関西特許研究会

KTK NEWS 2012 1

平成24年1月1日発行

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－ＫＴＫ １月・２月の会合予定－

１月・２月に開催する会合についてお知らせいたします。
なお、**１月・２月に開催する会合は、詳細をＫＴＫのホームページに掲載しています。**

※資料・会場手配の都合上、会合・懇親会等について、**出席ご希望の場合は事前にお知らせ下さい。**
キャンセルの場合もご一報下さい。懇親会費用は、原則各自負担となります。

※会合の申込方法について

近年、ＫＴＫでは、開催する会合の数が年々増加しており、出席者管理の効率化を推進することが求められています。従前のようなＦＡＸでの申込みでは、充分な管理を行うことができないため、この度、**ＫＴＫホームページからの申し込みを原則**とすることに変更させていただくことになりました。

会員の皆様のご理解とご協力をお願いいたします。

なお、従前通り、ＦＡＸでのお申し込みも可能です。ＦＡＸによりお申し込みをされる場合には、３ページの申込用紙をコピーしてお使いください。

－ＫＴＫホームページ－　**http://ktk-ip.com (ID:2005　パスワード：ktkmembership)**

１月会合案内　英文明細書研究班

１．日　時：平成24年１月11日(水) ６:30～８:30p.m.
２．場　所：日本弁理士会近畿支部室
３．テーマ：「米国特許法－判例による米国特許法の解説－」
４．担　当：三崎　伸吾　会員
５．テキスト：「米国特許法－判例による米国特許法の解説－」山下　道綱　著
６．範　囲：P467～489
７．概　要：第11章　特許侵害に対する抗弁
※担当者以外は予習の義務はありませんが、上記範囲に目を通しておいて下さるほうが望ましいです。

（槻尾　泰信　記）

１月会合案内　医薬・バイオ特許研究班

１．日　時：平成24年１月24日(火) ７:00～９:00p.m.
２．場　所：日本弁理士会近畿支部　会議室
３．テーマ：医薬・バイオ特許に関する研究
４．担　当：未定
５．テキスト：改訂第４版　化学・バイオ特許の出願戦略（細田芳徳著/財団法人経済産業調査会）
６．範　囲：予定/テキストP271～310（新規性と先願範囲の拡大）
７．内　容：テキスト輪読、審査基準の確認

（中西　博行　記）

―― 会合案内 ――

2月会合案内　医薬・バイオ特許研究班

1．日　時：平成24年2月2日(木) 6:30～8:00p.m.
2．場　所：日本弁理士会近畿支部　会議室
3．テーマ：医薬・バイオ特許に関する研究
4．講　師：市岡　牧子　先生
5．内　容：「世界の特許出願時の遺伝資源の出所開示に関する法律についての運用の調査報告」
最新の世界の特許出願時における遺伝資源の出所開示に関する法律についての運用を紹介する。

（中西　博行　記）

2月会合案内　意匠実務研究班

1．日　時：平成24年2月9日(木) 6:30～8:30p.m.
2．場　所：日本弁理士会近畿支部室
3．テーマ：(1)　部分意匠について
(2)　意匠審決について
4．講　師：(1)　松井　宏記　会員
担　当：(2)　垣木　晴彦　会員
5．概　要：
(1)　では、部分意匠について具体的な登録事例を紹介しながら、実務上どのように部分意匠を活用するのが妥当であるかについて議論ができればと思います。
(2)　最近の意匠審決を担当者がピックアップすることにより、審決ではどのように判断されているかについて確認すると共に、当該審決の内容の妥当性などについて議論できればと思います。

（垣木　晴彦　記）

2月会合案内　商標審判決研究班

1．日　時：平成24年2月23日(木) 6：30～8：30p.m.
2．場　所：日本弁理士会近畿支部　会議室
3．担　当：小野　正明　会員、太田　知二　会員
4．テーマ：商標・不正競争に関する審判決の研究
5．内　容：最近の商標の審決および商標・不正競争に関する判決を数件ピックアップし、各担当者に事件を説明していただいた上で、参加者の間で自由に議論します。取り上げる審判決は、会合日から最近2ヶ月以内の事案。一覧表にして報告いただきます。

（松井　宏記　記）

ＦＡＸ　：　０６－６２２３－２２５７　　平成　　年　　月　　日

北浜国際特許事務所　前井 宏之　行

ＫＴＫ会合申込用紙
（ＦＡＸ送信）

事務所（会社）名：＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿

氏名：＿＿＿＿＿＿＿＿＿＿＿＿　電話番号：＿＿＿＿＿＿＿＿＿＿＿＿

１．会合出席予定

※ 参加をご希望される会合の名称（部会又は研究班の名称）、開催日、及び、懇親会への参加の有無を、以下にご記入下さい。

※ 資料・会場手配の都合上、会合出席ご希望の場合は事前にお知らせ下さい。併せて懇親会の参加・不参加も事前にお知らせ下さい。事前連絡がない場合、参加をお断りさせていただく場合がございます。
キャンセルの場合もご一報下さい。懇親会費用は、原則各自負担となります。

会合名：＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿

会合開催日：　平成　　年　　月　　日

懇親会：　参加　・　不参加　（何れかに○をつけて下さい）

２．通信欄（連絡事項があればご記入下さい。）

Inventions Biotechnology and Pharmaceuticals and Chemicals- Specific peculiarities

By
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SINGLE WINDOW TO THE INDIAN SUBCONTINENT

Bangladesh, Pakistan, Sri Lanka, Myanmar, Nepal, Maldives, Bhutan.

DEFINITION OF INVENTION:

THE PATENTS (AMENDMENT) ACT, 2005-.

Section 2(1) (j)

"invention" means a new product or process involving an inventive step and capable of industrial application;

Therefore, the criteria for an invention to be patentable are,
(1) An invention must be novel
(2) has an inventive step and
(3) is capable of industrial application

Section 2(1) (ja):

"inventive step" means technical advancement which makes the invention not obvious to a person skilled in the art.

BIOTECHNOLOGY

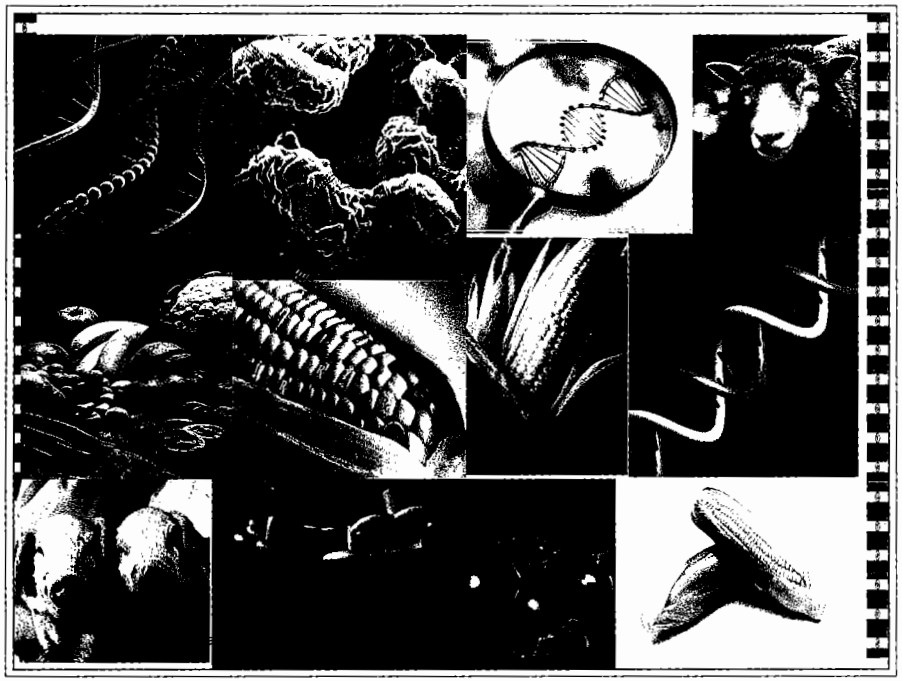
Biotech Industry Facts in India

Globally India is in the list of top 12 biotech markets and it is **3rd** in Asia Pacific region. (Over 280 biotech companies)

2% share of the global biotechnology industry.

By 2015, the total size of biotechnology industry in India will touch US$ 25 billion.

Rise in domestic business, new innovations and increase in exports has caused the 18% growth in the year 2008-09.



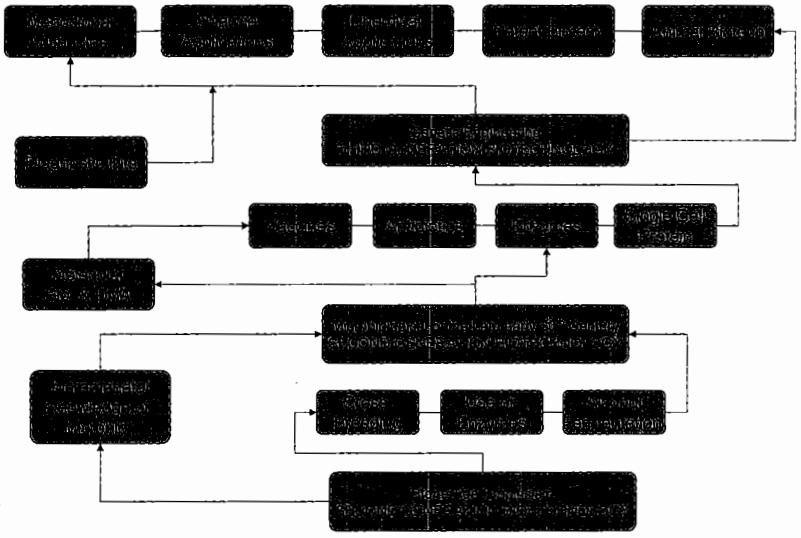
PATENTING OF BIOTECHNOLOGICAL INVENTIONS IN INDIA

6

CLASSIFICATION OF BIOTECHNOLOGICAL INVENTIONS

7

DOMAIN OF BIOTECHNOLOGICAL RESEARCH AND APPLICATION AREAS



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INDIAN PATENTING TREND

Table 1 Patents granted to Indian organizations by the USPTO and IPO during 1990-2008

Sectors	USPTO (% share)	IPO (% share)	Total patents
Chemical	278 (43%)	1073 (22%)	1798 (33%)
Pharmaceuticals	219(34%)	1579 (32%)	1351 (25%)
Machinery	28 (4%)	691 (14%)	719 (13%)
Instruments	17 (3%)	200 (4%)	217 (4%)
Biotechnology	*53 (8%)*	*130 (3%)*	*183 (3%)*
Transport	6 (1%)	122 (2%)	128 (2%)
Electrical equipment	1 (0.15%)	99 (2%)	100 (2%)
Electronics	9 (1%)	74 (2%)	83 (2%)

It has been observed from the Table 1 that chemicals and pharmaceuticals were the major areas in which Indian organizations had obtained patents. However, it has also been observed that Indian organizations also got patents in biotechnology.

Section 3: What are not inventions

Section 3(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"

e.g. Functional Antibodies

Section 3 (h):

"a method of agriculture or horticulture"

e.g. Method of production or Propagation of plants

Section 3: What are not inventions

Section 3 (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"

e.g. Method of treatment

METHOD OF TREATMENT/DIAGNOSIS

Diagnostic Method/Process is not patentable, the Indian Patent Office's purview is that since no diagnostic method on its own can render human being or animal free of disease.

The "method of treatment" or "method of diagnosis" claims in India are strictly not permissible.

The possible variant of such claims that are permissible by the Indian Examiners are the "kit" claims.

Section 3: What are not inventions

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 of propagation of plants and animals"

e.g. Cell, Tissue, Organ

ESSENTIALLY BIOLOGICAL PROCESS

Essentially biological process is defined as the one that "consists entirely of natural phenomena such as crossing or selection".

The decisive factor for categorizing a process as essentially biological process or non-essentially biological process depends on the amount of human intervention involved and its impact on the final result.

BIOLOGICAL MATERIAL

The isolated (discovered) biological material does not constitute a patentable subject matter by IPO despite the fact it is characterized by specific utility.

The biological material genetically modified preferably through substantial human interventions are patentable.

PATENT PROTECTION FOR PLANTS

Under section 3(j) of the Indian Patents Act, 1970 "plants and animals in whole or any parts thereof" are excluded from patentability.

In accordance with the TRIPS Agreement, India has enacted "Protection of Plant Varieties and Farmers' Rights' (PVPFR) Act, 2001" which is a *sui generis* system of plant variety protection.

Section 3: What are not inventions

Section 3(k):

"a mathematical or business method or a computer programme per se or algorithms"

e.g. Bioinformatics Tools

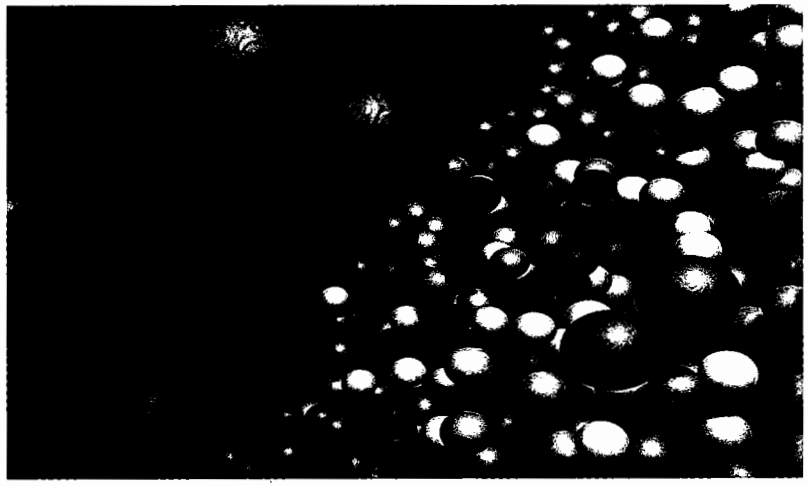
Section 3: What are not inventions

Section 3(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"

e.g. Turmeric or Neem for therapeutics

BIOTECHNOLOGICAL DOMAINS



PATENTABLE BIOTECHNOLOGICAL DOMAINS

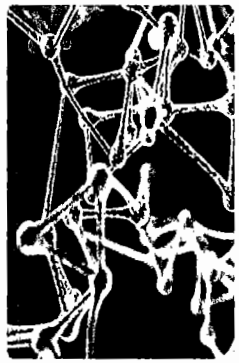
1. Genetic engineering process such as:
   - A process for recombinant production of a growth hormone
   - A modified interfering Ribonucleic acid molecule
   - A recombinant modified virus with proper genetic intervention
   - A recombinant plastid vector
2. Polypeptides such as
   - Markers
   - Antibodies
   - Vaccines

PATENTABLE BIOTECHNOLOGICAL DOMAINS

3. Method of isolation of microorganisms from culture medium;
4. Method of mutation;
5. Host cells (if transformed with a cloning/expression vector)
6. Mutants;
7. Plasmids

NUCLEIC ACID/ AMINO ACID SEQUENCES

- Must be Novel
- Involve Human intervention
- Must have a Utility



PATENTABLE NUCLEIC ACID FORMS

- cDNAs
- Promoters
- Enhancers
- Individual exons
- Expressed Sequence Tags (ESTs); only as probes
- Diagnostic kits

MICRO-ORGANISMS

The microorganisms are patentable, if:

- isolated,
- mutated,
- adapted and
- recombined successfully

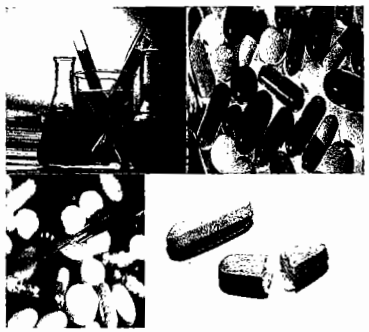
WHAT INDIAN PATENT OFFICE SAYS ABOUT BIOTECHNOLOGICAL PATENTABILITY?

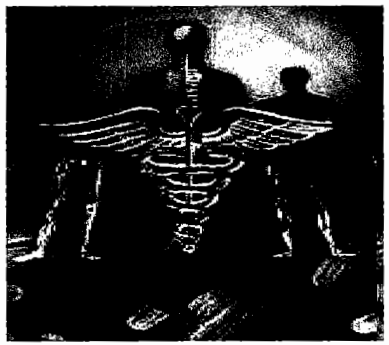
BIOTECHNOLOGICAL INVENTIONS	NON PATENTABLE	PATENTABLE
Living entities of natural origin	√	×
Seeds	√	×
Plants in whole or there part thereof	√	×
Plant Varieties	√	×
A method of treatment or diagnosis	√	×
A substance freely occurring in nature, if merely found or discovered	√	×
Any process of manufacture or production relating to living entities	√	×

Contd.

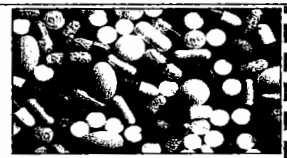
BIOTECHNOLOGICAL INVENTIONS	NON PATENTABLE	PATENTABLE
Micro-organisms	×	√
Cell line (if artificially produced)	×	√
Recombinant DNA, RNA, amino acid	×	√
Hybridoma Technology except protoplast fusion	×	√
Expressed Sequence Tags (ESTs), if it works as a probe	×	√

PHARMACEUTICAL





Some Facts .....



Indian pharmaceutical industry -

4th largest in volume.

13th largest (value wise), Growth rate-about 13%.

Worth $17.5 billion by 2008-domestic $11.5, export - $ 6 billion.

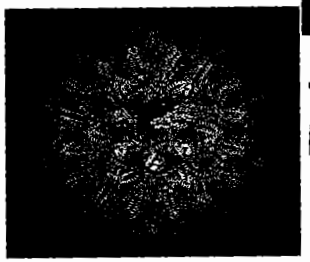
Contributes 22% to world's generic drugs market.

80% Ingredients used by US manufacturers- produced in India and China.

More than 100 US FDA approved plants- highest outside USA. *(More than combined total of China and Italy)*

Major Therapeutic Areas of Research and Development in India

ANTIDIABETICS- highest growth rate of 26.1%
CARDIOVASCULAR-growth rate 21.3%
GYNAECOLOGY- growth rate 18.3%
ANTIVIRAL
ANTI CANCER
HIV/AIDS
GASTROINTESTINAL
* Source: ORGIMS data



R & D EXPENDITURE

R&D Expenditure (Rs crore) one crore Rupees=0.25 million US$ (approx)	R&D Exp. Yearly	% to turnover Yearly
	276.12	7.3
	0.0	0.0
	226.05	13.0
	55.86	3.9
	48.68	3.6
	45.99	3.9
	88.2	7.5
	107.68	10.2
	60.41	7.9
	39.65	5.6
Total	948.64	

NUMBER OF PATENT APPLICATIONS FILED DURING LAST FIVE YEARS FROM 2002-03 TO 2006-2007 UNDER VARIOUS FIELDS OF INVENTIONS

Year	Chemical	Drug	Food	Electrical	Mechanical	Computer/ Electronics	Biotechnology	General	Total
2002-2003	776	966	119	690	1,257		46	562	4,416*
2003-2004	2952	2525	123	2125	2717		23	2148	12613
2004-2005	3916	2316	190	1079	3304	2787	1214	2659	17466
2005-2006	5810	2211	101	1274	4734	5700	1525	3150	24505
2006-2007	6354	3239	1223	2371	5536	5822	2774	1621	28940

* Excluding PCT National Phase Applications

COMPARISON CHART OF PRICES OF SOME MAJOR DRUGS

Comparison chart of prices of some major drugs-

Drugs/Brands	Company	India	Pakistan	Indonesia	UK	USA
Ranitidine (Zantac) 150mg x 10s Times costdier	Glaxo	7.16	122.16 (300 mg) (17.06)	658.85 (37.86)	320.85 (44.81)	739.60 (103.30)
Diclofenac Sodium (Voveran) 50mg x 10s Times costdier	Ciba Gergy	5.64	56.74 (10.06)	177.18 (27.30)	125.88 (22.27)	505.68 (89.66)
Piroxicam (Dilonex/ Feldene) 20 mg x 10s Times costdier	Pifizer	24.64	78.30 (3.18)	218.45 (8.86)	240.12 (9.75)	1210.88 (49.14)

DATE OF LAUNCH OF DRUGS BY THE INVENTOR IN THE INTERNATIONAL MARKET AND CORRESPONDING DATE OF LAUNCH IN THE INDIAN MARKET BY INDIAN COMPANIES

DRUG	INTRODUCED (YEAR) IN World Market by the Inventor	India Market by Domestic Co.'s
1. Ibuprofen	1967	1973
2. Salbutamol	1973	1976
3. Mebendazole	1974	1976
4. Rifampicin	1974	1980
5. Bromhexin	1976	1982
6.. Naproxen	1978	1982
7. Ranitidine	1983	1985
8..Norfloxacin	1984	1988
9. Ciprofloxacin	1985	1989
10..Astemizole	1986	1988

Non-Patentable Subject-Matter

All fields of technology are patentable

Section 3 and 4: What are not inventions

- Section 3(b): Contrary to public order and morality
- Section 3(c) – discovery of living things
- Section 3(d) – new forms of a known substance
- Section 3(e) – composition-mere admixture
- Section 3(i) – method of treatment of animals and humans
- Section 3(j) – plants, animals and parts thereof and Essentially Biological Processes
- Section 3(k) – computer programs per se

HOW TO DEAL WITH THE TECHNICAL OBJECTION DURING PROSECUTION

A. i) Claims do not constitute an invention under Section 2(1) (j) of Indian Patents Act, 1970.

ii) Distinguishing features as compared with prior art given is not clear.

Solution:

i) if the Examiner has objected that the subject matter is lacking novelty and inventive step under Section 2(1) (j), we present submissions by providing more detailed differences between the present invention and the prior art, clearly stating the inventive step and bringing out the uniqueness of the invention

ii) if the Examiner asks to pin-point the novelty in the main claim, we revise the main claim and in very special circumstances insert "characterized in that" clause to pinpoint the novelty. The insertion of the "characterized in that" clause in the main claim implies that the entire pre-characterized portion relates to the prior art and the post-characterized portion relates to the novel and inventive features of the invention.

A) Claims fall within the scope of Section 3(c) of Indian Patents Act, 1970.

" The mere discovery of a scientific principal or the formulation of an abstract theory or discovery of any living thing or non-living substances occurring in nature"

Solution: To escape from the purview of Section 3(c) the subject matter and the wordings of the claims should be such that mere discovery should not reflect in the claims.

The Applicant is required to show substantive human intervention in the invention and involving a structural modification.

B) Claims fall within the scope of Section 3(d) of Indian Patents Act, 1970.

Section 3(d):

"The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant."

Explanation- for the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;

Solution

If the claimed invention falls under the category of above quoted Section, the Examiner expects to be provided with submissions as to how the claimed invention is not a mere discovery of a new form of a known substance and further arguments and evidence to show enhanced efficacy of the prior substance and the new substance.

If the subject matter is objected under this Section, we present before the Examiner the difference in terms of the therapeutic effect of the prior drug/composition in contrast to the present drug/composition.

We are required to provide and properly disclose necessary comparative details with regards to efficacy between a new form of a known substance and original substance.

Efficacy is the ability to produce a desired amount of a desired effect OR success in achieving a goal. Also, efficacy should not be quantified in terms of numerical value.

To be Patentable a known substance has to incorporate at least one new reactant, which may result in the enhancement of its efficacy.

The Examples of new forms such as Isomers, Stereo Isomers, Homologues, Polymorphs, Metabolites, Pro drugs, Hydrate and Purification Compounds are defined in the manual.

The Examples of a known substance: amorphous to crystalline or crystalline to amorphous or hygroscopic to dried, or crystalline to crystalline having different crystalline structure or vice versa, one isomer to other isomer, metabolite, complex, combination of plurality of forms, salts, esters, ethers shall be considered same as of known substances unless such new forms significantly differ in the properties with regard to efficacy.

CASE STUDY-1

MAIN CLAIM AS ORIGINALLY FILED

1. Polymorph of a rifaximin characterized by a water content lower than 4.5% preferably between 2.0% and 3.0%, and by a powder X-ray diffranctogram showing peaks at value of the diffraction angles 20 of 6.6°; 7.4, 7.9°; 8.8°; 10.5°; 11.1°; 11.8°; 12.9°; 17.6°; 18.5°; 19.7°; 21.4°; 22.1°.

MAIN CLAIM AS ACCEPTED IN THE INDIAN PATENT OFFICE

An α-form of rifaximin characterized by powder X-ray diffractogram peaks at 6.6, 7.4, 7.9, 8.8, 10.5, 11.1, 11.8, 17.6, 18.5, 19.7, 21.4 and 22.1 degrees 2θ and by a water content lower than 4.5%.

HISTORY RELATED TO THE ABOVE CASE

The Indian Patent Office required detailed submissions to prove that the claims did not fall under the purview of section 3(d).

In order to point out that the novelty of the present invention, we submitted that the identification of polymorphic forms of rifaximin with an improved efficacy due to the novel bioavailable parameters.

The distinct polymorphic forms of rifaximin had significant advantages in terms of efficacy, in particular:

1. in case of severe infections due to invasive pathogens the γ-form might be preferred,
2. in case of less invasive pathogens the α-form might be preferred
3. in case of non-invasive pathogens the β-form might be preferred

In considering the overall efficacy of the polymorphic forms of rifaximin the reduction of adverse events proportional to the level of adsorption of rifaximin has to be included.

We submitted that the polymorphic forms of the present invention are novel and unique solid forms of rifaximin characterised by bioavailability parameters which differentiate these forms from any other coming from the state-of-art and among them.

Considering the above facts the Controller found that the conventional ways to generate polymorphic forms by modifying the crystallization condition such as solvents, temperature had been done away by the present invention.

Finally, the Examiner concluded that the Rifaximin form as claimed in the invention were different from the prior art and the subject matter was also not obvious to a person skilled in the art.

CASE STUDY -2

CLAIMS ORIGINALLY FILED

1. A pharmaceutical composition useful for the percutaneous delivery of an active pharmaceutical ingredient, comprising:-
   - A C1-C4 alcohol;
   - A penetration enhancer;
   - The active pharmaceutical ingredient; and
   - Water.

CLAIMS GRANTED

1.Method for making a dose packet containing a testosterone gel, comprising the steps of:

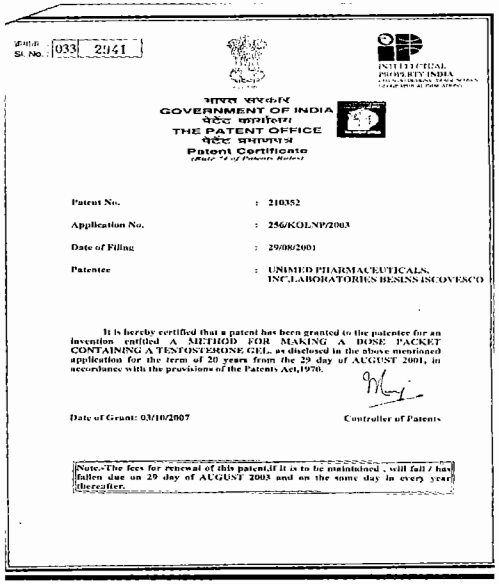
providing a foil packet comprising a polyethylene liner;
providing a transdermal testosterone gel comprising (w/w):
- 0.1 to 10 % of testosterone,
- 0.1 to 5.0 % of polyacrylic acid,
- 0.1 to 5.0 % of isopropyl myristate,
- 30 to 98 % of ethanol;

Contd..

Further adding isopropyl myristate to said gel in an amount of about 41% as compared to above amount of isopropyl myristate;

Placing said transdermal testosterone gel in said foil packet.

2. Method as claimed in claim 1, wherein the transdermal testosterone gel comprises (w/w):
   - 0.5 to 5.0 % of testosterone,
   - 0.1 to 2.0 % of polyacrylic acid,
   - 0.1 to 2.0 % of isopropyl myristate,
   - 40 to 90 % of ethanol.



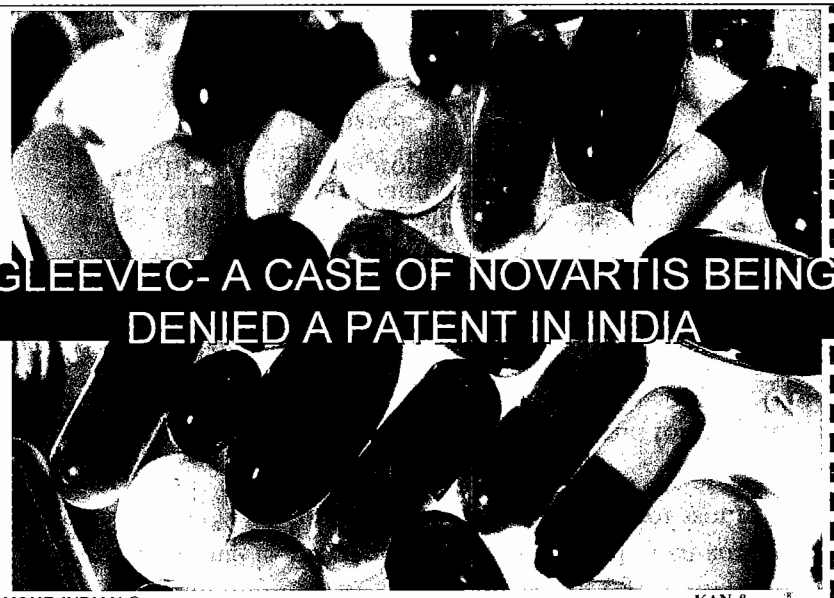
भारत सरकार
GOVERNMENT OF INDIA
पेटेंट कार्यालय
THE PATENT OFFICE
पेटेंट प्रमाणपत्र
Patent Certificate

Patent No. : 210352
Application No. : 256/KOLNP/2003
Date of Filing : 29/08/2001
Patentee : UNIMED PHARMACEUTICALS, INC.LABORATORIES BESINS ISCOVESCO

It is hereby certified that a patent has been granted to the patentee for an invention entitled A METHOD FOR MAKING A DOSE PACKET CONTAINING A TESTOSTERONE GEL, as disclosed in the above mentioned application for the term of 20 years from the 29 day of AUGUST 2001, in accordance with the provisions of the Patents Act,1970.

Date of Grant: 03/10/2007 Controller of Patents

Note.-The fees for renewal of this patent,if it is to be maintained , will fall / has fallen due on 29 day of AUGUST 2003 and on the same day in every year thereafter.



GLEEVEC- A CASE OF NOVARTIS BEING DENIED A PATENT IN INDIA

NOVARTIS- Rejection of Patent Application as well as EMR for Imatinib Mesylate[anti-cancer drug Gleevec]

The validity of Section 3 (d) of the Indian Patents was challenged by Novartis in its Petition before the Divisional Bench of the Chennai High Court being unconstitutional and not in conformity with the obligations of Indian Government under TRIPS.

The Petition of Novartis challenging the validity of Section 3 (d) of the Patents Act has been recently dismissed by the divisional bench of the Chennai High Court.

Contd...

Novartis filed an appeal against the decision of the Chennai Patent office rejecting its Patent Application under Section 3(d) of Indian Patents Act, 1970 filed in 1998, for Imatinib Mesylate (anti-cancer drug Gleevec) in Chennai Patent Office.

Against the said rejection Novartis filed appeal in the Chennai High Court.

After the Intellectual Property Appellate Board started functioning the Chennai High Court transferred the appeal to the Appellate Board.

Contd...

The Appellate Board upheld the decision of the High Court.

Novartis filed special Leave Petition before the Supreme Court of India.

Section 3 D ... A study

Section 3 lists what are not inventions under the Indian Patents Act, and thus it relates to "patent eligibility" and not "patentability".

The aim of Section 3(d) is to prevent trying to unduly extend a patent term by an invention which has no technical contribution i.e to prevent the so called "ever-greening".

Contd...

Therefore, it is clear that section 3(d) does not require A higher technical level than that the inventive step of section 2(1)(j). Thus, it is sufficient that if an invention shows remarkable effects which are unpredictable from the prior arts, the invention is regarded as meeting the requirements for Section 3(d).

Contd...

From the manner in which this section is worded, it will be apparent that in order that the highlighted portion of section 3(d) is attracted the following conditions must be satisfied:

What is claimed must be a mere discovery;

What is claimed must be a new form of a known substance; and

Such substance claimed does *not* result in increased efficacy over known substance.

If any of the above-mentioned three conditions are not met, section 3(d) cannot and should not be applicable.

Contd...

Mere discovery:

In contradistinction to the expression "invention" (defined in section 2(1)(j) of amended Indian patent act, 1970), the expression "discovery" has not been defined in any section of the Indian patent act or any rules there under.

Therefore, one of the logical conclusions to be derived with respect to the usage of the expression "discovery" in the act is that it has been used in the sense used in common everyday English language. "Discovery" is bringing to light something that existed before but was not known and "invention" is creation of something that did not exist.

Contd...

According to the webster's third international dictionary of the English language, the expression "discovery" refers to "the act, process or an instance of gaining knowledge of or ascertaining the existence of something previously unknown or unrecognised." Therefore, unlike "invention" which refers to a new product or process involving inventive step and capable of industrial application (section 2(1) (j) of the patents act, 1970), "discovery" essentially refers to finding out something which already existed in nature but was unknown or unrecognized.

Contd...

Accordingly, a claimed invention would have to relate to a something (be it chemical entity, biological sequence etc.) Which in some form or other existed in the natural environment to be considered a discovery.

Section 3(d) only prohibits the "mere discovery of new forms." "Discovering" a new form that already exists is very different from creating a new form. Therefore, new forms such as the present invention, does not fall within the purview of section 3(d): such new forms are "invented" or "created" and not "discovered."

Contd...

One might draw a distinction between new forms of existing substances that were merely discovered i.e Merely observed in that form, in its natural state, for the first time in the course of a search and new forms that were "invented" in the lab with the aid of human intervention. And argue that only the former would be subject to the section 3(d) hurdle and would therefore have to demonstrate significantly enhanced efficacy over the previously known substance in order to merit a patent.

INTERPRETATION OF "EFFICACY"

The Madras high court judgment in Novartis case relied on a medical dictionary definition to hold that the term "efficacy" in section 3(d) meant "therapeutic" efficacy. Under such a definition, the kind of derivatives that qualify for protection are likely to be severely limited. For instance, salt forms that provide more stability and enable the drug to remain on the shelf for longer or be transported to various parts of rural India without refrigeration will not be patentable. As shown above, this narrow definition may not sit well with a plain/literal reading of section 3(d), since the section is not limited to pharmacology.

  knk@kankrishme.com

Contd...

The Madras high court's assumption that section 3(d) is limited to drugs and therefore "efficacy" ought to be construed as "therapeutic efficacy." Is incorrect. A plain reading of section 3(d) would make clear that the section also applies to other "chemicals" such as agro-chemicals. A pesticide or fertilizer cannot be tested for patentability on the basis of whether it enhances a "therapeutic" effect on the human body! The court overlooks this aspect of section 3(d) and assumes that the explanation is limited to the field of pharmacology.

  knk@kankrishme.com

Ipab's holding in Novartis case that the term "efficacy" in section 3(d) means therapeutic efficacy is incorrect. If we go by ipab's finding in novartis case that the term "efficacy" meant therapeutic effect in the pharmaceutical field, which can not be applied to the other fields, one term in the statute could not have two different meanings.

  knk@kankrishme.com

Contd...

Narrow interpretation

In line with what the Madras high court suggests, section 3(d) could be restrictively interpreted to mean only "therapeutic efficacy." Therefore, all other kinds of advantages such as increased heat stability and new drug delivery forms do not qualify.

Wider interpretation

The term "efficacy" should not be restricted to just therapeutic efficacy, narrowly defined. Rather it should include all kinds of advantageous properties exhibited by the new form including heat stability, enhanced bioavailability, humidity resistance, new drug delivery mechanisms etc.

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EFFICACY AND BIOAVAILABILITY

Ipab on the basis of facts of the Novartis case gave the following reasoning :

"absorption relates to the amount of active ingredient that has been absorbed by the body. After the active ingredient is absorbed by the body for it to act, it must bind with the relevant reception of the target cell. This binding is the crucial step that determines effect. Where there are less number of receptor sites, increased availability of the active ingredient does not produce any therapeutic response. Therefore, binding and not absorption, is the key to healing the disease. Subsequently, after the receptor–drug binding occurs, the subsequent response can be measured.

Contd...

This response is typically in the form of increase or decrease of some parameters (in this case white blood cell count). Bioavailability relates to the absorption and not the binding stage of drug action and therefore is not a measure of efficacy of a drug. [See paragraph 7(3) supra]. Appellant has neither responded to this argument nor contradicted."

Contd...

However, all inventions cannot be the same as Novartis invention in the sense that germifloxacin mesylate of the present invention is different from glivec (imatinib mesylate). Glivec-which is a tyrosine kinase inhibitor-should bind with the relevant receptor of the target cell to act. However, germifloxacin mesylate- which is a quinolone-type antibacterial agent-can enter cells easily via porins, and then it kills bacteria by interfering with dna replication. Which means, if the increased amount of germifloxacin mesylate is absorbed by the body, it is sufficiently envisaged that the enhanced therapeutic efficacy can be shown. Therefore, in the present invention the increased bioavailability can be regarded as enhanced therapeutic efficacy.

Contd...

Different drugs have different mode of action and all drugs do not interact with target cells in the same way.

Therefore, the order of the Ipab in Novartis case holding that "binding and not absorption is the determining factor" may not be applicable to the facts of every case.

Section 3(d): Cases

Novartis v. Cipla (December 2009)

- Section 3(d) is not applicable to NCEs.

Ind Swift v. Cadila (Review Petition – August 2010)

- Original decision of Deputy controller in January 2009
- Patent application on crystalline Clopidogrel besylate; known substance was Clopidogrel bisulphate salt and solvated forms of Clopidogrel besylate
- Deputy Controller overruled Section 3(d) on the basis that the invention is more stable, has increased shelf life, is more free flowing and less cardiotoxic.
- This was upheld on Review.

Roche v. Cipla (August 2010)

- Section 3(d) does not apply to process
- A pharmaceutical composition of two known substances – Section 3(d) not attracted.

D) Claims fall within the scope of Section 3(e) of Indian Patents Act.

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."

Solution

To avoid attracting the requirements of **Section 3(e),** we provide **evidence** of the fact that the ingredients of the claimed composition enhance each others properties and do not **merely** perform their own role.

In other words, the ingredients could work together in a manner to enhance or improve the activity of one or more ingredients and also in the absence of a reaction between the claimed composition evidence is required to be given that the combination is a **synergistic mixture** of the ingredients where the end composition exhibits new, unexpected, surprising or synergistic properties not being exhibited by the ingredients when taken alone.

CASE STUDY-1

MAIN CLAIM AS ORIGINALLY FILED

A pharmaceutical composition for pharmacological addictive substance or intoxicant therapy comprising a modulator of the cholinergic system and a substance having antiexcitatory activity, characterized in that the modulator of the cholinergic system is an inhibitor of acetylcholinesterase which is selected from galanthamine, the pharmacologically acceptable salts and derivatives of galanthamine, deoxypeganinr and the pharmacologically acceptable salts and derivatives of deoxypeganine.

Main Claim as accepted in the Indian Patent Office

A pharmaceutical composition for pharmacological addictive substance or intoxicant therapy comprising a modulator of the cholinergic system and a substance having antiexcitatory activity selected from the group consisting of the NMDA receptor, antagonist selected from the group consisting of 100 to 5000 mg acamprosate, the pharmacologically acceptable salts and derivatives of acamprosate, 1 to 50 mg of memantine and the pharmacologically acceptable salts and derivatives of memantine and 0.1 to 100 mg of the modulator of metabotropic glutamate receptors is selected from such as herein described, characterized in that said modulator of the cholinergic systems is an inhibitor or

Contd...

acetylcholinesterase present in amount of 1 to 50 mg and is selected from the group consisting of galanthamine, the Pharmacologically acceptable salts and derivatives of galanthamine such as herein described, 10 to 50 mg of deoxypeganine and the pharmacologically acceptable salts and derivatives of deoxypeganine.

HISTORY RELATED TO THE FINAL ACCEPTANCE

The Indian Patent Office required detailed submissions to prove that the claims did not fall under the purview of section 3(e).

In order to meet the objection we presented that the claimed composition is a synergistic composition and that the components interact with each other synergistically.

Contd...

More particularly, the claimed composition solves the problem of providing a medicament through which the alcohol-induced excitation is depressed without impairing the physiological excitatory stimulus conduction to a relevant extent such that the medicament does not cause unreasonable side effects such as strong sedation or impairment of cognition.

Further, the claimed composition interact with each other and the alcohol-induced excitation is depressed but unreasonable effects are being avoided.

Finally, the Examiner concluded that the pharmaceutical composition for pharmacological addictive substance… as claimed in the invention is a **synergistic mixture** of the ingredients where the end composition exhibits new, unexpected, surprising or synergistic properties not being exhibited by the ingredients when taken alone.

E) Claimed invention falls under Section 3(i) of Indian Patents (Amendment) Act 2005

Section 3(i)

"(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 then free of disease or to increase their economic value or that of their products."

Contd…

Solution: If the claimed invention falls under category of Section 3(i) we present our submissions before the Examiner that the claimed subject matter is not a kind of medicinal, surgical, curative, prophylactic [diagnostic therapeutic] or other treatment of human beings or any process for a similar treatment of animals to render then free of disease or to increase their economic value or that of their products.

CASE STUDY-1
Section 3(i)

Claims as originally filed

A method of identifying one or more nucleotides at each of two or more designated polymorphic sites in one or more targets, the method containing the following steps:

a) providing a set of oligonucleotide primer pairs, each pair capable of annealing with complementary polynucleotide strands to delineate a region of the corresponding target which includes at least one designated polymorphic site;

Contd..

b) contacting said set of oligonucleotide primers with said targets under conditions allowing formation of amplicons with designated polymorphic sites corresponding to said designated polymorphic sites in corresponding targets, each amplicon comprising an amplicon sense strand corresponding to a target sense strand and an amplicon antisense strand corresponding to a target antisense strand;

Contd...

c) selecting a set of encoded probes wherein differently encoded probes are of different types, having different nucleotide sequences, said set selected such that at least a first type of said encoded probes has a complementary region, to an amplicon sense strand or a subsequence thereof, and at least a second type of said encoded probes has a complementary region, to an amplicon antisense strand or a subsequence thereof;

d) contacting the selected set of encoded probes with said amplicons under conditions permitting the formation of a probe elongation product, following annealing of said encoded probes to said amplicons, and wherein said probes are capable of annealing to an amplicon such that an interrogation site within a probe is aligned with a designated polymorphic site in said amplicon;

Contd...

e) wherein: (i) the first type of encoded probes are selected because they are predicted to have a greater degree of complementarity to said amplicon sense strand or a subsequence thereof, due to fewer non-designated or non-selected designated polymorphic sites on said amplicon sense strand in the region where the first type of encoded probes is designed to anneal, than does a probe that is capable of annealing to the amplicon antisense strand or a subsequence thereof and that has the same interrogation site as said first type of encoded probes; and

Contd...

(ii) the second type of encoded probes are selected because they are predicted to have a greater degree of complementarity to said amplicon antisense strand or a subsequence thereof, due to fewer non-designated or non-selected designated polymorphic sites on said amplicon antisense strand in the region where the second type of encoded probes is designed to anneal, than does a probe that is capable of annealing to the amplicon sense strand or a subsequence thereof and that has the same interrogation site as said second type of encoded probes; and

f) detecting probe elongation products.

CLAIMS AS ACCEPTED

MAIN CLAIM:

1. A method for identity testing by probe elongation-mediated analysis of variable sites in the HLA gene in a genome:

by providing sets of different cognate probes characterized in that the cognate probes are in a set capable of annealing to one or more amplicons, said amplicons generated by amplifying regions of the genome using asymmetric polymerase chain reaction, and said cognate probes further capable of being elongated with a detectably labeled nucleotide if, following annealing, the probe's interrogation site is complementary to the aligned nucleotide in the amplicon, wherein said probes are designed such that the aligned nucleotide is complementary to a nucleotide at a variable site;

Contd...

and designating for each set of amplicons, one strand (either sense or antisense) for the probe elongation-mediated analysis of the variable sites, depending on which strand has a greater degree of complementarity to its cognate probe in the terminal elongation initiation region of the cognate probe.

CASE STUDY -2

CLAIMS ORIGINALLY FILED

1. A method of treating, preventing or reducing the risk of developing a depressive disorder in a subject in need thereof, comprising: administering a depressive- disorder-effective amount of a composition to an area of skin of the subject for delivery of a steroid in the testosterone synthetic pathway to blood serum of the subject, wherein the composition comprises :

(a) about 0. 01% to about 70% of the steroid in the testosterone synthetic pathway;

(b) about 0. 01% to about 50% penetration enhancing agent;

(c) about 0. 01% to about 50% thickening agent; and

(d) about 30% to about 98% lower alcohol;

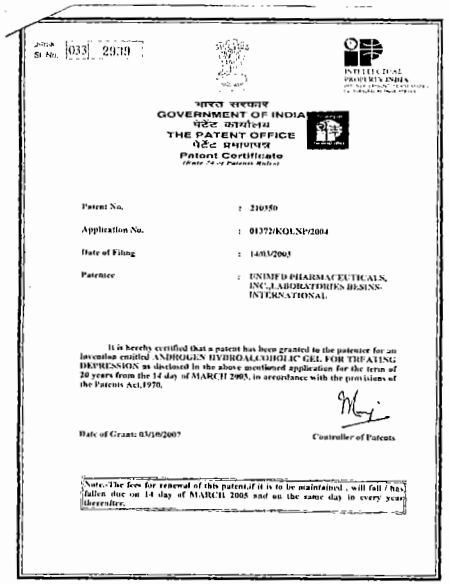
Contd...

wherein the composition is capable of releasing the steroid after applying the composition to the skin at a rate and duration that delivers at least about 10 μg per day of the steroid to the blood serum of the subject; and the percentages are on a weight to weight basis of the composition.

CLAIMS ALLOWED

1. A composition comprising a hydroalcoholic gel and an antidepressant agent as separate components to the composition wherein the hydroalcoholic gel comprises:
   - 0.01% to 70% of steroid in the testosterone synthetic pathway;
   - O.01% to 50% of penetration enhancing agent;
   - 0.01% to 50% of thickening agent; and
   - 30% to 98% of lower alcohol;

   wherein the percentage are on a weight to weight basis of the hydroalcoholic gel.



GOVERNMENT OF INDIA
THE PATENT OFFICE
Patent Certificate

Patent No. : 210350
Application No. : 01372/KOLNP/2004
Date of Filing : 14/03/2005
Patentee : UNIMED PHARMACEUTICALS, INC.,LABORATORIES BESINS-INTERNATIONAL

It is hereby certified that a patent has been granted to the patentee for an invention entitled ANDROGEN HYDROALCOHOLIC GEL FOR TREATING DEPRESSION as disclosed in the above mentioned application for the term of 20 years from the 14 day of MARCH 2005, in accordance with the provisions of the Patents Act,1970.

Date of Grant: 03/10/2007 Controller of Patents

Note:-The fees for renewal of this patent,if it is to be maintained , will fall / has fallen due on 14 day of MARCH 2005 and on the same day in every year thereafter.

Claimed invention falls under the purview of Section 3(j) of Indian Patents (Amendment) Act 2005

Section 3(j)

"plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals"

Anything relating to human body/part {here part includes basic unit of life i. e "cell"} and process employing any living part/cell will invariably relate to the Section 3[j] of the Indian Patents [Amendment] Act, 2005.

Also, animals, plants, humans, microorganisms and their parts such as genes and cells, are not patentable as these life forms are creations of God and Nature.

Examiners believe that life forms, even if they are genetically modified, are not inventions and thus do not meet the criteria of patentability.

Solution

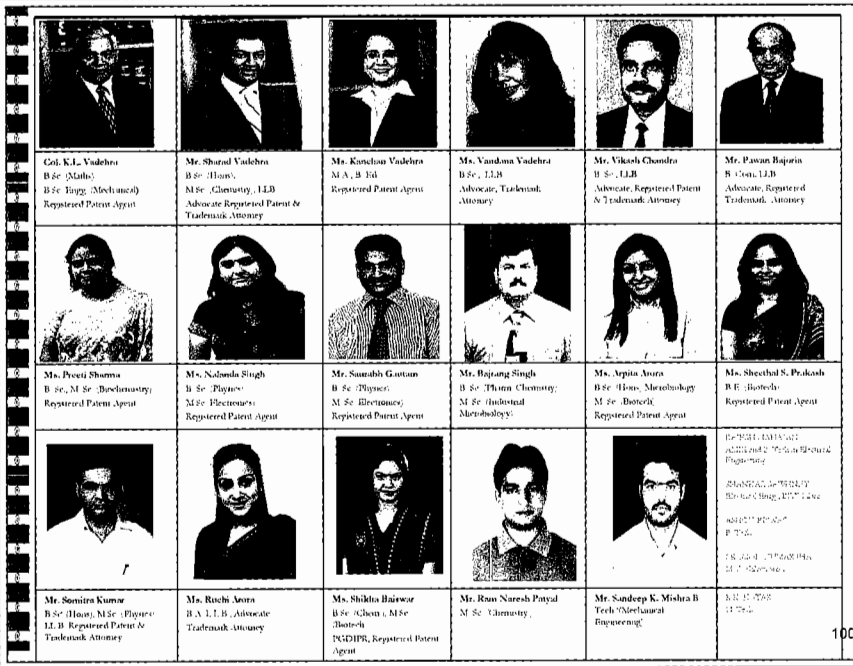
The invention if not confined to a particular plant or variety, in that case it is patentable.

Microorganisms are *patentable per se* if it they have not previously been made available to the public. A patent for the microorganisms can be granted if they are being genetically engineered, being transformed with a new sequence of DNA, if they are new and non-obvious.

EXAMINER'S ATTITUDE

- Very particular while examining pharmaceutical/chemical related applications;
- Very well-qualified and have decades of experiences in the subject matters;
- Number of examiners is more in pharmaceutical and chemical field than any other fields;
- Objections of the examiners in pharmaceutical/chemical very stringent (internal circular from the Controller General as to not give very broad claims);
- Requirements to be complied with in pharmaceutical/chemical related applications:
  For pharmaceuticals in order to evade Section 3(d), applicant should add sufficient data to prove enhance therapeutic efficacy/bioavailability of the compound;

- Pharmaceutical/chemical related applications when directed to composition should give broad range of all ingredients followed by the narrow ranges in sub-claim(s) with support in the specification;
- Generally additional/new ingredient not supported by main claim should not be covered in the sub-claim;
- The range of the ingredients should be in weight/ weight, weight /volume and not be in milligram/milliliter, dosage forms are not allowed;
- Swiss type of claims and use claims not allowed and hence should be avoided;
- In case of process related claims, besides range of the ingredients, broad process parameters generally preferred in the main claim and narrow range of the parameters may followed in sub-claim(s) with support in the specification;



連絡先のお知らせ

◇入会、退会、事務所移転など会員情報に関する連絡は、下記渉外担当幹事にお願い致します。

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◇ＫＴＫニュースへの投稿、内容、送付先などＫＴＫニュースに関する連絡は、下記ニュース担当幹事までお願い致します。

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※　**お知らせ**

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◇会費納入に関する連絡は、下記会計担当幹事にお願い致します。

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会費納入

納入金額：

15,000円（郵便物の送付先等として日本国内の住所等を希望する会員）
または30,000円（郵便物の送付先等として日本国外の住所等を希望する会員）
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普通預金　口座番号　6938601
受取人　　関西特許研究会　会計幹事　時岡　恭平（トキオカ　キョウヘイ）

※**お知らせ**

ＫＴＫの会計年度は１～12月です。2012年１月以降在会の方は、一部を除き原則、2012年度の年会費納付対象者となります。ご協力、よろしくお願いいたします。

編 集 後 記

私は、スタバが好きです。

店内の雰囲気が何となく心を和ませてくれます。

スタバに行ったとき、皆様は何を注文されるでしょうか？

私が注文するものはいつも決まっています。「カフェモカを豆乳で」・・・私のお気に入りです。

先日、久しぶりにスタバに行きました。

その前日、ちょっと辛いことがあり、気持ちが落ち込んでいたのですが・・・お気に入りのドリンクを注文してしばらく店内で過ごすと、心が少し和みました。

私には、学生時代から交際している彼女がいます（ここでは仮に“弁子”と呼ばせていただきます・・・ＫＴＫニュース３月号に登場した弁子は架空の人物であり、本号に登場する弁子とは一切関係ありません・・・f^_^;)。学生時代には、弁子と一緒に、毎日のようにスタバに通ったものです。

当時、私は、将来のことで思い悩んでいました。「将来、自分はどんな仕事をしたいのか？」「どんな職に就けば、遣り甲斐を持って仕事ができるのか？」・・・（ありきたりな悩みですが・・・）日々、そんなことに想いを巡らせていました。

普通の人よりちょっと長いモラトリアム・・・その時間の多くをスタバで過ごしました。・・・だいぶ遠回りしてしまいましたが・・・カフェモカを片手に過ごしたその時間が、今の自分の礎になっているような気がします。

ある日のスタバからの帰り道、弁子がふと口にした言葉があります。その言葉は、私の脳裏に深く刻み込まれています。

時が経つのは早いものですね・・・・・・・・ふと気が付くと、あれから10年近くの年月が流れていました・・・その間、いろんなことがありましたが・・・あの日弁子の言ってくれたその言葉は、今でも、私にとって大切な言葉です。私を支えてくれているような気がします。

「２人はベターハーフだね。」

その言葉をそっと胸に仕舞って、人生の駒を一歩前に進めます。

日々生活していると、楽しいこと、悲しいこと、嬉しいこと、腹の立つこと・・・いろんなことがあります。そんな中、「自分は、多くの人に支えられて生きているなぁ」ということを感じます。

職場の仲間、学生時代の友達、弁理士仲間・諸先輩方、同じ目標に向かって頑張った同士、よく一緒にお酒を飲みに行く人、一緒に旅行に行った人、お互い辛いときに一緒に過ごした人、尊敬できる人、刺激やきっかけを与えてくれる人、私を成長させてくれる人、私のことを慕ってくれる人、評価してくれる人、私に対して感謝してくれる人、ダメだしをしてくれる人、切磋琢磨できる人、夢を語り合える人、愚痴を言い合える人、悩みを共有できる人、一緒にいて楽しい人、安心感を与えてくれる人、一緒にいる時間が心地好い人、私のことをよく理解してくれている人、素の自分を曝け出せる人、私のことを受け入れてくれる人、ずっと見守ってくれている人。

ＫＴＫの幹事を務めさせていただいたことで、多くの方との出会いがありました。そして、多くの経験をさせていただきました。その出会いや経験は、今後、私にとって大切な財産になると思います。

編集後記を書くのも今回が最後となりました。１年間お付き合いいただきまして本当にありがとうございました。