Who's pulling your leg?

Professor Shima Gyoh celebrates big businesses' failure to start patenting genes and whatever would have been next on the list

In the medical world, patents are best known in the pharmaceutical industry. When a company develops a new effective drug it gives the drug a proprietary name, patents it, determines its market price, and legally maintains this monopoly over the specific period permitted by the patent. Patent laws protect the intellectual property of inventors and enable them recoup their investment and make profits.

The same philosophy was extended to the human body, raising serious ethical problems. For a long time, physicians knew that cancer of the breast tended to run in families, but the exact mode of transmission was not known. A company in the USA called Myriad Genetics Inc. discovered that when mutations occurred in two genes, BRCA1 and BRCA2, the chances of the affected women having cancer increased from a background rate of 12.5% to somewhere between 50–80% for cancer of the breast, and 20–50% for the rarer cancer of the ovary. This meant that, where incidence was high in a family, women could be examined for these genes and if they had the dangerous mutations, pre-emptive measures could be taken. Those who desired to have babies could have them early and get their breasts and ovaries removed before they reached the age of maximum incidence.

A good example was the stunning announcement in May 2013 from superstar Angelina Jolie's headline revelation about her positive genetic test for the BRCA1 mutation and subsequent double prophylactic mastectomy. She is rich and the question of cost would pose no problem. For the majority of poor people, the BRCA test would have been far above anything they could afford if the Supreme Court of the United States did not intervene on 13th June 2013.

Myriad Genetics had taken out several patents covering the various stages of the tests for BRCA 1 and 2 and legally enforced their monopoly, prohibiting other laboratories from doing it. The test alone cost US$4000, above the annual income of most people in the third world. Even in the USA, a large percentage of women that required this information could not afford it, and the patent further limited access. The results were devastating.

The Association for Molecular Pathology and other professionals in genetics sued Myriad Genetics Inc. The Patent Act provides that patents can be issued to whoever invents or discovers a new and useful composition of matter. Patents protect intellectual property and reward inventors, but also restrict information sharing and development. In the words of the Supreme Court, it 'strikes a delicate balance between creating incentives that lead to creation, invention and discovery, and impeding the flow of information that might permit, indeed spur invention.'[1]

Myriad had identified the exact location of the BRCA1 gene on chromosome 17's 80 million nucleotides and BRCA2 genes on chromosome 13's 114 million nucleotides. They had worked out the typical nucleotide sequence on the genes and how it differed in situations of familial breast cancer. They used the information to design tests to detect mutations in the two genes that were highly correlated with cancer: no mean achievements and of Nobel prize quality. A gene is a nucleotide on a chromosome made up of exons that determine the type of amino acids, and therefore the protein it is coded to synthesise, separated by introns that seem inactive. Did Myriad's discovery of these facts about the BRACA genes amount to a new discovery satisfying the condition for granting them a patent? They had at first lost but eventually won their case at lower courts. The Supreme Court was poised to make the most important judgement in the history of medicine. It was to its credit that it went to great lengths to comprehend the issues involved – its proceedings read like a chapter in an advanced textbook of genetics.

The court decided that discovery of the structure and position of the genes did not quite satisfy the provision of the patent law because Myriad had not created anything new. Natural substances did not qualify for patents. Complementary DNA (cDNA), produced when technicians remove the inactive introns leaving only the active exons, does not exist in nature but can be produced in the lab by technicians. Although the Court found it patentable, discovery of the BRCA genes was not and Myriad's monopoly on the genes was invalidated.

How frightful our world would have become if Myriad Genetics had won. There might have been a rush to take patents out on much of our bodies. Just imagine you have injured your leg in a fall. You must look for the doctor that has a licence to examine your leg, a radiologist that has one to X-ray it and a plaster can be cast only by a technician with a licence from the company holding the leg patent! You might begin to wonder who exactly owns your leg!

Prof Shima Gyoh has held many posts ranging from village doctor to DG of Nigeria's Federal Ministry of Health and Chair of the Medical and Dental Council of Nigeria.

Reference

1. Association for Molecular Pathology v. U.S. Patent and Trademark Office, No. 09-cv-4515, 94 USPQ2d 1683 (S.D.N.Y. March 29, 2010).