Law
Intellectual Property
Biotechnology Patents- Subject Matter Exclusions

1. Introduction:

"Protection of intellectual property is one of the core issues for biotechnology firms[1]."

In the modern day knowledge-based system, apart from information technology, biotechnology is one branch of science, which is helping the economy thrive. A significant number of crucial developments in the field of pharmaceutical, agro-chemicals, energy, and environment have biotechnology as their backbone. The great strides made in the specific areas of molecular biology, biotechnology and molecular medicine have established biotechnology as the lifeline for the pharmaceutical industry.

Since biotechnology is a research-intensive field, it is massively dependent on intellectual property, patents rights in particular. Owing to this, the incentive to innovate for biotechnology firms is strong[2].

However, one of the important challenges to the patent system is its ability to remain useful to new technologies. This is seen especially in the light of challenges posed by modern biotechnology to the patent system. The patent system which largely grew out of the days of mechanical and chemical invention has posed innumerable challenges in the area of biotechnology patents. Coupled with these technical challenges, patent law is burdened with a host of ethical and religious concerns relating to biotechnology. This is one reason why developed countries could not reach broader consensus on

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[1] https://www.ige.ch/fileadmin/user_upload/dienstleistungen/publikationen_institut/j10005e.pdf

[2] http://www.wipo.int/sme/en/documents/patents_biotech_fulltext.html#P17_1732

patenting higher life forms during the Uruguay Round negotiations in the TRIPS Agreement. This has provided immense flexibility in the hands of WTO member countries to treat patent law like a nose of wax on the issue of biotech patents. Many jurisdictions have implemented a wide list of patentable subject matter exclusions. India also does. The aim of this module of to offer insights into:

- Modern biotechnology and the types of claims received by the patent office
- Challenges posed to the patent system
- TRIPS Agreement and the list of exclusions allowed
- Early questions on biotechnology- a view from comparative jurisdictions
    - Patenting of a genetically modified organism
    - Patenting of plants
    - Patenting of animals
- New Challenges Posed
    - Gene Patents
    - Diagnostic Methods
- Position in India
    - Position prior to 2005 amendments
    - Nature of exclusions under Section 3
    - Additional requirements in the context of TK associated with genetic resources
    - Biotech Guidelines issued by the Indian Patent Office
    - Some Recent Developments in India
- Summary

Learning Outcome:

Will help students to understand how modern biotechnology has helped markets bring out innovative product that are technology intensive

Will help students to understand the role of patent in incentivising biotech inventions and challenges

Will help students to examine the early origins of patenting biotech subject-matter in comparative jurisdictions and in India

Will help students to understand the patent-eligibility of biotech subject matter in the context of the TRIPS Agreement

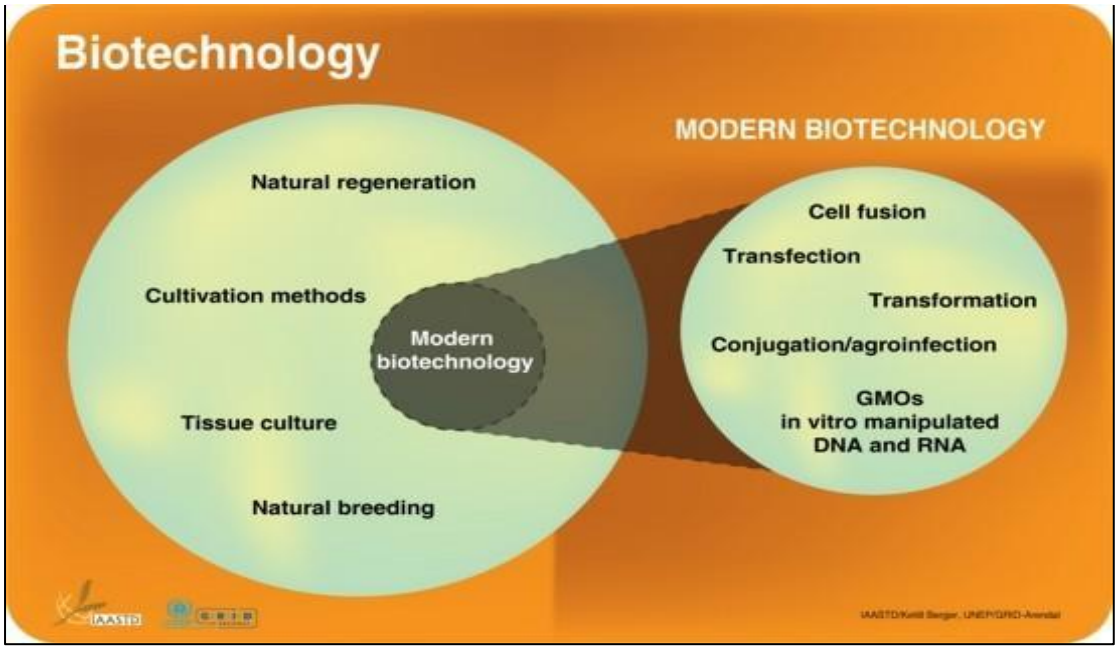
1. Modern biotechnology and the Types of Claims Received by The Patent Office

Biotechnology refers to the use of *biological processes, organisms, or systems* to create products which are capable of improving the quality of human life. The study and use of biology has been playing an imperative part in day-to-day human life; from the use of yeast to bake bread from the use of plants with medicinal properties to cure ailments.

Cross-breeding between different species of plants and animals has been the earliest form of biotechnology known to the farming community. However, complexity in technology has taken biotechnology from farms to the labs. Technical advances in the field have allowed it to touch major areas such as medical and pharmaceutical products, industrial processes, and agriculture; impacting almost all aspects of human life[3].

The following graphic aptly explains the nature of modern biotechnology and its difference with how biotechnology was previously perceived.

[3] https://www.epo.org/news-issues/issues/biotechnology-patents.html



Modern biotechnology

The UN Convention on Biological Diversity in Art. 2 states: "Any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific use" It is important to note that all DNA is made up of a base consisting of sugar, phosphate and one nitrogen base. There are four nitrogen bases: adenine (A), thymine (T), guanine (G), and cytosine (C). These nitrogen bases are found in pairs, with A & T and G & C paired together. The sequence of the nitrogen bases can be arranged in many infinite ways, and their structure is known as "double helix" It may be noted that the four nitrogen bases are the same for all organisms.

Discovery of Recombinant DNA technology changed everything: Recombinant DNA (rDNA) involves taking one strand of the DNA and combining it with different strands of DNA to effectuate a desired trait.

The range in which biotech products are produced is:

Modern biotechnology has applications in several areas, including but not limited to	Medicines Agriculture Industrial purposes (industrial fermentation etc..)

GMOs: Harvard oncomouse, Oxitec Mosquitos, transgenic plants etc..

Medicines : Rituxan (rituximab) (Genentech); Humira (adalimumab) (Abbott); Avastin (bevacizumab) (Genentech); Herceptin (trastuzumab) (Genentech); Epogen (epoetin alfa) (Amgen)

The IPO Guidelines on Biotech Subject Matter (2013) provides a useful list of the type of claims that are made in relation to biotech subject matter:

- Polynucleotides or gene sequences (product and/or process),
- Polypeptides or protein sequences (product and/or process),
- Vectors (e.g., plasmids) (product and/or process),
- Gene constructs or cassettes and gene libraries,
- Host cells, microorganisms and stem cells (product and/or process), transgenic cells,
- Plants and animals tissue culture (product and/or process)
- Pharmaceutical or vaccine compositions comprising microorganisms, proteins, polynucleotides (product and/or process),
- Antibodies or antigen binding fragments thereof (monoclonal or polyclonal), (i) Diagnostic kits and tests, and
- Diagnostic tests (products/process) such as a test for the detection of a mutation in a gene/protein which might be associated with a particular condition such as protein expression or a disease.

2. Challenges posed to the patent system

Research and Development in the arena of life sciences is fraught with risks and that is why the biotechnology sector is heavily dependent on the incentives provided by the patent system to offset the risks involved in making heavy investments for undertaking research & development activities in this field.

The patent system incentivises research & development in biotechnology, facilitates enhanced human health and increased food production, contributes to a safer environment, and generates employment. However, in relation to the field of biotechnology, it is not untouched by certain challenges that may act as impediments to development in many scientific fields, including molecular biology, biotechnology, embryology, genetics, and bioinformatics.

Firstly, there are administrative challenges in the form of Patent backlogs, overly broad ambiguous patent claims, and unnecessary litigation; which encumber the biotechnology sector with uncertainty and excessive costs, ultimately hindering innovations in the sector.

Then there are multiple legal challenges plaguing the biotechnology sector when it comes to patenting of an invention. The question on patentability of modified gene sequences, as highlighted in the *Myriad Case;* international protection of IP rights; defining the scope of infringement, particularly when an invention is used for the purpose of research; and finally the identification of *patentable utility, novelty, non-obviousness, and describing altered genomic and proteomic material* pose major challenges to the biotechnology sector.

Challenges in the field of innovation present another hurdle to the innovations in the biotechnology sector. The first challenge is to strike a balance between protecting intellectual property and promoting *openness, freedom, and collaboration.* Another big challenge is to define the scope of *pure research* as opposed to a commercial exercise, which is important for ascertaining the compensation in cases of patent infringement. Promoting the open sharing of bio-

medical data to bolster innovation presents another major legal predicament. Enabling efficient functioning of the patent system is another challenge, which is rife with problems created by *patent trolling, uneven IP protection, and privacy rules* and which may be helped by modifying the existing patent standards and instilling greater transparency in granting of patent. There is a view that biotech patenting leads to the tragedy of anti-commons where downstream product development may be impeded due to different parts of upstream technologies being held by several companies who may holdup and demand excessive royalties. Heller and Eisenberg proposed this in their famous work.[4] However, empirical evidence on anti-commons in the biotech industry points to the contrary noting that "the anti-commons effects are typically preempted or mitigated through cooperative arrangements among small numbers of IP holders or transactional solutions devised by entrepreneurial intermediaries for large numbers of IP holders".[5]

Lastly, there are ethical challenges which need to be addressed to foster rapid research and development in the biotechnology sector. The alteration of genetic code, unforeseen consequences arising from alteration of DNA, balancing public access to life-saving medicine with incentivizing innovation, and protecting personal genomic information from manipulation or misuse are some valid concerns which need to be addressed in respect of biotechnological innovations[6].

A graphic below provides a summary of challenges posed:

Administrative Challenges: Patent Backlogs, Overly Broad Patent Claims, and Excessive Litigation

Legal Challenges: Patentability of modified gene sequences, defining the scope of infringement, International Protection of IP Rights, Identification of Patentability Criteria

Innovation Challenges: Striking a Balance between Promotion of IP and Promotion of *Openness, Freedom, and Collaboration;* Defining the Scope of ***Pure Research; Enabling Efficient Functioning of Patent System, Open Sharing of Medical Data;***

Ethical Challenges: Alteration Of Genetic Code, Unforeseen Consequences Arising from Alteration of DNA, Balancing Public Access to Life-Saving Medicine with Incentivizing Innovation, Protecting Personal Genomic

Advance in sciences now make it possible to isolate and replicate a host of naturally occurring substances raises questions for patent law

Can it be shown that when viewed as a whole, an application incorporates a discovery brings about a technical change, it may be patentable.?

Finding of a new property of a known material or article to be treated a un-patentable discovery ?

Use of such properties to a practical use may be patentable ?

The difficulty in adjudging what forms invention v. discovery in biotechnology (specifically patents on DNA sequences and genes)

Human intervention the criterion

Both discoveries and inventions involve human intervention; both involve time, labour, skill and investment.

We thus need to question what type of human intervention is demanded for making an unpatentable discovery an invention

Guidance can be taken from patents that have been granted; it is otherwise too difficult to draw a plain line of difference and arrive at a straightjacket formula

The Indian Patent Office has a Manual Published- can be of some guidance

"There is a difference between discovery and invention. A discovery adds to the amount of human knowledge by disclosing something already existent, which has not been seen before, whereas an invention adds to the human knowledge by creating a new product or processes involving a technical advance as compared to the existing knowledge".

One of the most recent challenges in the area of biotech can be highlighted by taking a very contemporary example of the litigation involving CRISPR patents in the United States.

CRISPR is the acronym for 'Clustered Regularly Interspaced Short Palindromic Repeats', a gene-editing technology which allows the genome to be cut at a specific location, thereby modifying a specific part of DNA in plants and animals. The University of California ("UC") and The Broad Institute, Inc. have been developing and using the CRISPR technology and are involved in a Patent litigation surrounding the claims based on CRISPR-Cas9 systems and methods of DNA editing. In an Interference proceeding before the Patent Trial and Appeal Board ("PTAB"), UC claimed that based on the provisional application, Broad's Patent was obvious. However, the PTAB held that:

> *"ordinarily skilled artisans would not have had a reasonable expectation that CRISPR-Cas9 would work in eukaryotic cells and concluded that there was no interference in fact."*

The matter was appealed by UC to the Federal Circuit and the final outcome is likely to influence to the magnitude of control UC will have the right to exercise over the CRISPR technology[7]. The Federal Circuit has not pronounced any decision until August 2018.

3. TRIPS Agreement and the list of exclusions allowed

Biotechnology, as a branch of modern science, is only 30 years old. Yet, at the time of Uruguay Round of multilateral trade negotiations which brought about the TRIPS Agreement, the US and EU adopted considerably different approaches to patentability of biotechnology inventions. The European Union displayed strong resistance to making living organisms patentable. On the other hand, the US displayed strong proclivity to grant patents to anything man-made, with the exception of human beings. In the light of an ongoing debate, it was agreed that a minimal agreement will be incorporated into the TRIPS which will be revisited

[7] http://www.ipwatchdog.com/2018/08/17/crispr-tug-of-war/id=100378/

after four years of coming into force of TRIPS. This minimal agreement is reflected in Article 27.3 (b) of TRIPS[8].

- (Article 27:1) Availability and enjoyability of patent rights without discrimination
  - Place of invention
  - Field of technology
  - Whether products are imported or locally produced
    - Can lack of local manufacturing than be a ground for compulsory licence? Brazil- US dispute at the WTO DS (undecided)
- (Article 27:2) Members may exclude based on grounds of *ordre public* and morality
  - Must be based on commercial exploitation and not inherent problem with the invention (for. E.g. Cloning)
  - Members may exclude methods of treatment – diagnostic, therapeutic or surgical methods for treatment of human and animals (only methods) US provides patents but limits liability in cases of infringement by individual doctors
  - US provides patents but limits liability in cases of infringement by individual doctors. In Pallin case where a surgeon sued other surgeons for patent infringement , caused amendment in 1996 such that in principle patent rights do not apply to medical activity by physicians etc. (35 USC 287 (c)(1))

- Members may exclude plants, animals and essentially biological processes for the production of plants or animals.
  - However cannot exclude microorganisms, non-biological and microbiological process for the production of plants or animals.

[8] https://pdfs.semanticscholar.org/289f/7ca724596cbdb730c83081f14442dc2c037b.pdf

- (Article 27.3) Members may also exclude from patentability:
  - plants and animals other than micro-organisms; and
  - essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement[9].

The Doha Declaration, in paragraph 19 has given a wider scope to the discussion surrounding the patentability/non-patentability of plants and animals by stating that *"the TRIPS Council should also look at the relationship between the TRIPS Agreement and the UN Convention on Biological Diversity, the protection of traditional knowledge and folklore"*[10].

Despite being subject to a review after four years of coming into force of TRIPS, i.e. by 1999, the Article has not been reviewed yet.

4. Early questions on biotechnology- a view from comparative jurisdictions

The following graphics explain the question on excludable subject matter

a. Patenting of a genetically modified organism

One of the earliest case in the United States *Funk Brothers Seed Co. v. Kalo Inoculant Co.*[11] highlights a Supreme Court /decision where it was held that *"a facially trivial implementation of a natural principle or phenomenon of nature is not eligible for a patent"*. In this case, the patentee discovered that there are strains of each species of root nodule bacteria which do not exert a mutually inhibitive effect on each other and was able to provide a mixed culture of Rhizobia

[9] https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm#5
[10] http://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex3.pdf
[11] 333 U.S. 127 (1948)

capable of inoculating plants belonging to several groups. The Supreme Court Held:

"The majority opinion (per Justice Douglas) held that "the properties of inhibition or of non-inhibition in the bacteria were "the work of nature.," and therefore not subject to being patented. "[P]patents cannot be issued for the discovery of the phenomena of nature."

The Court added that *"the qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end".*

The Case of Diamond v Chakrabarty (US, 1980) dealt with the interpretation of 35 U.S.C. 101 which reads as ""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 therefor, subject to the conditions and requirements of this title. "We have cautioned that courts "should not read into the patent laws limitations and conditions which the legislature has not expressed."

The use of terms such as "manufacture" and "composition of matter," along with the use of the term "any" gave Congress the scope to construe patent laws widely.

The Court found that "*Congress had intended patentable subject matter to "include anything under the sun that is made by man*", and *"judged in this light, respondent's micro-organism plainly qualifies as patentable subject matter. His claim is ... to a non naturally occurring manufacture or composition of matter—a product of human ingenuity*"

However, the dissenting judgment stated that *"First, the Acts evidence Congress' understanding, at least since 1930, that 101 does not include living organisms. If newly developed living organisms not naturally occurring had been patentable under 101, the*

plants included in the scope of the 1930 and 1970 Acts could have been patented without new legislation. Those plants, like the bacteria involved in this case, were new varieties not naturally occurring." It also stated that "*The patent laws attempt to reconcile this Nation's deep-seated antipathy to monopolies with the need to encourage progress. Given the complexity and legislative nature of this delicate task, we must be careful to extend patent protection no further than Congress has provided. In particular, were there an absence of legislative direction, the courts should leave to Congress the decisions whether and how far to extend the patent privilege into areas where the common understanding has been that patents are not available.*"

b. Patenting of plants

Directive recital 29 "Whereas this Directive is without prejudice to the exclusion of plant and animal varieties from patentability; whereas on the other hand inventions which concern plants or animals are patentable provided that the application of the invention is not technically confined to a single plant or animal variety;"

Ciba –Geigy's Application

Claims directed towards plant propagating material that has been chemically treated so as to make the material resistant to other agricultural chemicals were not claims to a plant variety

Plant breeding introduced a trait to plants that reapperaed in subsequent generations, this did not occur with chemical treatment- hence claims are not for varieties

Similar reasoning adopted in Plant genetic systems case

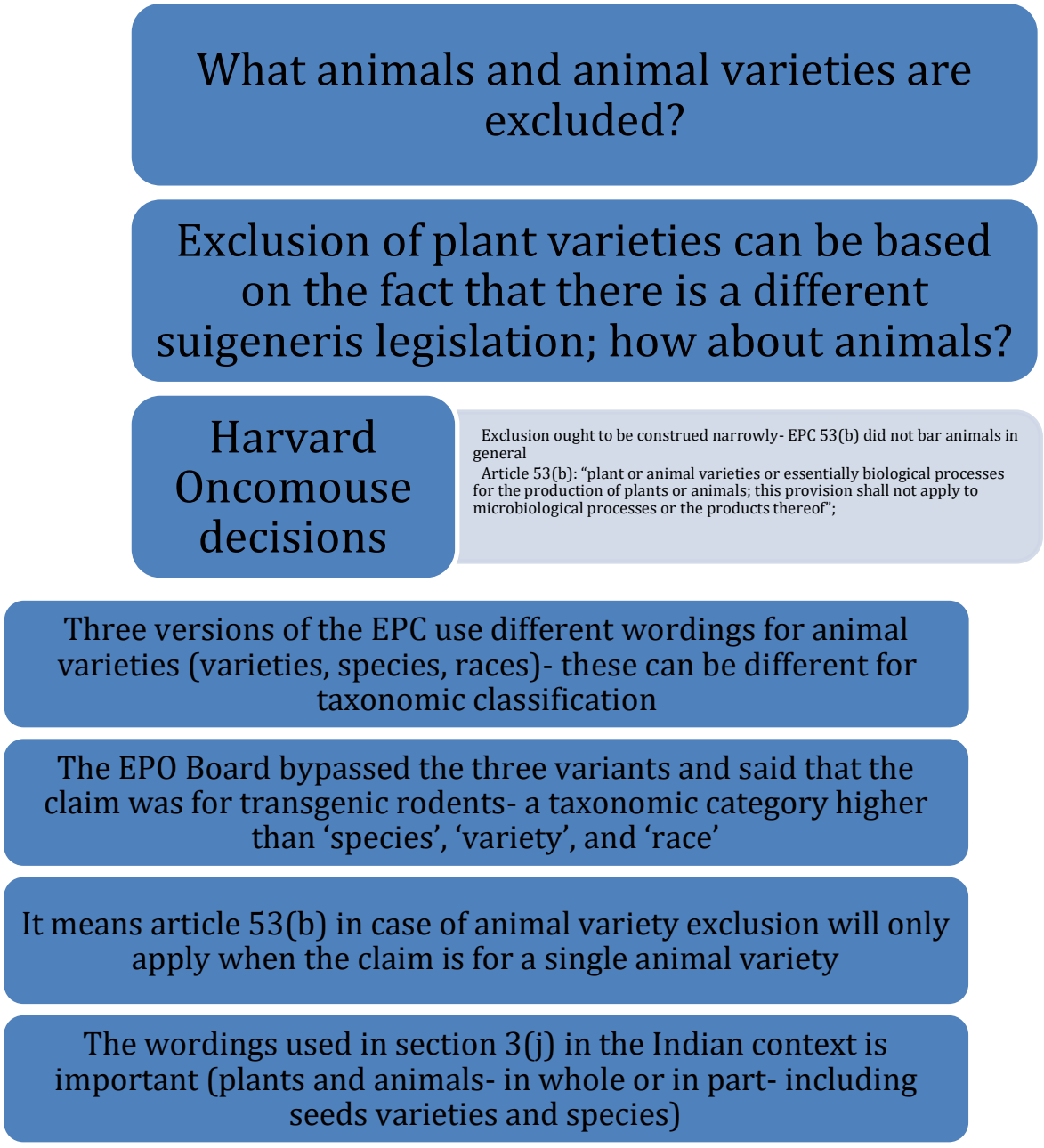
Article 1(2). Inventions which concern plants or animals shall be patentable if the **technical feasibility of the invention is not confined to a particular plant or animal variety**

Among the recent changes the European Patent Office amended the relevant Regulations in order to exclude from patentability "plants and animals exclusively obtained by an essentially biological breeding process", which took effect in 2017. [12]

c. Patenting of animals

Harvard Onco Mouse- EPO

[12] https://www.epo.org/news-issues/issues/biotechnology-patents.html

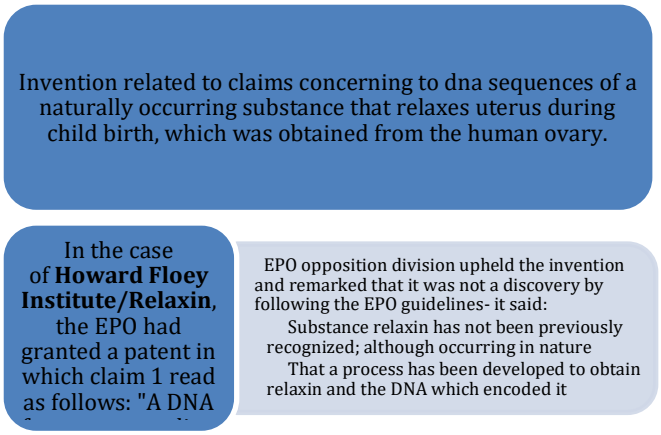


d. Essentially biological process

- Applies only to processes and not to products – off-spring of GMOs would be considered as products even if they were produced out of essentially biological process

- "essentially biological"
- Article 1(2) of the biotech directive: A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.

Howard Floey Institute/Relaxin (Relaxin Case T 74/91 (1995)



5. **New Challenges Posed**
    - Gene Patents

Association for Molecular Pathology v. Myriad Genetics, Inc. (US Supreme Court 2013)

Question involving whether or not human genes are patentable

It is important to note what is *not* implicated by this decision. First, there are no method claims before this Court. Had Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent. But the processes used by Myriad to isolate DNA at the time of Myriad's patents "were well understood, widely used, and fairly uniform insofar as any scientist engaged in the search for a gene would likely have utilized a similar approach,"

Similarly, this case does not involve patents on new *applications* of knowledge about the BRCA1 and BRCA2 genes.

"[a]s the first party with knowledge of the [BRCA1 and BRCA2] sequences, Myriad was in an excellent position to claim applications of that knowledge. Many of its unchallenged claims are limited to such applications."

" Nor do we consider the patentability of DNA in which the order of the naturally occurring nucleotides has been altered. Scientific alteration of the genetic code presents a different inquiry, and we express no opinion about the application of §101 to such endeavors. We merely hold that genes and the information they encode are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material."

In his concurring opinion, which relates to the scientific details in the majority opinion, Scalia wrote:

I join the judgment of the Court, and all of its opinion except Part I–A and some portions of the rest of the opinion going into fine details of molecular biology. I am unable to affirm those details on my own knowledge or even my own belief. It suffices for me to affirm, having studied the opinions below and the expert briefs presented here, that the portion of DNA isolated from its natural state sought to be patented is identical to that portion of the DNA in its natural state; and that complementary DNA (cDNA) is a synthetic creation not normally present in nature.

- Diagnostic Methods

***Mayo v. Prometheus*, (US Supreme Court 2012)**

In this case, the US Supreme Court invalidated the plaintiff Prometheus' methods patent for tests assessing the correct dosages of certain Crohn's disease medications and laid down the two-part test for determining patent eligibility as follows.

1. *Section 101 has three categories of unstated exceptions: laws of nature, natural phenomena, and abstract ideas. These exceptions are not patentable because they belong to everyone. The Court noted, by way of example, that this means Einstein could not have patented relativity, nor Newton any of his laws.*
2. *If an invention is based on an exception, it still might be patentable as long as it doesn't restrict others' use of that exception. The Court warned that judges should carefully examine such claims to avoid "interpreting patent statutes in ways that make patent eligibility "depend simply on the draftsman's [the attorney's] art."*

It also held that "*In consequence, we must hesitate before departing from established general legal rules lest a new protective rule that seems to suit the needs of one field produce unforeseen results in another. And we must recognize the role of Congress in crafting more finely tailored rules where necessary.... We need not determine here whether, from a policy perspective, increased protection for discoveries of diagnostic laws of nature is desirable*[13]."

6. Position in India

a. Position prior to 2005 amendments

Section 5(1) was interpreted to mean that some substances (microorganisms) were capable of being used in medicines, food- and they could be produced by chemical process (biotechnological process, bio-chemical, micro-biological process) would also be excluded from the definition- (2002 amendments added an explanation for clarification). 2005 amendments repealed section 5 to bring in line with the mandate of TRIPS Agreement.

[13] https://www.ipwatchdog.com/2018/07/19/6-years-later-effects-mayo-decision-diagnostic-methods/id=99206/

Dimminaco AG v. Controller of Patents (Cal HC decision 2002)

In this case, the Court laid down the vendibility test. The invention in question was an investigation related to a process for preparation of infectious Bursitis vaccine which was useful for protecting poultry against contagious burstis and contains a living virus as in any other vaccine. It was rejected by the Patent Office on grounds of Section 2 (i) (j) stating that it did not qualify as an invention under the Act. In an appeal filed before the Court, the court held that:

"Controller erred himself in law by holding that merely because end product contains live virus, process involved is not an invention. And as there is no statutory meaning of 'manufacture', dictionary meaning should be accepted which does not exclude a vendible product containing living organism from it. The order passed by the Controller that the process does not lead to manufacture of substance also cannot be accepted as it leads to vendible product. It is certainly a substance after going through the process of manufacture"[14]

b. Nature of exclusions under Section 3 read along with Patent Office Guidelines on examination of Biotech patent applications

The examination guidelines issued by the Patent Office lay down the framework in respect of examination of biotechnology applications for Patent[15].

- **Section 3 (B): Inventions Contrary To Morality Or Which Cause Serious Prejudice To Human, Animal Or Plant Life Or Health Or Environment**

"Adequate care should be taken while examining the inventions vis-a-vis their primary or intended use or commercial exploitation and it should be carefully dealt so that the subject-matter must not be contrary to public order, morality or causes serious prejudice to human, animal or plant life or health or to the environment. A few non limiting examples may further clarify the issues: (a) a process for cloning human beings or

[14] http://pfc.org.in/info/microbio.htm

[15] http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf

animals; (b) a process for modifying the germ line of human beings; (c) a process for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical or other benefit to man or animal, and also animals resulting from such process; (d) a process for preparing seeds or other genetic materials comprising elements which might cause adverse environmental impact; (e) uses of human embryos for commercial exploitation".

- **Section 3 (C): Scientific Principles Or Abstract Theory Or Discovery Of Living Things Or Non-Living Substances**

  "According to Section 3 (c) of the Act, the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature is not a patentable invention. Products such as microorganisms, nucleic acid sequences, proteins, enzymes, compounds, etc., which are directly isolated from nature, are not patentable subject-matter. However, processes of isolation of these products can be considered subject to requirements of Section 2 (1) (j) of the Act".

- **Section 3 (D): Discovery Of New Form Of Known Substance Which Does Not Result In Enhancement Of Efficacy**

  "The inventions relating to three-dimensional or crystal structure of a polypeptide attracts the provision of Section 3 (d) of the Act unless it is proved that such polypeptide differs significantly in the properties with regards to therapeutic efficacy".

- **Section 3 (E): Mere Admixture Resulting Only In Aggregation Of The Properties Or A Method Of Making Such Mere Admixture**

  "It is a well-accepted principle of Patent Law that mere placing side by side of old integers so that each performs its own proper function independently of any of the others is not a patentable combination, but that

where the old integers when placed together has some working interrelation producing a new or improved result, then there is patentable subject matter in the idea of the working inter relations brought about by the collocation of the integers".

- **SECTION 3 (H): Method Of Agriculture And Horticulture**

  "According to Section 3 (h) of the Act, a method of agriculture or horticulture is not considered as patentable subject matter. While deciding patentability under Section 3 (h), conventional methods performed on actual open fields should be construed as method of agriculture/horticulture".

- **Section 3 (I): Method Of Treatment**

  "According to Section 3 (i) of the Act, any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products is not an invention. In the context of Section 3 (i), the Manual of Patent Office Practice & Procedure states that this provision excludes from the patentability the followings: (a) Medicinal methods: As for example a process of administering medicines orally, or through injectables, or topically or through a dermal patch. (b) Surgical methods: As for example a stitch-free incision for cataract removal. (c) Curative methods: As for example a method of cleaning plaque from teeth. (d) Prophylactic methods: As for example a method of vaccination. (e) Diagnostic methods: Diagnosis is the identification of the nature of a medical illness, usually by investigating its history and symptoms and by applying tests. Determination of the general physical state of an individual (e.g. a fitness test) is considered to be diagnostic. (f) Therapeutic methods: The term "therapy'' includes prevention as well as treatment or cure of disease. Therefore, the process

relating to therapy may be considered as a method of treatment and as such not patentable. (g) Any method of treatment of animal to render them free of disease or to increase their economic value or that of their products. As for example, a method of treating sheep for increasing wool yield or a method of artificially inducing the body mass of poultry (h) Further examples of subject matters excluded under this provision are: any operation on the body, which requires the skill and knowledge of a surgeon and includes treatments such as cosmetic treatment, the termination of pregnancy, castration, sterilization, artificial insemination, embryo transplants, treatments for experimental and research purposes and the removal of organs, skin or bone marrow from a living donor, any therapy or diagnosis practiced on the human or animal body and further includes methods of abortion, induction of labour, control of estrus or menstrual regulation. (i) Application of substances to the body for purely cosmetic purposes is not therapy. (j) Patent may however be obtained for surgical, therapeutic or diagnostic instrument or apparatus. Also the manufacture of prostheses or artificial limbs and taking measurements thereof on the human body are patentable. Sometimes the claims are so drafted that a combination/composition of drugs in certain dosage forms is claimed, but the claimed subject-matter relates to application or administration of individual drugs in simultaneous, sequential or concomitant manner. In such cases, although the claims are directed to a combination/composition of drugs, but the claimed invention resides in the method of administration of individual drugs in the said manner and thus, it falls within the scope of section 3 (i) of the Act".

- **Section 3 (J): Plants & Animals in Whole Or Any Part, Seeds, Varieties, Species Other Than Microorganisms & Essentially Biological Processes Are Not Patentable Subject Matter**

"According to Section 3 (j) of the Act, plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals are not patentable inventions. Although, microorganisms are excluded from non-patentability list, a conjoined reading with Section 3 (c) of the Act implies that only modified microorganisms, which do not constitute discovery of living thing occurring in nature, are patentable subject matter under the Act. Claims relating to essential biological processes of growing plants, germination of seeds, of development stages of plants and animals shall be objected under Section 3 (j) of the Act".

- **Section 3 (K): Mathematical or Business Method or A Computer Programme Per Se or Algorithms**

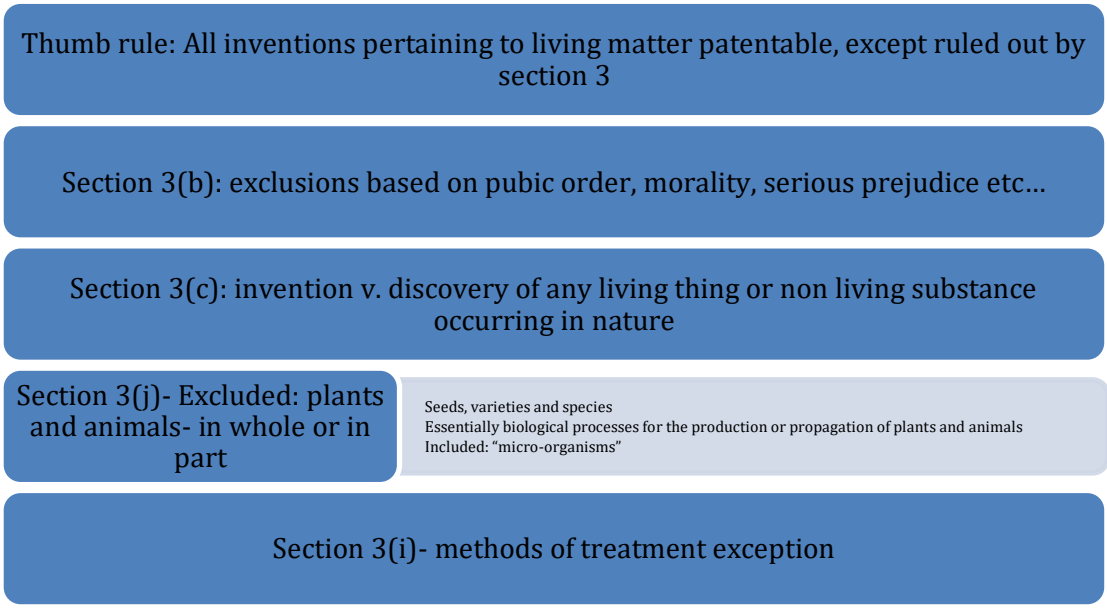
  "According to Section 3 (k) of the Act, a mathematical or business method or a computer programme per se or algorithms are not patentable inventions. Bio-informatics is a relatively young science and has emerged from the combination of information technology and biotechnology. Thus, the determination of patentability of inventions relating to bioinformatics requires special attention vis-a-vis exclusions under Section 3 (k) of the Act".

- **Sufficiency of Disclosure**

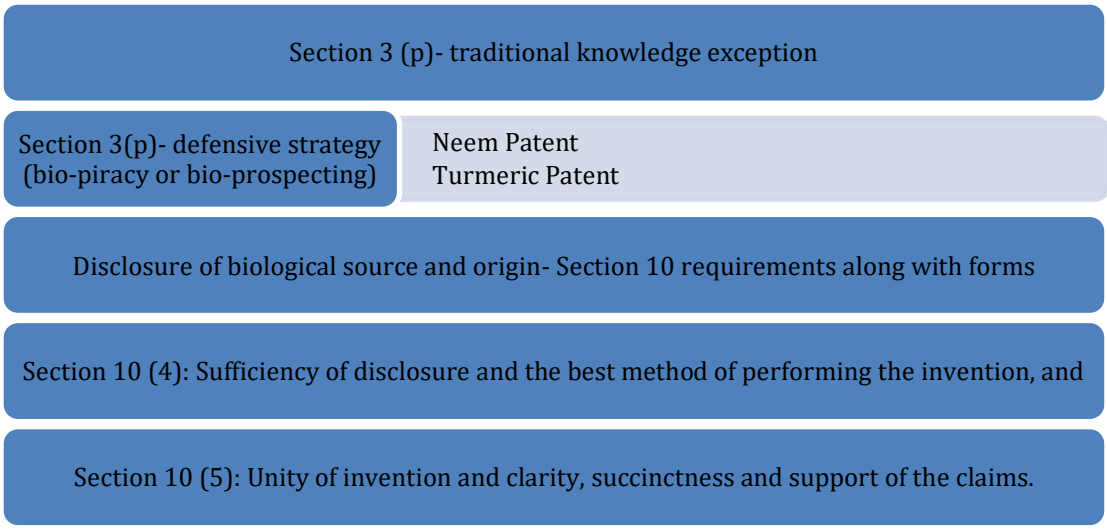
- "While assessing the sufficiency of disclosure, the examiner must be careful to ensure that at least one method for performing the invention must be described so that the whole subject-matter that is claimed in the claims, and not only a part of it, must be capable of being carried out by a skilled person in the relevant art without the burden of an undue amount of experimentation or the application of inventive ingenuity.
- If the specification discloses a listing of a wide range of unrelated diseases as potential future therapeutic or diagnostic targets of a claimed

gene or the protein that it encodes, the claims of such gene are known as Claims having laundry list.

- When claims seek to protect things that are not identified by the applicant at the time of filing the application, but that may be identified in the future by carrying out the applicant's process, such claims are not patentable on the ground of insufficiency of the description. Thus, the claims reach through to things, which are not yet identified by the applicant.
- Claims to antibodies that may have therapeutic or diagnostic potential are unsupported if a role for the target protein in a specific disease has not been identified and proved by sufficient data. If the invention relates to a biological material which is not possible to be described in a sufficient manner and which is not available to the public, the application shall be completed by depositing the material to an International Depository Authority (IDA) under the Budapest Treaty. The deposit of the material shall be made not later than the date of filing of the application in India and a reference of the deposit shall be given in the specification within three months from the date of filing of the patent application in India. All the available characteristics of the material required for it to be correctly identified or indicated are to be included in the specification including the name, address of the depository institute and the date and number of the deposit.
- With respect to the patenting of inventions related to traditional knowledge and biological material obtained from India, the instructions issued by the Controller General of Patents, Designs and Trademarks should be strictly followed".



c. Additional requirements in the context of TK associated with genetic resources



d. Biotech Guidelines of Indian patent office (2013) in the context of Gene Patents and other biotech claims:

"In relation to patenting of biotech subject matter it is important to reproduce (as it is several key points from the Biotech Guidelines (2013) issued by the Indian Patent Office.

"

- A claim to a polynucleotide sequence that was available, e.g. as part of a library before the priority date, lacks novelty, even if activity or function of the said sequence of the polynucleotide has not been previously determined. A claim to a specific fragment of polynucleotide may be considered to be novel, but subject to fulfilment of the inventive step and non-patentability under relevant clauses of Section 3 of the Act.
- If the claimed invention relates to a polynucleotide/polypeptide having mutation(s) in a known sequence of polynucleotide/polypeptide, which does not result in an unexpected property whatsoever, then the claimed subject-matter lacks inventive step.
- In the context of the gene sequences, it may be said that whatever ingenuity is involved in discovering a gene sequence, one cannot have a patent for it or a protein encoded by it unless it is disclosed how it can be used. It is therefore necessary to consider whether the invention claimed has a useful purpose, and whether the specification identifies any practical way of using it.
- The use of claimed subject-matter (e.g. a gene or a protein) disclosed in the specification should not be merely speculative, rather the said use should be specific, substantial and credible for establishing industrial applicability of the claimed subject-matter

  Fragments/ESTs (Expression Sequence Tag) are allowable if they in addition to other conditions satisfy the question of usefulness and industrial application. An EST whose use is disclosed simply as a 'gene probe' or 'chromosome marker' would not be considered to have an industrial application. A credible, specific and substantial use of the EST should be disclosed, for example use as a probe to diagnose a specific disease."

e. Some recent developments in India

The Monsanto Case:

In a decision with far reaching implications for agri-biotech innovation, a Delhi High Court bench of Justice S. Ravindra Bhat and Justice Yogesh Khanna[16] struck down Monsanto's BT patent (*Bacillus Thuringiensis* or 'BT'- bacteria toxic to bollworm pest that attacks cotton plants). Around 50 seed companies in India have so far benefited from Monsanto's high-tech Bollgard (BG) I (a previous unpatented version in India) and BG II inventions (Indian patent granted in 2008) as it widely licensed its technology for a license fee since the early 2000s. This led to a historic cotton revolution as India became the largest cotton producer and second largest exporter in the world.

Monsanto's patented invention (Bollgard II) claimed a method to infuse a BT gene (nucleic acid sequence) into the cotton plant genome which thereby produces insecticidal protein fusion (trait) that prevents bollworm attacks. Any cotton plant variety (with its own unique traits) when backcrossed with Monsanto's donor seed variety hybridises into a variety containing the BT technology which prevents it from bollworm attack under certain field conditions.

The court, however, invalidated the patent by construing Monsanto's narrow patent claim as falling within the broad biotech subject-matter exclusions. Noting that the BT "trait by itself has no intrinsic worth" since its function was to be part of a 'seed' (when the trait is introgressed or implanted in it) and later hybridised into a 'variety' (of plant), both of which are specially excluded by India's patent law.

The court further noted that the invention would fall within the exclusion of 'essentially biological processes'. Notwithstanding the human intervention required at the early stages to induce the plant protein fusion by introgression

[16] http://lobis.nic.in/ddir/dhc/SRB/judgement/12-04-2018/SRB11042018FAOOSCOMM862017.pdf

of nucleic acid sequences (otherwise not naturally found in those plant cells), the Court reasoned that such steps were insignificant to result in a fundamental alteration of the character of a known process of production of plants or seeds and that any subsequent propagation of transgenic plants involving a transfer of BT trait was a process of nature not requiring human intervention/control.

The Court also observed that Monsanto's technology qualifies as a variety under the Protection of Plant Varieties and Farmers' Rights Act, 2001 (although this question was not germane to the issue of patentability) noting that it was the intention of the Indian Parliament to provide such an alternative protection.

However, the plant varieties law, apart from a slew of exclusions, exceptions and lesser duration of protection is a misfit for biotech inventions which could in principle distinctly qualify for patents. Hybrid varieties that incorporate the BT trait could be separately registered under the plant varieties law if they satisfy the requirements therein.

More than what decision settles in terms of patent law is what it unsettles for agri-biotech innovation. It is pertinent to note that Plant Varieties law provides for compensation by an authority constituted under the Act in the form of 'benefit sharing' for use of the unique trait (such as Monsanto's BT trait) to produce new hybrid varieties that incorporate such BT technology in the downstream hybrid seeds market. This effectively replaces a default market determined voluntary bargain available under the patent law with a default regulator determined royalty under the Plant Variety law (something akin to price control on royalties or a compulsory licence).

Furthermore, the Court obliged Monsanto to continue the supply of its BT donor seeds to local seed companies (although anyone can now copy the unpatented technology) by interpreting it as a requirement under the Essential Commodities Act, 1955. Apart from several attempts since mid-2000 by various

State Governments to regulate royalties, the Central Government since 2015 has slashed Monsanto's royalties by up to 80%. Furthermore, an investigation by the Competition Commission of India for alleged abuse of dominance is pending.

Owing to such an uncertain regulatory environment, Monsanto has withdrawn its application to introduce the next generation (BG II RRF) in India. This herbicide technology kills the weeds surrounding the cotton plant without causing any damage to the plant. Seed companies are placing their bets on Government funded agro-research institutions like the ICAR and CICR to reduce dependence on Monsanto's technology.

If they develop clones of existing unpatented technology (which may however still be subject to patents in other markets), Indian cotton exports could take a hit. It remains to be seen if publicly funded R&D (which would effectively cross subsidise seeds companies at the cost of tax payers), will prove competitive and timely in launching better versions. Otherwise, Indian cotton farming may witness deep crises of productivity due to its self-inflicted technological apartheid.