INVENTOR GUIDANCE NOTES

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SCOPE: **This Inventor Guidance Notes provides information for scientists working in the area of Pharmaceutical science and explains what can and what cannot be patented.**	DATE: **02nd Feb 2013**
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A. SUMMARY

Category of invention	IN	USA	EP	Possible Eg Claim/Explanation
Chemical entity [drugs, chemicals]	✓ IN 228922	✓ US 5077297	✓ EP 675899	A compound having the formula R-CH= N-S-X, wherein R is an alkyl group selected from the group consisting of methyl, ethyl and isopropyl; and X is a halogen selected from the group consisting of chlorine and bromine….
New form of known substance [salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers etc]	X	X	X	With same efficiency as the known Form
	✓ IN239402	✓ US6043262	✓ EP2436377	With improved efficacy or surprisingly superior properties as compared to the known Form.
Diagnostic Kits	✓ IN219359	✓ US6478749	✓ 1813943	A kit for the detection of HCV...
Medical devices	✓ IN213643	✓ US5967973	✓ 1762255	Pressurized metered dose inhalers.
First medical use of novel (inventive) compounds	X	✓	✓	A chemical compound of chemical formula R-CH= N-S-X used as a medicine to treat skin burns…
Second medical use of known compounds	X	X	X	A chemical compound of chemical formula X used as a medicine to treat acne...
	X	✓	X	A process of using a known compound X for a novel medical use [heart medication]…
Method of preparation	✓ IN226803	✓ US6495651	✓ 1103546	A method for preparation of compound having the formula R-CH= N-S-X comprising steps of Taking substance (a) and heating at 60^{O} C…… adding substance (b)
Formulation/ Pharmaceutical product	✓ IN228654	✓ US6984395	✓ 778778	A pharmaceutical formulation adapted for intra-muscular injection comprising fulvestrant, 30% or less weight...
Method of treatment/ surgery/ prophylaxis/ diagnosis	X	✓ US5967973 US4845115 US3660559	X	A method for treatment of dementia and other cognitive disorders which comprises administering to a human or animal subject suffering from dementia or other cognitive disorders an effective amount for the treatment of said dementia or other cognitive disorders of 1,2,3,9,-tetrahydro-9-methyl-3-[(2-methyl-1H-imidazol-1-yl)methyl]-4H-carbazol-4-one or a physiologically acceptable salt or solvate thereof.

B. RELEVENT LEGAL EXTRACTS

COUNTRY	LEGAL EXCERPTS
INDIA **[The Patents Act,1970]**	S2 (1)(j) "invention" means a new product or process involving an inventive step and capable of industrial application S2 (1)(ia) "pharmaceutical substance" means any new entity involving one or more inventive steps. Drug includes all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of disease in human beings or animals S3 (b) an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment; S3 (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 new 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; S3 (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; S3 (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.
USA **[Title 35 USC]**	**35 U.S.C. 101 Inventions patentable.** Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent thereof, subject to the conditions and requirements of this title.
EUROPE **[EPC]**	**Article 53** **Exceptions to patentability** European patents shall not be granted in respect of: (a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States; (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof; (c) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

C. INTERPRETATION OF THE LAW AND EXPLANATION

INDIA:

Indian Patent Act -2005 [as amended] has provisions for granting product as well as process patent in all fields of Technology including chemicals, food, drugs & agrochemicals.

1. **Section 3 b:** Prohibits patenting of subject matter which could be contrary to public order or morality. Thus a Chemical/drug exclusively meant for Euthanasia or suicide is not Patentable in India.

2. **Section 3 d :**

Section 3d is a major obstacle for new forms (salts, polymorphs, solvates... *etc*) of pharmaceutical drugs substances, unless the patentee shows improved effectiveness over existing product.

According to the proviso to this sub-section, a known substance in its new form such as amorphous or crystalline, Hygroscopic or dried, one isomer to other isomer, metabolite, complex, combination of plurality of forms, salts, hydrates, polymorphs, esters, ethers, or in new particle size, shall be considered same as of known substances unless such new forms significantly differ in the properties with regard to efficacy.

Mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance is not patentable.

The Patents Act, as it exists today, accommodates incremental innovations, since the patents granted are not only for new molecules but also for new processes as well as new uses, combinations and dosage forms.

It is also worth noting that a limited study by the Indian Pharmaceutical Alliance has come out with a list of 86 patents granted for pharmaceutical products by India after 2005 which inventions are not breakthrough drugs but only minor variations of existing pharmaceutical products.

Table 1 illustrates a list of Patents for New Form of a Known Substance.

Table 2 illustrates a List of Patents for Combinations.

CASE STUDY:

The ruling:	Message:
Patent application No. 1577/Del/1996 was refused, *inter alia,* under the provisions of section 3(d) of the Patents Act, 1970. The Controller in his decision dated 12th June, 2007 held that "the present invention provides a new form of known substance either in anhydrous or hydrated form III of Atorvastatine having same therapeutic activity and in the same field. It only claims some improvement in physical property, which does not make any change in therapeutic efficacy of the compound as compared to the prior art compound. Therefore this new form does not qualify the requirement under section 3(d)	Mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance is not patentable.

3. **Mere discovery of new property of a known substance**

A mere discovery of a new property of known substance is not considered patentable. For instance, Paracetamol has proven antipyretic property. But further discovery of new property of paracetamol as analgesic cannot be patented.

Similarly, ethyl alcohol is used as solvent but further discovery of its new property as anti knocking, thereby making it usable as fuel, cannot be considered patentable.

CASE STUDY:

Invention:	Verdict:	Message:
In a patent application No. 782/Cal/l981, dated 13th July, 1981, an invention related to pharmaceutical composition exhibiting anti-phlogistic, antipyretic and analgesic activity and high gastroenteric tolerance in unit doses form which contained imidazol salicylate as the active ingredient in the amount of 100-600 mg and an inert carrier was claimed which was later amended to a process for the preparation of novel composition containing imidazole salicylate having	It was held by the Controller that the active compound such as imidazole salicylate was known in the art and applicant could not develop any special property or even improve upon the property of the compound to be mixed up with	A mere discovery of a new property of known

formula 1, as the active principle . The invention was characterized in a product that was previously obtained by reacting, mole by mole, acetylsalicylic acid with imidazole in an inert organic solvent and that, using the solid product obtained in the reaction after purification by recrystalization , homogenous composition were produced with pharmaceutically acceptable vehicles suitable for oral, parental or topic administration.	the usual carrier to form the composition. Furthermore, the description contained no indication of using any special type of solvent for its purification by re-crystallization and, therefore, the invention was not patentable under section 3(d) of the Act.	substance is not considered patentable.

4. **Mere discovery of any new use of known process**

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:- Mere use of a known process is not patentable unless such known process results in a new product or employs at least one new reactant. Similarly mere use of known apparatus or machine for another purpose is also not considered patentable.

5. **Section 3 e**

Section 3 e of the Patent act states that a mere admixture resulting only in the aggregation of properties is not patentable unless the admixture shows synergistic effect.

In the patent application No. 782/CAL/l981, dated 13th July, 1981, it was held by the Controller that the pharmaceutical vehicle having the primary intended function of acting as vehicle or carrier or diluents performed the very function when incorporated in the composition. There was no explicit disclosure or experimental data to indicate that the presence of the carrier in any way influenced the antiphlogistic, antipyretic and analgesic activity of the active ingredients. Therefore, the invention was held not allowable under Section 3(e) of the Act as well as and merely an admixture.

Thus, a mixture of different types of medicament or medicine to cure multiple diseases is also a mere admixture of substances and is not a patentable invention.

However, an admixture resulting into synergistic properties of a mixture is not considered as mere admixture, e.g., soap, detergent, lubricants and polymer composition etc.

CASE STUDY:

The ruling:	Message:
In the patent No. 143270 for the invention entitled "A fertiliser composition", it was held that alleged invention falls within sub-section(e) of Section 3 of the Act and the opponent had established the fourth ground of opposition, i.e. "not an invention or not patentable as the crop nutrient properties of the constituents like zinc sulphate, manganese sulphate, copper sulphate and magnesium sulphate were known as seen from know-how report and the steps of grinding, mixing and homogenizing were conventionally used in manufacture of the fertiliser.	A mere admixture resulting only in the aggregation of properties is not patentable unless the admixture shows synergistic effect.

6. **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.*

Patent may however be obtained for surgical, therapeutic or diagnostic instrument or apparatus. Also the manufacture of prostheses or artificial limbs and taking measurements therefor on the human body are patentable.

Methods of diagnosis practised on the human or animal body are excluded. Methods of diagnosis performed on tissues or fluids, which have been permanently removed from the body, are, therefore, not excluded from patentability.

Contraceptives processes are not patentable. However as Chemical contraceptives are notified as a Drug by the central government under the Drug & Cosmetics Act 1940, Chemical contraceptives are patentable.

USA:

1. Section 101 defines the subject matter that may be patented. According to the statute, one who invents or discovers any new and useful process, machine, manufacture, or any composition of matter, or any new and useful improvement thereof, may obtain a patent therefore.

2. An invention that falls within one of the four statutory categories – processes, machines, manufactures, and compositions of matter – may be subject to a so-called “utility patent.”

3. The pharmaceutical industry principally claims inventions that are chemical compounds, compositions of matter or processes.

4. Process claims are commonly: “method of using” and “method of making” claims.
   Suppose that an inventor manufactures a new pharmaceutical compound and also discovers that the compound may be used to treat a particular ailment. The manner in which the pharmaceutical may be employed to achieve a result may be drafted in the form of a claim towards a method of using. As well, the inventor may obtain claims for a method of making the compound, stating the techniques he employed to synthesize the compound.

5. Section 100(b) of the Patent Act notes that a process “includes a new use of known process, machine, manufacture, composition of matter, or method.” The statute thus allows inventors to obtain a proprietary interest in a newly discovered property of a known product.
   Suppose, for example, that an inventor discovers that a well-known chemical compound, understood to act as an explosive, also serves as a heart medication. The inventor could not obtain patent protection on a compound that already lies within the public domain. But he could seek a patent claiming a process of using the compound as a heart medication.

6. The United States Patents Act does not exclude methods of medical treatment of humans from patentability. [See US 4845115]

EUROPE:

1. The European Patent Convention (EPC) excludes "methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body" from patentability. The reason for this exclusion is the belief that public health would be at risk if patent rights could be used to impede physicians in the normal course of practicing medicine. However, this exclusion does not extend to known compounds or compositions for use in the treatment methods.

2. The inventor of the first use of a known compound for a therapeutic treatment can obtain claims covering all therapeutic uses, in other words protection for a generic medical use. This type of claim is referred to as the "first medical use claim" and takes the form:
   [Known compound or composition] for use as a medicament or as a therapeutic substance

3. The situation is more complex when the invention lies in the finding that a known compound which has already been used for a therapeutic purpose (first medical use) can be used to treat a different disease or disorder. An example of this is Aspirin. First, Aspirin was used to treat pain, then it was discovered that it could also be used in the treatment of cardiovascular disease. Until recently, European patent law enabled protection of such a "second medical use" invention by way of a "Swiss-type" claim which takes the form:
   [Known compound or composition] for use in the manufacture of a medicament for the treatment of [new disease]

4. A recent European decision (G 2/08) provides that where the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament, such claim may no longer have the format of the Swiss-type claim. This is due to the absence of any functional relationship of the features conferring novelty and inventiveness (i.e., the new therapeutic use) and the claimed manufacturing process. Instead, the "first medical use" form of claim must now be used, allowing claiming of second or further medical uses in a less convoluted manner. Such a claim would take the form:
   [Known compound or composition] for use in [new therapeutic use]

5. Importantly, this decision confirmed that second and further medical uses are not restricted to the treatment of a different disease or disorder but are directed to "any specific use" including a new dosage regime of a known therapeutic compound, a novel group of subjects to be treated, or a new route or mode of administration.

D. EXAMPLES:

List of Granted Patents:

India:

Patent No. & Title	Types of allowed claims	Granted Claims
213643 DEVICE FOR SEPARATING BETWEEN THE UPPER AND LOWER JAWS	1. Product claim for the device	1. A device, for separating between the upper and lower jaws, said device comprising two substantially U-shaped" ribs, connected at at least one end to one another, and a deformable member attached at a posterior end of a pair of ribs on at least the lingual side thereof such that said member gradually changes its shape when a pressure is applied on said ribs by the jaws, wherein the yield strength of said ribs is significantly greater than that of said deformable member.
219359 A KIT FOR THE DETECTION OF HCV	1. Product claim for a diagnostic kit	1.A kit for the detection of HCV comprising a)a solid phase coated with modified hcv core protein, hcv non-core protein, and at least one anti-hcv core monoclonal antibody, and b) a labeled anti-hcv core monoclonal antibody, wherein the modified core protein of part a) has been modified by removing the binding sites of the anti-core monoclonal antibodies of part a) and part b).
228654 AN UNIQUE COMBINATION OF AYURVEDIC COMPOUNDS FOR CORRECTING A RARE FORM OF MULLERIAN DYSGENESIS	1. Product claim for an Ayurvedic combination preparation	1.An unique combination for correcting a natural defect of a rare form of Mullerian Digenesis - rudimentary uterus - comprising l.Asoka Ghritham (AG), 2.Kalyanaka Ghritham (KG), S.Aswagandhadi Lehyam (AGL), 4. Rajapravavarthana Vati (RPV) , S.Kulatthadi Kashayam (KK), 6.Bala Thailam (BT), 7.Varanadi Kashayam (VK), S.Chandraprabha Vati (CPV),9. Pushing Choomam Tablet (PCT), 10. Asoka Arishtam (AA) and 1 l.Phalasarpis(PS).
227427 A PHARMACEUTICAL FORMULATION	1. Product claim for a pharmaceutical formulation	1. A pharmaceutical formulation comprising: - an immune response modifier (IRM) compound selected from the group consisting of imidazoquinoline amines, imidazopyridine amines, 6,7-fused cycloalkylimi dazopyridine amines, 1,2-bridged imidazoquinoline amines, thiazolo- and oxazolo- quinolinamines and pyridinamines, imidazonaphthyridine and tetrahydroimidazonaphthyridine amines; a fatty acid; a preservative system; and a carbomer.
228922 CYSTEINE PROTEASE INHIBITORS	1.Product claim for compounds of a general formula (I)	1.Compounds of general formula (I) wherein: Z = CR3R4, where R3.....
226803 NOVEL α-HYDRAZINO-α,β-UNSATURATED NITRO COMPOUNDS AND METHODS OF PREPARATION THEREOF	1.Product claim 2.Process claim for the novel compound	1. Novel vinylic nitro compounds of formula 5 with a hydrazino group at the a position and substituent R, p to the nitro group wherein R is alkyl, aryl, aralkyl, alkaryl, alkenyl; E is a group such as COOR', COR', CONR2\ CN, CF3, R'S02. 2. A process for the preparation of novel vinylic nitro compounds of formula 5, comprising reaction steps of: - reacting a nitroalkene and azo compound in the presence of an amine catalyst optionally in a solvent until the reaction goes to completion, - diluting the said reaction mixture with aqueous acid, - separating the aqueous layer, - extracting the said aqueous layer with organic solvent, - concentrating the combined organic layers to yield the vinylic nitro compound.

USA:

Patent No. & Title	Types of allowed claims	Claims
5967973 SURGICAL RETRACTOR AND METHOD OF SURGERY	1.Product claim for a medical device 18. Process claim for a method of surgery.	1. A surgical retractor comprising..... 18. A method of surgery comprising the steps of.....
6478749 DIAGNOSTIC KIT FOR SKIN TESTS, AND METHOD	1.Product claim for a diagnostic kit 11.Process claim for the method of use of the diagnostic kit.	1.A skin test diagnosis kit for detecting an cellular immune reaction against the oncoprotein E6 and/or E7 of a human papilloma virus type, said diagnosis kit containing an effective amount of the oncoprotein E6 and/or E7 and/or at least an immunologically effective portion of E6 and/or E7 of a human papilloma virus type. 11. A process for carrying out a skin test for detecting an immunological response with respect to the oncoproteins E6 and/or E7 of an HPV type, comprising the following steps; a) providing a diagnosis kit of claim 1; b) intracutaneous application of an effective amount of at least one oncoprotein E6 and E7 or effective portions thereof into a test person; c) after a sufficient incubation time, visual inspection of the skin regions of the application to detect an immunological response.
6984395 DRUG DELIVERY SYSTEM FOR HYDROPHOBIC DRUGS	1. Product claim for a pharmaceutical composition	1. A composition comprising micelles, said micelles comprising saturated and unsaturated phospholipids and one or more hydro-monobenzo-porphyrin photosensitizer Wherein the micelles in the composition have an average diameter below about 100 nm.
5077297 NOVEL COMPOUNDS	1.Product claim for a compound 8.Process claim for method of use 9.Product claim for a composition containing the claimed compound.	1. A compound of formula (I): ##STR14## wherein R.sup.1 and R.sup.2 are independently selected from halogen or nitro; R.sup.3 and R.sup.4 are independently selected from hydrogen or halogen; R.sup.5 is hydrogen, halogen or cyano; and R.sup.6 is halogen or haloalkyl; provided that R.sup.1, R.sup.2, R.sup.3 and R.sup.4 are not all fluorine 8. A method of killing or controlling insect or acarine pests which method comprises applying to the pest or to a locus thereof a insecticidally or acaricidally effective amount of a compound of formula (I) as defined in claim 1. 9. An insecticidal or acaricidal composition comprising a compound of formula (I) according to claim 1 in combination with a diluent or carrier.

7799353 PHARMACEUTICAL MIXTURE FOR HEPATITIS TREATMENT AND ITS PREPARATION METHOD	1.Product by process claim for a mixture 11. A product claim for its pharmaceutical formulation.	1. A hepatoprotective mixture prepared by a method comprising the following steps: (a) pulverizing a plant, macerating and extracting the plant with water to form an aqueous extract, wherein said plant is Boehmeria frutescens Thunberg or Boehmeria nivea; (b) concentrating the aqueous extract to form a first concentrate; (c) adding ethanol to said first concentrate to produce a precipitate and a liquid phase; (d) collecting and concentrating said liquid phase to form a second concentrate; (e) purifying said second concentrate with a macroporous, styrene serial adsorption/desorption resin by loading said second concentrate onto the resin and eluting the resin with water, water-ethanol mixture, and then ethanol; (f) collecting and combining the water-ethanol and ethanol elution fraction; and (g) Concentrating said combined elution fraction to form a third concentrate. 11. A pharmaceutical composition having a hepatoprotective effect containing a hepatoprotective effective amount of the mixture of claim 1.
4845115 METHOD OF MEDICAL TREATMENT	1. Process claim for a method of treatment by the claimed drug	1. A method for treatment of dementia and other cognitive disorders which comprises administering to a human or animal subject suffering from dementia or other cognitive disorders an effective amount for the treatment of said dementia or other cognitive disorders of 1,2,3,9,-tetrahydro-9-methyl-3-[(2-methyl-1H-imidazol-1-yl)methyl]-4H-carbazol-4-one or a physiologically acceptable salt or solvate thereof.
5290775 EUTHANASIA COMPOSITIONS	1.Process claim for a method of providing euthanasia 21.Product claim for the composition	1. A method for providing euthanasia in a mammal in need thereof which comprises: (a) premedicating by intravenous administration to tranquilize the mammal with a tranquilizer immediately prior to euthanasia; and (b) Introducing by injection into the mammal an aqueous euthanasia solution comprising an effective amount for producing euthanasia of a cardiotoxic compound selected from the group consisting of a quinacrine compound and a chloroquine compound and a water solubilized gamma-hydroxybutramide in an anesthetic amount, wherein euthanasia occurs in the mammal. 21. A composition for providing euthanasia in a mammal which comprises in admixture in an injectable aqueous solution: (a) a cardiotoxic compound selected from the group consisting of a quinacrine compound and a chloroquine compound; (b) a lidocaine selected from the group consisting of a water solubilized lidocaine as a base and water soluble salts thereof; (c) gamma-hydroxybutramide, wherein the solution contains a ratio of gamma-hydroxybutramide to chloroquine or quinacrine of between about 3 to 1 and 6 to 1 and a ratio of lidocaine to gamma-hydroxybutramide of between about 0.01 and 0.15 to 1 in an amount sufficient to produce euthanasia; and (d) an injectable carrier

EP patents:

Patent No. & Title	Types of allowed claims	Claims
1762255 COATED MEDICAL DEVICES	Product claims for medical device	1.A medical device for implantation into a treatment site of a living organism, comprising: a biocompatible vehicle affixed to at least a portion of the medical device; and at least one agent in therapeutic dosages incorporated into the biocompatible vehicle for the treatment of reactions by the living organism caused by the medical device or the implantation thereof. 81.A local drug delivery device comprising: a stent having a substantially tubular member having open ends, and a first diameter for insertion into a lumen of a vessel and a second diameter for anchoring in the lumen of a vessel; a biocompatible polymeric vehicle affixed to at least a portion of the stent; and rapamycin, in therapeutic dosages, incorporated into the polymeric vehicle.
1103546 PROCESS FOR PREPARATION OF PYRIDINE DERIVATIVES	Process claim for a method of manufacture of a drug	1. A process for the manufacture of a compound of formula EMI25.1 wherein R<1> is.....
675899 NOVEL INHIBITORS OF FACTOR Xa	Product claim for a new compound	1. A compound which selectively inhibits the catalytic activity of factor Xa but which does not appreciably inhibit the activity of factor XIa, thrombin or tissue plasminogen activator wherein said compound is a peptide aldehyde having a molecular weight less than about 1000 and wherein said compound is characterized by having Percent Selectivities for factor XIa, thrombin and tissue plasminogen activator which are less than or equal to 10.
1813943 NOVEL DIAGNOSTIC KIT FOR MALIGNANT MELANOMA	1.Product claim for a diagnostic kit 2. Process claim for a diagnostic method	1. A diagnostic kit for malignant melanoma, which comprises an antibody against SPARC and an antibody against GPC3. 2. A diagnostic method for malignant melanoma, wherein SPARC and GPC3 in a sample are measured.
778778 PROBIOTIC COMPOSITIONS	1. & 2. Product claim for a composition 16. Process claim for a method of forming the composition.	1.A probiotic composition comprising one or more probiotic microorganisms and a carrier which will function to transport the one or more probiotic microorganisms to the large bowel or other regions of the gastrointestinal tract, the carrier comprising a modified or unmodified resistant starch or mixtures thereof, which carrier acts as a growth or maintenance medium for microorganisms in the large bowel or other regions of the gastrointestinal tract. 2. A two part probiotic composition comprising a first part which includes one or more probiotic microorganisms and a second part which includes a carrier, the carrier comprising a modified or unmodified resistant starch or mixtures thereof, which carrier acts as a growth or maintenance medium for microorganisms in the large bowel or other regions of the gastrointestinal tract. 16. A method of forming a probiotic composition comprising drying, blending, co-extruding, spray cooling, entrapment, adhesion or micro-encapsulating one or more probiotic microorganisms with a modified or unmodified resistant starch or mixtures thereof.

E. REFERENCES:

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12. www.nipoonline.org/Section-report.doc
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Note: This IGN was finalized in the current form on 02nd Feb 2013. This is intended as a working document. Readers are requested to provide comments/suggestions & point to any errors (if any) so as to help improve this document. Comments may be sent to sv.kanitkar@ncl.res.in