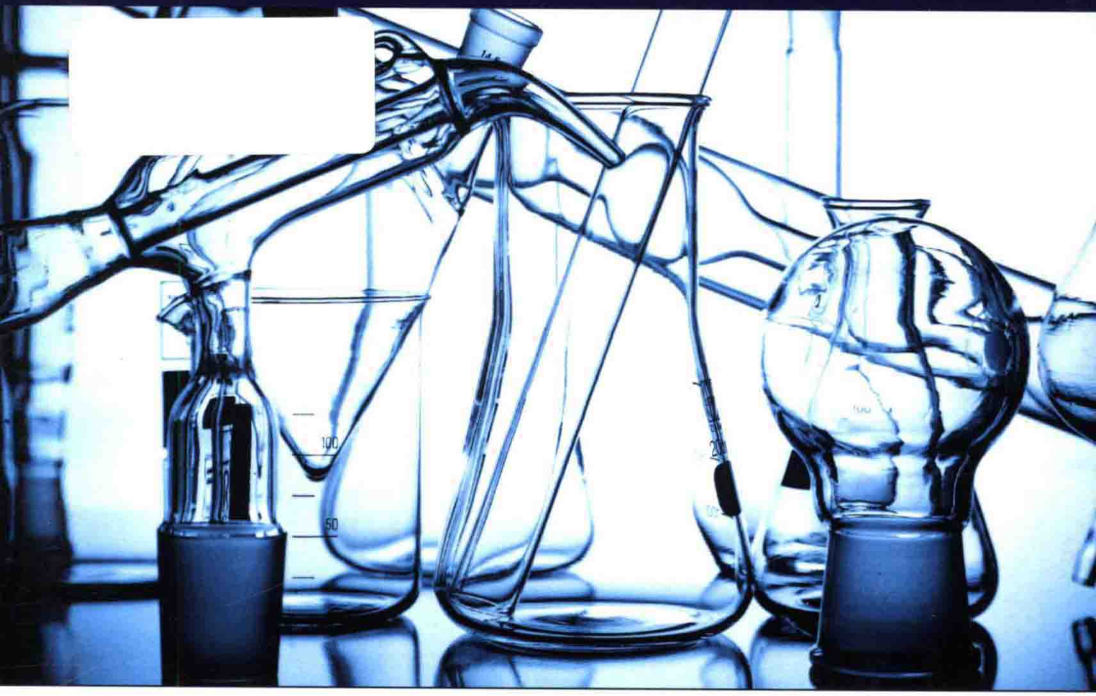

Jwala D. Thapa

Human gene patents: Placing the Helix in the Indian Patent Act, 1970

LAP LAMBERT Academic Publishing

Jwala D. Thapa

Human gene patents: Placing the Helix in the Indian Patent Act, 1970

LAP LAMBERT Academic Publishing

Impressum / Imprint
Bibliografische Information der Deutschen Nationalbibliothek: Die Deutsche Nationalbibliothek verzeichnet diese Publikation in der Deutschen Nationalbibliografie; detaillierte bibliografische Daten sind im Internet über http://dnb.d-nb.de abrufbar.

Bibliographic information published by the Deutsche Nationalbibliothek: The Deutsche Nationalbibliothek lists this publication in the Deutsche Nationalbibliografie; detailed bibliographic data are available in the Internet at http://dnb.d-nb.de.

Coverbild / Cover image: www.ingimage.com

Verlag / Publisher:
LAP LAMBERT Academic Publishing
ist ein Imprint der / is a trademark of
AV Akademikerverlag GmbH & Co. KG
Heinrich-Böcking-Str. 6-8, 66121 Saarbrücken, Deutschland / Germany
Email: info@lap-publishing.com

Herstellung: siehe letzte Seite /
Printed at: see last page
ISBN: 978-3-659-31980-8

Zugl. / Approved by: Kolkata, The WB National University of Juridical Sciences, Diss., 2008

Jwala D. Thapa

Human gene patents: Placing the Helix in the Indian Patent Act, 1970

CONTENTS

HUMAN GENE PATENTS: PLACING THE HELIX IN THE INDIAN PATENT ACT, 1970

Jwala D. Thapa

CONTENTS

Chapter 1

THE BLUE PRINT OF LIFE, TECHNOLOGIES AND VENDIBILITY: LAW'S CURIOUS PRESENCE

> "..However, certain aspects of biotechnology have become an especially controversial area of patent law.....particularly so in relation to patent on genes or on living organisms such as genetically modified animals. Much such controversy ignores that the patent system has been protecting inventions in this field for many years, for example in relation to naturally occurring but newly discovered living organisms, such as certain yeasts or microbes that have value as the source of medicinal products such as antibiotics, and that many patents with claims to genes in them are now so old that they have now expired."[1]

Ever since the structure of the DNA was unravelled, by Watson and Crick in 1953, it has been subjected to numerous studies and all scientific discoveries have been made to ensure that the knowledge about the DNA is used to the advantage of mankind and to cure human ailments. Also, the identification and understanding of proteins that a gene produces has helped in the synthetic production of therapeutic proteins, with functions

[1] Trevor Cook, *Pharmaceuticals Biotechnology and the Law*. Second Edition, , Lexis Nexis, Indian Reprint, 2009 at p.143

based on the naturally occurring proteins (for example, the Human Growth Hormone), and also certain diagnostic tests which help in the identification of genetic mutations that cause diseases. Of such studies have also evolved, certain branches like medical genetics and also recently pharmacogenetics[2], where the idea is to use the unique DNA fingerprint of an individual in his/her medical treatment.

In this chapter, I intend to look into the basic idea of a gene/DNA and the development in science which has been able to use the basic nature of a gene for the advantage of mankind. I will also go into the basics of patents and in the later Chapters, into how the patent law has been or can be applied to products using human genes.

I. HUMAN GENE: STRUCTURE AND FUNCTION

Proteins, genes and DNA

Genes are discrete segments of DNA molecules that contain the information necessary for producing specific proteins which performs specific

[2] ***Pharmacogenetics*** deals with the study of how a person's genetic variation affects his reaction to certain drugs or to certain chemicals in the drugs. Due to millions of deaths that are attributed to adverse drug reactions, this field of medical genetics is said to help in increasing drug safety and efficacy.

functions in the human body. A DNA is made up of a string of units called *nucleotides* and is a polymer of four deoxyribonucleotide bases and a gene is an ordered sequence of the bases [3]. The main components of each 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. The way these bases are paired together forms the basis on which DNA stores information. These base pairs can be arranged in the DNA molecule in an infinite variety of sequences. Each such sequence makes a particular *gene*. The total of all the DNAs which are present in an organism is called the *genome*.

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. 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.

---

[3] Philip B.C. Jones, *Patentability of the Products and Processes of Biotechnology*, 73 J. Patent & Trademark Off. Society, 374, 1991

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. Thus the ultimate biological function of a gene is the production of protein. Proteins are the molecules that help the cell carry out its functions[4]. All the processes and product in living cells depends on proteins. They do everything from activating essential chemical reactions, carrying messages between cells, to fighting infections, to making cell membranes, tendons, muscles, blood, bone, and other structural materials. Proteins are responsible for a cell's distinctive properties and proteins make an organism what it is. Whatever may be the different functions that proteins perform, all protein molecules are constructed in the same basic way. They are long, folded chains of smaller molecules called amino acids. There are 20 different types of amino acids in all, which can be combined in an almost infinite number of ways to produce different proteins. The number and arrangement of the amino acids determines the structure of the protein and the function it will perform in the cell. A subtle change in the arrangement of the amino

[4] Philip B.C. Jones, *Patentability of the Products and Processes of Biotechnology*, 73 J. Patent & Trademark Off. Society, 373, 1991

acids changes the nature of the protein produced by the cell and as a result, in the function of the cell. The unit of life is the same in all living organisms in this planet. The basic component of all life forms is the DNA and it is considered the blue print of life. But it is in the composition and the way in which the amino acids are arranged in a gene that makes the difference between a cat and a horse and both from a human body.

II. EXISTING TECHNOLOGIES: TURNING GENES INTO A VENDIBLE TANGIBLE PRODUCT

John J. Doll writes:

> "In the past two decades, there has been an explosion of innovative growth in the field of biotechnology. This growth has resulted in many new products and methodologies that are useful in agriculture, environmental biotechnology, food technology, and the diagnostics and pharmaceutical industries. Other results are new areas of research and development in genomics and bioinformatics."[5]

Biotechnology is the "engineering" of genetic material towards practical ends such as medical and veterinary advances, modified crops and improved

[5] John J. Doll,, *The patenting of DNA- concerns that practice may impede innovation and cooperation*, Science,May 1, 1998,Volume 280; Issue 5364,p1

animal breeds. It has been built up from a series of great biological revelations of our era[6]. John E. Smith writes that "Historically, biotechnology was an art rather than a science, exemplified in the manufacture of wines, beers, cheeses etc., where the techniques of manufacture were well worked out and reproducible but the molecular mechanisms were not understood. With a better understanding of microbiology and biochemistry, these processes now encompass a wide range of new products including antibiotics, vaccines and monoclonal antibodies, the production of which has been optimized by improved fermentation procedures. Biotechnology has been further diversified by a host of new molecular innovations, allowing unprecedented changes to be made to living systems. Transgenic plants and animals are heralding new age in agriculture, and gene therapy in humans may eradicate many previously incapacitating diseases."[7] The implementation of biotechnology to the field of genetics has led to the emergence of the filed of Genetic Engineering. Genetic engineering manipulates genetic material

---

[6] Cornish and Llewelyn, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, 2003, Fifth Edition, Thomson sweet and Maxwell, p.823

[7] John E. Smith, *Biotechnology*, 1996,(Third Edition), Cambridge University Press, p. xv

by intervention at the cellular and molecular levels rather than at the level of whole animals and plants[8]. According to Cornish and Llewelyn, there were three biotech revelations[9]:

1. The discovery of the structure of the DNA by Watson and Crick,
2. The invention of the Recombinant DNA Technology,
3. The Human Genome Project and the mapping of the Human Genome.

The advance of genetics in the 1990s has shifted the frontiers of the rapidly evolving discipline. In particular, much of the former hard labour of identifying genes, their associated proteins, the receptors through which they enter cells and the pathways they pursue, has ceased to be a matter of laboratory searching. Genome maps of numerous animals and plants are available and the number is mounting rapidly. Computational genetic searches, for such matters as gene identification between different species of animal, and for variations in the genetic make-up of individuals through automated micro-arrays, are increasing the role of bio-

---

[8] Dr Peter Wheale and Ruth McNally, *The Bio-Revolution, Cornucopia or Pandora's Box? Part I-Transgenic Manipulation, Patenting and Animal Welfare,* Edited by Wheale and McNally, 1990, Pluto Press, London, p.3.
"Man has always engaged in genetic engineering in its broadest sense, because the domestication and improvement of wild plants and animals is nothing more than the search for individuals with desirable naturally occurring genetic makeup that will breed true overtime." - 74 J. Pat. & Trademark Off. Soc'y 513 1992.
[9] Cornish and Llewelyn at p. 823-824.

informatics using computers. Knowledge of the biological function or functions of individual genes allows changes in cell types and tissues to be monitored, showing, for instance the presence of tumours or susceptibilities to cancer.[10]

The desire to unravel the secrets of the human genome has led scientists to try to find the answers to its structure as well as its functions. With the unravelling of these secrets led to the emergence of a new field of study which focused on using this knowledge for the benefit of mankind. Different fields of science emerged which fused the biological and medical sciences with technology to branch into biotechnology, genomics, genetic engineering and bioinformatics. The recent field which has emerged is of pharmacogenetics which fuses medical science with genetics or the study of genes to come out with answers that are useful to find cures that can be effective at the root of the human physiology; the genes.

Eric S. Grace writes:

> "The function of a gene is to produce a protein: nothing more, nothing less. The difference between species or between individual organisms, lie only in the particular numbers and specifications and combinations of their genes. Because the

---

[10] Cornish and Llewelyn at p.825.

> genetic code is universal, almost any cell in any organism can 'read' a gene and translate it into the relevant protein. Today for example, the insulin used to treat thousands of people with diabetes is produced on an industrial scale in huge vats by bacteria that have been genetically engineered to carry the human gene. This is the essence of biotechnology."[11]

Philip Grubb writes that biotechnology has been in practice for a long time, for example, the production of ethanol from yeast cells which is a very ancient technique to make alcoholic beverages. The use of biotechnology on an industrial scale can be said to have begun in the early 1900s with the use of the fermentation process. Classical biotechnology, as he terms the phase, mainly dealt with the production of ethanol from yeast cells and other industrial chemicals like acetic acid and acetone by the process of fermentation. This went on for the next 50 yrs. From the 1960s genetic science set out to locate genes along the DNA strands of a genome; and to determine how they could be made to express their cognate proteins; since it is by proteins that many biological changes are affected in a life-form. Above all, the aim has been to discover their functions as codes for biological effects around the

---

[11] Eric S. Grace, *Biotechnology Unzipped –Promises and Realities,* 1997, Universities Press (India) Ltd., p.30.