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Micro-organisms, Definitions and Options under TRIPS

And

*Micro-organisms, Definitions and Options under TRIPS:
Supplementary Thoughts*

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Micro-organisms, Definitions and Options Under TRIPs

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Introduction

The first half² of Article 27(3)(b) of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) states that:

Members may... 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.”

The line of patentable subject matter is thus apparently drawn. The only material which can be excluded from patent protection are plants and animals and essentially biological processes for the production of plants and animals. Member states are specifically not permitted to exclude from patent protection micro-organisms and non-biological and microbiological processes.

The language used in Article 27(3)(b) implies that a clear distinction can be made between plants and animals on the one hand and micro-organisms on the other. This, in turn, leads to a presumption that, on the face of it, there is a common definition of the term “micro-organism” which is acceptable to all members states of the Agreement and that this definition is regarded as sufficient for the purposes of distinguishing between that which is patentable and that which is not.

However, it would be incorrect to assume that a commonly accepted definition exists in practice. As will be demonstrated later in this paper there is no single scientific definition of a ‘micro-organism’. This lack of a common scientific definition has led to the practice, within the patent laws of developed countries, of not using a definition for patent law purposes.

The absence of a common definition is critical for those member states that have concerns over the extension of patent protection to living material. Any attempt to curb this extension by means which differ from the existing practice developed countries, for example by providing a definition of ‘micro-organism’ for local patent purposes, will be carefully

¹ The views expressed are those of the authors and should not be taken as those of Quaker UN Office. These views should not be taken as a definitive statement of the law.

² The second half of the Articles states that “*Members shall provide protection 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*”

scrutinised to assess whether this is in compliance or violation of the obligation set down in Article 27(3)(b).

The TRIPs Agreement

The function of the TRIPs Agreement is to set down minimum standards for intellectual property protection³. The aim of the Agreement is to ensure that each member state provides effective and adequate intellectual property protection thereby facilitating trade. As the Agreement was not intended to set up a world-wide system of intellectual property protection, and in recognition of the territorial nature⁴ of intellectual property rights and the need to maintain appropriate local differences, the provisions set down within the Agreement are drafted in very general terms.

The Obligation to Patent Micro-organisms

The relevant provision in respect of living material is Article 27. Article 27(1) sets down the basic requirement that member states must provide patent protection for all types of inventions irrespective of the field of technology. In recognition of the fact that many existing patent systems contained certain categories of excluded material⁵ Article 27 also contains three categories of optional excluded material. These are inventions the commercial exploitation of which would be contrary to morality [Article 27(2)]; inventions, which take the form of diagnostic, therapeutic, or surgical treatments for humans or animals [Article 27(3)(a)]; and plants and animals [Article 27(3)(b)]. As already stated member states may not exclude micro-organisms, or non-biological or microbiological processes, from patent protection. The reason for this is the extensive use of micro-organisms by the pharmaceutical industry and the reliance of this industry on the patent system to provide protection for the results of its investment intensive research. Member states must also provide either patent protection and/or a *sui generis* right for plant varieties.

No definitions are provided for any of these terms.

With regard to patent protection Article 27 states that inventions are patentable provided that they are new, involve an inventive step and are capable of industrial application. As with the categories of protectable material the Agreement is silent on the matter of what constitutes new, inventive step and industrial application other than to state that the terms ‘non-obvious’ and ‘useful’ can be used synonymously with ‘inventive step’ and ‘industrial applicability’.

The lack of any definition means that for those member states wishing to apply a restrictive approach to the legal protection of living material the determination of what is a plant, an animal, a micro-organism, non-biological & microbiological processes and a plant variety is crucial. Not least because any divergence from a developed country norm of what these terms mean for the purposes of patent law could bring the alleged implementing legislation under intense scrutiny.

It is clear from the patent activity taking place in so-called developed countries such as the United States, Europe and Japan that a very flexible interpretation is given to the concept of patentable subject matter. The emphasis is on inclusion not exclusion. Driving this approach,

³ See Preamble to the Agreement

⁴ These rights being enforceable only in those countries where they are acquired.

⁵ The key countries at the time of the coming into force of the Agreement were those which comprise the European Patent Convention community.

is the assertion of a need for equivalence of protection within the global market place. This equivalence being predicated on the practices of the developed countries. This shift to legal interpretations of scientific concepts such as ‘micro-organism’ begs the question of which is the appropriate language for the purposes of defining patentable subject matter - the language of science, law, or the market?

It is clear from the practice of patent granting offices in developed countries that there is no perceived need for a definition. The key issue for protection being whether or not the invention meets the patent granting criteria and not its subject matter. One of the reasons for reluctance to use a definition was provided by the European Patent Office (EPO) when asked as part of a Comparative Study undertaken by the World Intellectual Property Organisation in 1988. The EPO stated that “it does not seem expedient to introduce such a definition as the rapid evolution in the field of microbiology would necessitate its frequent updating”.

The convention in international law is that if the relevant treaty or Convention fails to provide a definition then the ordinary meaning of that term should be used.

This raises a number of questions

- Is it appropriate to accept the view of the European Patent Office that a definition of micro-organism should not be sought? Whilst the view appears to be predicated on the belief that developments in biotechnology would necessitate any definition to be revised repeatedly, it is also possible to read it as based on a view that a definition would serve to maintain exclusions rather than optimise inclusions. It is also relevant to ask whether it is still appropriate to rely on a study undertaken in 1988 as the basis for justifying a common position under TRIPs which is founded on the practice of developed countries
- Should the absence of any definition in the American, Japanese and European patent systems automatically preclude other member states of TRIPs from including such a definition for their own internal patent administration?
- If the answer to this, is that this action is not precluded then what, if any, definition would be permitted?
- Following on from this – what should be an appropriate source for defining a scientific concept? Should it be ordinary every day language or reliance on a scientific definition? If the latter, then which scientific meaning should be used?
- Are granting offices correct in taking as their starting point for determining patentability whether the invention, irrespective of what it comprises, complies with the granting requirements of novelty, inventive step and industrial application? The clear implication from this is that, if accepted, the **sole** determining factors are the granting criteria - the subject matter of the invention is irrelevant.

An appropriate starting point is providing a scientific definition of micro-organism.

Scientific Definition of Micro-organisms

Historical Aspects

Until the last century living organisms were classified as animals or plants by their obvious differences in form and constitution. These differences can be explained by the basic differences in their modes of nutrition. Animals are carbon heterotrophs, feeding on complex organic substances, whereas plants are carbon autotrophs, synthesising the substances needed for growth by utilising sunlight as a source of energy.

Thus it was easy to make sharp distinctions between plant kingdoms and animal kingdoms as long as little was known about micro-organisms. Even fungi had so many properties in common with higher plants that they could be included in the plant kingdom despite their generally heterotrophic nutrition. Much more difficult decisions arose in assigning bacteria, slime moulds and other unicellular organisms to one of the two kingdoms. Hence a third division of living organisms, with the collective name of Protista, was established by Haeckel in 1866. The kingdom Protista contained those organisms that were differentiated from plants and animals by their lack of morphological specialisation, most of them being unicellular. The protists were sub-divided further into two clearly differentiated groups on the basis of their cellular structure. The higher protists resembling plants and animals in their cell composition were called Eukaryotes. This group included algae, fungi and protozoa. The lower protists, which include bacteria and cyanobacteria, were called prokaryotes and their cellular structure is very different from that of all other organisms. Subsequent developments in the study of micro-organisms proved this distinction was not sufficient to fully describe the wide range of micro-organisms being discovered. Therefore, the kingdom Protista became reserved for eukaryotic microbial life forms, whereas prokaryotes have been placed into their own kingdom, the Monera ('new' Latin meaning non-nucleated protoplasmic masses).

Further study of evolutionary theory and cell theory has now provided us with a basis for the interrelation of all living things. The utilisation of Linneus' hierarchical classification system has resulted in (generally) five kingdoms of living organisms. However, recent studies strongly suggest that there are in fact six kingdoms with Archeobacteria being a kingdom in its own right. However, for the moment Monera encompasses both Eubacteria and Archaeobacteria. It should be noted that viruses are not considered living, as they are unable to replicate outside living cells, and therefore do not strictly fit into the classification below.

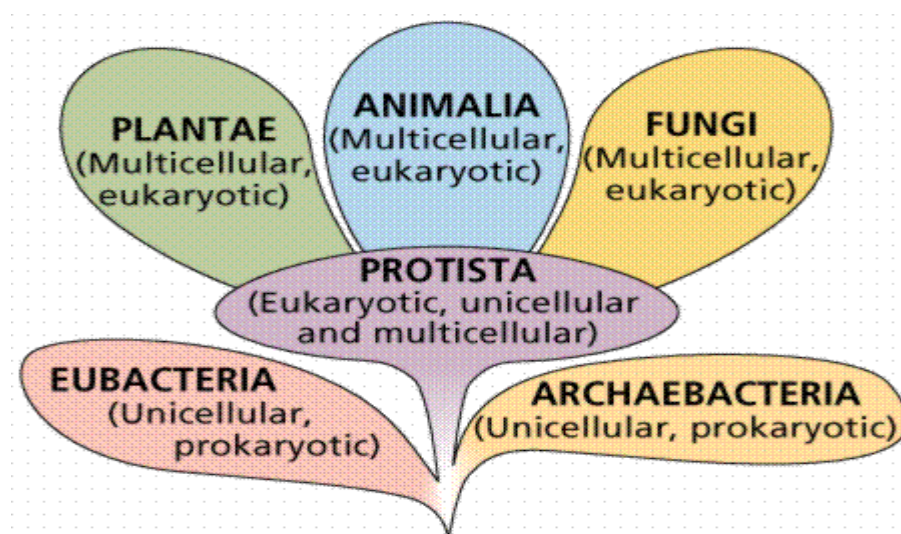


Figure 1. A simple phylogenetic representation of three domains of life. Archaeobacteria, Eubacteria, and Eukaryota (all eukaryotic groups: Protista, Plantae, Fungi, and Animalia).

Definition of micro-organism

The defining property of micro-organisms is the microscopic size of the individual. Their small dimension may have provided researchers with the original motive for categorising micro-organisms in a special group separate from the plant and animal kingdoms. However, of equal importance in the classification of micro-organisms is their morphology, activity, diversity, flexibility of metabolism, ecological distribution, and even their manipulation in the laboratory. Therefore, the term 'micro-organism' includes organisms that differ widely from one another in form, life cycle and mode of life. This has meant that there is no single definitive term that defines a 'micro-organism' as the following examples indicate.

1. Any of various microscopic organism, 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*).

Thus the term 'micro-organism' is used as a generic term that frequently includes the following organisms:

- Bacteria and cyanobacteria
- Archaeobacteria.
- Algae.
- Protozoa
- Slime moulds
- Fungi
- Bacteriophages.
- Plasmids
- Viruses

Conclusions

From an historical viewpoint the characterisation of micro-organisms has developed as our ability to study them has improved. Improvements in light microscopy, followed by the development of confocal and electron microscopy, has not only aided our discovery of new micro-organisms but also our ability to describe them as well.

This has resulted in the term 'micro-organism', as used by scientists, becoming widely used but in essence, ill defined. Our understanding of what a micro-organism is continually evolving, with a variety of definitions that encompass a ever widening range of diverse organisms. The discovery of Archaeobacteria by Woese and Fox in 1977 demonstrates just how dynamic this field is.

Furthermore, as figure 2 demonstrates (next page), the division between plants, animals and micro-organisms is not a strict one and there is significant overlap between the kingdoms. Many organisms have properties which mean that they cannot be readily characterised into a particular kingdom. There are many examples of which green algae is fairly typical. Green algae have many properties in common with members of the plant kingdom e.g. they contain photosynthetic pigments and are autotrophic, and yet many are microscopic and unicellular and can thus be considered to be micro-organisms. Furthermore, fungi are frequently included in the term micro-organism and yet many fungi are too large to be considered microscopic.

It is, therefore, clear that the term 'micro-organism' can have a variety of definitions, which may or may not be exhaustive.

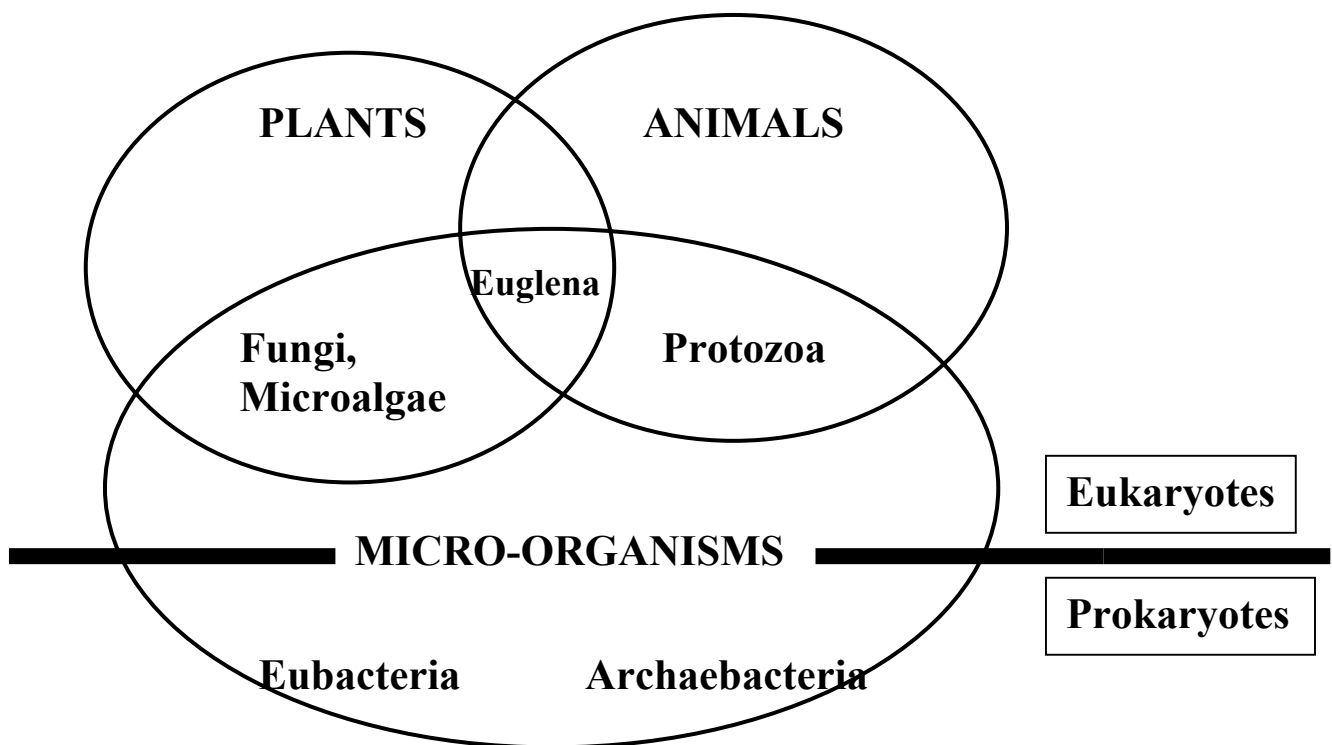


Figure 2. The kingdoms of plant, animals and micro-organisms and the separation into eukaryotes and prokaryotes.

Glossary

Eukaryotic organisms - (*eu* meaning true and *karyon* meaning a kernel) a complex arrangement of intercellular, variety of subcellular organelles, a proper membrane-bound nucleus.

Prokaryotic organisms - (*pro* meaning before) lack a clearly defined membrane-bound nucleus (present as naked DNA), no internal membranes or subcellular organelles.

The Five Kingdoms of Living Organisms

Figure 3. *Universal 18S rRNA Phylogeny*: (McArthur *et al* FEMS Microbial lett. 2000,)

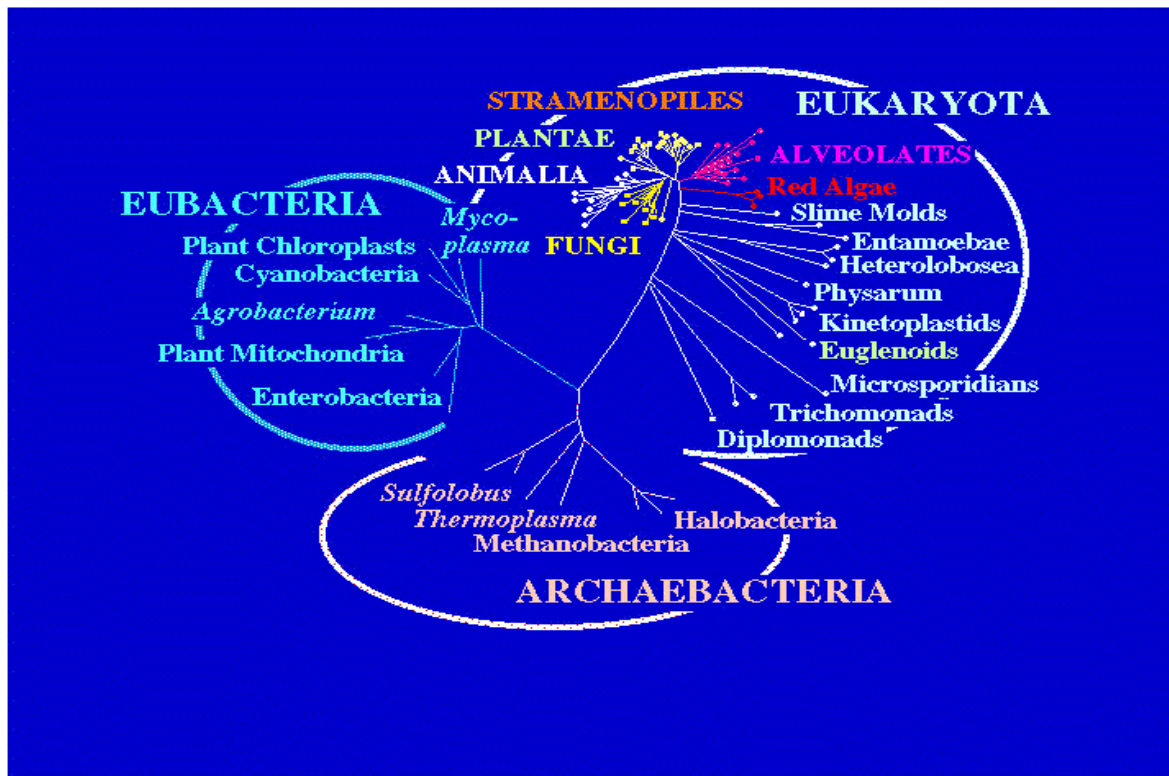


Figure 3 shows a phylogenetic reconstruction of the Tree of Life using aligned 18S ribosomal RNA sequences. Three major Kingdoms are resolved - Eubacteria, Archaeobacteria, and Eukaryota. (Animals, Plants, and Fungi are in the eukaryotic crown group). This diagram represents the genetic division of all organisms and their common ancestry. This demonstrates that our definition of the term 'micro-organism' is still developing. As new diagnostic techniques are developed they allow our understanding of micro-organisms to deepen which will result in the continuing redefining of what is meant by the term 'micro-organism'⁶. (See also Appendix 1)

It can be seen that it will be difficult to rely on science as providing a single definition. If an attempt is to be made to interpret the concept of a 'micro-organism' restrictively then it might be better to look at possible avenues within the law.

The Legal Definition of a Micro-organism

The patent offices of developed countries such as America, European countries and Japan have not to date concerned themselves with defining what is or is not a 'micro-organism'. The reason for this is quite simple. The term 'micro-organism' does not appear anywhere within patent legislation. In European patent law, unlike in American patent law, there are express exclusions of discoveries⁷, inventions which are contrary to morality⁸ and plant & animal varieties⁹ and essentially biological processes¹⁰. Each of these has been the subject of some

⁶ References: Biology of Micro-organisms. Hawker, Linton, Folkes and Carlile. Arnold (1977).; Introduction to Microbiology. Heritage, Evans and Killington. Cambridge University Press (1997); Micro-organisms; function, Form and Environment. Hawler and Linton. Arnold Publishers (1981); Biology of Micro-organisms. Madigan, Martinko and Parker. Prentise Hall Publishers (2000); The Giardia Genome Project Database. McArthur et al FEMS Microbial lett. (2000).

⁷ *Howard Florey/Relaxin* [1995] European Patent Office Reports 541

⁸ *Harvard OncoMouse*. [1990] O.J. EPO 476; [1992] O.J. EPO 589; *Plant Genetic Systems* (T356/93) [1995] European Patent Office Reports 357; *Howard Florey/Relaxin* *ibid*

⁹ *Plant Genetic Systems* *ibid*

¹⁰ *supra* note 7

discussion in the European Patent Office Boards of Appeal, in each with the clear emphasis on the restrictive application of any exclusions, but the issue of what constitutes a ‘micro-organism’ has not arisen. The presumption within patent circles is that these are patentable, and the only material which potentially could be excluded is falling within the specified categories of excluded material.

It is also clear from the current case law, and recent legislative activity within the European Union and EPO¹¹, that these exclusions are to be given a very restrictive application - again the emphasis is on inclusion not exclusion. The definition given also could be said to go further than that commonly adopted for scientific purposes as it encompasses more than unicellular living organisms capable of independent existence. Grubb¹² states that whilst “[m]ost patent laws do not deal specifically with the question of whether or not a new living strain of micro-organism is itself patentable...the [UK] Patents Act 1977 and the EPC do not exclude such a possibility.” He goes on to state that “[i]t must be remembered that the term ‘micro-organism’ is interpreted broadly so as to include not only bacteria and fungi but also viruses and animal and plant cells”. This corresponds to the practice of granting offices in the USA, Europe and Japan where patents have been granted over plant and animal cells.

The only debate of any kind has taken place in Europe but this has been at the level of what constitutes a plant, which is patentable, and a plant variety, which is not. The result of this has been agreement within patent granting offices that excluded material is that which is protectable by a plant variety right as determined by the UPOV Convention. Anything falling outside the scope of UPOV being protectable by a patent.¹³ The result of this is that patent protection is available for groupings of plants which encompass more than one variety provided the patentee has not claimed a plant variety as such. Anything, therefore, which does not take the form of a patent variety as such is patentable. It is not regarded as necessary to provide any further definitions.

It is clear that within developed countries the matter of patent protection for micro-organisms appears settled. And that the driving force behind this is the patent system itself which has repeatedly underlined its position as inclusive not exclusive. This inclusivity is based on a under-use of definitions rather than an overuse. However, this is not necessarily the position of all member states of TRIPs. If the position is that more rather than less should be excluded then the role of the definition of protectable material becomes crucial.

It is possible that the lack of a specific definition in the TRIPs Agreement could be read as indicating that a member state can choose whether or not to provide such a definition. If this route is followed, member states will have to ensure that this is expressly stated within the national patent law. For example, “For the purposes of this Act, the term ‘micro-organism’ will be given the following definition.... Any material not falling within the scope of this definition is excluded from patent protection.” The issue then will be whether any definition, which differs from that which is used by developed countries, e.g., those identified by Grubb, would be accepted as one which properly implements the obligation set down in the Agreement.

¹¹ See the EU directive on the Legal Protection of Biotechnological Invention EC/44/98 and the Decision of the Administrative Council 16 June 1999 to Amend the Implementing Rules of the European Patent Convention, see in particular Rule 23(b)(1) which states that the Directive “shall be used as a supplementary means of interpretation.” 1999 OJ EPO 437, 1999 OJ EPO 573. The Regulations came into effect on 1 September 1999

¹² *Patents for Chemical, Pharmaceutical and Biotechnology* Oxford University Press 1999 at page 226 and 227. Grubb is a European Patent Attorney and Intellectual Property Counsel for Novartis International AG in Switzerland.

¹³ see *Novartis/Transgenic plant (GOI/98)* [2000] EPOR 303; and Directive EC/44/98 Article 4(2) see also Recitals 29-32.

It is clear that the patent laws of developed countries are predicated on a presumption of patentability and the granting criteria are given a broad interpretation. Any exclusions are, therefore, necessarily given a restriction application. This means that where a country has adopted specific categories of excluded material, these exclusions are likely to be the subject of rigorous scrutiny particularly where the categories could be said to go beyond that which is permitted under the Agreement. It should be borne in mind that developed countries, and in particular the USA, Japan and Europe, are the driving force behind the WTO and it is their patent offices which are setting the standard for patent protection. This does not mean that an alternative view would not prevail, but that the underlying presumption in favour of granting patent protection is one which will have to be shown to be incorrect.

The Role of the Lawyers

The role of the lawyer in the development of the patent law interpretation of suitable material for protection should not be underestimated. Language is a lawyer's primary tool and if the objective is to ensure that protection is available then the ability to define material in such a way as to attain that objective becomes key. This can be seen in the recent decision of the Enlarged Board of Appeal of the European Patent Office in *Novartis* where it was accepted by the EPO that a claim for a plant grouping was patentable despite the explicit exclusion of plant varieties within the EPC on the grounds that the patent claims did not specifically refer to plant varieties as such.

The Enlarged Board was hearing an appeal from the Technical Board of Appeal. The Technical Board had stated that to allow such a claim would "not comply with the normal rules of logic" and the effect would be to allow the exclusion to be avoided simply by means of careful claims drafting¹⁴ with the result that "the outcome of an application would depend on the verbal skill of the patent attorney".¹⁵ The Enlarged Board of Appeal did not share these concerns and allowed the claim. Despite the eventual outcome the views of the Technical Board remain pertinent.

Where a definition is included within the patent legislation then the apparent role of the lawyer is to either show that the patent claims come within or without the scope of that definition depending on what it is the best interests of their client. This is of relevance to any country seeking to introduce a definition of a micro-organism even if that definition is acceptable to WTO.

Whatever form the definition employed might take, the fact will remain that lawyers seeking to acquire protection will seek ways of showing the definition does not apply in their client's case and the value of the definition itself could ultimately depend on the verbal skills of those patent lawyers charged with overseeing its application. It is worth remembering that the primary obligation of any lawyer is to their client.

In light of this, it is possible to envisage a situation whereby a number of patents are granted over the cells of a plant, with the result that each cell is patented. This would appear to mean that the plant itself is the subject of a patent and this practice would run counter to the spirit of the first half of Article 27(3)(b). However, the practice in developed countries would appear

¹⁴ *ibid* at page 136 para 36 and page 137 para 37

¹⁵ *ibid* at page 133 para 20

to indicate that this would not cause any problems provided none of the patents claim the plant itself¹⁶.

Summary

It appears possible for member states to provide a definition of a 'micro-organism' for their local patent purposes.¹⁷ However there are two problems with adopting a definition:

- a) the definition may not be accepted by the WTO as proper compliance with the obligations imposed by the TRIPs Agreement, this obligation being determined by reference to the existing patent practices of developed countries; and,
- b) that if such definitions are accepted the probability will remain for lawyers to continue to test the issue by arguing, in specific instances, that the definition does not apply.

There could be an argument, therefore, for not defining 'micro-organism' but rather to look at the options within the TRIPs Agreement itself for limiting the application of patent protection.

Alternatives Under TRIPs

Article 27(1) states that member states must provide patent protection for inventions which can be shown to be new, involve an inventive step and capable of industrial application. These terms are not further defined. There are three other Articles within the Agreement which could be used to mitigate the apparent severity of Article 27.

Article 1 enables member states to provide more extensive protection than that set out in the Agreement - *provided that such protection does not contravene the provisions of the Agreement.*

Article 7 sets down the presumption that the grant of such rights will be to the advantage of the producers of technological innovation but that they must be *in a manner conducive to social and economic welfare.*]

Article 8 adds the notion of public interest to the equation by enabling member states to adopt any necessary measure 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.*

There is the option, therefore, for member states to adopt a locally acceptable interpretation of the granting criteria, which would make it harder for inventions involving biological material to be patented. This could be done by raising the threshold of protection for biological material and making the concepts of novelty and inventive step harder to meet.

This action could be undertaken in conjunction with the premise set down in the Convention on Biological Diversity that member states have sovereign control over their genetic resources and that any access to such resources should be controlled by that country and any benefits

¹⁶ It is also an interesting anomaly that in European patent law where a patent is granted over a process any product produced directly by that process is also covered by the patent. Whilst neither the EPO nor the European Commission has directly commented on this indications are that where the product of that process is a plant or animal variety this will not make any difference.

¹⁷ The definition will only apply to the local patent law and is unlikely to be adopted by developed countries which will, therefore, still permit patent protection to be granted over a broader range of micro-organisms.

shared. This means that access to the material should be carefully controlled and these controls rigorously enforced. It is worth bearing in mind that the developing countries are actually in a potentially strong bargaining position given that they are custodians of the material developed countries wish to use.

However, member states wishing to apply restrictions on the grant of rights using as their basis Articles 1, 7 and 8 will have to demonstrate that these measures are a) necessary on the grounds that they protect social and economic welfare and that they serve to promote the public interest in sectors of great importance to socio-economic and technological development and b) that they are not inconsistent with expressed provisions of the TRIPs Agreement. Discharging both aspects of this burden could prove difficult in light of the existing policy in developed countries that micro-organisms, broadly defined, are patentable. More critically, it remains to be seen whether such any different interpretations to those used within developed countries, and application of these provisions, will be acceptable to the WTO.

Possible Options

a) To adopt an identical patent system to that provided by developed countries.¹⁸ The driving force behind this approach would be the ability of an invention to meet the granting criteria and not the issue of the subject matter making up the invention

All the other options are on the basis of member states proving that they comply with the stated objectives of the TRIPs Agreement and are, therefore acceptable to the WTO.

b) Member states could adopt a revised version of patent protection with refined categories of novelty, inventive step and industrial applicability.

c) Member states could provide a restricted patent law definition of “micro-organisms”. The exclusion of other material regarded by developed countries as ‘micro-organisms’ could be justified on the grounds that it is in the local economic and technological interest to permit patent protection over only a limited group of inventions of this type.

d) Member states could adopt both b) and c) to include a restrictive definition of a ‘micro-organism’ **and** use a higher threshold for protection for inventions involving living material.

e) Member states could refuse to provide patent protection for any form of living material irrespective of the material involved and fight for a total revision of Article 27(3)(b) to permit members to exclude all forms of living material from patent protection

It would seem that the WTO is unlikely to accept this last as a viable option.

¹⁸ bearing in mind that there are differences even between these countries as can be seen in US and European patent provision - Article 29 of the TRIPs Agreement also states that where the subject matter of a patent is a process then the exclusive right shall prevent third parties from using, offering for sale, selling or importing...at least the product obtained directly by that process.” Using has not defined but could be interpreted as including use for research purposes.

Conclusion

It would seem from the discussions which have already taken place within WTO and elsewhere that there would be powerful resistance to any attempts to introduce alternative interpretations of patent law which diverge with the practice of developed countries. However, the fact that such an approach may not be acceptable to developed countries should not automatically deter the developing countries from pursuing this option. In the 1950s the recognition that patent protection was unsuitable for the protection of valuable agricultural material led to the introduction of the UPOV system of plant variety protection. Whilst at first this system found little favour within the United States those companies involved in the production of genetically modified crops have come to realise that this form of protection is valuable at the international as well as the local level. The precedent set by the introduction of plant variety rights could serve to justify the alternative approach¹⁹ taken for the protection for micro-organisms provided that the countries so doing can persuade the WTO that it is in their local interest so to do and that by so doing they are not compromising the objectives of the TRIPs Agreement.

¹⁹ It is also worth noting that it would not be possible to use the second half of Article 27(3)(b) as the basis for introducing a *sui generis* system of protection for micro-organisms instead of providing patent protection. The *sui generis* option only applies to plant varieties. If a member state were to opt for a *sui generis* system for micro-organisms this would not remove the requirement in the first half of Article 27(3)(b) that patent protection must also be available.

Appendix 1:

The Five Kingdoms of Living Organisms

Monera, the most primitive kingdom, contain living organisms remarkably similar to ancient fossils. Organisms in this group lack membrane-bound organelles associated with higher forms of life. Such organisms are known as prokaryotes. Bacteria (technically the Eubacteria) and blue-green bacteria (sometimes called blue-green algae, or cyanobacteria) are the major forms of life in this kingdom. The most primitive group, the archaebacteria, are today restricted to marginal habitats such as hot springs or areas of low oxygen concentration.

Protista were the first of the eukaryotic kingdoms, these organisms and all others have membrane-bound organelles, which allow for compartmentalisation and dedication of specific areas for specific functions. The chief importance of Protista is their role as a stem group for the remaining Kingdoms: Plants, Animals, and Fungi. Major groups within the Protista include the algae, euglenoids, ciliates, protozoa, and flagellates.

Fungi are almost entirely multicellular (with yeast, *Saccharomyces cerevisiae*, being a prominent unicellular fungus), heterotrophic (deriving their energy from another organism, whether alive or dead), and usually having some cells with two nuclei (multinucleate, as opposed to the more common one, or uninucleate) per cell. Ecologically this kingdom is important (along with certain bacteria) as decomposers and recyclers of nutrients. Economically, the Fungi provide us with food (mushrooms; Bleu cheese/Roquefort cheese; baking and brewing), antibiotics (the first of the wonder drugs, Penicillin, was isolated from a fungus *Penicillium*), and crop parasites (doing several billion dollars per year of damage).

Plantae include multicelled organisms that are all autotrophic (capable of making their own food by the process of photosynthesis, the conversion of sunlight energy into chemical energy). Ecologically, this kingdom is generally (along with photosynthetic organisms in Monera and Protista) termed the producers, and rest at the base of all food webs. A food web is an ecological concept to trace energy flow through an ecosystem. Economically, this kingdom is unparalleled, with agriculture providing billions of dollars to the economy (as well as the foundation of "civilisation"). Food, building materials, paper, drugs (both legal and illegal), and roses, are plants or plant-derived products.

Animalia consists entirely of multicellular heterotrophs that are all capable (at some point during their life history) of mobility. Ecologically, this kingdom occupies the level of consumers, which can be subdivided into herbivore (eaters of plants) and carnivores (eaters of other animals). Humans, along with some other organisms, are omnivores (capable of functioning as herbivores or carnivores). Economically, animals provide meat, hides, beasts of burden, pleasure (pets), transportation, and scents (as used in some perfumes).

Virus Infectious chemical agent composed of a nucleic acid (DNA or RNA) inside a protein coat. They are not considered living organisms, as they cannot reproduce outside a living host cell.

Micro-organisms, Definitions and Options Under TRIPs
Supplementary Thoughts

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An addendum to the paper prepared for the Discussion Meeting
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Following the meeting on the 23rd November 2000, the speakers were asked to provide further details of a number of concepts raised in the original paper. In particular, they were asked to provide alternative definitions of 'micro-organism' and 'inventive step' to those currently utilised by the American and European patent offices. The speakers were also asked to comment on the function of the patent system and on the role morality might play in determining categories of patentable material.

Definition of a Micro-organism

During the discussion following the paper on Micro-organisms, Definitions and Options under TRIPS, three possible ways forward emerged regarding the term 'micro-organism'.

The first option was not to define the term 'micro-organism' at all. Due to the generic nature of the term it encompasses organisms which differ widely from one another and, apart from their size, have no one single characteristic in common.

A second approach may be to use a tight definition for micro-organism, possibly accompanied by an inclusive list. For example, the definition used by the Institute of Science, UK (see page 6 of the original paper) could be used as the basis for a new definition. The term 'micro-organism' could be defined as those organisms that are of the order of microns or tens of microns in size and include bacteria, mycoplasma, yeasts, single-cell algae and protozoa. Multicellular organisms are not included, nor fungi apart from yeasts. The inclusion / exclusion of viruses could be achieved simply by adding / deleting the term from the given list.

Alternatively, it is possible to use the Brazilian definition. Brazilian legislation defines the term 'transgenic micro-organism' *for the purposes of this Law, transgenic micro-organisms are organisms, except for all or part of plants or animals, that express, by means of direct human intervention in their, genetic composition, a characteristic normally not attainable by the species under natural conditions.*

The third approach could be described as an expanding ripple effect. The term 'micro-organism' could be defined as one that;

a) Includes only unicellular prokaryotes.

This would include only Eubacteria and Archaeobacteria

²⁰ The views expressed are those of the authors and should not be taken as those of Quaker UN.

b) Includes a) and unicellular eukaryotes

This would include all bacteria and moulds, protozoa, microalgae and yeasts.

c) Include a) and b) but excludes all multicellular eukaryotes.

This would include all bacteria, moulds, protozoa, microalgae and yeasts.

However, this would exclude animals, plants, fungi and algae. Furthermore, this would also have the effect of excluding animal and plant cell lines, as well as plant seeds.

However, as with the second approach, as viruses (which includes bacteriophages) are a special case and do not fit into any of the categories listed above, they would have to be included / excluded separately.

E.g.

a) Includes only unicellular prokaryotes and viruses.

This would include Eubacteria, Archaeobacteria and viruses.

(unicellular-composed of a single cell)

Each approach has its advantages and disadvantages. The first approach moves the onus for stopping the patenting of micro-organisms away from a definition of micro-organism to other areas such as novelty, obviousness and inventive step. With the second approach the definition is open to challenge, as with any definition. Although the definitions in the third approach are tightly defined scientific terms, this approach may be challenged as it may be perceived as being too restrictive.

Granting Criteria

It was suggested in the original paper that member states might wish to introduce a higher threshold for protection in respect of living material. This option would be exercised either in addition to or instead of providing a definition of a 'micro-organism'.

The following indicates a possible way in which this raised threshold for protection could be defined in practice.

Novelty

An invention involving biological material will not be regarded as novel if:

a) the information is already in the public domain; and/or

b) the invention merely replicates biological material, or the function of biological material, which already occurs naturally.

[The basis for this is Article 1(1)]

Inventive Step

1) An invention involving biological material will be regarded as lacking an inventive step if it:

a) merely identifies the biological material; and/or

b) merely identifies the natural function of the biological material

2) An invention will demonstrate an inventive step if it takes the form of a significant technical application of an identified function of the biological material. This technical application must go beyond a mere simple replication of the natural function of the biological material, and the technical application must represent a significant technical advance on the prior art.

[The basis for this is Article 1(1)]

Industrial Application

a) An invention involving biological material will be regarded as being capable of industrial application if it can be shown that it is capable of being used in a manner which provides a demonstrable public benefit.

b) Public benefit means that the invention must be capable of being used in a manner conducive to public health and to social, environmental and economic welfare.

[Paragraph b incorporates Articles 1, 7, 8 and 27(2)]

Each of these criteria has been worded in a manner to enable Governments, through their granting offices, to determine for their own local purposes the exact standard which an applicant will have to meet for a grant to be made. It is suggested that local patent offices should produce guidelines as to the meaning, for local purposes, of the terms “significant technical application”, “significant technical advance” and “demonstrable public benefit”.

It is also suggested that the applicant should only be able to claim the exact use of the biological material as specified in the application and no other uses. Broad claims should not be permitted.

The following is an example of how the criteria could be applied in practice.

- 1) Plant A contains a gene (G) for salt tolerance (ST) – the gene *in situ* is not patentable.
- 2) Breeder 1 isolates the gene for salt tolerance (GST) – the isolated gene is not patentable.
- 3) Breeder 1 replicates GST – the replicated GST is not patentable.
- 4) Breeder 1 places GST back into Plant A – the replicated GST in Plant A is not patentable.
- 5) Breeder 1 places GST into Plant B, which does not produce its own ST, thereby enabling the plant to grow in an environment where previously it could not grow – this could be a significant technical application resulting in a significant technical advance which is capable of providing a demonstrable public benefit. This could be patentable.
- 6) Breeder 2 places GST into Plant D which does not produce its own GST – as Breeder 1 has already thought to place GST into plants which do not produce their own GST, this might not be regarded as a significant technical advance – once Breeder 1 has placed GST into plants which do not produce their own GST it is obvious for Breeder 2 to do the same in other plants.

Breeder 2 is not prevented from putting GST into Plant D as any rights Breeder 1 has only relate to GST in Plant B, not to GST *per se*. Therefore Breeder 1's rights do not extend to the use of GST in any other plant.

7) Breeder 3 places GST into Animal G – this might constitute a significant technical application resulting in a significant technical advance provided that Breeder 3 can show that the use of GST in Animal G is capable of providing a demonstrable public benefit. Breeder 1 has no rights as any rights Breeder 1 has only relate to GST in Plant B, not to GST *per se* Breeder 3's 'invention' could be patentable.

Predictability & Certainty

In justifying a decision to raise the threshold for protection reference can be made to the current situation in Europe and the US and the reliance at the WTO on implementing legislation ensuring predictability and certainty.

At present the US and European patent granting offices operate an apparently low threshold for protection - the presumption being that a patent should be granted unless there is good reason why it should not. In a number of key instances, e.g. in respect of Neem, Turmeric, these patents have subsequently been revoked by the courts. A decrease in the threshold for protection has the effect of making the courts the key arbiters for determining patentability. This means that for those engaged in bioscience innovation there is greater uncertainty over the validity of, what is usually a very expensively obtained, patent. This has the result of **lowering** predictability and certainty as it will not be clear whether a court will uphold or revoke any given patent.

In contrast, raising of the threshold for protection can be justified on the basis that it will ensure that those inventions which deserve protection are protected and that this protection is less likely to be subsequently challenged in court. This can only result in **greater** predictability and certainty for the bioscience industry as a whole.

Benefits of Using Patent Protection

Whilst the emphasis of the paper was on how to avoid the over extension of patent protection to living material it should be recognised that used properly the system can be a very effective mechanism of protecting valuable information from unauthorised copying once commercialised. Patent lawyers would argue that it is no accident that the strongest patent protection is found in those countries with the strongest commercial markets.

Provided the requisite level of inventive activity has been demonstrated, patents are a very efficient means of ensuring that the inventor is rewarded for their inventive activity. It remains a truism that many inventions, especially those in the pharmaceutical sector, would not have been produced and made publicly available without the knowledge that the results of that innovative activity could be the subject of a patent grant. It is critical, therefore, that developing countries use the patent system as a mechanism to increase investment in local technological development and to protect the results of that technological development.

However, a balance has to be drawn between protecting that which deserves protection and protecting any material which might have a commercial market. The latter will result in an

increase in challenges to the patent grants, which might be good news for the patent lawyers, but is not such good news for those seeking certainty and predictability in the law.

Article 27(2) -Excluding inventions of the grounds of Morality

A question was asked whether Member States could use Article 27(2) as the basis for excluding certain categories of genetic material from patent protection even where member states are required to provide protection under Articles 27(1) and (3).

Whilst it might be possible to rely on this provision as an overarching exclusion which cannot be restricted by way of either 27(1) or (3) it would probably be difficult to demonstrate this in practice.

Member states would have to show that the commercial exploitation of the specific invention would be contrary to *ordre public or* morality. In light of the interpretation and application of the equivalent provision within the European Patent Convention, and recently reinforced in the EU directive on the Legal Protection of Biotechnological Inventions, it is unlikely that this would have a widespread use in preventing the granting of patents over genetic material.²¹

Given that the WTO appears to be using existing practice in developed countries as its standard by which all other systems of patent protection are to be assessed, and the European model is the only one to date with an extensive jurisprudence on the issue of inventions excluded on the grounds of being contrary to morality, it is unlikely that the WTO would accept a circumvention of the requirement in Article 27(3)(b) by the use of Article 27(2).

²¹ See *Harvard/Onco-mouse* [1990] EPOR 501, *Plant Genetic Systems/glutamine synthetase inhibitors (T356/93)* [1995] EPOR 357 and *Howard Florey/Relaxin*[1995] EPOR 541. In each case the arguments relating to morality was dismissed by the relevant examining board of the European Patent Office - it should be noted that *Harvard/Onco-mouse* is still on appeal.