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Bryan Schwartz examines the need to invent new ways of patenting designer genes

IF you build a better mousetrap the world will beat a path to your door, but if you build a better mouse will you be able to get it patented?

This is the sort of question that springs up when the current law governing patents meets the brave new world of biotechnology. Today's patent law is itself an invention. It does not always reward hard work and imagination with a new property right. You can spend your life discovering a law of physics or devising a new surgical technique and you cannot get a patent. In deciding on patentability, legislators weigh competing economic and social considerations.

Allowing patents can encourage innovators. They are rewarded with a monopoly; for years a patent holder can deny competitors the right to use the innovation, or charge them a royalty. The bad news is that a patent-holder's rights can inhibit research and production by others.

With pharmaceuticals, Canadian governments have struggled to find the right balance between encouraging invention and maintaining competition. The latest legislation still gives generic drug manufacturers limited rights to produce patented drugs, whether the originators like it or not. But what of the future and biotechnology? Some new patent law will have to be invented to deal with these new challenges. Let's start by looking at inventions of old mother nature and work our way up to those of our modern Dr. Frankensteins.

You currently cannot patent something that occurs naturally - say a previously unknown plant or animal. Perhaps a country should be guaranteed a share of the profits resulting from the use of rare species found within its borders. Governments would then have an added incentive to protect their natural treasures, like the rain forests.

What if you personally are a rare biological specimen? In the late 1970s, a California doctor successfully treated a patient by removing his spleen. The doctor used some of the tissue to establish a laboratory cell line, which he patented. Products developed from the line may be worth billions of dollars. The patient sued. The California Supreme Court agreed he should have been informed of the doctor's research interests. But it denied the patient any property rights in the cell line. It said that patent law should reward human ingenuity - like skilfully cultivating a cell line - but not being born with useful raw material.

Now what if you produce a better plant by selective breeding? In Canada, you can get patent-like protection under the new Plant Breeders Act. It is unclear whether ordinary patents are available to animal breeders.

Suppose you go to your lab and build a better mouse. In a landmark 1980 decision, the U.S. Supreme Court upheld a patent on a micro-organism that was genetically engineered to break down oil spills. Eight years later, a patent was issued for a larger organism. It was a lab animal, genetically engineered to have a cancer-causing gene: the "Harvard mouse."

WHAT about patenting human genes? True, you ordinarily cannot patent a product of nature. But on some occasions, the authorities have issued patents on a laboratory version of natural compounds. For example, a company was issued a patent for its version of vitamin B12 after it showed that it was much purer than the kind extracted from animals. Genes produced in a lab can be somewhat different from their natural counterparts.

Rather than allowing a series of court battles to settle the patentability of human genes, legislators should step in now and provide some clear direction. The brave new world needs some brave new patent law. An across-the-board denial of patents could be very costly in human terms. Research is expensive and there should be incentives for private investment.

Another virtue of the patent system is that in return for protecting new knowledge, it requires public disclosure and registration. If a company cannot obtain a patent, it may resist competition by keeping its discoveries secret.

Perhaps a compromise could be reached. The law might refuse to allow patents on the basic knowledge of what a particular gene is and does. The usual incentives for basic scientific research – government funding, personal prestige - may be sufficient to spur fundamental research. But a company could patent a novel way to produce or use a particular human gene.

The lawyers and legislators always seem to be one step behind the pace of scientific research and development. Maybe that is inevitable. We have to see innovations, and some of their social impact, before we can figure out how to regulate them. Some day, genetic engineering may produce even smarter scientists and engineers. The day after, we'll have to build some smarter patent lawyers.

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