LIFE SCIENCE PATENTING IN INDIA

A COMPARATIVE ANALYSIS

at
Venture Center
NCL, Pune
18th April, 2011

by
Gopakumar G. Nair
GNAnLex Hermeneutics Pvt. Ltd.& Gopakumar Nair Associates
Url: www.gnaipr.net
Email: gopanair@gnaipr.net

IP PORTFOLIO

Trade Mark (Amendment) Act, 2010 – Madrid Protocol

Novel & Inventive

Patent US7395821

Word, Symbol etc

Copyright

Trademark
Multi-Haler™

Package Insert / Information Leaflet

External Appearance

Trade Secret
Know-how

Confidential Informn & Undisclosed Tech

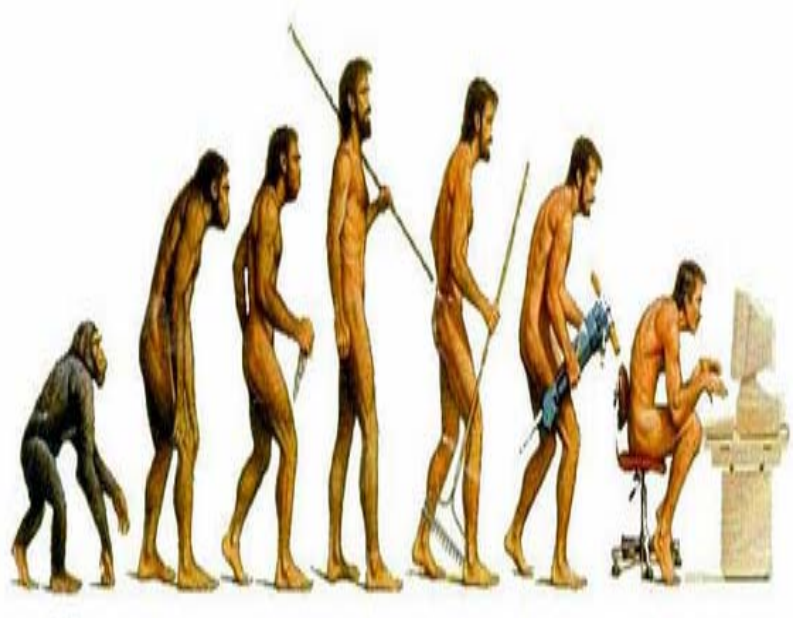
Design
No. 211208

INNOVATIONS

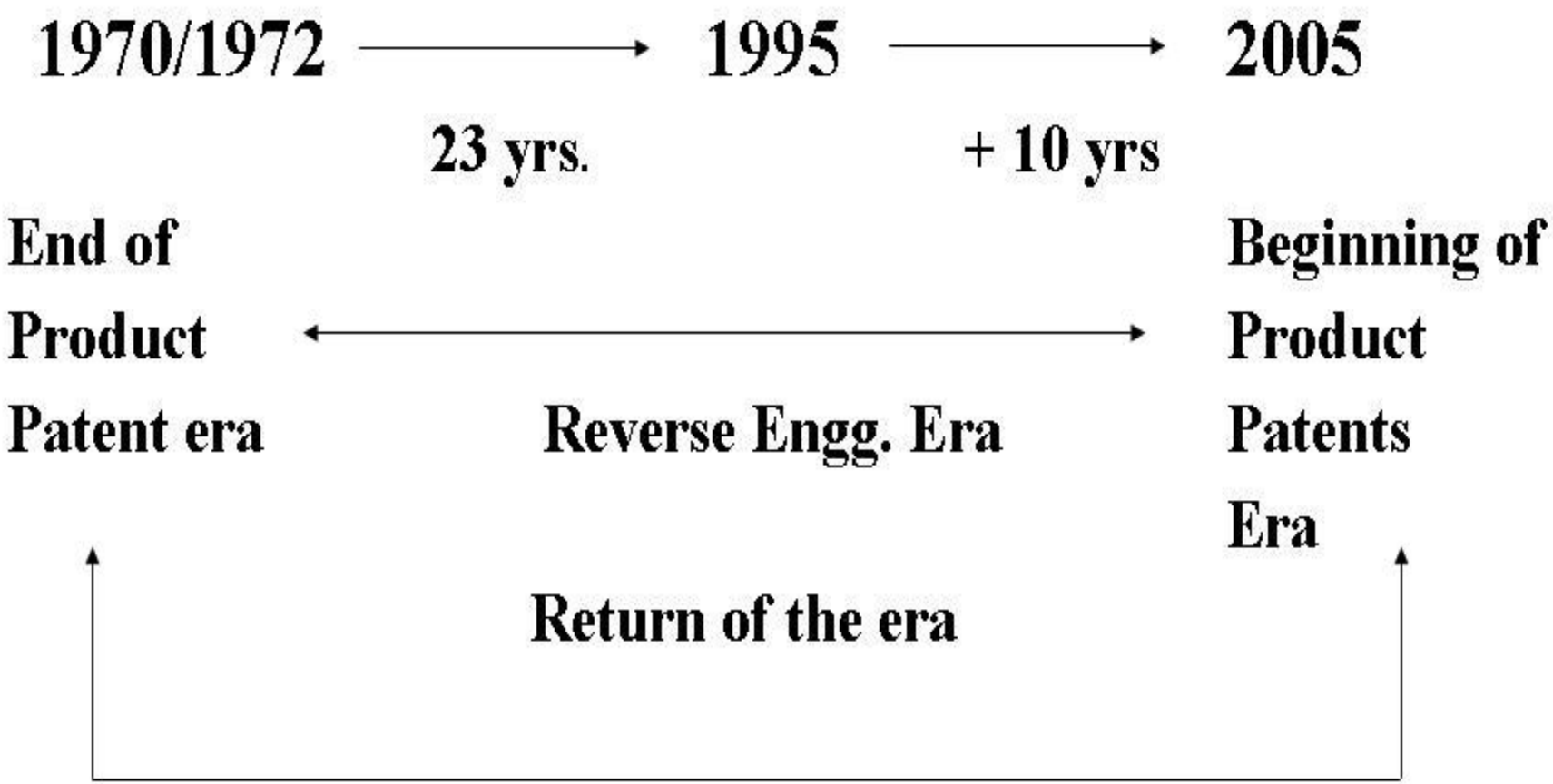
EVOLUTION

Sources

- Incremental Innovations
- Need-based Solutions
- Intensive Research
- Disruptive inventions
- Serendipity



PRODUCT PATENTS IN INDIA



GATT ⟶ WTO ⟶ TRIPs ⟶ IPA amendments

ARTICLE 27 OF TRIPS – PATENTABLE SUBJECT MATTER

1. Subject to the provisions of paragraphs 2 and 3, ***patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.*** *Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article,* ***patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.***

2. *Members* ***may exclude from patentability*** *inventions, the prevention within their territory of the commercial exploitation of which is necessary to* ***protect ordre public or morality****, including to protect human, animal or plant life or health or to* ***avoid serious prejudice to the environment****, provided that such exclusion is not made merely because the exploitation is prohibited by their law.*

Contd…..

3. Members ***may also exclude from patentability:***

(a) ***diagnostic, therapeutic and surgical methods for the treatment of humans or animals****;*

(b) ***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.*

Three Statutory Pillars of

PATENTABILITY

1. Novelty (new)

2. Inventive Step (non-obvious)

3. Industrial Applicability (utility)

PATENT - PATENTABILITY

An invention can be patented if it is

- **NOVEL**: Must be New,

  Must DISTINGUISH from "State of the Art" (PRIOR ART)

- Must have **INVENTIVE STEP**

  Non-obvious to a person "Skilled in the Art"

- Must have **INDUSTRIAL APPLICATION**

  Must be Useful

  Must have Utility

INDIA

Inventions Not Patentable under Section 3

(a) Frivolous, Contrary To Natural Laws

(b) Contrary to Public Order or Morality, Prejudice to Human, Animal or Plant Life or Health or to the Environment; ex.,

- Method of Cloning
- Terminator Gene Technology (Monsanto)

(c) Mere Discovery of Scientific Principle, Abstract Theory, Living Thing or Non-living Substances

(i)Method of Treatment

(j) Plants, Animals, Including Seeds Varieties, Species, Biological Processes. Exception: Microorganisms

- Mere discovery of microorganism is not patentable

(p) Traditional Knowledge

Contd…..

(a) an invention which is frivolous or which claims anything obviously contrary to well established natural laws;

(b) an invention the primary or intended use or commercial exploitation of which could be contrary public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;

(c) the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substances occurring in nature;

Contd…..

(i) 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.

(j) plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;

Contd…..

(p) an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties or traditionally known component or components.

GI / TK protection initiative in India

- Geographical Indications of Goods (Registration and Protection) Act, 1999
- Traditional Knowledge protected through Biodiversity Act.

PATENTABILITY FILTER

- ✓ Prior use/ prior publication/ prior disclosure
- ✓ Industrial applicability
- ✓ Novelty
- ✓ Non-obviousness- inventiveness
- ✓ Sec. 3 - Not patentable
- ✓ Written description / enablement requirements
- ✓ Application/ specification/ claims
- ✓ Patent prosecution
- ✓ Maintenance / Defense after grant

PATENTS ACT, 1970

Deposit of biological material

Sec.10(4)(ii): *if the applicant mentions a biological material in the specification which may not be described in such a way as to satisfy clauses (a) and (b), and if such material is not available to the public, the application shall be completed by depositing the material to an international depository authority under the Budapest Treaty and by fulfilling the following conditions, namely:—*

(A) the deposit of the material shall be made not later than the date of filing the patent application in India and a reference thereof shall be made in the specification within the prescribed period;

(B) all the available characteristics of the material required for it to be correctly identified or indicated are included in the specification including the name, address of the depository institution and the date and number of the deposit of the material at the institution;

(C) access to the material is available in the depository institution only after the date of the application of patent in India or if a priority is claimed after the date of the priority;

(D) ***disclose the source and geographical origin*** *of the biological material in the specification, when used in an invention.*

SECTION 10(4)(ii) PATENTS ACT, 1970

- When a biological material is described in the specification and when such material is not available to the public and cannot be described adequately as per the provisions of the Act, such material shall be deposited in order to make the application complete.
- Deposit shall be made with the International Depository Authority under the Budapest Treaty on or before the date of filing.
- The International Depository Authority in India is Microbial Type Culture Collection and Gene Bank (MTCC) at Chandigarh.
- For International Depositary Authorities please visit – http://www.wipo.int/export/sites/www/treaties/en/registration/budapest/ pdf/idalist.pdf
- For further information on Microbial Type Culture Collection and Gene Bank (MTCC) please visit – http://wdcm.nig.ac.jp/CCINFO/CCINFO.xml?773; http://www.imtech.ernet.in/mtcc/

Contd…..

- Reference of biological material is to be made in the Specification within 3months from the date of filing, giving all the available characteristics of the material required for it to be correctly identified or indicated including the name, address of the depository institution and the date and number of the deposit of the material at the institution.
- The source and geographical origin of the biological material specified in the Specification should also be disclosed.
- In the case of Biotechnology related inventions, relevant numbers of the sequence listing should be mentioned at appropriate place in the specification.
- Sequence listing should be given in electronic form. Fees with respect to the corresponding number of pages should also be paid.
- Access to the material is available in the depository institution after the date of the application of patent in India.

THE BIOLOGICAL DIVERSITY ACT, 2002

Section 6 - **Regulation of Access to Biological Diversity**

(1) ***No person shall apply for any intellectual property right, by whatever name called, in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application:***

Provided that if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the sealing of the patent by the patent authority concerned: Provided further that the National Biodiversity shall dispose of the application for permission made to it within a period of ninety days from the date of receipt thereof.

(2) ***The National Biodiversity Authority may, while granting the approval under this section, impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilization of such rights.***

(3) The provisions of this section shall not apply to any person making an application for any right under any law relating to protection of plant varieties enacted by Parliament.

(4) Where any right is granted under law referred to in sub-section (3), the concerned authority granting such right shall endorse a copy of such document granting the right to the National Biodiversity Authority.

Contd…..

Rule 18: Procedure for seeking prior approval before applying for intellectual property protection. -

- Any person desirous of applying for a patent or any other intellectual property based on research on biological material and knowledge obtained from India shall make an application in Form III.
- Every application under sub-rule (1) shall be accompanied by paying a fee of five hundred rupees.
- The Authority after due appraisal of the application and after collecting any additional information, on the basis of merit shall decide on the application, as far as possible within a period of three months of receipt of the same.
- On being satisfied that the applicant has fulfilled all the necessary requirements, the Authority may grant approval for applying for a patent or any other IPR subject to such terms and conditions as it may deem fit to impose in each case.
- The approval shall be granted in the form of a written agreement duly signed by an authorized officer of the Authority and the applicant. The form of the agreement may be decided by the Authority.
- The Authority may reject the application if it considers that the request cannot be acceded to after recording the reasons. Before passing order of rejection, the applicant shall be given an opportunity of hearing.

OVERCOMING BARRIERS SET OUT IN THE BIOLOGICAL DIVERSITY ACT, 2002

Section 2(c) "biological resources" *means plants, animals and micro-organisms or parts thereof, their genetic material and by-products* ***(excluding value added products)*** *with actual or potential use or value, but does not include human genetic material;*

OVERCOMING BARRIERS SET IN THE BIOLOGICAL DIVERSITY ACT, 2002

Title: Process for extraction of safed musli and characterization of the marker compound.

Patent No.: 247046

Patent Application No: 1262/MUM/2003

Abstract: A process for the preparation, standardization, characterization of and identification of marker compound from aqueous extract of Safed musli (Chlorophytum Borivillianum) and extracts of Safed musli thereof. Further the marker compound of safed musli extract was characterized by IR, UV, H1 NMR, C13 NMR, Mass and elemental analysis. A process for preparation of non-aqueous extract of Safed musli was also disclosed herein.

We claim:

1. A process for the preparation, standardization, characterization, and identification of the marker compound from aqueous extract of safed musli comprising the steps of :
    a) powdering the raw safed musli root, extracting the powder with water in ratio of 1:10 by heating till aliquot gives constant weight on drying;
    b) separating the marc from extract by centrifugation, drying said extract at temperature not more than 60°C to obtain solid;
    c) powdering said solid after complete drying, hydrolyzing the powder extract with sulfuric acid; partitioning the medium with chloroform;
    d) separating the chloroform fraction comprising marker compound;
    e) isolating the marker compound by column chromatography, purifying said marker by crystallization and characterizing the marker compound.
2. The process as claimed in claim 1, wherein said extraction is carried out at temperature 30° C to 100° C.
3. A process for preparation of non-aqueous extract of Safed musli root comprising the steps of:
    a) extracting the crude Safed musli root powder with petroleum ether;
    b) separating the ether layer to obtain a residue;
    c) extracting the residue with methanol at 50-55° C;
    d) cooling, filtering the extract;
    e) concentrating the filtrate under reduced pressure to obtain the extract in dry form and powdering said extract .

Dated this the 9th day of December 2004

Dr. Gopakumar G. Nair
Agent for the Applicant

TRADITIONAL KNOWLEDGE RELATING TO BIOLOGICAL DIVERSITY RULES, 2009

For protection, conservation and effective management of traditional knowledge relating to biological diversity

PROTECTION OF PLANT VARIETIES AND FARMERS' RIGHTS ACT, 2001

In order to provide for the establishment of an effective system for protection of plant varieties, the rights of farmers and plant breeders and to encourage the development of new varieties of plants it has been considered necessary to recognize and protect the rights of the farmers in respect of their contribution made at any time in conserving, improving and making available plant genetic resources for the development of the new plant varieties. Moreover, to accelerate agricultural development, it is necessary to protect plants breeders' rights to stimulate investment for research and development for the development of new plant varieties.

PROCESS FOR THE PREPARATION OF HUMAN CHORIONIC GONADOTROPIN (HCG) FROM PREGNANT HUMAN URINE

Indian Patent No: 159048

Date of Grant: 14/0/1987

Application No: 290/DEL/1983

Applicant: Council Scientific Industrial Research [IN]

Abstract: Human Chorionic Gonadotropin (HCG) is isolated from urine of pregnant women by urine……

LANDMARK CASE IN INDIA

- Dimminaco AG v Controller of Patents and Designs (2002).

The High Court of Calcutta held that where *"the word 'manufacture' has not been defined in the Act. In such situation since the word 'manufacture' has not been defined, the dictionary meaning of this word or the meaning attributed to in the particular trade or business must be accepted, if the end product is a commercial entity****. It is also admitted that there is no statutory bar to accept a manner of manufacture as patentable even if an end product contains a living organism".***

EXAMPLE OF SEQUENT LISTING PATENT GRANTED IN INDIA

Indian Patent No.: 243373 (279/MUM/2004)

Title: Artificial gene sequence for encoding recombinant super compound interferon with enhanced activity

Patentees: Sichuan Biotechnology Research Center

We Claim,

1. A method for producing a recombinant interferon for inhibiting HBV-DNA replication as well as secretion of HBsAg and HBeAg comprising the steps of:
   (a) Synthesizing an interferon DNA having a sequence as depicted in Figure 1 or 2 designed according to the codon usage;
   (b) Placing said interferon DNA in an appropriate host, preferably *E. coli* and
   (c) Expressing said recombinant interferon in said host having an amino acid sequence encoded by interferon DNA sequence shown in said Figure 1 or 2;

   wherein said recombinant interferon demonstrates changed spatial configuration and enhanced antiviral activity compared to an interferon with identical amino acid sequence but produced by a different method.
2. The method of claim 1, wherein the recombinant interferon is expressed via a high-expression vector achieved by using L-arabinose to activate the transcription of P_{BAD} promoter.
3. The method of claim 1, optionally comprising extraction of the recombinant interferon from fermentation broth, collection of inclusion body, and denaturation and renaturation of the harvested interferon.
4. The method of claim 1, wherein the recombinant interferon is α, β or ω.
5. The method of claim 1, optionally comprising, separating and purifying the recombinant interferon.
6. The method of claim 5, optionally comprising, lyophilization of the purified recombinant interferon.

Dated this 5th day of March, 2004

Dr. Gopakumar G. Nair
Agent for the Applicant

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5'          11          21          31          41          51
+1  M  C  D  L  P  Q  T  H  S  L  G  N  R  R  A  L  I  L  L  A
 1 ATGTGCGACC TGCCGCAGAC CCACTCCCTG GGTAACCGTC GTGCTCTGAT CCTGCTGGCT
   TACACGCTGG ACGGCGTCTG GGTGAGGGAC CCATTGGCAG CACGAGACTA GGACGACCGA

5'          71          81          91          101         111
+1  Q  M  R  R  I  S  P  F  S  C  L  K  D  R  H  D  F  G  F  P
61 CAGATGCGTC GTATCTCCCC GTTCTCCTGC CTGAAAGACC GTCACGACTT CGGTTTCCCG
   GTCTACGCAG CATAGAGGGG CAAGAGGACG GACTTTCTGG CAGTGCTGAA GCCAAAGGGC

5'          131         141         151         161         171
+1    Q  E  E  F  D  G  N  Q  F  Q  K  A  Q  A  I  S  V  L  H  E
121 CAGGAAGAAT TCGACGGTAA CCAGTTCCAG AAAGCTCAGG CTATCTCCGT TCTGCACGAA
    GTCCTTCTTA AGCTGCCATT GGTCAAGGTC TTTCGAGTCC GATAGAGGCA AGACGTGCTT

5'          191         201         211         221         231
+1  M  I  Q  Q  T  F  N  L  F  S  T  K  D  S  S  A  A  W  D  E
181 ATGATCCAGC AGACCTTCAA CCTGTTCTCC ACCAAAGACT CCTCCGCTGC TTGGGACGAA
    TACTAGGTCG TCTGGAAGTT GGACAAGAGG TGGTTTCTGA GGAGGCGACG AACCCTGCTT

5'          251         261         271         281         291
+1  S  L  L  E  K  F  Y  T  E  L  Y  Q  Q  L  N  D  L  E  A  C
241 TCCCTGCTGG AAAAATTCTA CACCGAACTG TACCAGCAGC TGAACGACCT GGAAGCTTGC
    AGGGACGACC TTTTTAAGAT GTGGCTTGAC ATGGTCGTCG ACTTGCTGGA CCTTCGAACG

5'          311         321         331         341         351
+1  V  I  Q  E  V  G  V  E  E  T  P  L  M  N  V  D  S  I  L  A
301 GTTATCCAGG AAGTTGGTGT TGAAGAAACC CCGCTGATGA ACGTTGACTC CATCCTGGCT
    CAATAGGTCC TTCAACCACA ACTTCTTTGG GGCGACTACT TGCAACTGAG GTAGGACCGA

5'          371         381         391         401         411
+1  V  K  K  Y  F  Q  R  I  T  L  Y  L  T  E  K  K  Y  S  P  C
361 GTTAAAAAAT ACTTCCAGCG TATCACCCTG TACCTGACCG AAAAAAAATA CTCCCCGTGC
    CAATTTTTTA TGAAGGTCGC ATAGTGGGAC ATGGACTGGC TTTTTTTTAT GAGGGGCACG

5'          431         441         451         461         471
+1  A  W  E  V  V  R  A  E  I  M  R  S  F  S  L  S  T  N  L  Q
421 GCTTGGGAAG TTGTTCGTGC TGAAATCATG CGTTCCTTCT CCCTGTCCAC CAACCTGCAG
    CGAACCCTTC AACAAGCACG ACTTTAGTAC GCAAGGAAGA GGGACAGGTG GTTGGACGTC

5'          491         501
+1  E  R  L  R  R  K  E  #
481 GAACGTCTGC GTCGTAAAGA ATAA
    CTTGCAGACG CAGCATTTCT TATT
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Figure 1

Dated this the 5th day of March, 2004

Dr. Gopakumar G. Nair

Agent for the Applicant

Figure 2

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  5'            11          21          31          41          51
+1  M  C  D  L  P  Q  T  H  S  L  G  N  R  R  A  L  I  L  L  A
 1 ATGTGTGATT TACCTCAAAC TCATTCTCTT GGTAACCGTC GCGCTCTGAT TCTGCTGGCA
   TACACACTAA ATGGAGTTTG AGTAAGAGAA CCATTGGCAG CGCGAGACTA AGACGACCGT

5'            71          81          91          1           11
+1  Q  M  R  R  I  S  P  F  S  C  L  K  D  R  H  D  F  G  F  P
61 CAGATGCGTC GTATTTCCCC GTTTAGCTGC CTGAAAGACC GTCACGACTT CGGCTTTCCG
   GTCTACGCAG CATAAAGGGG CAAATCGACG GACTTTCTGG CAGTGCTGAA GCCGAAAGGC

5'            31          41          51          61          71
+1    Q  E  E  F  D  G  N  Q  F  Q  K  A  Q  A  I  S  V  L  H  E
121 CAAGAAGAGT TCGATGGCAA CCAATTCCAG AAAGCTCAGG CAATCTCTGT ACTGCACGAA
    GTTCTTCTCA AGCTACCGTT GGTTAAGGTC TTTCGAGTCC GTTAGAGACA TGACGTGCTT

   5'            91          1           11          21          31
                +1  M  I  Q  Q  T  F  N  L  F  S  T  K  D  S  S  A  A  W  D  E
               181  ATGATCCAAC  AGACCTTCAA  CCTGTTTTCC  ACTAAAGACA  GCTCTGCTGC
TTGGGACGAA
          TACTAGGTTG TCTGGAAGTT GGACAAAAGG TGATTTCTGT CGAGACGACG AACCCTGCTT

 5'            51          61          71          81          91
     +1  S  L  L  E  K  F  Y  T  E  L  Y  Q  Q  L  N  D  L  E  A  C
241 AGCTTGCTGG AGAAGTTCTA CACTGAACTG TATCAGCAGC TGAACGACCT GGAAGCATGC
    TCGAACGACC TCTTCAAGAT GTGACTTGAC ATAGTCGTCG ACTTGCTGGA CCTTCGTACG

5'            11          21          31          41          51
               +1  V  I  Q  E  V  G  V  E  E  T  P  L  M  N  V  D  S  I  L  A
301 GTAATCCAGG AAGTTGGTGT AGAAGAGACT CCGCTGATGA ACGTCGACTC TATTCTGGCA
          CATTAGGTCC TTCAACCACA TCTTCTCTGA GGCGACTACT TGCAGCTGAG ATAAGACCGT
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Dated this the 5th day of March, 2004

Dr. Gopakumar G. Nair

Agent for the Applicant

BIOCON'S STORY
BUILDING ON A FOUNDATION OF IP

Using patent information as an integral tool, Biocon determined the areas on which the company's R&D should focus on. One such example is how the company used patent information to gain initial access to the field of human insulin production, where it is now a major player. The product patent on human insulin had long expired, but it was still protected by strong patents on processes of production.

Source: http://www.wipo.int/ipadvantage/en/details.jsp?id=2602

Contd…..

In search of a gap that would enable the company to gain a foot-hold in the market, Biocon went through all relevant published patents. “We noticed that most of the patented processes used e-coli and baker’s yeast,” Ms. Mazumdar-Shaw explained. “At Biocon we had expertise in another sort of yeast, and we had already licensed the intellectual property (IP) for it from a small company in the United States. So the way was clear. We started making our own insulin using pichia yeast. This was a new and unique process, which wasn’t covered by any of the existing patents.

Contd…..

The resulting product was Insugen, which was released in India in 2004. As of 2010, Insugen is sold throughout the world, including in international markets such as China and Germany. It was the world's first human insulin to use pichia yeast, which is the world's first recombinant (artificial DNA, or r-DNA) human insulin. Insugen allowed Biocon to enter the insulin market in India – which holds 25% of the world's population living with diabetes – and also start the company's efforts in treating diabetes, which is a central focus of the company's strategy. Biocon eventually hopes to develop orally administered insulin, a dream which is close to the heart of Ms. Mazumdar-Shaw. Through using patent information, Biocon was able to take the first steps towards realizing this goal.

INDIA*

Patentable

(a)Gene sequence / Amino Acid sequence

(b)A method of expressing above sequence

(c)An antibody against that protein / sequence

(d)A kit made from the antibody / sequence

(e)A Biopolymer produced from a genetically modified bacterium can be claimed for the following

- –Biopolymer
- –Genetically modified bacteria for producing the above said Biopolymer
- –Process of manufacturing genetically modified bacteria
- –Process for manufacturing the said biopolymer.

* - Draft Patent Manual 2008

FEW EX. OF PATENTS GRANTED IN INDIA

PATENT NO	APPLICATION NUMBER	DATE OF FILING	TITLE OF INVENTION	APPLICANT NAME
235486	75/DEL/2003	30/01/2003	Genes, vectors and production of stable lipase	Council Of Scientific & Industrial Research
233755	1037/DEL/2004	04/06/2004	Pharmacogenetic marker of human transforming growth factor BETA1 (TGFß1) for predicting predispodition to immunological disorders	Council Of Scientific & Industrial Research
244600	958/KOLNP/2004	08/07/2004	A bacterium having a genome that is genetically engineered for reduction of its size and method for making it	Wisconsin Alumni Research Foundation
244426	2129/CHENP/2007	17/05/2007	A method for producing a genetically modified micro-organ explant	Yissum Research Development Company

DISTINGUISHING INDIAN PATENTABILITY VIZ-A-VIZ US & EU

	India	US	EU
Method of Treatment	✗	✓	✗
Swiss Claim (New Use of Known Subs)	✗	?	✓
Composition of Matter	?	✓	?
Product by Process	?	✓	✓
Plant Patents	PVPFA	✓	Both
Research & Other Exemptions	✓	✓ (?)	✓ (?)
Biological Matter (other than Micro-organisms)	✗	✓	(?)
Stem Cells / Cloning	✗	(?)	✗

LANDMARK US JUDGMENTS

- **Diamond v. Chakrabarty**
  - Question on patentability of Genetically Modified Micro-organism.
  - The SC held that live, human-made micro-organism is patentable - Human Intervention.
- **Harvard Onco-Mouse**
  - Question on patentability of Genetically Modified Mouse.
  - In US - US4736866 (patent granted).
  - In EP - EP0169672 (patent revoked).

MADEY V. DUKE UNIVERSITY

Madey vs. Duke Univ.
307F 3d 1351
(Fed. Cir. 2003)
Cer.den. 539 US 958 (2003)
125 S.ct.at 2382.n.7

Exemption to include only those acts that are
"SOLELY FOR AMUSEMENT,
TO SATISFY IDLE CURIOSITY OR
STRICTLY FOR PHILOSOPHICAL INQUIRY"

MERCK KGA V. INTEGRA LIFESCIENCES, LTD.

The case Merck v. Integra poses the question should the Merck KGA, be allowed to use the research tool patents of tiny Integra Life Sciences, (a medical technology company), to look for drugs in USA that could help fight cancer?

Sec. 271(e) (1) of 35 USC,

The Federal law says that Merck can use the material for free as long as the use is “reasonably related” to getting a drug approved by the Food and Drug Administration (FDA).
[Bolar Exemption – Hatch-Waxman Act]

DISTINCTION BETWEEN

- **Merck Kga V. Integra Lifesciences, Ltd.** (2005)
  - Devices subject to FDA Approval are eligible for Safe Harbor protection under §271€(1).

AND

- **Proveris Scientific Corp. v. InnovaSystems, Inc.** (2008)
  - Background: Innova's device Optical Spray Analyser (OSA) was only used for basic research and for generating data for FDA. The OSA itself was not subject to FDA Approval.
  - Devices not subject to FDA Approval are ineligible for Safe Harbor protection under §271(e)(1).

DOLLY THE SHEEP PATENT

Title: Quiescent Cell Populations For Nuclear Transfer

Patentee: Roslin Institute

GB2318578: 31 claims directed to methods of nuclear transfer. The claims specifically cover instances where scientists might use a somatic cell as the nuclear donor. The patent also covers methods of producing cloned non-human animals and methods of producing animal (i.e., human and non-human) cells by nuclear transfer.

GB2331751: 28 claims directed to compositions of matter. The claims of this patent include claims to non-human animal embryos and cloned non-human animals produced using nuclear transfer. In addition, the patent covers non-human and human cell lines made using this technology.

Source: http://findarticles.com/p/articles/mi_m0DED/is_7_20/ai_59670423/

RECENT US CASE LAW

Myriad Gene Patent Litigation
Association for Molecular Pathology, et al. V. USPTO, et al.

- March 2010: US court found Myriad Genetics Inc.'s patents related to Method of detecting inherited breast and ovarian cancer BRCA 1 and BRCA 2 as invalid. U.S. District Judge Robert Sweet ruled that the patents are invalid being "*directed to a law of nature and were therefore improperly granted.*"

- 16th June, 2010: Notice of Appeal filed by Myriad Genetics Inc.'s.

- 29th October, 2010: US Department of Justice filed an amicus brief, distinguishing between isolated and altered DNA (is patentable) and on the other hand, "natural" DNA that has been merely isolated (is not patentable).

- 4th April 2011*: U.S. Court of Appeals for the Federal Circuit heard the Government's Appeal. An opinion is expected by late summer 2011.

*Audio recording of the argument - http://www.cafc.uscourts.gov/oral-argument-recordings/search/audio.html (Appeal Number 2010-1406).

US

- USPTO in 2001 issued ‘Utility Examination Guidelines’ to be used by Examiners.
- These guidelines also includes ‘Guidelines For Determining Utility Of Gene-Related Inventions’.
- For Gene-Related Inventions to be patentable, the Applicant has to show ‘substantial use’ / ‘utility’, i.e. industrial applicability.

For ex. “*If a patent application discloses only nucleic acid molecular structure for a newly discovered gene, and no utility for the claimed isolated gene, the claimed invention is not patentable. But, when the inventor also discloses how to use the purified gene isolated from its natural state, the application satisfies the “utility” requirement.”*

US Bill  Law

Genomic Research and Diagnostic Accessibility Bill, 2002

To provide for non-infringing uses of patents on genetic sequence information for purposes of research and genetic diagnostic testing, and to require public disclosure of such information in certain patent applications.

- Section 2 would have exempted from patent infringement those individuals who use patented genetic sequence information for noncommercial research purposes. This provision would have applied to all genetic sequence patents, not just human gene patents.
- Section 3 would have exempted medical practitioners using genetic diagnostic tests from patent infringement remedies.
- Section 4 of the bill would have required public disclosure of genomic sequence information contained within a patent application within 30 days of a patent application being filed, when Federal funds were used in the development of the invention.

EUROPE

- Section 1(2)(a) of the UK Patents Act 1977 and Art. 52(2) of the European Patent Convention state that '*discoveries are not inventions*'.
- However, the following may be patentable
  - Useful object or process that results from a discovery. (Re Gale's Application Nicholls LJ)
  - New property of known material if put to practical use.
  - Unrecognized substance occurring in nature which is shown to produce a technical effect, for ex. a gene which is discovered to exist in nature may be patentable if a technical effect is revealed, e.g. its use in making a certain polypeptide or in gene therapy.

EP BIOTECHNOLOGY DIRECTIVE 98/44/EC

- ***Art 3(2):*** *Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.*
- ***Art 5(1):*** *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.*
- ***Art 5(2):*** *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.*
- ***Art 5(3):*** *The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.*
- ***Art 6(2):*** Inventions not patentable

  (a) processes for cloning human beings;

  (b) processes for modifying the germ line genetic identity of human beings;

  (c) uses of human embryos for industrial or commercial purposes;

  (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Contd…..

- *Art 38: Whereas the operative part of this Directive…..include an illustrative list of inventions excluded from patentability.....a general guide to interpreting the reference to ordre public and morality; ….. this list obviously cannot presume to be exhaustive; whereas processes, the use of which offend against human dignity, such as processes to produce chimeras from germ cells or totipotent cells of humans and animals, are obviously also excluded from patentability;*
- *Art 40: Whereas there is a consensus within the Community that interventions in the human germ line and the cloning of human beings offends against ordre public and morality; whereas it is therefore important to exclude unequivocally from patentability processes for modifying the germ line genetic identity of human beings and processes for cloning human beings;*
- *Art 41: Whereas a process for cloning human beings may be defined as any process, including techniques of embryo splitting, designed to create a human being with the same nuclear genetic information as another living or deceased human being;*
- *Art 42: Whereas, moreover, uses of human embryos for industrial or commercial purposes must also be excluded from patentability; whereas in any case such* ***exclusion does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it;***

SOME GENE RELATED PATENTS

- **US4447538 -** Microorganism containing gene for human chorionic somatomammotropin.

- **US4992376 -** Biological pure culture of Streptomyces violaceus ATCC 53807. *(This strain was isolated from a soil sample collected in Hyderabad, Andhra Pradesh State, India).*

- **US5034322 & US6174724 -** Chimeric genes suitable for expression in plant cells.

- **US2010333216 -** Non-human gene-disrupted animal (mouse) with disrupted Adam11 gene.

- **US2010333222 -** Knockout mice for a P450 gene cluster.

PATENT ON EMBRYOS AND FULL-TERM CREATURES CONTAINING HUMAN ALONG WITH NON-HUMAN CELLS

Title: Chimeric Embryos And Animals Containing Human Cells

Publication No: US2003079240

Inventor: Stuart Newman

Abstract: A mammalian embryo developed from a mixture of embryo cells, embryo cells and embryonic stem cells, or embryonic stem cells exclusively, in which at least one of the cells is derived from a human embryo, a human embryonic stem cell line, or any other type of human cell, and any cell line, developed embryo, or animal derived from such an embryo.

Status: Abandoned

Stuart Newman's supposedly filed the patent as a challenge to existing US patent policy, and a way to prevent inappropriate uses of the technology (to set a precedence).

GENE PATENTING - BOON OR BANE ?

Boon

- Provides incentive for promoting innovation and research, especially towards life-saving technologies.
- Leads to tailor-made solutions for chronic diseases.
- Altered / modified genes could have unexpected therapeutic applications.
- Encourages/promotes wider participation in genomic research and funding.

Bane

- Fragmented ownership of the genome leading to interference with the progress of whole-genome sequencing and applications thereof.
- Impedes clinical research and diagnostics tests based on genome-wide genotyping.
- Blocks access to the relevant gene or process of gene isolation and testing.
- Researchers need to obtain plethora of licenses from gene Patentees
- Patent stacking: discourage product development due to high royalty.
- Morality and owners-ship issues from human subjects used in the research.