Report of the Technical Expert Group on Patent Law Issues

(Revised, March 2009)

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

(Dr. R.A. Mashelkar)
Chairman

(Prof. Goverdhan Mehta)
Member

(Moolchand Sharma)
Member

(Prof. NR Madhava Menon)
Member

(Prof. Asis Datta)
Member

INDEX

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 (TEG) 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 TEG 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 TEG studied the inputs received and also took into account other relevant literature to arrive at their assessment. The TEG has arrived at specific recommendations and conclusions as given below.

3.2 In making the recommendations, the TEG 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 and also the flexibilities allowed under the TRIPS Agreement to the Member states.

4.0 New Chemical Entities

4.1 Article 27 of TRIPS, which deals explicitly with the issue of patentability, inter alia, states that 'Member States may not exclude any field of technology from patentability as a whole and they may not discriminate as to the fields of technology, the place of innovation' etc. Reading this obligation in the light of the overall purpose of the Agreement, it appears that linking the grant of patents for pharmaceutical substances only to a new chemical entity or to a new medical entity may prima facie amount to 'excluding a field of technology' even when they satisfy the basic requirements of patentability'. In such a situation, TEG concludes that it is possible to hold the provision as being not TRIPS Compatible.

4.2 The TEG carefully examined the flexibilities allowed under the TRIPS Agreement to the member states (especially Articles 7 & 8) and also as a consequence of the Doha Declaration. The detailed analysis and reassessing provided in the Report has led TEG to conclude that it is debatable as to whether national interest or the flexibility allowed under the Agreement to Member States would be accommodated by such 'statutory exclusion' of an entire class of inventions.

4.3 Every effort must be made to prevent the practice of 'ever greening' often used by some of the pharma companies to unreasonably extend the life of the patent by making claims based sometimes on 'trivial' changes to the original patented product. The Indian patent office has the full authority under law and practice to determine what is patentable and what would constitute only a trivial change with no significant additional improvements or inventive steps involving benefits. Such authority should be used to prevent 'evergreening', rather than to introduce an arguable concept in the light of 4.1 and 4.2 above of "statutory exclusion" of incremental innovations from the scope of patentability.

4.4 The process of innovation is continuous and progressive leading to an ever extending chain of knowledge. Innovative incremental improvements based on existing knowledge and existing products is a 'norm' rather than an 'exception' in the process of innovation. Entirely new chemical structures with new mechanisms of action are a rarity rather than a rule. Therefore, "incremental innovations" involving new forms, analogs, etc. but which have significantly better safety and efficacy standards, need to be encouraged. What is important, however, is for the patent office to be vigilant about setting high standards of judging such innovations so that efforts on "evergreening" are scrupulously prevented.

4.5 The TEG was not mandated to examine the TRIPS compatibility of Section 3(d) of the Indian Patents Act or any other existing provision in the same Act. Therefore, the committee has not engaged itself with these issues.

5.0 Micro-organism

5.1 The TEG'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 TEG has concluded that excluding micro-organisms *per se* from patent protection would be violative of TRIPS Agreement.

1.0 Introduction

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 (TEG) 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:
(Positions as on 5 April 2005)*

Dr. R.A. Mashelkar — Chairman
Director General
Council of Scientific and Industrial Research
New Delhi

Prof. Goverdhan Mehta — Member
Director
Indian Institute of Science
Bangalore

Prof. Asis Datta — Member
Director
National Centre for Plant Genome Research
New Delhi

Prof. N.R. Madhava Menon — Member
Director
National Judicial Academy
Bhopal

Prof. Moolchand Sharma — Member
Director
National Law Institute University
Bhopal

1

[1] * The current positions and addresses are given below:

Dr. R.A. Mashelkar, Bhatnagar Fellow, National Chemical Laboratory, Pune 411 008, Prof. Goverdhan Mehta, Honorary Professor & CSIR Bhatnagar Fellow, Indian Institute of Science, Bangalore 560 012, Prof. Asis Datta+, Professor of Eminence, National Institute for Plant Genome Research, New Delhi 110 067, Prof.(Dr.) N.R. Madhava Menon, Member, Commission on Centre-State Relations, Vigyan Bhawan Annexe, Maulana Azad Road, New Delhi-110011, Prof. Moolchand Sharma, Vice Chairman, University Grants Commission (UGC), Bahadur Shah Zafar Marg, New Delhi 110 002

+ Resigned from TEG in 2007

1.3 Terms of Reference of the TEG 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 TEG 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 TEG studied the inputs received and also took into account other relevant literature to arrive at their assessment. The TEG has arrived at specific recommendations and conclusions as given below.

2.3 In making the recommendations, the TEG 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 and also the flexibilities allowed under the TRIPS Agreement to the member states.

2.4 The Report was submitted by the TEG to the Government on 29 December 2006. It was subsequently noted that there were some 'technical inaccuracies' in the Report. The Chairman wrote a letter dated 19th February 2007 to seek Government's approval to "withdraw the Report, re-examine it and resubmit a Report, which meets with the requirements of the highest standards". The Government, vide D.O. Letter No.12/14/2005-IPR III on 7th of March 2007 accepted this request.

2.5 Subsequently, due to certain developments, the Chairman of the Committee expressed his desire to resign from the Chairmanship of the TEG vide letter dated 15th of March 2007. The Government, however, did not accept this request of resignation vide D.O. letter No.12/14/2—5-IPR II dated 1st May 2007 and requested the TEG to submit the Report incorporating the changes. Further communications followed, and most recently, the same decision was communicated by the Government vide D.O. letter No.12/14/2005 – IPR III of 10th February 2009, and the TEG was requested to expedite and submit the Report at the earliest. Vide letter dated 9th March 2009, the Chairman, while respecting the decision by the Government, agreed to accept his responsibility as the Chairman again and to submit the Report. Accordingly, the Report, incorporating the changes, has been resubmitted.

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 TEG is presented in **Annex-III**.

5 Conclusions and Recommendations

5.1 Based on the interactions TEG had with various stakeholders and a detailed examination of the critical legal and technical issues involved, perusal of related literature, the TEG has done a detailed analysis and come to the conclusions and recommendations outlined below.

(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 Article 27 of TRIPS deals explicitly with the issue of 'patentability'. It, inter alia, states that 'Member States may not exclude any field of technology from patentability as a whole and they may not discriminate as to the fields of technology, the place of innovation' etc. Reading this obligation in the light of the overall purpose of the agreement, it appears that linking the grant of patents for pharmaceutical substances only to a new chemical entity or to a new medical entity may prima facie amount to 'excluding a field of technology' even when they satisfy the basic requirements of patentability. In such a situation it is possible to hold the provision as not TRIPS Compatible. Furthermore, as shown later (see the analysis provided in paras 5.12 – 5.28), it is debatable as to whether national interest or the flexibility allowed under the Agreement to Member States would be accommodated by such 'statutory exclusion' of an entire class of inventions.

5.7 Through various submissions that TEG had received, as well as the study of the published literature, TEG found a number of analyses and views on the TRIPS flexibilities. However, from a developing world perspective, it is important to note at this stage the conclusions in a Report by South Centre, which is an 'Intergovernmental Policy Think Tank of Developing Countries'. South Centre provides intellectual and policy support required by developing countries for collective and individual action, especially in international arena. The Report is authored by a well known international authority on IPR and its role in development, Prof. Carlos Correa. The Report is entitled "Integrating Public Health Concerns into Patent Legislation in Developing Countries (http://www.who.int/medicinedocs/fr/d/Jh2963e/6.html). The analysis and recommendations in this Report are especially relevant to the TOR of the TEG.

5.8. While examining Article 27, the same South Centre Report explicitly concludes:

"Literally interpreted, Article 27.1 does not permit the exclusion from patentability of medicines in general or, arguably, of specific groups thereof. Under this interpretation, WTO members could not exclude from patentability even the 'essential medicines' listed by the World Health Organisation (WHO)."

The statement that `Article 7.1 does not permit the exclusion from patentability of ..... specific groups thereof' is directly pertinent to the TOR of TEG.

5.9 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.

5.10 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.

5.11 The committee was not mandated to examine the TRIPS compatibility of Section 3(d) of the Indian Patents Act or any other existing provision in the same Act. Therefore, the committee has not engaged itself into these issues.

5.12 The committee took a careful look at the possible flexibilities provided under Article 7 (`objects') and Article 8 (`principles') of TRIPS. It also examined the possible flexibilities implicit in Doha Declaration on TRIPS and Public Health.

5.13 Article 7 states:

"The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights of obligations."

5.14 Article 8 states:

"1. Members may, in formulating or amending their laws and regulations, adopt measures, necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio economic and technological development, provided that such measures are consistent with the provisions of this Agreement."

"2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."

5.15 Article 7 provides a description of the `objects' in general terms. Article 27, however, provides a `specific mandate'.

5.16 Article 8.1, which provides `a principle', is also worded in general terms but, it explicitly states that the measures under this article have to be `consistent with the provisions of this agreement'.

5.17 The Committee concluded that however noble and welcome the objects given in Article 7, in its application to specific obligations mandated in the Agreement, one should be able to show 'special overriding situations' critical to the objects sought to be achieved. Otherwise, the specific mandate is to be respected.

5.18 There is a clear analysis about `special overriding situations', which might authorise exclusion of pharmaceuticals from patentability, that has been provided in the South Centre Report, which is quoted below (http://www.who.int/medicinedocs/fr/d/Jh2963e/6.htm).

5.19 *"A second exception which might authorize exclusion of pharmaceuticals from patentability is Article 8.1 of the TRIPs Agreement, which explicitly recognizes the right of WTO Members to adopt policies in accordance with public health concerns. However, the adopted policies are subject to a test of "necessity" and of consistency with other obligations under the TRIPs Agreement. The "consistency" requirement may permit patentability exclusions in cases of distinct public health emergencies as defined by the national government, and as distinct from ordinary or everyday health and nutrition measures."*

5.20 *"Emergency cases could trigger the application of a different test of "inconsistency" (as provided for under Article 8.1) or qualify as a situation not "conducive to social and economic welfare" (as provided for under Article 7). In such a case, a suspension or exclusion from patentability might be linked to and justified by a specific emergency. Once the emergency subsides, the TRIPs requirement of patentability could be restored."*

5.21 *"A key consideration is clearly the purpose for which any subject matter exclusion were to be adopted. If, for example, the same objective could be obtained by imposing permissible compulsory licenses under Article 31, an exclusion of patentability could be seen as merely an attempt to circumvent the preconditions of Article 31. If, instead, local situations posed such unusual problems as to merit a public interest exception, these problems might also justify overriding or limiting other articles, such as Article 31, in favour of some non-permanent exclusion of subject matter, if that exclusion was necessary to solving the problem."*

5.22 In summary, under 'normal circumstances', in respect of application of Articles 7 & 8.1 to the TOR, the TEG could not find justifiable reasons to override the mandate of Article 27.

5.23 Having dealt with both Article 7 & 8.1, TEG finds that Article 8.2 in specific terms deals with a situation, when a patent has been actually granted, and addresses the issue of `abuse' of IPR. So this article is not pertinent to determining the possible flexibility before the grant of a patent, an issue, which the committee is specifically examining.

5.24 The TEG also examined the possible flexibilities that may be implicit in Doha Declaration. The key paragraph in Doha Declaration is the opening phrase of paragraph 4, which states as follows:

We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, ***while reiterating our commitment to the TRIPS Agreement****, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.*

5.25 It is emphasized here that Members *'reiterate their commitment to the TRIPS agreement'*. This suggests that any flexibilities to cater to public health concerns have to be exercised 'within the overall confines' of the TRIPS agreement.

5.26 TEG noted that this `commitment to the TRIPS Agreement' is again reinforced by the opening phrase of paragraph 5, which states as follows:

"Accordingly and in the light of paragraph 4 above, ***while maintaining our commitments in the TRIPS agreement,*** *we recognize that these flexibilities include ....."*

5.27 Referring back to the point made in 5.17 about exceptions under `special overriding situations', it is worth re-examining and reemphasising the following from para 4 of Doha Declaration.

> *"1. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles."*
>
> *"2. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."*
>
> *"3. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other*

epidemics, can represent a national emergency or other circumstances of extreme urgency."

"4. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4."

5.28 In the above, clause 1 reemphasises the importance of Articles 7 & 8 of TRIPS. Clauses 2,3,4 pertain to the protection of public health in a `post grant' situation, but these do not deal with a `pre-grant' situation, which the TOR of TEG are mandated to address.

5.29 TEG concluded that Doha Declaration cannot override the express provisions of the TRIPS provisions, and any flexibilities therein have to be interpreted within the overall confines of TRIPS, which, as has been explained, rules out any `statutory exclusion' from patentability of entire class of inventions.

National Interest perspective

5.30 TEG recommends that every effort must be made to prevent the practice of 'ever greening' often used by some of the pharma companies to unreasonably extend the life of the patent by making claims based sometimes on 'trivial' changes to the original patented product. The Indian patent office has the full authority under law and practice to determine what is patentable and what would constitute only a trivial change with no significant additional improvements or inventive steps involving benefits. Such authority should be used to prevent 'evergreening', rather than to introduce an arguable concept in the light of the foregoing discussion (paras 5.6 – 5.8 and paras 5.12 – 5.29) above of 'statutory exclusion' of incremental innovations from the scope of patentability.

5.31 The analysis leading to conclusion 5.29 is endorsed again by the South Centre Report entitled 'Integrating Public Health Concerns into Patent Legislation in Developing Countries (http://www.who.int/medicinedocs/fr/d/Jh2963e/6.htm), which also examines the possible exceptions and concludes as follows:

"In sum, under the current TRIPs Agreement, a straightforward exclusion from patentability of pharmaceuticals – even the category of essential medicines – does not seem to be a viable option. The admissibility of exceptions based on ordre public will depend on the interpretation of both Article 27.2 and Articles 7 and 8, but does not seem a promising basis for exclusion from patentability. Exclusions to meet specific public health emergencies, especially if limited in time, might be justifiable if they are a necessary part of an overall strategy for addressing the emergency."

"Policy makers should recognize that, while health-related inventions may require special attention, ***the rules adopted will apply to all fields of technology,*** *and that the* ***personnel of the Patent Office should be well trained*** *in order to adequately apply the provisions on this matter."*

5.32 The process of innovation occurs continuously and contributes to the ever extending chain of knowledge. Innovative incremental improvements based on existing knowledge and existing products is a 'norm' rather than an 'exception' in the process of innovation. Entirely new chemical structures with new mechanisms of action are a rarity. Therefore, "incremental innovations"

involving new forms, analogs, etc. but which have significantly better safety and efficacy standards, need to be encouraged. What is important, however, is for the patent office to be vigilant about setting high standards of judging such innovations so that efforts on "evergreening" are scrupulously prevented.

5.33 Restricting patentability just to NCEs or NMEs could have both legal and scientific ramifications. Drug discovery research is still finding its feet in India. The TEG noted that a few Indian companies, which had invested in discovery research, were beginning to see some success in building a pipeline of new molecules. However, these molecules are in early stages of evaluation and entry and success in the marketplace is still awaited. Overall, it seems, that at least as of now, restricting patentability to just NCEs would mean that most of the pharmaceutical product patents would be owned by MNCs.

5.34 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.

5.35 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.

5.36 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.

5.37 The TEG examined the 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, when the TEG Report was first submitted in the year 2006. It is clearly seen that most of them were based on incremental inventions.

5.38 **The TEG concludes that it would not be TRIPS compliant to limit granting of patents for pharmaceutical substance to New Chemical Entities only, since it prima facie amounts to a "statutory exclusion of a field of technology". 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.*

5.39 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."

5.40 The Institute of Science, UK (www.i-sis.org.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, (Edward Arnold, London, 1979) 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. The authoritative text (Pearson, London, 2008) for introductory biology, namely Brock Biology of Microorganisms (edited by Madigan, Martinko Dunlap Clark and Brock) describes micro-organisms, as a microscopic organism consisting of a single cell or cell cluster, including the viruses. Heritage, Evans and Killington in their book 'Introductory Biology (Cambridge University Press, Cambridge, 1996) define Micro-organisms as microscopic life forms including microscopic fungi, Protista, prokaryotes and viruses. Hawker, Linton, Folkes and Carlile in their book (Edward Arnold, London, 1960) titled as 'Biology of Micro-organisms' describe micro-organisms as consisting of several distinct groups of organism, most of whose members are of microscopic dimensions.

5.41 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.

5.42 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.

5.43 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.

5.44 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. "

5.45 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.

5.46 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

5.47 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.

5.48 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.

5.49 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.

5.50 **The TEG has concluded that 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.

Annex - II

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 proceeding 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.

Annexe - III

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 entitites 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 Article27(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, manufactures, 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"~~ 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) (l): "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) (l): "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)(l) instead of the phrase 'state of the art';

(iv) In the definition of inventive step the conjunction 'or' between ....existing Knowledge, having economic significance ....should 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 inter changeable 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 from, 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. It 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 through 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 LIMITD
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 DIRED 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-PRECIPITATED 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 2,3-0-ISOPROPYLIDENE-1-0-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 PHARAMCEUTICAL 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

ANNEXURE V

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)-campothecins	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 ihe 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- quinazolinyl]methoxyjphenyl -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, theft 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 reffered 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 ihe 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) - Bioavilable 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 :unmicroflized clarithromycin	Pending application	Ranbaxy Lab. Ltd.
36	P10212931 (WO03028704) - Extended releasepharmaceutical composition containing metforrnin	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 clarithrornycin or tinidazol	Pending application	Ranbaxy Lab. Ltd.
40	P10209842 (WO02094828) - Process for the preparation of imipenem	Pending application	Ranbaxy 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 ihe 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
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 preperaUon of sodium salts of statins, namely Compactin, Lovastatin and Pravastatin	Pending application	Ranbaxy Lab. Ltd.
46	P10311642 (WO03103635). Extended release pharmaceutical composition comprising divaiproex	Pending application	Ranbaxy Lab. Ltd.
47	P10215685 (WO03O84928) Alpha,ornega- 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 hypolipaemic 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.

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."

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 preparatiobn 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 pral 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.

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."

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-ionylidencacetaldehyde	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) Proceass 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 crysatlline 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

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."

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.
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."			
C Momsen, Leonardos & Cia, 2005.			