

Inquiry Into Gene Patents

Senate Standing Committee on Community Affairs

Public Submission by David T. Bath

2009-03-19

I thank the Parliament and the Committee for the opportunity to comment on this important issue.

My thoughts on these matters are influenced by my

- training in human health sciences, including a little experience in the early 1980s using restriction endonucleases for recombinant genetic engineering and gross mapping of antibiotic resistance genes in plasmids found in *E. coli*; and
- work as a programmer and systems administrator in both a pharmaceutical manufacturer and a not-for-profit organization that provided pathology testing services to the public as well as supporting epidemiological research.

Overview

Few disagree that gene patents can affect the cost and quality of the health care provided to a population, but too many consider it a special case rather than an illustration of the wider problem with the administration of patents and intellectual property.

In many ways, the way patent administration has changed since the last century, particularly in the scope of what is patentable, has constrained the delivery of innovative and cost-effective products to society.

Patents were originally intended to cover inventions, not discoveries. They were required to be detailed enough to create an application immediately. They were properly assessed with respect to prior art and obviousness. With decreased adherence to these principles, it has become easier to subvert the patenting regime to disadvantage society.

Rather than develop complex and domain-specific regulations for patenting, a better definition of the allowed scope of patents, tighter requirements for the description of the patented invention, and greater resources for patent examination would lead to better results, affecting not only health provision, but throughout all economic sectors.

The greatest problem is not the improvement of regulations country by country, but the development of a consistent international approach to innovation and the protection of true innovators.

Patent Scope

Discovery versus Invention

Render unto Caesar the things which are Caesar's, and unto God the things which are God's – Matthew 22:21

One of the original principles for patents was that discoveries of things put in front of us all by Nature could not be patented, for these are the common property of all.

The patenting of a gene found in nature is similar to claiming copyright and performance royalties for the song of a bird transcribed into standard musical notation.

Gene sequences, and the amino-acid sequences in the proteins encoded by nucleic acids, are obviously not inventions if that sequence is found in Nature.

It is possible, however, that a sequence of genes or amino acids might be an invention and therefore patentable. One example might be where gene sequences are designed and inserted into micro-organisms to produce compounds that previously were synthesized by industrial chemists.

A good example of a discovery that was patented and would increase costs to society so much that some countries, hospitals and medical specialists are refusing to pay royalties is the BRCA family of genes, that analysis by the broad scientific community (particularly epidemiologists) demonstrated had a correlation with breast cancer.^{1,2}

1 "The Age" (2008-11-12): <http://www.theage.com.au/national/senate-to-examine-gene-patents-20081111-5mkj.html>

From November 6, Genetic Technologies secured rights to the testing of two genes — BRCA1 and BRCA2 — that are associated with high risks of breast cancer. Hundreds of tests at the Peter MacCallum Cancer Institute and the Royal Melbourne Hospital each year will no longer be carried out.

The \$2100 test will still be available on the public purse only if family history suggests women are at risk. Cancer specialists fear the monopoly could raise prices, stop research and encourage profit-motivated marketing.

2 "Nature" News Online (2008-12-02): <http://www.nature.com/news/2008/081202/full/456556a.html>

Europe to pay royalties for cancer gene. BRCA1 patent decision may be ignored in clinics.... "We had all been freely testing the BRCA genes since they were first described in the early 1990s," she says.

Trolls and Squatters

The terms “trolls” and “squatters” is sometimes applied to those who make intellectual property claims of such a generic nature, or without a clear knowledge of the application (such as claiming rights to an almost random gene sequence without even knowing what protein the gene codes for).

These claims are not to protect their own innovations, but to extract funds from those who have already, or are expected to, create true innovations. Such claims decrease the availability of true innovations and/or increase costs to consumers.

Some of these claims, even those that have been awarded, have been demonstrated to be prior art or obvious, meaning those rights should not have been granted. The most famous of these is the Australian Innovation Patent granted to a “Circular Transportation Facilitation Device”³, which describes the wheel, and specifically written by a lawyer working mainly in the intellectual property field as a means of demonstrating failures in the system.

These frivolous claims can only be ruled out by improved examination.

The problem is that if the examination is funded by government, either by direct employees or outsourced to private companies, the costs to government or true innovators will become prohibitive. Recent “anti-troll” changes to patent rules in the US have raised concerns about increased costs to true innovators.

There is a way to avoid these costs through crowd-sourcing, with intellectual property offices reaching out to qualified people in the community to help with examination of claims. Such crowd-sourcing has been discussed in associations of IT professionals, with offers to donate time to demonstrate prior art.

It is possible that many members of the biomedical community would be willing to offer similar services to the community, spreading the load of examination of intellectual property claims.

3 For the background and body of the “Wheel Patent”, see http://www.ipmenu.com/archive/AUI_2001100012.pdf

Granted Innovation Patent Application Number: AU 2001100012 A4

Inventor: Keogh, John Michael

Application Date: 2001-05-24

International Patent Classification(s): B60B 001/00

Abstract: In accordance with the first aspect of the present invention, there is provided a transportation facilitation device including a circular rim, a bearing in which a hollow cylindrical member is rotatable about a rod situated within the hollow cylindrical member, and a series of connecting members connecting the circular rim and the hollow cylindrical member in substantially fixed relation, wherein the rod is positioned on an axis perpendicular to the plane of the circular rim, and substantially central of the circular rim.

Examples of Frivolous Claims

Outside the Domains of Medicine and Genetics

- A description of the structure of a “Twelve-Bar Blues” in the jargon of physicists and/or musicologists as a means of achieving changes in mood, and the effects of changing tempi.
- Patenting a chemical compound (that may or may not exist in Nature) without knowing what that compound might do.
- A claim that covers all blue roses (not found in Nature, whether initially achieved by the claimant by genetic engineering or selective breeding) when others could get the same result through selective breeding or by engineering a different gene.
- Randomly generating sequences of notes and claiming copyright on any part of any of those sequences.
- Claims for business processes such as the use of a hyperlink and “click-through payments” in software products. There were such claims made and granted, and the costs of fighting such frivolous claims were considerable.

Within the Domains of Medicine and Genetics

- Claiming rights to RNAi acting on a particular gene, or the protein product of that gene, given that if you know a DNA, RNA, or protein sequence, and that sequence exists in Nature, the RNAi sequence is implied.
- Claiming rights to any test for presence or absence of a gene, rather than the process used to manufacture a particular test.

International Considerations

Changes in the scope of what is patentable, and the specificity of patents, cannot be done effectively outside the context of international agreements.

The EU and the US are starting to tighten up on “trolls”, discoveries, and claims for “business processes”.

For “minor powers” in intellectual property such as Australia, strengthening the power of international conventions and the WIPO to reject unjust intellectual property claims is our only practical way forward. This should not be difficult as almost all nation-states are recognizing that the patents system is being rorted, and can be manipulated to prevent innovation by others or increase costs to societies overall.

The Problem of Specificity to Genes and Health

Just as unjust claims were made (and granted) as IT expanded into mainstream society, just as we are recognizing the problems of intellectual property regimes with genetic medicine expanding outside the laboratory, there may well be other emerging technologies that will be rorted in the future if our revised intellectual property regimes are specific to one particular technology and/or one specific application domain.

While we are now grappling with the difficulties of managing costs of products defined by gene sequences (and protein sequences determined by those genes), the new discipline of epigenetics will raise similar issues in the near-to-mid future. For example, there might be intellectual property claims on testing for methylation levels as predictors of risk for cognitive and psychological problems in children. This might sound highly technical and innovative, but it is merely the application of a known phenomenon (a discovery) and the implied use.

Even in the domain of gene sequences and health services, there will be new approaches collectively discovered and developed, and doubtless some will make intellectual property claims for the obvious applications of these general phenomena and approaches.

There will be similar difficulties with other fields of discoveries where the applications are unknown or even the discipline does not have a name yet, but given the rate at which discoveries are made and generic techniques using those discoveries will be important to societies, it would be useful to have national and international conventions and administrative processes that can readily be applied to new fields.

This implies developing a generic framework that can differentiate between discovery and invention, between a general approach and a specific mechanism, and administrative techniques to examine intellectual property claims in a timely and efficient manner (which will probably involve some form of crowdsourcing).

The more generic the administrative and regulatory framework, the more effectively it will deal with new technical applications, the more it will encourage true innovation, and the lower the cost of delivering services to societies.

Comments on Other Submissions

I agree with the general opinions expressed in the submissions published so far (up to number 16). Where I indicate agreement, I ask the Committee to give extra consideration to those points made by others.

1. Michael Partington : Agreed
2. G.K. Sutherland: Agreed
3. Anne Ronan: Agreed with points 1 through 3. I disagree with her points 4 through 6, as her analogy with software, and considering software as an invention is flawed. (Hyperlinking is not an invention, but an approach, while the creation of a complex compression or cryptographic algorithm might be considered an invention if the research work had been privately funded and was not in a large part due to general scientific community effort). Her point 5 does indicate the need for strong international conventions that limit scope for inappropriate patents.
4. Centre for Governance of Knowledge and Development: Agreed. The arguments about the end purpose of having a patent system, and the differentiation between discoveries and inventions is excellent, and I need not repeat it.
5. Charles Lawson: Arguing mainly about Compulsory Licensing issues and the needs of the citizens, his points are good. I do, however, consider that arguments about what should and should not be patentable are more important.
6. Bee Winfield: Agreed.
7. Australian Medical Association: Agreed, especially their "Common Heritage" point.
8. John Hamblin: Agreed, especially on the dependence on prior knowledge that is often taxpayer-funded.
9. Judy Kirk: Agreed
10. Bob Such: Agreed
11. Rhonda and Dennis Haskell: Agreed
12. NHMRC: Agreed with the statement that BRCA genes are an excellent example of the dangers. I have not read the other documents referred to.
13. Jan Wahlstrom: Agreed. As well as highlighting the difference between discovery and invention, Jan also highlights the need for major reform of the patenting system as a whole.
14. Western Australian Government: General disagreement, as while the importance of new applications is important, there is no differentiation between one hand hand, novel creations (such as a pharmaceutical compound not found in nature or a specific manufacturing technique) and on the other hand, discoveries the routine application of general approach.

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15. Mark Willcox: Agreed. He makes a good point talking not only of human genes, but those from other organisms as discoveries and our common heritage.
16. South Australian Government: Agreed. Excellent points on discovery versus invention again, the generic failures of intellectual property systems, particularly the ability to challenge claims that should be challenged.