

Patents and biotechnology

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Recent advances in science and technology have brought with them many questions. One of these, affecting the state of medicine, is the advent of gene patenting.

Patents are a part of a larger subset called 'Intellectual Property (IP)' which grant monopoly to those with new ideas or knowledge. Legally, a patent is a monopoly granted by the patenting and trademark organisation of a given country for the use, manufacturing, and sale of an invention. An invention must meet the criteria of being novel, useful, and non-obvious for it to be patentable.

Generally, an invention is patentable while a discovery is not. While this rule may, in other areas, appear well defined, in biotechnology, it is often the cause of differences in regulations between countries. 'Discovery' is merely making available what already exists in nature. A substance freely occurring in nature is not patentable. However, if the substance found in nature must first be isolated from its surroundings, the process for obtaining it is patentable.

In the United States, the first patent law was developed in 1790. This and other IP rights were formed 'to promote the progress of science and the useful arts by securing to authors and inventors the exclusive right to their respective writings and discoveries'.⁽¹⁾ David B. Resnik writes, "The fact is that most industries require sufficient patent protection in order to secure an adequate return on their research and development investments. Without this protection, many companies would either protect their intellectual properties through trade secrecy or they would invest less money in research and development. Since trade secrecy can have detrimental effects on the progress of science and medicine, and private investment in research and development can promote innovation and discovery, it is important to develop laws and policies that protect intellectual property rights, including property rights in biotechnology and pharmaceuticals."⁽²⁾

Some argue that patenting forces scientists to be secretive about their data out of fear that others will beat them to the patenting office if they share their results with the scientific community.⁽³⁾ Others hold that competition can promote research and therefore further science and medicine. Once patented, the information becomes public knowledge, facilitating the spread of new discoveries and innovations.

'Bio-prospecting' is a potential gold mine for both science and business, since genetic material found in the developing world may yield cures for diseases as well as cash. What also looms on the horizon is 'bio-piracy', where corporations use the folk wisdom of indigenous peoples to locate and understand the use of medicinal plants and then exploit them

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commercially.

DNA is the core genetic material of all life forms. It is broken up into segments called genes. Some of these genes code for the proteins in the body that allow the organism to function. Isolating these genes allows researchers to better control the proteins. In order for a gene to be patented, it must fulfill the criteria of being novel, useful, and non-obvious. Robert Cook-Deegan writes, "The rationale for DNA patenting is - you aren't patenting the gene in your body or my body. You are taking the gene, you are isolating it, and you are turning it into a useful form. So for you to get a patent on a fragment of DNA, you have to prove that you've done something that is new, that is novel."⁽⁴⁾

This can be viewed differently. India's Patents Act of 1970 lists many conditions for which patents cannot apply, including the following: "The discovery of a new use or new property for a known substance. The mere re-arrangement of known devices."⁽⁵⁾ Although the gene is being used independent of the body, is using it in the laboratory just a new use or re-arrangement of a known substance?

Others argue that patenting genes takes away human beings' intrinsic ownership over their genes. In the US court case Moore vs. Regents of the University of California (1990), Dr David Golde patented a cell line, developed from tissue taken from the cancerous spleen of his patient, Moore. This became a very valuable research tool; it also had a commercial potential of \$3 billion.⁽⁶⁾ When Moore heard of the research, and the patent, he sued for commercial rights to his own tissue.^(3, supra note 3) The court ruled that Golde violated Moore's right to informed consent but not any property rights to his own cells. Patenting a gene does not give the patentee ownership of the gene; only the right to exclude others from 'making, using, selling, offering for sale, or importing patented items.

In 1990, a US patent applicant tried to patent a cell line derived from a 26-year-old Guyami Indian woman from Panama. The tribe demanded that the patent application be withdrawn and the cell line returned to the country of origin. The United States Commerce Secretary, said, "Under our laws, as well as those of many countries, subject matter relating to human cells is patentable."⁽⁷⁾

If DNA is the genetic basis to all life, is life patentable? Life can be defined on two levels: thermodynamically and consciously.⁽⁸⁾ The former is based in the fact that all living things are involved in a constant energy exchange with their environment. But life can also be defined in terms of consciousness which gives a living entity its uniqueness. According to the thermodynamic definition of life, the fertilised egg is alive in the same sense that cells are alive in donated blood or donated organs. But this single cell does not represent human life in the special sense. There is a unique conscious quality that makes a human being alive in a different sense than a fertilised egg.

Some argue that human DNA patents violate human dignity,

that they 'treat human beings as having only a market value.'(2, supra note 2) To commodify an object is to assign it some value. An item that has only market value is a complete commodity. If it has market value in addition to some other value, it is an incomplete commodity.(2, supra note 2) Some critics of DNA patenting argue that human beings are treated as complete commodities. Others hold that "human DNA patents only treat parts of human beings as complete commodities; they do not treat whole human beings as complete commodities."(2, supra note 2) Similarly, some say patenting DNA is like slavery because it gives the patentee control over another human being's genetic material. But slave owners both controlled their slaves and owned them. Patents do not give the patentee rights of ownership, only the right to exclude others from using the product.

How does DNA patenting affect Indians?

So far, India does not recognise product patents in pharmaceuticals – about which the United States and European Union complained to the Dispute Settlement Board of the WTO. India is required to update its existing Patent Act of 1970 with legislation for patenting microorganisms (i.e. DNA) by December 2004. (9) A joint parliamentary committee is in the process of drafting recommendations to the second amendment to the Patent Law that will introduce product patents from 2005. All member countries of the World Trade Organization must 'apply intellectual property rights to the use of plants, microorganisms, and other life forms' under the Uruguay Round Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This act bypasses the patent system to grant exclusive marketing rights (EMR) as a statutory right to pharmaceutical and agrochemical transnational corporation (TNCs) India's patent law on pharmaceuticals allows local manufacturers to sell drugs at about a third the price of that even in neighboring countries. The new law will give EMRs at prices unaffordable to most Indians for drugs and agrochemicals for specified periods in India if they hold single patent in another country. A TNC now can claim EMRs on formulations based on herbs and plants by making minor modifications in methods of extraction and processing and then claiming that they are inventions. However, knowledge of indigenous systems of medicine and practice are in the public domain and therefore are rights under the constitutions that can not taken away by enactment.

India is a storehouse of biological resources. In a world that patents DNA, India must follow current trends to advance its research and development. In recent years the rise in investment in biotech-oriented industries is poised to take India to a different level in the world market. However, western nations are at an advantage in research given their better technological and financial resources. India's Technology Information, Forecasting, and Assessment Council discussed this issue recently: "If microorganisms isolated from the nature for the first time are considered patentable, then minerals and ores discovered from the interior of the earth and the deep sea bed would qualify for patenting. The isolation will call for a much higher class of technology and large financial resources. Obviously, countries having such resources will have a very distinct advantage

and smaller countries may have the risk of losing their own resources if the ores and minerals are allowed to be patented."(9)Vandana Shiva discusses the dangers of losing rights over cell lines indigenous to India. She illustrates this with the example of the neem tree. Over centuries, Indians have used 'the neem *datun* (toothbrush) to protect their teeth with its medicinal and anti-bacterial properties.' Since 1985, however, many US and Japanese firms have taken out patents on formulas for neem-based solutions. She quotes *Science* magazine: "Squeezing bucks out of the neem ought to be relatively easy."(10, pg. 69-70) Similarly, she sees the patenting of genes unique to certain indigenous people as taking their land.(10, pg. 3) However, if Indians patent things native to India through their own research, scientific advancement involving Indians can remain in the country.

Conclusion

As scientific research advances, more patents of human DNA and cell lines will emerge, as will many fundamental questions on human life for which there are no 'correct' answers. Efforts must be made to understand the legal, social, scientific, clinical, and psychological effects of patenting genetic material. Patenting can help further scientific development by making research public knowledge. However, research cannot occur without financial and technological resources, putting developing nations such as India at a disadvantage.

Indians also risk losing monopoly over scientific advancements involving indigenous people, plants, and animals. Hence, they must be able to apply for patents in their own country, enabling them to have monopoly and financial rights over their own scientific findings. India must choose between the more conservative European approach and the US or some other approach for the needs of its emerging economy. Indian companies, inventors, investors and physicians venturing into the biotech sector must be well informed and aware of domestic and international laws as they seek to join the biotechnology competition.

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