Ownership Of Your Genes at Issue

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As genetic technologies play stronger role, ethics questions arise; public debate ahead

In 1976, doctors at the University of California removed a patient's spleen in the treatment of hairy cell leukemia. The patient became suspicious when, in 1983, his doctor urged him to assign all rights to cell lines taken from his spleen. Later, the patient discovered that not only had the hospital obtained a United States patent on a cell line cultured from white blood cells taken from his organ, the cell line had been sold to a biotechnology company for US$1.7 million.

In feeling a sense of "essence-rape" the patient said, "What the doctors had done was to claim that my humanity, my genetic essence, was their invention and their property. They viewed me as a mine from which to extract biological material. I was harvested."

The "invention" was a cell line that surprisingly produced blood proteins of great value in treating immuno-suppressive diseases and has since generated more than US$3 billion dollars in business for its owners.

WHO OWNS YOU?

So who does own your body: you, society, or a business? Has life become a commodity? Biotechnological sciences have for some time been raising serious social, legal, ethical, political and economic questions. They are being addressed at a far slower rate than the advances in the scientific field itself.

Should agribusiness be entitled to a patent monopoly on a species of animal or plant? Should drug companies be entitled to patent body parts? In the United States, such questions have been addressed, in a legal sense at least, by a ruling that the patient's spleen ceased to be his property when it left his body.

PATENT LAWS

Although the World Trade Organization (WTO) is endeavoring to harmonize the patent laws of its member countries, there remain substantial differences of opinion between politicians, manufacturing companies, scientists, bio-ethicists, members of the clergy and farm lobbyists as to the patentability of certain biotechnological inventions. Bitter divisions between these groups have merged within the European Economic Community where the European Union (EU), in support of the U.S. Supreme Court ruling on removed human tissues, is seeking a directive that would allow the patenting of all human, animal and plant tissues. The European Parliament, however, presently believes that genes and cell lines removed from the human body do not constitute an "invention" and, as such, should not be patentable.

The laws of society should reflect society's values on various tissues, but the laws are invariably slow to change and so are often out of date. Generally, however, patent laws of most developed (and developing) countries have reflected changes up-to-date with rapid changes in technology and changing societal circumstances. Australian patent laws are no exception and since the 1950s have shown a growing independence from their roots in British law, to the point where today, these laws are generally free from imperial or colonial idiosyncrasies.

Although the historical origins of the modern patent system are somewhat obscure, the grant of monopoly rights began in Britain in the late Fifteenth Century as a means of attracting new industries and technologies from abroad. Indeed, this remains a political motivation in many countries, despite a contradiction with fundamental antimonopolistic philosophies.

The British Statute of Monopolies of 1623 declared that monopolies were generally unlawful, with certain exceptions. Section 6 of the statute, which defines one such exception for letters patent granted for"...the sole working or making of any manner of new manufacture...so as also they be not contrary to the law, non mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient." The definition of "invention" under the Australian Patents Act of 1990 preserves the provisions of Section 6 of the Statute of Monopolies.

MANUFACTURE REVOLUTION

Throughout the industrial revolution and the subsequent technological revolution, courts have successfully ruled on a widening range of "manners of new manufacture." Both British and Australian courts have steadfastly held that methods of treatment of human beings were not patentable subject matter.

In 1993, the federal court of Australia, in the landmark case, *Rescare Pty Ltd v. Anaesthetic Supplies Pty Ltd* (1993) 90 AIPC 951, held that a method of treatment of sleep apnoea was a "method of manufacture," as there was no essential distinction between a patent for the

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method of treatment of a human body and a patent for a pharmaceutical substance. The grant of a patent for such a method was of economic significance and otherwise not "generally inconvenient."

On appeal from that decision, the history of decisions relating to methods of treatment of human beings was considered exhaustively. Taking into account Section 18(2) of the Australian Patents Act 1990 which provides that: "Human beings, and the biological processes for their generation are not patentable inventions," a majority decision of the appeals court upheld the primary judge's findings on patentability of methods of treatment of human beings (*"Anaesthetic Supplies Pty Ltd v. Rescare Ltd* (1994) 91 AIPC 076). In a dissenting judgment, Sheppard J acknowledged a substantial body of international thinking that believes it is undesirable for patents to be granted for inventions relating to methods of treatment of disease and other abnormalities in human beings.

In upholding the judgment Wilcox J said: "I find unpersuasive the alternative bases for the exception (patentability of methods of treatment of human beings) advanced by some judges. They involve matters of ethics and social policy upon which the courts have no special expertise. In my opinion, for the courts to resort to any of them, in order to engraft onto a recently enacted statute (the 1990 Patents Act) an exception that Parliament has chosen not to adopt, would be to usurp that institution's role."

That decision, unless subsequently overturned, adds the final piece to the jigsaw of patentable biotechnology subject matter in Australia, as it has long been established that biologically derived materials and methods for their manufacture are patentable subject matter.

While the Australian Patents office has traditionally readily adapted to changing social, political and legal opinions on patentable subject matter in the field of biotechnology, that has not always been the case in the United States. Louis Pasteur was granted a United States patent in 1873 for "A yeast free from organic germs of disease as an article of manufacture." The first vaccine patent was granted in the United States in 1877, followed by the first patent for a bacterial vaccine in 1904 and the first viral vaccine in 1916.

Even though there was no longstanding administrative interpretation by the United States Patent and Trade Marks Office (USPTO), which excluded living matter from patent protection, it did exhibit a substantial shift in mindset in the early 1970s, to preclude life forms from patent protection.

USPTO AND LIFE FORMS

The landmark case, which created a paradigm shift in USPTO, was a 1972 patent application by Chakrabarty concerning a bacterium from the genus *Pseudomonas* containing at least two stable energy generating plasmids. Initially, the USPTO rejected certain claims as directed to a "product of nature." On appeal to the appeal board, the patent office Examiner maintained his rejection on the basis that the subject bacteria were, in effect, artificially created mutants that (like naturally occurring mutants) were "products of nature" and as such unpatentable.

The Examiner expressed the view that although U.S. patent law did not expressly exclude living organisms, in his opinion the law, neither in words nor intent, encompasses products of nature. "To do so would open the floodgates to patentability for all newly produced microorganisms as well as for all newly developed multi-cellular mammals such as newly bred chickens and cattle." The U.S. Supreme Court subsequently held that Chakrabarty's invention was in fact a "manufacture" or "composition of matter within the law" and that the organism "is not nature's handiwork [sic], but his (Chakrabarty's) own; accordingly it is patentable subject matter..."

The Australian and United States examples illustrate that it was not the laws themselves that precluded life forms and methods of treatment of human beings from patentability. It was the interpretation of those laws by individuals and courts. Equally, it has been the courts of these countries that have resolved differences of opinion in favor of patentability, not in some expression of the current views of society, but in an interpretation of the intent of Parliament or Congress in framing their respective laws.

MONEY AND ETHICS

While there is no doubt that there is an economic benefit to holders of biotechnology patents, can we construe this paradigm shift toward patentability of all aspects of biotechnology to be a governmental bias in favor of big business?

Moreover, do these court decisions illustrate a growing conflict of interest for governments in allowing legal monopolies for privatization of life forms on the one hand, and the public's right to benefit freely from advances in biological technology on the other hand?

The commercial organizations argue strongly that patents provide insurance to protect enormous investments in research and without that protection there would be no incentive to develop new products and technologies. In contrast, bioethicists and sections of the scientific community argue that a relatively small number of companies are potentially colonizing science and express alarm that the development of human gene banks in particular may lead to humanity's heritage becoming private property. The Human Genome Diversity Project, a $20 million multigovernment funded program to establish a gene bank of endangered peoples, has come under furious attack in the UN by indigenous groups who ask, "How soon before they apply for intellectual property rights and sell us?"

Despite these fears and concerns, there are signs that the scales of (natural) justice may be tipping away from the specter of excessively monopolistic control of biotechnology developments by abuses of the patent system. A United States patent of sweeping breadth has been granted for all forms of genetically engineered cotton, regardless of the methods or biological

material to create them. Another U.S. patent gives broad rights to use antisense RNAs to block activity of specific genes in any crop, while a European patent of wide scope covers all genetically engineered soybeans. All of these patents are under attack from disadvantaged competitors and outraged groups representing the agricultural community.

QUESTIONS OF CONTROL

The U.S. Department of Agriculture has joined the controversy surrounding the cotton patent, and an agricultural group claims the European soybean patent should be disallowed under the "public morality" provisions of the European Patent Convention. A spokesman said: "A patent granting a single corporation monopoly control over genetic research on one of the world's most important food crops is a threat to world food security." According to the spokesman, this "demonstrates the patent system is recklessly out of control."

While some charge that new genetic technologies will increasingly dominate existing health care and agriculture, therefore adding to costs, and that private companies rather than publicly funded science are now setting the health care and agricultural agenda, others suggest that the ethical debate is still failing to take the basic commercial facts of life into account.

Whatever the arguments put forward, it should not be overlooked that the broader public have been involved only marginally in this debate, which so far has been confined to special interest groups. An Indian physicist and author, Vandana Shiva, has said: "The privatization of life is now broadening out and entering uncharted waters which society is not ready for or prepared to accommodate."

True perhaps, but is the broader community sufficiently equipped, in a scientific sense, to understand the ethical debate and moral dilemma, let alone be prepared to participate?

So whose genes are they anyway? It's probably safer to keep your genes on until the issues are resolved with greater clarity.

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