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Get rid of the patent absurdities

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AUSTRALIA'S patent laws need to be updated for the 21st century to accommodate a range of frontier technologies in the life sciences.

Recently J. Craig Venter and his institute filed a patent application in respect of a minimal bacterial genome that they have dubbed *Mycoplasma laboratorium*.

The contentious scientist declared: "My company, Synthetic Genomics Inc, is already trying to develop cassettes - modules of genes - to turn an organism into a bio-factory that could make clean hydrogen fuel from sunlight and water or soak up more carbon dioxide."

The ETC Group, a bunch of Canadians opposed to synthetic biology, has dubbed the artificial organism Synthia, the Original Syn Organism. The group complains that synthetic biology poses ethical and environmental concerns about the use of biodiversity to build new life forms. According to the group's representative Pat Mooney, "Synthetic biology is a form of extreme genetic engineering that has enormous implications for everyone who lives on this planet."

The controversy over synthetic biology has reignited a longstanding debate over the law and the ethics of patenting life.

Patent law is a system of intellectual property that provides exclusive economic rights to exploit novel, inventive, and useful scientific inventions.

Ideally, it is designed to promote innovation, investment in research and development, and access to scientific information.

During the past few decades, patent law has expanded from its traditional focus on mechanical inventions and chemicals to accommodate various forms of biotechnology, from micro-organisms, plants and animals to human genes and stem cells. In a gold rush sparked by large-scale genetic sequencing projects, biotechnology companies, pharmaceutical manufacturers and bio-prospectors have filed patent applications in the fields of agriculture, medicine and environmental genetics. In the past decade, patent offices and courts have struggled to cope with the flood of gene patent applications from public researchers and private industry.

The Australian Parliament has been slow to respond to the challenges posed by biological inventions. In 2004, the Australian Law Reform Commission handed down a report on gene patents and human health, with more than 50 recommendations for reform.

The Howard government paid little heed to the report, believing that the status quo was sufficient to stimulate investment in biotechnology. The Rudd Government has not yet established its priorities in respect of patent law reform.

In the meantime there has been a passionate debate about the law and ethics of patenting life in the public arena. Patent abolitionists - including environmentalists, organic farmers, animal rights groups, religious organisations and latter-day Luddites - have contended it is unethical and immoral to patent biological organisms. Even the Vatican has weighed into the debate, with the Pope declaring genetic engineering to be one of seven deadly sins of the modern era.

Advocates of law reform have expressed concerns that patent law has created a tragedy of the anti-commons, in which access to genetic research is hampered by overlapping, fragmented patent rights. Accordingly, there has been a push for procedural and substantial reform of patent law.

Even the biotechnology and pharmaceutical industries have conceded that there could be scope for reform. There has been a particular concern about the rise of patent trolls: companies that hoard patents on emerging fields of technologies with the purpose of holding others to ransom through the threat of litigation.

In my view, there is a need to update Australia's patent laws for the 21st century to address the ramifications of frontier technologies in the life sciences. I would make five recommendations for reform.

* Greater efforts should be made to preserve and conserve what US Supreme Court judge Stephen Breyer called the storehouse of knowledge: the public domain and the intellectual commons.

As the judge notes: "Patent law seeks to avoid the dangers of overprotection just as surely as it seeks to avoid the diminished incentive to invent that underprotection can threaten."

* Patent offices and courts need to raise the thresholds of novelty and inventiveness demanded of patent applicants. Patent examiners and judges need to attribute greater creativity and problem-solving abilities to a person skilled in the art, to ensure that the patent system rewards more than nominal improvements to scientific knowledge and art in the public domain.

* There should be greater scope for post-grant review of patent applications. Patent trolls should not be allowed to hold public and private investors in R&D to ransom.

There needs to be greater scope for challenging patent applications by civil society and public interest groups, such as the Public Patent Foundation.

* Given the expansion of the scope of patentable subject matter, there is a need to broaden the range of exceptions to patent infringement. As recommended by the ALRC, there should be a broad statutory defence in respect of experimental use.

The commission noted that the lack of a research exemption "has the potential to result in under-investment in basic research and to hinder innovation if researchers become concerned that their activities may lead to legal action by patent holders".

* Finally, there is a need for patent law to take notice of larger concerns about bioethics and human rights. The UNESCO Universal Declaration on Bioethics and Human Rights 2005 emphasises the need for informed consent and benefit-sharing in respect of genetic research.

Such recommendations will better prepare patent offices, courts and legislatures in the regulation of the next generation of frontier inventions and pioneer technologies, such as Venter's foray into synthetic biology.

As Australian High Court judge Michael Kirby has observed, our approach to the question of patenting life will "help define the ethics of a future that includes nothing less than the future of our species".

Matthew Rimmer is a senior lecturer at the Australian National University and an associate director of the Australian Centre for Intellectual Property in Agriculture. He is the author of Intellectual Property and Biotechnology: Biological Inventions (Edward Elgar, 2008) and Digital Copyright and the Consumer Revolution: Hands Off My iPod (Edward Elgar, 2007).