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BIOTECH INVENTIONS: ESSENTIALS OF DRAFTING A PATENT SPECIFICATION

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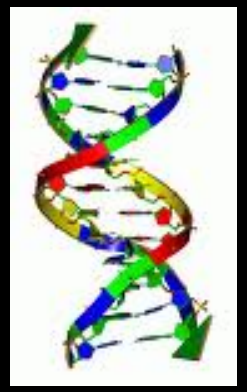
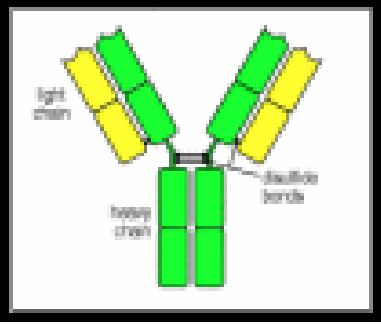


PATENTS IN BIOTECHNOLOGY MAY BE FOR INVENTIONS RELATED TO RECOMBINANT DNA TECHNOLOGY INCLUDING GENE SPLICING TECHNIQUES, TRANSFORMATION AND EXPRESSION, ANTI SENSE TECHNOLOGY; CELL THERAPY; GENE THERAPY; MICROBIOLOGICAL INVENTIONS; VACCINES; MONOCLONAL ANTIBODIES; PLASMIDS, COSMIDS, VECTORS, CYTOKINES AND INTERFERONS; TECHNIQUES LIKE PCR; TRANSGENIC PLANTS AND ANIMAL; CLONING LIFE FORMS AND PATENTING ANIMALS AND PLANTS

STATUTORY EXCLUSIONS



BIOTECH INVENTIONS ARE CONSIDERED IN THE SAME LIGHT AS OTHER TECHNICAL INVENTIONS

Biotechnology patent applications will be decided on the basic issues of **novelty**, **inventive step** and **industrial application**, as well as on the requirements that the description should be sufficient and should support the claims.

According to the UK Act " "**biological material**" means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system;”

"**biotechnological invention**" means an invention which concerns a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used;".

"**essentially biological process**" means a process for the production of animals and plants which consists entirely of natural phenomena such as crossing and selection;

"**microbiological process**" means any process involving or performed upon or resulting in microbiological material;

According to US MPEP

“**biotechnological process**” means-

(A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to-

(i) express an exogenous nucleotide sequence,

(ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or

(iii) express a specific physiological characteristic not naturally associated with said organism;

(B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and

(C) a method of using a product produced by a process defined by subparagraph (A) or (B), or a combination of subparagraphs (A) and (B).

MICROBIOLOGICAL INVENTIONS INCLUDE
(A) MICROORGANISMS *PER SE*

(B) PRODUCT OF MICROORGANISMS

TERM MICROORGANISM INCLUDES: BACTERIA, FUNGI, VIRUS, PLANT AND ANIMAL CELLS.

NEW STRAIN OF MICROORGANISMS MAY BE SUCH THAT PRODUCE
(I) A NOVEL COMPOUND
OR (II) A KNOWN COMPOUND BUT MORE EFFICIENTLY
OR (III) THAT THE MICROORGANISM POSSESSES SOME BENEFICIAL PROPERTIES.

- Louis Pasteur was awarded U.S Patent Number 141,072 in 1873 for a yeast

- A man-made microorganism was awarded patent in 1980. The US Supreme Court took a historic 5-4 decision in the case of Chakrabarty v. Diamond for the genetically engineered *Pseudomonas aeruginosa* bacterium that is capable of breaking down the four major components of crude oil.

Patenting of life forms

- **The patenting movement then took on to higher order animals with one of the first patents to be issued was U.S. Patent Number 5,476,995 for an invention that claimed a transgenic sheep that expressed the transgene in the mammary gland so as to produce the target protein in its milk. Since then there has been a spate of patents expressing diverse proteins in pig, sheep, goat, cattle (Fibrinogin, Protein C), Sheep (Blood coagulation), mouse (human antibodies), pig (human hemoglobin) etc and the race continues…….**

FIRST ONE HAS TO LOOK INTO THE NATURE OF THE INVENTION/ UNDERSTAND THE INVENTION AND DECIDE HOW BEST TO PROTECT

WHETHER ALLOWABLE UNDER THE LAWS OF THE COUNTRY?

Some countries allows method of treatment claims, some don’t. Genetically modified animals are allowed in some countries and not in others

What is a patent specification?

A document providing technical details and legal protection

- describes the invention
- provides the extent/scope of monopoly protection

PATENT SPECIFICATION

- WHAT OTHERS DID
- WHAT NEED EXISTS
- WHAT I HAVE DONE
- WHAT OTHERS SHOULD NOT DO

The practical reality is that the specification is a species of sales literature. It should be written to sell patentability.

A PATENT APPLICATION MUST UNDERGO AN EXAMINATION BEFORE IT IS ALLOWED.

IT MAY FACE

- PRE /& POST GRANT OPPOSITIONS
- REVOCATION
- INFRINGEMENT

FOR EACH ABOVE STAGES OBJECTIONS/GROUNDS

NOVELTY/ ANTICIPATION

OBVIOUSNESS/ LACK OF INVENTIVE STEP

INSUFFICIENCY

STATUTORY EXCLUSIONS

HOW TO BRING OUT NOVELTY IN A PATENT SPECIFICATION ?

- CLOSELY DEFINE PRIOR LITERATURE/ART
- DISCUSS DRAWBACKS OF PRIOR ART
- DEFINE OBJECTS OF INVENTION
- DEFINE BROAD ASPECTS OF INVENTION
- DEFINE EMBODIMENTS AND ILLUSTRATE WITH WORKING EXAMPLES AND DRAWINGS

How much to protect?

The scope of protection sought should not be too broad as to be drowned in prior art or too narrow to leave out the aspects of invention unprotected.

While broadening the scope it is to be kept in mind the subsequent discoveries which may occur and invalidate the present invention if it is too narrow.

Specially for biotech cases, where taking cue and with slight modification a further invention may be claimed.
A process of making insulin and claims all possible means. Even though he uses biochemical methods only, claiming all methods may attract insufficiency. Alternatively a competitor may develop biotech method which would be cheaper & make his invention obsolete. But then one cannot have reach through claims. So judicial balance.

Often, the written description and enablement requirements will sufficiently disclose an invention's usefulness.

However, a practical utility is not always evident in a biotechnology invention. For example, the creation of a new microorganism or cell line may not necessarily teach the utility thereof.

Merely producing something that is the object of scientific research is insufficient to justify the grant of a patent.

Unless and until a biotechnology invention is refined and developed to the point where a specific benefit exists, the usefulness of the invention is unproven.

PATENT SPECIFICATION MAY BE

- **provisional** providing basic idea of the invention without details as to working of invention and claims

or

- **complete** providing details of invention, best mode of working, claims, abstract

Who looks into the specification - different perspectives

- persons skilled in the art working the invention
- scientists and researchers
- patent examiner
- competitors
- infringers
- court (in case of infringement)

United States Patent [19]

Bakaysa et al.

[11] **Patent Number: 5,474,978**

[45] **Date of Patent: Dec. 12, 1995**

[54] **INSULIN ANALOG FORMULATIONS**

[75] Inventors: **Diane L. Bakaysa**; **David N. Brems**; **Bruce H. Frank**; **Henry A. Havel**; **Allen H. Pekar**, all of Indianapolis, Ind.

[73] Assignee: **Eli Lilly and Company**, Indianapolis, Ind.

[21] Appl. No.: **260,634**

[22] Filed: **Jun. 16, 1994**

[51] **Int. Cl.**[6] **A61K 38/28**; C07K 14/62

[52] **U.S. Cl.** **514/4**; 514/3; 530/304

[58] **Field of Search** 530/304; 514/3, 514/4

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Primary Examiner—Jill Warden

Assistant Examiner—Benet Prickril

Attorney, Agent, or Firm—Steven P. Caltrider; David E. Boone; Gerald V. Dahling

[57] **ABSTRACT**

The present invention discloses a human insulin analog hexamer complex and formulations. More specifically, the present invention relates to various parenteral formulations, which comprise: human insulin analogs in a hexamer conformation, zinc ions, and at least three molecules of a phenolic derivative selected from the group consisting of m-cresol, phenol, or a mixture of m-cresol and phenol. The formulation provides a rapid onset of action.

13 Claims, 3 Drawing Sheets

ESTABLISHING NOVELTY/ INVENTIVE STEP

WHAT WAS KNOWN/ WHAT OTHERS DID??

PRIOR ART SEARCH
PAID/ FREE DATA BASES

KEY WORD SEARCH
INTERNATIONAL CLASSIFICATION SEARCH

- Brange et al. in Diabetes Care 13: 923-954 (1990).
- U.S. patent application Ser. No. 07/388,201
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- Brange et al.Current Opinion in Structural Biology 1:934-940:1991

US 5474978/ 675/CAL/195

BACKGROUND OF THE INVENTION

commercial pharmaceutical formulations of insulin
contain insulin in the self-associated state and predominately
in the zinc-hexamer form, - the rate-limiting step
for the absorption of insulin is the dissociation of the self-aggregate
insulin hexamer.

To accelerate this absorption process, monomeric insulin analogs have been developed. These monomeric analogs possess a comparatively more rapid onset of activity than insulin while retaining the biological activity of native human insulin.

Modifications to insulin, which cause these analogs to be monomeric, also result in a high rate of polymer formation in parenteral formulations - expiration of insulin preparations occurs when levels of 1% polymer are obtained .

So to minimize this type of degradation formulate monomeric analogs in such a manner to cause the analog to self-associate to form a stable conformation, yet maintain its rapid absorption .

The addition of certain metal ions, primarily zinc, enhance the chemical stability by driving the insulin to associate and form hexamers, specifically the Zn(II)-T_6 conformation. Further, phenolics have been shown to specifically bind to the insulin hexamer and induce an allosteric conformational change whereby the eight N-terminal amino acids of the B-chain are converted from the extended conformation to an alpha-helix. This phenolic-bound conformation state is known as the Zn(II)-R state

Early studies with monomeric insulin analogs revealed that any aggregation between zinc and the insulin analog is distinct from that observed with insulin.

The highly stable Zn-hexamer complex as seen with insulin is not observed with monomeric analogs. Monomeric LysB28 ProB29 -hI is less prone to dimerization and self-association to higher molecular weight forms than human insulin. AspB28 ProB29 -hI, AlaB28 ProB29 -hI, and LysB28 ProB29 -hI show little or no Zn-induced association and that ProB29 insulin, LysB28 insulin, AspB28 insulin, and AlaB28 insulin demonstrate Zn-induced association, but less than Zn-insulin.

Association between the analog and zinc differs from insulin. The association that is observed with these analogs is distinct from the predominate, well-defined, Zn-insulin hexamers. Monomeric Insulin analogs do not form the Zn(II)-T_6 conformation LIKE insulin.

Further when injected subcutaneously, the Zn(II)-R6 conformation does not dissociate directly but must transform through the Zn(II)-T6 conformation. These conformational changes and the dissociation therefrom delay the onset of activity. Therefore, one skilled in the art at the time of invention believed that efforts to chemically stabilize the monomeric insulin analog with zinc by forming a well defined, hexamer complex would be unsuccessful, or if successful, would sacrifice the rapid onset of action desired.

ADMITTED PRIOR ART & PROBLEMS

•NATIVE INSULIN READILY ASSOCIATE INTO DIMERS & WITH ZN-FORM HEXAMERS - SLOW ACTING

•TO PROVIDE FAST ACTION INSULIN ANALOGUE MONOMER DESIGNED-DO NOT ASSOCIATE- TEND TO FORM FIBRILS

•TO STABILIZE MONOMERS ZN – FORM HEXAMERS ZN(II)T6-ADD PHENOL FURTHER STABILIZE-
BUT CONFORMATIONAL CHANGE TO ZN(II)R– ON ADMINISTRATION – REQUIRES TO CHANGE THE CONFORMATION R-T WHICH IS ACTIVE- TAKES TIME

•STABLE ZN-HEXAMER WITH ANALOGUES NOT FORMED – IF FORMED WILL NOT DISSOCIATE FAST

Present invention affords monomeric insulin analogs in a well defined, stable zinc-phenol hexamer complex.
This hexamer complex is uniquely different from those complexes observed with insulin under identical conditions. Insulin complexes with zinc and phenol are in a Zn(II)-R6 conformation. The hexame complex of the present invention is not identical to this conformatio Also quite remarkably, the insulin analog hexamer complex has a much greater propensity to dissociate than insulin. This propensity to dissociate translates into the desired fast-acting property.

The rate of absorption for the hexamer complex is at least two times that observed with insulin. Yet, when the hexamer complex is formulated, it is equally stable when compared to insulin against chemical degradation. Remarkably; when formulated, this hexame complex retains the fast-acting properties associated with the monomeric insulin analog. Accordingly, present invention provides a parenteral formulations of the insulin analog hexamer complex that is stable and fast-acting

SUMMARY OF THE INVENTION

This invention provides a human insulin analog complex, which comprises: six molecules of a human insulin analog, two zinc ions, and at lease three molecules of a phenolic derivative selected from the group consisting of m-cresol, phenol, or a mixture of m-cresol and phenol; such that the analog complex is a hexamer. The invention further provides parenteral formulations comprising the hexamer complex

FULLY & PARTICULARLY DESCRIBE THE INVENTION
AND THE BEST MODE OF ACTION

DETAILED DESCRIPTION

- HUMAN MONOMERIC INSULIN COMPLEX
- HOW IS IT FORMED
- WORKING
- DRAWINGS
- ESTABLISHING DIFFRENCE WITH PRIOR ART
- BY WAY OF EXAMPLES

DETAILED DESCRIPTION AND PREFERRED EMBODIMENTS

the invention provides a monomeric human insulin analog complex as a hexamer. ……
The insulin analogs of the present invention complex with zinc ions and a phenolic derivative to form a stable, hexamer conformation.

Both the zinc and phenolic derivative are critical to achieve a complex that is stable and capable of rapid dissociation and onset of action.

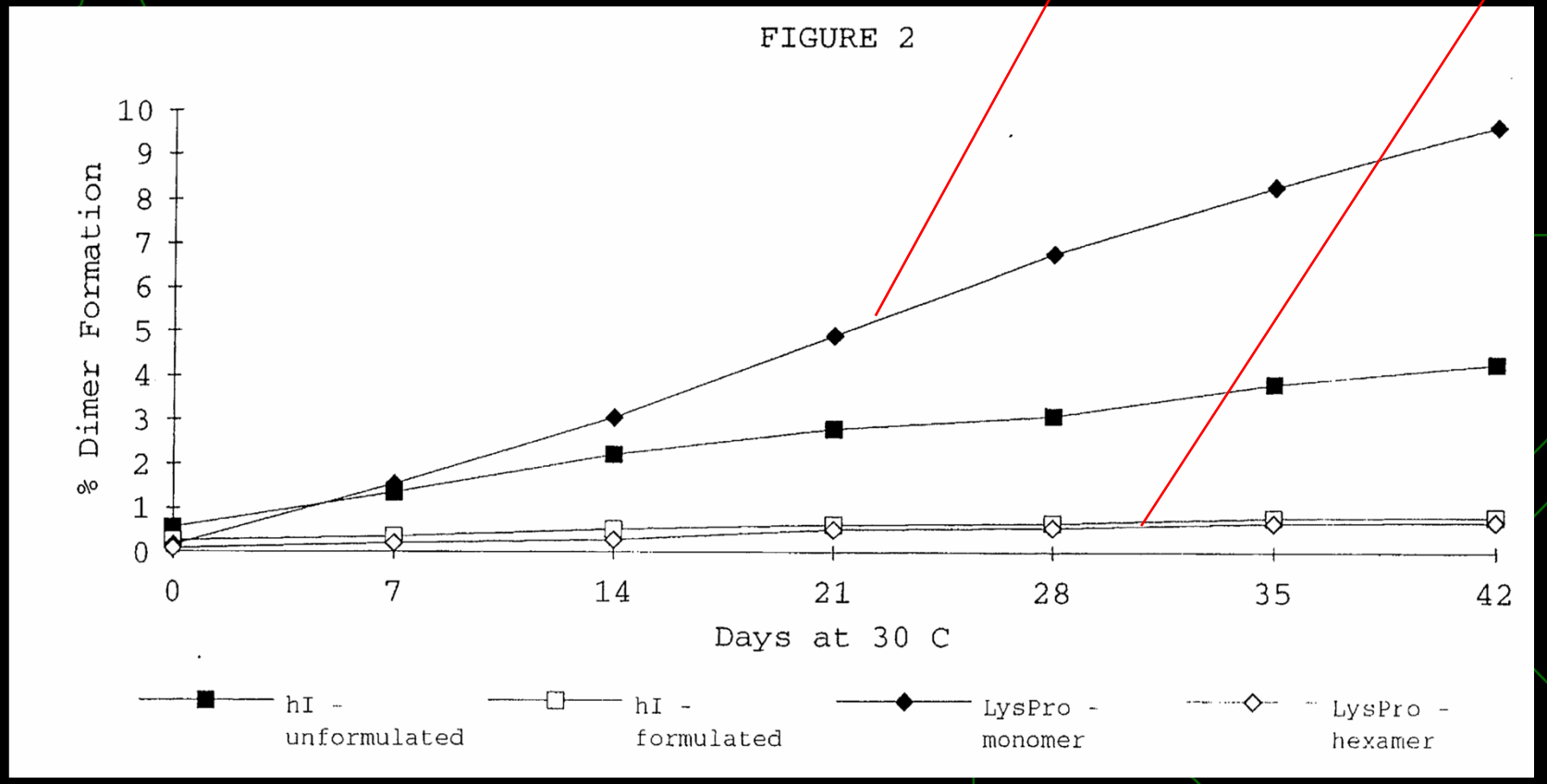
The hexamer complex consists of two zinc ions per hexamer of human insulin analog and at least three molecules of a phenolic derivative selected from the group consisting of m-cresol, phenol, or a mixture of m-cresol and phenol.

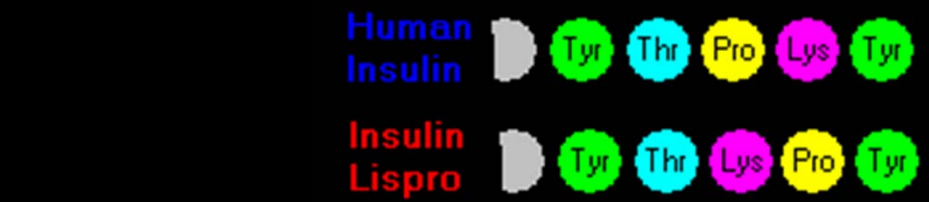
The formulation comprising the insulin analog complex as hexamer is stable. In comparative studies, monomeric LysB28 ProB29 –hI shows the greatest rate of degradation with a 1.63% per week increase in polymer formation over the six week study. Unformulated human insulin undergoes a slower rate of polymer formation of 0.61% per week. Upon formulation, however, the rate of high molecular weight polymer formation is reduced to 0.095% per week for insulin.
Formulated LysB28 ProB29 -hI, as a hexamer complex, exhibits a diminished rate of higher molecular weight polymer formation of 0.11% per week, which is comparable to the rate seen for formulated insulin

Graphical representation of profile of action of LysB28 ProB29 -hI and human insulin. The graph is the mean glucose infusion response rate. The figure demonstrates the advantages of the present invention.

LYSPRO MONO

LYSPRO HEXAMER

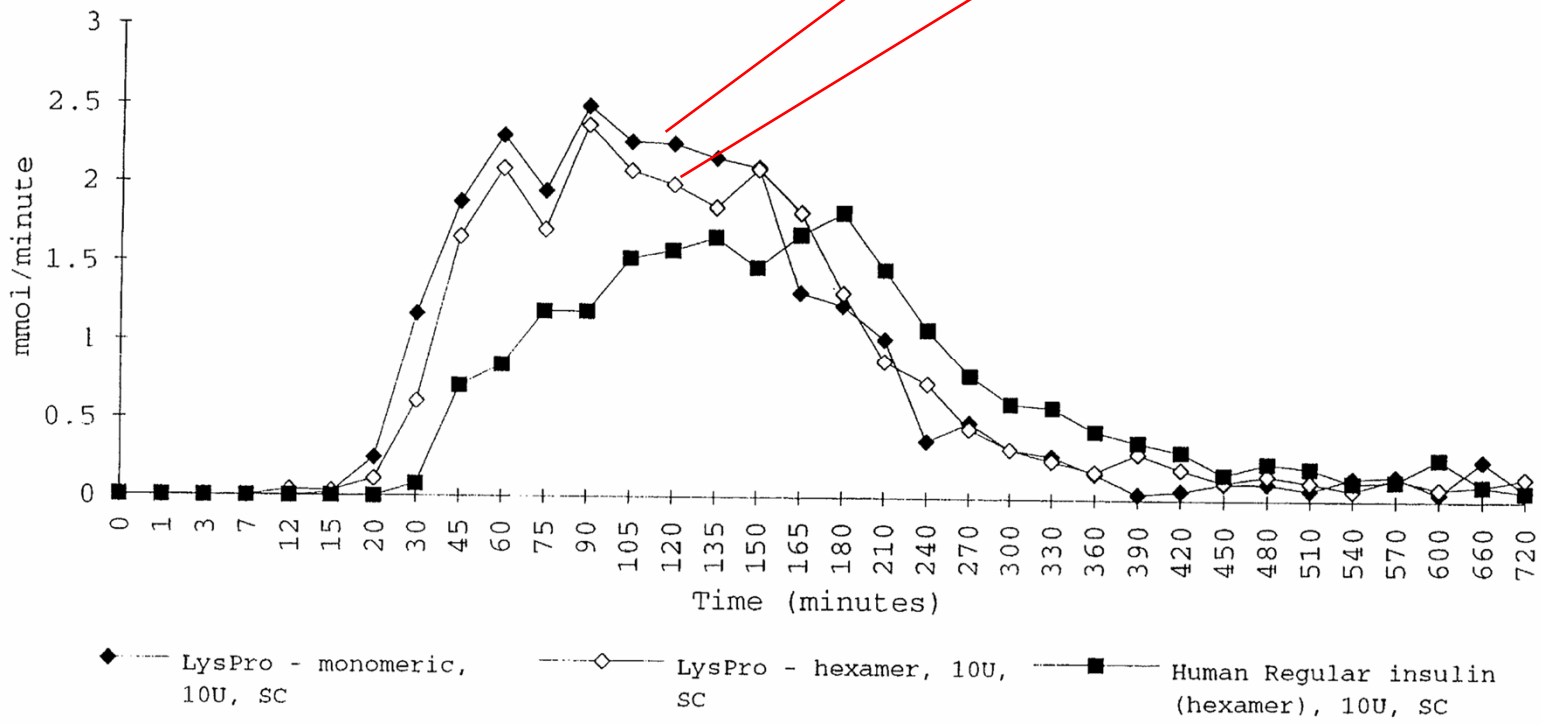




LYSPRO MONO

LYSPRO HEXA

FIGURE 1



CLAIMS :DEFINE THE SCOPE OF PROTECTION

1. A human insulin analog complex, which comprises: six molecules of a human insulin analog, two zinc ions, and at least three molecules of a phenolic derivative selected from the group consisting of m-cresol, phenol, or a mixture of m-cresol and phenol; such that the insulin analog complex is a hexamer; wherein the human insulin analog is human insulin wherein Pro at position B28 is substituted with Asp, Lys, Leu, Val, or Ala, and Lys at position B29 is Lys or Pro; des(B28-B30)-human insulin; or des (B27)-human insulin.

675/CAL/1995

1. A human insulin analog complex, which comprises: six molecules of a human insulin analog, two zinc ions, and at least three molecules of a phenolic derivative selected from the group consisting of m-cresol, phenol or a mixture of m-cresol and phenol, wherein the human insulin analog is $Lys^{B28}Pro^{B29}$ – human insulin.

United States Court of Appeals for the Federal Circuit
04-1465
(Serial No. 09/619,643)
IN RE DANE K. FISHER and RAGHUNATH V. LALGUDI,

The claimed invention in'643 relates to five purified nucleic acid sequences that encode proteins and protein fragments in maize plants. The claimed sequences are commonly referred to as "expressed sequence tags" or "ESTs."

"*A substantially purified nucleic acid molecule that encodes a maize protein or fragment thereof comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 5*. "

Fisher did not know the precise structure or function of either the genes or the proteins encoded for by those genes.

The ’643 application generally discloses that the five claimed ESTs may be used in a variety of ways, including: (1) serving as a molecular marker for mapping the entire maize genome, which consists of ten chromosomes that collectively encompass roughly 50,000 genes; (2) measuring the level of mRNA in a tissue sample via microarray technology to provide information about gene expression; (3) providing a source for primers for use in the polymerase chain reaction (“PCR”) process to enable rapid and inexpensive duplication of specific genes; (4) identifying the presence or absence of a polymorphism; (5) isolating promoters via chromosome walking; (6) controlling protein expression; and (7) locating genetic molecules of other plants and organisms.

USPTO Final rejection,
claim 1 rejected for
lack of utility
lack of enablement

The examiner found that the claimed ESTs were not supported by a specific and substantial utility.
disclosed uses were generally applicable to any EST.

that one skilled in the art would not know how to use the claimed ESTs because the ’643 application did not disclose a specific and substantial utility for them.

Federal Circuit

F: 7 specific uses disclosed, regardless whether function of genes of EST known, Board applied high standard, general commercial success of ESTs confirms the utility of the claimed ESTs.

FC: Fisher's alleged uses are so general as to be meaningless. that the same generic uses could apply not only to the five claimed ESTs but also to any EST derived from any organism.

A claim directed to a polynucleotide disclosed to be useful as "gene probe" or "chromosome marker," fails to satisfy the specific utility requirement unless a specific DNA target is also disclosed

No Substantial or Specific Utility

It thus opined that the seven utilities alleged by Fisher are merely starting points for further research, not the end point of any research effort. – Research Intermediates

F: compares the claimed ESTs to certain other patentable research tools, such as a microscope. claimed ESTs could be used to identify polymorphisms or to isolate promoters

FC Analogy inapt & Fisher has not presented any evidence, showing that the claimed ESTs have been used in either way. All uses hypothetical. Because Fisher failed to prove that its claimed ESTs can be successfully used in the seven ways disclosed in the '643 application and does not identify the function for the underlying protein-encoding genes, the claimed ESTs do not have a utility though the ESTs may have contribution in Biotech research.

As to commercial success of EST no evidence showing that agricultural companies have purchased or even expressed any interest in the claimed ESTs.

HELD: CLAIMS LACK UTILITY

Structure of Patent specification

Title provides the title of invention

Field of invention: provides broad outline of the invention

Background & Prior Art: Available published and known art

Objects of Invention to score over prior art

Summary independent aspects of invention

Description & Drawings & Examples & Sequence Listing
Description of invention achieving to score over prior art, its working as illustrated by drawings and examples and sequence listings in defined format

Claims Define scope invention to be protected

Abstract Provides help to patent searchers

Title

The title of the invention, which should be as short and specific as possible (no more than 500 characters), (ordinarily not more than 15 words).

- Broadly describe the invention
- Help the Patent Office classify the invention & assign it to the proper group of patent examiners
- Avoid limiting language

Field of Invention

Provides the technical field of invention. This may be broadly regarded as Biotechnology but specific field of the invention is preovided

Biotechnology is the application of knowledge about living organisms, and their components, to industrial products and processes. The technology has application across the whole breadth of its application: from pharmaceuticals and diagnostics, through speciality chemicals, food and agriculture, to the environment

MICROBIOLOGICAL INVENTIONS

THE MICROORGANISMS MAY BE PRODUCED IN LAB BY ARTIFICIALLY INDUCED MUTATION/SPECIFIC TECHNIQUE LIKE GENETIC ENGINEERING.

I) NOVEL PRODUCT MAY BE ANTIBIOTIC. IF ITS STRUCTURE IS DETERMINED OR CAN BE CHARACTERIZED BY FINGERPRINT CLAIM THIS PRODUCT CAN BE CLAIMED.

II) FOR KNOWN COMPOUND PROCESS CAN BE CLAIMED BUT THIS PROTECTION IS WEAK. BETTER TO CLAIM THE MICROORGANISM ITSELF.

III) IF THE MICROORGANISM POSSESSES SOME BENEFICIAL PROPERTIES LIKE FEEDING ON OIL SLICKS, THE PRODUCT SOLD IS THE SAID BACTERIA ITSELF. HERE A *PER SE* CLAIM TO MICROORGANISM IS APPLICABLE.

Recombinant DNA technology encompasses:

i) techniques / methods for production of gene products

(i) Eg. Techniques: patent claiming method of producing protein by expression of a gene inserted in any unicellular host;

Claiming process or novel vector systems like plasmids giving good replication in host like promoter system which can regulate inserted genes to give high expression rates of products.

ii) specific products-proteins & gene sequences coding proteins

Eg. (a) a product whose structure (amino acid sequence) is already known like human insulin, tissue plasminogen factor;

or (b) a product that has been isolated in pure state but its structure not yet known

Here a product per se claim is not possible but invention can be claimed in a no. of ways in effect covering the product whenever made by recombinant DNA technique. Thus isolated gene for the product, a vector containing the gene, host cell transformed with vector, process of obtaining any of these, process for obtaining the end product can all be claimed.

or (c) a product known only by its activity. Here the product *per se* can be claimed as a new compound characterized by its structure. The gene itself, or at least the c-DNA coding for the protein can also be claimed.

Background and Prior Art

WHAT OTHERS HAVE DONE

- to **search** the relevant technical field for published documents
- to discuss all patent/non patent documents published any where in the world, prior knowledge and use in the same technical field
- to distinguish the invention from the known/prior art

Search

To establish the novelty and inventiveness it is essential that a prior art search be conducted. It is better to cite relevant documents and distinguish the invention from the same than waiting for patent office to cite documents and narrow down the invention to avoid the same.

Prior art refers to scientific and technical information that exists prior to the effective date of the claimed invention. Prior art may be found in any published documents such as patents, technical publications, conference papers, marketing brochures, products, devices, equipment, processes and materials. Even photographs act as prior art if it is publicly available

Patents on the Internet

Important sites:

- **www.uspto.gov:** Web site of the American Patent and Trademark Office
- **ep.espacenet.com:** Patent applications in European Patent Office and the PCT as well as abstract and title of 30 million documents worldwide
- **stnweb.cas.org:** Independent pay site containing patent documents around the world
- **ipaustralia.gov.au:** Web site of the Australian Patent Office

Objects of the invention

WHAT IS THE NEED IN THE FIELD ?

State the objects of invention which should reflect the points/advantages which the present invention has over prior art;

Why the invention is designed and the goal which the invention sets to achieves

There could be multiple objects.

Care should be taken while designing the examples and description as well as framing the claims so that all objects are achieved

Summary

WHAT THE INVENTOR HAS DONE

A brief summary of the invention indicating its nature and substance, which may include a statement of the object of the invention should precede the detailed description. The summary should be commensurate with the invention as claimed and any object recited should be that of the invention as claimed.

If there are many independent aspects all the independent aspects which will form independent claims may be recited in the summary.

If the invention relates to a nucleic acid comprising specific nucleic acid sequence or protein comprising specific amino acid sequence mention the same in the summary.

Detailed Description

The detailed description provides the details of the further limitations: the process of isolation, the use of the sequence i.e. its utility, description of structure of the supporting variants like structures of the gene or protein encoded by the gene, or regions important for function of protein(active site), method of production of cDNA, etc Short nucleic acid fragment like oligonucleotide which may be used as primer or probe may be described. Their length to be specified and the hybridisation technique to be mentioned

Biotechnology is one of the fastest evolving field of technology.

In biotechnology
inventions, the scope of enablement must be more detailed as the level of unpredictability of the invention rises.As for the written description requirement, the utility of the stricter standard is probably best illustrated by reference to DNA. Since DNA structures contain four bases in a plethora of combinations, with one change altering the whole strain, an adequate written description of DNA requires more than a mere statement that it is part of an invention and the method for isolating it.
What is required in such cases is a description of the DNA itself, since without the precise description of the sequence of constituent bases, it is impossible to establish that the inventor actually invented the DNA he claims.

A Biopolymer produced from a genetically modified bacterium can be describedclaimed for the following (Accession Number of the bacterium & Name of the International Depository Authority should be mentioned in the complete specification) :

(a) Biopolymer, if it is novel

(b) Genetically modified bacteria for producing the above Said Biopolymer, if it is novel

(c) Process of manufacturing genetically modified bacteria

(d) Process for manufacturing the said biopolymer.

For any invention the statute requires the same to be described and inventions for micro organism per se is no exception. Hence the strain has to be defined. A strain is not fixed structure but is a living organism. So it changes its structure with change in the environment. People trying to work the invention would not be able to do so unless it has access to the particular strain isolated. Further even if adequate description of the strain is possible the strain, it does not make the public in possession of the strain after expiry of the patent(which is the purpose of the patent system). Hence the requirement for deposit of strain with International Depository Authority under the Budapest treaty.

MICROBIAL TYPE CULTURE COLLECTION AND GENE BANK (MTCC)
Institute of Microbial Technology (IMTECH)
Sector 39-A,Chandigarh-160 036 (Union Territory)
Telephone: (91-172) 269 05 62, 269 52 15
Facsimile: (91-172) 269 05 85, 269 06 32
E-mail: idamtcc@imtech.res.in, curator@imtech.res.in

The invention must clearly convey to those skilled in the art that the inventor possesses the claimed invention so that they are able to work the invention without undue experimentation

Sufficiency of disclosure is achieved when the skilled person following the instructions given in the patent specification is able to carry out the invention without undue burden.

There are two aspects to enablement: firstly, the patent had to teach the practical steps necessary to perform the invention, and, secondly, the teaching provided had to be sufficient or the invention to be performed over the whole area claimed.

The disclosure must also be sufficient to enable the whole width of the claimed invention to be performed.

Description should not only say how to make the invention (DNA/protein) but also how to use the same

The US/EPC law requires identification of the complete coding sequence and the function/role played by the gene or its expression product

Patents not granted on sequences lacking a characterized function

EU Biotech Directive Recital 23 (“Whereas a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention”).

In India also it is required to provide the Function of the sequ

EPO Board of Appeals
Case Number: T 0029/06 - 3.3.08
Application Number: 96902830.7

Applicant: Aventis Pasteur Limited

The application had been refused for reason of non-compliance with the requirements of Articles 84 and 56 EPC,for which the applicants appealed.

Claim 1 relates to A nucleic acid molecule comprising a *Bordetella* promoter operatively coupled to a heterologous nucleic acid sequence encoding a non-*Bordetella* gene product and a leader sequence for secretion of the non-*Bordetella* gene product. The nucleic acid molecule specific DNA sequences corresponding to a 5‘and 3’flanking sequence of a selected *Bordetella* gene.

Claims 2-14 dependent on claim 1 and
claim 14 related to plasmids like DS-546-1 with reference to eg & fig and adapted for transformation of a *Bordetella* strain comprising the nucleic acid molecule.

Board: sufficiency of disclosure in connection with the subject -matter of claim 14 questioned, it was doubtful whether skilled person would be capable of reproducing plasmids of claim 14

only a general idea of the structure and organisation of the plasmid -no detailed indication as to the nucleotide sequence, in particular -of the non-coding portions of the DNA molecule, is too vague and -imprecise to enable the skilled person to construct the plasmids.

Though the oligo and some plasmids are available but two plasmids required to form a specific plasmid DS-546-1 of claim 14 is not available.
No deposition of material made and no disclosure of the nucleotide sequence, including non coding region.

Therefore, the present application does not disclose the invention which claim 14 is directed in a manner sufficiently clear and comple for it to be carried out by a person skilled in the art.

Determining industrial application of biotech invention can be difficult, such as a gene or protein sequence, is very often not apparent from the invention itself

In case of proposed functions of sequences identifiable by homology to sequences of known function, a “nature identical” polynucleotide or polypeptide sequence, which has no assigned function, or a "nature identical" polynucleotide or polypeptide, where the function is speculative is not capable of industrial application.

The lack of any specific, substantial and credible industrial application for one aspect of an invention can have implications for other aspects of that invention

Demonstration of the invention with working examples and drawings are to be provided

At least one embodiment of the invention or at least one method for performing the invention must be described so that it can be reproduced without the need for inventive ingenuity. If a skilled person following the directions given in the specification has to find out something that is new in order to reproduce the invention, the disclosure is insufficient

The claimed invention is defined as a therapeutic agent for selectively blocking the translation of an mRNAinto a targeted protein comprising a stabilizedoligonucleotide of 14 to 23 bases having a base sequence substantially complementary to a portion of the coding region of the mRNA coding for said targeted protein.

The specification should teach:

(a) how to identify the relevant portion of the mRNA encoding the targeted protein (mRNAs being longer than 14 to 23 bases),
(b) how to devise an oligonucleotide of 14 to 23 bases of substantial complementarity and synthesize it,
(c) how to stabilize said nucleotide and
(d) how to test for its ability to enter the cells and to selectively block translation of the target

Mention that the examples are for illustration only.

It is helpful to provide comparative examples to demonstrate **improvement** in the invention.

It is important that inferences from the examples are to be mentioned.
One may provide data but no inference form the examples.
Then it becomes difficult during prosecution, specially Indian .

Drawings

When there are drawings, there shall be a brief description of the drawings, and the detailed description of the drawings

shall refer to the different views by specifying the numbers of the figures, and to the different parts by use of reference numerals if any. Each no. referred in drawings should be described in specification and vice versa

Brief description of (Accompanying)Drawings

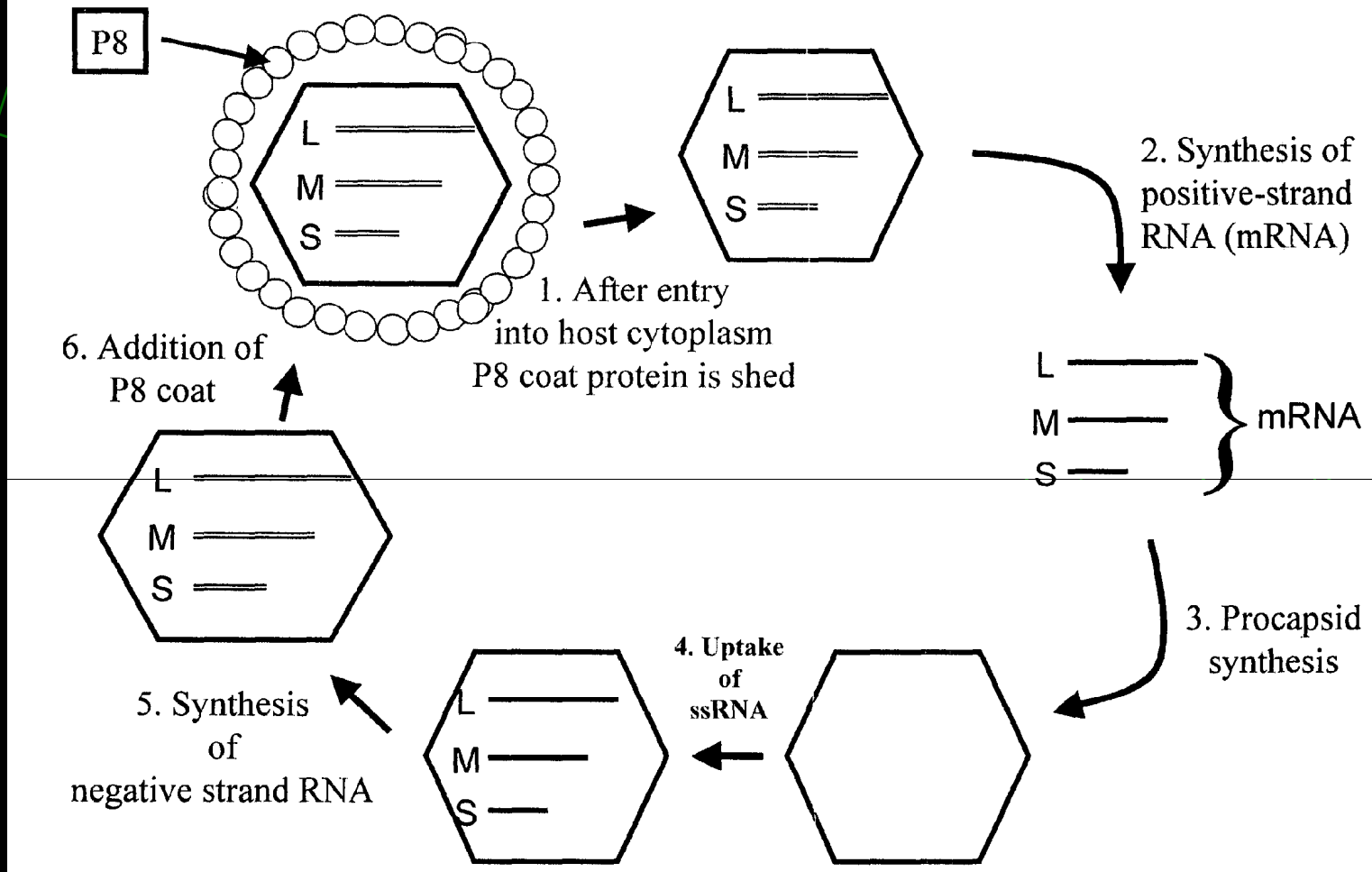
Fig 1. schematic drawing showing the replication of dsRP nucleocapsids in bacterial cytoplasm…

Fig 2 Schematic representation of the SEQ ID 4…

Detailed description of the drawings.. Description of drawings

Figure 1

Replication of dsRP nucleocapsids in the bacterial cytoplasm



SEQUENCE LISTING FORMAT

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<120> Title of Invention :
<130> File reference :

*<140> Current Patent Application : : PCT/ IN….
*<141> Current filing date :
*<150> Earlier Patent Application : -
*<151> Earlier Appln. Filing Date : -

<160> Number of SEQ ID Nos. : 2
*<170> Software :

<210> Information for SEQ ID No. : 1
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<212> Type : DNA
<213> Organism : Artificial

{ If the sequence is artificial incorporate columns 220 & 223
For modified bases/amino acids incorporate 221 and 222 }
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*<222>: Location
*<223> Other information Description character, if any
Primer sequence A for pdxJ
*<300> Publication Information :
*<301> Authors :
*<302> Title (Title of Publication)
*<303> Journal (Journal name in which data published
*<304> Volume (Journal volume in which data published)
*<305> Issue (Journal issue No. in which data published
*<306> Pages (Journal page nos. in which data published
*<307> Date (Journal date in which data published (CCYY MM DD
*<308> Database accession[Accession no. assigned by database
incl. (CCYY MM DD) incl. Database name}

*<309> Database entry date :
{Date of entry in database ((CCYY MM DD)}
*<310>Document No.(Document no.for patent type citations only)
*<311> Filing date
Document filing date. For patent type citations only.)
*<312> Publication date :
(Document publication date. For patent type citations only.)
*<313> Relevant residues in SEQ ID NO: X : from to :

<400> SEQ ID NO. : 1
sequence tcccatatgc ctgcaaagct ctcc 24

(*As per rules triplet codons are to be grouped as triplets, otherwise groups of 10 with a gap in between are to be given*).

<160> NUMBER OF SEQ ID NOS: 1

<210> SEQ ID NO 1
<211> LENGTH: 264
<212> TYPE: PRT
<213> ORGANISM: Equus

<400> SEQUENCE: 1

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1               5                  10                  15

Ser Ala Leu Leu Asp Ala Glu Pro Pro Val Leu Tyr Ser Glu Tyr Asp
            20                  25                  30

Ala Thr Arg Pro Phe Asn Glu Ala Ser Met Met Gly Leu Leu Thr Asn
        35                  40                  45

Leu Ala Asp Arg Glu Leu Val His Met Ile Asn Trp Ala Lys Arg Val
    50                  55                  60

Pro Gly Phe Val Asp Leu Ser Leu His Asp Gln Val His Leu Leu Glu
65                  70                  75                  80

Cys Ala Trp Leu Glu Ile Leu Met Ile Gly Leu Val Trp Arg Ser Met
                85                  90                  95

Glu His Pro Gly Lys Leu Leu Phe Ala Pro Asn Leu Leu Leu Asp Arg
            100                 105                 110

Asn Gln Gly Lys Cys Val Glu Gly Met Val Glu Ile Phe Asp Met Leu
        115                 120                 125

Leu Ala Thr Ser Ser Arg Leu Arg Met Met Asn Leu Gln Gly Glu Glu
    130                 135                 140

Phe Val Cys Leu Lys Ser Ile Ile Leu Leu Asn Ser Gly Val Tyr Thr
145                 150                 155                 160

Phe Leu Ser Ser Thr Leu Lys Ser Leu Glu Glu Lys Asp His Ile His
                165                 170                 175

Arg Val Leu Asp Lys Met Thr Asp Thr Leu Ile His Leu Met Ala Lys
            180                 185                 190

Ala Gly Leu Thr Leu Gln Gln His Arg Arg Leu Ala Gln Leu Leu Leu
        195                 200                 205

Ile Leu Ser His Ile Arg His Met Ser Asn Lys Gly Met Glu His Leu
    210                 215                 220

Tyr Ser Met Lys Cys Lys Asn Val Val Pro Leu Tyr Asp Leu Leu Leu
225                 230                 235                 240

Glu Met Leu Asp Ala His Arg Leu His Ala Pro Ala Asn His Gly Gly
                245                 250                 255
```

Claims

WHAT INVENTOR WANTS OTHERS NOT TO DO

The specification must conclude with a claim or claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as the invention. The portion of the application in which the applicant sets forth the claim or claims is an important part of the application, as it is the claims that define the scope of the protection afforded by the patent and on which questions of infringement are judged by the Courts.

It is the area, where trudging without the applicants permission would amount to infringement and hence forbidden territory

Claims may be independent, dependent, multiple dependent

Claims in dependent form shall be construed to include all of the limitations of the claim incorporated by reference into the dependent claim. A multiple dependent claim shall be construed to incorporate all the limitations of each of the particular claims in relation to which it is being considered.

The claim or claims must conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.

Structuring Patent Claim

- Identify essential elements of the invention
- Claims should relate to one invention/more embodiments within one inventive concept
- Say less to protect more
- Use broader terms as far as applicable
- Define interrelationship of the components
- Basis on the disclosure

- **Broad and narrow claims to cover different aspects and limitations**
  - Include claims of varying scope. Since claims provide the area of protection, the scope protected is to be well defined so that one is aware so as not to overlap with scope of existing art and at the same time prevent others from practicing what you have invented

Patent Claims

Define the scope of protection sought

Set the boundaries of the invention trudging on same would amount to trespassing

Tell the world what has been invented

THE CLAIM HAS 3 PARTS:

preamble

transitional phrase

body

A CLAIM IS WRITTEN AS A SINGLE SENTENCE

Preamble

Provide a category for the invention

Eg.: A nucleic acid ….

A monoclonal antibody which is reactive to…..

A transgenic microbial cell,

Transition

- Open or Closed
- Follows the preamble
- May begin with a comma
  - A protein, **comprising**…
- What's an "open" word and what's a "closed" word varies around the world

Open

- Recited elements are the minimum needed for infringement
- The presence of other elements in an infringing device does not defeat infringement claim

Closed

- Recited elements are everything required for infringement
- The presence of other elements in an infringing device defeats infringement claim

Body

- Follows the transitional phrase
- Provides the main feature/features of the process/product and the inter relation between the components

EP1878744

1. A functional T-cell receptor (TCR) alpha or beta chain fusion protein, comprising:
   a) at least one epitope-providing amino acid sequence (epitope-tag), and
   b) the amino acid sequence of an alpha or beta chain of a TCR,wherein said epitope-tag is selected from
   a) an epitope-tag added to the N- and/or C-terminus of said alpha and/or beta chain,
   b) an epitope-tag inserted into a constant region of said alpha and/or beta chain, and
   c) an epitope-tag replacing a number of amino acids in a constant region of said alpha and/or beta chain.

2. The functional T-cell receptor (TCR) alpha or beta chain fusion protein according to claim 1, wherein said epitope-tag has a length of between 6 to 15 amino acids, preferably 9 to 11 amino acids.

3. The functional T-cell receptor (TCR) alpha or beta chain fusion protein according to claim 1 or 2, wherein said fusion protein comprises two or more epitope-tags, either spaced apart or directly in tandem.

4. The functional T-cell receptor (TCR) alpha or beta chain fusion protein according to any of claims 1 to 3, wherein said epitope-tag is selected from a myc-tag, FLAG-tag, T7-tag, HA (hemagglutinin)-tag, His-tag, S-tag, GST-tag, and GFP-tag.

5. The functional T-cell receptor (TCR) alpha or beta chain fusion protein according to any of claims 1 to 4, wherein said fusion protein is selected from two myc-tag sequences that are attached to the N-terminus of an alpha TCR-chain and/or 10 amino acids of a protruding loop region in the beta-chain constant domain being exchanged for the sequence of two myc-tags.

6. A method for producing a fusion protein according to any of claims 1 to 5, comprising a chemical synthesis of said peptide.

7. A functional TCR formed by the association of one or two of the fusion proteins according to any of claims 1 to 5, wherein the TCR is an alpha/beta-TCR.

8. An isolated nucleic acid molecule encoding the fusion protein according to any of claims 1 to 5 or the TCR according to claim 7.

9. The nucleic acid molecule according to claim 8, wherein said molecule is selected from DNA, RNA, PNA, CNA, mRNA or mixtures thereof.

10. A vector, preferably in the form of a plasmid, shuttle vector, phagemide, cosmid, expression vector, retroviral vector, retroviral expression vector, adenoviral vector or particle and/or vector to be used in gene therapy, comprising a nucleic acid molecule according to claim 8 or 9.

11. A host cell, transfected with a vector or infected or transduced with a particle according to claim 10.

12. The host cell according to claim 11, wherein said cell is a T-cell or a T-cell-precursor cell or a non-pluripotent stem cell.

13. The host cell according to claim 11 or 12, wherein said host cell expresses a fusion protein according to any of claims 1 to 5 or the TCR according to claim 7 on its surface.

14. A method for selecting a host cell population expressing a fusion protein selected from the group consisting of
a) a functional fusion protein comprising at least one epitope-providing amino acid sequence (epitope-tag), and the amino acid sequence of a protein that is expressed on the surface of said host cell, wherein said epitope-tag is selected from i) an epitope-tag added to the N- and/or C-terminus of said protein, ii) an epitope-tag inserted into a region of said protein, and an epitope-tag replacing a number of amino acids in said protein,
b) a fusion protein according to any of claims 1 to 5, and
c) a TCR according to claim 7on the surface of the host cell, comprising contacting host cells in a sample with a binding agent that immunologically binds to the epitope-tag, and selection of said host cells based on said binding.

15. The method according to claim 14, wherein said host cell is selected from hematopoietic cells, such as NK cells or tumor cells, T-cells and T-cell-precursor cells and non-pluripotent stem cells

16. The method according to claim 14 or 15, wherein said epitope-tag has a length of between 6 to 15 amino acids, preferably 9 to 11 amino acids.

17. The method according to any of claims 14 to 16, wherein said fusion protein comprises two or more epitope-tags, either spaced apart or directly in tandem.

18. The method according to any of claims 14 to 17, wherein said epitope-tag is selected from a myc-tag, FLAG-tag, T7-tag, HA (hemagglutinin)-tag, His-tag, S-tag, GST-tag, and GFP-tag.

19. The method according to any of claims 14 to 18, further comprising an enriching of th host cells based on said binding and/or an inactivation of the host cells based on said binding.

20. A method for producing a fusion protein according to any of claims 1 to 5, comprising: expressing a nucleic acid molecule in a host cell according to any of claims 11 to 13, and purifying said fusion protein or said TCR from said host cell.

21. A pharmaceutical composition, comprising a fusion protein according to any of claims 1 to 5, a nucleic acid molecule according to claim 8 or 9, a vector according to claim 10 or a host cell according to any of claims 11 to 13, together with a pharmaceutically acceptable carrier.

Use of the **Trademarks**

The use of trade marks and similar expressions in claims are not be allowed as it may not be guaranteed that the product or feature referred to is not modified while maintaining its name during the term of the patent. They may be allowed exceptionally if their use is unavoidable and they are generally recognised as having a precise meaning

- Support of the claim language to be reflected in the specification.
  - every claim should have adequate support in the specification
  - Words and terminology should be consistent

  Eg If the specification mentions the recombinant Micro organism as mutant ensure that it is referred as “Mutant” in the claims as well and not as “variant” unless it is mentioned in the specification that the terms are interchangeable.

Abstract

A brief abstract of the technical disclosure in the specification including that which is new in the art to which the invention pertains, must be set forth on a separate page immediately following the claims.

Should contain the main technical features of the invention to assist in searching

The abstract should be in the form of a single paragraph of 150 words or less, under the heading “Abstract”

Often the title is present at the beginning of the abstract.

If the specification has figure/s the most pertinent one may be provided with the abstract

Sometimes the reference numerals are to be provided in the Abstract in line with figure

If flow diagram best define the invention the same may be provided in abstract


THANKYOU

Biotechnology Can Transform Humanity - Provided Humanity Wishes to be Transformed

-Geoffrey Carr

IP Management

By

Dr. Kalyan C. Kankanala

www.brainleague.com

Blog: www.sinapseblog.com

kalyan@brainleague.com

Latest Book: FUN IP, Fundamentals of Intellectual Property - www.funip.net

Business and IP

- Business Plan
- Goals - Short Term and Long Term
- Resources - Human and Financial

The Business of IP

The Business of IP

- Generation and Excavation
- Protection and Maintenance
- Portfolio Development and Management
- Commercialization and Licensing
- Risk Clearance or Mitigation

Generation/Excavation

- Development Plan

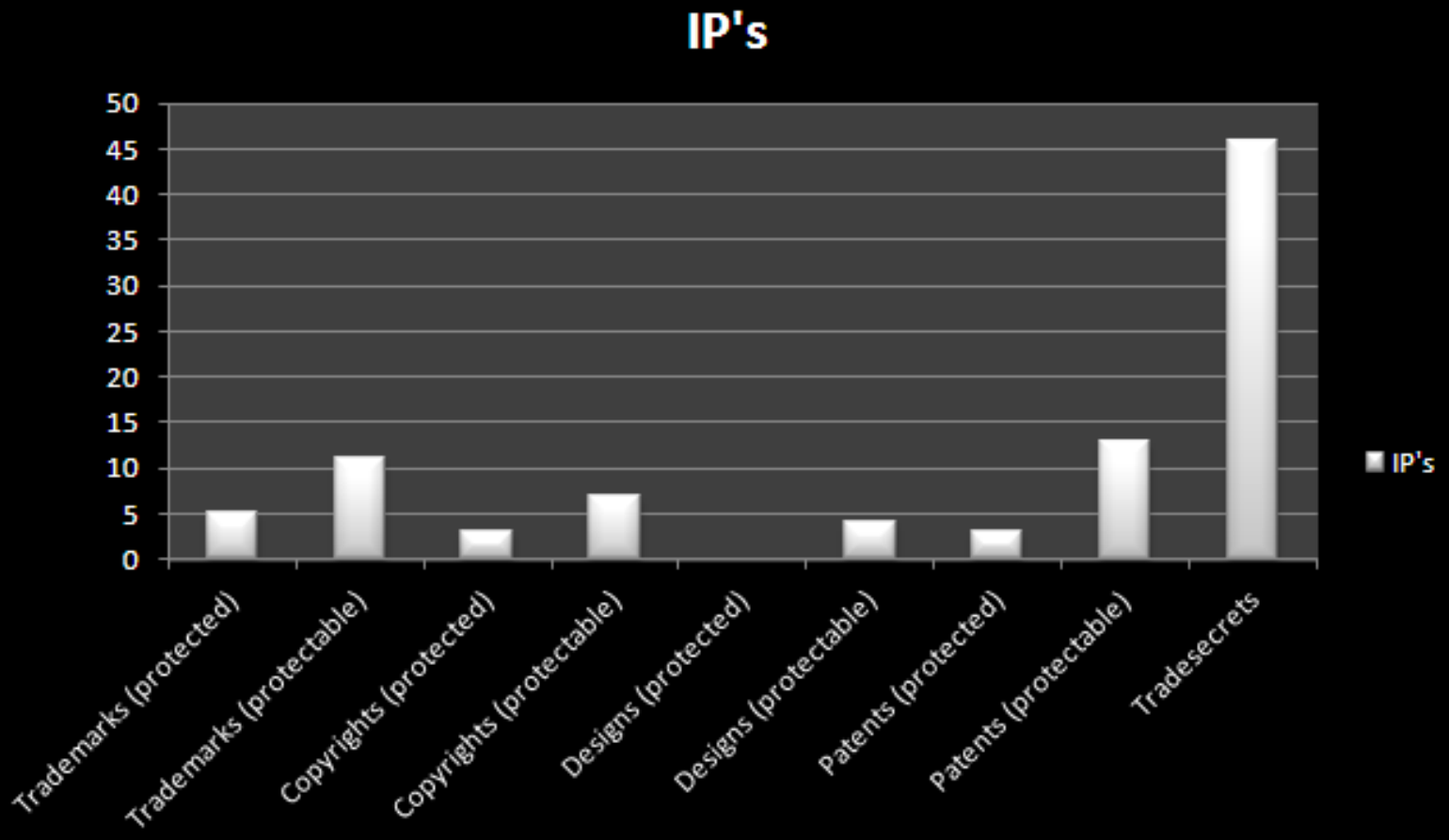
  – Open Grounds

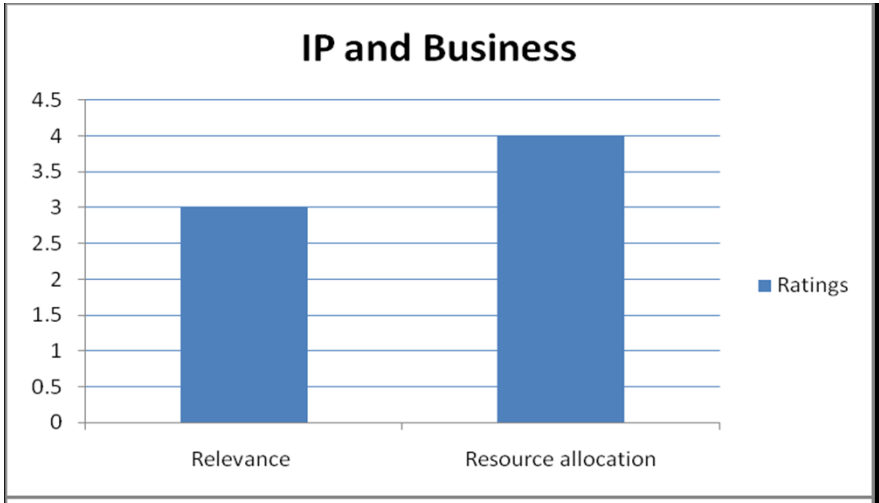
  – Road Blocks


USA Government
Merck & Co., Inc.
Institut Pasteur
Chiron Corporation
Medical Research Council
Duke University
Trimeric Glycoprotein Ectodomain
Receptor Covalently Linked
Sulfhydryl Cysteine Nonpeptide Mutant Coat
Monoclonal Antibody Accession Hybridoma
Chain Light Chain Diagnostic
Conjugate Linked Multivalent
Sp Sulfhydryl Papilloma
Protect Synthetic Therapeutic
Isoleucine Alkyl Carbons Valine
Bacterial Fusion Sp
Glycoprotein Complex Env
Lentivirus Glycoprotein Signal Functional Fragment Cellmediated
Hybrid Complex Polynucleotide
Pathogen Tuberculosis Mycobacterium
Therapeutic Nuclear Localization Fragment Mutants
Tag Hla Conserved
Hla Molecule Stimulate Cytotoxic Lymphocyte Immunity
Determining Monoclonal Therapeutic
Moiety Mammalian Receptor
Gly Gln Glu

Generation/Excavation

- Mining and Audit

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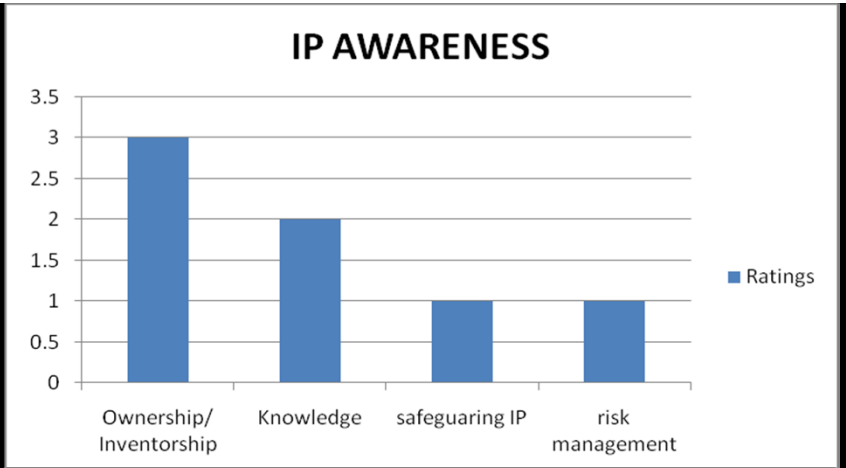
Relevance
Resource allocation
Ratings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Knowledge
safeguaring IP
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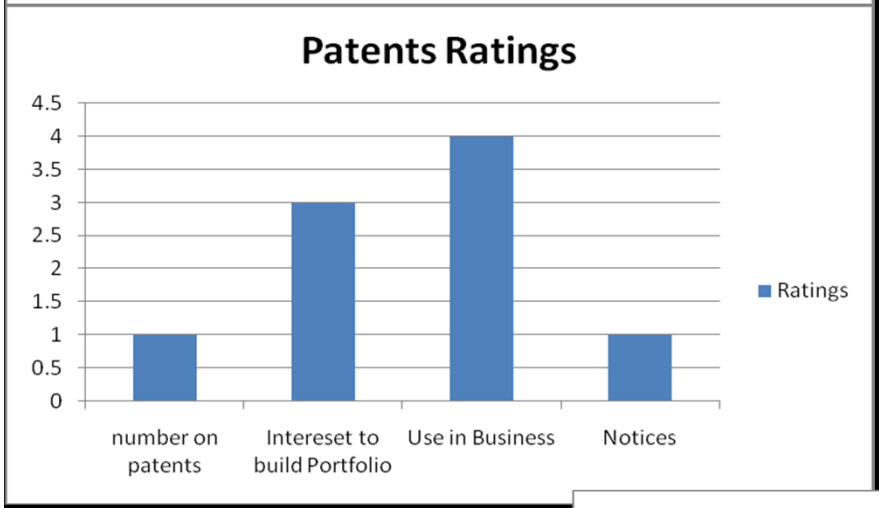
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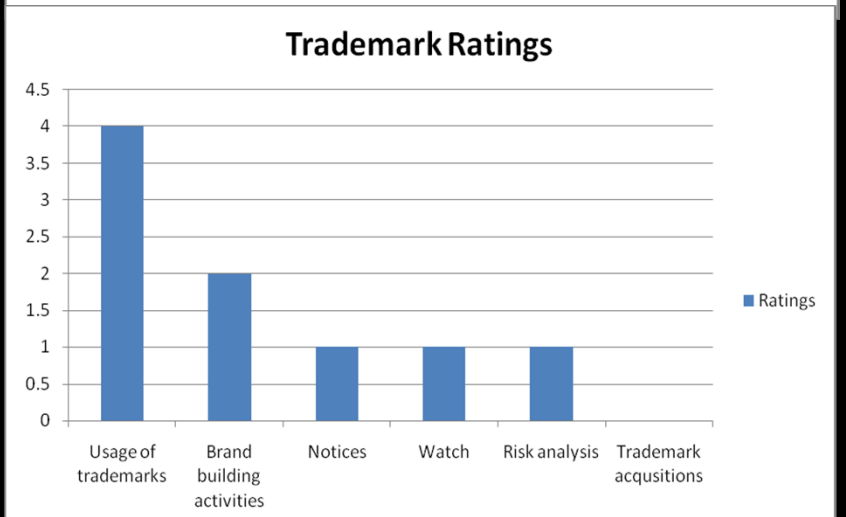
number on patents
Intereset to build Portfolio
Use in Business
Notices
Ratings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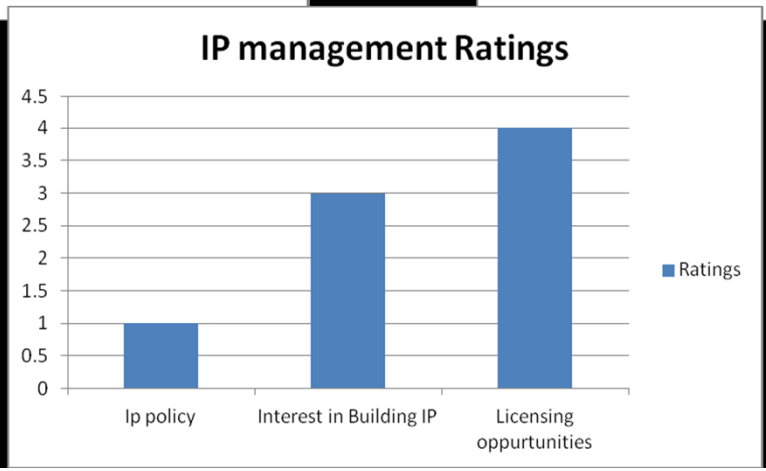
Watch
Risk analysis
Trademark acqusitions
Ratings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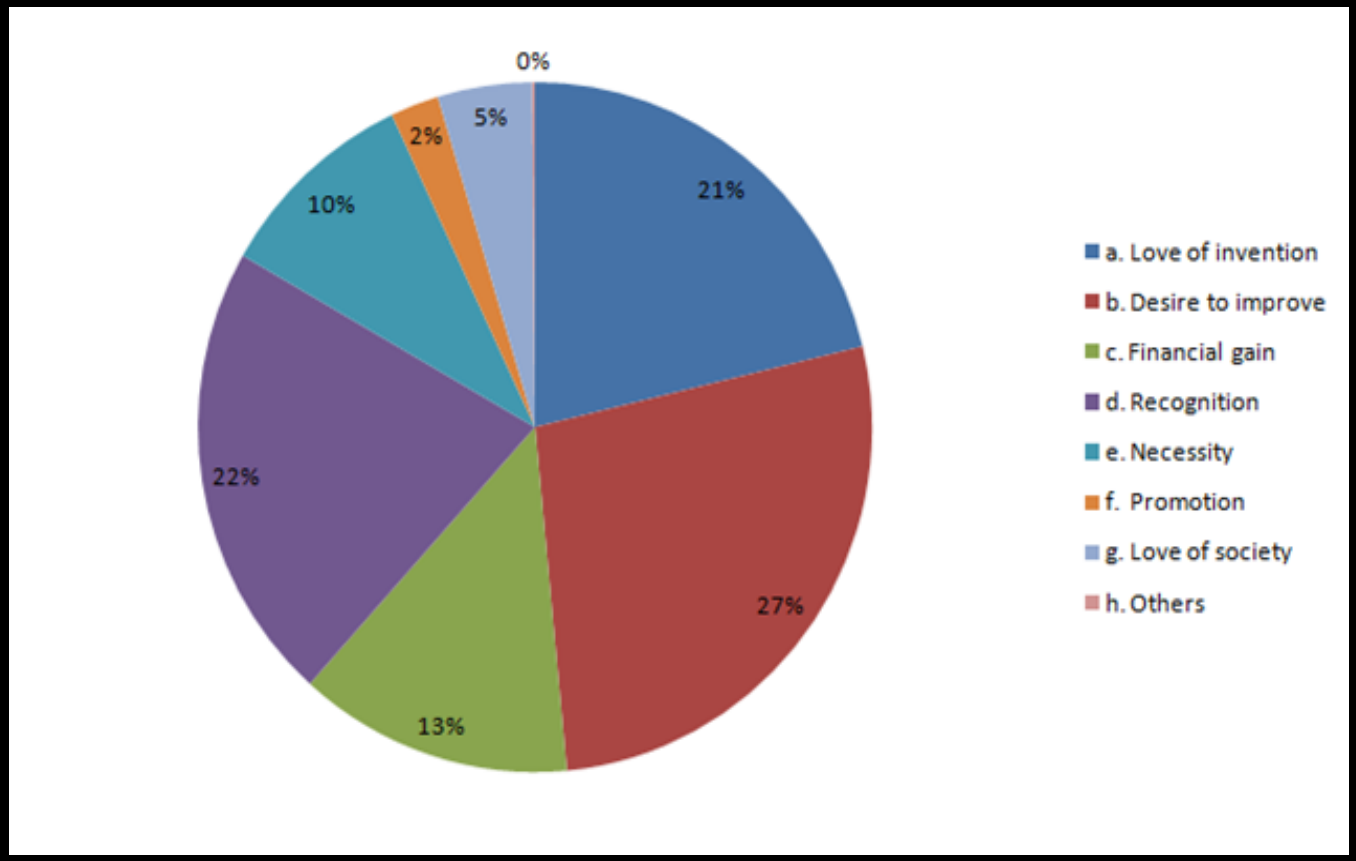
Ip policy
Interest in Building IP
Licensing oppurtunities
Ratings

Generation/Excavation

- Team Incentives



Research by SiNApSE blog

Protection/Maintenance

- Integrated Protection
- Resource Planning and Strategy
- Application Management
- Keeping IP alive

Portfolio Management

- Development and Clustering

Sequences	9
Formulations	14
Preparation process	9
Method of treatment	2
Related medical use and Administration	5

- Strategic Alliance and Collaboration
- Assessment Metrics

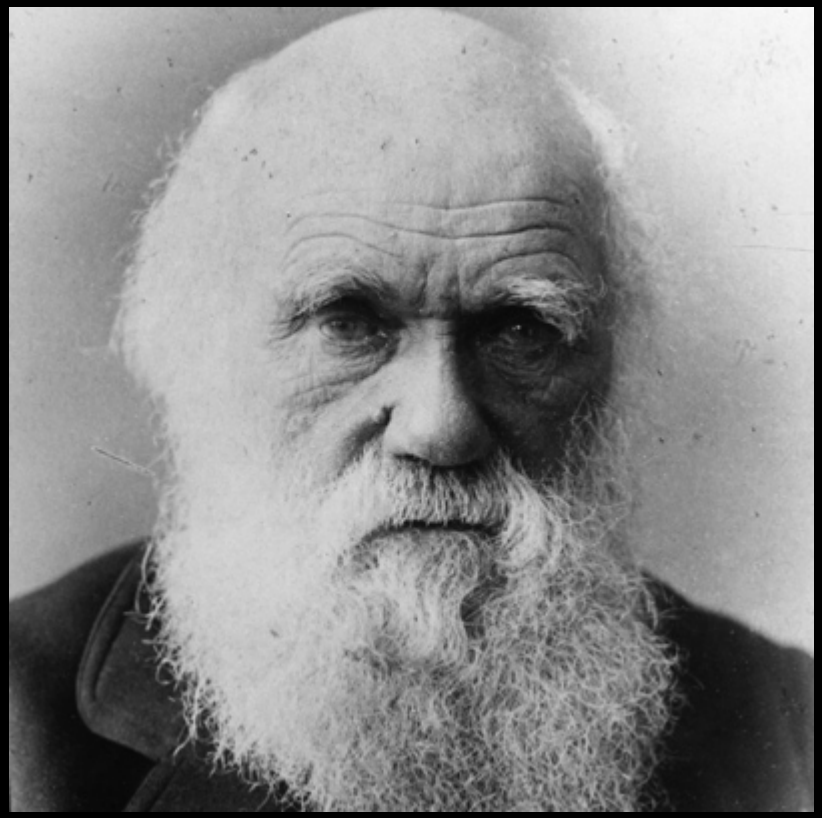
Commercialization/Licensing

- IP Quality
- Portfolio
- Pooling
- Deal Making

- **Medicines Patent Pool: HIV Treatment**

Risk Clearance

- Clearance Search and Analysis
- FTO Analysis
- Licensing and Permissions
- Litigation Management and Strategy



“It is not the strongest of the species that survives, nor the most intelligent that survives. It is the one that is the most adaptable to change.”

By

Charles Darwin

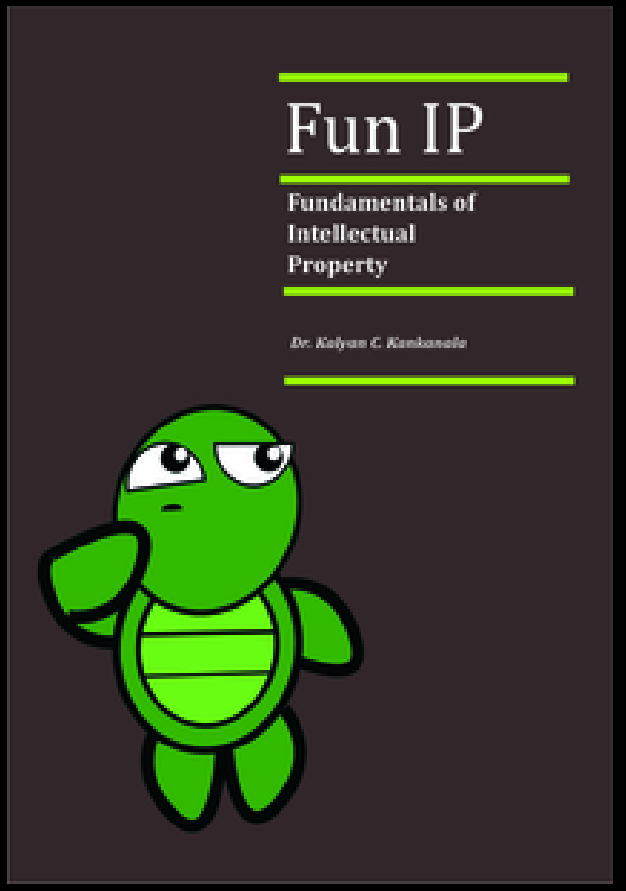
Seminar on IP Dynamics for Pharma Industry

- Interesting Topics and focuses on:
  - IP hurdles and risks affecting product launches
  - Risk mitigation strategies in product launches
  - Analysing the nuances in scope of claims
  - Dealing with barriers & strategic planning in licensing new molecules
  - Understanding the various stages in licensing

- www.ipseminars.com
- Contact : Mr. Ishan Raina (ishan@brainleague.com)

Book on FUN IP

- For Beginners and Non-lawyers
- Buy - www.funip.net



Thank You!

- For ppt and more info: www.sinapseblog.com
- Email: kalyan@brainleague.com
- Thanks to Vikram for his kind assistance!

KEY CONSIDERATIONS FOR PATENTING IN LIFE SCIENCES

T.V.MADHUSUDHAN

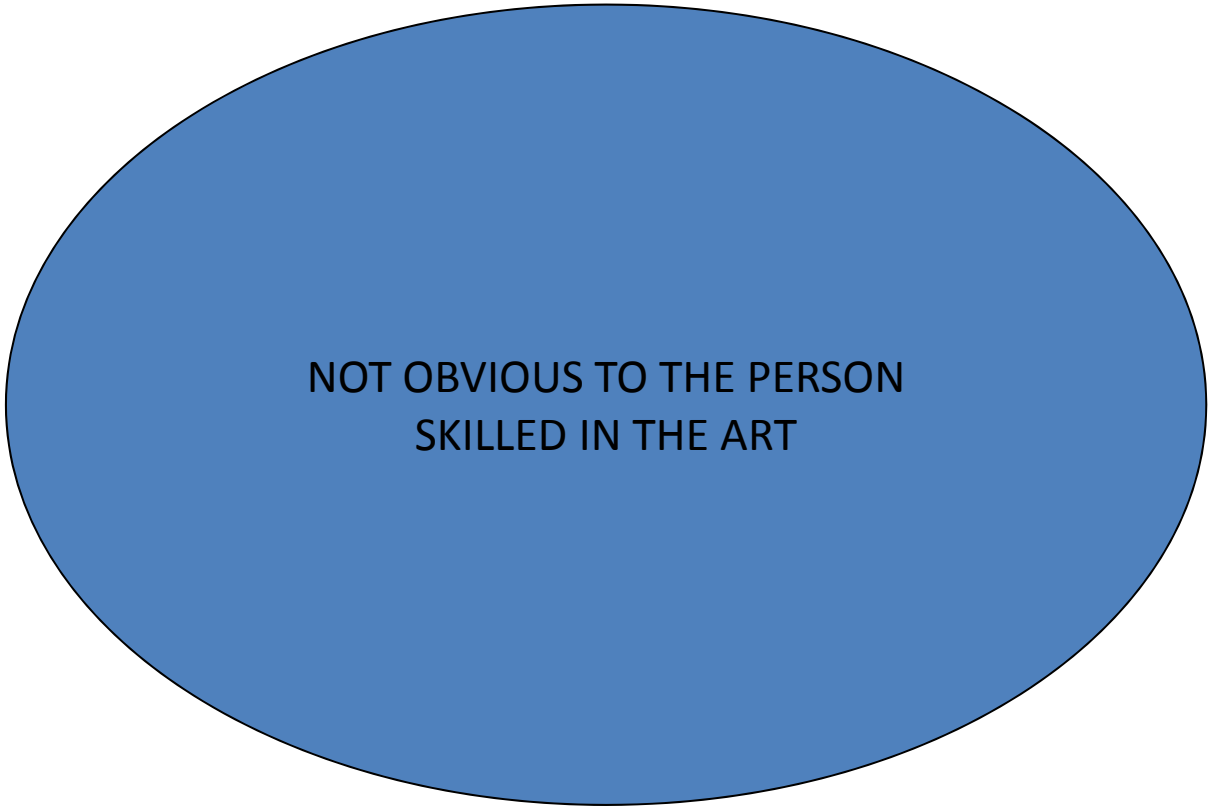
Assistant controller of Patents & Designs, Chennai

INDIAN PERSPECTIVE

- PRE 20th MAY 2003
- NOVELTY
- INDUSTRIAL APPLICABILITY
- STATUTORY EXCLUSIONS

- POST 20th MAY 2003
- NOVELTY
- INVENTIVE STEP
- INDUSTRIAL APPLICABILITY
- STATUTORY EXCLUSIONS

INVENTIVE STEP – DEF.



SECTION 3(a)

an invention which is frivolous or which claims any thing obviously contrary to well established laws

- Apple, without applying any external force, moves against gravity

SECTION 3 (b)

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

SECTION 3 (c)

The mere discovery of a scientific principle or the formulation of or discovery of any living thing or non-living substance occurring in nature

WHAT IS DISCOVERY?

- ANY LIVING OR NON-LIVING PER SE?
- IS IT AVAILABLE IN NATURE AS SUCH?
- OR IS IT EMBEDDED INSIDE SOMETHING?
- FOR EXAMPLE A FRUIT IS DISCOVERED THEN WHAT ABOUT A SEED PRESENT INSIDE THE FRUIT?

WHAT IS DISCOVERY?...CONTD.,

- WHETHER A NOVEL METAL WHICH IS EXTRACTED IS DISCOVERED OR INVENTED?
- FOR EXAMPLE A MICROORGANISM IS DISCOVERED THEN WHAT ABOUT THE UNRAVELLING AND FINDING THE SEQUENCE OF GENETIC MATERIAL?
- FOR EXAMPLE IDENTIFYING THE USE OR UTILITY OF THE SEQUENCE?

SECTION 3 (e)

A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance.

SECTION 3 (h)

A method of agriculture or horticulture

Section 3(g) was deleted which was read

A method or process of testing applicable during the process of manufacture for rendering the machine, apparatus or other equipment more efficient or for the improvement or restoration of existing machine, apparatus or other equipment or for the improvement or control of manufacture.

SECTION 3 (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.

SECTION 3 (p)

An invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components

MANDATORY REQUIREMENTS IN THE SPECIFICATION

PREAMBLE

When an applicant mentions a biological material which may not be described in such a way in the specification so as to satisfy to fully and particularly describe the invention and its operation or use and method by which it is to be performed and disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection shall;

MANDATORY REQUIREMENTS IN THE SPECIFICATION

- Deposit such mentioned biological material with an international depository authority under the Budapest Treaty
- Shall deposit before the date of filing patent application in India
- Reference of such deposition shall be made in the specification either on the filing date or within 3 months from the date of filing the specification.

MANDATORY REQUIREMENTS IN THE SPECIFICATION

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 [Accession number] of the material at the institution

MANDATORY REQUIREMENTS IN THE SPECIFICATION

- Access to the material is available in the depository institution only after the date of the application for patent in India or if a priority is claimed after the date of priority;
- Disclose the source and geographical origin of the biological material in the specification, when used an invention.

Deposit of biological material

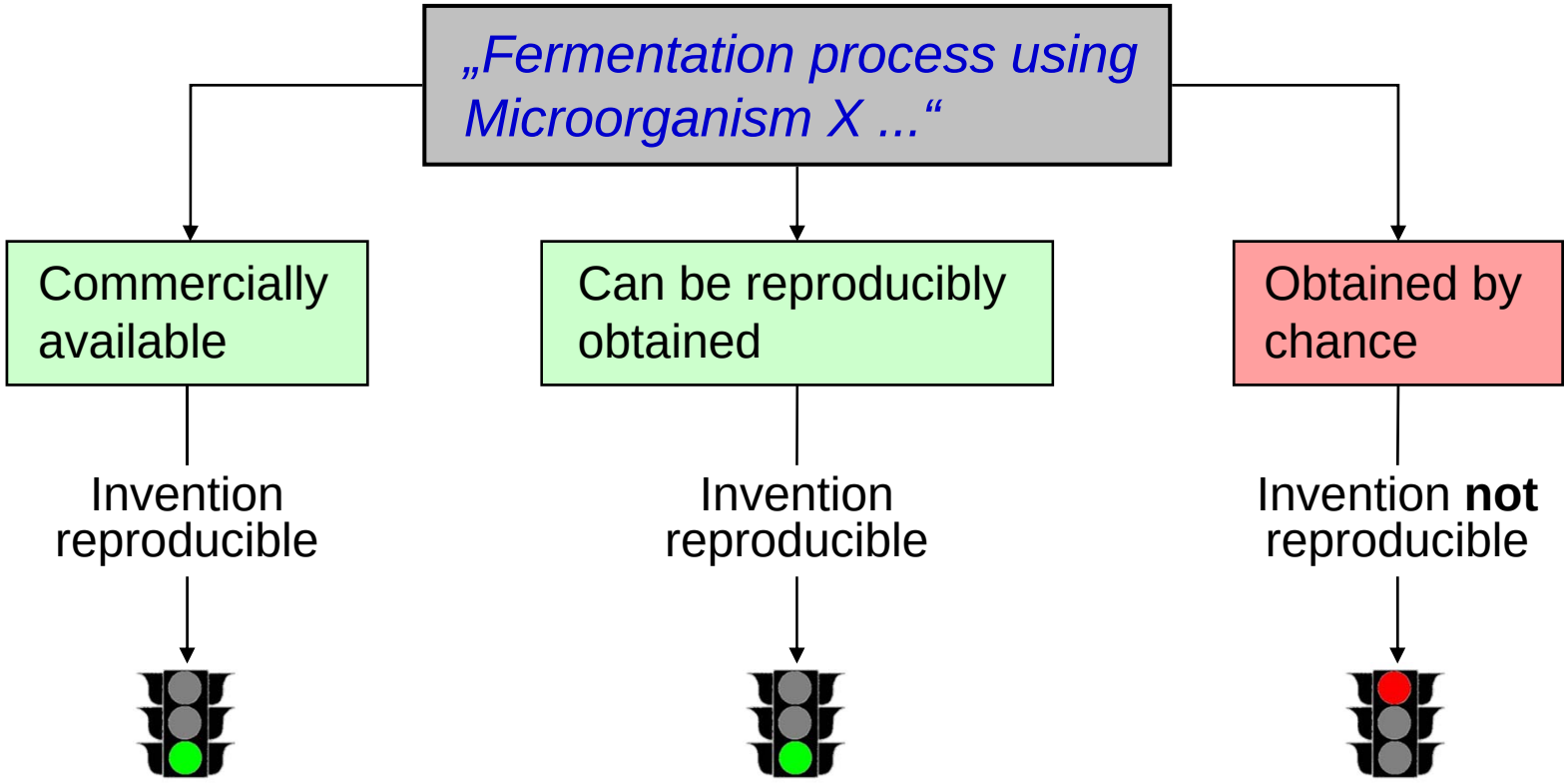
If biological material used in an invention cannot be reproducibly obtained, a sample thereof has to be
deposited at a cell collection institution.

WHY ?

- Storage of the culture over a long period
- Guaranteed identity of the culture
- Delivery of a sample to everybody
- Delivery of a sample at any time

Sufficient description of biological material

If an invention involves biological material, the public **must** have access to it. Example:



MANDATORY REQUIREMENT

Approval From National Biodiversity Authority Under section 19 (2)

Any person who intends to apply for a patent or any other form of intellectual property protection whether in India or outside India referred to in sub section (1) of section 6, may make an application in such form and in such manner as may be prescribed to the National Biodiversity Authority

THE INDIAN BIO-DIVERSITY ACT --- 2002

The Indian Bio-diversity Act, 2002 addresses the basic concerns of access to, and collection and utilization of biological resources and knowledge by foreigners, and sharing of benefits arising out of such access. Section 6 or the Act provides that any person seeking any kind of IPRs in or outside of India for any invention based on any biological resource or information on a biological resource obtained from India, is required to obtain prior permission of the NBA, which may determine benefit sharing fee or royalty for the benefits arising out of the commercial utilization of such rights.

Patents and boundaries to Ethics

- Ethics are about what is regarded right or wrong by a society
- Ethical norms and values may vary from culture group to culture group, or even from country to country
- Ethical norms and values may change over time
- Technology may progress over time

Patents and boundaries to Ethics

- Since ethical standards may vary, only those inventions should be excluded from patentability for *ordre public* or morality reasons, for which there is a clear consensus in overwhelming parts of society that the underlying activities are contrary to ethical standards
- According to TRIPs, WTO-members may exclude from patentability inventions in order to protect *ordre public* or morality, provided that such exclusion is not made merely because the exploitation is prohibited by their law (see TRIPS, Art. 27.2)
- Illegality of an activity is not sufficient to exclude it from patentability for *ordre public* or morality reasons

Example: Human Embryonic stem Cells (hEC)

Patents shall not be granted for uses of human embryos for industrial or commercial purposes“ (EU-Biotech Dir 98/44)

- Patents on methods to cultivate or differentiate hEC
- Patents are NOT directed to uses of human embryos
- Patent Offices have taken different positions:

- **European Patent Office**: excluded from patentability, because it was contended that hEC are necessarily consumed in order to provide the starting material for the claimed process; question is pending before the Enlarged Board of Appeal (G2/06)
- **Patent Offices in Sweden, Great Britain and Germany**: allowed patents, because carrying out the process as claimed does not make use of human embryos for industrial or commercial purposes

- **Federal Patent Court in Germany** revoked part of a patent which was directed to a process to prepare purified cells with certain properties wherein the first step was „cultivating [human] embryonic stemcells…“
- reasoning: patents that do not claim but require as a precondition to be carried out with human embryonic stem cells which were derived by consuming an embryo fall under the exclusion due to „uses of human embryos for industrial or commercial purposes “
- Court did not address that human embryonic stem cells may be legally derived from other sources, e.g. existing embryonic cell lines and that such research is substantially funded and promoted by public institutions (e.g. EU-commission or DFG)

I claim a genetically modified bacterial cell which is capable of expressing a novel protein having the desired characteristics as described herein.

- Not allowable as there is no mention of deposition of such biological material.
- Not clear how the GM bacteria has been obtained. In other words questioning the INVENTIVE STEP.
- Not clear with respect to which problem is solved with which solution.

Probable redraft of the claim

I claim

A genetically modified bacterial Cell identified by Accession Number ATCC 11111 which is capable of expressing a novel enzyme capable of hydrolyzing ……

The genetically modified bacterial cell as claimed in claim 1 wherein the modification is carried out by irradiation.

EXAMPLE

I CLAIM
An isolated DNA having the sequence as shown in SEQ.ID No. 1

DRAWBACKS

It appears that the isolated DNA may be novel but probably a discovery.

The use or functionality of the DNA is not mentioned.

A REFUSED CLAIM U/S 15

A food,pet food,cosmetics or pharmaceutical composition for the health of the mouth comprising lactic bacteria that:

- i) is not part of the resident microflora of the mouth
- ii) is capable of adhering directly to the pellicle of the teeth,ie.having a low percentage of adhesion to saliva coated hydroxyapatite beads of atleast 1.96 after adhesion during 45 minutes at 37^0C, and
- iii) is less acidifying than pathogenic strains,ie.it provides a pH value superior to 4 to a sucrose fermentation medium when cultured at 37^0C for atleast 20 min

REASONS FOR REFUSAL

- LAB is not new
- As admitted it is only a selection among the existing LAB
- Said property already exists and the finding such property is a discovery
- No synergy has been explained either in the description or in the claims of the alleged composition
- LAB with desired properties are being added to the desired carrier that is the carrier can be a food or a pet food or cosmetic composition or a pharmaceutical composition. The principal claim fails in inventive step, read with Section 2(1)(j)(a) of the Patents Act.


THANK YOU FOR ATTENTION

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"Relevance of Intellectual Property Rights for Life Sciences"

BCIL WORKSHOP ON STRATEGIC MANAGEMENT OF IPR- HYDERABAD 11 JULY 2012

In this session....

- Role of IPR-R&D/Innovation/asset creation
- Basics of Copyright
- Basics of Trade Mark
- Basics of GI
- Basics of PPVFR
- Basics of Trade Secrets

The changing modes of wealth creation

- Hunting gathering
- Agrarian Economy
- Raw Material based production economy
- Knowledge based economy

Elements of IP

- Copyright
- Trademark
- Patents
- Other Ips- Geographical indicators
- Industrial Designs
- Integrated Circuits
- Trade Secrets
- Plant Varieties

Copyright- a statutory definition

- Copyright means the exclusive right to do or authorise others to do certain acts in relation to (1) literary, dramatic or musical works, (2) artistic work, (3) cinematograph film and (4) record.
- S14 of the Copyright Act 1957

What constitutes the basics of Copy right ?

- The work has to be original
- A Work has to be in a tangible form
- It has to be **Creative**
- It is the expression part not the idea part
- **Utility** is not a criteria in the work unlike patents

Scope of Copyright

- To **reproduce** work in any material form
- To issue **copies**
- To make **translation**
- To make any **adaptation**
- Reproduce **two dimensional** drawing in **three dimensional** object

Public Communication- The key in infringement

- “Communication to the public” means making any work available for being seen or heard or otherwise enjoyed by the public directly or by any means of display or diffusion other than by issuing copies of such work regardless of whether any member of the public actually sees, hears or otherwise enjoys the work so made available.
- For the purposes of this clause, communication through satellite or cable or any other means of simultaneous communication to more than one household or place of residence including residential rooms of any hotel or hostel shall be deemed to be communication to the public.

Exemptions

- 1) fair dealing for purpose of private use including research;
- 2) fair dealing for purposes of criticism, parody review and news reporting;
- 3) certain educational uses;
- 4) certain uses by libraries and archives;
- 5) certain uses for the purposes of public administration (such as use for Parliamentary and judicial proceedings)

Copyright duration

- Author’s Life +60 years by the 1994 Act
- Applicable for works from December28th of 1991

Remedies for Infringement of Copy Right

- TYPES OF REMEDIES:
- CIVIL

- CRIMINAL

- ADMINISTRATIVE

Let us play the judge – Case #1 – Phone Directory

- **Rural Telephone company** publishes a directory of white and yellow pages. It obtained the information in the white pages from the company's subscribers.

- **Feist** – a publishing company specializing in area-wide telephone directories asks for the right to use Rural Telephone Company's Directory- But Rural Telephone refuses to give the data for publication

- **Feist** went ahead and published the directory with the white pages .
- Rural Telephone Company sued Feist for infringement. What is your judgment ?

Case #2 – Video Games

- **Sega** makes a game console which requires game cartridges to have a 25 bit security code.
- If the code is not found, the game will not play. **Accolade-** a rival company reverse engineered **Sega games** and determined the code which they then incorporated into their games.
- Is this an infringement?

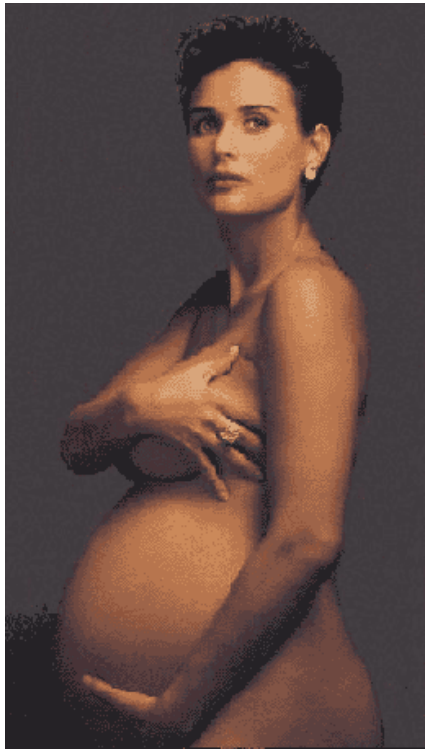
Case #3 – Sculpture vs. Photo

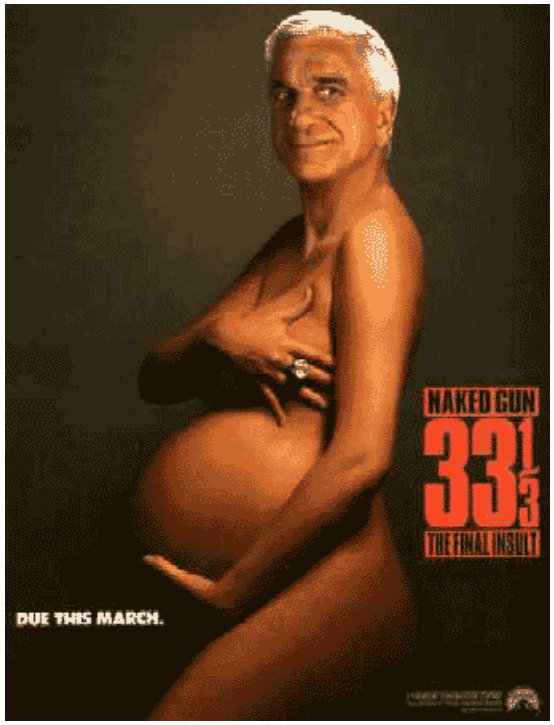
- A sculpture (right) was created based on a photograph (left). Is this copyright infringement?

Source: http://www.law.duke.edu/copyright/html/events/curriculumMaterials.html

Case #4 – Poster vs. Photo

- A movie poster (right) was created based on a photograph (left)





Source: http://www.benedict.com/visual/visual.asp

Case #1 – Phone Directory

- Feist Publications v. Rural Telephone Service Co.
- US Supreme Court says that the white pages are not copyrightable because they are not sufficiently original

Case #2 – Video Games

- Sega Enterprises, Ltd. v. Accolade, Inc.
- 9th US Circuit Court of Appeals ruled this fair use

Case #3 – Sculpture vs. Photo

- Rogers v. Koons
- Court did not consider this fair use.

Case #4 – Poster vs. Photo

- Leibovitz v Paramount Pictures
- Ruled fair use

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Law of Trademarks and Domain name issues

Trademarks


NESCAFÉ
DECAFFEINATED
SAINSBURY'S
FULL ROAST
DECAFFEINATED
DIGESTIVE
Digestive
diet Coke
SAINSBURY'S
Diet
Classic
Cola
Ambrosia
CREAMED
RICE
PUDDING
ASDA
Creamed
RICE
PUDDING
ASDA
Chocolate
Cadbury's
Bournville

Why Brands ?

- To protect the public so that it may be confident in getting the product which it asks for and it wants to get.
- To protect an owner's investment from misappropriation by pirates and cheats
- Trademark helps customers to select goods. By identifying the source of goods, they convey valuable information to consumers

How Brands connect ?

- Functional Benefit - A BMW automobile include power, excellent brakes and great cornering ability
- Emotional level – BMW Engine sound and sensations of excitement that come from accelerating down an open highway
- Self Expressive sense - A BMW owner feels his or her own success resulting from ownership of an expensive and distinctive vehicle

Brand value

- When Philip Mores bought Kraft, the maker of cheese, the price was 12.9 Billion US $ for the brand names, which was four times Kraft's tangible assets
- Nestle paid 2.5 Billion US $ for the brand name KITKAT, which was 5 times Rowndstree's book value
- In the Life Insurance joint venture between Bajaj Auto and Allianz of Germany, a premium of Rs. 72 crores has been paid to Bajaj Auto for using the brand name BAJAJ in the life Insurance business by the joint venture

TRADE MARKS

- Device, heading,
- Label, ticket, name, signature,
- Word, letter, numeral
- Shape of goods, packaging or
- Combination of colours or any
- Combination thereof.
- Services
- **New act - Trade Marks Act, 1999**

A Device


Windows Vista

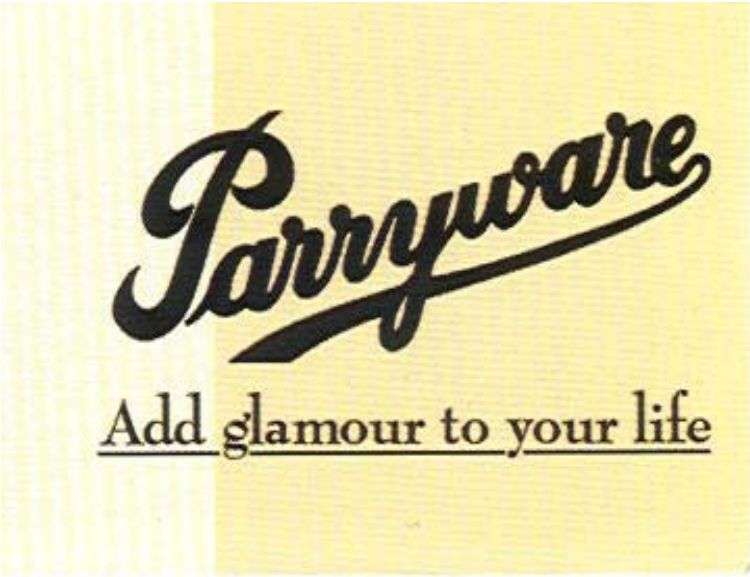

CHAVI
चावी
SUPERIOR
QUALITY
DAMP-PROOF
PRICE RE. 0-05.
TENZING MATCH WORKS, TIRUTTANGAL.
SAFETY MATCH

Heading

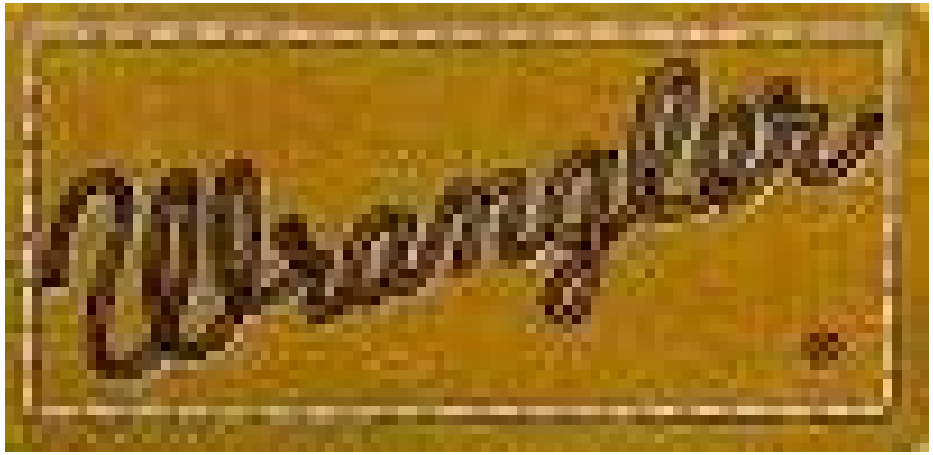
DR. REDDY'S

LIFE. RESEARCH. HOPE

Labels



Tickets



NAME

Signature

Word – Dictionary &Invented

Word

Number

Shape of Goods

Packaging

Combination of Colour

Services

NALSAR

What does not constitute a TM

- A trademark should NOT have the following features:

- a) It should NOT be deceptively similar to any other existing mark
- b) It should not be a descriptive of the goods.
- c) It should NOT be a word that defines the nature of the product
- d) It should not be the name or the surname of a person
- e) It should not be a geographical name

How do you acquire a Trade Mark ?

- You can apply on various categories permitted under the law
- The mark if it is a word has to be distinctive than descriptive
- E.g. apple cannot be for apples but can be for computers
- Invented words get protection across the categories

TRADE MARK

- A Dictionary Word can be given as mark to others in other categories
- If it is an invented word the holder gets the exclusive right across all categories
- Eg. **INVENTED WORD- KODAK, DUREX**

How do you acquire a Trade Mark ?

- You can use a mark without registration
- It establishes you as a senior player
- However it only allows you to stop others of using your mark
- Registration of mark allows you to claim damages and profits of the infringer
- Registration to be done with the Trade mark registrar

Infringement of Trademark

- The test laid down by the Supreme court is a person of average intelligence with imperfect memory – Amritdhara case AIR 1963 SC 449. This test is followed by the Supreme Court and by various High Courts all over India.

LET US PLAY THE JUDGE—
CASTROL VS PENTAGON
IS THERE ARE INFRINGEMENT ?

NYLE VS KAMILL- IS THERE AN INFRINGEMENT ?

SABENA VS SUBEENA
IS THERE AN INFRINGEMENT ?

Marks different – Get up same
CASTROL VS PENTAGON

- Where the marks are different, but the colour scheme, get up and layout are identical, injunction has been granted in a suit for passing off.

- Castrol Vs. Pentagon Lubricants – C.S. No. 327 of 1999 – Order of Mr. Justice A. Ramamurthi dated 22.12.1999. The Learned Judge observed that in view of the colour scheme, packing being identical, an ordinary person would assume that the defendants' goods also emanate from Castrol.

NYLE VS KAMILL

- Beauty Cosmetics Vs.Kamil cosmetics – C.S. No. 415 of 1998 Mr. Justice Akbar Basha Khadiri
  by an order dated 25th June 1998 granted an injunction restraining Kamil Cosmetics from selling Shampoo with a label similar to Nyle Shampoo label although the marks Nyle and Kamil are completely different

Marks similar, getup similar

- Scientific Compounds Vs. Hanuman Cottage – (2001) 1 CTMR 403
- Mr. Justice A.K. Rajan of Madras High Court granted an order of injunction in a suit for infringement and passing off on the ground that the trade marks SABENA and SUBEENA are similar, the colour scheme, getup are similar.

Geographical Indications- Appellation of origin

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What is Geographical Indication ?

- Geographical Indication is a notice which notifies that a product originates from a geographical area which could be an agricultural product or an industrial product.It is a method of IP protection by a decree or by a register.

Why GI ?

@ To inform the consumers the origin and also to protect them from deceptive goods or products.

@To protect the market of the producers

@To Promote the economic prosperity and a fair share of the products and goods of a region which enjoys the reputation.

Appellation of origin

- An appellation is a geographical indication that declares the quality of the goods for which it is used to be derived from essentially or exclusively from the area of production.
- All application of origin are geographical indication, but not all geographical indication are appellation of origin.

Some examples

- Darjeeling tea(India)
- Scotch Whisky (scotland)
- Champagne (France)
- Kancheepuram Saree (Kancheepuram

Geographical Indications of Goods (Registration and Protection) Act 1999

- Geographical Indication, in relation to goods, means an indication which identifies such goods as agricultural goods, natural goods, or manufactured goods as originating, or manufactured in the territory of a country or a locality in that territory, where a given quality, reputation or other characteristic of such goods is essentially attributable to its geographical origin and in case where such goods are manufactured goods one of the activities of either the production or of processing to preparation of the goods concerned takes place in such territory, region, or locality as the case may be.

- The office for registration of Geographical indications for the whole of India is located only at Chennai.
- Any Association of persons or producers or any organization or any authority established by or under any law for the time being in force representing the interest of producers of the concerned goods can apply for registration.
- .

Contd…

- Once the application is accepted, it is advertised in a journal and can be opposed by any interested party within a total period of four months from the date of advertisement

- If the mark is not opposed or the opposition is dismissed, the mark will proceed to registration with effect from date of filing of the application. The certificate of registration would be issued.
- The registration is valid for a period of 10 years and can be renewed from time to time.

Contd....

- The most important feature of this Act is the provision for registered users. If a co-operative Society registers Darjeeling for tea or Coorg for coffee, every plantation owner in Assam or Kodagu can become registered user authorise to use the name indicating the origin of the product with particular quality, characteristic and distinctiveness.

Indian GI

- In India there are several internationally well reputed indications such as Kancheepuram for silk sarees, Mansoon Coffee for the coffee exported from Malabar Coast, Darjeeling Tea, Pochampally Cotton, and may be Tirunelvelli Halwa.
- In order to register these internationally well known geographical indications, you should have standards fixed, the geographical areas defined and a proper apex society formed, which should be the owner of the named and the actual users become registered users.

- For Eg. If you take Kancheepuram saree there should be available standards fixed such as quality of zari used, the weight of the silk, the quality of the dye whether eco friendly vegetable dye or chemical dye with certain parameters regarding toxicity, the weave and the waft and the districts of Tamil Nadu wherein only Kancheepuram saree can be woven. May be any of you are not aware that a Kancheepuram saree can be only of lengths 6 yards, 8 yards and 9 yards. You cannot have a saree of the length of your choice – a genuine Kancheepuram Saree.

- The standards should be fixed by Textile experts in consultation with the weavers who are involved in day to day weaving of sarees. The standard should be published and should be easily accessible.
- After the standards are fixed, an Apex body should be formed, which would become the applicant and proprietor of the geographical name, Kancheepuram in respect of silk saree.

- Each co-operative society and may be the individual weavers can become registered users authorised to call their saree, Kancheepuram Saree provided, the standards of quality are followed. Otherwise, in the international market, you cannot maintain monopoly over the word “Kancheepuram”.

AGRICULTURAL GOODS

- RICE - BASMATI, NELLORE, DEHRADUN
- WHEAT- PUNJAB
- FRUIT- ALPHONSO, DASERI, RATNAGIRI, BIHAR LICHIS, NAGPUR ORANGES
- VEGETABLES, BANGALORE BRINJAL, CALICUT GINGER
- MILK - ANAND
- SPICES- MALBAR PEPPER

NATURAL GOODS

- COAL - NEW CASTLE
- LIGNITE- NEYVELLI
- GOLD - KOLAR, JOHANNESBURG, S. AFRICA
- PETROLEUM - ARABIAN

MANUFACTURED GOODS

- SARI - BANARAS, KANCHIPURAM
- SLIPPER - KHOLAPUR
- LOCK - ALIGARH
- SHIVAKASHI - MATCHWORKS
- SHOLAPUR - BEDSHEETS
- MYSORE - SANDAL WOOD
- GOA - FENI

FOOD STUFFS

- BENGAL - RASGOLLA
- BIKANEER - BHUJIA
- ANDHRA - PICKLES
- WARNA - SHRIKAND
- AGRA - PETHA

TEN STEP GUIDE FOR REGISTRATION

1. FILING OF APPLICATION
2. PRELIMINARY SCRUTINY
3. CONSTITUTION OF CONSULTATIVE GROUP OF EXPERTS
4. EXAMINAT ION
5. SHOW CAUSE NOTICE
6. PUBLICATON IN GI JOURNAL
7. OPPOSITION
8. REGISTRATION
9. APPEAL
10. RENEWAL

Protection of plant varieties & Farmers rights

Differing concepts of resources and ownership

Plant – cultivated, wild or managed

Botanical variety

Genome

Knowledge about use and management

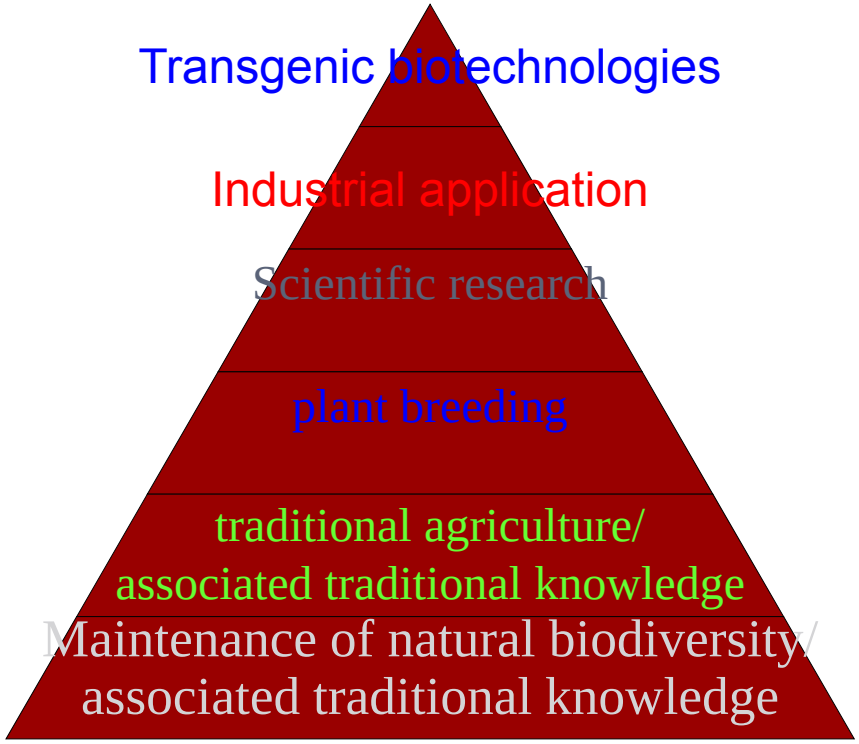
property, access control, resource sovereignty (visa, permit)

Variety right

Patent right

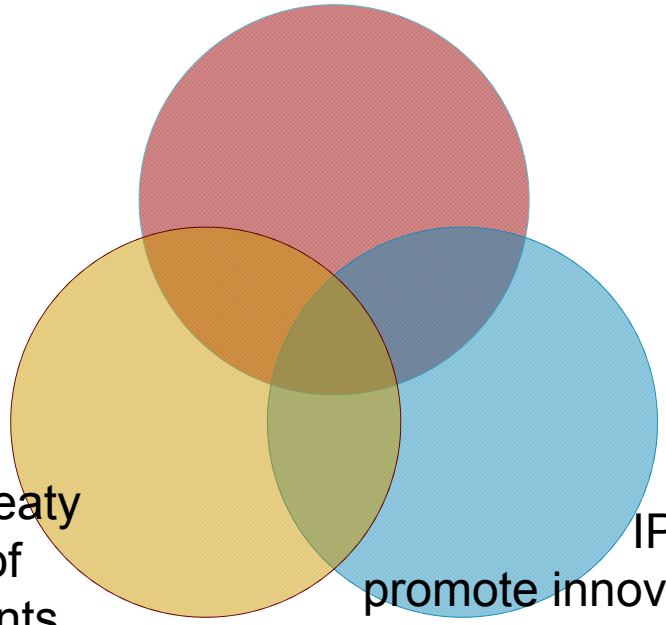
Knowledge and cultural rights

The Pyramid of stake holders



Overlapping international mechanisms

Convention on Biological Diversity:
In situ conservation



FAO – International Treaty
access to and use of
exotic agricultural plants
in germplasm collections

IP system and TRIPS
promote innovation, development of innovatio
transfer and dissemination of technology

Protection of Plant Varieties and Farmers Rights Act of 2001

- **Plants produced through conventional breeding such as crossing and selection are considered biological and would not be protected.**
- **Plant varieties through biotechnological methods, genetic manipulation, gene insertion or transfer can be protected.**
- **Concept of non-biological process is very complex and new.**
- **The variety should be distinct, new, homogenous and stable.**

PPVFR ACT 2001

- The Act provides for registration of a new variety, which does propagation.
- not contain any gene or any gene consequences involving terminator technology.

The Act provides for protection to distinct and new plant varieties asexually produced.

- The new variety should be distinct, it is clearly distinguishable by at least one essential characteristic from any other variety whose existence is a matter of common knowledge.
- The new variety should be uniform in its essential characteristic.
- Should be stable, its essential characteristic remains unchanged after repeated cultivation

PROTECTION OF PLANT VARIETIES AND FARMERS' ACT 2001.

- **New variety can be registered with a denomination.**
- **Criteria for registration of denomination is similar to trademark registration.**
- **Each applicant should make available with application such quantity of seeds of variety for purpose of conducting tests.**
- **On acceptance of an application it would be advertised.**
- **Is subject to opposition by any person within a period of three months from date of advertisement.**

PROTECTION OF PLANT VARIETIES AND FARMERS' ACT 2001.

- Registration is valid for 9 years in case of trees and vines.
- For a period of 6 years in case of other crops.
- Maximum protection granted in case of trees and vines is 18 years.
- In case of extant varieties 15 years.
- In other cases 15 years.

PROTECTION OF PLANT VARIETIES AND FARMERS' ACT 2001.

Registration grants exclusive rights on the breeder or his successor or his agent or licensee to

- Produce
- Sell
- Market
- Distribute
- Import or export
- Variety.

- The Act provides for a Register called National Register of Plant Varieties at the head office of the Plant Varieties Registry wherein shall be entered:-
- The names of all the registered plant varieties with names and addresses of their respective breeders;
- The right of such breeders in respect of the registered variety;
- The particulars of the denomination of each registered variety;
- Its seed or other propagating material along with specification of salient features thereof
- And such other maters as may be prescribed.

Applicant

- Breeder of the variety
- Any successor of the breeder of the variety
- Assignee of the breeder of the variety
- Farmer or group of farmers or community of farmers claiming to be breeder of the variety.
- Any University or funded Agricultural Institution claiming to be breeder of the variety.

Farmers' Rights

- Farmer who has bred or developed a new variety is entitled to registration and protection like a breeder.
- Farmer shall be entitled to save, use, sow, resow, exchange, share or sell his farm produce including seed of a variety protected under this Act in the same manner as he was entitled before the coming into force of the Act.

Rights of Communities

- Any person, group of persons or any Governmental or non-governmental organization may on behalf of any village or local community in India file application for protection of any claim attributable to the contribution of the people of that village or local community in the evolution of any variety.
- Farmer or Group of farmers or village or community shall not be liable to pay any fee.

Disclosure

- Breeder or any other person applying for registration shall disclose in the application information regarding use of genetic material conserved by any Tribal or rural families in the breeding or development of such variety.
- Non-disclosure of such information would lead to rejection of the application.

Gene fund

- National Gene Fund shall be constituted by the Central Govt. for meeting.
- Any amount paid by way of benefit sharing.
- The compensation payable.
- The expenditure for supporting the conservation and sustainable use of genetic resources including in situ and ex situ collections.
- The expenditure of the scheme relating to benefit sharing.

Compulsory License

- Compulsory license to undertake production, distribution and sale of the seed or other propagating material of the variety can be filed to the authority after expiry of 3 years from date of issue of certificate of registration on the ground that
- Reasonable requirements of the public for seeds or other propagating material of the variety have not been satisfied.
- The seed or other propagating material of the variety is not available to the public at reasonable price.

The Law of Trade Secrets

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What is a trade secret?

- A trade secret must be something that is
  - Used in business that gives the owner a competitive advantage
  - Guarded from disclosure
  - Not common knowledge

1. A Trade Secret is information that gives a competitive advantage

(Any formula, pattern, device or compilation of information.)

Things like:

- Customers lists
- Client information
- Formulas
- Blueprints
- Recipes

cont' d

- Processes for manufacturing, treating, or preserving materials
- Methods for production of goods
- Methods of offering services
- Patterns for machines or devices
- Marketing Plans and Strategies
- Bidding systems
- Technology/Training/Service manuals

2. Trade secrets must be guarded from disclosure

- Because there is no formal method of protecting a trade secret, to be considered a trade secret, the information must be <u>treated</u> as a secret.

- It is always the burden of the person claiming trade secret status to prove secrecy.

3. A Trade Secret must be information that is NOT common knowledge

- Advertiser lists
- "Sales pitches" used to solicit clients
- General ideas
- Compilation of public domain information
- Client lists or leads that could be discovered by independent means or are generally known in the industry

What are some of the basic differences between trade secrets and patents?

- Patent- open disclosure & lasts 20 years
- Trade Secrets- guarded- may be infinite
- Patents- 20 years monopoly
- Trade secrets- competitors can work it independently
- Patents- strict conditions for award
- Trade secrets- no need to meet conditions and can have commercial gains

LETS PLAY THE JUDGE- CASE #1

- FOREST LABORATORIES, INC. v. PILLSBURY CO.United States Court of Appeals, Seventh Circuit, 1971. 452 F.2d 621, 171 USPQ 731
- FACTS OF THE CASE-
- FOREST LABS HAD GIVEN A TRADE SECRET OF MAKING TABLETS TO TIDY HOUSE CORP TAKEN OVER BY PILLSBURY
- FOREST ACCUSED PILLSBURY OF VIOLATING THE TRADE SECRET BY ACQUIRING ALONG WITH THE ASSETS OF TIDY HOUSE
- IS THERE A TRADE SECRET VIOLATION

LETS PLAY THE JUDGE- CASE #2

- E.I duPONT deNEMOURS & CO., INC. v.CHRISTOPHER-United States Court of Appeals, Fifth Circuit, 1970.431 F.2d 1012, 166 USPQ 421, cert.denied 400 U.S 1024, 91 S.Ct.581, 27 L.Ed.2d 637(1971
- FACTS
- CHRISTOPHER AN AERIAL PHOTO SPECIALIST TOOK PHOTOS OF DU PONT PLANT
- DUPONT ACCUSED TRADE SECRET VIOLATION
- CHRISTOPHER CONTENDED THAT NO RULES WERE VIOLATED OF THE AIR SPACE WHICH IS PUBLIC AND HE HAS A LICENCE TO FLY FOR AERIAL PHOTOGRAPHY

LETS PLAY THE JUDGE- CASE #3

- EMERY INDUS., INC. V. COTTIER United States District Court Ohio,1978. 202 USPQ 829.

- FACTS
- COTTIER WORKED FOR EMERYIN O3 TECHNOLOGY AND JOINED ANOTHER COMPETITOR
- EMERY PLEADED FOR RESTRAINT OF EMPLOYMENT AS IT INVOLVED TRADE SECRET

JUDGEMENT- FOREST LAB VS PILLSBURY

- PILLSBURY IS NOT THE SUCCESSOR FOR TRADE SECRETS OF TIDY
- SHOULD HAVE NEGOTIATED SEPERATELY WITH FOREST
- TIDY CANNOT GIVE A TRADE SECRET IN USE

JUDGEMENT- DUPONT VS CHRISTOPHER

- CHRISTOPHER'S ACTION IS BY IMPROPER MEANS
- SHOULD DISCLOSE THE CLIENT TO KNOW THE INTEREST IN THE TRADE SECRET
- DISTASTEFUL MEANS WILL ALSO BE A VIOLATION OF TS

JUDGMENT- EMERY VS COTTIER

- THERE IS TRADE SECRET INVOLVED
- CAN RESTRAINT COTTIER
- EMERY TO PAY THE SALARY OF COTTIER FOR THE PERIOD OF RESTRAINT

Conclusion:

- Any Questions?
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