



**LIMITING THE PATENTABILITY OF PHARMACEUTICAL
INVENTIONS AND MICRO-ORGANISMS: A TRIPS
COMPATIBILITY REVIEW**

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I TERMS OF REFERENCE

The Patents (Amendment) Act 2005 (hereafter '2005 Act') was India's last step towards achieving complete TRIPS¹ compliance.² This Act has had a long fairly long innings³ and generated considerable debate, both domestically and internationally. Despite the passing of this Act, there remained certain unresolved issues pertaining to demands made by the Left Parties, as highlighted in the press conference statement below:⁴

Two of the amendments by the Left parties were not accepted by the government. We wanted micro-organisms excluded from the scope of patentability and a specific definition of new entities. Since the Left parties consider these changes necessary, we insisted that they be taken up. The government responded with an assurance on the floor that an expert committee will be set-up to go into this matter and make recommendations.

In keeping with its promise, the government, on April 5, 2005, requested a Technical Expert Group on Patents law issues, Chaired by Dr. R.A. Mashelkar, to study:

"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."

¹ The Agreement on Trade Related Aspects of Intellectual Property Rights (15 April 1994) LT/UR/A-1C/IP/1. <http://www.wto.org/english/docs_e/legal_e/27-trips.pdf> (25 August 2005).

² This Act was published as law in the Gazette of India on 5 April 2005. *The Patents (Amendment) Act, 2005*, No. 15 of 2005 (The Gazette of India, reg. No.DL-N(04)/0007/2003-05). In order to comply with TRIPS, the Patents Act 1970 (India) had been amended twice earlier, first in 1999 (The Patents (Amendment) Act 1999) and more recently in 2002 (Patents (Amendment) Act 2002). The Patents Act 1970 as amended upto 2005 will be referred to henceforth as the 'Indian Patents Act'.

³ It began as the Patents (Amendment Bill) 2003 (hereafter 'Bill') under the BJP (Bharatiya Janata Party) government. The Bill lapsed owing to a change in government at the Centre and the consequent dissolution of the Lok Sabha (India's lower house of Parliament). The new Congress led coalition government endorsed the Bill—however, since they were unsure of whether it would go through Parliament well in time to meet the TRIPS deadline of 1 January 2005, they had it passed as a Presidential Ordinance (Patents (Amendment) Ordinance 2004). Owing to pressure from the Left parties, changes were made to the Ordinance and cleared by the Parliament in the third week of March as the Patents (Amendment) Bill 2005. After receiving Presidential assent and being published in the official gazette, it finally came into force with retrospective effect from 1 January 2005.

⁴ Statement Issued at the Press Conference of the four Left parties – CPI(M), CPI, Forward Bloc and RSP (held at AKG Bhavan on 23 March 2005). See 'Amendment to the Indian Patents Act' 29 (13) *Peoples Democracy* (27 March 2005).

The Technical Expert Group was requested to submit its report to the Department of Industrial Policy and Promotion. I have been requested by the Intellectual Property Institute (IPI)⁵ to provide a comprehensive and independent opinion on the foregoing issues. This legal opinion is prepared in my private capacity, but is endorsed by the IPI.⁶

II SUMMARY OF FINDINGS

This report finds as follows:

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*

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

B *Whether it would be TRIPS compatible to exclude micro-organisms from patenting.*

⁵ The IPI is a UK based, independent charitable organisation, which carries out research on intellectual property matters with particular reference to the economic and social impact of the law. See <http://www.ip-institute.org.uk/>.

⁶ This research was commissioned by the IPI and financially supported by INTERPAT, a Swiss association of major European, Japanese and US research-based pharmaceutical companies committed to the improvement of intellectual property laws around the world.

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. The various options available to India are highlighted below:

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 micro-organism by known procedures will not render it patentable. Rather, only truly 'invented' micro-organisms 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 in 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.

Of 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.

III ISSUE 1

The referral states: *Whether it would be TRIPS compatible to limit the grant of patents for pharmaceutical substances to new chemical entities or new medical entities involving one or more inventive steps?*

A DEFINING THE TERMS USED

Before addressing the issue, it is important to have a clear sense of the terms used in the referral—in particular, Pharmaceutical Substance, New Chemical Entity (hereafter 'NCE'), New Medical Entity (hereafter 'NME') and Inventive Step. For the sake of consistency, most of the terms used in this paper will, unless the context otherwise requires, bear a meaning that broadly conforms with those in the Patents Act, 1970, as amended up to 2005 (hereafter 'Patents Act'). For the same reasons, this paper will assume, unless the context proves otherwise, that most of the terms used in the referral are used in the sense in which they are used in the Indian Patents Act.

1 Pharmaceutical Substance

The term 'pharmaceutical substance' has been defined in section 2 (1) (ta) as 'any new entity involving one or more inventive steps'. Apart from lacking in specificity,⁷ the term 'pharmaceutical substance' does not find mention anywhere else in the Patents Act. In the absence of a specific mention of the term 'pharmaceutical substances' in the main body of the statute, it is doubtful as to what purpose such a definition can serve.

Section 92A, which deals with compulsory licences in the context of exports to countries with minimal manufacturing capabilities, uses the term 'pharmaceutical products'. However this term is used in a very specific sense to mean only 'patented products or processes' of the pharmaceutical sector 'needed to address public health concerns'. The definition in section 2(1)(ta) cannot therefore apply to 'pharmaceutical products' under section 92A.

It may therefore be helpful to rely on an Australian definition, which states:

A "pharmaceutical substance" means a substance (including a mixture or compound of substances) for therapeutic use whose application (or one of whose applications) involves:

⁷ For a critique of this definition, see Shamnad Basheer *India's Tryst with TRIPS: The Patents (Amendment) Act 2005* (forthcoming article in the first issue of the Indian Journal of Law and Technology—IJLT).

(a) a chemical interaction, or physico-chemical interaction, with a human physiological system; or

(b) action on an infectious agent, or on a toxin or other poison, in a human body; but does not include a substance that is solely for use in *in-vitro* diagnosis or in *in-vitro* testing.⁸

2 New Chemical Entity

The term 'new chemical entity' is generally understood to mean a chemical compound not previously known or described.⁹ This term is also used in the United States in a drug regulatory context to mean 'a drug that contains no *active moiety* that has been approved by the Food and Drug Administration (FDA) in any other application submitted under section 505(b)' of the Food, Drug and Cosmetic Act'.¹⁰

However the above FDA definition is not entirely accurate for the purpose of our discussion here. Although a drug containing an active moiety may not have been approved by the FDA and is therefore treated as a 'new chemical entity' by the FDA, it is possible that such active moiety is already known or described in scientific or technical literature—and cannot therefore be a 'new chemical entity' in the true sense of the term.

It is pertinent to note that the term 'new chemical entity' also finds mention in Article 39.3 of TRIPS dealing with the protection of regulatory data.¹¹ However, the term is not defined and it appears that TRIPS leaves it to member states to define this term, as they deem fit.¹²

⁸ Section 6 of the Australian Patents Act, 1990

<<http://www.iporganisers.com.au/products/pharmaceuticalextensions2.htm>>.

⁹ See Trevor Cook et al *Pharmaceuticals Biotechnology and the Law* (Stockton Press New York 1991)

71. See also *Glossary of Terms Used in Medicinal Chemistry*

(IUPAC Recommendations 1998) <<http://www.chem.qmul.ac.uk/iupac/medchem/ix.html>> (18 July 2005) which defines an NCE as '*a compound not previously described in the literature*'.

¹⁰ Section 314.148 of 21 CFR 314 (Title 21 of the Code of Federal Regulations (CFR) is reserved for rules of the Food and Drug Administration). An 'active moiety' has in turn been defined as '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 non-covalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.' *id.*

¹¹ In pertinent part, it reads: 'Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use'.

¹² See NS Gopalakrishnan & BK Kadavan *Study on Testdata Protection in India* 1st edn (Eastern Book Company Lucknow 2005) 30 where they state: 'In the context of drug development, one

For the purpose of this paper, the term 'new chemical entity' will be used to refer to a new chemical compound not known or described previously.

3 New Medical Entity

The term 'new medical entity' is not generally used in the pharmaceutical art. In the context of the referral above, this term appears to be used in a sense similar to NCE (new chemical entity), with the intention of covering any other medical product that may be 'new' but may not qualify strictly as a 'chemical' entity. Thus, for example, it could cover biological products—products such as cellular products, blood, proteins etc that normally rely on organic activity to achieve a therapeutic result, as opposed to the therapeutic action of chemical compositions.

4 Inventive step

This is defined in section 2(ja) of the Patents Act 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 the person skilled in the art.'¹³

B CATEGORISING THE EXCLUSIONS

Given the above understanding of the terms used, it is evident that restricting the grant of pharmaceutical patents to only NCEs/NMEs would be tantamount to excluding a wide range of pharmaceutical inventions, some of which are mentioned below.

1 Pharmaceutical Compositions

These can broadly be classified as:

interpretation of the term 'new chemical entity' is to include any drug with any modification in its use, dosage or combination. The other interpretation is to limit it to drugs with new molecules that are not in existence'.

¹³ As can be seen from this definition, while the basic yardstick of an 'inventive step' remains that which is 'non obvious to a person skilled in the art', a requirement that the invention involve a 'technical advance' or have an 'economic significance' of some sort has been added. The term could therefore now be interpreted in a manner that renders it more onerous to satisfy. For an analysis of this definition and how it differs from the earlier 'non obviousness' standard, see reference 7.

- i) Combination preparations, comprising two or more known pharmaceutically active ingredients.¹⁴
- ii) New drug delivery systems or galenic forms.¹⁵

2 Polymorphs

Certain pharmaceutical substances may exist and be isolated in different discrete physical forms, including both crystalline forms and amorphous forms. Such crystalline forms are generally referred to as 'polymorphic' forms.¹⁶ Some of these forms have advantageous properties useful for large-scale manufacture, such as improved stability and improved flowability.¹⁷

3 Enantiomers

In organic chemistry, most compounds which comprise a carbon atom with four different substituents are capable of existence in two forms, which are mirror

¹⁴ In India, section 3 (e) excludes such inventions from patentability, unless synergism or a super additive affect can be shown. This section states that 'a substance obtained by mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance' is not patentable.

¹⁵ Illustratively, see US Patent No. 6,623,762 issued to Ranbaxy Laboratories Ltd on 1 November 2005. The abstract of the invention reads:

A pharmaceutical composition in the form of tablets or capsules provides a combination of temporal and spatial control of drug delivery to a patient for effective therapeutic results. The pharmaceutical composition comprises a drug, a gas generating component, a swelling agent, a viscolyzing agent, and optionally a gel forming polymer. The swelling agent belongs to a class of compounds known as superdisintegrants (e.g., cross-linked polyvinylpyrrolidone or sodium carboxymethylcellulose). The viscolyzing agent initially and the gel forming polymer thereafter form a hydrated gel matrix which entraps the gas, causing the tablet or capsule to be retained in the stomach or upper part of the small intestine (spatial control). At the same time, the hydrated gel matrix creates a tortuous diffusion path for the drug resulting in sustained release of the drug (temporal control). A preferred once daily ciprofloxacin formulation comprises 69.9% profloxacin base, 0.34% sodium alginate, 1.103% xanthan gum, 13.7% sodium bicarbonate, 12.1% cross-linked polyvinylpyrrolidone, and optionally other pharmaceutical excipients, the formulation being in the form of a coated or uncoated tablet or capsule.

¹⁶ 'A polymorph is a solid crystalline phase of a given compound resulting from the possibility of at least two crystalline arrangements of the molecules of that compound in the solid state'. See WC McCrone *Physics and Chemistry of the Organic Solid State* Vol. 2 (Wiley Interscience 1965) 725.

¹⁷ A number of patent applications have been filed in respect of such new physical forms. See Carlos M Correa *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre Geneva 2001) <<http://www.southcentre.org/publications/publichealth/publichealth.pdf>> (25 August 2005) 53. It is pertinent to note however that section 3 (d) of the Indian Patents Act stipulates that such new forms would be patentable only if they demonstrate an increased efficacy. See reference 7.

images of each other.¹⁸ Such mirror image forms (the R form and the S form) are termed 'enantiomers' and an equal mixture of these forms is termed a racemate. Separating ('resolving') a mixture of enantiomers may be difficult, since they have virtually identical physical properties, apart from the property of equal and opposite degrees of rotation of optically polarized light. Similarly, producing a pure enantiomer or a mixture enriched in one enantiomer by stereospecific synthesis from optically active starting materials can involve considerable chemical ingenuity.

Patents have been granted for individual enantiomers of a compound known previously only in racemic form, on the basis of an unexpected difference in biological properties.¹⁹ In some cases, all of the biological activity may be present in one enantiomer, so that it is then possible for lower dosages of purer compounds to be administered.²⁰

4 Prodrugs and Active Metabolites

A compound which itself is inactive but which must be hydrolysed or otherwise converted in the body to form the active drug is considered to be a 'pro drug'.²¹ Administering such a pro-drug may be advantageous because it may be better absorbed or tolerated than the 'drug' itself and thus provide a therapeutic advantage. Conversely, the substance that results from such metabolism/hydrolysis and constitutes the active therapeutic ingredient is known as the 'active metabolite'. If a compound owes its activity to the fact that it is metabolized to another compound, it may be merely a matter of historical accident whether the compounds related in this way are considered to be a prodrug and drug, or drug and active metabolite.²²

5 Method of Use Claims

¹⁸ Most complex organic molecules are likely to contain in their structure at least one asymmetric carbon atom, a carbon atom which is joined to four different types of substituents. See *Cook et al* (n 9) 84.

¹⁹ See *Beecham Group Ltd's Application* ([1980] RPC 261, where a patent over amoxicillin, an antibiotic which is an optical isomer of a known racemate, was upheld in the United Kingdom since it was shown that amoxicillin had particularly high activity on oral administration, when compared with the racemate. In other words, the unexpected nature of the advantage obtained by resolution succeeded in overcoming an obviousness rejection. See *Cook et al* (n 9) 86.

²⁰ In the case of some drugs (such as thalidomide), since one of the forms is harmful, locating and administering the other form is of tremendous significance. See *Cook et al* (n 9) 84.

²¹ Philip W Grubb *Patents for Chemicals, Pharmaceuticals and Biotechnology* (Clarendon Press Oxford 1999) 211.

²² *id.*

When a substance that is already known is found to have a new pharmaceutical use, claims for such new uses are permitted in some countries.²³ However, in other countries, including India, claims to new uses of known substances are prohibited.²⁴

C REPHRASING THE ISSUE

The issue as posed in the 'terms of reference' suggests that the above list of exclusions²⁵ would be denied patents outright, without an individual determination on merits i.e. whether they satisfy patentability criteria (novelty, non obviousness, utility and adequate description) or not.

The issue may therefore be rephrased as: Would the outright exclusion of the above sub-categories from the scope of patentability (hereafter '*proposed exclusion*') be TRIPS compatible?

D ARTICLE 27 OF TRIPS

The starting point for a discussion on the TRIPS compatibility of the *proposed exclusion* is Article 27 of TRIPS, which reads in pertinent part as below:

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. (emphasis by author)

²³ In the United States, patents on uses are confined to a particular 'method-of-use', which does not encompass protection of the product as such. See RP Merges *Patent Law and Policy: Cases and Materials* (Contemporary Legal Educational Series Boston 1992) 489. In Europe, the patentability of a known product for a new specific purpose is allowed under Article 54(5) of the European Patent Convention. Thus, the identification of the first medical indication of a known product may permit patenting of the product. See *Resource Book on TRIPS and Development* ICTSD-UNCTAD Capacity Building Project on IPRs and Sustainable Development (2004) 356.

²⁴ See section 3 (d) of the Indian Patents Act. For an analysis of this provision, see reference 7. Such a claim could also fall foul of the 'method of medical treatment' exception encapsulated in S 3 (i). This section excludes from patentability, '*any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings...*'

²⁵ A new 'process' for producing a pharmaceutical substance (patentable in most member states) has not been included within the above excluded categories. The issue as framed is limited to 'pharmaceutical substances' and this would clearly exclude 'processes'.

The key terms in Article 27 are 'invention' and 'discrimination'. Before analyzing these terms however, it is important to appreciate an underlying distinction in Article 27 between patent eligibility and patentability.

1 Patent Eligibility Versus Patentability

At a conceptual level and drawing from the patenting practices of most member states, one can draw a distinction between 'patent eligibility' and 'patentability'.

'Patent eligibility' broadly refers to the requirement that a subject matter for which a patent is sought be inherently suitable for patent protection, in the sense of falling within the scope of subject matter that patent law *prima facie* exists to protect. The term 'patentability', on the other hand, refer to those set of principles that inform the requirements that must be satisfied for a patent eligible subject matter (i.e., an invention) to be granted a valid patent. Principally they are the requirements of novelty, inventiveness (non-obviousness), utility (industrial applicability) and sufficient description.²⁶

As noted by a commentator:

Analytically, this proposition exemplifies the familiar Aristotelian dichotomy between essence/kind on the one hand, and attributes/quality on the other, also reflected in other intellectual property laws. Thus, in copyright law, what qualifies as an artistic work (its 'essence' or 'kind') is analytically distinct from the question whether the work is 'original' or not (its 'attribute' or 'quality').²⁷

In short, the term 'patent eligibility' or 'inherent patentability' denotes limitations in terms of the kind of 'subject matter' that would qualify for patent protection—this question is different from and often precedes the question of whether the said subject matter meets the 'patentability' criteria.

In most member countries, the principle of patent eligibility is embodied in the term 'invention' i.e. a poem, though new and useful, cannot be patented, since it is not an 'invention'.²⁸ This is true with TRIPS as well, with Article 27.1 drawing a

²⁶ See Justine Pila *Bound Futures: Patent Law and Modern Biotechnology* 9 Boston Univ Journal of Science and Technology Law (2003) 326.

²⁷ See David Vaver *Invention in Patent Law: A Review and a Modest Proposal* 11 (3) Intl J Law and IT (2003) 287. However, he cautions in a footnote that 'the distinction between kind and quality cannot be pressed too far. For example, one might fairly argue that novelty and non-obviousness are part of an invention's essence'. *id.*

²⁸ See Section 3(l) of Indian Patents Act which excludes 'a literary, dramatic, musical or artistic work...'. See also Article 52 (2) (b) of the European Patent Convention (EPC) which similarly excludes all 'aesthetic creations'.

sharp distinction between patent eligibility and patentability, by its use of the term 'invention'.

Based on this appreciation of the *patent eligibility vs patentability* distinction, it is possible to construe the *proposed exclusion* in two ways:

- i) The *proposed exclusion* is treated as an issue of 'patent eligibility' i.e. one that categorizes pharmaceutical inventions other than NCEs/NMEs as non-patentable subject matter.
- ii) The *proposed exclusion* is treated as an issue of patentability i.e. the law deems that all non NCE inventions do not, ipso facto, meet one or more of the patentability criteria such as the 'inventive step' or 'novelty' criteria, without an individual determination on merits.

This note will go on to show that either construction of the *proposed exclusion* is likely to violate Article 27 for the reason that:

- 1. It contravenes the mandate to grant 'patents to all *inventions*'
- 2. It violates the non-discrimination provision embodied in the latter half of Article 27.

It bears noting that the key focus of this report is to broadly simulate a WTO panel decision i.e. assuming that this issue were to come up before a panel, how is it likely to be decided?

E 'INVENTION'

The TRIPS Agreement does not define the term 'invention'. This does not however give member states a *carte blanche* to define it in any manner that they deem fit. Absent a statutory definition, one has to rely on other sources to help interpret the term 'invention', in accordance with the framework below:

1 Interpretative Framework

As per the Disputes Settlement Understanding (DSU),²⁹ the Appellate Body is to interpret the provisions of GATT 1994 and the other 'covered agreements' of the WTO Agreement such as TRIPS 'in accordance with customary rules of

²⁹ Article 3.2 of the DSU (Understanding On Rules And Procedures Governing The Settlement Of Disputes) reads: 'The dispute settlement system of the WTO is a central element in providing security and predictability to the multilateral trading system. The Members recognize that it serves to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law. Recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements.'

interpretation of public international law'. Following this mandate, in *United States - Standards for Reformulated and Conventional Gasoline*, (hereafter '*WTO—US Gasoline*')³⁰ the appellate body stressed the need to refer to the fundamental rule of treaty interpretation set out in Article 31(1) of the *Vienna Convention on the Law of Treaties* (hereinafter '*Vienna Convention*').³¹ They held that Article 31 (1) and Article 32 of the Vienna Convention had 'attained the status of a rule of customary or general international law'.³²

Article 31.1 of the Vienna Convention provides that '[a] treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose'.

Therefore, primary regard is to be given to the ordinary meaning of the term 'invention', in context, and in the light of the object and purpose of TRIPS. In the case of ambiguity, Article 32 stipulates that resort may be had to specified supplementary means of interpretation including the 'preparatory work of the treaty and the circumstances of its conclusion'.³³ In addition, factors such as 'subsequent state practice'³⁴ may be relied upon.

The Appellate Body made clear in its first report that the direction given by Article 3.2 of the Dispute Settlement Understanding (DSU)³⁵ 'reflects a measure of recognition that the General Agreement is not to be read in clinical isolation from public international law'.³⁶ In this regard, it bears noting that, of late, the opinions of jurists are gaining recognition and being cited increasingly in Appellate Body and Panel Reports.³⁷

³⁰ WT/DS2/AB/R (Adopted 20 May 1996) 17.

³¹ 23 May 1969, 1155 U.N.T.S. 331; 8 *International Legal Materials* 679.

³² See *WTO—US Gasoline* (n 30) 17. See also *Japan--Taxes on Alcoholic Beverages* WTO Doc. WT/DS8/AB/R (adopted 1 Nov 1996) (hereafter '*WTO—Japan Alcohol*') 9.

³³ Illustratively, one may take help from derestricted official documents from the 1986–94 Uruguay Round trade talks available on the WTO website at <http://www.wto.org/english/tratop_e/trips_e/trips_e.htm> (11 August 2005).

³⁴ Article 31.3(b) expands on Article 31.1 by stating that while interpreting a treaty term, one has to also take into account 'any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation'.

³⁵ See n 29.

³⁶ See *WTO—US Gasoline* (n 30) 15.

³⁷ See for example, AB report in *WTO India: Patent Protection For Pharmaceutical And Agricultural Chemical Products* (19 December 1997) WT/DS50/AB/R (hereafter '*WTO—India Patent*'), where the writings of jurists are referred to in footnotes 26, 28 and 52. As noted in Matsushita et al *The World Trade Organisation: Law, Practice and Policy* (OUP Oxford 2003) 66: 'The authors of WTO reports... seem to be far more willing than their GATT predecessors to refer to the teachings of highly qualified publicists in justifying their positions'. See also Michael Blakeney 'International Intellectual Property Jurisprudence after TRIPS' in David Vaver and Lionel Bentley (ed) *Intellectual Property in the New Millenium* (Cambridge Univ Press Cambridge 2004) 6 who states: 'In the rapidly developing field of international intellectual property law, the writings of jurists can play an important role in promoting consistency and coherence'.

Despite this elaborate interpretative framework, the WTO panel/appellate body tends towards a predominantly textual approach.³⁸ In the words of a commentator:

The Appellate Body has resisted consideration of context, and object and purpose, instead attaching the greatest weight to "the ordinary meaning to be given to the terms" of the treaty. ... The preparatory work of the treaty has been accorded even less weight, because of "the secondary rank attributed to this criterion by the Vienna Convention, the lack of reliable records, and the ambiguities resulting from the presence of contradictory statements of the negotiating parties."³⁹

As to the weight to be accorded to panel/appellate body decisions, it is pertinent to note the observations of the Appellate Body in *WTO Japan—Alcohol*:⁴⁰

Adopted panel reports are an important part of the GATT acquis. They are often considered by subsequent panels. They create legitimate expectations among WTO Members, and therefore, should be taken into account where they are relevant to any dispute. However, they are not binding, except with respect to resolving the particular dispute between the parties to that dispute.

However, a commentator rightly notes that '...in general, previous decisions and doctrine are so highly persuasive in WTO jurisprudence, and their use is so central to the discourse of dispute settlement, that it may be said that the WTO observes de facto stare decisis.'⁴¹

³⁸ See Graeme B Dinwoodie and Rochelle Cooper Dreyfuss 'WTO Dispute Resolution and the Preservation of the Public Domain of Science under International Law' in Keith E Maskus & JH Reichman (eds.) *International Public Goods And Transfer Of Technology Under A Globalized Intellectual Property Regime* (Cambridge Univ Press 2005) 866 who state in pertinent part that '... we inform our analysis with the observation that WTO panels tend to hew closely to text when resolving disputes'.

³⁹ Richard Steinberg 'Judicial Lawmaking at the WTO: Discursive, Constitutional, and Political Constraints' (2004) 98 AJIL 247. He goes on to note: 'According to Claus-Dieter Ehlermann, a former member of the Appellate Body, this bias was adopted to protect the Appellate Body from "criticism that its reports have added to or diminished the rights and obligations provided in the covered agreements," which would contravene DSU Article 3.2'. See also JH Reichman *The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries?* 32 Case W Res J Int'l L 441 (2000) 3, who states in relation to *Canada -- Patent Protection of Pharmaceutical Products, Report of the Panel* WT/DS114/R (17 March 2000) (hereafter '*WTO—Canada Pharmaceuticals*'): 'In its groundbreaking opinion, the Appellate Body opted for a strict constructionist interpretation of the TRIPS Agreement, in keeping with its view of Article 31 of the Vienna Convention on the Law of Treaties.'

⁴⁰ (n 32) 13.

⁴¹ See Steinberg (n 39) 7.

Using the above interpretative framework, it is clear that, by stating in broad terms that patents '*shall be available for all inventions, whether products or processes, in all fields of technology*', Article 27 is aimed at strictly limiting the possible exclusion of any kind of technology from patent eligibility.⁴² In other words, the term 'invention' in Article 27 is extremely wide in its import and cannot be defined restrictively by a member state.

2 Defining 'Invention'

An argument that since the term 'invention' has not been defined, members states can define it in any matter as they deem fit runs the risk of rendering the term redundant. Member states could simply exclude almost any technology as not amounting to an invention—perhaps even pharmaceutical inventions altogether. This would clearly run contrary to the spirit of TRIPS, the negotiating history of which suggests that one of the key aims of this agreement was to even out the disparate levels of protection for pharmaceutical products in different member states.⁴³

It is pertinent to note the appellate body ruling in *WTO—Japan Alcohol* which makes clear that one cannot interpret TRIPS in a manner as to render a term redundant:⁴⁴

A fundamental tenet of treaty interpretation flowing from the general rule of interpretation set out in Article 31 is the principle of effectiveness (*ut res magis valeat quam pereat*). In *United States - Standards for Reformulated and Conventional Gasoline*, we noted that "[o]ne of the corollaries of the 'general rule of interpretation' in the Vienna Convention is that interpretation must give meaning and effect to all the terms of the treaty. An interpreter is not free to adopt a reading that would result in reducing whole clauses or paragraphs of a treaty to redundancy or inutility".

⁴² See *WTO—India Patent* (n 37) para 7.27, where the appellate body states that 'Article 27 requires that patents be made available in all fields of technology, subject to certain **narrow exceptions**'. (emphasis by author).

⁴³ The panel in *India -- Patent Protection for Pharmaceutical and Agricultural Chemical Products* WT/DS50/R (adopted on 5 September 1997) (hereafter *WTO—India Patent (Panel)*) para 55 notes that '... in the negotiation of the TRIPS Agreement, the question of patent protection for pharmaceutical and agricultural chemical products was a key issue, which was negotiated as part of a complex of related issues concerning the scope of the protection to be accorded to patents and some related rights and the timing of the economic impact of such protection'. See also Markus Nollf *TRIPS, PCT and Global Patent Procurement* (Kluwer Law International 2001) 12 who states that 'the transitional arrangements in TRIPS Article 70.8 make clear that pharmaceutical and agrochemical products are not excluded...' from the ambit of Article 27.

⁴⁴ See *WTO—Japan Alcohol* (n 32) 15.

It is also pertinent to note the arguments by Canada in *WTO—Canada Pharmaceuticals*.⁴⁵

The TRIPS Agreement was not a free-standing intellectual property convention like the Paris Convention for the Protection of Industrial Property and the Berne Convention for the Protection of Literary and Artistic Works. Rather, it was a part of a much larger system, **the overarching purpose of which was to reduce barriers to trade**. The full title of the TRIPS Agreement was the Agreement on Trade-Related Aspects of Intellectual Property Rights, **and the very first line of its Preamble recited the desire of Members "to reduce distortions and impediments to international trade [...]"**. (emphasis by author).

The term 'invention' is a critical component of this equation to reduce barriers to trade and it cannot be derogated from, unless specifically permitted by other TRIPS provisions. The difficulty is in identifying the precise contours of the term 'invention', particularly, since there is no consensus amongst member states as to its definition.

Although panel decisions have often relied on dictionary definitions,⁴⁶ a dictionary definition is only of limited use in our context,⁴⁷ since the term 'invention' has a special meaning in patent law, and this meaning ought to be the 'ordinary meaning in context' under Article 31.1 of the Vienna Convention.⁴⁸ The trouble is that although the term invention has a specific legal import, the contours of this term are not definite. As an English judge aptly points out:⁴⁹

⁴⁵ See *WTO—Canada Pharmaceuticals* (n 39) para 4.39 (c). For an elaborate discussion of this case, see text after n 100.

⁴⁶ Illustratively, see *WTO—Canada Pharmaceuticals* (n 39), where Canada relied on the *The Shorter Oxford English Dictionary* to interpret the term 'limited' as used in Article 30 (para 7.29). See also Graeme B Dinwoodie 'The Architecture of the International Intellectual Property System' 77 Chicago Kent Law Review 993, 1005-06 (2002) who notes that 'Webster's has become an essential research tool in WTO TRIPS litigation.'

⁴⁷ The Oxford English Dictionary defines the term 'invention' thus: 'Something devised or produced by original contrivance; a method or means of doing something, an instrument, an art, etc. originated by the ingenuity of some person, and previously unknown; an original contrivance or device.' See *The Oxford English Dictionary* (2nd ed. 1989) OED Online (Oxford University Press 4 Apr. 2000) <<http://dictionary.oed.com/cgi/entry/50120501>>.

⁴⁸ 'Some kinds of ideas cannot be patented at all – even if new and very ingenious. For example, you could not patent the plot of a detective story. It would not be considered to be an 'invention' under patent law. Nor could J.S. Bach have patented his Two-Part Inventions, and for much the same reason'. It goes to show that patent law uses the word 'invention' in a rather special way. See Peter Prescott J's ruling in *In the Matter of Patent Applications GB 0226884.3 and 0419317.3 by CFPH LLC* [2005] EWHC 1589 (Pat) available at <<http://www.bailii.org/ew/cases/EWHC/Patents/2005/1589.html>> (26 August 2005).

⁴⁹ Id. See also *NRDC's Application* [1961] RPC at 162, where their Honours said in relation to the term 'invention': 'To attempt to place upon the idea the fetters of an exact verbal formula could never have been sound...'

How, then, does the law define what is an 'invention'? The answer is that nobody has ever come up with a satisfactory, all-embracing definition and I do not suppose anybody will. By its very nature, therefore, the subject cannot be reduced to a precise verbal formula. It is, indeed, something of a moving target, because the progress of technology continues apace.

At best, the term could be understood to mean something having a 'technical character' of some sort.⁵⁰ The fact that Article 27 uses this term in close conjunction with the phrase 'fields of technology' makes this nexus even more evident.

Owing to this definitional difficulty, most member states resort to a 'negative' or exclusionary definition.⁵¹ Thus for example, in Europe, 'invention' is defined to exclude the following: discoveries, scientific theories and mathematical methods; literary, dramatic, musical and artistic works, and any other aesthetic creations whatsoever; schemes, rules and methods for performing a mental act, playing a game or doing business, and programs for a computer; presentations of information; and methods of medical treatment.⁵² It may therefore help to do the same here as well to determine what is excluded from the ambit of the term 'invention' and whether the *proposed exclusion* fits in within any of the exclusions so determined.

3 Exclusions from Patentability in Article 27

⁵⁰ Comments made in relation to the 2000 European Patent Convention (EPC) revision are illustrative in this regard:

'Nevertheless, the point must be made that patent protection is reserved for creations in the technical field. This is now clearly expressed in the new wording of Article 52(1) EPC. In order to be patentable, the subject-matter claimed must therefore have a "technical character" or to be more precise - involve a "technical teaching", i.e. an instruction addressed to a skilled person as to how to solve a particular technical problem using particular technical means. It is on this understanding of the term "invention" that the patent granting practice of the EPO and the jurisprudence of the Boards of Appeal are based.'

See *Basic Proposal for the Revision of the European Patent Convention* 13 October 2000. <http://patlaw-reform.european-patent-office.org/epc2000/documents/mr/_pdf/em00002a.pdf> (24 October 2005). See also '*CFPH LLC Patent Applications*' (n 48) where Peter Prescott J clarifies: 'By 'be an invention', I mean not be excluded by Article 52(2). If something is an invention in that sense, we can call it "technology" for short'.

⁵¹ See *NRDC* (n 49) which states that '... in telling us about patentable inventions, the Patents Act 1977 does not try to define what is an 'invention'. Instead, it contains a list of things that are not inventions.'

⁵² Art 52(2) of the European Patent Convention, 1977 (hereafter 'EPC'). Section 3 of the Indian Patents Act, also contains a similar list of exclusions and begins with 'The following are not inventions within the meaning of this Act'. See also Article 15 of the Andean Community law (Decision 486-Common Provisions on Industrial Property (14 September 2000), available at WIPO Collection of Laws for Electronic Access (CLEA) database) for a similar list of exclusions. <<http://www.wipo.int/clea/en/index.jsp>> (14 September 2005).

Article 27 itself excludes certain categories of inventions from patentability by stipulating that the mandate to grant patents to all inventions is '*subject to the provisions of paragraph 2 and 3...*'

Paragraph 2 of Article 27 provides for what is commonly referred to as the 'morality' exception and states that:

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.

Paragraph 3 excludes 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.

These 'specific exclusions' could be taken to constitute the 'context' for the interpretation of the term 'invention'. It is clear that the *proposed exclusion* (limiting the patentability of pharmaceutical substances to NCEs/NMEs) cannot be justified under either of these exclusions under Article 27.

It is difficult to argue that a pharmaceutical substance that is sought to be patented as a product amounts to a 'method of medical treatment' under 27.3 (a) above. Besides, if this were so, even new chemical entities (NCEs) would fall within this exclusion. This result is contrary to one of the key underlying aims of TRIPS to provide for a common minimum level of patent protection to pharmaceutical inventions. A commentary on TRIPS notes:

It can be argued that pharmaceutical products constitute a therapeutic treatment for humans and animals, and therefore might be excluded from patentability. However, it would be difficult to sustain this argument in light of the negotiating history of TRIPS, which addressed at some length issues surrounding pharmaceutical

patents, as well as provisions such as the Article 70.8 “mailbox” rule that expressly cover pharmaceutical patents.⁵³

In so far as the morality exception under 27.2 is concerned, a similar underlying concern to protect pharmaceutical inventions in a meaningful way would negate an interpretation favouring the total exclusion of pharmaceutical patents from patentability. Article 27.2 makes clear that a member state cannot invoke this provision merely on the ground that the ‘invention’ is contrary to ordre public or morality—rather, it is the ‘commercial exploitation’ of the invention that is to contravene ordre public or morality. One of the key reasons for introducing the ‘commercial exploitation’ aspect in this provision was to prevent member states from excluding pharmaceutical inventions from patentability on the ground that doing so would be harmful to public health.⁵⁴ In other words, such exclusion would be permissible only if member states could demonstrate that it was immoral to commercially exploit (e.g. sell) pharmaceutical inventions. Clearly, no member state would wish to prevent the sales of pharmaceutical inventions within their territory.

Apart from these express exclusions, the negotiating history of TRIPS demonstrates that member states cannot unilaterally read in other exceptions to the general rule in 27(1). The drafting of Article 27.1 was ‘inspired in part by Article 10 of an early draft of the WIPO Patent Law Treaty....’⁵⁵ Article 10(2) of this draft⁵⁶ had 2 alternatives. Alternative A provided that:

Contracting States may, on grounds of public interest, national security, public health, nutrition, national development and social security, exclude from patent protection, either in respect of products or processes for the manufacture of those products, certain fields of technology, by national law.

⁵³ See *Resource Book on TRIPS* (n 23) 386.

⁵⁴ See Akira Ojima *Detailed Analysis of TRIPS (Chikujo Kaisetsu TRIPS Kyotei)* Japan Machinery Center for Trade and Investment, 1999, page 127. (Copy on file with author). See also See *Correa: Integrating Public Health* (n 17) 15 where he considers excluding essential medicines on the grounds of morality and states that ‘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.’

⁵⁵ WIPO Patent Law Treaty, adopted in Geneva on 1 June 2000. Text from early (pe-TRIPS) drafts of the PLT were used as inspiration by TRIPS negotiators.’ See Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (2nd edn Sweet and Maxwell 2003) 220.

⁵⁶ See *The Basic Proposal for the Treaty and the Regulations* Diplomatic Conference for the Conclusion of a Treaty Supplementing the Paris Convention as far as Patents are Concerned The Hague (June 3-28, 1991) WIPO Document PLT/DC/3 (December 21, 1990) 19-20; cf, Nuno Pires de Carvalho *The TRIPS Regime of Patent Rights* (Kluwer Law International New York 2002) 142.

Although the final text of the TRIPS Agreement included numerous provisions from this draft Treaty, it excluded Article 10(2)⁵⁷ and instead made it mandatory for patents to be available in all fields of technology, without discrimination.⁵⁸

This historical insight lends further support to the argument that the ambit of the term 'invention' as used in TRIPS is severely curtailed and grounds such as public interest, public health, etc. mentioned in the pre TRIPS draft above can no longer be invoked to justify denying a patent for an invention.⁵⁹ A commentator notes:

Combined with the explicit inclusion of both product and process inventions and the part of the last sentence, which prohibits any distinction concerning the field of technology, one might say that a general principle of eligibility to be patented is established. Any exclusion from patentability would therefore be looked upon as an exception to that rule.⁶⁰

Article 27 states that patents shall be available for *any inventions*, whether products or processes, in *all fields of technology*. Therefore, the 'context' for the interpretation of the term 'invention' is also informed by the word 'any', and the phrases 'whether products or processes' and 'in all fields of technology', as used in immediate conjunction with the term 'invention'.

These phrases indicate that the term 'invention' is of wide import. The *WTO—Canada Pharmaceuticals* decision is illustrative in this regard. In interpreting the term 'limited' used in Article 30, the panel relied on its close proximity with the word 'exception' and noted that:

Although the word itself can have both broad and narrow definitions, the narrower being indicated by examples such as "a mail train taking only a limited number of passengers", the narrower definition is the more appropriate when the word "limited" is used as part of the phrase "limited exception". The word "exception" by itself connotes a limited

⁵⁷ It is pertinent to note that only one ground i.e. 'national security' from Article 10 (2) was retained by TRIPS (section 73). See *Carvalho* id 143.

⁵⁸ Article 32 of the *Vienna Convention* provides that while interpreting a treaty term, recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion. Illustratively see *WTO—Canada Pharmaceuticals* (n 39) para 7.28, where the panel considered the negotiation history of Article 9(2) of the Berne Convention (from which part of the text of Article 30 of TRIPS was drawn) to determine the import of Article 30.

⁵⁹ See *Carvalho* (n 56) 143 .

⁶⁰ The author then states in a footnote that "this means *interalia* that it [any exclusion] should be interpreted in a restrictive fashion and be the subject of future negotiations towards its elimination." See *Gervais* (n 55) 220. See also *Vaver* (n 27) 301 who notes that 'TRIPS has effectively imposed a worldwide standard under which the availability of patents for inventions in all fields of technology has become the norm. States may choose what exceptions to make from a short closed list'.

derogation, one that does not undercut the body of rules from which it is made. When a treaty uses the term "limited exception", the word "limited" must be given a meaning separate from the limitation implicit in the word "exception" itself. The term "limited exception" must therefore be read to connote a narrow exception - one which makes only a small diminution of the rights in question.⁶¹

It must be noted that the proposition in the Canada case above does not apply on all fours in helping construe the term 'invention'.⁶² Rather, it is illustrative of an approach that takes into account accompanying words and phrases whilst construing a treaty term.

Apart from the above words and phrases used in immediate conjunction with the term invention, the 'non discrimination' principle encapsulated in the latter half of Article 27 lends further support to the argument that the term invention is of very wide import. It reads thus: '**....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**'⁶³ (emphasis by author).

4 Other Exclusions

Most member states exclude the 'discovery of natural phenomena' from patentability.⁶⁴ One may therefore legitimately question as to whether such an exclusion that does not find mention in paragraphs 2 or 3 of Article 27 is compliant with TRIPS.

The 'discovery' exclusion is best captured in a ruling from the United States—a member state that is often perceived as one that permits the least derogation from patentable subject matter. Douglas J observed thus in *Funk Brothers v. Kalo Inoculents*⁶⁵:

⁶¹ *WTO—Canada Pharmaceuticals* (n 39) para 7.29.

⁶² For one, the term 'limited' in the above case is not a 'term of art' in the sense that the term 'invention' is. Further, given the fact that the term 'exception' already implied a limitation of some sort, construing the term 'limited' narrowly would not have made sense and may have even rendered the term 'limited' redundant. I thank Justine Pila for alerting me to this caveat.

⁶³ This 'non discrimination' principle is discussed more elaborately later in this paper.

⁶⁴ See, for example, section 3 (d) of the Indian Patents Act and Article 52(2)(a) of the EPC.

⁶⁵ *Funk Bros Seed Co v Kalo Inoculant Co* 333 US 127, 131 (1948); 76 USPQ (BNA) 280. The court held that packets containing mixtures of bacteria were 'no more than the discovery of some of the handiwork of nature' and were therefore not unpatentable. See also *O'Reilly v. Morse* 56 US (15 How.) 62 (1853) (holding that abstract principles are not statutory subject matter) and *Diamond v. Diehr* 450 US 175, 185 (1981) ('[e]xcluded from ...patent protection are laws of nature, natural phenomena, and abstract ideas'). More recently, the Supreme Court granted certiorari in an appeal from the CAFC decision in *Metabolite Laboratories Inc and Competitive*

...patents cannot issue for the discovery of the phenomena of nature. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.

As evident from the above observation, a mere 'discovery' cannot constitute an 'invention', notwithstanding the fact that truly unique characteristics/properties of a natural substance have been unearthed. At some level, this conclusion derives from the ordinary meaning of the term 'invention'. While inventions are artificial creations, discoveries are not the result of creation – even if creativity is needed to reveal information concealed in nature.⁶⁶

It is pertinent to note in this connection that an earlier WIPO draft, on which certain provisions of TRIPS are significantly based, included the 'discovery' exception.⁶⁷ As to its removal from the final version of TRIPS, a commentator notes that 'the exceptions under paragraph (1) (iii) have not been repeated in Article 27 because the creations mentioned therein are not inventions for the purposes of Article 27.1 and therefore, they are excluded from patentability *per se*.'⁶⁸

This indicates that the term 'invention' admits of some exceptions that flow from the ordinary meaning of this term. In much the same way as a 'discovery', a

Technologies Inc v Laboratory Corporation of America Holdings 370 F.3d 1354 (Fed Cir 8 June 2004) despite the view of the Solicitor General that the issues raised by this case did not warrant the grant of a certiorari (2005 US Lexis 8202; 2005 WL 2864545). The issue before the Supreme Court is:

Whether a method patent setting forth an indefinite, undescribed, and non-enabling step directing a party simply to "correlat[e]" results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result.

In short, the Supreme Court is likely to look into is whether a patent covering the co-relation between high levels of homocystine and a Vitamin B12 or folic acid deficiency is invalid because it covers a 'law of nature' or 'natural phenomena'. The relevant claim in the patent describes a 2 step method involving: a) assaying a sample for high levels of homocysteine: and b) co-relating a value higher than a certain number to a Vitamin B12 or a folic acid deficiency.

⁶⁶ See *Carvalho* (n 56) 146. See also *Mackay Radio & Telegraph Co Inc v Radio Corporation* 306 U.S. 86 (1939) which states at page 94: 'While a scientific truth, or the mathematical expression of it, is not [a] patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.'

⁶⁷ Article 10 (1) (iii) of Alternative A. See Gervais (n 55).

⁶⁸ See *Carvalho* (n 56) 143.

poem, though novel, non-obvious and useful, cannot be termed an 'invention', in the technical sense of the term.⁶⁹ These exclusions are present, more or less, in all member states and may be said to constitute 'state practice' within the meaning of Article 31(3)(b) of the Vienna Convention, which states that 'there shall be taken into account, together with the context, any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation'.

It is pertinent to note in this regard that the standard for claiming that something amounts to state practice is a fairly rigorous one. The Appellate Body ruled in *Japan – Alcoholic Beverages* that:

Generally in international law, the essence of subsequent practice in interpreting a treaty has been recognized as a 'concordant, common and consistent' sequence of acts or pronouncements which is sufficient to establish a discernable pattern implying the agreement of the parties regarding its interpretation.' An isolated act is generally not sufficient to establish subsequent practice; it is a sequence of acts establishing the agreement of the parties that is relevant.⁷⁰

Thus far, there has been no formal recognition of an accepted 'state practice' (subsequent to the adoption of the Agreement) in the context of an interpretation of TRIPS provisions.⁷¹ In *WTO—Canada Pharmaceuticals*, the panel considered comparative law relating to the extension of the patent term for pharmaceuticals to compensate for delays in obtaining marketing approval. It concluded that such practice 'has not been universal' and that therefore, such extension could not be considered a 'widely recognized policy norm'.⁷²

As opposed to 'discoveries' and 'aesthetic' works which are treated as non patentable subject matter in almost all member states, other subject matter such as software and business methods are contentious. It is not the intention of this paper to resolve those issues or to definitively define the precise contours of the

⁶⁹ Article 52 (2) (b) of the EPC excludes all aesthetic creations from the ambit of patentability (see n 28). It is also pertinent to note the views of Laddie J in *Fujitsu Limited's Application* [1996] RPC 507, 530, who suggests that another reason for their exclusion could be public policy. He cites the example of a literary work and states: 'Such things are to be protected, if at all, under copyright law. Not only does copyright law refuse to protect a general idea, it freely allows the publication of similar works if there has been no copying. Imagine what would happen if literary works could be protected by patent. Literary creativity would tend to be stifled, and authors would have to conduct patent infringement searches before the expiry of their copy-deadlines'.

⁷⁰ See *WTO—Japan Alcohol* (n 32) 16.

⁷¹ See Carlos M Correa *TRIPS Disputes: Implications for the Pharmaceutical Sector* (Occasional Paper 5, Quaker UN Office June 2001) <<http://www.geneva.quino.info/pdf/OP5.pdf>> (15 August 2005) 7.

⁷² The panel was determining whether the interest claimed by the EU, in having such a patent term extension was in fact a 'legitimate' one under Article 30. See *WTO—Canada Pharmaceutical* (n 39) paras 7.77—7.79.

term 'invention'.⁷³ Rather, it is to suggest that the term invention is of wide import and that it admits of very few exceptions.⁷⁴ It is difficult to see how the *proposed exclusion* (excluding all non NCE/NME inventions from the scope of patentability) could be treated as not amounting to an 'invention' in the same way as a discovery or a poem, especially since:

- i) it has a definite 'technical character'.⁷⁵
- ii) There is no accepted state practice on this. India would perhaps be the only country with such an exclusion in its patent regime.

5 Legitimate Expectation

At the time of negotiation of the TRIPS Agreement and even today, member states that granted patents to pharmaceutical inventions did not make any distinction between new chemical entities and other pharmaceutical inventions. Rather, patents were granted for all pharmaceutical inventions, provided that they complied with the patentability pre-requisites (novelty, non-obviousness, utility and adequate written description).

In order to accommodate the needs of developing countries, TRIPS provided for a deferred implementation period with respect to those developing countries that did not grant product patents to pharmaceutical inventions in 1995, the year of the signing of TRIPS.⁷⁶ In the interim, applications claiming such inventions were to be put away in a mailbox, to be examined in 2005.⁷⁷

⁷³ A panel when faced with this issue is likely to adopt a similar approach and rule only on the specific issue that it is confronted with. Illustratively, see *WTO—Canada Pharmaceutical* (n 39) paras 7.33—7.34, where the panel notes that 'the question of whether the stockpiling exception is a 'limited' exception turns on the extent to which the patent owner's rights to exclude "making" and "using" the patented product have been curtailed'. The panel then rules only on the specific issue, without attempting to lay down a broader legal principle: 'Without seeking to define exactly what level of curtailment would be disqualifying, it was clear to the Panel that an exception which results in a substantial curtailment of this dimension cannot be considered a "limited exception" within the meaning of Article 30 of the Agreement.' The panel did the same with the term 'discrimination' as well (see text to n 105 below). See, however, Akiko Kato 'Progressive Development of Protection Framework for Pharmaceutical Invention under the TRIPS Agreement: Focusing on Patent Rights' Institute of Intellectual Property (Chiteki Zaisan Kenkyujo March 2003) 62, who states that the 'the findings on the stockpiling exception are not considered to be sufficiently grounded' as they 'lack specifics'.

⁷⁴ See *Gervais* (n 55) who states that such exclusions have to be strictly construed (n 60).

⁷⁵ See n 50.

⁷⁶ Article 65.4 of TRIPS. *The Patents (Amendment) Act, 2005* (n 2) by India is in pursuance of this obligation. For an analysis of this legislation, see reference 7.

⁷⁷ Popularly labelled the 'mailbox facility', this provision is mandated by art 70.8 of TRIPS. In the WTO dispute filed by the United States against India for a failure to comply with this provision, the WTO appellate body held that India was obliged to provide a sound legal mechanism for an interim mailbox arrangement. See *WTO—India Patent* (n 37). India therefore amended her patent regime (by introducing the Patents (Amendment) Act 1999) to comply with this obligation. This legislation

The panel in *WTO—India Patent (EU)*⁷⁸ case notes:

... A critical part of the deal struck was that developing countries that did not provide product patent protection for pharmaceuticals and agricultural chemicals were permitted to delay the introduction thereof for a period of ten years from the entry into force of the WTO Agreement. However, if they chose to do so, they were required to put in place a means by which patent applications for such inventions could be filed so as to allow the preservation of their novelty and priority for the purposes of determining their eligibility for protection by a patent after the expiry of the transitional period.

In addition to the 'mailbox facility', Article 70.9 of TRIPS required developing countries to grant 'exclusive marketing rights' (EMR) to those mailbox applications that met the criteria below:⁷⁹

- i) A corresponding patent application should have been filed in a foreign country (after 1 January 1995) and a patent should have been granted on such application;
- ii) Approval to market the product should have been granted by a relevant authority in the foreign country in which patent above was obtained, and
- iii) Approval to market the product should be obtained from the relevant authority in India.

As the name itself suggests, the crux of this uniquely devised protection is a limited right to exclusively market the drug or medicine in question and was introduced into the TRIPS regime as a sort of pipeline protection for agro-

was passed soon after the WTO dispute and was given retrospective effect from 1995, the date on which India was supposed to have instituted these measures under TRIPS. As per information received from the Office of the Controller General of Patents, Designs and Trademarks, there are around 8926 mailbox applications filed with the Indian patent office that now await examination under the 2005 Act.

⁷⁸ *India: Patent Protection For Pharmaceutical And Agricultural Chemical Products* (24 August 1998) WT/DS79/R para 7.40 (hereafter *WTO—India Patent (EU)*)

⁷⁹ While the US complaint against India focussed on the absence of a mailbox facility under Article 70.8, a complaint filed by the EU alleged that India contravened its obligation under Article 70.9, in that its patent regime did not provide for the grant of 'exclusive marketing rights'. The panel held in favour of the EU. See *WTO—India Patent (EU)* id.

chemicals and pharmaceuticals.⁸⁰ Of the 14 applications filed for EMR's, four have been granted.⁸¹

Given these grants and the mailbox applications filed, there is a credible expectation amongst applicants (and member states from where they hail) that the criteria for the grant of patents to incremental pharmaceutical inventions would be the same as that for other such inventions in the Indian Patents Act. However, it is pertinent to note the views of the Appellate Body in *WTO—India Patents*, which suggests some caution in basing arguments upon the 'legitimate expectations' of parties:

The legitimate expectations of the parties to a treaty are reflected in the language of the treaty itself. The duty of a treaty interpreter is to examine the words of the treaty to determine the intentions of the parties. This should be done in accordance with the principles of treaty interpretation set out in Article 31 of the Vienna Convention. But these principles of interpretation neither require nor condone the imputation into a treaty of words that are not there or the importation into a treaty of concepts that were not intended.⁸²

In the present case however, the 'legitimate expectations' of parties are not used to import words or concepts—or to even argue a contravention of Article 27 independently. Rather, it is to support an argument already made and independently established, that the *proposed exclusion* contravenes Article 27. In short, the express words of Article 27, established state practice and negotiating history weigh heavily against the TRIPS compatibility of the *proposed exclusion*. It is likely that a panel deciding such a dispute would take into account such expectations of private parties and member states (from where they hail), as additional factors strengthening a case already made out.

6 Articles 7/8 of TRIPS and The Doha Declaration

It is clear from Article 31 of the Vienna Convention that one cannot look to a treaty term in isolation—rather, the treaty has to be 'interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context *and in the light of its object and purpose*'.

⁸⁰ The exclusive marketing rights last five years or until the issuance or rejection of a patent (s 24B of the Patents Act). For a historical account of these provisions, see M Blakeney *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPS Agreement* (Sweet and Maxwell London 1996).

⁸¹ The remaining were either refused or the applications are still pending (information received from the Office of the Controller General of Patents, Designs and Trademarks).

⁸² See *WTO—India Patent* (n 37) para 44.

It is here that Article 7 (titled 'Objects') and 8 (titled 'Principles') of TRIPS and more recently, the Doha Declaration on TRIPS and Public Health (hereafter '*Doha Declaration*'),⁸³ become important. One might argue that these articles give sufficient flexibility to member states to define 'invention' restrictively to exclude incremental pharmaceutical innovations from the scope of patentability.⁸⁴

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 and obligations.

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.

As can be seen, Article 7 declares that one of the key goals of the TRIPS Agreement is a balance between the intellectual property rights and other important socio-economic policies of WTO Member governments. Article 8 elaborates the socio-economic policies in question, with particular attention to health and nutritional policies. The text of these provisions make evident the fact that they are not open ended and member states cannot construe them in any manner as they deem fit.

Article 7 and Article 8.1 are worded in general terms and one cannot use such general terms to derogate from the specific mandate under Article 27. It bears

⁸³ *Declaration on the TRIPS Agreement and Public Health* (WTO Doc WT/MIN(01)/DEC/2 of 20 November 2001).

⁸⁴ See *Correa: Integrating Public Health* (n 17) 13-14 who states: '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.'

noting that Article 7 is a 'should' provision, as opposed to Article 27, which is a 'shall' provision.⁸⁵ Similarly, Article 8.1 which begins with 'member states *may...*' cannot be used to derogate from the 'shall' mandate in Article 27. This is further buttressed by the fact that measures under Article 8 have to be 'consistent with the provisions of this agreement', including Article 27.⁸⁶

Article 8.2 specifically addresses a situation where the patent has already been granted and measures need to be put in place to check an abuse of monopoly. This Article appears essentially to be a policy statement that explains the rationale for post patent grant measures taken under Articles 30, 31 and 40.⁸⁷

These articles cannot therefore be construed in a manner as to contravene the express stipulation in Article 27. In this context, it is pertinent to note that:

[W]hen one is dealing with the object and purpose of a treaty, which is the most important part of the treaty's context, the object and purpose does not constitute an element independent of that context. The object and purpose is not to be considered in isolation from the terms of the treaty; it is intrinsic to its text. It follows that, under Article 31 of the Vienna Convention, a treaty's object and purpose is to be used only to clarify the text, not to provide independent sources of meaning that contradict the clear text⁸⁸.

As stated earlier in this paper, TRIPS borrowed considerably from an earlier WIPO draft.⁸⁹ Article 10(2) of the draft treaty had provided for exceptions from patentability on several grounds including public interest, national security, public health and nutrition. Of these grounds, only national security made it to the final version of TRIPS as a ground for denying patents.⁹⁰ The other grounds such as 'public health' and 'nutrition' were relegated to Article 8. Any construction of Article 8 that seeks to exclude patents on the grounds of public health would amount to re-instating the terms of the earlier 10(2) and thereby contravening what the drafters of TRIPS intended. A resource book on TRIPS rightly notes:

'..the public interest clause in paragraph 1.5B above was not included as such in the final version of TRIPS. National security interests are referred to under Article 73. Public health and nutrition as well as the public

⁸⁵ Article 27.1 states that 'patents *shall* be available ... in all fields of technology....'. See *Gervais* (n 55) 116.

⁸⁶ See *Matsushita et al* (n 37) 416 where they state that '... Article 8.1 cannot derogate from the patentability requirement of Article 27.'

⁸⁷ *Gervais* (n 55) 121.

⁸⁸ *United States v. Iran* No. 130-A28-FT, para 58 (Iran-U.S. Cl. Trib. Rep. 2000). In the TRIPS context, see Frederick M Abbott *The TRIPS Agreement, Access to Medicines and the WTO Ministerial Declaration*, 5 *Journal of World IP* (2002) 15.

⁸⁹ See n 55, n 56 and accompanying text.

⁹⁰ See Article 73.

interest in more general terms are included under Article 8.1 as objectives that Members may promote and protect in the formulation of domestic IPR legislation. But this provision does not authorize Members to deviate from the substantive obligations under TRIPS, as is made clear by its final phrase ("provided that such measures are consistent with the provisions of this Agreement").⁹¹

In terms of the weight to be accorded to Articles 7 and 8, it is also pertinent to note the arguments and ruling in the Canada case. The EC had argued that:

Articles 7 and 8 are statements that describe the balancing of goals that had already taken place in negotiating the final texts of the TRIPS Agreement. According to the EC, to view Article 30 as an authorization for governments to "renegotiate" the overall balance of the Agreement would involve a double counting of such socio-economic policies. In particular, the EC pointed to the last phrase of Article 8.1 requiring that government measures to protect important socio-economic policies be consistent with the obligations of the TRIPS Agreement.⁹²

In response to this argument, the panel ruled:

.... Article 30's very existence amounts to a recognition that the definition of patent rights contained in Article 28 would need certain adjustments. On the other hand, the three limiting conditions attached to Article 30 **testify strongly that the negotiators of the Agreement did not intend Article 30 to bring about what would be equivalent to a renegotiation of the basic balance of the Agreement.**⁹³ (emphasis by author)

An interpretation which stretches Articles 7 or 8 to a degree where it contravenes the express mandate to grant patents to all inventions would lead to a *renegotiation of the basic balance present of the TRIPS agreement*. After considering *inter alia*, the prospects of using Articles 7 and 8 to limit the scope of patentability to pharmaceutical substances, Professor Carlos Correa notes:

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....

More recently, the *Doha Declaration* provides a firmer base on which to justify measures adopted in the interests of public health. The operative portion of the *Doha Declaration* is paragraph 4, which states:

⁹¹ See *Resource Book on TRIPS* (n 23) 355.

⁹² *WTO—Canada Pharmaceuticals* (n 39) para 7.25.

⁹³ *Id.* para 7.26

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.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

Here again, the Doha Declaration cannot derogate from the express mandate in Article 27 to provide patents to *all inventions in all fields of technology*. It is pertinent to note the first clause of paragraph 4, which states 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 contours of the TRIPS Agreement. This is again reinforced by the opening phrase of paragraph 5 which states:

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

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.

Although this *Declaration* enhances the importance of Article 7 and 8 by confirming in paragraph 1 that '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',⁹⁴ such enhanced status does not yield a conclusion different from the above. The *Doha Declaration* merely reaffirms the flexibilities already inherent in TRIPS. As a commentator rightly notes:

The importance accorded to these articles in the Doha negotiations is unlikely to formally change the legal status of these provisions, especially in the case of Articles that contain the phrase 'provided that such measures are consistent with the provisions of this Agreement'. The impact of the Doha Declaration could convince a panel to take a longer look at how these provisions should be interpreted in the context of the Agreement as a whole.⁹⁵

A careful reading of the other clauses (2, 3 and 4) leads to the conclusion that the *Doha Declaration* addresses a post grant situation— patent rights (once granted) could be made to yield in certain limited ways in the broader interests of public health. It does not envisage a situation where a member state excludes from patentability an entire class of inventions.

Therefore, the Doha Declaration cannot override the express provisions of the TRIPS provisions, and any flexibilities therein have to be interpreted within the contours of TRIPS.

To conclude this section, it is clear that neither Articles 7 and 8 nor the Doha Declaration can be used to derogate from the specific mandate under Article 27 to grant patents to all inventions.

F 'DISCRIMINATION'

The above discussion shows that the *proposed exclusion* contravenes the mandate under Article 27 to grant patents to all 'inventions'. Apart from this, it also violates the mandate under Article 27 to desist from discriminating against any specific 'field of technology'.

The latter half of Article 27.1 reads thus:

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*

⁹⁴ See *Gervais* (n 55) 122. See also James Thuo Gathii 'The Doha Declaration on TRIPS and Public Health Under the Vienna Convention of the Law of Treaties' 15 (2) *Harvard Journal of Law and Technology* (2002) 292, who *inter alia* goes on to examine if the *Doha Declaration* amounts to a subsequent agreement under Article 31.3(a) of the Vienna Convention or 'evidence of subsequent practice establishing the understanding of WTO members regarding interpretation of the TRIPS Agreement' under Article 31.3 (b).

⁹⁵ *Gervais* (n 55) 122.

enjoyable without discrimination as to the place of invention, the *field of technology* and whether products are imported or locally produced.

The essence of Article 27.1 in this respect shall be labeled, for the sake of convenience, as the 'non discrimination' principle. Article 27.1 prohibits discrimination in relation to both the *availability* of patents and in terms of the nature of patent rights enjoyable by a patentee.

We are concerned with the first kind of discrimination i.e. the non-availability of patents to some kinds of pharmaceutical inventions. The absolute nature of the 'non-discrimination' provision embodied in Article 27 is evident from the limited exceptions that have been spelt out. It is only inventions referred to in paragraph 4 of article 65, paragraph 8 of Article 70 and paragraph 3 of Article 27 that may be discriminated against.

Paragraph 4 of Article 65⁹⁶ and paragraph 8 of Article 70⁹⁷ deal with transitional arrangements in relation to those developing countries that availed of the extra time granted under TRIPS to introduce pharmaceutical and agro-chemical product patents. Since India availed itself of such extra time and introduced product patents for pharmaceuticals earlier this year,⁹⁸ it cannot resort to this provision anymore.

Paragraph 3 of Article 27 has already been elaborated upon in the previous section dealing with 'invention'.⁹⁹ This provision, which deals with the 'method of medical treatment' exception and the exclusion of plants and animals, cannot save the '*proposed exclusion*', where some pharmaceutical inventions are denied patents outright.

1 Canada Pharmaceuticals Case

The ambit of the 'non discrimination' principle enshrined in Article 27 can, to some extent, be ascertained from the panel ruling in *Canada — Patent Protection of Pharmaceutical Products*¹⁰⁰. The key issue before the Panel was whether

⁹⁶ This provision reads: 'To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years'.

⁹⁷ For an elaboration of this provision, see text to n 76 and 77.

⁹⁸ India had time till 1 January 2005 to do so. The Patents Amendment Act 2005 is a response to this obligation.

⁹⁹ See portion titled 'Exclusions from Patentability in Article 27' after n 52.

¹⁰⁰ *WTO—Canada Pharmaceuticals* (n 39). This case is even more pertinent for India since it entered itself as an interested party to this dispute and even made submissions to the panel. See PK Vasudeva 'EU- Canada Patents Row; How does it affect India?' *Economic and Political Weekly Commentary* (6 May 2000).

Canada's regulatory review exception¹⁰¹ and stockpiling exception¹⁰² violated Article 27.1 and 28.1¹⁰³ of the TRIPS agreement. Canada sought refuge under Article 30 of TRIPS, which provided for limited exceptions from patent rights.¹⁰⁴

The panel ultimately ruled that while the regulatory review (*Bolar*) exception was a 'limited' exception under Article 30 that did not unduly prejudice the normal exploitation of the patent, the stockpiling exception went beyond the confines of the Article 30 exception. However, for the purpose of this paper, we are more concerned with the issue pertaining to discrimination i.e. the allegation that the Bolar and stockpiling exceptions targeted the pharmaceutical industry and therefore violated the 'non discrimination' principle under Article 27.

At the outset, whilst mentioning the various earlier GATT/WTO rulings on 'discrimination',¹⁰⁵ the panel was careful enough to rule that it was not attempting a definition of discrimination:

As the Appellate Body has repeatedly made clear, each of these rulings has necessarily been based on the precise legal text in issue, so that it is not possible to treat them as applications of a general concept of discrimination. Given the very broad range of issues that might be involved in defining the word 'discrimination' in Article 27.1 of the

¹⁰¹ Subsection 55.2(1) of the Patent Act, colloquially referred to as the 'regulatory review exception', the 'early working exception', or the 'Bolar exemption', applied to patented products such as pharmaceuticals whose marketing is subject to government regulation, in order to assure their safety or effectiveness. The purpose of this exception is to permit potential competitors of the patent owner to obtain marketing approval during the term of the patent, so that they will have regulatory permission to sell in competition with the patent owner by the date on which the patent expires. Without this exception, the patent owner's right to exclude any person from 'making' or 'using' the patented good (as guaranteed by Article 28 of TRIPS) would enable the patent owner to prevent potential competitors from using the patented product during the term of the patent.

¹⁰² Subsection 55.2(2) of the Patent Act, popularly referred to as the 'stockpiling' exception allows competitors to manufacture and stockpile patented goods during a period of six months immediately prior to the expiration of the patent. Without the additional permission to stockpile during the term of the patent, competitors who obtain regulatory permission to sell on the day the patent expires would still not be able to enter the market on that day, because they would first have to manufacture a sufficient stock of goods.

¹⁰³ Under Article 28.1 of the TRIPS Agreement, 'patent owners shall have the right to exclude others from making, using, selling, offering for sale or importing the patented product during the term of the patent.'

¹⁰⁴ Article 30 of TRIPS states: 'Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.'

¹⁰⁵ See e.g. *WTO—Japan Alcohol* (n 32); *European Communities - Regime for the Importation, Sale and Distribution of Bananas*, WT/DS27/AB/R (adopted 17 November 1997); *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R (adopted 15 February 1998); *United States - Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R (adopted 6 November 1998)

TRIPS Agreement, the Panel decided that it would be better to defer attempting to define that term at the outset, but instead to determine which issues were raised by the record before the Panel, and to define the concept of discrimination to the extent necessary to resolve those issues.¹⁰⁶

The limited focus of the panel was in determining whether section 55.2 of the Canadian Patent Act resulted in a discriminatory treatment of pharmaceutical patents. The panel held that since the statute did not single out the pharmaceutical industry, there was no discrimination. In pertinent part, it noted:

In sum, the Panel found that the evidence in record before it did not raise a plausible claim of discrimination under Article 27.1 of the TRIPS Agreement. It was not proved that the legal scope of Section 55.2(1) was limited to pharmaceutical products, as would normally be required to raise a claim of *de jure* discrimination. Likewise, it was not proved that the adverse effects of Section 55.2(1) were limited to the pharmaceutical industry, or that the objective indications of purpose demonstrated a purpose to impose disadvantages on pharmaceutical patents in particular, as is often required to raise a claim of *de facto* discrimination. Having found that the record did not raise any of these basic elements of a discrimination claim, the Panel was able to find that Section 55.2(1) is not inconsistent with Canada's obligations under Article 27.1 of the TRIPS Agreement. Because the record did not present issues requiring any more precise interpretation of the term "discrimination" in Article 27.1, none was made.¹⁰⁷

Explicitly excluding all incremental pharmaceutical innovations from the scope of patentability (*proposed exclusion*), when similar exclusions are not imposed on other fields of technology would clearly amount to a *de jure* discrimination.¹⁰⁸ This contravenes the specific mandate under Article 27 of TRIPS to desist from discriminating against a field of technology. As two scholars note:

The language of article 27 is clearly aimed at prohibiting *de jure* discrimination with respect to the availability and enjoyment of patent rights. The legislative history of the Agreement is replete with indications that a primary concern of the negotiators was to eliminate

¹⁰⁶ *WTO—Canada Pharmaceuticals* (n 39) para 7.98. The panel later noted that: 'Because the record did not present issues requiring any more precise interpretation of the term 'discrimination' in Article 27.1, none was made'.

¹⁰⁷ *WTO—Canada Pharmaceuticals* (n 39) para 7.105.

¹⁰⁸ The panel explained the distinction between *de jure* and *de facto* discrimination thus: 'Discrimination may arise from explicitly different treatment, sometimes called 'de jure discrimination', but it may also arise from ostensibly identical treatment, which, due to differences in circumstances, produces differentially disadvantageous effects, sometimes called 'de facto discrimination'. See para 7.94.

blanket exclusions of certain types of patentable subject matter (most notably drugs, agrochemicals, and foodstuffs).¹⁰⁹

Although the panel desisted from exploring the concept of 'discrimination' in any detail, some of the panel's findings in this regard are noteworthy:

The primary TRIPS provision that deals with discrimination, such as the national treatment and most-favoured-nation provisions of Articles 3 and 4, do not use the term 'discrimination'. They speak in more precise terms. The ordinary meaning of the word 'discriminate' is potentially broader than these more specific definitions. It certainly extends beyond the concept of differential treatment. It is a normative term, pejorative in connotation, *referring to results of the unjustified imposition of differentially disadvantageous treatment*.¹¹⁰

The above ruling suggests a distinction between 'discrimination' and 'differentiation', noting that it is only an 'unjustified imposition of 'differentially disadvantageous treatment' that is targeted by the Article 27.

That the *proposed exclusion* amounts to a 'differentially disadvantageous treatment' is beyond doubt—as it detrimentally impacts all incremental pharmaceutical inventions.

As to whether such disadvantageous treatment is 'justified' depends significantly on the scope of the term 'justified'. As the panel notes, 'the standards by which the justification for differential treatment is measured are a subject of infinite complexity.'¹¹¹

Although there is no panel decision on the kind of factors that one could invoke to justify a purported discrimination under Article 27, it seems reasonable to assume that one such factor could be the fact that absent such differentiation, a supposedly neutral measure results in a *de facto* discrimination. In other words, in order to avoid a *de facto* discrimination claim, a member state has to differentiate between fields of technology.¹¹² The panel in *WTO—Canada Pharmaceuticals* avoided making a ruling on this issue, stating in a footnote that:

On the record before the Panel, there was no occasion to consider the question raised by certain third parties -- whether measures that are

¹⁰⁹ Dinwoodie and Dreyfuss (n 38) 866.

¹¹⁰ Id. para 7.94.

¹¹¹ *WTO—Canada Pharmaceuticals* (n 39) para 7.94.

¹¹² See *United States - Section 337 of the Tariff Act of 1930*, BISD 36S/386, para 5.11, which suggested that formally identical treatment of products could constitute discrimination, and in such a situation a WTO Member might be required to apply formally different treatment to ensure that there was no discrimination. Although this panel ruling deals with the concept of "national treatment", it provides guidance in approaching the discrimination analysis under Article 27.1.

limited to a particular area of technology - *de jure* or *de facto* - are necessarily "discriminatory" by virtue of that fact alone, or whether under certain circumstances they may be justified as special measures needed to restore equality of treatment to the area of technology in question. The Panel's decision regarding Section 55.2(1) did not touch upon that issue.

Even assuming that the panel had ruled in favour of such a justification (i.e. that one could differentiate a field of technology in order to avoid a claim of *de facto* discrimination), in the context of the *proposed exclusion*, an argument that such differentiation is necessary to avoid a claim of *de facto* discrimination may not hold much water.

Could one argue that Article 7, 8 and the Doha Declaration and the underlying public health goals could supply a valid justification for a measure such as the '*proposed exclusion*'? This seems unlikely for the same reasons discussed while analysing the term 'invention' i.e. the general nature of these provisions as opposed to the more specific and mandatory tenor of Article 27.

The two broad justifications which might be advanced in this context are:

- i) To prevent a phenomenon commonly referred to as 'ever-greening' of pharmaceutical products and;
- ii) To further public health aims by restricting the extent of patentability of pharmaceutical inventions, so as to keep down the prices of drugs.

2 Evergreening and Patentability Criteria

'Evergreening' is a term used to refer loosely to inappropriate extensions in the period of patent exclusivity for a pharmaceutical product.¹¹³ Typically, it denotes a set of practices by patentees, wherein largely trivial or insignificant changes are made to a patented pharmaceutical product and then a secondary patent applied for on such modified product—if such patent is granted and if a generic product on the market is modified to include the features mentioned in the secondary patent, the monopoly of the patentee is extended beyond the period of the first patent.

¹¹³ 'Evergreening' under one definition occurs when a manufacturer supposedly 'stockpiles' patent protection by obtaining separate 20-year patents on multiple attributes to a single product. See *Patentee Attorneys Challenge Assertions re FTA Patent Practices* (Press Release dated 4 August 2004) <http://www.ipta.com.au/forms¬ices/FTA_Release.doc> (5 July 2005). See also Mickey Cantor *US Free Trade Agreements and the Public Health* Submission to the WHO's CIPIH <<http://www.who.int/intellectualproperty/submissions/en/>> who states that evergreening '... is a concept which is often poorly defined. Some critics of intellectual property rights have claimed that intellectual property protection on products can be extended for much longer than the length of the original patent or other intellectual property protection and call such extension of IP protection as "evergreening"'.

As is evident from the above, 'evergreening' can easily be tackled on two fronts:

1. by not granting secondary patents on the basis of trivial and insignificant changes to the original pharmaceutical product.
2. by ensuring that generic versions of the original drug can be marketed after patent protection has expired. This could be aided by inter alia ensuring that regulatory approval for the original product (free to be copied after the original patent expires) is retained as a reference product for generic copies.¹¹⁴

An effective application of patentability criteria in patent offices and the courts would ensure that trivial and insignificant changes do not merit patent protection.¹¹⁵ A good example is the invalidation of secondary patents protecting the use of sildenafil citrate (Viagra™) in erectile dysfunction in the UK¹¹⁶ and Europe¹¹⁷ for lack of novelty and/or inventive step.¹¹⁸ It is important to bear in mind that Viagra™ is a so called 'second medical use' invention—i.e. the active agent, sildenafil citrate, was originally evaluated as a cardiovascular agent and

¹¹⁴ This issue featured in a recent case, where Europe's Competition Commission imposed a heavy fine on AstraZeneca for misusing rules and procedures applied by the national medicines agencies responsible for issuing market authorisations for medicines by selectively deregistering the market authorisations for Losec™ capsules in Denmark, Norway and Sweden with the intent of blocking or delaying entry by generic firms. At the time, generic products could only be marketed if there was an existing reference market authorisation for the original corresponding product (Losec™). Subsequent changes to EU legislation have made it impossible to repeat the specific conduct which led to the fine. See *Commission Press Release* IP/05/737 of June 15, 2005).

¹¹⁵ In response to the suggestion that patents should not be granted for incremental pharmaceutical innovations, the International Chamber of Commerce (ICC) notes that '... if any such inventions do not satisfy the basic patentability criteria, patents should not be granted for them; and if patents are found wrongly to have been granted, courts and patent offices should correct those errors, just as they should for patents in any field and for any category of innovation. This approach should address, and is addressing, concerns about illegitimate extension of patent term, or 'evergreening'. There is no need for separate or new legislation to deal with this issue'. See *'The Importance of Incremental Innovation for Development'*, Submission to the WHO's CIPIH by International Chamber of Commerce (ICC) 7 June 2005 <<http://www.who.int/intellectualproperty/submissions/en/>> (22 July 2005).

¹¹⁶ *Lilly Icos Ltd v Pfizer Ltd* [2002] EWCA Civ 1 (Court of Appeal, 23 January 2002).

¹¹⁷ Decision of Board of Appeals of the EPO, No T 1212/01- 3.3.2 <<http://legal.european-patent-office.org/dg3/pdf/t011212eu1.pdf>> (3 February 2005).

¹¹⁸ The patent was invalidated in China as well, on the grounds of lack of enablement. See Geoffrey K Cooper *Patent Invalidation In Post-Wto China: Pfizer's Sildenafil Use* <<http://www.jurisnotes.com/IP/articles/patentinvalidation.htm>> (2 November 2005). However, this 'non enablement' ground appears to be a tenuous one and Pfizer has sued China's Patent Re-examination Board (PRB) of the State Intellectual Property Office for wrongfully invalidating its patent. See *Beijing Court Hears Wrangle on Viagra Patent* <http://www.chinadaily.com.cn/english/doc/2005-03/31/content_429704.htm> (5 November 2005).

patented as such by Pfizer.¹¹⁹ When sildenafil citrate's now well known use in treating erectile dysfunction was discovered, it could only be patented in the form of an additional new medical use i.e. a method of treating erectile dysfunction.¹²⁰

However, following a challenge by various pharmaceutical companies, the UK courts and the EPO found that the claimed invention was obvious, on the basis of previously published journal articles. These articles disclosed the underlying physiological mechanism of compounds like sildenafil citrate and their potential in treating impotence.¹²¹

Another example is the invalidation of a secondary patent on a polymorph of cimetidine (granted approximately five years after the original patent), in the UK and other countries on the grounds that such polymorph could not be considered 'novel'—i.e. it was inevitably obtained by applying the process already claimed in the original patent.¹²²

The Indian Patents Act has wide ranging provisions that could be used effectively to prevent the grant of patents to trivial and insignificant pharmaceutical inventions:¹²³

1. The Act stipulates that in order to qualify as a 'new invention', the said invention should not have '*been anticipated by publication in any document or used in the country or elsewhere in the world*'.¹²⁴ The novelty standard under the Act is therefore 'absolute', as opposed to being a 'relative' one. In other words, an assessment of novelty would involve a consideration of prior art not only from India ('relative') but the whole world ('absolute')—consequently, fewer pharmaceutical inventions would clear the 'novelty' bar.

¹¹⁹ The original patents are due to expire in the UK in 2013. See Roger Dobson *Pfizer Considers Appeal over Viagra Ruling* 321 *BMJ* (2000) 1244

<<http://bmj.bmjournals.com/cgi/content/full/321/7271/1244/a>> (28 October 2005).

¹²⁰ Claim 1 of the patent claimed the use of a known compound for the manufacture of a medicament for the curative or prophylactic treatment of erectile dysfunction in a male. This is a Swiss-type claim and is permissible under section 2(5) of the UK Patents Act 1977. However, such an application would not be entertained in India, since the patent regime prohibits patents on a mere new use. See n 24.

¹²¹ *Lilly Icos Ltd v Pfizer Ltd* (n 116).

¹²² *Smith Kline and French Laboratories Ltd v Evans Medical Ltd* [1989] FSR 561; cf *Cook et al* (n 9) 89. See also Dow Chemicals Application (unreported—SRIS O/179/83) and Shell International's Application (unreported SRIS O 187/83), where claims to optically active isomers were rejected as obvious because the improved properties were not unexpected and there was either an expectation, or it was predictable that this would be so. *Cook et al* (n 9) 86.

¹²³ See reference 7

¹²⁴ See section 2 (I) of the Indian Patents Act, added by the 2005 amendments.

2. As noted earlier in this paper, the definition of 'inventive step' has been made more onerous in some respects by the 2005 Act.¹²⁵ It is now defined in section 2(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 the person skilled in the art.' As can be seen from this definition, while the basic yardstick remains that which is 'non obvious to a person skilled in the art', a requirement that the invention involve a 'technical advance' or have an 'economic significance' of some sort has been added.¹²⁶ A proper application of the non-obviousness test will therefore help filter out non-meritorious pharmaceutical inventions.
3. The 2005 Act has significantly amended the 'new use' exclusion,¹²⁷ with the intention of specifically addressing the problem of ever-greening.¹²⁸ In addition to the earlier position where any new use of a known substance was not patentable, it now clarifies that 'the mere discovery of a new form of a known substance' is not patentable, unless it results in the enhancement of the known efficacy of that substance'. It then states (via an explanation to the section) that salts, esters, ethers, polymorphs, metabolites etc shall be considered as the 'same substance', unless they 'differ significantly in properties with regard to efficacy'.

The scope of this exclusion will depend, to a significant extent, on how the term 'efficacy' is interpreted. It is interesting to note in this connection that this provision in the 2005 Act, which finds no parallel in any other patent legislation in the world, has been derived from a European Directive dealing with drug safety regulation. Article 10 (2) (b) of Directive 2004/27/EC¹²⁹ which defines a 'generic medicinal product' states in pertinent part that:

¹²⁵ See n 13 and accompanying text.

¹²⁶ The term could therefore now be interpreted in a manner that renders it more onerous to satisfy. For an analysis of this definition and how it differs from the earlier 'non obviousness' standard - see reference 7.

¹²⁷ Prior to the 2005 amendments, Section 3(d) of the Patents Act provided that 'the mere discovery of any new property or new use for a known substance....' is not patentable.

¹²⁸ Sri Kamal Nath, Minister of Commerce and Industry, while answering the concerns voiced by other members of the Lok Sabha (Lower House) in relation to the 'evergreening' of patents, quoted section 3(d) and said that 'There is no question of evergreening'. See *Lok Sabha Debates* (22 March 2005) <<http://164.100.24.230/Webdata/datalshom001/dailydeb/22032005.htm>> Kamal Nath. This ministerial assurance notwithstanding, it is debatable as to how far the amended new use provision goes in stalling ever-greening.

¹²⁹ Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use *Official Journal L 136*, 30/04/2004 P. 0034 – 0057.

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.

This makes it more likely that the term 'efficacy' would be construed in a 'drug regulatory' sense—consequently, the requirement would be a difficult one for most patent applicants to satisfy. Pharmaceutical companies generally file patent applications at the initial stage of discovery of a drug; it is only much later in the development process that clinical studies (phase III) are conducted to gather information pertaining to the therapeutic efficacy of the drug. Requiring information on 'efficacy' at the stage of filing a patent application is therefore an onerous requirement.¹³⁰

If on the other hand, the term 'efficacy' were construed in a rather liberal manner to include even a general hint of an added advantage in using the new form, it is possible that a good number of formulations would qualify as new substances, upon the showing of an increased efficacy. It is open to the Indian patent office/courts to work out an appropriate standard in this regard that permits the patentability of only those pharmaceutical inventions that provide some concrete advantage.

4. Apart from the 'new use' exclusion, the Patents Act has several patent eligibility or subject matter exclusions such as the 'method of medical treatment' exception¹³¹ and the 'product of nature' exclusion.¹³² These could be used to limit the range of patentable pharmaceutical inventions.

In the context of the above provisions, it is pertinent to note that the patent office historically adopted a conservative approach towards patentability.¹³³

¹³⁰ 'The task of proving efficacy is much more difficult, expensive, and time-consuming than the task of proving safety.' The Independent Institute, *History of FDA Regulation: 1902-Present*, at <http://www.fdareview.org/history.shtml>. Another commentator notes: 'Thanks to a 1963 law, the FDA requires pharmaceutical and medical device manufacturers to prove that new drugs and devices are both safe and effective -- but the agency has refused to give a clear definition of efficacy.' J. Bovard, *Bureaucratic Tyrants* 25(23) Connecticut Law Tribune 15 (7 June 1999).

¹³¹ S 3 (i) excludes from patentability, 'any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings...'.
¹³² S 3 (c) excludes the 'discovery of any living thing or non-living substances occurring in nature'.

¹³³ For a detailed discussion on this, see S Basheer '*Policy Style*' *Reasoning at the Indian Patent Office* 3 IPQ (2005) 309-323.

Relying on the Ayyangar Report and the mantra that fewer patents are conducive to a more robust indigenous industry, the patent office has, in the past, demonstrated a 'policy style' approach to the issue of patentability and denied protection to several inventions that merited patents in other parts of the world. Indeed, this trend was discernible as late as 2001, when the patent office refused an application by a Swiss biotechnology company, claiming a method of producing a live vaccine, on the ground that the term 'manufacture' did not include a process that had as its end product, a 'living substance'.¹³⁴

Therefore, it is likely that patentability criteria and subject matter exclusions will be applied by the patent office in a rigorous manner so as to filter out inventions that do not represent a genuine therapeutic advance.

Article 27 of TRIPS stipulates that 'patents shall be available for any inventions... provided that they are *new, involve an inventive step and are capable of industrial application*'.¹³⁵ This leaves some flexibility in the hands of member states to define patentability criteria in a manner that suits their specific national interests.¹³⁶ Member states have, in fact, refined patentability criteria in the context of specific fields of technology, taking into account the unique concerns posed by such technologies.¹³⁷ Illustratively, in 2001, the United States Patent and Trademark Office (USPTO) revised its utility guidelines to cater specifically to biotechnology inventions.¹³⁸ These guidelines came about as a result of the

¹³⁴ *Dimminaco AG v. Controller of Patents and Designs & Others* (2002) IPLR July 255 (Kolkata High Court). See *Basheer* id.

¹³⁵ A footnote to this Article states that 'for the purposes of this Article, the terms 'inventive step' and 'capable of industrial application' may be deemed by a Member to be synonymous with the terms 'non-obvious' and 'useful' respectively'.

¹³⁶ See Commission on Intellectual Property Rights (2002) Integrating Intellectual Property Rights and Development Policy <<http://www.iprcommission.org>> (16 August 2005) 114 that states: '[T]here is ...ample scope for developing countries to determine for themselves how strictly the common standards under TRIPS should be applied and how the evidential burden should be allocated.' It goes on to recommend the application of strict standards of novelty, inventive step and industrial application or utility and asks developing countries to consider higher standards than currently applied in developed countries. Id 123.

¹³⁷ This is normally done through 'examination guidelines' to be followed by the patent offices of member states. In the context of pharmaceutical inventions, see 'Examination Guidelines for Patent Applications relating to Medical Inventions in the UK Patent Office' (March 2004). <<http://www.patent.gov.uk/patent/reference/mediguilines/claims.htm>>

¹³⁸ USPTO 'Guidelines for Examination of Applications for Compliance with Utility Requirements', 66 (4) Fed Reg 1092 (5 January 2001) <<http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf>> (26 August 2005). Such a requirement is now to some extent also being applied by the EPO (EPO Opposition Decision revoking EP0630405 (*ICOS Corporation*) 20 June 2001 (Unreported)). In relation to these guidelines, the *CIPR Report* (n 136) 117 notes: 'It is to be hoped that this new standard will prevent patents being granted on inventions for which only a speculative application is disclosed..... Developing countries providing patent protection for biotechnological inventions should assess whether they are effectively susceptible to industrial application, taking account of the USPTO guidelines as appropriate'.

difficulty in determining whether certain biotechnology-related inventions, such as those covering genes or proteins have any industrial application—often any such application is not evident from the invention itself. The guidelines therefore require that an applicant assert a ‘specific’, ‘substantial’ and ‘credible’ utility for the claimed invention.

These guidelines were recently invoked in *In re Fisher*,¹³⁹ where the United States Court of Appeals for the Federal Circuit (CAFC) upheld the USPTO’s decision to deny patent to Expressed Sequence Tags (ESTs), on the ground that they failed to meet the ‘specific’¹⁴⁰ and ‘substantial’¹⁴¹ utility standard required by the guidelines.

It is also pertinent to note a German provision brought in to ensure that the patent monopoly on a gene sequence is limited to the specific function disclosed and not to all functions.¹⁴² The ‘new use’ exclusion embodied in section 3(d) of the Indian Patents Act is also an example of refinement of the ‘non obviousness’ standard in the context of pharmaceutical inventions—where most forms of existing pharmaceutical substances are considered obvious, unless they demonstrate increased ‘efficacy’.¹⁴³

In fact, it could be argued that a blanket rule applying across the board to all technologies, without taking into account their underlying differences, could in some cases, result in a *de facto* discrimination against a particular sector.¹⁴⁴

Apart from ‘novelty’ and ‘non-obviousness’ standards, another area of potential refinement in so far as pharmaceutical inventions are concerned is in the type of claims that are permitted. Although functional claims have generally been

¹³⁹ 2005 US App Lexis 19259.

¹⁴⁰ The *Fisher* court *Id* at 18, quoting from the Manual of Patent Examination Procedures, stated that: ‘[a]ccording to the Utility Guidelines, a specific utility is particular to the subject matter claimed and would not be applicable to a broad class of invention’. Manual of Patent Examination Procedure § 2107.07.

¹⁴¹ The *Fisher* Court (n 139) stated at page 16: ‘Simply put, to satisfy the ‘substantial’ utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public.’ And later, at page 18: ‘The Utility Guidelines also explain that a substantial utility defines a ‘real world’ use. In particular, utilities that require or constitute carrying out further research to identify or reasonably confirm a “real world” context of use are not substantial utilities.’

¹⁴² An amendment approved by the German Parliament in 2004 limits patent protection on human gene sequences to ‘disclosed functions’ at the time of the patent application i.e. a patent on a human DNA sequence used for a specific function would not cover a second function discovered later by another researcher using the same DNA sequence. See N Stafford ‘German Biopatent Law Passed’ <<http://www.bintegrating omedcentral.com/news/20041209/01>> (24 December 2004).

¹⁴³ See text after n 127 above. This provision also implicates the ‘utility’ standard to some extent.

¹⁴⁴ See n 108. See also *Correa: Integrating Public Health* (n 17) 8 where he states that ‘.....differential treatment does not necessarily mean discriminatory treatment because different technologies might require different treatment.’

admitted in the United States, the European Patent Office (EPO) accepts functional claims only when there is no other means to describe the invention in a more precise manner. More specifically, 'product-by-process' claims¹⁴⁵ are generally admitted by the EPO and some European countries only if it is impossible to define a product by its structural features, and if the obtainable product as such is new and inventive.¹⁴⁶

The TRIPS Agreement does not oblige Members to admit functional or other non-structural claims. India is therefore free to determine the extent of specificity required in a patent application before a product claimed therein can be granted protection.

In conclusion, tailoring patentability criteria to address specific technologies and then applying such criteria in an appropriate manner would be a far more sensible approach than barring an entire class of inventions, comprising both meritorious and non-meritorious inventions. An absolute rule barring certain kinds of pharmaceutical inventions, without an individual determination on the merits of each specific case, results in 'discriminatory treatment' under Article 27.

The above conclusion holds good even if the *proposed exclusion* is treated as an issue of patentability i.e. one deems that all non NCE inventions do not, ipso facto, fulfill one or more of the patentability criteria, such as the 'inventive step' or 'novelty' criteria. Assuming that all pharmaceutical inventions, barring NCEs/NMEs do not meet one or more of patentability criteria (such as the fact that all such inventions are 'obvious'), without an individual determination on merits, amounts to discriminating against a specific field of technology (in this case, 'pharmaceuticals')

3 Public Health and Article 7/8/Doha Declaration

It might be argued that the *proposed exclusion* is necessary to further the public health policy objectives of India by reducing the scope of patentable pharmaceutical inventions, and that the objects and principles in Articles 7 and 8 provide sufficient flexibility to enable this. Consequently, the *proposed exclusion* ought not to fall foul of the 'non discrimination' provision in Article 27.

As has already been elaborated upon in the first section of this paper (dealing with interpreting the term 'invention' in Article 27), Articles 7 and 8 are general

¹⁴⁵ Under product-by-process' claims, protection is accorded only to the product *obtained* with the claimed process and not to the product per se; hence, the same product if obtained by another process would not infringe. See *Grubb* (n 21) 203.

¹⁴⁶ See, for instance, the decision of the Board of Appeals of the European Patent Office T0150/82 (07.02.84); cf *Correa: Integrating Public Health* (n 17) 33.

provisions and there are limits to the extent to which such provisions can derogate from the specific mandate under Article 27. While balancing between the availability of patent rights on the one hand, and a socially oriented public health policy on the other, one has to ensure that Articles 7 and 8 are not interpreted in so wide a manner as to bring about a '*renegotiation of the basic balance of TRIPS*'.¹⁴⁷

One of the key purposes of TRIPS was to even out the disparate levels of protection accorded to pharmaceutical inventions by member states. Therefore the ability to target pharmaceutical inventions under Article 7 and 8 is limited. As noted by the panel in *WTO—Canada Pharmaceuticals*.¹⁴⁸

Moreover, to the extent the prohibition of discrimination does limit the ability to target certain products in dealing with certain of the important national policies referred to in Articles 7 and 8.1, that fact may well constitute a *deliberate limitation rather than frustration of purpose*.

4 Incremental Pharmaceutical Innovations and the Indian Industry

It is important to distinguish between 'ever-greening' on the one hand and 'incremental innovation' on the other. While 'ever-greening' loosely refers to an improper extension of patent monopoly in relation to a specific pharmaceutical product, incremental innovation generally refers to sequential developments of existing products or technologies that can help bring in improved products to the market, capable of addressing unmet public health needs. To this extent, classifying all 'incremental innovations' as tantamount to 'evergreening' is misguided.

It is to be noted that incentives are just as necessary for sequential pharmaceutical developments, as they are for the creation of new chemical entities (NCEs). This is particularly relevant in the Indian context, where local capabilities may not, as yet, be conducive to the discovery and development of new chemical entities.¹⁴⁹

¹⁴⁷ See text to n 93.

¹⁴⁸ *WTO—Canada Pharmaceuticals* (n 39) 7.92.

¹⁴⁹ It needs to be noted however that basic reverse engineering skills (organic chemistry skills) are different from the skills required to arrive at new drugs (medicinal chemistry skills). Besides, the costs of researching upon and introducing a new drug into the market are colossal. See Dr S Subramaniam *Pharmaceutical R&D in India: Addressing the Emerging Model of Drug Innovation* Presentation at Chatham House Conference (London 1 February 2005) <http://www.chathamhouse.org.uk/pdf/conferences/proceedings/subr0105.ppt>. The current average capitalized costs of developing a new drug are estimated to be US\$ 870 million. See DiMasi, J. A., Hansen, R.W. and Grabowski, H. J. 'The Price of Innovation: New Estimates of Drug Development Costs', *Journal of Health Economics*, vol. 22 (2003), pp. 151-185. This estimate has been criticized as not representing '....what companies *actually spend* to discover and develop new molecular entities.

It has been the case so far that most R&D activities that Indian firms engage in are minor modifications of pharmaceutical products developed in foreign (mainly western) countries, and that very little R&D effort has been devoted towards the development of any new drugs.¹⁵⁰ However, this situation is likely to change soon with the emergence of major Indian R&D companies such as Ranbaxy and Dr Reddy's Laboratories.

Further, incremental innovations that cater to the local requirements of India (such as new drug delivery systems and formulations that are created specifically to withstand tropical temperatures) can be of immense value.¹⁵¹ An excellent example in this regard is Wockhardt Ltd, which developed humidity resistant salt forms and isomers of known antimicrobial substances. The original compounds had been patented by Otsuka Pharmaceutical Company as potential antimicrobial agents against bacteria that were resistant to conventional antibiotics. When compared with these original compounds, the salts developed by Wockhardt had better solubility characteristics and greater stability in the presence of high humidity climates.¹⁵² Such incremental innovations are of tremendous value in a

It includes the expense of using money for drug research rather than other investments (known as the "opportunity cost of capital"). See *Critique of the DiMasi/Tufts Methodology and Other Key Prescription Drug R&D Issues*

<http://www.citizen.org/congress/reform/drug_industry/articles.cfm?ID=6532> (15 July 2005).

¹⁵⁰ See Carsten Fink 'How Stronger Patent Protection in India Might Affect the Behavior of Transnational Pharmaceutical Industries' *The World Bank Working Paper No 2352* (The World Bank, Washington DC 2000) 9. A recent news item points out that '[d]omestic pharma majors fear that the new negative list on patenting substances will discourage indigenous research and development (R&D). Since they are far from launching a new chemical entity of their own, some of India's largest pharmaceutical companies are focusing on novel drug delivery systems (NDDS) for the time being.' See KG Narendranath and Ravi Krishnan 'Long Negative List of Patentability Discouraging Research and Development' *Financial Express*

<http://www.financialexpress.com/fe_full_story.php?content_id=98948> (12 September 2005). On the basis of all these reasons, it is often claimed that the Indian industry is not invention based, aiming at the production of new chemical entities, but rather innovation-based, aiming at producing incremental modifications of existing drugs. It is pertinent to note in this regard that, during the course of Parliamentary debates, Shri Kharabela Swain, a member of Parliament, opined that patents ought to be given for incremental innovations as Indian scientists did not have the know-how or capital to come up with new chemical entities, but do have the know how to make improvements. See *Lok Sabha Debates* (n 128).

¹⁵¹ The example of Ranbaxy is noteworthy in this regard—when it came up with an innovative drug delivery system for Ciprofloxacin. The invention sold as Cipro-OD enabled a patient to take the medicine just once a day (OD) and was successfully licensed to Bayer AG. See Padmasree G Sampath 'Economic Aspects of Access to Medicines after 2005: Product Patent Protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry' Study commissioned by the CIPIH, WHO <<http://www.who.int/intellectualproperty/studies/PadmashreeGehlSampathFinal.pdf>> (10 July 2005).

¹⁵² The new salt innovations have been patented: arginine salt forms (6,514, 986; 6,753,333); specific isomers of arginine salts referred to as L-arginine salts (6,664,276); and optically pure carboxylic acid salt forms (6,750,224; 6,608,078). See Follow-on Innovation and Intellectual

country like India and the Indian patent regime ought to incentivise such innovations.

G CONCLUSION

In conclusion, granting patents only to NCEs/NMEs and thereby excluding other categories of pharmaceutical inventions (the '*proposed exclusion*') is likely to contravene the mandate under Article 27 to grant 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.

Further, 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.

If the aim of the *proposed exclusion* is to prevent a phenomenon loosely referred to as 'ever-greening', this can be done by a proper application of patentability criteria, as present in the current patent regime.

Lastly, it is important to distinguish '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 developments ought to be encouraged by the Indian patent regime.

IV ISSUE 2

The referral states: *Whether it would be TRIPS compatible to exclude micro-organisms from patenting?*

A THE TRIPS MANDATE: ARTICLE 27.3(b)

Article 27 (3) (b) of TRIPS reads as follows:

Members may also exclude from patentability... (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...

From the above, it is clear that a member state cannot exclude micro-organisms *per se* from patentability. It further suggests that non-biological and microbiological *processes* of producing micro-organisms or plants/animals are to be granted patents.¹⁵³

B THE INDIAN POSITION

Section 3(j) of the Indian Patents Act¹⁵⁴ is worded in similar terms as Article 27 (3) (b) and provides that the following shall not be considered an invention:

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

However, despite this apparent mirroring of the TRIPS position, it is pertinent to note that micro-organisms *per se* were, till recently, excluded from the scope of patentability.

This result stemmed from section 5 (1) of the Patents Act, 1970 which read as follows:

¹⁵³ See generally Charles R McManis 'Patenting Genetic Products and Processes: A TRIPS Perspective' 50 *Advances In Genetics Incorporating Molecular Genetic Medicine* (2003) 79 who states:

...Article 27.3(b) permits the exclusion of "macrobiological" products and any associated biological processes (other than microbiological processes) for producing the same—namely any commercially valuable plants and animals (other than microorganisms), and any commercially valuable but essentially biological processes (other than microbiological processes) for the production of plants and animals.

¹⁵⁴ This section was added by the Patents (Amendment) Act, 2002 which came into effect on 20 May 2003.

In the case of inventions –

- (a) claiming substances intended for use, or capable of being used, as food or as medicine or drug, or
- (b) relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds),

no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable.

Quite apart from the fact that some micro-organisms are capable of being used as 'medicine' or 'drug' or even 'food', most of them could be said to have been *produced by a chemical process*. Any doubts as to whether a 'chemical process' would include a biotechnological process were laid to rest by the 2002 amendments¹⁵⁵ which clarified that a 'chemical process' in section 5 would include a 'bio-chemical', 'bio-technological' and 'micro-biological' process.

The 2005 amendments¹⁵⁶ did away with Section 5, with the result that micro-organisms are now patentable as products. Further, one can no longer mount an objection on the ground that the invention claims 'living' matter and is therefore non-patentable subject matter.¹⁵⁷

Notwithstanding the TRIPS mandate and section 3(j), the 'terms of reference' above seem to suggest that the government may now be considering whether a reversion to the earlier position (i.e. treating micro-organisms as non patentable subject matter) is compatible with TRIPS.

The short and direct answer is 'no'. However, should Indian policy imperatives call for some limitation on the extent of patentability of micro-organisms (at least when compared with the patent regimes of the developed world),¹⁵⁸ it is possible to strategically utilize the flexibilities in the TRIPS agreement to achieve this end.

¹⁵⁵ Explanation to s 5 (2) of the Patents Act, added by the 2002 amendments.

¹⁵⁶ n 2.

¹⁵⁷ In *Dimminaco* (n 134), the Kolkata High Court categorically ruled that the term 'manner of manufacture' (the precursor to the term "invention") in the Indian Patent Act did not preclude the patenting of 'living organisms'.

¹⁵⁸ This assumption is based on the fact that despite a clear mandate under TRIPS, such a referral has been made in the first place. Secondly, India's statements at various international fora seem to suggest that it is interested in a more restrictive approach to the issue of patentability of micro-organisms and other living matter, than its Western counter-parts. Illustratively, see India's submissions relating to the review of Article 27.3(b) to the Council for the Trade Related Aspects of Intellectual Property Rights, Document IP/C/W/161 (3 November

C TRIPS FLEXIBILITIES

The various flexibilities within TRIPS and the options available to India in this regard are discussed below under the following heads.

- 1 Definitional Flexibility: Defining 'micro-organisms' strictly.
- 2 Patent Eligibility Standards: Strengthening 'patent eligibility' grounds, in particular the 'discovery' exception and the 'morality' exception to reduce the scope of patentability in so far as micro-organisms are concerned.
- 3 Patentability Criteria: Tailoring patentability criteria (by evolving examination guidelines) and applying them strictly to restrict the extent of patentability of micro-organisms.

1 Definitional Flexibility

As noted in the section on new chemical entities (NCE),¹⁵⁹ Article 31.1 of the Vienna convention stipulates that '[a] treaty shall be interpreted in good faith in accordance with the **ordinary meaning** to be given to the terms of the treaty, in their context and in the light of its object and purpose.' (emphasis by author).

In determining the 'ordinary meaning' of the term 'micro-organism', the dictionary/scientific definition of 'micro-organisms' is not conclusive, since there are several such definitions, embodying different approaches.¹⁶⁰ Illustratively, the

1999) < http://www.iprsonline.org/submissions/article273_1999.htm > (11 November 2005) where it states: 'There are many grey areas in defining the scope of patentable microorganisms and microbiological processes multilaterally. The WTO could consider various dimensions of this in these discussions. The first is the difference between discovery and invention – only the latter should be patented. For example, patent on *Streptomyces Vioaceus* a micro-organism accessed from the soil in Hyderabad, India (Patent No. 4992376), granted by US PTO in 1991, to Bristol Myers would not be a valid patent'. This seems to suggest that India would use the 'discovery' exception in a more effective way to deny patents to micro-organisms, although the same may have been patented in the US.

¹⁵⁹ Text after n 32.

¹⁶⁰ However, some member states opine that, in accordance with the Vienna Convention, one should still look to a dictionary, when interpreting the term 'microorganism'. See *The Relationship between the TRIPS Agreement and the Convention on Biological Diversity: Summary of Issues Raised and Points Made* Note by WTO Secretariat IP/C/W/368 (8 August 2002) <http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm#secretariatdocs >:

The question of how WTO Members and, if necessary, a WTO panel should interpret the term "micro-organism" given the absence of a definition has been discussed. One view has been that the principles of international law regarding the interpretation of treaties, in particular Articles 31 and 32 of the Vienna Convention on the Law of Treaties, should be used. (US IP/C/W/209.) The Vienna Convention provides that the basic rule of interpretation is the ordinary meaning of terms in their context and in the light of the agreement's object and purpose. In this regard, it has been said that the dictionary meaning should suffice for distinguishing plants and animals from micro-organisms for the purposes of the TRIPS Council. (Japan, IP/C/M/29 para. 151; Korea, IP/C/M/32 para. 140; Switzerland, IP/C/M/30

following definitions compiled by two commentators (Adcock and Llewelyn) highlight this dilemma:¹⁶¹

1. Any of various microscopic organisms, including algae, bacteria, fungi, protozoa and viruses. (The Concise Oxford Dictionary).
2. Any organism, such as a virus, of microscopic size. (Collins English Dictionary).
3. A micro-organism is 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. (Institute of Science, UK).
4. 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. (Micro-organisms, Function, Form and Environment. Hawker and Linton).
5. A microscopic organism consisting of a single cell or cell cluster, including the viruses. (Biology of Micro-organisms. Brock).
6. Micro-organisms are microscopic life-forms including microscopic fungi, Protista, prokaryotes and viruses. (Introduction to Microbiology. Heritage, Evans and Killington).
7. Micro-organisms consist of several distinct groups of organism, most of whose members are of microscopic dimensions. (Biology of Micro-organisms. Hawker, Linton, Folkes and Carlile).

para. 163, IP/C/W/284; United States, IP/C/M/35 para. 222, IP/C/M/28 para. 131, IP/C/W/209.) The *Concise Oxford Dictionary* defines the ordinary meaning of "micro-organism" as "an organism not visible to the naked eye, e.g., bacterium or virus".

In response to the above, developing countries such as India and Brazil argue that, in interpreting the term "micro-organism", Article 31(4) of the Vienna Convention on the Law of Treaties is more relevant, namely the negotiating history of Article 27.3(b). In this regard, it has been said that negotiators of the TRIPS Agreement questioned, but did not investigate, whether patents would extend to cell-lines, enzymes, plasmids, cosmids and genes and therefore the Agreement contained terms on the meaning of which agreement was not reached. (India, IP/C/M/25 para. 70). It has also been said that a dictionary reference is not very helpful for dealing with the several "borderline" categories of life-forms that could be classified as either micro-organisms or as plants and animals. Moreover, the view has been expressed that the term is obviously intended to have a special meaning in the context of patentability and the dictionary explanation and example of a bacterium or virus do not necessarily concern patentable micro-organisms. (Brazil, IP/C/M/29, para. 146; India, IP/C/M/30, para. 168).

¹⁶¹ Mike Adcock and Margaret Llewelyn *Micro-organisms, Definitions and Options Under TRIPS* Quaker United Nations Office Programme (QUNO) on The TRIPS Process: Negotiating Challenges and Opportunities, Occasional Paper 2 (23 November 2000) <<http://www.quno.org/geneva/pdf/economic/Occasional/Adcock-Llewelyn.pdf>> (16 August 2005) 6.

Adcock and Llewelyn note that 'in the realm of science, definitions keep changing as more is learnt about the subject matter in question'¹⁶² and that if a country were to adopt one or the other definitions above, it would have to update its definition in the light of technological advancements.¹⁶³ It is therefore not surprising that patent regimes of developed countries such as the US and Europe desist from defining the term at all.¹⁶⁴

The ambiguity associated with defining the term 'micro-organism' is noted by another commentator¹⁶⁵ in the context of the Budapest Treaty.¹⁶⁶ The author cites a WIPO document which states:¹⁶⁷

The term microorganism is not defined in the Treaty so that it may be interpreted in a broad sense as to the applicability of the Treaty to microorganisms to be deposited under it. Whether an entity technically is or is not a microorganism matters less in practice than whether deposit of that entity is necessary for the purposes of disclosure and whether an IDA will accept it. Thus, for example, tissue cultures and plasmids can be deposited under the terms of the Treaty, even though they are not microorganisms in the strict sense of the word.

However, one needs to bear in mind the specific context of the Budapest Treaty—it evolved as a means to aid disclosure norms in the context of micro-biological inventions. It is therefore not surprising that it would have preferred the widest

¹⁶² For a detailed discussion on how the scientific definition of the term microorganism has changed over the years, see *Adcock and Llewelyn* (id) 4-7.

¹⁶³ *Adcock and Llewelyn* (n 161) 4.

¹⁶⁴ *Adcock and Llewelyn* (id) 4. See *Comparative Study of Patent Practices in the Field of Biotechnology Related Mainly to Microbiological Inventions* (Prepared Jointly by the European Patent Office, the Japanese Patent Office and the US Patent and Trademark Office on 20 January 1988) which states at page 3:

None of the laws administered by any of the Offices contains a formal definition of the term 'micro-organism'. Where definitions are used in either classification definitions or administrative guidelines, the term is defined as a non-exclusive list of organisms which are included within the scope of that term. As noted by the EPO, it does not seem expedient to introduce such a definition as the rapid evolution in the field of microbiology would necessitate its frequent updating.

¹⁶⁵ See Paul Oldham 'Global Status and Trends in Intellectual Property Claims: Microorganisms' Submission to the Executive Secretary of the Convention on Biological Diversity (2004) 5 <www.cesagen.lancs.ac.uk/resources/docs/microorganisms/microorganismspublished.doc> (16 August 2005) 30.

¹⁶⁶ WIPO *International Patent Classification*. (7th edition 1999). <http://www.wipo.int/classifications/fulltext/new_ipc/index.htm> (15 September 2005) as quoted in *Oldham* (Id) 30.

¹⁶⁷ WIPO *Introduction to the Budapest Treaty* Paragraph 10 <<http://wipo.int/about-ip/en/budapest/guide/download.htm>> (15 September 2005) cf *Oldham* (n 165) 33.

possible meaning for the term 'micro-organism'. However, in a context such as patent eligibility, a similar approach may not work and member states (particularly developing and least developed country members) may opt to define the term more restrictively.

Based on the above, it would be fair to argue that TRIPS envisages some flexibility in defining the term 'micro-organism'. The Commission on Intellectual Property (CIPR), in its report opined that:¹⁶⁸

Even where TRIPS requires patent protection to be available, for example in respect of micro-organisms, there is still scope for developing countries to restrict the scope of protection. In particular, in the absence of any universally recognised definition of what constitutes a "micro-organism", developing countries remain free to adopt a credible definition that limits the range of material covered.

The UK government endorsed the view above:¹⁶⁹

We support the conclusion that it may be in the interests of many developing countries to restrict the application of patenting in biotechnology consistent with TRIPS. The absence of a definition of the term 'microorganism' in TRIPS means that it is legitimate for WTO member states to make a reasonable definition themselves. They should do so based on the potential research benefits to the extent that they have, or wish to develop, biotechnology research capacity.

It is also pertinent to note that in its submission to the TRIPS Council, India stated that '[n]ational laws vary considerably on this issue. Therefore, it should be left to national policy to decide what are patentable micro-organisms.'¹⁷⁰

It may therefore be appropriate to conclude that India has some flexibility in defining the term 'micro-organism' in a manner consistent with its current socio-economic imperatives. The fact that the precise contours of such flexibility are uncertain does not mean that a member state has unqualified freedom in this regard. India cannot therefore resort to an extreme definition, that would have the effect of denying protection to micro-organisms altogether.¹⁷¹ Further, if the term is defined too narrowly, it may run foul of: (a) the clear mandate under Article 27 of TRIPS to grant patent protection to all 'inventions' and (b) the 'non discrimination' principle under Article 27.1.

¹⁶⁸ See CIPR Report (n 136).

¹⁶⁹ See *UK Government Response to the Report of the Commission on Intellectual Property Rights: Integrating Intellectual Property Rights and Development Policy* <www.iprcommission.org/papers/pdfs/govt_response/govt_response.pdf> (13 August 2005) 10.

¹⁷⁰ n 158.

¹⁷¹ A treaty has to be interpreted in good faith and no term in the treaty is to be made redundant. See text to note n 44.

Under TRIPS, most biotechnological inventions, barring plants/animals and essentially biological processes for their production, have to be granted patent protection. Assuming that a member state were to define the term 'micro-organism' restrictively to exclude subject matter labelled for the sake of convenience as 'X', this does not automatically mean that 'X' is excluded from patent protection. Since Article 27 mandates that all 'inventions' have to be granted patent protection, X cannot be excluded, unless an application claiming X falls foul of other patent eligibility or patentability criteria. Thus, for example, if X is an animal or a plant, then it can be legitimately excluded from patentability. Similarly, if X is a naturally occurring micro-organism, a patent can be denied on the ground that what is being claimed is a mere discovery.

However, if X is a virus and the definition of a micro-organism under the patent law of the member state in question does not include a virus, it is difficult to see how a genetically modified virus (that cannot be excluded as a mere 'discovery'), can be denied patent protection. Therefore, rather than restrictively defining the term 'micro-organism', a better approach would be to focus on limiting the scope of patentability of micro-organisms by relying on existing patentability and patent eligibility criteria.

2 Patent Eligibility Standards

(i) The 'Discovery Exception'

Most patent regimes exclude mere discoveries or 'phenomena of nature' from patentability. This distinction between invention and discovery has been extensively discussed in the first half of this paper dealing with NCEs (New Chemical Entities) and the *proposed exclusion*.¹⁷²

Although the 'discovery' exception is not explicitly mentioned in TRIPS, it could be read in, whilst interpreting the term 'invention'.¹⁷³ However, the extent to which such an exception could be stretched without contravening TRIPS is uncertain. It is pertinent to note that although most member states provide a general exception against patenting principles of nature or products of nature, they embody different approaches in terms of when such 'discoveries' would cross over to 'inventions'.

Thus, for example, the patent regimes of developed countries such as the United States,¹⁷⁴ the EU¹⁷⁵ and Japan¹⁷⁶ provide that the discovery of hitherto unknown

¹⁷² See text after n 64.

¹⁷³ See text to n 67.

¹⁷⁴ See *Park-Davis & Co. v. HK Mulford & Co.*, 189 F.95 (C.C.S.D.N.Y 1911). Also see *Application of Kratz*, 592 F. 2d 1169 (CCPA 1979) (where the chemical that gives the distinctive flavor to

natural substances (including micro-organisms) is patentable, provided that such substances have been isolated or purified. The US, European, and Japanese Patent Offices made the following policy statement as far back as 1988:

Purified natural products are not regarded under any of the three laws as products of nature or discoveries because they do not in fact exist in nature in a purified form. Rather they are regarded for patent purposes as biologically active substances or chemical compounds and eligible for patenting on the same basis as other chemical compounds...¹⁷⁷

Developing countries such as Brazil and Argentina, on the other hand, apply a stronger version of the 'discovery' exception. Article 18(III) of the Brazilian patent law¹⁷⁸ and Article 7 (b) of Argentine law¹⁷⁹ suggest that merely isolating or purifying a micro-organism does not render it patentable. In fact, an Argentine examination guideline expressly states that '[l]iving matter and substances preexisting in nature, even if purified and isolated and/or characterized, are considered discoveries and in consequence will not be patentable'.¹⁸⁰

strawberries was isolated for the first time and was held patentable on the ground that it was not found in pure form in strawberries).

¹⁷⁵ While 'discoveries' are generally unpatentable under Article 52 (2) (a) of the European Patent Convention (EPC), Art 3(2) of Directive 98/44 of the European Parliament and of the Council on the *Legal Protection of Biotechnological Inventions* 1998 OJ (L 213) 13 requires Contracting States to provide national patent protection for 'naturally occurring biological material' that is 'isolated from its natural environment or produced by means of a technical process'.

¹⁷⁶ As per the JPO *Guidelines for Examination of Inventions of Microorganisms* (Ch 1 para. 3, 1979), micro-organisms as such may be patented provided 'that in the case of a micro-organism that has been isolated from nature, the claim must include the phrase 'isolated in a substantially pure form''. See John Richards *International Aspects of Patent Protection for Biotechnology* 4 Fordham Intell Prop Media & Ent LJ 433, 460 (1993).

¹⁷⁷ See R. Stephen Crespi 'Patents On Genes – Do They Have A Future?' <<http://www.law.ed.ac.uk/ahrb/publications/online/Crespi.htm>> (15 June 2005).

¹⁷⁸ Article 18 III provides that the below are not patentable:

living beings, whole or in part, except for transgenic microorganisms meeting the three requirements of patentability - novelty, inventive step and industrial application - provided for in article 8 and which are not mere discoveries (emphasis by author).

Industrial Property Law 1996 (Law No. 9,279 of 14 May 1996) <http://www.wipo.int/clea/docs_new/en/br/br003en.html> (3 November 2005).

¹⁷⁹ The section reads:

All biological and genetical (sic.) material existing in nature or its replica, in the biological processes implicit in animal, plant and human reproduction, including the genetic processes relating to material capable of conducting its own duplication under normal and free conditions, such as they occur in nature."

See María Dolores Pigretti Öhman *Access to and Intellectual Property Rights over Genetic Resources with a Special Focus on Fair and Equitable Benefit Sharing: International Context and the Argentinean Case* (IIIEE Reports 2002:6) <<http://www.inta.gov.ar/santacruz/Informe%20CFI/CD/Documentos/10tesisPigretti.pdf>> (16 August 2005) 79.

¹⁸⁰ para 2.1.7.1 (Part C, Chapter IV) of Resolution 243/03.

Although India might wish to follow the Brazilian/Argentine approach and limit the extent of patentability of micro-organisms, the TRIPS compatibility of such a provision is not entirely clear, particularly since a WTO panel is yet to rule on the scope of the term 'invention' in Article 27.¹⁸¹ It appears reasonable to argue that if a 'discovery' exception is compatible with TRIPS since it is implicit in the import of the term 'invention', then a rule that seeks to uphold this exception to the fullest extent (by not permitting a mere isolation or purification to convert what would otherwise be a 'product of nature' into a patentable substance) should also be compatible with TRIPS.

Therefore, section 3(c) of the Patents Act, 1970, which embodies the discovery or product of nature exception and states that the "...*discovery of any living thing or non-living substance occurring in nature*" is not a patentable invention could be clarified in the context of natural products (including micro-organisms) to suggest that merely purifying or isolating such natural products using known procedures would not render them patentable. In other words, only something truly non-natural, such as a genetically engineered micro-organism, would be treated as patentable.¹⁸² An ASEAN working group meeting made a similar recommendation i.e. that only genetically engineered microorganisms ought to merit patent protection and that 'naturally occurring and mutated/selected microorganism should be excluded from patentability.'¹⁸³

(ii) Exclusions under Article 27 (2): *Ordre Public* and Morality

Article 27 (2) of the TRIPS agreement and the ambit of the 'morality' exception enshrined therein has already been discussed in the first half of this paper dealing with the *proposed* exclusion and its compatibility with Article 27.¹⁸⁴ As discussed, it is the commercialization (of the invention) that must be contrary to *ordre public*/morality

¹⁸¹ In relation to the Brazilian law dealing with the patentability of naturally occurring substances, McManis (n 153) 90 opines that this law '....in design and effect, discriminates against biotechnology as a field of technology, thus violating the non-discrimination provision of Article 27.1 of TRIPS' and that allowing the Brazilian interpretation would lead to the return of the ban on pharmaceutical product patents 'by way of a slightly smaller back door'.

¹⁸² The landmark case in this regard is *Diamond v Chakrabarty* 447 U.S. 303 (1980) where the Supreme Court found that Chakrabarty's genetically engineered bacterium (capable of breaking down crude oil bacterium) was patentable on the ground that it is an artificially made composition of matter that has properties not found in any naturally occurring bacterium.

¹⁸³ *Recommendations of the Working Group on Biodiversity, Biotechnology, Traditional/Indigenous Knowledge, and Traditional Medicine* ASEAN Regional Working Group Meeting, Jakarta, Indonesia, (2-4 May 2000), cf Chakravarthi Raghavan *ASEAN for Protecting Indigenous/Traditional Knowledge* (5 May 2000) <<http://www.twinside.org.sg/title/asean.htm>> (13 August 2005). See *Correa: Integrating Public Health* (n 17) 20 who states: '[i]f a more explicit and restrictive approach is preferred, national laws may provide for [a] specific exclusion...' that may be worded as "A substance found in nature, including DNA, even if purified or isolated, shall not be regarded as an invention." See also the Argentine example in text to n 180.

¹⁸⁴ See text after n 53.

and not the grant of the patent itself. In other words, one cannot deny a patent to a micro-organism on the ground that it is 'immoral' to do so, whilst at the same time permitting the same to be commercialised.¹⁸⁵

Given India's recent focus on biotechnology, prohibiting all forms of commercialization of micro-organisms does not appear to be a feasible solution.¹⁸⁶

Further difficulties in invoking this exception arise from the fact that morality standards are largely indeterminate and that, in terms of institutional competence, it is difficult for patent examiners to engage with moral/ethical standards. A good example is the *Harvard Onco-Mouse* case, where the main issue was whether allowing a patent for a transgenic non-human mammal prone to developing cancer contravened the *ordre public*/morality clause in the EPC.¹⁸⁷ The EPO held that the usefulness of the invention in cancer research outweighed any suffering that might be caused to the animal, and that the invention was therefore a 'moral' one. The adoption of such a 'utilitarian' approach raises questions about the appropriateness of requiring courts and patent offices to make judgments involving moral and ethical standards.¹⁸⁸

3 Patentability Criteria

Member states have some flexibility under TRIPS in tailoring patentability criteria to address specific technologies.¹⁸⁹ Therefore, another way to limit the extent of

¹⁸⁵ One of the key reasons for introducing the 'commercial exploitation' aspect in this provision was to prevent member states from excluding pharmaceutical inventions on the ground that it was harmful to public health. See Akira Ojima (n 54). See also *Correa: Integrating Public Health* (n 17) 15 where he considers excluding essential medicines on the grounds of morality and states that '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.'

¹⁸⁶ A recent article in *Nature* states: 'The biggest boost to the biotechnology industry has come from the government itself. "Biotech is the government's priority area," says science minister Kapil Sibal. Less than a year after Sibal took office, the Department of Biotechnology (DBT) released an ambitious plan to create a biotechnology industry that would generate US\$5 billion in revenues per year and create one million jobs by 2010.' KS Jayaraman 'Biotech Boom' *Nature* (28 July 2005) 480. See also the Draft National Biotechnology Development Strategy <<http://dbtindia.nic.in/biotechstrategy/BiotechStrategy.pdf>> which states that 'Biotechnology can deliver the next wave of technological change that can be as radical and even more pervasive than that brought about by IT. Employment generation, intellectual wealth creation, expanding entrepreneurial opportunities, augmenting industrial growth are a few of the compelling factors that warrant a focused approach for this sector'.

¹⁸⁷ *Onco-Mouse* [1989], Official journal of the European Patent Office (Exam) 476; [1990] Official journal of the European Patent Office, 476, 490 (IBA); [1991] E.P.O.R. 525 (Exam).

¹⁸⁸ See S Basheer *Patenting Genes and Gene Sequences: The Next El Dorado* EDIP (2003) 30 <<http://users.ox.ac.uk/~edip/basheer.pdf>> (7 November 2005).

¹⁸⁹ See text to n 136. See also CIPR Report (n 136) 123: '[T]here is ample scope for developing countries to determine for themselves how strictly the common standards under TRIPS should be applied and how the evidential burden should be allocated.' It goes on to recommend the application of strict standards of novelty, inventive step and industrial application or utility and asks developing

patentability of micro-organisms is by tailoring patentability criteria (by evolving examination guidelines) and applying them rigorously during the patent granting process.¹⁹⁰

As noted earlier in this paper (when dealing with first issue concerning NCEs and the *proposed exclusion*), various member states have tailored patentability criteria and examination guidelines for particular technology sectors, in furtherance of their policy goals.¹⁹¹ India is free to adopt a similar approach and develop specific guidelines in relation to the patentability of microorganisms to ensure that only truly meritorious inventions are protected. Using a 'guideline' based approach rather than a substantive law approach has the advantage of flexibility and ease of amendment in the light of changing technologies and policy considerations.

D CONCLUSION

The above discussion may be summarised as below:

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. The various options available to India are highlighted below:

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 micro-organism by known procedures will not render it patentable. Rather, only truly 'invented' micro-organisms 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,

countries to consider higher standards than currently applied in developed countries. See also *Reichman* who states that there is no international standard for novelty and non-obviousness and countries are free to "pick and choose" from the various options: *Reichman* (n 39) 30. Also see *Correa: Integrating Public Health* (n 17) 3

¹⁹⁰ Mike Adcock and Margaret Llewelyn *Micro-organisms, Definitions and Options Under TRIPS: Supplementary Thoughts* Quaker United Nations Office Programme on The TRIPS Process: Negotiating Challenges and Opportunities, Occasional Paper 2 (23 November 2000)

<<http://www.quno.org/geneva/pdf/economic/Occasional/Adcock-Llewelyn.pdf>> (16 August 2005) 17, 18.

¹⁹¹ See text to n 137.

- prohibiting any form of commercialisation of a micro-organism, a result that may not fit in 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.

Of 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.