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The battle for our genes

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You may not realise it, but during the past 15 to 20 years the Australian Patent Office, known as IP Australia, has issued hundreds, if not thousands, of patents over genes, including human genes.

That it has done so demonstrates a systemic failure on the part of Australia's bureaucracy to protect the public and economic interests of this country and amounts, not only to a gross abuse of the public's trust, but also a serious misuse of its power.

How can the DNA of human genes and the proteins which they code for be 'inventions'? Simply because they have been associated with a disease, illness, bodily function or characteristic and then removed from their natural environment, why should they be monopolised? Where did the legitimisation of this aberrant thinking come from given that the US Supreme Court has repeatedly held that 'manifestations of ... nature [are] free to all men and reserved exclusively to none'?

The key is 'isolation' and that somehow, by isolating a naturally occurring gene or protein it becomes an invention. The patents granted over the BRCA 1 and 2 human gene mutations that are linked to breast and ovarian cancers are merely examples, but there are more - gene mutations that are implicated with prostate, renal, uterine, small cell-lung cancers, endometrial carcinomas, meningioma and acute T-cell leukaemias have been patented in Australia. Even human genes that are linked to epilepsy and fragile-X syndrome are the subject of patent monopolies that permit the patent owners to control what others can do with those genes in medical and scientific research and in the development of diagnostics, treatments and cures.

To me, and I suspect most people, this is a paradox. How can DNA be considered to be an invention once it has been identified for the very first time and then extracted from its natural state and transferred to a Petrie dish?

Yet in Europe this paradox is now the law.

In 1998 the European Parliament passed the Biotech Directive. This Directive has now been adopted by most of the 27 countries that are members of the European Union and the other five countries that are

signatories to the European Patent Convention.

According to this Directive "biological materials" derived from "any natural source" including "elements" from the human body that are either "isolated or produced by means of a technical process" even those identical to the "natural elements" are presumed to be "inventions".

The term "biological materials" as defined by the Directive includes such things as viral, plant, animal and human proteins and genetic materials that code for them.

The European Parliament passed this law at the behest of the pharmaceutical and biotechnology industries who had known for some time that this paradox was unlikely to pass the scrutiny of the courts.

In fact, in 1988, the UK Court of Appeal held that isolated t-PA (or human tissue plasminogen activator) a protein that is produced naturally in humans and that activates the conversion of plasminogen into plasmin, an enzyme capable of dissolving fibrin in blood clots, was not an invention under UK patent law and the European Patent Convention.

If there was any doubt about this Court's interpretation of the law, in 2004 the House of Lords, the highest appellate body in the UK, held that claims to a European patent granted by the European Patent Office in 1984 over isolated erythropoietin, a hormone made by humans in their kidneys and which stimulate the production of red blood cells by bone marrow, were invalid because erythropoietin, even when isolated, was not new.

The fact is that many patents over isolated biological materials have been justified on the basis of the link between a specific gene mutations and human illnesses.

However, in Europe, where a battle has raged between Myriad, the patent owner, and the 20 European organisations that have vigorously opposed these patents in Europe, Myriad conceded and reduced the scope of its patent monopoly to women of Ashkenazi Jewish descent. How desperate is that!

Yet in Australia, where apathy rules supreme and aided by IP Australia's complicity, Myriad has patents that apply to everyone. That Myriad's exclusive licensee in Australia, Genetic Technologies, has only recently relented from enforcing Myriad's patent rights over these genes, after threatening to sue every publicly funded laboratory in this country that performed this service, is besides the point.

Certainly there can be no accusation of ethnic discrimination in this country, since all women are effected, but the paradox must be addressed because a human gene, a naturally occurring biological material, even if it is isolated, even if it is purified, even if it is synthetically made, is and can never be an invention

And unless something is an invention, as the US Supreme Court has said, it cannot lawfully be the subject of a patent monopoly.

This paradox must be addressed but in the absence of an Australian court decision that will force IP Australia to reconsider its policy, it will be up to the Australian Parliament to do so.

On November 19, the Australian Senate launched an inquiry into patent monopolies granted over genes and how these patents are impacting upon this country.

We can all have a say and apathy has no place in this debate. Unless we make our feelings known to the Senate Committee conducting this inquiry, we will give these well-organised and wealthy corporations, and those that have vested interests, every opportunity to justify the status quo.

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