Patent Amendment (Human Genes and Biological Materials) Bill 2010, 29 April 2011, Questions on Notice

Witness	Hansard page No.	Senator	Question
Palombi	24-25	Pratt	**Senator PRATT:** What I am unclear about is why we need a special rule for biology as opposed to other natural processes, because it appears to me the logic is exactly the same and that therefore what we are talking about is a need to raise the standard for patents in overall terms. There is no doubt that the problems that you have outlined are very real, but clearly as you have also acknowledged there are a wide diversity of problems with the patent system, many of which point to the same questions in terms of standards of patents that have arisen in relation to biological phenomenon. **Dr Palombi:** I really think your question is a very good one and I want to give it full attention. Would you mind if I take that question on notice and ask you: could you give me an example of precisely what it is that you are concerned about and then I will specifically address that in response? Would that be something that you would be open to do? **Senator PRATT:** Most certainly, but it is an in-principle question as opposed to I suppose specifics. I am uncomfortable with carving out one set of natural phenomenon and creating a special category of patents processes for them when the principal issue is of how natural phenomenon should be treated is a universal one. **Dr Palombi:** I find that it often helps to talk in more specific terms rather than generalities. If you can do that for me then I would do my very best to give you a very full answer.

Answer: It has long been regarded as settled law that natural phenomena are not patentable subject matter. And although that prohibition has never been written into any patent legislation in either Australia, the U.K or the U.S., the courts in those countries have established a body of judicial-made law in each jurisdiction making this clear. For example, in 1884 the U.S. Supreme Court held that an artificial or synthetically made dye, alizarine, could not be patented because it was identical to natural alizarine, a dye made from biological materials extracted from the Madder plant. While the chemical process was patentable the product of that process was not because there was no way to distinguish it chemically - indeed the chemical formula for alizarine is exactly the same regardless of its source or how it is made. In 2004 the U.K. House of Lords applied the same approach when it held the human protein, erythropoietin, could not be patented even if it was artificial or synthetically made.

The need for a 'special rule' or express prohibition such as proposed by the *Patent Amendment (Human Genes and Biological Materials) Bill* has become necessary because IP Australia, the organisation responsible for the administration of the Australian patent system, decided, without the benefit of any judicial authority, to implement a practice inconsistent with this settled law. That practice was implemented in about 1988. IP Australia continues to abide by this practice and it has stated both before the Senate Community Affairs Committee and this Committee that it will continue doing so until such time as it is countered by legislation or court ruling.

Unfortunately, there has been no Australian court ruling on the legality of IP Australia's practice and although a test case has been brought before the Australian Federal Court by Cancer Voices Australia there is no guarantee that the case will be concluded with a decision. The last occasion the Australian Federal Court was given the opportunity to consider the legality of this practice was in 1993 when an Australian patent granted over the hepatitis C virus was challenged. Regretfully

that case settled and no decision was handed down. We simply cannot continue to wait for an opportunity for the Australian courts to rule on the legality of IP Australia's practice.

Thus in the absence of a 'special rule' IP Australia will continue to grant patents over a myriad of biological materials which, in my view and the view of other notable scientists such as Prof Sir John Sulston and the United States Department of Justice, are not and never will satisfy the judicial-made law that prohibits patents over natural phenomena.

It must be understood that these biological materials are not technologies. They are not 'natural processes'. They are not even artificial processes. These things are not the product of human ingenuity or invention. And this is the basis upon which the courts have long justified their refusal to allow natural phenomena to be patented. Thus, absent a special rule there will be nothing to stop this current practice continuing in the foreseeable future. The act of discovery has never been considered sufficient to justify the grant of a 20 year patent monopoly.