

PATENTING MICROORGANISMS

LEXORBIS
Intellectual Property Practice

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MICROORGANISMS

Microorganisms - What are they?

We relate them to

- Diseases
- But they too help to cure diseases, how???

Different Uses of Microorganisms in fields of Molecular Biology & Biotechnology

- Gene Silencing
- Gene Therapy
- Cloning & Transformation
- Vaccine - Edible Vaccines, Live Vaccines
- Transgenic

RNAi- Mechanism of Action

- ◆ Introducing long double stranded RNA leads to sequence-specific degradation of homologous gene transcripts.
- ◆ Long double stranded RNA metabolized to small 21-23-nucleotide siRNAs by endogenous RNase Dicer.
- ◆ siRNAs bind to protein complex RISC with dual function helicase- unwinding and RNase activity.
- ◆ Unwind siRNA allowing antisense strand to bind to target.
- ◆ Hydrolyses of target by endonuclease activity of helicase.

RNAi Patentability issues

- ◆ Consider a broad claim to:

An siRNA that inhibits expression of a nucleic acid encoding protein X.

Can also be claimed more broadly as short interfering nucleic acid.

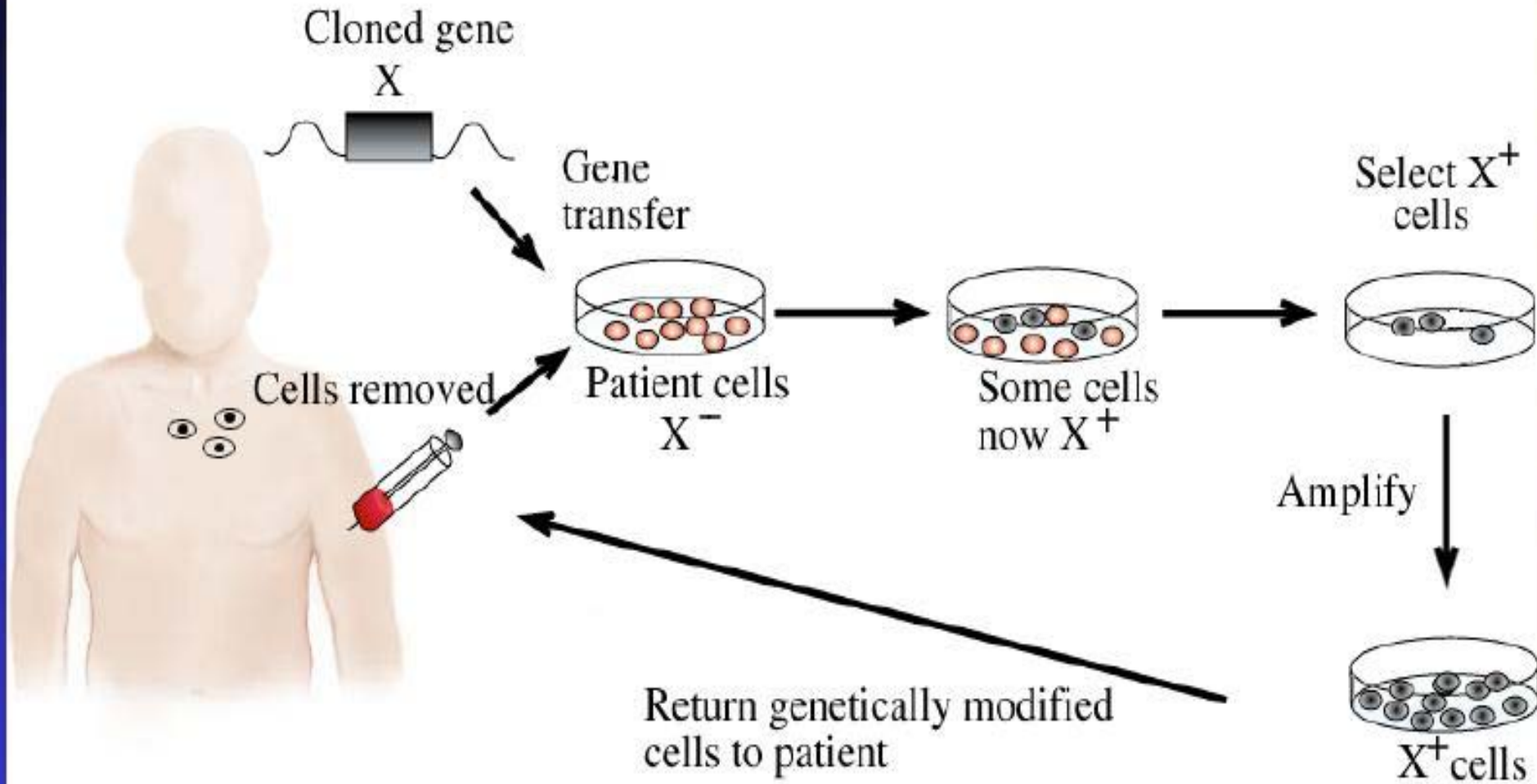


Gene Therapy - Why and How?

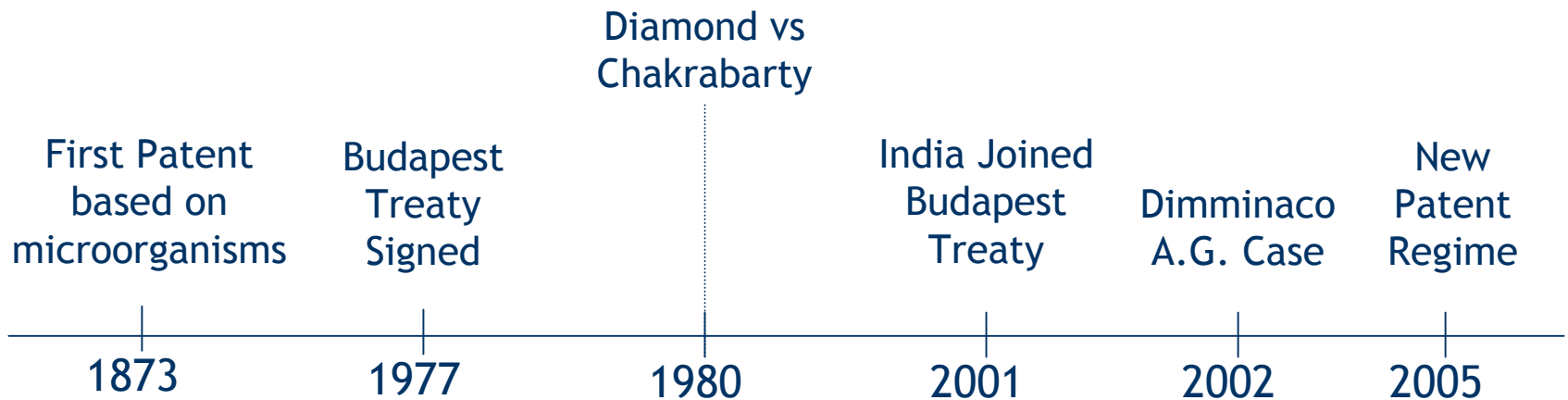
Gene therapy could be very different for different diseases

- Gene transplantation
(to patient with gene deletion)
- Gene correction
(To revert specific mutation in the gene of interest)
- Gene augmentation
(to enhance expression of gene of interest)
- Targeted killing of specific cells by introducing killer gene
- Gene ablation - targeted inhibition of gene expression

In Vivo and Ex Vivo Gene Therapy



Patents on microorganisms - Timeline

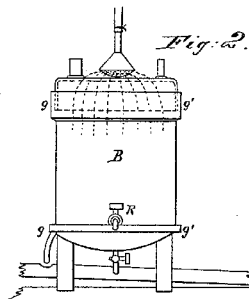
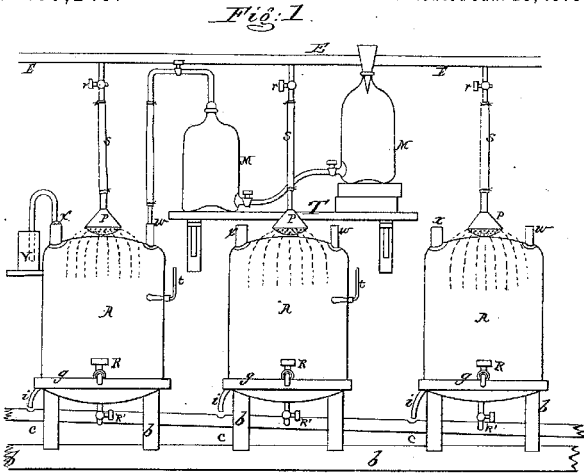


- ◆ Before 1980, Patents were given for inventions based on microbiological processes
- ◆ No patent was given for the living entities per se which were considered to be the products of nature.

First patent based on microorganisms

On January 28, 1873, Louis Pasteur received a patent for process of fermenting beer
Claim: "... invention produces a better quality and greater quantity of beer from the same quantity and quality of wort (the boiled extract of malt or other material)... the yeast, or pure ferment is added to provoke or induce fermentation."

L. PASTEUR.
Brewing Beer and Ale.
No. 135,245. Patented Jan. 28, 1873.



Witnesses,
E. Wolf
J. Helbel

Inventor
Louis Pasteur
By his attorney
C. M. Keller

AM. PHOTO-LITHOGRAPH. "U. S. PATENT OFFICE."

Patents on microorganisms - Timeline

- ◆ In 1980, the U.S. Supreme Court, during the hearing of the patent law case of Chakrabarty, for the first time ruled that -
a live microorganism is patentable
- ◆ Currently, many microorganisms are patentable in various countries
 - Bacteria
 - Plant and Animal Virus
 - Filamental fungi
 - Protozoa
 - Unicellular algae

Diamond vs Chakrabarty

The Invention

- ◆ Ananda Mohan Chakrabarty, Genetic engineer, GE
 - Developed a bacterium capable of breaking down crude oil
 - To use in treating oil spills
- ◆ A transmissible plasmid found specifies a degradative pathway for
 - Salicylate - an aromatic hydrocarbon, and,
 - Naphthalene - a polynuclear aromatic hydrocarbon
- ◆ Unique single-cell microbes developed containing
 - Various stable combinations of plasmids, combined with,
 - A non energy-generating plasmid
- ◆ The versatility of these “novel” microorganisms was demonstrated by the substantial extent to which degradation of complex hydrocarbons - such as crude oil - was achieved

Diamond vs Chakrabarty

The Ruling

- ◆ According to the U.S. Charter (35 U.S.C. 101): *Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent thereof, subject to the conditions and requirements of this title*
- ◆ Ruling
 - Based on the above section of the U.S. Charter
 - *A live, human-made microorganism is patentable subject matter. Respondent's microorganism constitutes a "manufacture" or "composition of matter" within that statute.*

The Budapest Treaty

- ◆ Signed April 29, 1977; amended Sept. 26, 1980
- ◆ Special agreement under the Article 19 of the Paris Convention, thus, only members of the Paris Convention are qualified for becoming members
- ◆ Aim:
 - To eliminate/reduce repetition of the complex & costly procedures of the deposit of the microorganism in each of the countries seeking patent
 - Enable one deposit to serve the purpose of all the deposits

The Budapest Treaty

- ◆ International Depository Authority, IDA
 - Scientific institution capable of collecting microorganisms
 - Must comply with certain requirements of the Treaty
 - Provides the testing of the viability of the deposited microorganisms
- ◆ Deposit to the IDA
 - Must meet the descriptive requirements of patent legislation governing an invention involving a microorganism or the use of a microorganism
 - Can be accessed for the purpose of testing and experimenting and for commercial use when the patent expires
- ◆ It is not necessary for the entity being deposited to be a microorganism - it should only be required for the purposes of disclosure and must be acceptable to the IDA
 - Tissue cultures and plasmids can be deposited

TRIPS & PATENTING MICROORGANISMS

- ◆ Article 27(3)(b) of the TRIPS Agreement states:

Members may exclude from patentability:

- *Plants and animals other than microorganisms*
 - *Essentially biological processes for the production of plants and animals other than non-biological and microbiological processes*
- ◆ In recognition of territorial nature of IPR and the need to maintain appropriate local differences, TRIPS sets down minimum standards for protection, thus, provisions are drafted in very general terms

TRIPS

Ambiguity in definition of microorganisms

Reading of Article 27(3)(b) implies that a clear distinction can be made between plants and animals on the one hand and microorganisms on the other. Is that true???

TRIPS

Ambiguity in definition of microorganisms

- ◆ So what definition should be considered or it is on discretion of the Examiner or the Applicant
 - Any of various microscopic organism, including algae, bacteria, fungi, protozoa and viruses. (*The Concise Oxford Dictionary*)
 - Any organism, such as a virus, of microscopic size: (*Collins English Dictionary*)
 - Microorganisms are microscopic life-forms including microscopic fungi, Protista, prokaryotes and viruses. (*Introduction to Microbiology. Heritage, Evans and Killington*)
 - A microscopic organism consisting of a single cell or cell cluster, including the viruses: (*Biology of Micro-organisms. Brock*)

- ◆ Does a quotation from an English dictionary would be sufficient to provide a definition of the term "microorganism".

TRIPS

Ambiguity in definition of microorganisms

A more precise and scientific definition is required for the purposes of providing a clear definition of the scope of exceptions to patentability set out in Article 27.3(b).

Criteria of novelty for patenting of microorganism per se

Is discovery of a microorganism from nature for the first time an inventive step?

- ◆ “A microorganism exists in nature as a part of the nature, its discovery is NOT an invention”
 - If it is an invention, logic of treating scientific theories and principles as non-patentable inventions gets defeated
 - If microorganisms isolated from the nature for the first time are considered patentable, then minerals and ores discovered from the interior of earth and deep sea bed would qualify for patenting
- ◆ Thus, microorganisms can be considered an invention only if-
 - The microorganism has not been described in the literature
 - There is an element of human intervention with the discovery
- ◆ Patent on *Streptomyces Violaceus*, a microorganism accessed from the soil in Hyderabad, India, granted by US PTO in 1991 to Bristol Myer would not be a valid patent

The Indian Scenario before 2002

- ◆ Patent Act of India, 1970, Section 2(1)(j) defines an invention as a new and useful “*manner of manufacture*’ or a “*substance produced by manufacture*”
- ◆ No definitions of “*manner of manufacture*” or “*substances*”
- ◆ Patent Office adopted the practice of interpreting a “*manner of manufacture*” as a patentable subject matter only if it results in a *tangible nonliving substance*

2002: The Dimminaco A.G. Case

- ◆ Application:
 - Applicant: Dimminaco A.G., a Swiss Company
 - Process for preparation of a live vaccine for Bursitis
- ◆ Rejected by the Patent Office:
 - Reason: statutory definition of '*manufacture*' did not include a process that resulted in a '*living organism*'
- ◆ Decision by Calcutta High Court:
 - In the absence of a definition, the normal dictionary meaning of these words should be accepted
 - No statutory bar in the Act to accept a manner of manufacture as patentable even if the end product contains a living organism
 - Directed the Patent Office to reconsider the patent application in light of the Court's observations
- ◆ Patent was finally granted (Indian Patent 187970)

India - Towards a new patent regime

- ◆ Budapest Treaty: joined on 17 December 2001.
- ◆ IDA: Microbial Type Culture Collection and Gene Bank (MTCC) of the Institute of Microbial Technology (IMTECH), Chandigarh, acquired the status of an IDA on 4 October 2002

Second Amendment (2002) to The Patents Act, 1970

Microorganisms per se are not patentable

Allows patenting of processes pertaining to microorganisms as well as non-biological and microbiological processes

Made changes in the definition of “what is not an invention” (sec. 3)

- ◆ Section 3(i) the word "plants" was deleted
- ◆ This deletion implies that a process for treatment of plants can now be counted as an invention and therefore can be patented

Second Amendment (2002) to The Patents Act, 1970

- ◆ A new clause to Section 3 was added i.e. 3(j) which excluded as inventions “plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production of propagation of plants and animals”
- ◆ Since plants produced through the use of biotechnological processes, which are not technically considered “essentially biological,” section 3j has found another way to create room for patentability of life forms



2005 Amendment to The Patents Act, 1970



Product Patent for Microorganism Section 5- Deleted



Thank you