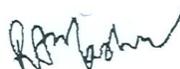


Report of the Technical Expert Group on
Patent Law Issues

December 2006

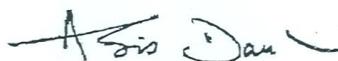
We, the Members of Technical Expert Group on Patent Law Issues, hereby submit our Report:



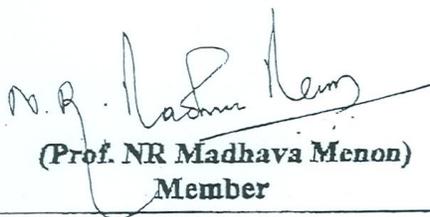
(Dr. RA Mashelkar)
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(Prof. NR Madhava Menon)
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(Prof. Moolchand Sharma)
Member

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EXECUTIVE SUMMARY

1.0 Background

The Patents (Amendment) Bill, 2005, introduced in the Parliament in March, 2005 with the objective of making the Patents Act compatible with India's international obligations, particularly under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) had the benefit of detailed discussion in both the Houses. During the debate, the issues regarding patentability of micro-organisms and the definition of 'pharmaceutical substance' to mean "a new chemical entity (NCE)" or "new medical entity (NME)" were raised. The Commerce and Industry Minister then assured the Parliament that he would refer these issues to an Expert Committee for detailed examination and report the matter to the Parliament. Accordingly, a Technical Expert Group on Patent Law Issues was set up by the Government of India, Ministry of Commerce & Industry, Department of Industrial Policy & Promotion *vide* O. M. No. 12/14/2005-IPR-III dated April 5, 2005.

2.0 Terms of Reference of the Group:

- 2.1 whether it would be TRIPS compatible to limit the grant of patent for pharmaceutical substance to new chemical entity or to new medical entity involving one or more inventive steps; and
- 2.2 whether it would be TRIPS compatible to exclude micro-organisms from patenting.

3.0 Approach

- 3.1 The Expert Group adopted a consultative approach to seek inputs from different stake holders such as industry associations, non-governmental organizations, intellectual property attorneys, etc. through written submissions, presentations, etc. The Group studied the inputs received and also took into account other relevant literature to arrive at their assessment. The Expert Group has arrived at specific recommendations and conclusions as given below.
- 3.2 In making the recommendations the Group was guided by the need for access of affordable medicines to Indian people at large, encouraging innovation by Indian industry, its current capabilities in R&D, and balancing of India's obligations under international agreements with the wider public interest.

4.0 New Chemical Entities

- 4.1 In the light of the above discussion, it would not be TRIPS compliant to limit granting of patents for pharmaceutical substance to New Chemical Entities only. However, every effort must be made to provide drugs at affordable prices to the people of India. Further, every effort should be made to prevent the grant of frivolous patents and 'ever-greening'. Detailed Guidelines should be formulated and rigorously used by the Indian Patent Office for examining the patent applications in the pharmaceutical sector so that the remotest possibility of granting frivolous patents is eliminated.

5.0 Micro-organism

- 5.1 The group's conclusion is based on the requirements of Article 27.3 of the TRIPS as articulated in 5.23 above and the provision of Indian Patent Act (Section 3 (j)). However, strict guidelines need to be formulated for examination of the patent applications involving micro-organisms from the point of view of substantial human intervention and utility.
- 5.2 Excluding micro-organisms *per se* from patent protection would be violative of TRIPS Agreement.

1.0 Backdrop

1.1 The Patents (Amendment) Bill, 2005, introduced in the Parliament in March, 2005 with the objective of making the Patents Act compatible with India's international obligations, particularly under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) had the benefit of detailed discussion in both the Houses. During the debate, the issues regarding patentability of micro-organisms and the definition of 'pharmaceutical substance' to mean "a new chemical entity (NCE)" or "new medical entity (NME)" were raised. The Commerce and Industry Minister then assured the Parliament that he would refer these issues to an Expert Committee for detailed examination and report the matter to the Parliament. Accordingly, a Technical Expert Group on Patent Law Issues was set up by the Government of India, Ministry of Commerce & Industry, Department of Industrial Policy & Promotion *vide* O. M. No. 12/14/2005-IPR-III dated April 5, 2005 (**Annex-I**).

1.2 The Technical Expert Group consisted of the following:

| | |
|--|----------|
| Dr. R.A. Mashelkar Director General Council of Scientific and Industrial Research New Delhi | Chairman |
| Prof. Goverdhan Mehta Director Indian Institute of Science Bangalore | Member |
| Prof. Asis Datta Director National Centre for Plant Genome Research New Delhi | Member |
| Prof. N.R. Madhava Menon Director National Judicial Academy Bhopal | Member |
| Prof. Moolchand Sharma Director National Law Institute University Bhopal | Member |

1.3 Terms of Reference of the Group were:

1.3.1 whether it would be TRIPS compatible to limit the grant of patent for pharmaceutical substance to new chemical entity or to new medical entity involving one or more inventive steps; and

1.3.2 whether it would be TRIPS compatible to exclude micro-organisms from patenting.

2 Approach

2.2 The Expert Group adopted a consultative approach to seek inputs from different stake holders such as industry associations, non-governmental organizations, intellectual property attorneys, etc. through written submissions, presentations, etc. The Group studied the inputs received and also took into account other relevant literature to arrive at their assessment. The Expert Group has arrived at specific recommendations and conclusions as given below.

2.3 In making the recommendations, the Group was guided by the need for access of affordable medicines to Indian people at large, encouraging innovation by Indian industry, its current capabilities in R&D, and balancing of India's obligations under international agreements with the wider public interest.

3 Practices in Other Countries

3.1 Patenting practices relating to new chemical entities and micro-organisms in some countries are summarised in **Annex-II**.

4 Summary of Submissions and Presentations

4.1 A summary of the various submissions and presentations made to the Group is presented in **Annex-III**.

5 Conclusions and Recommendations

5.1 Based on the interactions the Group had with various stakeholders and a detailed examination of the critical legal and technical issues involved, perusal of related literature, the Group has come to the following conclusions and recommendations:

(a) New Chemical Entity

Terms of Reference: *Whether it would be TRIPS compatible to limit the grant of patent for pharmaceutical substance to new chemical entity or to new medical entity involving one or more inventive steps:*

5.2 The term "**new chemical entity**" appears for the first time in International Intellectual Property agreements in the TRIPS Agreement of 1994, under Article 39.3:

"Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize **new chemical entities**, (emphasis added) the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use."

- 5.3 According to the United States (US) Food and Drug Administration (FDA), a new molecular entity (NME) or new chemical entity (NCE) means a drug that contains no active moiety that has been approved by FDA in any other application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act.
- 5.4 The term "**new medical entity**" has neither been used nor defined in the TRIPS Agreement.
- 5.5 Article 27 of the TRIPS Agreement elaborates the scope of patentable subject matter as follows:
1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
 2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
 3. Members may also exclude from patentability:
 - (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
 - (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement."
- 5.6 Granting patents only to NCEs or NMEs and thereby excluding other categories of pharmaceutical inventions is likely to contravene the mandate under Article 27 to grant patents to all 'inventions'. Neither Articles 7 and 8 of the TRIPS Agreement

nor the Doha Declaration on TRIPS Agreement and Public Health can be used to derogate from this specific mandate under Article 27.

- 5.7 Article 1 of the TRIPS Agreement requires compliance to the provisions of the Agreement, while TRIPS plus provisions are optional. This would mean that limiting grant of patents to pharmaceutical substances to new chemical entities only, and excluding new forms of crystals, polymorphs, etc., if they satisfy the criteria of patentability, is not consistent with TRIPS Agreement.
- 5.8 Section 2 (1) (j) of the Indian Patents Act defines "invention" as a new product or process involving an inventive step and capable of industrial application. The term "pharmaceutical substance" has also been defined in Section 2 (1) (ia) as any new entity involving one or more inventive steps. The term "inventive step" has been defined in Section 2 (1) (ja) as a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art. Thus, a chemical to be patentable must be new, non-obvious and have utility. However, Section 3 excludes certain inventions from being patented. This, *inter alia*, includes the exclusions under Section 3 (d) as under:

"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."

Thus, the new form of a known substance would not be patentable unless it differs significantly in properties with regard to efficacy.

National Interest perspective

- 5.9 If the aim of limiting patents to new chemical entities is to prevent a phenomenon loosely referred to as 'ever-greening', this can be done by a proper application of patentability criteria as present in the current patent regime.
- 5.10 It is important to distinguish 'ever-greening' from what is commonly referred to as 'incremental innovation'. While 'ever-greening' refers to an extension of a patent monopoly, achieved by executing trivial and insignificant changes to an already existing patented product, 'incremental innovations' are sequential developments that build on the original patented product and may be of tremendous value in a country like India. Therefore, such incremental developments ought to be encouraged by the Indian patent regime.
- 5.11 Restricting patentability just to NCEs or NMEs could have both legal and scientific ramifications. There is a perception that even the current provisions in the Patents Act could be held to be TRIPS non-compliant. Drug discovery research is still finding its feet in India. Though many companies are investing, it will at least

- be a decade before a critical mass is in place and results start accruing. Thus, restricting patentability to just NCEs would mean that most of the pharmaceutical product patents would be owned by MNCs.
- 5.12 In case of patenting of drugs, the protection to various forms of same substance (salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixture, etc.) is often seen as 'ever-greening' (extending incremental protection to a subsisting patent) and hence such protection is objected to.
- 5.13 In most countries, patenting of an invention for different forms of the same substance is subjected to the test of novelty, non-obviousness (unexpected effect) and utility before it is granted patent protection. Such a protection in the form of incremental inventions in respect of known and new molecules or a process potentially provides an added advantage to an inventor or a firm to retain its market share or capture a space in the established market. However, patenting an invention does not imply that a person can practice the invention; he would have to exercise due diligence and ensure that the rights of others are not infringed.
- 5.14 Many drug industry stakeholders feel that the use of the expression "new chemical entity" under the Patents Act would lead to many interpretations. While some Indian drug industry representatives feel that limiting grant of patents to new chemical entities will not be conducive to competitive growth, some others feel that patent protection should only be given based on the strict compliance of the patentability criteria. Many Indian industry representatives are not in favour of widening the scope of patentability.
- 5.15 The group examined the current level and type of R&D innovations that the Indian drugs and Pharma industry was undertaking. Annexure IV and V provide some representative samples of international patents filed by the Indian industry. It is clearly seen that most of them are based on incremental inventions.
- 5.16 **In the light of the above discussion, it would not be TRIPS compliant to limit granting of patents for pharmaceutical substance to New Chemical Entities only. However, every effort must be made to provide drugs at affordable prices to the people of India. Further, every effort should be made to prevent the grant of frivolous patents and 'ever-greening'. Detailed Guidelines should be formulated and rigorously used by the Indian Patent Office for examining the patent applications in the pharmaceutical sector so that the remotest possibility of granting frivolous patents is eliminated.**

(b) Micro-organisms:

Terms of Reference: *Whether it would be TRIPS compatible to exclude micro-organisms from patenting.*

- 5.17 The Concise Oxford Dictionary, defines the term micro-organism as "Any of various microscopic organisms, including algae, bacteria, fungi, protozoa and viruses" and the Collins English Dictionary, defines this term as "Any organism, such as a virus, of microscopic size."
- 5.18 The Institute of Science, UK describes micro-organism as an organism that can be seen only under a microscope, usually, an ordinary light microscope. They are

usually of the order of microns (millionths of a metre) or tens of microns in linear dimensions, and include bacteria, mycoplasma, yeasts, single celled algae and protozoa. Multicellular organisms are normally not included, nor fungi, apart from yeasts. Viruses are also not automatically included; many scientists do not classify them as organisms, as they depend on cells to multiply. Hawker and Linton in their book 'Micro-organisms, Function, Form and Environment' state that the term micro-organism is derived from the minute size of the various organisms. Viruses are included, though they are non-cellular particles, which are not capable of independent life and can proliferate only in living cells. Brock in his book 'Biology of Micro-organisms' describes micro-organisms, as a microscopic organism consisting of a single cell or cell cluster, including the viruses. Evans and Killington in their book 'Introduction to Microbiology, Heritage' define Micro-organisms as microscopic life forms including microscopic fungi, Protista, prokaryotes and viruses. Hawker, Linton, Folkes and Carlile in their book 'Biology of Micro-organisms' describe Micro-organisms as consisting of several distinct groups of organism, most of whose members are of microscopic dimensions.

- 5.19 Microbiological inventions include new products, processes, uses and compositions involving biological materials. These inventions cover methods to isolate and obtain new organisms, improve their character, modify them and find their new and improved uses.
- 5.20 Patenting of new micro-organisms is based on their differences with the characters and uses of micro-organisms as available in the prior art. Known micro-organisms are restricted to new uses, wherever patent law permits such a protection. The same is the case with genetically modified micro-organisms. Genes and gene products are treated similar to chemical compositions. Patenting of animal and human genes quite often attracts issues regarding public order and morality.
- 5.21 Position of Micro-organisms in the Indian Patents Act, 1970 as amended up to 2005 is as follows:

Section 3 of the Patents Act specifies inventions which are not patentable. The relevant provisions of that Section are as below:

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."

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."

The above provisions clearly identify micro-organisms as patentable subject matter, provided they fulfil the prescribed criteria.

In the *Dimminaco AG vs. Controller of Patents*, the Calcutta High Court held in 2002 that a patent on a micro-organism is valid. The court ruled that the Act did not preclude a living end product from being patented.

- 5.22 Article 27.3 of the TRIPS Agreement states that Members may also exclude from patentability:
- “(a) diagnostic, therapeutic and surgical method for the treatment of humans or animals;
(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes. ”
- 5.23 Thus, Article 27.3 of the TRIPS Agreement clearly excludes plants and animals from being patented, but regards micro-organisms as different from plants and animals. While naturally occurring micro-organisms should not qualify for patenting, micro-organisms involving human intervention and utility are patentable subject matter under the TRIPS Agreement, provided they meet the prescribed patentability criteria.
- 5.24 Universally, as practised by most patent offices, new micro-organisms isolated for the first time from the natural surrounding can only be patented if they differ in character from the known micro-organisms and find a new or improved use or function. The issue has been discussed and debated in Europe for a number of years. In many countries, including European countries, USA, Republic of Korea, Japan and China, patenting of micro-organisms is not an issue. Claims to micro-organisms have been allowed on the grounds that they are the products of micro-biological processes.

National Interest perspective

- 5.25 Biotech industry is one of the fastest growing industries in the world, including in India. India being one of the bio-diversity rich countries, it would, thus, be prudent for us to protect biotechnological inventions as that would help Indian biotechnology research compete globally attracting collaborations, FDI, contract R&D, etc. to the best advantage of the Indian R&D and biotech industry. India needs to reap the due benefits from its rich bio-resources with an enabling provision for protection of intellectual property in bio-technological innovations and inventions.
- 5.26 There have been instances of patenting of Indian biological materials by other countries. It would, thus, be in our interest to document, protect and modify new micro-organisms isolated from various parts of our country and find their new and improved industrial uses. This step would help Indian biotech industry.
- 5.27 The group’s conclusion is based on the requirements of Article 27.3 of the TRIPS as articulated in 5.23 above and the provision of Indian Patent Act (Section 3 (j)). However, strict guidelines need to be formulated for examination of the patent applications involving micro-organisms from the point of view of substantial human intervention and utility.
- 5.28 **Excluding micro-organisms *per se* from patent protection would be violative of TRIPS Agreement.**

Annex-I

Copy of Government of India, Ministry of Commerce & Industry,
Department of Industrial Policy & Promotion *vide* Order No.
12/14/2005-IPR-III dated April 5, 2005

ORDER

Subject:- Technical Expert Group on Patents law issues

A Technical Expert Group comprising the following persons has been constituted to study certain patents law issues:

- | | | | |
|----|--|---|----------|
| 1. | Dr. R.A. Mashelkar Director General Council of Scientific and Industrial Research 2, Rafi Marg, New Delhi – 110 001 | - | Chairman |
| 2. | Prof. Goverdhan Mehta Director Indian Institute of Science Bangalore – 560 012 | - | Member |
| 3. | Prof. Asis Datta Director National Centre for Plant Genome Research JNU Campus New Delhi – 110 067 | - | Member |
| 4. | Prof. Madhav Menon National Judicial Academy Bhopal | - | Member |
| 5. | Prof. Moolchand Sharma Director National Law Institute University Bhopal | - | Member |

Contd.....

2. The Group will have the following terms of reference:
 - a) whether it would be TRIPS compatible to limit the grant of patent for pharmaceutical substance to new chemical entity or to new medical entity involving one or more inventive steps; and
 - b) whether it would be TRIPS compatible to exclude micro-organisms from patenting.
3. The group will submit its report to the Department of Industrial Policy and Promotion.
4. The group will be serviced by the Department of Industrial Policy and Promotion.

Sd/-
(Rajeev Ranjan)
Director

Copy to:

All the members of the Group.

Copy also to

1. Prime Minister's Office
2. Cabinet Secretariat.
3. Office of CIM
4. Office of Secretary (IPP)
5. Ministries/Departments of Chemicals & Petro-chemicals, Health, Biotechnology, Science & Technology, Commerce, Scientific and Industrial Research, Agricultural Research & Education, Environment & Forests.

Patenting Practices in Other countries

Examination Guidelines for Patent Applications relating to Biotechnological Inventions at the UK Patent Office

These Guidelines set out the practice within the UK Patent Office as it relates to patent applications for biotechnological inventions. The 2000 Regulations came into force on 28 July 2000 and implemented the provisions of Articles 1 to 11 of the European Directive 98/44/EC on the legal protection of biotechnological inventions.

In the UK, the Patents Regulations 2000 confirmed and clarified that inventions concerning biological material, including gene sequences, may be legitimately the subject of patent applications. In other words, these Regulations have established beyond doubt the legitimacy of biotechnology patents in the UK.

"An invention shall not be considered unpatentable solely on the grounds that it concerns (a) a product consisting of or containing biological material; or (b) a process by which biological material is produced, processed or used"

[Paragraph 1, Schedule A2 to the Patents Act 1977]

Universally, it is an established practice that a natural substance which has been isolated for the first time and which had no previously recognized existence, does not lack novelty because it has always been present in nature.

It is generally agreed, and it is particularly relevant in the field of biotechnology, that a patent should not be granted merely because the applicant had been involved in laborious and costly effort. If the goal is known and sufficient of the theory and practice is known for the applicant to predict where he is going, without there being an original step, then an obviousness objection would be well founded.

Following the sequencing of various genomes, there is unlikely to be an inventive step in identifying from within a sequenced genome any new gene, even those without known homologues. It is obvious to trawl the genome for previously unidentified genes, and any skilled worker would have some expectation of success. In *Genentech*, an idea was considered obvious if "the materials in question were lying in the road and ready for a research worker to use", even if the skilled man faced a number of obstacles in proceeding to his goal. However, if overcoming these obstacles required "a spark of imagination....beyond the imagination properly attributable to him as a man skilled in the art" then there may be some element of inventive step. The use of bioinformatics tools would not seem to pose obstacles requiring a spark of imagination to overcome.

Paragraph 2 of Schedule A2 to the British Patents Act, 1977 permits biological material which is isolated from its natural environment or produced by means of a technical process to be the subject of an invention even if it previously occurred in nature. Claims to micro-organisms *per se* have been allowed on the grounds that they are products of microbiological processes. This applies even

when they are merely isolated from their natural surroundings, their isolation, culture, characterization and the finding of a utility turning what would be a discovery into an invention.

Claims for micro-organisms *per se* which have been isolated or obtained by artificially induced random mutation, are allowed but generalizations from such specific micro-organisms to novel species would not normally be permitted. On the other hand, claims to genetically modified micro-organisms derived from readily available known micro-organisms where the invention resides in the gene introduced, may be claimed more generally. Also claims to mutants and variants of a specified deposited micro-organism are allowed provided they possess the same inventive property as the deposited micro-organism.

Patenting of Micro-organisms in China

Claims for micro-organisms *per se* are allowed in China. DNA sequences are considered to be large chemical compounds, and may be patented as compositions of matter. Although patent claims to naturally occurring DNA sequences might be expected to trigger the 'products of nature' rule, courts have upheld patent claims covering 'purified and isolated' DNA sequences as new compositions of matter resulting from human intervention. An excised gene is eligible for a patent as a composition of matter or as an article of manufacture because that DNA molecule does not occur in that isolated form in nature; or synthetic DNA preparations are eligible for patents because their purified state is different from the naturally occurring compound.

Article 25 of the Chinese Patent Law states that:

For any of the following, no patent right shall be granted:

- (1) Scientific discoveries;
- (2) Rules and methods for mental activities;
- (3) Methods for the diagnosis or for the treatment of diseases
- (4) Animal and plant varieties;
- (5) Substances obtained by means of nuclear transformations.

For processes used in producing products referred to in items (4) of the preceding paragraph, patent right may be granted in accordance with the provisions of the Law.

Patenting of Micro-organisms in Europe

The European Union has defined "biological material" instead of "micro-organism", as under [Article 2.1 (a)]

"Biological material means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system"

In Plant Genetic Systems application (T356/93) European Board of Appeal was seized with the question as to what is meant by the term 'micro-organism' The Board held that a micro-organism would include bacteria, yeast, fungi, algae, protozoa, plasmids and viruses, but also animal or plant cells and generally all unicellular entities with dimensions beneath the limits of human vision.

Article 53(b) of the European Patent Convention (EPC) provides that European patents shall not be granted in respect of 'plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof'.

In its decision of 16 June 1999 the Administrative Council inserted a new Chapter VI entitled 'Biotechnological inventions' in Part II of the EPC Implementing Regulations. The new provisions entered into force on 1 September 1999 and implemented the requirements of the EU Biotechnology Directive in European patent law. The EPO has introduced four new rules, Rules 23b to 23e. Rule 23b sets out general matters and defines the meaning of biotechnological inventions, biological material, plant variety, and microbiological process. Rule 23c states patentable biotechnological inventions, including:

- Biological material isolated from their environment, even if known in nature. This particularly applies to genes that are isolated from their natural environment by means of technical processes and made available for industrial production.
- Plants or animals if the invention is not confined to a single variety

The provision clarifies the scope of Article 53(b) of EPC. It indicates that a plant grouping characterized only by a particular gene, but not by its whole genome, is not covered by the protection of new varieties and therefore is in principle patentable. This also applies if such plant grouping comprises plant varieties.

Rule 23d sets out what is not patentable. This includes processes for cloning human beings, processes for modifying the genetic identity of human beings, using human embryos for commercial purposes and modifying the genetic identity of animals such as may cause them suffering without substantial medical benefit. The list is to be seen as giving concrete form to the concepts of 'ordre public' and 'morality'.

Rule 23e indicates what is and is not patentable with respect to the human body. The human body and its elements cannot be patented. However, elements of the body, when isolated from the body, may be patented.

Patenting of Micro-organisms in Japan

In 1997, the Japanese Patent Office (JPO) published its 'Implementing Guidelines for Inventions in Specific Fields'. Inventions in the biotechnology field in the Guidelines are divided into four types: genetic engineering, micro-organisms, plants and animals. Inventions relating to genetic engineering include those of a gene, a vector, a recombinant vector, a transformant, a fused cell, a recombinant protein, and a monoclonal antibody. Inventions relating to micro-organisms include micro-organisms *per se* as well as those relating to the use of micro-organisms.

In Japan, micro-organism means yeast, molds, mushrooms, bacteria, actinomycetes, unicellular algae, viruses, protozoa, etc. and further includes undifferentiated animal or plant cells as well as animal or plant tissue cultures.

Patenting of New Chemical Entity in US:

According to the United States (US) Food and Drug Administration (FDA), a new molecular entity (NME) or new chemical entity (NCE) means a drug that contains no active moiety* that has been approved by FDA in any other application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act.

Patenting of Micro-organisms in USA

Art. 35 USC Sec 101 of the US patent law states: whoever invents or discovers any new and useful process, machine, manufactures, or composition of matter, or any new and useful improvement thereof, may obtain a patent thereof..."

In USA, utility requirement in respect of biotech inventions are very strict. A discovery that is not a creation does not meet the requirement of utility. A newly discovered micro-organism existing in nature, a newly discovered plant *per se* are discoveries because they do not involve creativity. Inventions that are incapable of industrial application do not meet the requirement of utility. Inventions of a gene, a vector, a recombinant vector, a transformant, a fused cell, a recombinant protein and a monoclonal antibody whose utility is not described in a specification or cannot be inferred, do not meet the requirement of utility. An invention of a micro-organism *per se*, a plant *per se* or an animal *per se* whose utility is not described or cannot be inferred does not meet the requirement of utility.

According to the new 'Utility Examination Guidelines' of the USPTO, if an isolated DNA fragment has a specific, substantial, and credible utility, the DNA fragment invention satisfies the requirement of utility and a patent can be granted for the DNA fragment. Where a new use is discovered for the patented DNA fragment, that new use may qualify for its own process patent. Of course, the later patent is a dependent patent of the DNA fragment patent.

Patenting of Micro-organisms in Australia

The Australian patent law defines invention as "any new manner of manufacture."

The question of patents for living organisms was considered at length in Ranks Hovis McDougall Ltd.'s Application [1976 A OJP 3915] and the Court held that:

- a) No objection can be taken to a claim to a new organism on the ground that it is something living;
- b) Any new variants claimed must have improved or altered useful properties and not merely have changed morphological characteristics which have no effect on the working of the organism; and
- c) Naturally occurring micro-organisms *per se* are not patentable as they represent

* An active moiety means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.

(Source: <http://en.wikipedia.org>)

a discovery and not an invention, but a claim to a pure culture in the presence of some specified ingredients would satisfy the requirement of a technical intervention.

The guidelines for a micro-organism in Australian Patent Law states, "what is discovered in nature without any practical application, is a mere chemical curiosity" and is not patentable [Part 8.2.5.3 Australian Manual of Patent Practice]. However, isolated micro-organisms are considered patentable.

Patenting Practices of Micro-organism in Brazil

Article 10 states that the following shall not be considered inventions or utility models:

"all or part of natural living beings and biological materials found in nature or isolated there from, including the genome or the germ plasm of any natural living being and any natural biological process."

Article 18 states that the following should not be patentable:

"living beings, in whole or in part, except for transgenic micro-organisms meeting the three requirements of patentability - novelty, inventive step and industrial application - in accordance with Article 8 and which are not mere discoveries."

For the purposes of this law, transgenic micro-organisms mean organisms, except for plants or animals in whole or in part, that due to direct human intervention in their genetic composition express a characteristic that cannot normally be achieved by the species under natural conditions.

Summary of Submissions and Presentations

Ranbaxy

New Chemical Entity (NCE):

As India's leading Pharmaceutical Company committed to R& D in the field of drug development, we are of the opinion that incremental innovations in terms of developing new forms, new derivatives and new delivery systems of existing drug should be granted patent protection provided they are new, involve an inventive step and have commercial utility. This will provide the necessary fillip to development of Novel Drug Delivery System (NDDS) in our laboratories.

Restricting patentability to NCEs may appear to be an attractive solution in the short –term to companies with a 'Reverse –Engineering' mind–set, but will not benefit hundreds of scientists working in our public & private R & D Centers, who are just starting off on the difficult task of new drug discovery research.

Restriction of patentability to NCEs alone is likely to benefit only MNCs which have the resources and the experience to develop NCEs. Indian companies that have far less resources are better placed to benefit from early commercialization of incremental innovations. A prerequisite to successful licensing deal for such products is the protection of the IP in the form of a patent, preferably in the country itself since products are being manufactured here.

Restricting patentability to NCEs is not compliant with Article 27.1 of TRIPS.

Patent Applications filed by Ranbaxy:

| Strategic Direction | | | |
|----------------------------|------------|-----------|------------|
| Segment | 2004 | 2007 | 2012 |
| Generics | *** | *** | *** |
| NDDS | * | ** | *** |
| NDDR | | | *** |
| Global Sales | US \$ 1 Bn | US \$ 2Bn | US \$ 5 Bn |

*Stars indicate importance/direction in the segment

AREAWISE PATENT FILING /GRANT TO RANBAXY
(Total number unique patent applications filed: 709)

| | India | | USA | |
|---------|--------------|-----------------|--------------|----------------|
| | Filed | Granted* | Filed | Granted |
| Process | 388 | 95 | 88 | 38 |
| APIs | 246 | 58 | 64 | 30 |
| Dosage | 142 | 37 | 24 | 08 |

| | | | | |
|-----------|-----|-----|-----|----|
| NDDS | 75 | 21 | 18 | 08 |
| NDDR | 75 | 23 | 40 | 13 |
| Herbal | 06 | - | - | - |
| Packaging | 01 | - | - | - |
| Total | 545 | 139 | 146 | 59 |

*includes accepted patent

The firm emphasizes that *NDDS products need patent protection since strength of Indian scientists lie in innovations that improve existing products*. Further, NDDS programs are less expensive, have lower gestation periods and result in IP that can be licensed. Example Cipro OD licensed by Ranbaxy to Bayer.

Ranbaxy has further tried to define "efficacy" as the capacity of the drug to produce a desired effect. In medical terms, clinical efficacy is the maximal effect that can be produced by a drug. Any factor such as bioavailability that substantially enhances a clinical outcome benefit would be deemed to be included in the definition of efficacy. Any invention on derivatives or properties that affect these factors should be deemed to be patentable, if it demonstrably and significantly influences the efficacy. This would include inventions on chemical modifications such as prodrugs, salts, polymorphs, etc. Such inventions should be patentable provided they meet the stringent patentability criteria under Section 3 (d) and 3 (e) and the invention is novel, non-obvious and industrially useful.

Micro-organisms:

No comments.

Krishna & Saurastri, Trademarks & Patent Attorneys

New Chemical Entity (NCE):

- a. It will not be TRIPS compatible to limit the grant of patent to pharmaceutical substances to new chemical entity or to new medical entity involving one or more inventive steps;
- b. Both the above things will be against specific interests of Indian inventors and a bonanza for multinational companies;
- c. Time has come to re-examine entire IPR policy of India. Best policy will be to ensure implementation of provisions of compulsory licensing provisions and Section 66 in letter and spirit. With fear of misuse or mischievous use gone, make scope of patentability as broad as possible by deleting ALL restrictive provisions on patentability except Sections 3 (b), 3 (p), 4, 39. This will give a real business impetus in investing in innovations, which will empower individual Indian inventors, which shall result in national as well as personal benefits.
- d. Article 1 of the TRIPS Agreement clearly indicates that what has been included in the Agreement is the compliance to minimum commitment is mandatory. If anything is optional, it is giving more extensive protection than has been stipulated in the Agreement. This clearly means that

excluding pharmaceutical substances other than new entities, which may include new forms of crystals, polymorphs etc, is not consistent with TRIPS requirements if they satisfy the criteria of patentability.

- e. In process patents regime, strength of Indian pharmaceutical companies was in their capability to invent new processes. Now in product patent regime also, this ability shall help them to reassert themselves. R&D in new chemical entities requires a huge financial commitment, staying ability and R&D capability, which very few Indian Pharma companies have. Even at present, patents portfolio of most Indian pharma companies, except one exception, is very poor as compared to the patents culture in similar companies in developed countries. Strength of our pharma companies lies at present in working around in presently generic products.
- f. This may include finding out better forms which have some strategic economic advantage such as better handling properties, better stability, *etc.*
- g. It is also possible that a new efficient process of an economically generic drug may be patented, but except for a new shape of crystals of the product produced by that process, there is nothing that can help in detecting that the patented process has been used by the infringer, in which case, although pharmaceutical substance produced is not a new chemical entity, the new crystal structure as a product claim shall have extraordinary strategic and economic importance. However, denying a patent to this claim shall work to disadvantage of such inventions, which are distinctly possible from Indian inventors in generics.
- h. When a new process is different and far more efficient, uses some reactants not used in earlier prior-art processes, and same chemical entity with same physical properties of its particles are produced, in such cases, even when such a process may be patented, the only practical and effective way to detect infringement will be given by only a product claim which claims presence of this impurity in trace quantities. Limiting patentability to new chemical entities only shall lead to denial of such a product claim from being granted, which shall work against the interest mainly of Indian inventors. They will find it circuitous and more expensive to prove that their process is being infringed in absence of an express product claim being granted.
- i. Many such examples are possible, and many unanticipated and unexpected may arise in future, where the proposed restrictions on patentability may turn out to be counterproductive.
- j. This means that they will be producing inventions, which shall be in the category other than "new chemical entities". By opting to exclude pharmaceutical substances other than new chemical entities from patenting in pharmaceutical area, we shall be offering bonanza to multinational companies, because "new chemical entities" is their exclusive strength at present and excluding all other pharmaceutical substances from patentability will make their competitive position further exclusively protected. This approach will hit Indian pharma companies. Loss of the multinationals will be marginal.
- k. The entire reason for excluding "New Forms" from being held patentable

emerges from the fear of "Greening of Patents". This is basically not a practical fear because even if a "New Form" is patented, this does not revive patent protection to the off-patent form nor to that chemical entity. What has expired as patent protection has expired. May be, the patentee can exercise his exclusivity on the "New Form", which shall not include protection to the chemical entity, but just the new form. But as long as the "Old Form" is useful for its purpose, the patent on "New Form" can be ignored and not used at all by the world. On the contrary, the "New Form" has such a significant improvement that its use is indispensable, in such a case why should anyone have a grudge against its patentability and licensing it lawfully'?

- l. Restrictive provisions on patentability are mainly on account of fear of misuse or mischievous use of exclusivity. This threat should not exist for us due to very strong compulsory licensing provisions and defensive provision. It shall be enough to give confidence that Sections 84 and 91 shall be implemented in case of genuine cases without any delay. These provisions protect the existing innovation based companies from possible crippling effects of monopolies from arrival of new critical patents from patentees of other countries. It is misconceived that they are useful only in national emergencies or only if public demand is not satisfied. If read properly, these sections are available not only in case of national emergencies; but even when a patentee is producing the product to satisfy public demand, if an already existing enterprise faces closure due to the new patent, compulsory license is available to avert the closure (See section 84 (7) (a) (i)). The only objection and that too valid one is that one has to wait for three years from the date of sealing of the patent for application of this provision. This problem, however, is solved by the very revolutionary provision of Section 91, where, if an enterprise has active R&D in the same field and the new patent is related to their existing ongoing R&D, they get the right from the date of sealing the patent. These two provisions between them avert any threat to Indian business and shall herald an era of cooperative business rather than competitive killer instinct based business.
- m. To take benefit of the potential profits from licensing of new molecules, Indian companies will have to start genuine work on several types of molecules. Once R&D culture settles in Indian Pharma companies, this avenue will also appear attractive and practical to them. This will mean a genuine and substantial change in Indian pharma R&D, which shall bring benefits to the Inventive individuals and companies for themselves and for the country. In course of time, lead molecules may emerge even from India.

Micro-organism:

- a. It will not be TRIPS compatible to exclude micro-organisms from patenting;
- b. It may be pointed out here that we have fully exploited the permitted exclusions under Section 3 of the Article 27. However, same provision very specifically and expressly excludes permission to exclude micro-organisms from patentability. With so clear express provisions, here is no way to interpret that micro-organisms can be excluded from patentability.

Shri V.R. Krishna Iyer

New Chemical Entity:

It is well within the TRIPS norms to limit patentability to new chemical entities in respect of pharmaceutical inventions

Micro-organism:

It was observed that micro-organisms, which occur in nature and which at best, could be regarded, as discoveries cannot constitute patentable inventions. There should be no patent protection in respect of such cases.

In clause 3(j), the expression "other than micro-organisms, but" should be deleted. Alternatively, under proviso to section 1(3) of the Act, the commencement of the provision should be deferred till a review of the question of according patent protection to micro-organisms and non biological and micro biological processes, as initiated by the WTO in 1999, is completed, and the position is reviewed afresh by India. It is significant globally there is opposition to such protection."

Biocon

New chemical Entity.

No Comments

Micro-organisms.

The following should be considered un-patentable:

- a. Where the commercial exploitation would be contrary to morality or order public;
- b. Process for cloning human beings;
- c. Use of human embryos for industrial or commercial purposes;
- d. The human body, at the various stages of its formation and development;
- e. Naturally occurring gene and DNA sequences and minor variations thereof;
- f. Inherent utilities such as gene sequences coding for amino acids, peptides, proteins.

Eric Hoehrenberg

New Chemical Entity.

Patent search carried out by the leading Brazilian patent law practice concerning patents on salts, esters, polymorphs and similar "incremental innovation" by Indian companies in Brazil. There are 84 such patents from CIPLA, Dr. Reddy's Labs, and Ranbaxy. It should be noted that many of these patents are also pending at the European Patent Office. Thus, it seems that whatever rhetoric may be used within India regarding such inventions, it is clear that leading Indian companies view such innovations as indeed important enough to patent in key markets outside of India. We would strongly suggest that patents on salts,

esters etc. should indeed be granted if such products meet the internationally-accepted conditions of novelty, involving an inventive step, and capable of industrial application (TRIPS Article 27(1)).

The EU and US have addressed the issue of patents on "incremental" or "adaptive" innovation as follows:

Article 35 under Section 101 of the US patent law states: "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..."

A report by the EU working Group on Pharmaceuticals and public health noted in its 28 March 2000 report to the High-level Committee on health for policies and Actions in the framework of the EU treaty of Amsterdam that: "Innovation in pharmaceuticals encompasses many different options, going from the development of a completely new medicine for the treatment of a disease otherwise incurable, to modifications of known formulations to improve benefits for the patients, such as a less invasive administration route or a simpler administration schedule."

Micro-organisms:

No Comments.

Indian Drug Manufacturers' Association

New Chemical Entity:

Our submission is that the Parliament had only an NCE in mind when it approved Section 2 and 3 particularly Section 3 clauses (d), (e) and (f);

The US FDA uses only term New Chemical Entity although their patent law is very broad and unsuitable for a developing country like India.

Definition of New Chemical Entity in USA - US FDA Rule Sec. 505 (b) describes a 'new chemical entity' as ". . . a drug that contains no active moiety that has been approved by FDA in any other application submitted under section 505 (b) of the Food, Drug and Cosmetic Act. . . ." The patentability criteria should be such so as to

- a. Avoid 'Me-Too' patents and ever-greening of patents. Patentability criteria should not be too broad so as to give rise to ever-greening of patents. We do not want to follow the US example where for example - there are 28 new patents issued between 1995-2005 on the same one drug Meningitis Vaccine, mostly for minor variations.
- b. The definition of NCE should include 'salts', 'esters', 'metabolites', 'derivatives' etc. This will avoid multiplicity of patent applications and gross abuse of patent monopolies and thus, would reduce litigation and public exploitation.

- c. It should support the policy of the Government to bring down medicine prices.
- d. The new definition of patentable 'pharmaceutical substance' should be supported by other provisions of the Patents Act particularly Sections 2 and 3.

Suggestion 1:

Section 2 (1) (ta):

Present Text: "pharmaceutical substance" means any new entity involving one or more inventive steps;

Proposed text: Section 2 (1) (ta) - "pharmaceutical substance" means any new chemical entity with a significant therapeutic advancement with one or more inventive steps.

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,~~ and therefore, shall not be patentable.

Suggestion 2:

Present Text

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 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'

Proposed text:

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 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~~" and, therefore, shall not be patentable.

Suggestion 3

Section 2 (1) (ja)

Present Text: "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art.

Proposed text:

Section 2 (1) (ja) - "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge ~~or~~ and having economic significance ~~or both~~ and that makes the invention not obvious to a person skilled in the art.

Suggestion 4:

Present Text:

Section 2 (1) (I): "new invention" means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art.

Proposed Text:

Sec. 2 (1) (I): "new invention" means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of ~~state of the art~~ prior art.

Changes suggested:

(i) To use the term 'New Chemical Entity' instead of the term 'New Medical entity' with a view to reduce litigation, public exploitation and ever-greening by MNCs;

(ii) To drop words like "efficacy", "mere", "significant" from the text of Section 3 of the Patents Act.

(iii) The term 'Prior art' is preferred in Section 2(1)(I) instead of the phrase 'state of the art';

(iv) In the definition of inventive step the conjunction 'or' betweenexisting Knowledge, having economic significanceshould be replaced with 'and'.

Micro-organisms:

It is our submission that naturally occurring micro-organisms and other naturally occurring allied biological materials should be considered non-patentable.

Suggested text of Section 3 (j)

Plants and animals in whole or any part thereof ~~other than micro-organisms~~ other than man-made or biotechnologically altered micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.

Changes suggested:

(i) Micro-organisms should be made patentable as per TRIPS. However, in Section 3(j) the relevant phrase 'micro-organisms' should be replaced with 'Man-made or biotechnologically altered micro-organisms';

(ii) On the issue of patentability of micro-organisms, mandatory review of TRIPS provisions by the TRIPS Council should be awaited;

Gene Campaign

New Chemical Entity:

No Comments.

Micro-organisms:

Patentability of micro-organisms should be for those micro-organisms which have been produced by adequate human intervention and fulfil the criterion of novelty, non-obviousness and industrial utility. Mere discovery and isolation will not be considered sufficient human intervention.

Patents should not be granted on materials obtained from national and international collections and depositories.

When a material is taken from a country, Article 15 of the Convention on Biological Diversity should be respected. No patent should be granted without prior informed consent and material transfer agreements.

When a patent is granted, the patent holder should be obliged to share the economic benefits with the communities of the country from where the material was obtained.

In view of the critical nature of the subject matter, patents involving micro-organisms should not be granted on a broad basis (overarching patents with a very wide scope).

Patents should be granted strictly based on patentability criteria with no generalisation, that is, for the organism only with respect to that particular function or property that constitutes the invention. The organism should remain free for others to create inventions.

Oxford Intellectual Property Research Centre, University of Oxford, U.K.

New Chemical Entity:

No Comments.

Micro-organism:

The issue regarding protection to micro-organism is an independent one. The world has now moved far beyond this debate and we ought, in view of the rapid progress of our biotech industry, to grant protection to those micro-organism that are new and non obvious. The above suggestions are confined to addressing the TRIPS compliant legal options.

Drug Action Forum

New Chemical Entity:

We feel that there is an urgent need to restrict the definition of new chemical entity. The definition of patentable 'pharmaceutical substance' should be as follows – "Pharmaceutical substance means new drug molecule involving one or more inventive step". And the definition of 'patentable invention' should be as follows – "Invention means a basic product or process involving an inventive step and capable of industrial application".

Micro-organisms:

No Comments.

National Working Group on Patent Law:

New Chemical Entity:

- (i) The scope of 'invention' should be limited to basic novel product or process involving inventive step and capable of industrial application;
- (ii) The scope of 'pharmaceutical substance' should be limited to new molecular entity with significant therapeutic advancement involving one or more inventive steps;
- (iii) There is lacuna about the definition of 'pharmaceutical substance'. Apart from the definition there is no mention of this patentable subject matter anywhere in the amended Patents Act 1970. Section 5 of the Act has been omitted through the Patents (Amendment) Act 2005. We would suggest this Section which could incorporate specifically 'pharmaceutical substance' should be re-introduced with the following version:

Section 5

Patents shall be available for basic novel inventions including pharmaceutical substances as defined in Section 2 whether products or processes in all fields of technologies excluding inventions stipulated under Section-3 provided that they are new, involve an inventive step and are capable of industrial application.

To sum up our suggestions in regard to definitions of 'invention' and 'pharmaceutical substance' are in harmony with each other and clause (d) including its explanation under Section 3 quoted above. We would emphasize that basically the incrementally changed presentation must not be allowed for patenting.

Micro-organism:

- (i) Patenting of life forms may have at least two dimensions. Firstly, there is the ethical question of the extent of private ownership that could be extended to life forms. The second dimension relates to the use of IPRs' concept as understood in the industrialized world and its appropriateness in the face of the larger dimension of rights on knowledge, their ownership, use, transfer and dissemination.
- (ii) Micro-organisms as such occur in nature. If any micro-organism is discovered it cannot be called invention, it falls in the category of discovery. Micro-organism when genetically modified falls in the category of invention because of human input. Genetically modified micro-organism may perform any number of activities. If a researcher is able to research upon a particular activity, and he is allowed patenting of his genetically modified micro-organism this will result in blocking of further research on that micro-organism. This is a peculiar situation arising out of patenting of micro-organisms. In view of these circumstances it would not be appropriate even to allow patenting of genetically modified micro-organism also as such.

Association of Biotechnology Led Enterprises

New Chemical Entity:

No Comments.

Micro-organisms:

The inventions to be considered patentable which have novelty, inventive steps and commercial utility.

The following to be considered non-patentable:

- where the commercial exploitation would be contrary to morality or *ordre public*
- Process for cloning human beings
- Use of human embryos for industrial or commercial purposes
- The human body, at the various stages and sequence and minor variations thereof

- Naturally occurring gene and DNA sequence and minor variations thereof.
- Inherent utilities such as gene sequences coding for amino acids, peptide, proteins.

Indian Pharmaceutical Congress Association

New Chemical Entity:

The recent Patent Act disqualifies grant of patents for salts, esters, ethers, polymorphs, metabolites, pure forms, particle size, isomers, mixture of isomers, complexes, combinations and other derivatives of known substance and shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy. This may help to prevent ever greening of patents.

This clause is akin to the Directive 2004/27/EC of the European Parliament and Council of 31 March 2004, which provides guidelines for "generic medicinal product". The Official Journal of European Union L 136/39 dated 30.4.2004 under Article 10 See 2.(b) "generic medicinal product" shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorized active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines. This directive is aimed to avoid ever greening of patents.

Micro-organisms:

No Comments.

Indian Pharmaceutical Alliance

New Chemical Entity:

It would be TRIPS compatible to limit the grant of patent to new chemical entities or new medical entity involving one or more inventive steps.

Micro-organisms:

No Comments.

Affordable Medicines & Treatment Campaign

New Chemical Entity:

The terms '**New chemical entity**' and '**new medical entity**' are not interchangeable terms and each term has its own legal meaning.

The specific terminology used in the patent legislation can make a significant difference in expanding or alternatively restricting the scope of patentability, directly affecting access to affordable drugs. Expanding the scope of patentability will lead to greater number of drugs being patented adversely affecting access to affordable drugs. On the other hand restricting that scope of patentability will prevent trivial patenting of drugs leading to access to cheaper generic drugs.

The term "**new chemical entity**" is normally restricted only to mean a new chemical substance, which is not known earlier. On the other hand the term "new medical entity" is an expansive term which includes different forms of the same chemical entity i.e. usage form, dosage form, salt form, etc. Hence all new chemical entities are new medical entities but all new medical entities are not new chemical entities.

The limiting the scope of patentability is absolutely necessary for India not only to address the public health concerns but also for the survival of the domestic pharmaceutical industry. To effectively limit the scope of patentability the criteria of novelty, inventive step and industrial application should be defined as per national interests. This is to be done by amending the definitions of patentable criteria in the present Patents Act. Further, the definition of pharmaceutical substance to be replaced with a new definition and this definition should be then linked to the provisions and exclusions mentioned in Section 3 of the Act.

It would be TRIPS compatible to limit the grant of patent to new chemical entities.

Micro-organisms:

No Comments.

The International Association for the Protection of Industrial Property (AIPPI) (India Group)

New Chemical Entity:

The AIPPI (Indian Group) felt that the current exclusions should follow the TRIPS Agreement and the explanation to Section 3(d) should be deleted.

The Group felt that NCE is not a "patent" term but a "regulatory" term and it is not appropriate to define the said term in the Act.

The Group felt that Section 3(d) which prevailed between the period 1st January,

2005 to 8th April 2005 was the best and that the word 'mere' ought to be restored in *the* Section. The Group also felt that the Ordinance 2004 amended Section 3(d) to ensure that what is not patentable is only mere new use. If a second medical indication or therapeutic use of a known drug molecule passes the test that it is not a mere new use- as per the Ordinance it would have been patentable. The Patents Amendment Act, 2005 changed this position. Instead, it contains a rather too long explanation on the exemption to patentability under Section 3(d). According to this Section what is not patentable is:

- a) 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;
- b) The mere discovery of any new property or new use for a known substance; and
- c) The mere use of a known process, machine or apparatus unless such process results in a new product or employs at least one new reactant.

Consequently, if a discovery of a new form of a known drug molecule results in an enhancement of its known efficacy, it is patentable. However, the mere discovery of a new use of a known substance is not patentable. The amended Section 3(d) when read in conjunction with Section 3(i) would ensure that all method of use inventions are non-patentable. A joint reading of the amended Section 3(d) and Section 3(i) is capable of keeping a major portion of pharmaceutical R&D outside the scope of patents.

If this cannot be done then at least the explanation to the said Section ought to be deleted under the present Act so that the Section should go back to its old form prior to the 1st of January, 2005.

The Group also felt that substantial and unexpected qualitative departure of properties of the claimed NCE should qualify for inventiveness. When there is a significant difference in effectiveness or utility compared to basic compounds, salts, esters, derivatives, isomers, purified forms, complexes, hydrates, crystalline forms, etc., should be considered as having inventive merit. The Group made the following suggestions:

- (i) The Explanation to Section 3 (d) of Patents Act should be deleted.
- (ii) 'New Chemical Entity' is not a patent term but only a regulatory term and it is not appropriate to define it in the Patents Act.

Micro-organisms:

- An inconsistency exists between the actual laws which are based upon the general principle that a living organism *per se* cannot be the subject matter of a patent, and the state of science which nowadays makes it possible to describe and repeat procedures for the modification of a living organism.
- Patent protection for particular biotechnological inventions exists in most countries.
- Processes involving the industrial use of living organisms are generally patentable.

- Micro-organisms *per se* and other biological materials, including plants, *per se*, are patentable in many countries.
- Plants and even animals are also protectable in some countries by special rights.
- AIPPI re-affirms the principle that inventions relating to living organisms, be they micro-organisms, plants, animals or parts thereof, or to other biological material or to processes for obtaining or using them should be patentable on the sole condition that they comply with the usual criteria of patentability. The Resolution of Rio de Janeiro, which laid down this principle has been well accepted and has had a positive influence on the ongoing work in WIPO.
 - Resolution : A new Special Arrangement under Article 15 of the Paris Convention should be made, providing for:
 - deposition in a culture collection of the micro-organism (s) described in a patent specification and not available to the public as a requisite for grant of a patent;
 - deposition in one culture collection approved under this Arrangement as being sufficient to meet the requirements of all States parties to this Arrangement;
 - deposition on or before the filing of the first patent application (with the possibility of formal details of deposition being furnished, later within a prescribed period.
- The following suggestions are made:
 - (i) Exclusion of patenting of micro-organisms might be violative of TRIPS. Only the scope of the term should be clarified.
 - (ii) The broadest definition for micro-organisms should be used. The definition should be a guideline or directive rather than a statutory definition.
 - (iii) Cell lines should not be excluded from patentability.

Lex Orbis

New Chemical Entity:

- (i) It would be TRIPS violative if Indian Patent Law expressly excludes non-NCE Pharmaceutical product inventions from patentability
- (ii) The possibility of setting a high threshold with Section 3 (d) to justify the exclusion of non-NCE pharmaceutical substances from patentability is to be explored;

Micro-organisms:

- (a) Article 27(3)(b) of TRIPS mandates WTO Members not to exclude "micro-organisms", "non-biological" and "microbiological processes" from the scope of patentability. Thus under Article 27(3) (b) of TRIPS, the Members are under obligation to provide patents for micro-organisms.
- (b) In order to bring the Indian law in compliance with the aforesaid TRIPS provisions, a new clause to Section 3 was added in the Indian Patents Act (by the Patents (Amendment) Act, 2002) which excluded from patentability, 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.

- (c) Thus TRIPS and the Indian law clearly provide that 'micro-organisms' are patentable. As such, it will violate TRIPS if 'micro-organisms' *per se* are excluded from the scope of patentability. The approach, therefore, has to be more 'definitional' and 'interpretative' than a blanket direct exclusion that attracts yet another dispute at the WTO. The key question that follows is - whether it is possible for India to adopt a very narrow and limited definition of 'micro-organisms' to exclude everything other than "microscopic organisms including ONLY algae, bacteria, fungi, protozoa and viruses. In the alternative, should there be an expansive definition of 'micro-organism' to include within its scope all 'biological materials' containing genetic information and capable of reproducing itself or being reproduced in a biological system (as in the Europe).
- (d) It could be in India's national interests to make 'micro-organisms' patentable and also to provide an expanded definition of 'micro-organism' so as to include in its scope 'biological materials' including DNA fragments, genes, and proteins as China provides.
- (e) An alternative approach is to adopt the European approach (European Directive (98/44/EC) and provide for a further broader definition of "Biological material" to include "any material containing genetic information and capable of reproducing itself or being reproduced in a biological system" and bring that under the scope of patentable subject matter.
- (f) An explanation to Section 3(j)- could be added with a balanced definition on the following lines:

Explanation - for purposes of this clause, "micro-organism" means only microscopic organisms including algae, bacteria, fungi, protozoa, viruses, DNA fragments, genes, and proteins.

Crop Life

New Chemical Entity.

The discovery and development of a new molecule is an expensive proposition in developed countries, a new drug cost about \$1 billion for a new pesticide molecule, the cost is about \$ 300 million. In India, all this could be done at a much lower cost.

Still, the cost would be huge, about \$ 300 million (Rs. 1,350 Crore) for a new drug; Indian companies at their current level of R & D spending (5-7 percent of their turnover) are not in a position to undertake such a high level of investment

Besides, the risk is very high. But incremental innovations are well within their reach. Our laws should promote these. This will enable our Scientists to put their creativity to best use. When Indian companies can tap these opportunities abroad (where these innovations are patentable), why not our own turf?

Patenting of incremental innovations should not be confused with the so called ever greening of a patent. Such a situation could arise only when the patentee having already enjoyed the 20-year term of his innovation, gets a further extension. The Patent office will simply not allow this.

The patenting of a new dosage form, say, liquid of an existing medicine is a totally impendent step. It does nothing to extend the patent term of the

medicine in its original form (solid) which on its expiry becomes open to competitors to come up with generic versions.

In order to give desired incentive for innovations at all levels, the Patent Law should provide for patenting of new forms, new uses and new formulations as well as combinations of known compounds so long as these fulfil three fold criteria of novelty, inventive step and capable of industrial application.

Micro-organisms:

No Comments.

Bradly Codon and Tapen Sinha

New Chemical Entity:

In the context of global and neglected diseases, uniformity of TRIPS obligations relating to patented medicine impose unnecessarily high costs on users and poor distribution of costs and benefits among producers and users of intellectual property. Uniform rules can have disparate effects that worsen inequalities rather than correct them. To achieve the correct balance between the rights of producers and users of patented medicine, a broader range of factors must be taken into account than are currently used in the WTO and UN contexts.

Micro-organisms:

No Comments.

Medicine San Frontiers, France

New Chemical Entity:

This submission approaches this question with an incremental approach-dividing pharmaceutical product related inventions other than New Chemical Entities (NCEs) into different categories, in particular new uses and new forms of known compounds and examining the patentability or otherwise of those categories.

Based on the provisions of the TRIPS Agreement and taking the present Indian legislation as a guide [especially Section 3(d)], it is argued that it is TRIPS compatible to exclude, as the present Indian legislation does, new uses of known compounds as new forms of known substances that fail to meet the requisite threshold tests. The determination of where the threshold tests (for example the meaning of 'mere' discovery, and the requirements for efficacy and inventive step) will be set is critical in determining which other inventions, other than NCEs will be patentable.

The logical end-point of a process of raising the thresholds required would be a position where only NCEs would be regarded as patentable.

Micro-organisms:

No Comments.

Organisation of Pharmaceutical Producers of India (OPPI)

New Chemical Entity:

Restricting Patentability to NCEs would have significant negative consequences for the discovery and developments of future treatments for all disease areas and also will be an area of concern to all investors, domestic and foreign because of the precedent it sets for the treatment of Intellectual Property in India.

Micro-organisms:

A clear definition of micro-organism needs to be provided.

I.P. Institute, London:

New Chemical Entity:

1. Limiting the grant of patents to NCEs/NMEs and thereby excluding other categories of pharmaceutical inventions the 'proposed exclusion' is likely to contravene the mandate under Article 27 of TRIPS to grant of patents to all 'inventions'. Neither Articles 7 and 8 nor the Doha Declaration can be used to derogate from this specific mandate under Article 27.
2. The proposed exclusion amounts to an unjustified differentially disadvantageous treatment of pharmaceutical inventions and is therefore likely to violate the 'non discrimination' mandate under Article 27.
3. If the aim of the proposed exclusion is to prevent a phenomenon loosely referred to as 'ever-greening', this can be done by a proper application of patentability criteria, as present in the current patent regime.
4. Lastly, it is important to distinguish the phenomenon of 'ever-greening' from what is commonly referred to as 'incremental innovation'. While 'ever-greening' refers to an undue extension of a patent monopoly, achieved by executing trivial and insignificant changes to an already existing patented product, 'incremental innovations' are sequential developments that build on the original patented product and may be of tremendous value in a country like India. Therefore, such incremental development ought to be encouraged by the Indian patent regime.

Micro-organisms:

India may not provide for a *per se* exclusion of 'micro-organisms' from patentability. However, should Indian policy imperatives require some limitation on the scope of protection provided for 'micro-organisms', the TRIPS agreement does provide some latitude by which this might be achieved. It is suggested that

1. The term 'micro-organism' could be defined in precise terms. However, this route suffers from certain drawbacks and the TRIPS implications of such a solution are not entirely clear.

2. The 'discovery' exception could be strengthened by stipulating that mere isolation or purification of a microorganism by known procedures will not render it patentable. Rather, only truly 'invented' microorganisms such as genetically engineered ones would be granted patent protection. Here again, in the absence of a WTO panel ruling on this or a related aspect of patent law, the extent to which the 'discovery' exception could be stretched without contravening TRIPS is not absolutely certain.
3. In principle, the 'morality' exception could be used to deny patents to micro-organisms. However, this could not be done without, at the same time, prohibiting any form of commercialisation of a micro-organism, a result that may not fit well with the government's recent policy towards fuelling the growth of the biotechnology industry.
4. The general patentability criteria (novelty, non obviousness, utility and written description) could be tailored to specifically apply to patent applications claiming micro-organisms. This could be in the form of examination guidelines to be applied strictly by the patent office to ensure that only truly meritorious inventions are granted patent protection.

On the various options, 2 and 4 may be best suited for India --- these options cater appropriately to India's current policy imperatives (given its current socio-economic realities), whilst at the same time remaining compliant with India's international obligations under TRIPS.

K&S Partners

New Chemical Entity:

In general, the scope of protection granted in respect of a drug/chemical extends to:

- The chemical that has been disclosed
- The application/use for which disclosed

It does not extend to

- Undisclosed derivatives, salts, esters etc which have a significant or unexpected property or result
- Metabolites that may be formed upon ingestion of drug
- New use of the drug

Suggested approach:

In view of the above discussion regarding Section 3, it is suggested that the Committee ought not to define the term "new chemical entity" or "new medical entity".

However, should the Committee proceed to define this term, the following workable definition is proposed:

Suggested definition:

"A new chemical entity is an entity that is new, not obvious to a person skilled in the art in the form and for the application claimed".

Final comments:

- Defining "new chemical/medical entity" is unwarranted as far as patent is concerned.
- New chemical entity should never be the basis for patentability.
- If the definition of "new chemical/medical entity" limits or conflicts with TRIPS Art 27 then it would violate TRIPS.
- Patent Act is for inventors, R&D institutions.

Micro-organisms:

With regard to higher life forms such as animals (e.g. Harvard mouse), WTO Members retain the discretion to grant or not to grant patent protection. However, as per TRIPS there is no discretion with regard to micro-organism since micro-organism should be patentable in all countries.

TRIPS makes it mandatory for the Members to grant patent protection for micro-organism. Hence, a law that does not provide patent protection for micro-organisms is TRIP-violative.

Isolated' Vs. 'Genetically modified micro-organisms:

TRIPS (Article 27.3) does not distinguish between 'isolated' and 'genetically modified micro-organisms'. The only criteria for patentability of micro-organisms is novelty, non-obviousness and industrial applicability, implying thereby that any substance (including microbes) that is new, non-obvious with utility ought to be granted patent protection.

Any Member country implementing laws drawing distinctions between isolated and genetically modified micro-organism would be violative of TRIPS.

Alternative Law Forum

New Chemical Entity:

No comments

Micro-organism:

It is important to devise proper novelty and non-obvious tests for the patenting of micro-organisms, use the flexibilities available within TRIPS to set up appropriate tests of novelty and non-obviousness for determining the patentability of micro-organisms so as to avoid the granting of patents which offer no or little inventiveness and ultimately would amount to discoveries.

As TRIPS allows Member States to define the scope of micro-organisms, patents over micro-organisms should be strictly limited to the scientific definition of the term, i.e. virus, bacteria, fungi, protozoa and algae. Member States are free to determine the scope of invention. Therefore, the Patents Act should exclude the patenting of materials found in nature, even if isolated or purified from plants and animals.

By providing a scientific definition of micro-organism, the Patents Act should exclude patents over genes, proteins, DNA sequences, cells, seeds, etc.

The prior art and novelty tests should be constructed in such a way that micro-organisms known to perform a definite function or process in an environment be recognised as already existing or known, in case the new claim is over the micro-organism performing similar functions or processes in another environment or organism.

Centre for Study of Global Trade System and Development

New Chemical Entity:

1. Pharmaceutical products with annual sales totalling nearly \$1 billion in Canada have had their market monopolies extended by ever greening strategies under the patented medicines (Notice of Compliance) Regulations.
2. Brand-name drug companies have employed strategies under the Regulations to extend their exclusive marketing rights on blockbuster drugs.
3. Health Canada approved only 16 new active substances in 2003, yet brand-name drug companies added 103 patents to health Canada's Patent Register in that same year.
4. Under the Regulations, brand-name drug companies are allowed to list patents for uses of a drug; even though the drug is not approved for that use by Health Canada. Patents can be listed to restart the automatic stay even years after the basic patent on the drug has expired.
5. Policymaker' concerns - Various policymakers have expressed concerns about the Regulations. The Romanow Report of November 28, 2002 referred to ever greening as a particular concern affecting the cost of drugs.
6. A particular concern with current pharmaceutical industry practice is the process of "ever greening," whereby manufacturers of brand name drugs make variations to existing drugs to extend their patent coverage. This delays the ability of generic manufacturers to develop cheaper products for the marketplace and is a questionable outcome of Canada's patent law.
7. A number of examples illustrate the use of multiple-patent strategies to keep generic products off the market in Canada and the U.S. has been employed increasingly for block-buster drugs whose basic patents have expired, to extend market exclusivity as long as possible.
8. It is important to ensure that such ever greening as in Canada does not happen in India.

ANNEXURE IV

PCT Applications filed by Indians in the field of drug and pharmaceuticals (mostly pertaining to different forms of same substance)

| Sr. No. | PCT Application / Title | Assignee |
|----------------|---|---|
| 1 | (WO 2001/097775) CONTROLLED RELEASE ANTI-INFLAMMATORY FORMULATION | AJANTA PHARMA LIMITED |
| 2 | (WO 2006/080029) EXTENDED RELEASE FORMULATION OF LEVETIRACETAM | ALEMBIC LIMITED |
| 3 | (WO 2006/046256) EXTENDED RELEASE FORMULATION OF PRAMIPEXOLE DIHYDROCHLORIDE | ALEMBIC LIMITED |
| 4 | (WO 2004/108117) EXTENDED RELEASE OSMO-MICROSEALED FORMULATION COMPRISING VENLAFAXINE | ALEMBIC LIMITED |
| 5 | (WO 2000/009071) A NOVEL LIPOSOMAL FORMULATION USEFUL IN TREATMENT OF CANCER AND OTHER PROLIFERATION DISEASES | ALL INDIA INSTITUTE OF MEDICAL SCIENCES |
| 6 | (WO 2006/123243) PHARMACEUTICAL DOSAGE FORMS OF AN ANTIDEPRESSANT | AUROBINDO PHARMA LIMITED |
| 7 | (WO 2006/111853) STABLE SOLID DOSAGE FORMS OF ACID LABILE DRUG | AUROBINDO PHARMA LIMITED |
| 8 | (WO 2006/109175) SOLID DOSAGE FORM OF AN ANTIDIABETIC DRUG | AUROBINDO PHARMA LIMITED |
| 9 | (WO 2006/087629) RAPIDLY DISINTEGRATING COMPOSITION OF OLANZAPINE | AUROBINDO PHARMA LIMITED |
| 10 | (WO 2006/082523) PHARMACEUTICAL SUSTAINED RELEASE COMPOSITION OF METFORMIN | AUROBINDO PHARMA LIMITED |
| 11 | (WO 2006/054175) STABLE DOSAGE FORMS OF ACID LABILE DRUG | AUROBINDO PHARMA LIMITED |
| 12 | (WO 2006/100602) IMMEDIATE RELEASE STABLE SOLID DOSAGE FORMS OF AN ANTIHYPERTENSIVE DRUG | AUROBINDO PHARMA LTD |
| 13 | (WO 2006/035313) SOLID UNIT DOSAGE FORMS OF 5-HT1 AGONIST | AUROBINDO PHARMA LTD |
| 14 | (WO 2005/060942) EXTENDED RELEASE PHARMACEUTICAL COMPOSITION OF METFORMIN | AUROBINDO PHARMA LTD |
| 15 | (WO 2006/021965) EUKARYOTIC BASED SYNERGISTIC FORMULATION FOR GASTRO-INTESTINAL DISORDERS | BHARAT BIOTECH INTERNATIONAL LIMITED |
| 18 | (WO 2002/069983) AMPHOTERICIN B AQUEOUS COMPOSITION | BHARAT SERUMS & VACCINES LTD. |
| 19 | (WO 2001/097796) CLEAR AQUEOUS ANAESTHETIC COMPOSITION | BHARAT SERUMS & VACCINES LTD. |
| 20 | (WO 2004/022699) LIQUID STABLE COMPOSITION OF OXAZAPHOSPHORINE WITH MESNA | BHARAT SERUMS AND VACCINES LTD. |
| 21 | (WO 2002/100438) ORAL CONTROLLED RELEASE DRUG DELIVERY SYSTEM WITH HUSK POWDER FROM LEPIDIUM SATIVUM SEEDS | BLUE CROSS LABORATORIES LIMITED |

| Sr. No. | PCT Application / Title | Assignee |
|----------------|---|---|
| 25 | (WO 2005/123134) A CONTROLLED RELEASE DELIVERY SYSTEM FOR METFORMIN | CADILA HEALTHCARE LIMITED |
| 26 | (WO 2005/107716) CONTROLLED RELEASE PAROXETINE-CONTAINING TABLETS BASED ON A CORE AND A COATING | CADILA HEALTHCARE LIMITED |
| 27 | (WO 2004/106322) POLYMORPHS OF ARIPIPRAZOLE | CADILA HEALTHCARE LIMITED |
| 28 | (WO 2004/002445) NOVEL FLOATING DOSAGE FORM | CADILA HEALTHCARE LIMITED |
| 30 | (WO 2003/086343) FAST DISINTEGRATING ORAL DOSAGE FORMS | CADILA HEALTHCARE LIMITED |
| 31 | (WO 1999/049875) THE PROCESS FOR THE PREPARATION OF A STABLE FIXED DOSE PHARMACEUTICAL COMPOSITION OF ANTI INFECTIVE AGENT/AGENTS AND MICRO ORGANISMS AS ACTIVE INGREDIENTS | CADILA PHARMACEUTICALS (E.A.) LTD. |
| 32 | (WO 2005/076748) THERAPEUTIC COMPOSITION AND METHOD FOR PREPARING FROM DODONAEA SP | CHODAVARAPU, Janakiram |
| 35 | (WO 2001/032185) A PHARMACEUTICAL COMPOSITION CONTAINING BISPHOSPHONIC ACID(S) OR SALT(S) THEREOF AND A PROCESS OF PREPARING THEREOF | CIPLA LTD. |
| 36 | (WO 2001/032143) A PHARMACEUTICAL COMPOSITION FOR THE ADMINISTRATION OF WATER-INSOLUBLE PHARMACEUTICALLY ACTIVE SUBSTANCES AND A PROCESS FOR PREPARATION THEREOF | CIPLA LTD. |
| 37 | (WO 2006/067807) PHARMACEUTICAL COMPOSITION FOR THE TREATMENT OF INVASIVE PULMONARY ASPERGILLOSIS | COUNCIL OF SCIENTIFIC AND INDUSTRIAL RESEARCH |
| 43 | (WO 2006/067537) A SYNERGISTIC ANTIPYRETIC FORMULATION | COUNCIL OF SCIENTIFIC AND INDUSTRIAL RESEARCH |
| 47 | (WO 2004/087127) SYNERGISTIC HEPATOPROTECTIVE COMPOSITION AND A METHOD THEREOF | COUNCIL OF SCIENTIFIC AND INDUSTRIAL RESEARCH |
| 55 | (WO 2004/084852) NONTOXIC DENTAL CARE HERBAL FORMULATION FOR PREVENTING DENTAL PLAQUE AND GINGIVITIS | COUNCIL OF SCIENTIFIC AND INDUSTRIAL RESEARCH |
| 56 | (WO 2003/080847) CATIONIC AMPHIPHILES FOR INTRACELLULAR DELIVERY OF THERAPEUTIC MOLECULES ITS COMPOSITION, PROCESS AND USE THEREOF | COUNCIL OF SCIENTIFIC AND INDUSTRIAL RESEARCH |
| 60 | (WO 2003/080081) SYNERGISTIC COMPOSITION OF TRANS-TETRACOS-15-ENOIC ACID AND APOCYNIN AND USE THEREOF | COUNCIL OF SCIENTIFIC AND INDUSTRIAL RESEARCH |
| 66 | (WO 2003/080052) A USE OF TREATMENT FOR FUNGAL INFECTIONS WITH A SYNERGISTIC FORMULATION OF ANTIFUNGAL AGENTS | COUNCIL OF SCIENTIFIC AND INDUSTRIAL RESEARCH |
| 68 | (WO 2001/074353) A SYNERGISTIC ANTI-MALARIAL FORMULATION | COUNCIL OF SCIENTIFIC AND INDUSTRIAL RESEARCH |
| 73 | (WO 2001/072317) FORMULATION COMPRISING THYMOL USEFUL IN THE TREATMENT OF DRUG RESISTANT BACTERIAL INFECTIONS | COUNCIL OF SCIENTIFIC AND INDUSTRIAL RESEARCH |

| Sr. No. | PCT Application / Title | Assignee |
|----------------|---|---|
| 74 | (WO 2001/072304) A NOVEL ANTI-MICROBIAL COMPOSITION AND METHOD FOR PRODUCING THE SAME | COUNCIL OF SCIENTIFIC AND INDUSTRIAL RESEARCH |
| 75 | (WO 2004/032972) AN ORAL FORMULATION OF METHYLGLYOXAL AND ITS IMINO ACID CONJUGATES FOR HUMAN USE | DABUR RESEARCH FOUNDATION |
| 78 | (WO 2002/094256) LYSINE AND/OR ANALOGUES AND/OR POLYMERS THEREOF FOR PROMOTING WOUND HEALING AND ANGIOGENESIS | DATTA, Debatosh |
| 79 | (WO 2003/066612) NOVEL POLYMORPHIC FORMS OF BICYCLIC ANTIDIABETIC AGENTS: PROCESS FOR THEIR PREPARATION AND PHARMACEUTICAL COMPOSITIONS CONTAINING THEM | DR. REDDY'S LABORATORIES LIMITED |
| 80 | (WO 2003/013480) IMPROVED ENTERIC FORMULATION OF FLUOXETIN | DR. REDDY'S LABORATORIES LTD. |
| 81 | (WO 2002/069936) PHARMACEUTICAL COMPOSITION OF IBUPROFEN | DR. REDDY'S LABORATORIES LTD. |
| 82 | (WO 2000/063192) NOVEL POLYMORPHIC FORMS OF AN ANTIDIABETIC AGENT: PROCESS FOR THEIR PREPARATION AND PHARMACEUTICAL COMPOSITIONS CONTAINING THEM | DR. REDDY'S RESEARCH FOUNDATION |
| 83 | (WO 2000/063191) NOVEL POLYMORPHIC FORMS OF AN ANTIDIABETIC AGENT: PROCESS FOR THEIR PREPARATION AND A PHARMACEUTICAL COMPOSITION CONTAINING THEM | DR. REDDY'S RESEARCH FOUNDATION |
| 84 | (WO 2001/035943) DEXTROSE AND INSULIN FLUID FORMULATION FOR INTRAVENOUS INFUSION | GANGAL, Hanamaraddi, T. |
| 85 | (WO 2006/090268) PROCESSES FOR THE PREPARATION OF ALFUZOSIN AND SALTS THEREOF AND NOVEL CRYSTALLINE FORMS OF ALFUZOSIN | GLENMARK PHARMACEUTICALS LIMITED |
| 87 | (WO 2005/046648) EXTENDED RELEASE PHARMACEUTICAL DOSAGE FORMS COMPRISING ALPHA-2 AGONIST TIZANIDINE | GLENMARK PHARMACEUTICALS LTD. |
| 90 | (WO 2004/089935) NOVEL CRYSTALLINE FORMS OF S-OMEPRAZOLE MAGNESIUM | HETERO DRUGS LIMITED |
| 95 | (WO 2006/103688) A NOVEL CRYSTALLINE FORM OF RUPATADINE FREE BASE | HETERO DRUGS LIMITED |
| 96 | (WO 2004/089952) NOVEL CRYSTALLINE FORMS OF ABACAVIR SULFATE | HETERO DRUGS LIMITED |
| 100 | (WO 2004/089281) NOVEL POLYMORPHS OF TOLTERODINE TARTRATE | HETERO DRUGS LIMITED |
| 101 | (WO 2004/087688) NOVEL CRYSTALLINE FORMS OF GATIFLOXACIN | HETERO DRUGS LIMITED |
| 102 | (WO 2004/085416) NOVEL CRYSTALLINE FORMS OF (S)-CITALOPRAM OXALATE | HETERO DRUGS LIMITED |
| 103 | (WO 2004/083191) NOVEL CRYSTALLINE FORMS OF LAMOTRIGINE | HETERO DRUGS LIMITED |
| 104 | (WO 2004/083183) NOVEL CRYSTALLINE FORMS OF ARIPIPRAZOLE | HETERO DRUGS LIMITED |
| 105 | (WO 2004/076443) AMORPHOUS FORM OF LOSARTAN POTASSIUM | HETERO DRUGS LIMITED |
| 106 | (WO 2004/076417) NOVEL CRYSTALLINE FORMS OF | HETERO DRUGS LIMITED |

| Sr. No. | PCT Application / Title | Assignee |
|----------------|--|--------------------------------------|
| | TRANDOLAPRIL | |
| 107 | (WO 2004/074350) BICALUTAMIDE POLYMORPHS | HETERO DRUGS LIMITED |
| 108 | (WO 2004/100682) A NOVEL COMPOSITION OF COMPLEX METAL SALT OF GARCINIA ACID, A PROCESS FOR PREPARING THE SAME AND USE THEREOF | INDFRAG LIMITED |
| 109 | (WO 2004/100968) A SYNERGISTIC COMPOSITION FOR THE TREATMENT OF DIABETES MELLITUS | INDUS BIOTECH PVT. LTD. |
| 110 | (WO 2006/109318) NOVEL POLYMORPH OF 3-HYDROXY-3-(3'-SULFAMYL-4'-CHLOROPHENYL)PHTHALIMIDINE | IPCA LABORATORIES LIMITED |
| 111 | (WO 2002/043707) PHARMACEUTICAL FORMULATION | KHAN, Abdul Rehman |
| 129 | (WO 2005/102289) CLARITHROMYCIN EXTENDED RELEASE FORMULATION | LUPIN LIMITED |
| 138 | (WO 2005/030178) EXTENDED RELEASE FORMULATION OF BETA-LACTAM ANTIBIOTICS | LUPIN LTD. |
| 149 | (WO 2005/065682) RABEPRAZOLE CONTAINING FORMULATION | LYKA LABS LIMITED |
| 150 | (WO 2006/054316) METHOD(S) OF PREPARATION, STABILIZATION, COMPOSITION, AND ADMINISTRATION OF GAMMA-LINOLENIC ACID FOR BRAIN TUMORS | MAGENE LIFE SCIENCES PRIVATE LIMITED |
| 151 | (WO 2005/115423) USING ORGANIC AND/OR INORGANIC POTASSIUM AND ITS SALTS TO TREAT AUTOIMMUNE AND OTHER HEALTH DISORDERS AND METHODS OF ADMINISTERING THE SAME | MEDASANI, Munisekhar |
| 152 | (WO 2005/092356) A NOVEL HERBAL COMPOSITION FOR TREATING HIV/AIDS AND FUNGAL INFECTIONS SECONDARY TO HIV | MEENAKSHISUNDARAM, Palaniappan |
| 153 | (WO 2006/123354) ORAL PHARMACEUTICAL COMPOSITION | MEGA LIFESCIENCES PVT. LTD. |
| 154 | (WO 2005/115090) A HERBAL COMPOSITION HAVING POTENT ANTIMICROBIAL AND WOUND HEALING PROPERTIES | MEHTA, Dilip, Sukhlal |
| 155 | (WO 2006/048894) NOVEL CRYSTALLINE FORMS OF ATORVASTATIN CALCIUM AND PROCESSES FOR PREPARING THEM. | MOREPEN LABORATORIES LIMITED |
| 156 | (WO 2004/084855) KERATOLYTIC COMPOSITION WITH ANTI-ALLERGIC ANTI-INFLAMMATORY PROPERTIES | MUNISEKHAR, Medasani |
| 159 | (WO 2006/082598) NOVEL CRYSTALLINE FORMS OF RIZATRIPTAN BENZOATE | NATCO PHARMA LIMITED |
| 161 | (WO 2006/054314) POLYMORPHIC FORMS OF IMATINIB MESYLATE | NATCO PHARMA LIMITED |
| 162 | (WO 2006/040779) CONTROLLED RELEASE GASTRIC FLOATING MATRIX FORMULATION CONTAINING IMATINIB | NATCO PHARMA LIMITED |
| 163 | (WO 2005/105036) CONTROLLED RELEASE MUCOADHESIVE MATRIX FORMULATION CONTAINING TOLTERODINE AND A PROCESS FOR ITS PREPARATION | NATCO PHARMA LIMITED |
| 164 | (WO 2005/077933) NOVEL POLYMORPHIC FORM OF IMATINIB MESYLATE AND A PROCESS FOR ITS PREPARATION | NATCO PHARMA LIMITED |
| 165 | (WO 2005/053659) AN IMPROVED PHARMACEUTICAL FORMULATION CONTAINING TAMSULOSIN SALT AND A | NATCO PHARMA LIMITED |

| Sr. No. | PCT Application / Title | Assignee |
|----------------|--|---|
| | PROCESS FOR ITS PREPARATION | |
| 166 | (WO 2004/098573) AN IMPROVED AND STABLE PHARMACEUTICAL COMPOSITION CONTAINING SUBSTITUTED BENZIMIDAZOLES AND A PROCESS FOR ITS PREPARATION | NATCO PHARMA LIMITED |
| 167 | (WO 2001/039836) A RAPID ACTING FREEZE DRIED ORAL PHARMACEUTICAL COMPOSITION FOR TREATING MIGRAINE | NATCO PHARMA LIMITED |
| 168 | (WO 2001/035926) AN IMPROVED PHARMACEUTICAL COMPOSITION FOR TREATING MALE ERECTILE DYSFUNCTION | NATCO PHARMA LIMITED |
| 169 | (WO 2001/064163) AN IMPROVED HERBAL COMPOSITION HAVING ANTIALLERGIC PROPERTIES AND A PROCESS FOR THE PREPARATION THEREOF | NATURAL REMEDIES PRIVATE LIMITED |
| 170 | (WO 2004/032899) ANTIBIOTIC FORMULATION FOR INTRAMAMMARY ADMINISTRATION IN MILKING ANIMALS | ORCHID CHEMICALS & PHARMACEUTICALS LTD. |
| 172 | (WO 2004/019901) SUSTAINED RELEASE PHARMACEUTICAL COMPOSITION | ORCHID CHEMICALS & PHARMACEUTICALS LTD. |
| 173 | (WO 2004/016251) SUSTAINED RELEASE PHARMACEUTICAL COMPOSITION OF A CEPHALOSPORIN ANTIBIOTIC | ORCHID CHEMICALS AND PHARMACEUTICALS LTD. |
| 174 | (WO 2004/016250) SUSTAINED RELEASE PHARMACEUTICAL COMPOSITION OF A CEPHALOSPORIN ANTIBIOTIC | ORCHID HEALTH CARE |
| 175 | (WO 2004/014390) NOVEL PHARMACEUTICAL COMPOSITION OF CEFTIOFUR | ORCHID HEALTH CARE |
| 176 | (WO 2001/052897) THERAPEUTIC ANTI-INFLAMMATORY AND ANALGESIC COMPOSITION CONTAINING SELECTIVE COX-2 INHIBITORS | PANACEA BIOTEC LIMITED |
| 177 | (WO 2001/039749) FAST DISSOLVING COMPOSITION WITH PROLONGED SWEET TASTE | PANACEA BIOTEC LIMITED |
| 178 | (WO 2001/022791) CONTROLLED RELEASE COMPOSITIONS COMPRISING NIMESULIDE | PANACEA BIOTEC LIMITED |
| 179 | (WO 2005/065685) CONTROLLED RELEASE PHARMACEUTICAL COMPOSITION COMPRISING AN ACID-INSOLUBLE AND A BIOADHESIVE POLYMER | PANACEA BIOTEC LTD. |
| 180 | (WO 2005/065641) NON-DISINTEGRATING ORAL SOLID COMPOSITION OF HIGH DOSE OF WATER SOLUBLE DRUGS | PANACEA BIOTEC LTD. |
| 181 | (WO 2005/065640) COMPOSITIONS OF BUCCAL DOSAGE FORMS FOR EXTENDED DRUG RELEASE AND THE PROCESS OF PREPARING SUCH COMPOSITIONS | PANACEA BIOTEC LTD. |
| 182 | (WO 2000/013696) COMPOSITION FOR IMPROVING MENTAL CAPABILITIES IN MAMMALS | PANDITA, Maharaj, Krishen |
| 183 | (WO 2004/108114) ANTI-FUNGAL COMPOSITION AND A PROCESS FOR ITS MANUFACTURE | PATEL, Dinesh, Shantilal |
| 184 | (WO 2000/072884) A NOVEL FORMULATION OF N-(4-NITRO-2-PHENOXYPHENYL)METHANESULFONAMIDE | PATEL, Dinesh, Shantilal |
| 185 | (WO 2006/046257) AN AYURVEDIC COMPOSITION AND PROCESS FOR PREPARING THE COMPOSITION TO ACT AS ANTI SNAKE-VENOM | PAWAR, Geeta, Pandurang |
| 187 | (WO 2006/117616) POLYMORPHIC FORM I OF LUMEFANTRINE AND PROCESSES FOR ITS PREPARATION | RANBAXY LABORATORIES LIMITED |

| Sr. No. | PCT Application / Title | Assignee |
|----------------|---|------------------------------|
| 188 | (WO 2006/103551) CONTROLLED RELEASE FORMULATIONS OF OXYCODONE | RANBAXY LABORATORIES LIMITED |
| 189 | (WO 2006/100574) AMORPHOUS CEFDITOREN PIVOXIL GRANULES AND PROCESSES FOR THE PREPARATION THEREOF | RANBAXY LABORATORIES LIMITED |
| 190 | (WO 2006/085208) STABLE SOLID DOSAGE FORMS OF AMLODIPINE AND BENAZEPRIL | RANBAXY LABORATORIES LIMITED |
| 191 | (WO 2006/085168) SOLID ORAL DOSAGE FORMS OF ZIPRASIDONE CONTAINING COLLOIDAL SILICONE DIOXIDE | RANBAXY LABORATORIES LIMITED |
| 192 | (WO 2006/077492) SUSTAINED RELEASE ORAL DOSAGE FORMS OF GABAPENTIN | RANBAXY LABORATORIES LIMITED |
| 194 | (WO 2006/072921) SWEETENER COMPOSITION OF STEVIA EXTRACT AND MALTOL AND PROCESSES OF PREPARATION THEREOF | RANBAXY LABORATORIES LIMITED |
| 195 | (WO 2006/072878) ORAL DOSAGE FORMS OF SERTRALINE HAVING CONTROLLED PARTICLE SIZE AND PROCESSES FOR THEIR PREPARATION | RANBAXY LABORATORIES LIMITED |
| 196 | (WO 2006/070248) METHODS FOR THE PREPARATION OF STABLE PHARMACEUTICAL SOLID DOSAGE FORMS OF ATORVASTATIN AND AMLODIPINE | RANBAXY LABORATORIES LIMITED |
| 197 | (WO 2006/064304) ACID ADDITION SALTS OF MUSCARINIC RECEPTOR ANTAGONISTS | RANBAXY LABORATORIES LIMITED |
| 198 | (WO 2006/059217) STABLE SOLID DOSAGE FORMS OF AMLODIPINE BESYLATE AND PROCESSES FOR THEIR PREPARATION | RANBAXY LABORATORIES LIMITED |
| 199 | (WO 2006/046114) OSMOTIC DOSAGE FORMS PROVIDING ASCENDING DRUG RELEASE, AND PROCESSES FOR THEIR PREPARATION | RANBAXY LABORATORIES LIMITED |
| 200 | (WO 2006/046105) OXCARBAZEPINE DOSAGE FORMS | RANBAXY LABORATORIES LIMITED |
| 201 | (WO 2006/046100) PHARMACEUTICAL COMPOSITION OF ALENDRONIC ACID | RANBAXY LABORATORIES LIMITED |
| 202 | (WO 2006/046096) A POLYMORPHIC FORM OF NARWEDINE AND ITS USE IN THE SYNTHESIS OF GALANTAMINE | RANBAXY LABORATORIES LIMITED |
| 203 | (WO 2006/040643) POLYMORPHIC FORMS OF EFAVIRENZ AND PROCESSES FOR THEIR PREPARATION | RANBAXY LABORATORIES LIMITED |
| 204 | (WO 2006/035293) POLYMORPHIC FORMS OF QUETIAPINE HEMIFUMARATE | RANBAXY LABORATORIES LIMITED |
| 205 | (WO 2006/035291) CRYSTALLINE FORMS OF CEFDINIR POTASSIUM | RANBAXY LABORATORIES LIMITED |
| 206 | (WO 2006/035286) PROCESS FOR PREPARATING ENANTIOMERICALLY PURE FLUVASTATIN SODIUM AND A NOVEL POLYMORPHIC FORM THEREOF | RANBAXY LABORATORIES LIMITED |
| 207 | (WO 2006/035277) NOVEL PROCESSES FOR PREPARING AMORPHOUS ROSUVASTATIN CALCIUM AND A NOVEL POLYMORPHIC FORM OF ROSUVASTATIN SODIUM | RANBAXY LABORATORIES LIMITED |
| 208 | (WO 2006/030303) ORAL EXTENDED RELEASE DOSAGE FORM COMPRISING A HIGH DOSE BIGUANIDE AND A LOW DOSE SULFONYLUREA | RANBAXY LABORATORIES LIMITED |

| Sr. No. | PCT Application / Title | Assignee |
|----------------|--|------------------------------|
| 209 | (WO 2006/025029) EXTENDED RELEASE COMPOSITION OF DIVALPROEX | RANBAXY LABORATORIES LIMITED |
| 211 | (WO 2006/018807) CRYSTALLINE FORMS OF CEFDINIR | RANBAXY LABORATORIES LIMITED |
| 212 | (WO 2006/003587) SOLID ORAL DOSAGE FORMS OF AZABICYCLO DERIVATIVES | RANBAXY LABORATORIES LIMITED |
| 213 | (WO 2005/123721) AMORPHOUS AND POLYMORPHIC FORMS OF CANDESARTAN CILEXETIL | RANBAXY LABORATORIES LIMITED |
| 214 | (WO 2005/123137) LYOPHILIZED PHARMACEUTICAL COMPOSITION COMPRISING MOXIFLOXACIN HYDROCHLORIDE | RANBAXY LABORATORIES LIMITED |
| 215 | (WO 2005/107717) ORAL DOSAGE FORM FOR THE EXTENDED RELEASE OF BIGUANIDE AND SULFONYLUREA | RANBAXY LABORATORIES LIMITED |
| 216 | (WO 2005/099672) A MODIFIED RELEASE PHARMACEUTICAL FORMULATION COMPRISING AMOXICILLIN AND CLAVULANATE | RANBAXY LABORATORIES LIMITED |
| 217 | (WO 2005/092886) PROCESS FOR THE PREPARATION OF AMORPHOUS FORM OF TIAGABINE | RANBAXY LABORATORIES LIMITED |
| 219 | (WO 2005/092852) PROCESS FOR THE PRODUCTION OF ATORVASTATIN CALCIUM IN AMORPHOUS FORM | RANBAXY LABORATORIES LIMITED |
| 220 | (WO 2005/090301) CRYSTALLINE FORM OF ATORVASTATIN HEMI CALCIUM | RANBAXY LABORATORIES LIMITED |
| 221 | (WO 2005/087198) PROCESSES FOR THE PREPARATION OF SOLID DOSAGE FORMS OF AMORPHOUS VALGANCICLOVIR HYDROCHLORIDE | RANBAXY LABORATORIES LIMITED |
| 222 | (WO 2005/084636) A PROCESS FOR THE PREPARATION OF CONTROLLED-RELEASE PHARMACEUTICAL COMPOSITION OF METOPROLOL | RANBAXY LABORATORIES LIMITED |
| 223 | (WO 2005/082330) CO-PRECIPIATED AMORPHOUS CEFDITOREN PIVOXIL AND DOSAGE FORMS COMPRISING THE SAME | RANBAXY LABORATORIES LIMITED |
| 224 | (WO 2005/082329) PROCESS FOR THE PREPARATION OF SOLID DOSAGE FORMS OF VALSARTAN AND HYDROCHLORTHIAZIDE | RANBAXY LABORATORIES LIMITED |
| 225 | (WO 2005/077392) HERBAL FORMULATION COMPRISING EXTRACTS OF WITHANIA, TINOSPORA AND PICRORHIZA AS A PEDIATRIC TONIC | RANBAXY LABORATORIES LIMITED |
| 226 | (WO 2005/077332) STABLE SUSTAINED-RELEASE ORAL DOSAGE FORMS OF GABAPENTIN AND PROCESS FOR PREPARATION THEREOF | RANBAXY LABORATORIES LIMITED |
| 227 | (WO 2005/066196) AMORPHOUS FORM OF FINASTERIDE AND PROCESSES FOR ITS PREPARATION | RANBAXY LABORATORIES LIMITED |
| 228 | (WO 2005/051489) FAST DISSOLVING SOLID ORAL DOSAGE FORMS OF GALANTHAMINE | RANBAXY LABORATORIES LIMITED |
| 229 | (WO 2005/049003) EXTENDED RELEASE DOSAGE FORMS OF BUPROPION HYDROCHLORIDE | RANBAXY LABORATORIES LIMITED |
| 230 | (WO 2005/044238) MODIFIED RELEASE SOLID DOSAGE FORM OF AMPHETAMINE SALTS | RANBAXY LABORATORIES LIMITED |
| 231 | (WO 2005/040134) PROCESS FOR THE PREPARATION OF AMORPHOUS ROSUVASTATIN CALCIUM | RANBAXY LABORATORIES LIMITED |

| Sr. No. | PCT Application / Title | Assignee |
|----------------|---|------------------------------|
| 232 | (WO 2005/026140) PROCESS FOR THE PREPARATION OF CRYSTALLINE FORMS OF ORLISTAT | RANBAXY LABORATORIES LIMITED |
| 233 | (WO 2005/021000) SOLID ORAL DOSAGE FORMS OF GATIFLOXACIN | RANBAXY LABORATORIES LIMITED |
| 234 | (WO 2005/011666) STABLE SUSTAINED RELEASE ORAL DOSAGE FORM OF GABAPENTIN | RANBAXY LABORATORIES LIMITED |
| 235 | (WO 2005/009432) NEW DOSAGE REGIMEN IN CASE OF CONCURRENT INTAKE OF GABAPENTIN WITH FOOD AND AN INCREASED ORAL BIOAVAILABILITY THEREWITH | RANBAXY LABORATORIES LIMITED |
| 236 | (WO 2004/105735) CONTROLLED RELEASE PHARMACEUTICAL COMPOSITIONS OF TOLTERODINE AND PROCESSES FOR THEIR PREPARATION | RANBAXY LABORATORIES LIMITED |
| 237 | (WO 2004/104010) CRYSTALLINE FORM OF CEFDINIR | RANBAXY LABORATORIES LIMITED |
| 238 | (WO 2004/103361) A PHARMACEUTICAL DOSAGE FORM OF CITALOPRAM | RANBAXY LABORATORIES LIMITED |
| 239 | (WO 2004/099229) PROCESS FOR THE SYNTHESIS OF BASE ADDITION SALTS OF 2,3-O-ISOPROPYLIDENE-1-O-SUBSTITUTED-5,6-DIDEOXY-5-N- (4-(2-HYDROXY-2-OXOETHYL)-PHENYLAMINOCARBONYL) AMINO-L-GULOFURANOSIDES | RANBAXY LABORATORIES LIMITED |
| 240 | (WO 2004/098572) BIPHASIC RELEASE OF GLIPIZIDE FROM MONOCOMPARTMENT OSMOTIC DOSAGE FORM | RANBAXY LABORATORIES LIMITED |
| 241 | (WO 2004/082589) NASALLY ADMINISTRABLE, BIOAVAILABLE PHARMACEUTICAL COMPOSITION OF LORATADINE | RANBAXY LABORATORIES LIMITED |
| 242 | (WO 2004/076442) POLYMORPHS OF LOSARTAN | RANBAXY LABORATORIES LIMITED |
| 243 | (WO 2004/076440) POLYMORPHS OF S-OMEPRAZOLE | RANBAXY LABORATORIES LIMITED |
| 244 | (WO 2004/075881) STABLE PHARMACEUTICAL COMPOSITION OF RABEPRAZOLE AND PROCESSES FOR THEIR PREPARATION | RANBAXY LABORATORIES LIMITED |
| 245 | (WO 2004/075826) EXTENDED RELEASE, MULTIPLE UNIT DOSAGE FORMS OF PHENYTOIN SODIUM AND PROCESSES FOR THEIR PREPARATION | RANBAXY LABORATORIES LIMITED |
| 246 | (WO 2004/075825) DOSAGE FORMS OF AMLODIPINE AND PROCESSES FOR THEIR PREPARATION | RANBAXY LABORATORIES LIMITED |
| 247 | (WO 2004/064834) CO-PRECIPITATED AMORPHOUS LOSARTAN AND DOSAGE FORMS COMPRISING THE SAME | RANBAXY LABORATORIES LIMITED |
| 248 | (WO 2004/056354) CONTROLLED RELEASE PHARMACEUTICAL COMPOSITIONS OF TAMSULOSIN | RANBAXY LABORATORIES LIMITED |
| 249 | (WO 2004/056336) CONTROLLED RELEASE, MULTIPLE UNIT DRUG DELIVERY SYSTEMS | RANBAXY LABORATORIES LIMITED |
| 250 | (WO 2004/054550) AN EXTENDED RELEASE PHARMACEUTICAL COMPOSITION OF PHENYTOIN SODIUM | RANBAXY LABORATORIES LIMITED |
| 251 | (WO 2004/052345) COATING COMPOSITION FOR TASTE MASKING COATING AND METHODS FOR THEIR APPLICATION AND USE | RANBAXY LABORATORIES LIMITED |

| Sr. No. | PCT Application / Title | Assignee |
|----------------|--|------------------------------|
| 252 | (WO 2004/045622) PHARMACEUTICAL DOSAGE FORMS OF BIGUANIDE-SULFONYLUREA COMBINATIONS | RANBAXY LABORATORIES LIMITED |
| 253 | (WO 2004/045584) BUPROPION HYDROCHLORIDE SOLID DOSAGE FORMS | RANBAXY LABORATORIES LIMITED |
| 254 | (WO 2004/039352) AMORPHOUS FORM OF LOSARTAN POTASSIUM | RANBAXY LABORATORIES LIMITED |
| 255 | (WO 2004/010979) PROCESSES FOR THE PREPARATION OF ORAL DOSAGE FORMULATIONS OF MODAFINIL | RANBAXY LABORATORIES LIMITED |
| 261 | (WO 2004/004692) PROCESSES FOR THE PREPARATION OF ORAL DOSAGE FORMULATIONS OF MODAFINIL | RANBAXY LABORATORIES LIMITED |
| 262 | (WO 2003/103635) EXTENDED RELEASE FORMULATION OF DIVALPROEX SODIUM | RANBAXY LABORATORIES LIMITED |
| 263 | (WO 2003/103634) SUSTAINED RELEASE ORAL DOSAGE FORMS OF GABAPENTIN | RANBAXY LABORATORIES LIMITED |
| 264 | (WO 2003/084514) CONTROLLED RELEASE PHARMACEUTICAL COMPOSITIONS OF CARBIDOPA AND LEVODOPA | RANBAXY LABORATORIES LIMITED |
| 265 | (WO 2003/049716) STABLE TOPICAL FORMULATION OF CLARITHROMYCIN | RANBAXY LABORATORIES LIMITED |
| 268 | (WO 2003/039527) CONTROLLED RELEASE TABLETS OF METFORMIN | RANBAXY LABORATORIES LIMITED |
| 269 | (WO 2003/028704) EXTENDED RELEASE PHARMACEUTICAL COMPOSITION CONTAINING METFORMIN | RANBAXY LABORATORIES LIMITED |
| 270 | (WO 2003/026610) PROCESS FOR THE PREPARATION OF FAST DISSOLVING DOSAGE FORM | RANBAXY LABORATORIES LIMITED |
| 271 | (WO 2003/017981) CONTROLLED RELEASE FORMULATION OF CLARITHROMYCIN OR TINIDAZOL | RANBAXY LABORATORIES LIMITED |
| 272 | (WO 2002/094774) OXCARBAZEPINE DOSAGE FORMS | RANBAXY LABORATORIES LIMITED |
| 273 | (WO 2002/067943) ORAL PHARMACEUTICAL COMPOSITION OF CEFPODOXIME PROXETIL | RANBAXY LABORATORIES LIMITED |
| 275 | (WO 2002/047607) PROCESS FOR THE PREPARATION OF A FAST DISSOLVING DOSAGE FORM | RANBAXY LABORATORIES LIMITED |
| 276 | (WO 2002/024203) CONTROLLED RELEASE FORMULATIONS FOR ORAL ADMINISTRATION | RANBAXY LABORATORIES LIMITED |
| 277 | (WO 2002/017885) CONTROLLED RELEASE FORMULATION OF ERYTHROMYCIN OR A DERIVATIVE THEREOF | RANBAXY LABORATORIES LIMITED |
| 278 | (WO 2002/005816) A BIOAVAILABLE DOSAGE FORM OF LORATADINE | RANBAXY LABORATORIES LIMITED |
| 279 | (WO 2001/095886) BIOAVAILABLE DOSAGE FORM OF ISOTRETINOIN | RANBAXY LABORATORIES LIMITED |
| 280 | (WO 2001/019349) EXTENDED RELEASE FORMULATION OF ETODOLAC | RANBAXY LABORATORIES LIMITED |
| 282 | (WO 2000/071124) AMORPHOUS FORM OF FEXOFENADINE HYDROCHLORIDE | RANBAXY LABORATORIES LIMITED |
| 283 | (WO 2002/011716) LIQUID FORMULATION OF METFORMIN | RANBAXY SIGNATURE LLC |
| 286 | (WO 2002/022158) SELFEMULSIFIABLE FORMULATION HAVING ENHANCED BIOABSORPTION AND IMMUNOSUPPRESSION ACTIVITIES | RPG LIFE SCIENCES LIMITED |

| Sr. No. | PCT Application / Title | Assignee |
|----------------|---|---------------------------------------|
| 288 | (WO 2004/012701) NOVEL pH DEPENDENT ROBUST ENTERIC POLYMERIC CONTAINER, AN IMPROVEMENT OVER EXISTING ENTERIC DOSAGE FORMS. | SCITECH CENTRE |
| 293 | (WO 2005/046567) SYNERGISTIC FORMULATION OF ANTIOXIDANTS AND ANTIMYCOBACTERIAL AGENTS: A METHOD OF MAKING THE SAME | SHELGAONKAR, Meena |
| 294 | (WO 2003/011257) COMPOSITION AND PROCESS THE MANUFACTURE OF SOLUBLE CONTAINERS WITH IMPROVED GEL-STRENGTH | SINGH, Jasjit |
| 295 | (WO 2006/097938) STABLE LIQUID SUSPENSION FORMULATION COMPRISING TIBOLONE AND PROCESS FOR PRODUCING THE SAME | STRIDES ARCOLAB LIMITED |
| 296 | (WO 2005/120517) STABLE LIQUID SUSPENSION FORMULATION COMPRISING SYNTHETIC STEROIDS AND PROCESS FOR PRODUCING THE SAME | STRIDES ARCOLAB LIMITED |
| 297 | (WO 2005/120459) PHARMACEUTICAL COMPOSITION CONTAINING A STABLE AND CLEAR SOLUTION OF ANTI-INFLAMMATORY DRUG IN SOFT GELATIN CAPSULE AND PROCESS FOR PRODUCING THE SAME | STRIDES ARCOLAB LIMITED |
| 298 | (WO 2003/101378) PHARMACEUTICAL FORMULATION IN A DRUG DELIVERY SYSTEM AND PROCESS FOR PREPARING THE SAME | STRIDES ARCOLAB LIMITED |
| 299 | (WO 2003/070156) ORALLY ADMINISTRABLE PHARMACEUTICAL FORMULATION COMPRISING EPHEDRINE HYDROCHLORIDE AND PROCESS FOR PREPARING THE SAME | STRIDES ARCOLAB LIMITED |
| 300 | (WO 2003/070155) ORALLY ADMINISTRABLE PHARMACEUTICAL FORMULATION | STRIDES ARCOLAB LIMITED |
| 301 | (WO 2003/070154) ORALLY ADMINISTRABLE PHARMACEUTICAL FORMULATION COMPRISING PSEUDOEPHEDRINE HYDROCHLORIDE AND PROCESS FOR PREPARING THE SAME | STRIDES ARCOLAB LIMITED |
| 302 | (WO 2002/092078) ORAL CONTROLLED RELEASE PHARMACEUTICAL COMPOSITION FOR ONE-A-DAY THERAPY FOR THE TREATMENT AND PROPHYLAXIS OF CARDIAC AND CIRCULATORY DISEASES | SUN PHARMACEUTICAL INDUSTRIES LIMITED |
| 303 | (WO 2006/123358) STABLE ORAL PHARMACEUTICAL COMPOSITION | SUN PHARMACEUTICAL INDUSTRIES LIMITED |
| 304 | (WO 2006/123357) PHARMACEUTICAL COMPOSITION | SUN PHARMACEUTICAL INDUSTRIES LIMITED |
| 305 | (WO 2005/115092) MICRONIZED ORAL PHARMACEUTICAL COMPOSITION | SUN PHARMACEUTICAL INDUSTRIES LIMITED |
| 306 | (WO 2005/101982) A STABLE OPHTHALMIC COMPOSITION | SUN PHARMACEUTICAL INDUSTRIES LIMITED |
| 307 | (WO 2005/065047) STABLE ORAL COMPOSITION CONTAINING DESLORATADINE | SUN PHARMACEUTICAL INDUSTRIES LIMITED |
| 308 | (WO 2005/062722) FEXOFENADINE CONTAINING PHARMACEUTICAL FORMULATION | SUN PHARMACEUTICAL INDUSTRIES LIMITED |
| 309 | (WO 2005/046566) STABLE GABAPENTIN CONTAINING COMPOSITION | SUN PHARMACEUTICAL INDUSTRIES LIMITED |

| Sr. No. | PCT Application / Title | Assignee |
|----------------|---|---------------------------------------|
| 310 | (WO 2004/087648) STABILIZED PHENYTOIN CONTAINING COMPOSITION | SUN PHARMACEUTICAL INDUSTRIES LIMITED |
| 311 | (WO 2004/087043) STABLE OPHTHALMIC FORMULATION CONTAINING AN ANTIBIOTIC AND A CORTICOSTEROID | SUN PHARMACEUTICAL INDUSTRIES LIMITED |
| 312 | (WO 2004/082590) A LOW DOSE CORTICOSTEROID COMPOSITION | SUN PHARMACEUTICAL INDUSTRIES LIMITED |
| 314 | (WO 2003/026637) DOSAGE FORM FOR TREATMENT OF DIABETES MELLITUS | SUN PHARMACEUTICAL INDUSTRIES LIMITED |
| 318 | (WO 2003/011256) ORAL CONTROLLED RELEASE PHARMACEUTICAL COMPOSITION OF A PROKINETIC AGENT | SUN PHARMACEUTICAL INDUSTRIES LIMITED |
| 319 | (WO 2006/025070) NEBIVOLOL AND ITS PHARMACEUTICALLY ACCEPTABLE SALTS, PROCESS FOR PREPARATION AND PHARMACEUTICAL COMPOSITIONS OF NEBIVOLOL | TORRENT PHARMACEUTICALS LIMITED |
| 325 | (WO 2004/012700) DOSAGE FORM COMPRISING HIGH DOSE HIGH SOLUBLE ACTIVE INGREDIENT AS MODIFIED RELEASE AND LOW DOSE ACTIVE INGREDIENT AS IMMEDIATE RELEASE | TORRENT PHARMACEUTICALS LIMITED |
| 329 | (WO 2004/012699) MODIFIED RELEASE COMPOSITION COMPRISING COATED MICRO MATRIX PARTICLES CONTAINING THE HIGH SOLUBLE ACTIVE INGREDIENT AND A RELEASE CONTROLLING AGENT | TORRENT PHARMACEUTICALS LIMITED |
| 330 | (WO 2003/104192) CONTROLLED RELEASE FORMULATION OF LAMOTRIGINE | TORRENT PHARMACEUTICALS LIMITED |
| 331 | (WO 2006/095363) INJECTABLE PREPARATIONS OF DICLOFENIC AND ITS PHARMACEUTICALLY ACCEPTABLE SALTS | TROIKAA PHARMACEUTICALS LTD |
| 332 | (WO 2006/008753) CRYSTALLINE AND AMORPHOUS FORM OF RANOLAZINE AND THE PROCESS FOR MANUFACTURING THEM | UNICHEM LABORATORIES LIMITED |
| 333 | (WO 2006/100686) NOVEL POLYMORPH FORM G OF FLUVASTATIN SODIUM AND PROCESS FOR THE PREPARATION THEREOF | USV LIMITED |
| 334 | (WO 2006/011154) A NOVEL POLYMORPH OF (1-BENZYL-4-[(5,6-DIMETHOXY-1-INDANONE)-2-YL] METHYL PIPERIDINE HYDROCHLORIDE (DONEPEZIL HYDROCHLORIDE) AND A PROCESS FOR PRODUCING THEREOF | USV LIMITED |
| 335 | (WO 2006/001031) 1-BENZYL-4-[(5,6-DIMETHOXY-1-INDANONE)-2-YL] METHYL PIPERIDINE OXALATE (DONEPEZIL OXALATE) AND ITS POLYMORPHS | USV LIMITED |
| 336 | (WO 2001/087228) SUSTAINED RELEASE PHARMACEUTICAL COMPOSITION CONTAINING GLIPIZIDE AND METHOD FOR PRODUCING SAME | USV LTD. |
| 337 | (WO 2006/054315) NONAQUEOUS LIQUID PARENTERAL ACECLOFENAC FORMULATION | VENUS REMEDIES LIMITED |
| 338 | (WO 2006/011001) CONTROLLED RELEASE COMPOSITIONS OF DIVALPROEX SODIUM | WOCKHARDT LIMITED |
| 339 | (WO 2006/010995) CONTROLLED RELEASE COMPOSITIONS OF DIVALPROEX SODIUM | WOCKHARDT LIMITED |

MOMSEN LEONARDOS & CIA

| S.NO. | Brazilian Application # (PCT international application and / or European Patent granted) subject matter of the invention claimed, | Current status | Owner |
|---|--|---------------------|---|
| 1 | P10308062 (WO03072564) — Citalopram, purified base | Pending application | Cipla LTD |
| 2 | P10213398 (WO03033508) — Alendronate, amorphous form | Pending application | Cipla LTD |
| 3 | P10308063 (WO03072563) - Amorphous pharmaceutically acceptable salt&of.citalopram | Pending application | Cipla LTD |
| 4 | P10308603 (WO03080589) - Purified citalopram hydrochloride or hydrobromide | Pending application | Cipla LTD |
| 5 | P10308060 (WO03072562) - Amorphous citalopram base | Pending application | Cipla LTD |
| 6 | P10211488 (WO03011826) - Crystalline forms of atorvastatin calcium | Pending application | Dr. Reddy's Lab. Ltd |
| 7 | P10113732 (WO0220553) - Novel polymorphic form of 17- beta -(N-ter.butyl carbamoyl)-4-aza-5- alpha - androst-1-en-3-one | Pending application | Dr. Reddy's Lab. Ltd |
| 8 | P1001 0683 (WO0063192) - Novel Polymorphic an Forms of Antidiabetic Agent | Pending application | Dr. Reddy's Research Foundation |
| 9 | PI0116571 (WO002051819) - Novel oxazolidinone Compund | Pending application | Dr. Reddy's Research Foundation |
| 10 | P19812770 - Novel antiobesity and hypocholesterolemic compounds | Pending application | Dr. Reddy's Research Foundation INC. - Reddy-Cheminor |
| 11 | P19711098 (CA2258949) - Novel antidiabetic comPounds | Pending application | Dr. Reddy's Research Foundation INC. - Reddy-Cheminor |
| 12 | P10114196 (WO0226737) - Novel polymorphic/pseudopolymorphic forms of 5-[4-[2[N-methyl-N-(2-pyridyl)amino]ethoxy]benzyl] thiazolidine-2,4-dione maleate | Pending application | Dr. Reddy's Research Foundation |
| 13 | P10117054 (WO021 02777) - Novel polymorph of Fexofenadine and Fexofenadine hydrochloride | Pending application | Dr. Reddy's Lab. Ltd |
| 14 | PI0214675 - Novel antidiabetic, hypolipidemic, antiobesity and hypocholesterolemic compounds | Pending application | Dr. Reddy's Lab. Ltd |
| 15 | P19812772 (WO9919313)- Beta -aryl- alpha - oxysubstituted alkylcarboxylic acids | Pending application | Dr. Reddy's Research Foundation INC. - Reddy-Cheminor |
| 16 | P10212990 (WO03027118)— Pharmaceutically acceptable salts of 20(S)-camptothecins | Pending application | Dr. Reddy's Lab. Ltd |
| 17 | P (EP0847397B1) - Water-soluble C-ring analogues of 20(S)-camptothecin | Pending application | Dr. Reddy's Research Foundation INC. - Reddy-Cheminor |
| Regularly filed pending pharmaceutical patent applications filed by Indian corporation in Brazil and its corresponding European Patents (granted by the EPO) or international applications filed via the Patent Cooperation Treaty (WIPO-PCT) for salts, esters, polymorphs, hydrates, isomers and metabolites of known substances. According to the patent owners, these pending applications and issued patents do not claim mere discoveries; frivolous patents"; "evergreening" or the same known substance." | | | |
| C Momsen, Leonardos & Cia, 2005. | | | |

| S.NO. | Brazilian Application # (PCT international application and / or European Patent granted) subject matter of the invention claimed, | Current status | Owner |
|---|--|-----------------------|--|
| 18 | P1991 5835 (WO00321 91) - Stable pharmaceutical composition containing 5-[[4-[3-Methyl-4-oxo-3,4-dihydro-2-quinazoliny]methoxy]phenyl-methyl]thiadiazolidine -2,4-dione | Pending application | NOVO NORDISK A/S and Reddy's Research Foundation |
| 19 | P10213380 (WO03033481, WO03033456) - Propionic acid derivatives | Pending application | Dr. Reddy's Lab. Ltd |
| 20 | P10010139 (WO0066572) - Antiobesity and hypocholesterolemic compounds, their derivatives, their analogs, their tautomeric forms, their stereoisomers, their polymorphs, their pharmaceutically acceptable salts, their pharmaceutically acceptable solvates and pharmaceutically acceptable compositions containing them | Pending application | Dr. Reddy's Research Foundation |
| 21 | P19914438 (WO0026200) - Improved process for the preparation of antidiabetic compounds | Pending application | Dr. Reddy's Research Foundation |
| 22 | P10213350 (WO03033481, WO03033456) - Propionic acid derivatives | Pending application | Dr. Reddy's Lab. Ltd |
| 23 | P 7155 (WO0050414) - Hypolipidemic, antihyperglycemic, antiobesity and hypocholesterolemic compounds, their derivatives, their analogs, their tautomeric forms, their stereoisomers, their polymorphs, their pharmaceutically acceptable salts, their pharmaceutically acceptable solvates and pharmaceutically acceptable compositions containing Them. | Pending application | Dr. Reddy's Research Foundation |
| 24 | P19914493 (WO00i 5638) - Improved process for the preparation of 5-[4-[3-Methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy] benzyl] thiazolidine-2, 4-dione | Pending application | Dr. Reddy's Research Foundation |
| 25 | PI10108064 (WO0157026)- Derivatives of Andrographolide, their stereoisomers, their polymorphs, their pharmaceutically acceptable salts, and their pharmaceutically acceptable solvates | Pending application | Dr. Reddy's Lab. Ltd |
| 26 | PI0114031 (WO0218390) - Method for the preparation of hydrates of Olanzapine, process for conversion of olanzapine referred to as form-I | Pending application | Dr. Reddy's Lab. Ltd |
| Regularly filed pending pharmaceutical patent applications filed by Indian corporation in Brazil and its corresponding European Patents (granted by the EPO) or international applications filed via the Patent Cooperation Treaty (WIPO-PCT) for salts, esters, polymorphs, hydrates, isomers and metabolites of known substances. According to the patent owners, these pending applications and issued patents do not claim mere discoveries; frivolous patents"; "evergreening" or the same known substance." | | | |
| C Momsen, Leonardos & Cia, 2005. | | | |

| S.NO. | Brazilian Application # (PCT international application and / or European Patent granted) subject matter of the invention claimed, | Current status | Owner |
|--|--|-----------------------|-------------------|
| 27 | PI0212772 (WO03027072) - cost effective and industrially advantageous process for the preparation of repaglinide | Pending application | Ranbaxy Lab. Ltd. |
| 28 | PI0312728 (WO2004014337) - Dispersible tablets of cephalexin | Pending application | Ranbaxy Lab. Ltd. |
| 29 | PI0215686 (WO03084541) - Carboximide derivatives | Pending application | Ranbaxy Lab. Ltd. |
| 30 | PI0106752 (WO0195886) - Bioavailable pharmaceutical composition of 13-cis vitamin A acid (also known as 13-cis retinoic acid and isotretinoin) | Pending application | Ranbaxy Lab. Ltd. |
| 31 | pi0111193 (WO0190049) - Novel amorphous form of sertraline hydrochloride | Pending application | Ranbaxy Lab. Ltd. |
| 32 | PI0306928 (WO03059330) - Stable pharmaceutical compositions comprising ACE inhibitor(s) | Pending application | Ranbaxy Lab. Ltd. |
| 33 | PI0110926 (WO0187831) - Novel amorphous form of omeprazole salts | Pending application | Ranbaxy Lab. Ltd. |
| 34 | PI0108958 (WO0164183) - Once daily tablet formulation for oral administration in humans for the controlled release of ciprofloxacin | Pending application | Ranbaxy Lab. Ltd. |
| 35 | PI0308989 (WO03082241) - Pharmaceutical composition which includes micronized clarithromycin and exhibits improved dissolution characteristics relative to a pharmaceutical composition that includes :unmicrofized clarithromycin | Pending application | Ranbaxy Lab. Ltd. |
| 36 | P10212931 (WO03028704) - Extended release pharmaceutical composition containing metformin | Pending application | Ranbaxy Lab. Ltd. |
| 37 | P10308990 (WO03082248) - Pharmaceutical composition which includes erythromycin A or a derivative thereof and alginic add | Pending application | Ranbaxy Lab. Ltd. |
| 38 | P10012866 (EP1 204637B1) - Process for the preparation of isotretinoin, in a single step. | Pending application | Ranbaxy Lab. Ltd. |
| 39 | P102 (EP1423097) - Controlled release formulation of clarithromycin or tinidazol | Pending application | Ranbaxy Lab. Ltd. |
| 40 | P10209842 (WO02094828) - Process for the preparation of imipenem | Pending application | Ranbaxy Lab. Ltd. |
| <p>Regularly filed pending pharmaceutical patent applications filed by Indian corporation in Brazil and its corresponding European Patents (granted by the EPO) or international applications filed via the Patent Cooperation Treaty (WIPO-PCT) for salts, esters, polymorphs, hydrates, isomers and metabolites of known substances. According to the patent owners, these pending applications and issued patents do not claim mere discoveries; frivolous patents"; "evergreening" or ihe same known substance."</p> | | | |
| C Momsen, Leonardos & Cia, 2005. | | | |

| S.NO. | Brazilian Application # (PCT international application and / or European Patent granted) subject matter of the invention claimed, | Current status | Owner |
|--|---|-----------------------|-------------------|
| 41 | P10012864 (WO0108633)- Process for the production of an improved torn, of Form I celiprolol hydrochloride | Pending application | Ranbaxy Lab. Ltd. |
| 42 | P10209843 (WO02094742) - Cost effective and industrially advantageous process for the preparation of amorphous cilastatin sodium. | Pending application | Ranbaxy Lab. Ltd. |
| 43 | P1021 0426 (WO02100323) - Methyl analog of simvastatin | Pending application | Ranbaxy Lab. Ltd. |
| 44 | P10112597 (WO0205816) - Bioavailable oral dosage form of loratadine of specific particle size and surface area. | Pending application | Ranbaxy Lab. Ltd. |
| 45 | P10016400 (WO0144144) - Process for the preparation of sodium salts of statins, namely Compactin, Lovastatin and Pravastatin | Pending application | Ranbaxy Lab. Ltd. |
| 46 | P10311642 (WO03103635). Extended release pharmaceutical composition comprising divalproex | Pending application | Ranbaxy Lab. Ltd. |
| 47 | P10215685 (WO03084928) Alpha,omega- dicarboximide derivatives | Pending application | Ranbaxy Lab. Ltd. |
| 48 | PI0113102 (WO0211716) - Liquid formulation of metformin | Pending application | Ranbaxy Lab. Ltd. |
| 49 | PI0112598 (WO0206289) - Process for the preparation of highly pure crystalline form of cefuroxime axetil | Pending application | Ranbaxy Lab. Ltd. |
| 50 | PI0311195 (WO03097614) - Process for the preparation of Rosuvastatin | Pending application | Ranbaxy Lab. Ltd. |
| 51 | PI0309853 (WO03092660) - Monocompartment osmotic controlled drug delivery system | Pending application | Ranbaxy Lab. Ltd. |
| 52 | PI0114100 (WO0224203) - Pharmaceutical composition in the form of an oral controlled release solid dosage form | Pending application | Ranbaxy Lab. Ltd. |
| 53 | PI0112024 (WO0200615) - Process for the preparation and isolation of the hypolipaeic active substance lovastatin in substantially pure form | Pending application | Ranbaxy Lab. Ltd. |
| 54 | PI0214209 (WO03042215) - Cost effective and industrially advantageous process for the preparation of imipenem of high purity | Pending application | Ranbaxy Lab. Ltd. |
| 55 | PI0212807 (WO03026610) - Process for the preparation of fast dissolving dosage form, such as tablet, which disintegrates quickly in the mouth | Pending application | Ranbaxy Lab. Ltd. |
| 56 | PI0207640 (WO02067943) - Stable pharmaceutical composition of cefpodoxime proxetil | Pending application | Ranbaxy Lab. Ltd. |
| <p>Regularly filed pending pharmaceutical patent applications filed by Indian corporation in Brazil and its corresponding European Patents (granted by the EPO) or international applications filed via the Patent Cooperation Treaty (WIPO-PCT) for salts, esters, polymorphs, hydrates, isomers and metabolites of known substances. According to the patent owners, these pending applications and issued patents do not claim mere discoveries; frivolous patents"; "evergreening" or the same known substance."</p> | | | |
| C Momsen, Leonardos & Cia, 2005. | | | |

| S.NO. | Brazilian Application # (PCT international application and / or European Patent granted) subject matter of the invention claimed, | Current status | Owner |
|--|--|-----------------------|-------------------|
| 57 | PI0209844 (WO02094773) - Cost effective and industrially advantageous process for the preparation of imipenem of high purity | Pending application | Ranbaxy Lab. Ltd. |
| 58 | PI0310074 (WO03097059) - Polymorphic forms of phenyl oxazolidinone derivatives | Pending application | Ranbaxy Lab. Ltd. |
| 59 | PI0112826 (WO0206278) - Substituted phenyl oxazolidinones | Pending application | Ranbaxy Lab. Ltd. |
| 60 | PI0010923 (WO0071116) - Process for the preparation of amorphous atorvastatin calcium and hydrates | Pending application | Ranbaxy Lab. Ltd. |
| 61 | PI0212390 (WO03018544) - Efficient and industrially advantageous process for the preparation of pure cilastatin. | Pending application | Ranbaxy Lab. Ltd. |
| 62 | PI0011490 (WO0077006) - Process for the preparation of the esters of 1,8-disubstituted-1,3,4,9-tetrahydropyrano (3,4-b)-indole-1-acetic acid | Pending application | Ranbaxy Lab. Ltd. |
| 63 | PI9912318 (WO0005205) - Novel piperazine derivatives substituted on one nitrogen by an aromatic system and on the other nitrogen by (2,5-dioxopyrrolidin)-1-yl) alkanes or (2,6-dioxopiperidin-1-yl) alkanes | Pending application | Ranbaxy Lab. Ltd. |
| 64 | PI0209845 (WO02094774) - Dosage forms of oxcarbazepine for oral administration | Pending application | Ranbaxy Lab. Ltd. |
| 65 | PI0207895 (WO02072565) - Improved and industrially advantageous process for the preparation of citalopram | Pending application | Ranbaxy Lab. Ltd. |
| 66 | PI0007489 (EP1144425B1) - Substituted pentose and hexose monosaccharide derivative | Pending application | Ranbaxy Lab. Ltd. |
| 67 | PI0007553 (EP1147119B1) - 2,3-O-isopropylidene derivatives of monosaccharides as cell adhesion inhibitors | Pending application | Ranbaxy Lab. Ltd. |
| 68 | PI0115865 (WO0244151) - 1,4-disubstituted piperazine derivatives | Pending application | Ranbaxy Lab. Ltd. |
| 69 | PI0012981 (WO0110419) - Gastro-retentive oral drug delivery system structurally comprised of a highly porous matrix comprising a drug | Pending application | Ranbaxy Lab. Ltd. |
| 70 | PI0309298 (WO03086362) - Stable bupropion hydrochloride tablet | Pending application | Ranbaxy Lab. Ltd. |
| 71 | PI0208504 (WO02076376) - Stable pharmaceutical composition of pravastatin | Pending application | Ranbaxy Lab. Ltd. |
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| C Momsen, Leonardos & Cia, 2005. | | | |

| S.NO. | Brazilian Application # (PCT international application and / or European Patent granted) subject matter of the invention claimed, | Current status | Owner |
|---|--|-----------------------|-------------------|
| 72 | PI0309113 (WO03084514) - Controlled released pharmaceutical composition of carbidopa and levodopa | Pending application | Ranbaxy Lab. Ltd. |
| 73 | PI0212388(WO03018522)- Industrially advantageous process for the preparation of beta-ionylidencetaldehyde | Pending application | Ranbaxy Lab. Ltd |
| 74 | PI9910723 (WO9961022)-A stable oral pharmaceutical composition containing a substituted pyridylsulfinyl benzimidazole | Pending application | Ranbaxy Lab. Ltd |
| 75 | PI0113661 (WO0217923)- Pharmaceutical composition for tropical delivery comprising a cyclooxygenase-2 enzyme inhibitor. | Pending application | Ranbaxy Lab. Ltd |
| 76 | PI9917219 (WO0056266)-Coating composition for the film coating of pharmaceutical cores | Pending application | Ranbaxy Lab. Ltd |
| 77 | PI0208513 (WO02076375) Process for the preparation of benazepril | Pending application | Ranbaxy Lab. Ltd |
| 78 | PI0110970(EP1287003B1)- Process for the preparation of a pure and pharmacopoeial amorphous form of cefuroxime axetil | Pending application | Ranbaxy Lab. Ltd |
| 79 | PI9913696 (WO0015198)- Pharmaceutical composition in the form of tablets or capsules provides a combination of temporal and spatial control of drug delivery | Pending application | Ranbaxy Lab. Ltd |
| 80 | PI0116570 (WO02051408)- Derivatives of specially substituted azole compounds | Pending application | Ranbaxy Lab. Ltd |
| 81 | PI0009177(EP1165051B1)-Process of mixing of crystalline cefuroxime axetil with amorphous cefuroxime axetil for the preparation of a bioavailable oral dosage form comprising amorphous cefuroxime axetil | Pending application | Ranbaxy Lab. Ltd |
| 82 | PI0110925(EP1283821B1)- Cost effective and industrially advantageous process for the selective methylation of a hydroxy group at the 6 position of erythromycin A | Pending application | Ranbaxy Lab. Ltd |
| 83 | PI0208999(WO02083634)-Improved and cost effective process for the industrial preparation of cefpodoxime acid | Pending application | Ranbaxy Lab. Ltd |
| <p>Regularly filed pending pharmaceutical patent applications filed by Indian corporation in Brazil and its corresponding European Patents (granted by the EPO) or international applications filed via the Patent Cooperation Treaty (WIPO-PCT) for salts, esters, polymorphs, hydrates, isomers and metabolites of known substances. According to the patent owners, these pending applications and issued patents do not claim mere discoveries; frivolous patents; "evergreening" or the same known substance."</p> | | | |
| C Momsen, Leonardos & Cia, 2005. | | | |

| S.NO. | Brazilian Application # (PCT international application and / or European Patent granted) subject matter of the invention claimed, | Current status | Owner |
|--|--|-----------------------|-------------------|
| 84 | PI0211691 (WO03014060)- Cost effective and industrially advantageous process for the preparation of tolterodine | Pending application | Ranbaxy Lab. Ltd. |
| 85 | PI0215709 (WO03091261)- Process for the preparation of cefdinir or an industrial scale | Pending application | Ranbaxy Lab. Ltd. |
| <p>Regularly filed pending pharmaceutical patent applications filed by Indian corporation in Brazil and its corresponding European Patents (granted by the EPO) or international applications filed via the Patent Cooperation Treaty (WIPO-PCT) for salts, esters, polymorphs, hydrates, isomers and metabolites of known substances. According to the patent owners, these pending applications and issued patents do not claim mere discoveries; frivolous patents"; "evergreening" or the same known substance."</p> | | | |
| <p>C Momsen, Leonardos & Cia, 2005.</p> | | | |