

## Philos 3: Technology & Society

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### *Ethics of Patenting DNA*

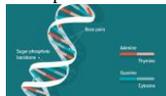
## The Issue

- It has been estimated that approximately 20% of the human genome is patented.
- Is patenting an element of life immoral because it allows owning or treating genetic material as property?
- Should a person or a company have the right to own a piece of all humans?

2

## Proteins, Genes, and DNA

- Genes are discrete segments of DNA molecules that contain the information necessary for producing specific proteins. DNA is made up of a string of units called *nucleotides*. The main component of these nucleotides are bases, which are arranged in a specific sequence. There are four different bases in DNA: *adenine* (A), *thymine* (T), *cytosine* (C), and *guanine* (G). These bases are bonded together in pairs, A with T and C with G, to make the DNA double helix. Genes can range in size from fewer than 100 base pairs to several million base pairs and are separated from one another by spacer DNA.



3

- The base sequence is the crucial feature of the gene. It is this sequence that carries the genetic information essential for the synthesis of an RNA molecule that may subsequently direct the synthesis of a protein molecule or may itself be functional in the cell. This process is called *gene expression*; it has two stages. The first stage in gene expression is *transcription* (the process by which the gene's DNA sequence is copied into RNA) and the second stage is *translation* (the process by which RNA directs the synthesis of a protein). Proteins are composed of amino acids and are the molecules that carry out the work of the cell. All the DNA in an organism is called the *genome*.



4

## What is a Patent?

- Patents are exclusive rights granted for a limited period of time by states through their legal systems to inventors to prevent others from exploiting the patent holder's invention. Patent applications contain claims which set out the precise nature of the protection.
- The commercial exploitation of something within the scope of the claim of a patent that has been granted, without the authorization of the owner of the patent, is called *infringement*.

5

### Criteria for granting a patent:

- the claimed invention must be eligible for patenting;
- it must be novel;
- it must be inventive or non-obvious;
- it must be useful or have industrial application;
- it must be fully disclosed in the patent application.

In addition, to be eligible, the invention must not be contrary to morality or *ordre public*.



6

- Patents are a form of **intellectual property** (IP) which confer rights over an invention on its inventor. These are privileges which enable inventors to capitalize on their invention, subject to wider constraints such as public interest and the IP and rights of others. Other forms of IP are copyright, registered designs and trademarks.
- The overall goals of the patent system are to stimulate innovation for the public good and to reward people for useful new inventions. The patent system aims to achieve this by allowing inventors exclusive rights for a limited period to exploit their inventions, while at the same time promoting competition and innovation by ensuring that such inventions are fully disclosed to the public.

7

## Ethical Concerns about Patenting DNA

- Many feel uncomfortable with the fact that genes and their mutations can be claimed for commercial gain. It is argued that the human genome is unique and distinctive, so it should be treated differently from others such as the genomes of mice or maize.
  - Some claim that there should be no property rights in genes;
  - Others claim that, while there may be property rights relating to genes, such rights should be the subject of shared public ownership rather than being in private hands.

8

## Inalienable Nature of Genes

- We can own objects but not people. People may not be owned by others as slaves. Some argue that this inalienable right to self-ownership brings with it an inalienable right to ownership of one's body, including one's genes.
- This right to ownership of one's genes is widely affirmed – as in Article 5 of the European Directive on the legal protection of biotechnological inventions (Directive 98/44/EC):

§5 The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

9

- The problem with this argument is that patents with claims to DNA sequences do not entail ownership of genes as they occur in our bodies – they relate instead to the isolated versions of such sequences which are held to be patentable.

- Thus, Article 5 of the EC Directive 98/44/EC continues:

§5 'An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.'

- Sometimes it is difficult to combine these two principles consistently.

10

## Genes as Public Property

- Genes should be publicly rather than privately owned. They should be treated like navigable waterways, shorelines and public parks.
- The designation of resources as public property is primarily to ensure freedom of access. This does not necessarily entail that such resources cannot be developed for profit, provided that such development does not prevent access: the central question is whether such access must necessarily be free and unrestricted.

11

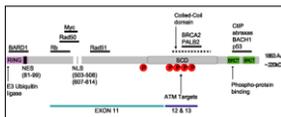
## Genes as Discoveries

- The underlying issue is whether genes and DNA sequences – whether isolated or not – are inventions or discoveries.
- A **discovery** is the acquisition of knowledge of a new but already existing fact about the world.
- An **invention** is something that someone creates or develops which did not previously exist.
- Discoveries do not qualify for the grant of a patent.

12

## Case Study: BRCA1

- BRCA1 is a gene that has been discovered to indicate susceptibility to breast cancer. BRCA1 is located on chromosome 17. The gene and its mutations have been part of numerous patent applications by a range of privately and publicly-funded research groups.



Domain map of BRCA1: RING, serine containing domain (SCD), and BRCT domains are indicated. Horizontal black lines indicate protein-binding domains for the listed partners. Red circles mark phosphorylation sites. Source: <https://en.wikipedia.org/wiki/BRCA1>

13

14

- In 1996, another US patent application was filed by a company called *OncorMed* for a 'consensus sequence' of the BRCA1 gene. The patent, which was awarded in 1997, asserts rights over a method of identifying individuals with a normal copy of the gene, and of identifying seven mutations in the gene. In 1998, *Myriad Genetics* acquired the rights to the genetic testing business of *OncorMed*.
- In January 2001, *Myriad Genetics* was granted a European patent that asserted rights over the diagnostic use of the BRCA1 gene (but did not claim the sequence itself). As a result of this patent, *Myriad Genetics* has a temporary monopoly on diagnostic testing for BRCA1 in many European countries.

15

- The original discovery of the BRCA1 gene was reported in 1994 by researchers from the University of Utah and the US company *Myriad Genetics*.
- In 1995, two patent applications were filed jointly by *Myriad Genetics*, the University of Utah Research Foundation and the US Secretary of Health, and were subsequently granted. The applications asserted rights over the normal BRCA1 gene sequence and various mutations, diagnostic tests for detecting mutations in BRCA1, and methods for screening samples taken from tumors.

- In 2001, another European patent was granted, which covers a method for diagnosing susceptibility to breast and ovarian cancer linked to the BRCA1 gene and covers the use of a further 34 specific mutations of the gene in diagnosis.
- The European Parliament adopted a resolution in October 2001 opposing the patenting of the BRCA1 gene.
- In 2013, the U.S. Supreme Court declared human genes off-limits for patent protection. All nine Justices on the Court agreed that the segments of DNA that make up human genes are not patentable because they are products of nature. But genes created in the lab are patentable.

16

- Justice Thomas writes: “A naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but complementary DNA is patent eligible because it is not naturally occurring.”
- Note the Supreme Court decision only concerns human genes, not genes of other living things. Nor does the law allow courts to consider whether patenting human genes—or anything else—should be disallowed on grounds of morality. The distinction between “natural” DNA and a lab-created synthetic version called complementary DNA is, however, difficult to maintain over the long run.
- Many of the older human gene patents have expired by now.

17

**Issues:**

- Is it in the public interest that there is only one diagnostic test available for a particular disease?
- Will patents on diagnostic tests prevent other diagnostic tests from being developed and used? Alternatively, will they stimulate further development?
- Will patents such as those that assert rights over BRCA1 inhibit further research, even in the context of other diseases?

18