisations, just as they did in 1990. There has been no measurable increase in indigenous innovation, at least as far as the patent data indicates. If that's not bad enough, for the past 20 years, IP Australia, Australia's patent office, has been granting patents over things that are not even inventions—genes and proteins that are identical or almost identical to those that occur in nature.

Patents over such things as human genes and gene mutations that have been linked to human diseases should not be the subject of patent monopolies—monopolies that drive up the price of biological materials—because they inhibit free competition and either stop scientists using them in medical and scientific research or drive up the cost of this research. There are 15,000 patents over virus, plant, animal and human genes, proteins and their components or derivatives in Australia. These patents almost always claim a monopoly over the use of these materials in all manner of medical, scientific and technical applications, some of which are so obvious as not to be patentable inventions while others are so speculative that they are truly science fiction.

An example of the former are the patents over BRCA1 and 2 human gene mutations that cause breast and ovarian cancer. These patents were all granted to Myriad Genetics, a US corporation. They not only claim all mutations on the BRCA1 and 2 genes, even though the patents only identified some of the mutations, but they also claim the use of all such mutations in genetic tests, tests that any competent Australian laboratory could make, and at the moment does, without reference to these patents. Indeed, there is nothing at all remarkable or inventive in using genetic materials in gene tests. It was and is an obvious thing to do.

An example of the latter is a patent granted by IP Australia in 2005 to the Children's Hospital of Philadelphia for a gene therapy treatment for human haemophilia. Even then, the scientific literature showed that the science described in that patent was useless. The so-called invention didn't work.

In 1992, IP Australia granted Chiron Corporation, yet another US corporation, a patent over hepatitis C virus vaccines. But, in 1999, one of the so-called inventors, Dr Michael Houghton, confirmed in a scientific paper that 'there is no HCV vaccine'. How was it possible for Chiron to seek and be granted a patent monopoly over something that did not exist? Why is IP Australia granting patents to foreign institutions over technology that does not even work? Why is IP Australia stopping our scientists from freely researching and working in these fields by granting patent monopolies over science fiction? Is it incompetence or corruption?

This is not a far-fetched question. During one of the most bitterly fought patent battles that raged the world, Chiron Corporation, via an intermediary, offered an inducement to Dr Sidney Brenner while he was engaged as a court appointed expert by Justice Aldous, a judge of the High Court of England. When this very issue was brought to the attention of Justice Burchett of the Federal Court of Australia during the Australian trial which scrutinised the validity of the corresponding Australian patent—624105—he said a:

... judge should not sit to hear a case if in all the circumstances the parties or the public might entertain a reasonable apprehension that he might not bring an impartial and unprejudiced mind to the resolution of the question involved in it.

It is telling that within a week of Chiron being required by Justice Burchett to produce all documents relating to or concerning any communication between Chiron, its officers, servants, employees or agents and affiliates and Dr Sidney Brenner, the patent litigation that had brought my clients, Murex Diagnostics Australia Pty Limited and its parent, International Murex Technologies Inc, to their financial knees was suddenly and unexpectedly resolved in an worldwide out-of-court settlement that was very favourable to Murex. That Chiron's patent made claims to all hepatitis C virus proteins and their use in blood screening tests, which Justice Aldous and the UK Court of Appeal, also served by Dr Brenner, found to be valid and enforceable, and which were seven years later—and this is important—revoked by the European Patent Office, the very organisation that granted the patent in the first place, raises even more questions. Was this a case of incompetence or corruption?

Did you know that the worldwide sale of erythropoietin, a naturally occurring protein that occurs in the human body and which stimulates it to produce red blood cells, in 2003 amounted to US\$10.1 billion? The very high prices charged for this so-called biopharmaceutical, which costs very little to make, is attributable solely to worldwide patent monopolies and the licensing practices of the company that owns them, Amgen Inc. Naturally, whether a patent is granted can make a significant difference to a company's financial performance. The potential for corruption is, therefore, real.

In 1995, an Australian Deputy Commissioner of Patents, Mr David Herald, presiding over an opposition to the grant of an erythropoietin patent, came to a conclusion that was completely at odds with a finding made six years earlier by a US court. According to the US court:

... the overwhelming evidence, including Amgen's own admissions, establishes that ...

recombinant erythropoietin—

is the equivalent to the natural hormone.

I want you to note that, given some of the answers you were given earlier this afternoon about the differences between these materials. Instead, Mr Herald concluded that:

... the molecules—

to recombinant erythropoietin—

have been deliberately changed from the naturally occurring form—that is, they are directed to artificially created states of affairs.

Apart from being a lie, this was not an insignificant finding. Mr Herald relied on that finding to hold that the patent concerned something that was an invention. Interestingly, the opponents did not even challenge the patent on the ground that it was not an invention. But that did not stop Mr Herald making this finding. This committee needs to find out what motivated him to do so. Was this a case of incompetence or corruption?

In all seriousness, how can a human gene and the corresponding protein, even if synthetically produced, be an invention? Genetic information is not something that anyone conceived, created or invented. This is why raw fundamental data, which is what President Clinton and Prime Minister Blair called it when they announced that the human genome had been mapped in March 2000, should, as they said, 'be made freely available to scientists everywhere'.

But the words of President Clinton and Prime Minister Blair have been subverted by patent attorneys and patent offices around the world using clever legal semantics—namely, that isolated genes are not natural genes. A study published in *Science* in 2005 revealed that nearly 20 per cent of human genes are explicitly claimed as US intellectual property. Of the 23,688 human genes that made up the human genome database of the National Centre for Biotechnology Information, their study confirmed that 4,382 of them were the subject of 4,270 patents within 3,050 patent families and controlled by 1,156 patent owners, of which 63 per cent were private firms. The single largest patent owner of some 2,000 human genes was Incyte Genomics, a US corporation.

Blaming IP Australia for making it difficult for Australian doctors and scientists to freely access these biological materials is easy. But the fault is also that of the Commonwealth and state departments of health, which must accept responsibility for failing to use powers available to them under the patents legislation. It is also that of the courts for lowering the invention threshold. Indeed, even the High Court of Australia has handed down two decisions in the past seven years which, rather than making it harder to get a patent by strengthening the standards of novelty and inventiveness, as Barry Jones expressly said was one of the key objectives of the legislation, is now actually easier. Recently, a British patents judge, Justice Kitchen, himself an experienced patent barrister prior to his elevation, said this about our courts:

It is perhaps noteworthy that currently Australian courts seem to be taking a very pro-patent view of obviousness and that patents are being upheld there which are not upheld elsewhere. The Hassle case and the Viagra case ... are perhaps examples of this. Whether, if that is so, it is good for the Australian economy is not my concern.

Well it might not be the concern of Justice Kitchen, but it should be the concern of every member and senator of this parliament that the economy of this country is being damaged by the High Court's judicial activism.

In his dissenting and, respectfully, correct judgement in the case which Justice Kitchen calls the Hassle case, Justice Kirby said:

As was said in another context, courts must be wary of the professional danger that 'attends the formulation of principles and doctrines and all reasoning a priori in matters which in the end are governed by the meaning of the language in which the Legislature has expressed its will'.

This committee needs to understand that in overturning the decision of four Federal Court judges who had invalidated the patent, the High Court in the Hassle case ignored the parliamentary intent to make it harder, not easier, to get patents.

According to the report *Venturous Australia* produced by the review of the National Innovation System chaired by Dr Terry Cutler, himself a board member of the CSIRO:

... the tests of non-obviousness ... have become much less stringent—as some have argued, to the point of vacuity.

Delivered in August last year to the Hon. Kim Carr, the Minister for Innovation, Industry, Science and Research, the report warned:

... where intellectual property rights are too easily granted, and where they are ambiguously defined—

there is—

... mounting evidence that this is impeding rather than stimulating innovation.

This inquiry will, despite what the Australian Law Reform Commission believes, for the first time independently examine how it is that patents over raw fundamental data have been granted by IP Australia. The results of its investigation will be important not only for the development of patent law in this country but for the rest of the world. It is hoped that this committee will start the process that will free the world's scientists and doctors to use their ingenuity to provide affordable diagnostics, medicines, treatments and cures for all people. Thank you.

CHAIR—Thank you. It is just very important to note that the terms of reference for this inquiry are purely on the gene aspect and not on a review of all of IP Australia.

Senator HUMPHRIES—I am trying to determine what the nature of the problem here is. You have indicated that there is some fault attached to state and territory health departments not using provisions in the IP legislation which allow them to prevent the overreach—I hope I am interpreting you correctly—of corporations who seek to patent what it was not intended should be patented. You have also accused the High Court of being—I think you said this—judicially adventurous. Is there also fault in the drafting of the legislation? Is it inadequately clear to deal with these issues?

Dr Palombi—I think we have to accept that the legislation, in terms of defining what the appropriate inventive steps should be and what novelty should be, needs to be radically overhauled. We have had to live now as lawyers with various judges trying to interpret these provisions. It has been going back and forth between the Federal Court and the High Court. Unfortunately, the High Court is ultimately the highest court, so it is now binding on the Federal Court. But I think if you look at the number of judgements, it is quite difficult because different judges have taken different views. It is very confused. Frankly, it is now unsatisfactory. Even IP Australia acknowledged that the test of inventiveness is too low. The fact that internationally judges have mooted this as well I think is significant.

Senator HUMPHRIES—Noted it about Australian law or noted it about general patents?

Dr Palombi—No. Noted that Australia is out of sync in terms of its test for inventiveness. In effect, it makes it easier to get a patent for trivial and probably non-inventive inventions that would be struck down in other countries.

Senator HUMPHRIES—So are you saying it is the consensus of commentators on these things that we do in Australia have too low a test for inventiveness and, as a result, patents have

been granted for things which would not be granted in equivalent circumstances in other countries?

Dr Palombi—I think you will find patent attorneys are very happy with this because it just means they can make more money from patents. But, generally speaking, the short answer is I think it is safe to say yes.

Senator HUMPHRIES—So of the kind of patent for the tests that Senator Bilyk was talking about before—I think you heard her talking about that; I forget what she called it—are you suggesting that that kind of patent which was granted in Australia would not have been granted in other Western countries?

Dr Palombi—I think it needs to be understood that there is a big difference between patents that are granted and are valid patents. Patent officers are in the habit of granting lots of patents. They do that for a number of reasons. Firstly, they generate fees from granting patents. Secondly, a patent has to be examined. When you are dealing with thousands of patent applications and you have only got so many examiners, and productivity demands a certain output, shortcuts have to be taken. The quality of the examination is a significant issue. It is a worldwide issue. It is well-noted around the world that patent officers, because of the vast numbers of patent applications that they are now having to deal with, are at their wits end as to how they are going to deal with the demand and produce patents quickly. So, as a result, you will find—and it is often the case—that there will be equivalent patents like this granted.

But the question really is: are they valid? We do not know often if they are valid or not because there is no mechanism in Australia, for instance, to actually independently test the validity of these patents unless someone who has a lot of money—usually a multinational corporation who can afford to spend in excess of \$2 million to \$3 million in legal fees—can afford to take these patents to the Federal Court and challenge them and decide whether or not they are valid. The consequence of that—that does not happen very often, naturally enough—is that we have a lot of patents on the register. I would venture to say a great majority of them are strictly invalid.

Senator HUMPHRIES—When you say invalid, do you mean that the patent does not work? It has been granted over a particular process or invention but, when you apply it, it does not actually have any effect? It is not commercially or functionally effective?

Dr Palombi—Not quite, Senator. It can be that. There are four significant criteria for patentability. The first is you have to have something that is an invention. Generally speaking, that is never really an issue. We all know that a pen is something that potentially could be an invention. The question is: is that pen new? Is there an inventive step involved in that pen? Is it industrially applicable? For the majority of implements that is never an issue. The question is you look at the prior art. You look at what the inventor claims to be the invention and you make an assessment.

It is quite different when it comes to genes because then you have to decide whether that is an invention. So unless each of those criteria are satisfied and are ticked, the patent is invalid. That is what I mean.

Senator HUMPHRIES—Which is the item that is not getting the tick, in your opinion, or which is being ticked inappropriately?

Dr Palombi—Well, with gene patents, the first. We are granting patents over things that are simply not inventions. They are discoveries. But there are other instances. This goes back to the issue of speculation as opposed to science fiction. If the application of the gene for a diagnostic test is obvious, it lacks an inventive step. So it is invalid because it lacks an inventive step. On the other hand, if it purports to be, say, a therapy but it does not work, it is not industrially applicable. It is useless. It lacks utility. In any event, there is no invention as well. So one would say that it probably fails the first test as well. So there are a number of criteria. The first criterion is: do you have something that is capable of being an invention? If the answer to that is yes, the next question is: is it novel? The next is: is there an inventive step? Finally, is it industrially applicable? Only if you get a yes to all of that do you have a valid patent.

Senator FURNER—If it is not an invention, a gene patent, then what is it?

Dr Palombi—It is a discovery.

Senator FURNER—A discovery?

Dr Palombi—It is. There is no specific exclusion under our legislation. There is in Europe. For instance, under the European patent convention, they actually say that a discovery is not something that is patentable subject matter. It is not an invention.

Senator FURNER—But surely if you discover something, that is an invention?

Dr Palombi—No. If you discover that there is a particular gene and it is linked to a particular disease, that is a discovery. You did not invent the gene and you did not invent the disease. What you have done is deduce that there is a gene that is linked to a particular disease. That is what we would call a discovery. If I discover a mineral, that is a discovery. I have not invented that mineral. If I discover a flower in the forest, I have discovered that. That is what discovery is all about. The general principle is in the Statute of Monopolies of 1623, where all of this started. That statute basically bans all monopolies. It cleans the slate. Section 1 says that there shall be no monopolies whatsoever. The reason why it does that is that our forefathers understood that free competition is very, very good for economic development.

However, if you have an invention—in this case, it is defined in the legislation as a manner of new manufacture, and there are certain other preconditions, but let us just leave it at that for the time being—we can make an exception. So unless you have an invention, you do not even get past the first hurdle. You have no entitlement. It does not matter how ingenious that discovery is. It does not matter how fantastic it might be. It does not matter what it might lead to. You must have an invention. That is what a patent system is about—granting a monopoly over an invention. And it is only if the invention is new and has an inventive step and is industrially applicable. I have to tell you that that is enshrined both in TRIPS and the US-Australia FTA, so it is a well-adopted principle that has stood by our system for nearly 400 years.

Senator HUMPHRIES—When you were talking about industrial applicability, you were talking about the hepatitis C patent that was granted to a US company. You said that the patent

does not work. I suppose by that you meant that it should have failed to get a tick because it did not have any industrial applicability.

Dr Palombi—That was haemophilia I was talking about.

Senator HUMPHRIES—Haemophilia. Sorry. So you would argue that, because it did not work, it should not have had any industrial applicability and, therefore, should not have been granted?

Dr Palombi—Well, I said two things. It is probably not an invention either because it does not work. But, even if you overcome that hurdle, it has no utility.

Senator HUMPHRIES—I recall people from IP Australia—perhaps I misunderstand them—saying that it is not their job, as the people who approve patents, to work out comprehensively whether a particular patent will work because the granting of the patent is a precursor to its application in research so that it can be used to determine whether it holds the key to curing diseases or producing particular chemicals or whatever. I assume the test for industrial effectiveness is quite a low test. It is a test of what seems to be potentially effective rather than what can actually be demonstrated or proved to be actually capable of achieving the objective it is designed for.

Dr Palombi—Unfortunately, that is probably true. But that results in crazy situations where we get a lot of speculative claiming going on. I have to tell you that in terms of gene patents the general assumption is this. This is the way it works. I discover the gene. The assumption is that that means that anything that you do with that gene, whether it is actual, for example, in a diagnostic test, or speculative, as in, for example, its use in a vaccine, means I am entitled to that. It does not matter how speculative it is now. To me, that just is crazy. We should not be doing that. Once we grant a patent of that kind, we effectively inhibit competition and ingenuity. What we want to do is allow as many people as they can to use the gene in their research to develop a vaccine. The first person that can prove, in my view, that they have developed a vaccine in a human that works or have credible scientific data that indicates that it is going to work, that is fine.

Let me give you an example with Chiron's hepatitis C vaccine. They were granted a patent by IP Australia in world record time. I think it was one of the first patent offices to give them a patent within a matter of three years. The claims definitely included claims to the use of hepatitis C viral materials and a vaccine. Once a claim like that is there, it effectively means that if anyone uses that material to develop a vaccine, they are effectively subjugated, by the priority of Chiron's patent, to have to deal with Chiron.

Senator HUMPHRIES—And they could be sued by Chiron for breaching their patent?

Dr Palombi—Well, they could be sued or they might have to enter into some sort of negotiations with them and Chiron will set terms. Now that might be good or it might be bad, but it just to me seems ridiculous, especially when five or seven years later one of the inventors actually admits in a scientific paper, 'We actually didn't have a vaccine.' This was litigated before the High Court, the patents court, in England. Chiron spent a lot of money. They called a lot of very expensive scientific witnesses before Justice Aldous. There were some very senior

patent barristers. They defended their claim to hepatitis C vaccines tooth and nail. They were not mucking around. They reckoned they invented a vaccine. The judge basically said, 'Well, look, I'm not convinced. I'm going to invalidate the claims to vaccines because I have found that it would actually take another 30 man years of research to develop a vaccine.' Now that is the kind of speculation that I just think is crazy. We are not helping.

Senator BILYK—I have a technical question. Are there definitions for innovation, discovery and speculative patents? Are there definitions within the patent process of those areas, do you know?

Dr Palombi—I think that probably requires a detailed answer. If you do not mind, could I, with the leave of the committee, provide that to the committee?

Senator BILYK—Yes. That is fine. Thank you.

Senator HEFFERNAN—I have a series of questions that I will put on notice because we have only five or 10 minutes. Can you give some examples to this committee of patents that we really should be more closely examining?

Dr Palombi—Yes, I will. I will provide that answer to you.

Senator HEFFERNAN—You can do it now if you want to. Would you prefer to take it on notice?

Dr Palombi—No.

CHAIR—I would prefer you take that on notice—that is, if you have a significant answer and it could be the start of another line of questioning.

Senator HEFFERNAN—For expediency, I will hurry through. In part 2 of your submission, you give six examples of patents that you say should interest this committee. In those examples, has public money played a role in achieving what the patent owners claim to be the invention?

Dr Palombi—Yes. Significant public moneys.

Senator HEFFERNAN—To what extent have or are these patents hindering doctors, scientists, laboratories and public hospitals from providing diagnostic or medical treatment for Australians?

Dr Palombi—Quickly, I will refer you to the article that was in the *Sydney Morning Herald* written by Julie Robotham over the epilepsy test. This is a perfect example of where public moneys went into developing the technology that is now the subject of a patent. One of our own public hospitals cannot afford to access the test. It is double-dipping, as far as I am concerned. Taxpayers paid for the research and they gave substantial moneys by way of AusIndustry grants to Bionomics. Because of a licensing deal that they did with GTG, Westmead cannot actually afford to do the test. As a result, they are having to ration the test. It just does not make any sense.

Senator HEFFERNAN—Is that right? To fit the public budget in public hospitals, they are rationing the test?

Dr Palombi—They are rationing the test. The crazy thing is that that test could be produced in-house within their own laboratories. They do not even need to go to GTG.

Senator HEFFERNAN—Under the licensing requirements, they cannot do those tests in their own laboratory, which they would be capable of doing?

Dr Palombi—It is not because of the licensing they cannot. It is because of the patent. The patent is to Bionomics. Bionomics have done a deal giving exclusive rights to GTG.

Senator HEFFERNAN—In your opening address to this committee, you referred to the biopharmaceutical called erythropoietin. It had worldwide sales of some US\$10 billion in 2003, which was subject to a patent in Australia. I note that in part 2 of your submission at page 24 the patent expired in 2006 and it had a life of more than 20 years. How did Amgen manage to get a patent for more than 20 years? What did Amgen actually do to justify the 22-year patent?

Dr Palombi—I would actually like IP Australia to answer that question because they were the ones who granted the extension beyond 20 years. But in terms of what Amgen actually did, Amgen discovered the gene that codes for erythropoietin. That is what they did. It is very simple.

Senator HEFFERNAN—So, of the US\$10 billion, how much of that is just the licence? Of the expenditure, is it a quarter or a half?

Dr Palombi—Again, I think that is a question that Amgen could probably answer very carefully. But I would imagine that the cost of making the protein is insignificant compared to the price they charged. You have to understand that once you grant a patent like this, they can charge whatever they want. There is no control on price. You have given them a monopoly. They set the price.

Senator HEFFERNAN—So is that demonstrated in Canada with the BRCA1 and 2?

Dr Palombi—Yes. That is exactly what has happened with Myriad and BRCA. They determine the price. There is no justification for what that price is. There is no market control. They just say the price is going to be X, and that is what it is going to be. They have the exclusive rights.

Senator HEFFERNAN—To an unattached person standing at the back of the room or the person on the tram to wherever, would that not relate to pure monopolistic behaviour?

Dr Palombi—Well, that is what a patent is. A patent is a monopoly.

Senator HEFFERNAN—Then you combine that into a global cartel.

Dr Palombi—If you happen to have an invention—and generally speaking, a gene is pretty unique; there is only one gene, for example, that codes for erythropoietin—there is no chance of

a substitution. Every scientist will tell you that you want to ultimately produce the protein as it exists in our bodies because otherwise it is not going to work as well and that is what you want. So once you have a patent over the gene, you effectively monopolise every way of making that protein.

Senator HEFFERNAN—Senator Humphries referred to the global position. I think you referred to Brazil, which has decided, like Clinton and Blair, that maybe there is a public good in not having these patents licensed?

Dr Palombi—Well, we do not need to do what Brazil does. We just need to enforce the law. The thing is that the law has not been enforced. That is why we do not have a court decision which tells us. Why do we not have a court decision? Because it costs a lot of money to bring the patent litigation. I know because I acted for Murex and I know what it cost them when they were fighting over hepatitis C diagnostics. So, as a result, we do not have an audit body that regulates IP Australia. IP Australia can do what it likes. They determine what the policy is in cahoots with the patent attorneys. They have a very nice little arrangement.

CHAIR—Dr Palombi, that is a very large claim.

Dr Palombi—I know it is a large claim and I do not make it lightly, Senator. But as a result of the fact there has been regulatory capture of IP Australia by the professions and by the profession's clients, which are essentially multinational corporations, there has been a complete breakdown of proper policy development. We do need desperately an overarching regulator. Whether it is the ACCC or another organisation, we do need a regulator that will oversee the development of policy that is not related to the IP profession.

Senator HEFFERNAN—Would it be fair to say that if we do not get the balance right between the incentive for research and the monopolisation of things and the anti-competitive effect of that, this will become a money-making exercise for a lot of corporates?

Dr Palombi—Yes. I will pass to Dr Moir to answer that question in more detail.

Dr Moir—Just very briefly and to follow up, the Cutler report on the national innovation review recommended that the patent system be moved into the competition portfolio so that it has a greater comprehension of the need for balance and for the role of competition as a major incentive driving research. There is actually more data supporting the view that competitive markets are a big incentive for the development of new products and services than there is to prove that patent monopolies do that.

Senator HEFFERNAN—This is my very last question. My mind is boggling. What happens if a company ties up all the research and all the sampling? Professor Judith Kirk and those people at Westmead Hospital are dinky-di, good Australians concerned about the wellbeing of families. They are terrified at the propositions behind what is happening with BRCA1 and 2. What would happen if it went to Genetic Technologies Australia? They are not all that financially sound. If they went belly up, would all their research and patents be sold, such that it is, 'Who wants this? Who wants that?' Would there be the disbursement of all the samples and research and good work that has gone on in all the public laboratories? Would it just get sold to the highest bidder?

Dr Palombi—Yes, Senator. That is correct.

Senator HEFFERNAN—Well, God help us where we are going, if that is the case.

CHAIR—Thank you, Dr Palombi and Dr Moir. I think it is clear that this afternoon's introductory hearing indicates that there is going to be a need for more in terms of getting people back. I thank all the witnesses who gave their time this afternoon. We will adjourn this hearing and go into a private meeting about available dates for future references. Thank you very much. Dr Palombi, Senator Heffernan has a number of other questions, which he will provide you on notice.

Dr Palombi—Thank you, Senator.

Committee adjourned at 5.40 pm