Intellectual Property Rights (Patents and Copyrights) in Genomics and Proteomics

Intellectual Property Rights (IPR)

A ***biological patent*** is a patent on an invention in the field of biology that by law allows the patent holder to exclude others from making, using, selling, or importing the protected invention for a limited period of time.

The scope and reach of biological patents vary among jurisdictions and may include biological technology and products, genetically modified organisms and genetic material. The applicability of patents to substances and processes wholly or partially natural in origin is a subject of debate (Wikipedia).

Gene Patent: A gene patent is the exclusive rights to a specific sequence of DNA (a gene) given by a government to the individual, organization, or corporation who claims to have first identified the gene.

Gene patents have often resulted in companies having sole ownership of genetic testing for patented genes.

Other gene inventions and technologies being patents include:

- Associations between a DNA variant and a disease, condition, or function

- The DNA sequence that makes a particular protein, regulates a gene, or is useful for studying genetic variations
- RNA sequences that turn genes on or off, or control other functions
- Cell lines, methods of treatment, and diagnostics
- Transgenic animal models of disease and genes used to make them

Gene patents generally claim one or more of these five purposes https://www.thehastingscenter.org/briefingbook/gene-patents/:

1) Drugs from therapeutic proteins or gene transfer into cells
2) Genetic tests for diagnosis or screening
3) Research tools
4) Nonmedical uses for identification, forensics, and ancestry-tracing
5) Controlling which genes are turned on or off in a cell or tissue

A single patent may fit in more than one category. A patent may claim a DNA sequence that is both a research tool and a

method to make a protein, for example, or one that is both a research tool and a diagnostic test.

Patents are issued to encourage innovation, and provide protection to allow those investing in an innovation the opportunity to maximize the profit from their investment.

Patents issued for genetic technologies such as new methods of DNA sequencing are no different and their issuance has been extremely valuable to those developing products based on genetic discoveries.

However, when patents limit the use of basic genetic information, they threaten to inhibit or unduly constrain biomedical research, and the translation of research discoveries to clinical applications (https://www.genome.gov/about-genomics/policy-issues/Intellectual-Property)

History

1982. U.S. Supreme Court case of Diamond vs. Chakrabarty: According to the Title 35 of USA Code, a patent may only be granted on "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.

1997. Bermuda Principles- All DNA sequence information should be released into publicly available databases within 24

hours of being generated. This policy of open access to the genome has been a core ethos of genomics ever since.

2009. Questions regarding gene patents finally went to court when the Association of Molecular Pathologists, the American Civil Liberties Union, and a coalition of other groups, filed a lawsuit against Myriad Genetics, the USPTO, and the University of Utah Research Foundation. The suit challenged the constitutionality and validity of the BRCA1 and BRCA2 gene patents. Myriad Genetics had been particularly active in enforcing their exclusive license to these breast cancer genes, sending cease and desist letters to other labs and even researchers it felt were infringing its intellectual property.

2010 the Secretary's Advisory Committee on Genetics, Health and Society published a report, Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests. On the basis that patents on human genes were acceptable, the report recommended that diagnostic (but not therapeutic) genetic tests, be exempted from patent infringement, along with a research use exemption.

June 13th 2013, the Supreme Court published their ruling in the case, unanimously finding that isolated but otherwise unmodified genes were products of nature and therefore not patentable. However, the court did find that cDNA, synthetic

DNA molecules that contain only the exons of a gene, do involve an inventive step, and thus remain patent eligible.

Critics of Gene patents: There are 3,000–5,000 U.S. patents on human genes and 47,000 on inventions involving genetic material. Gene patenting is unethical to those who see the human genome as our common heritage. One concern is that patents might make the cost of genetic tests and genetic therapies unacceptably high

1) genes are naturally occurring, and while much intellectual effort may have gone into discovering them within the DNA sequence, discovery is not the same as invention.
2) Secondly, with the completion of the Human Genome Project in 2003 all of the human gene sequences were in the public domain and, therefore, prior art.
3) Finally, many argued that discovering the location of a gene cannot be considered as invention. One fifth of human genome under patent

Gene Patenting in India

While the Patents Act, 1970 in India prohibits patenting naturally occurring substances, patents covering genetic material and nucleotide sequences have been granted. Indian Patent Act under section 3 (c) and (j) clearly states that plants

or animals or any part thereof are not patentable subject matter, similarly the mere discovery of any substance found naturally occurring in nature are not patentable.

Copyright of genetic material

A copyright is a collection of rights that automatically vest to someone who creates an original work of authorship – like a literary work, song, movie or software. These rights include the right to reproduce the work, to prepare derivative works, to distribute copies, and to perform and display the work publicly.The potential applicability of copyright to engineered DNA has long been noted, particularly by a small number of academics who understand the theoretical underpinnings of copyright protection for software and recognize the similarity between genetic and computer code.