Commission on Intellectual Property Rights

Study Paper 7

Study on the Implementation of the TRIPS Agreement by Developing Countries

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Executive Summary

An analysis of the current intellectual property (IP) laws of over 70 developing and least developed countries was undertaken. The majority of these laws have recently been amended to take account of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

The analysis centred primarily on the implementation of Section 5 of TRIPS which covers patents since this is the area where most concern has been raised. The study does however explore issues relating to other categories of intellectual property including copyright, plant breeders' rights and protection of undisclosed information.

The analysis shows that very few developing countries are still denying patent protection for pharmaceutical products. The analysis also revealed that all but three of the 30 Least Developed Countries (LDC) in Africa are apparently already providing patent for such products despite not having to do so until 2016 at the earliest. This protection is available in a large number of these countries through the two African regionally based intellectual property IP organisations.

An analysis of patents issued by these two regional African IP organisations shows a high proportion to be related to medicines. Indeed in some years more than 50% of patents issued appear to be related to medicinal products.

It would also appear from the analysis that developing countries are to a large extent fully aware of the legislative possibilities provided under TRIPS, although only a few appear to have taken advantage of all of the possible flexibilities. Numerous examples now exist of national legislative provisions seeking to give effect to these flexibilities.

These provisions cover the more obvious and more legally certain flexibilities such as providing for international patent exhaustion and the use of a patented product without the consent of the patent holder for regulatory approval purposes (Bolar type exception). Of the countries analysed, over 30% now specifically provided for international exhaustion. At least 8 developing countries now also include specific Bolar type provisions in their legislation.

Specific provisions are also included in the legislation of at least 9 developing countries requiring patent applicants to disclose the source of any biological material used in the invention. This provision extends in some cases also to any associated traditional knowledge.

Despite being able to exclude animals and plants from patentability under TRIPS, over 75% of the countries studied still provide patent protection for at least some inventions covering plants and animals. A significant number of countries analysed (over 60%) also provide patent protection for new uses of known or previously patented subject matter.

All of the countries analysed provided some form of compulsory licensing to prevent against abuses of IP rights.

In respect of other categories of intellectual property, it was noted that a significant number of developing countries have taken advantage of the flexibilities provided by TRIPS by providing for example sui-generis systems of plant variety right protection including fairly broad exceptions to enable farmers, especially small farmers, to save and exchange seeds. In the field of copyright some countries have also provided fairly generous exceptions to copyright particularly for educational purposes.

Objective of the study

The principle objective of the study was to analyse how developing countries have implemented the TRIPS Agreement and in particular to determine whether the flexibilities provided within the agreement have been utilized.

Methodology

All developed and developing members of the WTO are required under TRIPS Article 63 to notify to the TRIPS Council the laws giving effect to the TRIPS Agreement in their countries. These laws have been the primary source of information for this study. Recourse has also been made to a considerable amount of information freely available on the internet.

Scope of the study

The main focus of the report is on the patent requirements set out in Part II Section 5 of the TRIPS Agreement since these have been the subjects of the most criticism. Information on other aspects of the agreement has been included where this is readily available.

The report examines the prevailing legislation in the three main regional intellectual property systems of relevance to developing countries: the African Regional Industrial Property Organisation (ARIPO), the African Intellectual Property Organisation (OAPI) and the Andean Community. Together these three bodies provide legislation for over 35 developing and least developed countries.

The report examines national legislation in a further 35 countries representing on the whole those developing countries which have participated most in the review of legislation by the TRIPS Council.

Disclaimer

The analysis of laws undertaken for this study which is set out in the Appendices is based primarily on the authors reading and understanding of the laws of the countries concerned as notified to the TRIPS Council. The main focus of the study is not to provide definite statements on situations in individual countries but rather to assess the general uptake of the flexibilities provided by the TRIPS Agreement. Anyone seeking definitive information on the laws and practices of particular countries should not rely exclusively on the material contained in this study.

AFRICA

Introduction

The history of patent protection in Africa, at least until recent years, is not surprisingly greatly influenced by the colonial history of the particular countries. For example, at the beginning of the 1980s patent protection in over 1/5th of all African countries could be obtained merely by the local re-registration of a grant United Kingdom Patent. Nowadays such practice is possible in only a few African countries.

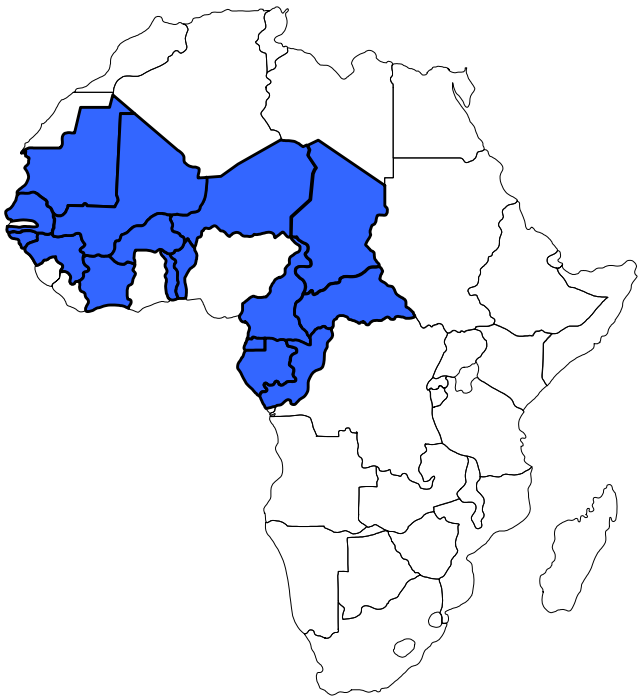
Instead countries have either introduced national systems of protection or joined with other countries to form regional IP systems such as the African Regional Industrial Property Organisation (ARIPO) for the predominantly English speaking African countries and the African Intellectual Property Organisation (OAPI) for the French speaking African Countries.

OAPI and ARIPO

The members of these two organisations represent about 70% of sub-Saharan African countries. The two systems are significantly different in nature with OAPI being the only industrial property authority for its member states whereas ARIPO Member States have maintained national systems for obtaining patent rights (similar to the system in Europe with the European Patent Convention (EPC) operating in parallel with national systems).

African Intellectual Property Organisation (OAPI)

Until 1962, patent rights in the majority of francophone member states of OAPI, were governed by French laws. The French National Patent Rights Institute (INPI) was the National Authority for each of these states, then grouped within the French Union (Union Française). The majority of the French Union member countries having become independent in 1960, found it necessary to create a body of their common territory, in respect of conventions on patent rights.



The creation found its legal justification in article 19 of the WIPO Paris Convention for the protection of patent rights, which states that countries, which are signatories to this convention, serve the right to undertake separately among themselves, specific agreements for the protection of patent rights, so long as these arrangements are not in contradiction with the provisions of the said convention. It is on the basis of this provision that 12 African countries together decided to create a single body to act as the national patent rights authority for each of them. The African and Malagasy Patent Rights Authority (OAMPI) was thus born on 13th September 1962 by the agreement known as the 'Libreville Agreement. The Libreville Agreement were based on three fundamental principles

- The adoption of a uniform legislation by the putting in place and application of common administrative procedures resulting from a uniform system of patent rights protection.

- The creation of a common authority, as the organisation serves as a national patent rights protection department, for each of the member states.

The centralisation of procedures, as the existence of a uniform legislation and of a common authority naturally created for the centralisation of procedures such that a single title issued comprised as many independent national rights as member countries.

The withdrawal of the Malagasy Republic coupled with the need to expand coverage to other categories of IP led the Member States to revise the Libreville Agreement and to create the African Intellectual Property Organisation (OAPI) by the adoption of a new convention signed in Bangui on 2nd March 1977.

The Bangui Agreement as amended henceforth legislates patent rights in each of the 16 member states, which now make up the OAPI territory. To date, the OAPI territory covers a surface area of over 7 million square Km and has about 100 million inhabitants.

Current membership of OAPI

Benin	***Burkina Faso***	Cameroon	***Central African Republic***
Congo	Cote d'Ivoire	Equatorial Guinea	Gabon
Guinea	***Guinea Bissau***	***Mali***	***Mauritania***
Niger	***Senegal***	*Chad*	***Togo***

[Countries in ***italics*** are United Nations designated Least Developed Countries (LDC)]

The 1977 Bangui Agreement

Patents granted by OAPI are considered to be independent national rights subject to the legislation of each member state. All members of OAPI are automatically designated. In respect of patents granted by the European Patent Office, national provisions deal with post grant issues in the EPC member states. In OAPI however, the Bangui Agreement also legislates for post grant actions such as infringement and compulsory licencing even though they are dealt with on a national basis in national courts. The patent law of all OAPI Members is that set out in the Bangui Agreement.

The Bangui Agreement as amended in 1999.

The Bangui Agreement was amended in 1999 to give clearer affect to the provisions of the TRIPS Agreement. The revised agreement prescribes the legislation applying in all OAPI countries in the areas of patents, utility models, trademarks and service marks, industrial designs, trade names, geographical indications literary and artistic property, protection against unfair competition including confidential information and layout designs of integrated circuits.

The revised agreement updates the previous agreement in the following main areas:

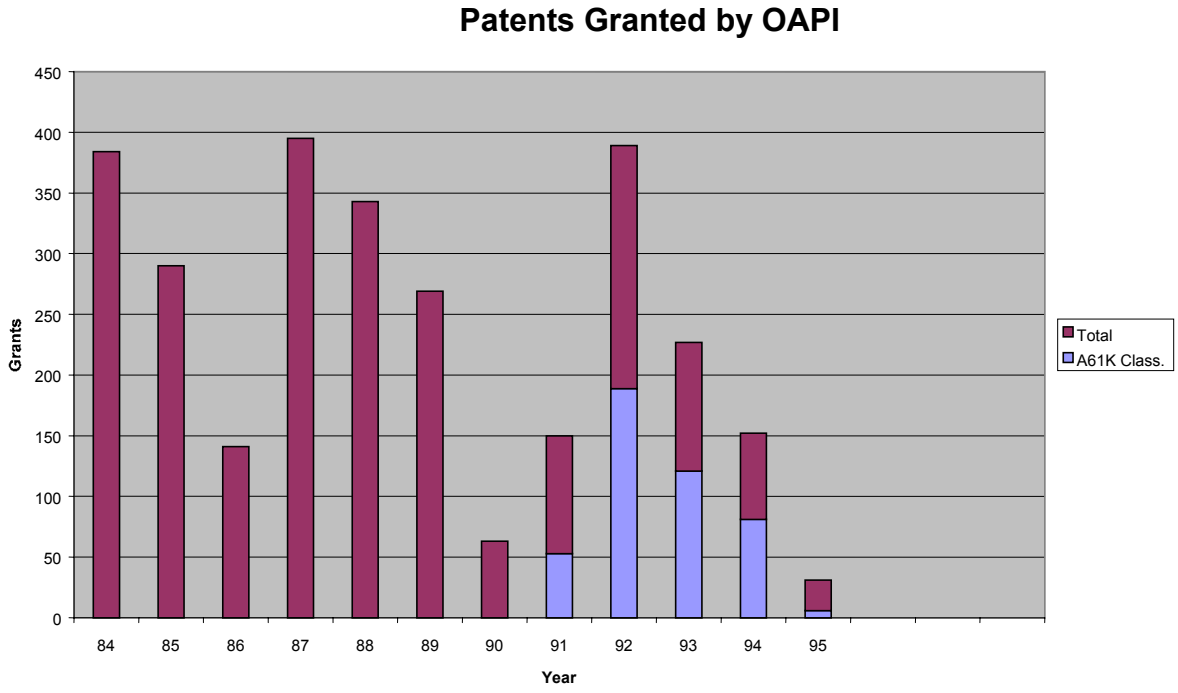
- Members are required to accede to UPOV Act 1991
- Patent term now 20 years rather than 10 years + 2 renewable 5 year periods.
- Compulsory licences no longer possible if demand is being met by importation.
- Grace period extended by 6 months to 12 Months but still only for disclosures at official exhibitions.
- Exceptions to patent infringement introduced for experimental acts and those associated with scientific and technical research.
- Wording corresponding generally with TRIPS Article 39(3) provided for protecting data submitted for regulatory approval purposes.

- Introduction of wording mirroring that of Section 6 of Part II and those provisions of the Washington Treaty in respect of Integrated Circuits incorporated by reference into that section.

The Revised Agreement entered into force for all OAPI members in early 2002 following ratification by at least 10 OAPI states.

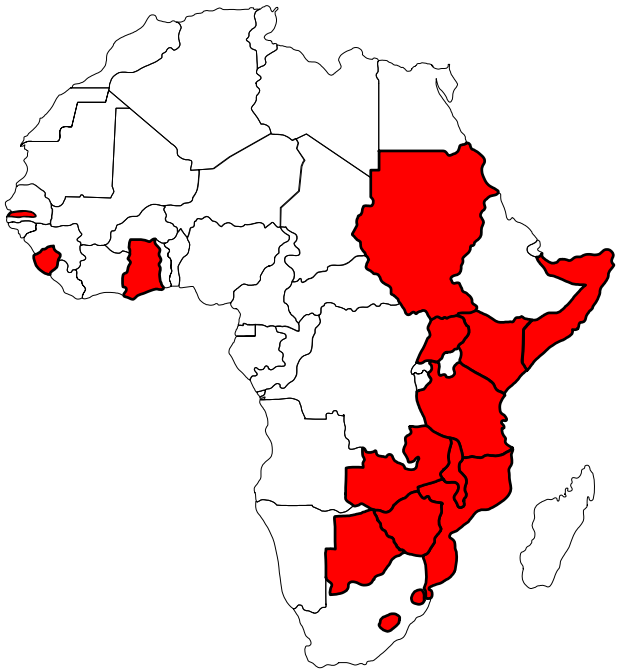
OAPI Patent Statistics

Figure 1 illustrates the patents granted by OAPI over a 12 year period from 1984 to 1996. Also indicated is the proportion of these patents classified under IPC classification mark A61K (preparations for medical, dental, or toilet purposes) or having a corresponding patent filed elsewhere classified under mark A61K. [Note: since medicinal related inventions can also be classified under other marks, the figures shown should only be taken to represent the bottom end of possible medicinal related patents.]



African Regional Industrial Property Organisation (ARIPO)

A draft Agreement on the Creation of the Industrial Property Organization for English-speaking Africa (ESARIPO) known as the Lusaka Agreement was adopted in 1976. The ESARIPO was therefore born on the 9th December 1976. The Lusaka Agreement came into force on 15th February 1978.



In December 1985, the Lusaka Agreement was amended in order to open up the membership of the Organization to all African states members of the United Nations Economic Commission for Africa or the Organization of African Unity (OAU) and changed its name to the African Regional Industrial Property Organization (ARIPO)

Current Membership of ARIPO

Botswana	***Gambia***	Ghana	Kenya
Lesotho	***Malawi***	***Mozambique***	***Sierra Leone***
Somalia	***Sudan***	Swaziland	***United Republic of Tanzania***
Uganda	***Zambia***	Zimbabwe	

[Countries in ***italics*** are United Nations designated Least Developed Countries (LDC)]

The Harare Protocol

The Harare Protocol adopted in 1982 empowers the ARIPO Office to receive and process patent and industrial design applications on behalf of states party to the Protocol. The Protocol, to which all ARIPO member states except Somalia are a party, entered into force in 1984.

Under the Protocol an applicant for the grant of a patent or the registration of an industrial design can, by filing only one application, designate any of the Contracting States in which he wishes his invention or industrial design to be accorded protection. The Harare protocol also sets down the basic requirements relating to patentability. Member states of ARIPO however have the possibility of not

recognising in their territory patents granted by ARIPO on the basis that they are contrary to their national legislation (In the past Ghana refused to recognise patents on pharmaceutical patents.)

The Banjul Protocol

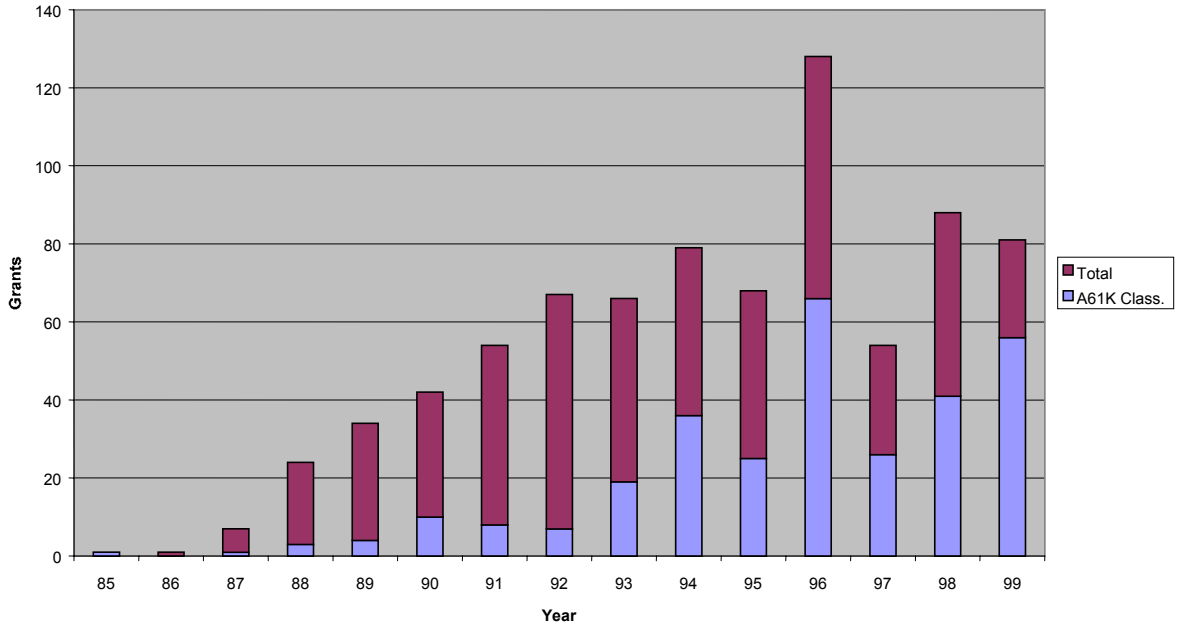
The Banjul Protocol on Marks, which was adopted in 1993, establishes a trademark filing system along the lines of the Harare Protocol. Under the Banjul Protocol an applicant may file a single application either at one of the contracting states or directly with the ARIPO Office and designate states in the application where he wishes his mark to be protected.

The Protocol came into force on March 6, 1997 and the following are Contracting States: Malawi, Swaziland, Zimbabwe, Lesotho and Tanzania.

ARIPO Patent Statistics

Figure 2 illustrates the patents granted by ARIPO over a year period from 1985 to 1999. Also indicated is the proportion of these patents classified under IPC classification mark A61K (preparations for medical, dental, or toilet purposes) or having a corresponding patent filed elsewhere classified under mark A61K. [See note above in respect of OAPI statistics.]

Figure 2 Patents Granted by ARIPO



African Model Legislation for the protection of the rights of local communities, farmers and breeders, and for the regulation of access to biological resources (OAU Model law)

The model law, which was ratified by the heads of state/governments of the OAU in 1998, seeks, inter alia , to regulate access to genetic resources. The Ministerial Council of the OAU has recommended that African States pass legislation based on the draft law, that they negotiate a Convention in order to create a regional instrument to coordinate action, and that they develop a common African negotiating position in the revision of Article 27.3(b) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

The model legislation includes a number of provisions impacting on intellectual property rights. For example, access agreements prohibit the collector of the biological resource from applying for any form of IP over the resource or over any community innovation, practice, knowledge or technology without the prior informed consent of the original provider.

Moreover the legislation requires that patents over life forms and biological processes should not be recognised. The collector of the biological resource is required not to apply for such patents although how this is to be enforced is unclear. Possibly if such an application is made then the access permit will be refused or revoked.

Protection for community rights is also provided in line with the customary laws of those communities. Such communities are granted an inalienable right to carry on using, exchanging or sharing their biological resources in line with customary laws and practices. The law also provides that the publication of a written or oral description of a biological resource or its associated knowledge or the presence of these resources in a collection will not prevent the local community from exercising their rights in relation to those resources.

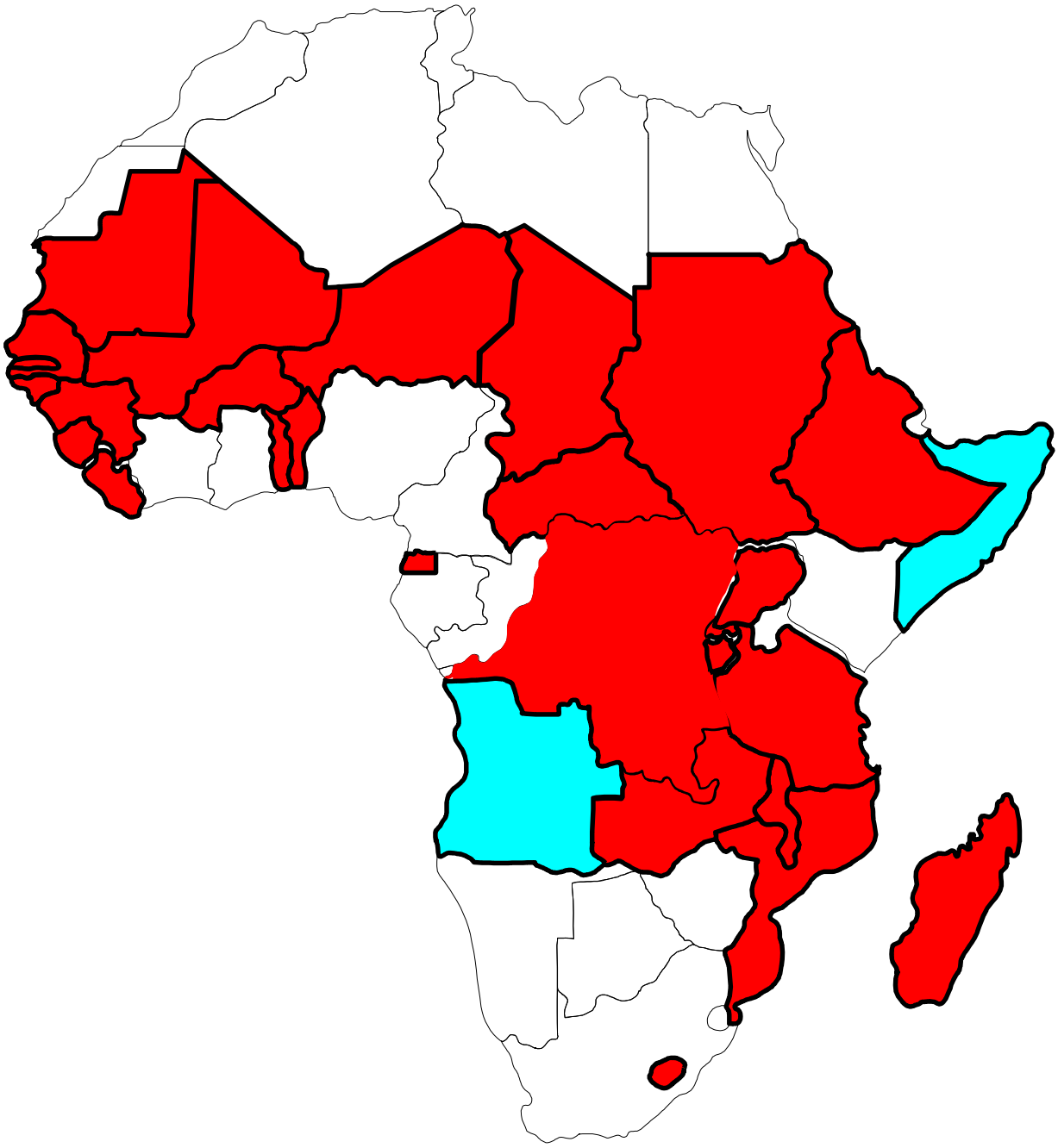
The farmer's right to protect their TK and to save, use, exchange and sell (other than on a commercial scale) farm saved seed is also recognised. Farmers are also allowed to use a protected variety to develop farmers' varieties.

LEAST DEVELOPED COUNTRIES

Under Article 66 of the TRIPS Agreement, least developed countries are allowed to defer implementing the TRIPS Agreement until at least 1 January 2006. The recent Ministerial meeting in Doha provided a further 10 year transition period in respect of introducing patents for pharmaceutical products and protecting undisclosed information submitted to a regulatory body to approve such products. It is however noted that the requirement to provide patent protection for pharmaceutical products has already been met by the vast majority of LDC in Africa.

Pharmaceutical Product Protection in African Least Developed Countries

Country	WTO	ARIPO (Harare Protocol)	OAPI	Pharmaceutical Product Protection
Angola	1996			Excluded under 1992 law.
Benin	1996		1977	Yes
Burkina Faso	1995		1989	Yes
Burundi	1995			Available under Patents Act 1964 as amended.
Central African Rep.	1995		1978	Yes
Chad	1996		1978	Yes
Congo DR	1997			Yes under law N0 82-001 as amended
Ethiopia				Apparently allowed under 1995 IP Provisions.
Eritrea				No patent law
Gambia	1996	1986		Yes
Guinea	1995		1991	Yes
Guinea Bissau	1995		1997	Yes
Guinea Equatorial			2000	Yes.
Lesotho	1995	1987		Yes. Certainly since 1997 and probably since 1989
Liberia				1972 Act does not specifically exclude pharmaceutical products.
Madagascar	1995			Yes. Article 27.1 applied rather than Law 89-019
Malawi		1984		Yes. Harare Protocol incorporated into national legislation
Mali	1995		1984	Yes
Mauritania	1995		1983	Yes
Mozambique	1995	2000		Yes
Niger	1996		1993	Yes
Rwanda	1996			Apparently allowed under Patents Act 1963
Senegal	1995		1978	Yes
Sierra Leone	1995	1999		Yes
Somalia				Probably not. ARIPO Member but not signed Harare Protocol
Sudan		1984		Yes
Tanzania	1995	1999		Yes. Probably since 1987 Act came into force in 1994
Togo	1995		1978	Yes
Uganda	1995	1984		Yes. Reregistering of UK patents up to 1994, pharmaceutical patents provided in 1991 Act.
Zambia	1995	1986		Yes



Patent Protection of Pharmaceutical Products in African Least Developed Countries

(No protection available in Eritrea which is not shown on the map)

Apparently With Protection

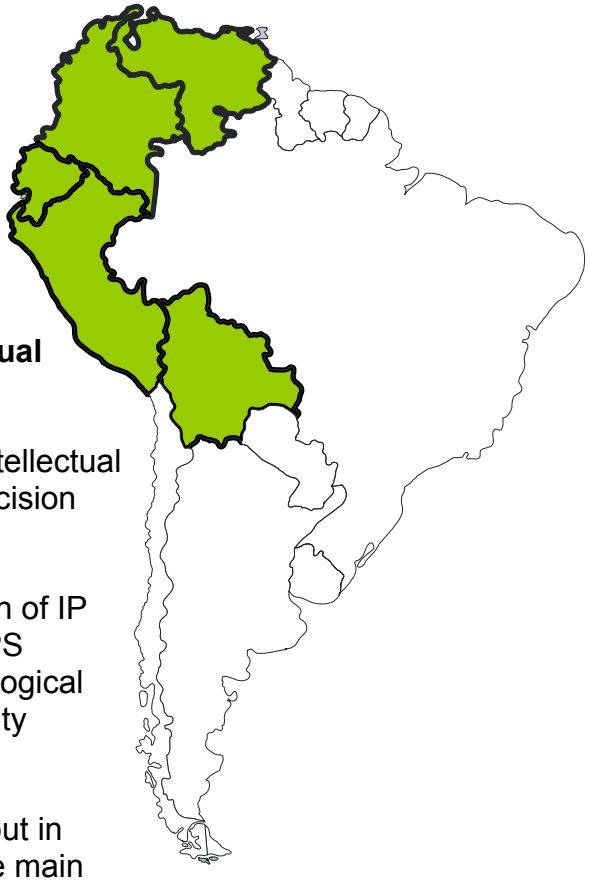
Apparently Without Protection

Non African Least Developed Countries

Country	Latest Patent Law	Pharmaceutical Products
Afghanistan	No Law	No
Bangladesh	1911 (amended 1988)	Would appear to be allowed see BL1002908
Bhutan	1997	
Cambodia	Draft law before Parliament	Allowed under draft law
Cape Verde	No Law	No
Comoros	No Law	No
Djibouti	1977 (Bangui Agreement)	Yes
Haiti	1922	
Kiribati	1924	
Lao PDR	No Law	No
Maldives	No Law	No
Myanmar	1945	
Nepal	1965 (amended 1987)	
Samoa	1972	
Sao Tome and Principle	No Law	No
Solomon Islands	1924 (amended 1968)	
Tuvalu	1924 (amended 1933)	
Vanuatu		

SOUTH AMERICA

Andean Pact Countries



The Andean Community comprises Bolivia, Columbia, Ecuador, Peru and Venezuela.

Legislation, usually in the form of Decisions, relating to the development of the Andean Common Market is binding on the Member States of the community.

Decision 486 - Common Intellectual Property Regime

The prevailing common legislation on intellectual property is Decision 486 which replaces Decision 344.

Decision 486 seeks to ensure that protection of IP is consistent with agreements such as TRIPS whilst also safeguarding and respecting biological and genetic heritage together with community based knowledge.

The main features of Decision 486 are set out in Table 1 which details the key features of the main regional IP systems. It is noted that the Andean Community have taken advantage of a number of key flexibilities allowed under the TRIPS Agreement.

In particular 486 provides for international exhaustion of both patent and trade marks rights. Rights are considered exhausted when the product is introduced into channels of commerce by the patent holder, by someone authorised by him or by someone with economic ties to him.

The scope of protection provided by Decision 486 also includes notable exceptions from patentabilty including any living thing as found in nature and biological material as existing in nature including the genome or germ plasm of any living thing as well as plants and animals. Micro-organisms are patentable pending the review of Article 27(3)(b) of TRIPS.

The legislation also appears to outlaw the patenting of further uses of previously patented products or processes although the precise scope of this provision is the subject of cases pending before the Andean Court of Justice. .

The only obvious omission in respect of the possible TRIPS patent flexibilities is an explicit “Bolar-type” exception to patent rights. Acts carried out exclusively to

experiment with subject matter of the patented invention are excluded and these might conceivably include acts associated with obtaining regulatory approval for a product. The legislation also provides an exception from infringement for acts carried out exclusively for the purposes of teaching or scientific or academic research.

Compulsory licences are available if the patentee fails to exploit his invention, to remedy anti competitive practices and upon the existence of an emergency or in the public interest.

Decision 486 also requires that the patent application includes a copy of the access contract if the invention is developed from genetic resources originating in one of the member states. Similarly any patent application for an invention based on traditional knowledge originating in any of the Member States must also include proof that knowledge was lawfully obtained. Failure to provide such information may lead to the application being deemed to have been abandoned.

Decision 351 - Common Provisions on Copyright and Neighbouring rights.

Provisions governing terms and scope of protection for copyrighted works including computer programs are set out in Decision 351. Duration of protection for copyright material is essentially life + 50 years or 50 years from time of making, disclosing or publication of the work.

Fair use provisions extend to reproduction by reprographic means of newspaper or magazine articles and short extracts from other published works for teaching purposes and to productions of works to restricted audiences (staff family etc) in educational establishments.

Protection for computer programs includes the program in source or object code. Unauthorised adaptation of a computer program is allowed insofar as it is essential for the use of the program. Reproduction for personal use, other than to provide a back-up copy, requires the authorisation of the copyright holder.

It is noted that the legislation does not clearly specify the exhaustion regime applicable to copyright material.

Decision 345 – Common Provisions on the Protection of the rights of Breeders of New Plant Varieties

Legislation provides strong rights to the breeders of new varieties including in respect of varieties essentially derived from the protected variety (UPOV 91 type rights). The legislation does however seek to provide a balance by also providing broad exceptions to allow farmers to save and sell as food or raw material the product of his cultivation.

Provisions are also provided to make varieties freely available (subject to adequate remuneration) in times of exceptional circumstances.

Decision 391 – Common Regime on Access to Genetic Resources.

This legislation regulates the procedures to obtain agreement to access and utilise non-human genetic and biological material originating in the Andean Community Member States. Such access is conditional on obtaining the required contract which must take account of the legitimate interests of the providers of the material. Although the contract is between the state and the prospector, the state is obliged to recognize and value the rights of local communities to decide about their know-how, innovations and traditional practices associated with genetic resources and their by-products.

The legislation also makes provision for the recognition of intangible components associated with genetic and biological resources. These would include any valuable knowledge, innovation or individual or collective practice associated with those resources.

The Legislation also requires that the Member Countries not acknowledge rights, including intellectual property rights, over genetic resources, by-products or synthesized products and associated intangible components that were obtained or developed through an access activity that does not comply with the provisions of the Decision. To facilitate this requirement the national intellectual property offices are required to exchange information about rights granted and access contracts agreed.

IMPLEMENTATION OF THE TRIPS AGREEMENT BY DEVELOPING AND LEAST DEVELOPED COUNTRIES

PATENTS

Scope of protection

What TRIPS Requires

Article 27(1) requires that 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.

The agreement however allows a certain freedom of interpretation to Members in respect of what constitutes an “invention”, and how the requirements of novelty, inventive step and industrial applicability are determined.

Pharmaceutical Patents

One of the more controversial aspects of the agreement is the requirement to provide product protection for pharmaceuticals. Historically many countries have provided only process-related patents in the pharmaceutical field. The strength of such process patents is considerably less than patents to the products per se.

Whereas developing countries were required to implement TRIPS by 1 January 2000, Article 65(4) allows developing country Members that are obliged to extend product patent protection to areas of technology not so protectable a further delay of 5 years.

Developing countries taking advantage of this further delay are required to notify the TRIPS Council under the terms of Article 70.

Such notifications have been received from: Argentina, Cuba, India, Pakistan, Jordan, Uruguay, Egypt, United Arab Emirates and Turkey. A number of these countries have since introduced pharmaceutical product protection.

All other developing country members can be assumed to already provide pharmaceutical product protection.

Following the Doha Ministerial meeting of 2001, Least Developed Members (LDC) of the WTO have a further period until at least 2016 before having to provide patent protection for pharmaceutical products and to protect against unfair use pharmaceutical related data submitted to a regulatory authority. However, as already noted above the vast majority of LDC, at least in Africa, already provide patent protection for pharmaceutical products

Plant and animals

What TRIPS Requires?

Article 27(3)(b) provides that Members may exclude from patentability: 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.

The scope of this exception appears to allow Members to provide a greater exclusion than that existing in many developed countries by excluding not only plant and animal varieties or breeds but also any plant or animal even if it satisfies the usual patentability criteria of novelty, inventiveness and industrial applicability.

What developing countries have done

The Developing and Least Developed Countries analysed implemented this provision as follows:

Options	Specific exclusion for all plants and Animals	Exclusion for all plants and animals as existing in nature (GM presumably allowable)	Specific exclusion of plant and animal varieties only.	No specific provisions (analysis of patents issued by ARIPO would appear to indicate that such protection is available).
Countries taking advantage of option	11 + Andean Community	2	13 + OAPI	5 + ARIPO
Total (% of sample)	16 (24%)	2 (3%)	29 (44%)	19 (29%)

Genetic material

What TRIPS Requires?

TRIPS does not contain any specific provisions concerning the patentability of inventions consisting of genetic material such as DNA sequences. A Member seeking to exclude such inventions would most likely rely on the morality exception of Article 27(2), or the general novelty, inventiveness and industrial applicability requirement applying to all inventions.

What developing countries have done?

Specific exclusion for all genetic material	Exclusion for all genetic material as existing in nature or isolated there from (GM presumably allowable)	No specific provisions	All allowed either through specific provisions or practice
3 (Egypt, Nicaragua, Costa Rica)	5 + Andean	19	3+ ARIPO + OAPI
3 (5%)	10 (15%)	19 (29%)	33 (51%)

New Uses for known products -1st and 2nd Medical Use

What TRIPS Requires?

The novelty requirement would normally prevent a patent being issued in respect of an invention relating to a known product for which a new use had been found. The use would however be eligible for protection through a method or use type claim except in the medicinal field where such method patents are prevented by the exclusion from patentability of various methods for the treatment of humans or animals provided in most patent laws (EPC 52(4)) and specifically provided for in TRIPS Article 27(3)(b). In order to effectively circumvent this particular exception, patent law in a number of countries, most notably within Europe, have modified the concept of novelty and developed claim construction to allow such new and second uses to be protected. TRIPS does not require its Members to follow this route but instead allows them to retain the classical approach to novelty and exclude such new or second uses.

What developing countries have done?

Further use allowed either specifically or through practice	Further use specifically excluded	No specific provision
6 + ARIPO + OAPI	8 + Andean[1]	7
36 (64%)	13 (23%)	7 (13%)

Novelty Requirement

What TRIPS require

TRIPS requires merely that inventions for which patents are sought should be new. The Agreement does not however define how the novelty of an invention should be assessed and in particular what constitutes the prior art against which this criteria is determined.

[1] Article 21 Andean Pact Decision 486 provides:- Products or processes already patented and included in the state of the art within the meaning of Article 16 of this Decision may not be the subject of new patents on the sole ground of having been put to a use different from that originally contemplated by the initial patent.

What developing countries have done

The vast majority of countries studied provide for absolute novelty wherein any public disclosure whether written, oral or by use anywhere in the world shall be taken into account. The only country providing any limited form of novelty was Sri Lanka[2] where only oral disclosure or use in Sri Lanka is taken into consideration.

EXCEPTIONS TO PATENT RIGHTS

Exhaustion of rights

What TRIPS Requires

TRIPS is very specific on the rights that a patent should confer on its owner. These are set out in Article 28 and include inter-alia the right to prevent third parties not having the patent owner's consent from importation the patent product or a product produced by a patented process. This particular right is however subject to Article 6 which states that nothing in [TRIPS] shall be used to address the issue of exhaustion of intellectual property rights. A WTO Member therefore has a degree of freedom in choosing the exhaustion of rights regime to apply in the patent field. Options include: a **national exhaustion** regime where the rights are said to exhausted when a patented product has been put on the market with the consent of, or by the patent holder in the country where the patent was issued; a **regional exhaustion** system extending the foregoing principle to other countries within a region (as in the European Union where for example a British patent holder is unable to use the rights in his British patent to prevent the import of products that he has already marketed in Germany); and finally an **international exhaustion** regime where rights in a patented product are exhausted in respect of those products put on the market anywhere in the world.

A further issue surrounding exhaustion of IP rights concerns the meaning of consent and whether this needs to be express consent eg. the patent holder expressly authorizes a third party to market the patented product or whether implied consent is sufficient. The latter might apply for example where the prospective patentee chooses not to take out a patent in a particular country therefore allowing others to freely and legitimately enter the market.

What developing countries have done

National/Regional Exhaustion	International Exhaustion
13 + OAPI[3]	14 + Andean
29 (60%)	19 (40%)

[2] Section 61(2) of IP law of 1979 defines prior art as everything disclosed to the public anywhere in the world by written disclosure or in Sri Lanka, by oral disclosure, by use or in any other way.

[3] Article 3 of 1999 Revision provides that rights shall be independent national rights subject to the legislation of each member state in which they have effect. Article 8 on patents states that rights shall not extend to subject matter brought on to the market of the territory of a member state by the patent owner or with his consent. [Unclear whether this applies to any of the member states or the member state where action is to be taken].

Among those providing international exhaustion Argentina has perhaps the broadest provision[4] in that instead of referring to consent", it merely refers to products put legitimately on the market. Such wording could be interpreted to cover not only cases where the product has been put on the market by the patentee or with his consent, but other cases where products are legitimately marketed for example under a compulsory license or in the case referred to above where the inventor does not take out a patent. The implementing regulations to this provision apparently attempt to exclude the latter "legitimate case" from the scope of the provision. This particular provision is however one of the subjects of an ongoing WTO dispute settlement action.

Other exceptions to patent rights

What TRIPS says

In the absence of an agreed list of exceptions to patent rights, the drafters of the TRIPS Agreement adopted a general exception clause which 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".

Guidance on the intended scope of this provision has already been provided by the Dispute Settlement Body of the WTO in the dispute between the EU and Canada. In this case the DSB found that a provision allowing a third party to make and use a patented product for the purposes associated with obtaining regulatory approval for a similar product (the so-called Bolar type exception) was a legitimate exception within the meaning of TRIPS.

Bolar – what developing countries have done

Specifically provided	Not specifically provided but may be covered be other common general exceptions
8	20 + OAPI + Andean Community
8 (16%)	41 (84%)

Included among those providing a Bolar are those countries that have clearly done so, e.g. Jordan [5] and the Dominican Republic[6] and those with less specific provisions which nevertheless would appear to cover the same type of activities e.g. Uruguay[7].

[4] Article 36(c) provides that patent rights shall not extend to:
Any person, who imports, acquires, uses, or commercialises in any other way the product patented or obtained by the patented process, once this product had been put legally on the market in any country. It will be understood that the putting in the commerce is allowed when it is in accordance with the TRIPS.

[5] Article 21(c) of Jordan's patent law provides

A. Notwithstanding any conflicting provision in this law or any other law, all types of scientific research and development and filing applications for obtaining marketing permits carried out before the elapse of the patent protection period shall not be regarded as infringement neither civil nor criminal.

General Research and experimental use exceptions

Among the other exceptions to patent rights that would safely fall within the scope of the TRIPS Agreement are those historically found in a significant number of patent systems namely those relating to private and non-commercial uses and those relating to acts done for experimental purposes relating to the subject matter of the invention The latter was considered especially important in that it allows parties to understand and invent around the patented invention therefore promoting further innovation.

What developing countries have done

With the exception of a few countries such as South Africa and OAPI Member States, the countries analysed all provide some form of research or experimental use type exception. A significant number of countries provide broad exceptions covering all non-commercial acts. An equal number of countries, particularly in South America also provide an exception for acts carried out exclusively for the purposes of teaching or scientific or academic research. In Guatemala where protection for plant varieties is available through the patent system, a specific exception is provided to enable farmers to save second generation seed and livestock produced through us of the protected variety.

Compulsory Licensing

What TRIPS says

Although Article 31 of TRIPS provides a series of detailed measures that must be followed when issuing a compulsory licence, the grounds on which such a licence can be awarded are essentially left to the discretion of the Member. Note should however be made of Article 5 of the Paris Convention incorporated into TRIPS by reference which could suggest that such grounds should relate to the prevention of abuses of patent rights.

What developing countries have done

Only one Country, Kenya[8], has apparently provided for unauthorised use of a patented product without payment of any remuneration to the patent holder. The following table illustrates the different grounds provided in the countries analysed. Note : countries often provide a number of grounds for granting compulsory licences.

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[6] Article 30g (exceptions) applies to "those uses which are necessary to obtain sanitary approval and to market a product after the patent protecting it has expired.

[7] Uruguay Article 39D provides that patent rights shall not extend
Those actions made exclusively with experimental aims, even the ones made for the preparation of a future commercial exploitation, carried out within the term of one year before the patent expiration

[8] Kenya Industrial Property Act 2001 Section 80(1A & 1B) provides that the Minister may authorize the manufacture, importation, or authorization of any molecule or substance. The authorization shall remain in force until revoked by the Minister. An order made under this section shall not require the payment of compensation to the patent holder.

Grounds for granting Compulsory Licences	Countries providing such grounds	Total (% of countries analysed)
Failure to exploit or exploit on Reasonable terms	16 + OAPI	32 (60%)
Public interest	8 + Andean	13 (25%)
National emergency or health emergency	8 + Andean	13 (25%)
Remedy anti-competitive practices, unfair competition	6 + Andean	11 (20%)
Failure to obtain licence under reasonable terms	4 [9]	4 (7%)
Failure to work domestically	2 [10]	2 (4%)
Dependent Patents	Not covered	Not covered
No apparent provisions	2[11]	2 (4%)

Disclosure Requirements

TRIPS Article 29 specifies the requirements that may be imposed on patent applicants. These include the requirement to disclose the best mode for carrying out the invention as well as providing information concerning corresponding applications and grants. The best mode requirement, which is not present in European legislation, is intended to ensure that the applicant does not conceal the preferred embodiment of his invention.

Information, such as search and examination reports, on corresponding filings may be of particular assistance to those countries not having the technical capacity to properly examine patent applications.

What developing countries have done

Best Mode	Yes	No
Countries	11 + ARIPO + Andean Community	14 + OAPI
Total (% of sample)	30 (50%)	30 (50%)

Virtual all the countries analysed included provisions allowing the examining authorities to ask the applicant to provide information on corresponding filings including for example copies of search and examination reports and copies of official correspondence covering those cases. The only notable exceptions were the OAPI countries where no specific provisions are provided. Some of the countries requiring this information can rely on it instead of conducting their own investigations[12].

[9] Including China,
[10] Egypt and Brazil – see argument in IP/C/W/278
[11] Sri Lanka, El Salvador
10. Andean Decision 486, Art 46 provides that
If the examination of the patentability of the invention requires it, the applicant shall, at the request of the competent national

Source of genetic material and Prior Informed Consent (PIC)

The Convention on Biological Diversity and the growing recognition of the potential value of biological resources has led to suggestions that the patent system should be more supportive not only of the CBD but the rights of countries and communities supplying biological resources. One particular suggestion is that patent applicants should be required to disclose the information about the source of any material or associated traditional knowledge that constitutes a significant part of the invention to be protected. The EU legislation on biotechnology inventions encourages applicants to provide such information however failure to do so does not prejudice any patent rights. In a number of developing countries however punitive sanctions are imposed, for example the patent application is refused or the rights declared void or unenforceable.

What TRIPS allows

As noted above, Article 29 provides that patent applicants may be required to disclose the best mode for carrying out the invention as well as providing information concerning corresponding applications and grants. If this list is considered to exhaustive then an additional requirement for the applicant to disclose the source of origin of biological material or TK may be considered to be outside the scope of Article 29.

What have developing countries done

Of the countries studied, 6 countries (Egypt, Costa Rica, Bolivia, India and China) together with the Members of the Andean Community clearly required a patent applicant to disclose the source of biological material used in, or to develop, the invention. In addition the Costa Rican[13] legislation on access to genetic resources also requires the applicant to present a certificate of access to show that the genetic resources on which the invention is based was acquired with the approval of the

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office and within a period of no more than three months, submit one or several of the following documents connected with one or more foreign applications referring to all or part of the invention being examined:
a) a copy of the foreign application;

b) copies of the findings of the examinations of the novelty or patentability of the invention conducted with respect to the foreign application in question;

c) a copy of any patent or other patent protection that may have been granted on the basis of this foreign application;

d) a copy of any order or decision that may have been handed down rejecting or denying the foreign application; or,

e) a copy of any order or decision that may have been handed down annulling or invalidating the patent or other patent protection that was granted on the basis of the foreign application.

The competent national office may accept the results of the examinations referred to under letter b) as sufficient to certify that the conditions for the invention's patentability have been fulfilled.

[13] Article 80 of Biodiversity Law of Costa Rica

relevant communities. A similar provision relating also to traditional knowledge is provided in Decision 486 of the Andean Community[14]

Plant Variety Protection

What TRIPS says

Article 27(3)(b) provides that members may also exclude from patentability plants and animals other than micro-organisms. 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.

What developing countries have done

The predominant sui generis system is the UPOV Convention (Acts of 1978 and 1991). 13 of the countries analysed have signed up to the 1978 Act of UPOV. The majority of these are in South America with the only African countries being Kenya and South Africa.

Other countries have relied on their own sui generis systems. The exceptions to the rights of plant breeders provided in a significant number of countries (13 out of 18 analysed), including both those adhering to UPOV and those opting for their own sui generis system, include broad provisions allowing farmers to save, exchange and sell in a limited way seeds produced by the protected variety.

Protection of undisclosed information

What TRIPS requires

Article 39(3) requires requires that WTO 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. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

Of particular interest in this respect is whether information provided to a pharmaceutical regulatory authority can be relied on by a subsequent applicant seeking to obtain approval for a bio-equivalent product or whether further applicants must provide similar data including for example clinical trial data.

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[14] Decision 486 Article 26.- Applications for patents shall be filed with the competent national office and shall contain: h) a copy of the contract for access, if the products or processes for which a patent application is being filed were obtained or developed from genetic resources or by products originating in one of the Member Countries;

i) if applicable, a copy of the document that certifies the license or authorization to use the traditional knowledge of indigenous, African American, or local communities in the Member Countries where the products or processes whose protection is being requested was obtained or developed on the basis of the knowledge originating in any one of the Member Countries, pursuant to the provisions of Decision 391 and its effective amendments and regulations;

What developing countries have done:

Can second applicant rely on previously submitted data	Yes	No	Unclear/no provision
No of countries	6	4	10 + Andean + OAPI
Total (% of sample)	6 (15%)	4 (10%)	31 (75%)

An example of a country allowing such use is Chile which provides that pharmaceutical products whose patents have expired, may be replaced by similar products produced by third parties who apply for market authorization from the Public Health Institute (ISP). If the therapeutic molecule in question has the same qualitative and quantitative formula as the original product, the national regulations accept the information supplied by this original producer (the owner of the patent) as the basis on which to authorize the marketing by third-party producers, there being no need to furnish further background information. The Public Health Institute does not grant market authorizations to third parties for products currently protected by a patent.

COPYRIGHT

Fair use provision for educational purposes

To date, very little concern has been raised about the TRIPS obligations in the copyright field. One area that might become increasingly important is that of fair use provisions relating to educational needs.

What TRIPS requires

The TRIPS Agreement provides a general exception clause for copyright similar to that mentioned above in respect of patent rights. The agreement also incorporates by reference, Article 10(2) of the Berne Convention which provides that it shall be a matter for national legislation to permit the utilization, to the extent justified by the purpose, of literary or artistic works by way of illustration in publications, broadcasts or sound or visual recordings for teaching, provided such utilization is compatible with fair practice and Article 9(2) which, in summary, provides that it shall be a matter for national legislation to permit the reproduction of literary and artistic works in certain specified cases provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author.

What developing countries have done

The majority of countries studied provided, in cases of uses for educational purposes, only a limited exception to copyright to allow incorporation of short extracts of works in teaching material or to allow the performance of a copyrighted work by way of education. A number of countries provide slightly broader exceptions allowing for example any use by approved educational institutions provided such

copies are subsequently destroyed[15], for educational purposes Sri Lanka's proposed amendment to its IP Law provides that the fair use of a work including such use by reproduction in copies or by any other means for purposes such as… teaching (including multiple copies for classroom use shall not be an infringement of copyright[16].

[15] Nigeria
[16] IP/N/1/LKA/C/1/Add.1

Commission Study Paper 7: Study on the Implementation of the TRIPS Agreement by Developing Countries

APPENDIX 1

Table 1: Analysis of regional Intellectual Property Systems

Agreement	OAPI 1977 Bangui Agreement	OAPI 1999 Bangui Revision	ARIPO Harare Protocol	Andean Community Decision 486
WTO Member/Status Least Developed Country LD/Developing country DC	Benin (LD), Burkina Faso (LD), Cameroon, Central African Republic (LD), Congo, Ivory Coast, Gabon, Guinea (LD), Guinea Bissau (LD), Guinea Equatorial (Non WTO), Mali (LD), Mauritania (LD), Niger (LD), Senegal (LD), Chad (LD), Togo (LD).	Cameroon, Ivory Coast, Gabon, Guinea (LD), Guinea Equatorial (Non WTO), Mali (LD), Mauritania (LD), Senegal (LD), Chad (LD) (10 ratifications needed to bring it into force)	Botswana, Gambia (LD), Ghana, Kenya, Lesotho (LD), Malawi (LD), Mozambique (LD), Sierra Leone (LD), Sudan (Obs), Swaziland, Tanzania (LD), Uganda (LD), Zambia (LD) and Zimbabwe. [Somalia (non WTO) is not a party to the protocol].	Bolivia Columbia Ecuador Peru Venezuela
Paris Convention	Requires joining of Paris.	Requires joining of Paris.		----
Berne Convention	Requires joining of Berne.	Requires joining of Berne.		---
UPOV (1978 or 1991 Act)		1999 Revision requires joining of UPOV 1991.		
Search & Examination	Search and examination before publication (usually sub-contracted)	Search and examination before publication (usually sub-contracted)	Search and examination- (usually sub contracted)	Yes after publication. Art 46 provides that national office may accept results of another office as sufficient to satisfy patentability requirements
Novelty		Absolute	Absolute	Absolute
Exhaustion regime		Unclear whether it is national or regional Exhaustion	Prescribes for pre grant only.	International
Early working (Bolar)		Not specifically provided	See above	Not specifically provided.
Compulsory licensing	Extensive provision against demand not being met on reasonable terms, met by importation	Not being worked on territory Demand not being met on reasonable terms. Dependent Patent	See above	Non exploitation. In public interest or for an emergency or national security consideration. Anti competitive behaviour.
Government use		Vital interest, public health, national defence.	See above	
2nd Medical use	Not explicit but appears to be allowed – OA9495, OA10158	Not explicit	Allowed AP868	Excluded

Disclosure requirements Foreign filings and search & exam reports	No	Not required	May be requested.	Required
Disclosure requirements (origin of material)	No	No		Yes for biological material and also for TK.
Best Mode	No	No	Yes	Yes
Multiple independent claims	Probably	Probably allowable	Yes	Yes
Grace Period	6 Months (exhibitions only)	12 months (exhibitions only)	6 Months (exhibitions only)	12 Months
Patents on parts of human body include gene sequences	Not explicitly excluded Human genetic material – OA10163	Not explicitly excluded	Not explicitly excluded Human genetic material – AP411	Excluded are any living thing, either complete or partial as found in nature, natural biological processes and biological material, as existing in nature, or able to be separated, including the genome or germ plasm of any living thing. Art15(b). Artificially created genes patentable.
Patents on plants and animals	Not on plant varieties and animal species Genetically modified plants patentable – OA9664 And animals – OA9669	Not on plant varieties and animal species	Plants – AP655 Transgenic plants AP752 Transgenic animals – AP411	No
General exceptions				
Research exceptions	No exceptions provided.	Acts carried out for experimental purposes in course of scientific and technical research		Private & non commercial research. Experiments with subject matter and acts carried out exclusively for the purposes of teaching or scientific or academic research
Protection of undisclosed information		Protected against dishonest use except where necessary to protect the public		Article 39 wording.
Pharmaceutical products	Yes	Yes	Yes	Yes
Utility models	Yes	Yes		
Improvement patents	Certificate of addition available to patentee	Certificate of addition available to patentee		
Comments	Protection also provided for folklore and cultural heritage			
Term of patent protection	20 years (10 + 2 renewable 5 year periods)	20 Years	20 years	20 years

APPENDIX 2

Country Analysis

Table 2. Africa Data 1

COUNTRY					
	Democratic Republic of Congo (Former Zaire)	**Jordan**	**Kenya**	**Morocco**	**Nigeria**
Membership of international or regional treaties/bodies					
WTO Member	1997	---	1995	1995	1995
Paris Convention	1975	1972	1965	1917	1963
Berne Convention	1963	1999	1993	1917	1993
UPOV (1978 or 1991 Act)	---	---	1999 (78)	----	---
CBD (ratified)	1994	1993	1994	1995	1994
Member of regional body	---	---	ARIPO	UCC	UCC
PATENTS					
Search & Examination	Not normally necessary unless requested by applicant except in relation to food or pharmaceutical fields which are subject to prior examination by substance.	If application fulfils all criteria then abstract published then 3-month objection period before grant.	Yes. Subcontracted to WIPO		Granted without substantive examination – at risk to applicant
Novelty		Absolute	Absolute	Absolute	Absolute
Exhaustion regime	Probably national.	Would appear to be international.	International (although Act fails to mention consent).	National	National
Early working (Bolar exception)	Not explicitly.	Yes.	Yes	Not specifically	Not specifically
Compulsory licensing	If not worked in an efficient, conscientious and continuous manner.	For national security, emergency situations or public non-commercial benefit, to remedy anti competitive practices, failure to exploit.	Supplied on unreasonable terms	Failure to satisfy market. In the interests of public health requires payment of royalty	Failure to work, demand being met on unreasonable terms or by importation
Government use	Yes.	Yes – see above	Yes. Public interest Anti competitive. Special provision allowing ministerial authorisation to import or produce substances without payment to the patent holder.		Yes
2nd Medical use	Excluded. First use only.		Not specifically excluded	Excluded, but not specifically	Not specifically excluded

Disclosure requirements Foreign filings and search & exam reports	Required.	Required	May be requested		May be requested
Disclosure requirements (origin of material)	Not specifically		No		No
Best Mode	No	Yes	No	No	No
Multiple independent claims	Apparently yes.	Yes	Yes		Yes
Grace Period	6 Months.	12 months (18 month priority period)	12 months	6 Months	6 Months – exhibitions only.
Patents on parts of human body include gene sequences	Discovery of matter already existing in nature excluded.	Not specifically excluded	Not specifically excluded	Not specifically excluded	Not specifically excluded
Patents on plants and animals	Not specifically excluded but see above.	No	Plant varieties excluded.	Not on plant varieties	Not on plant or animal varieties.
Research exceptions	Rights extend only to acts carried out for industrial and commercial purposes and not to acts for sole purpose of scientific research.	Research and development apparently allowed.	Rights extend only to industrial or commercial acts.	Private and non commercial, Experimentation on the subject matter of the patent.	Non-commercial uses permitted.
Pharmaceutical products	Yes	Apparently not. Provisions exist for mailbox filings.	Yes	Yes but mailbox will apply to 2006?	
Improvement patents		Yes. To patentee for remainder of duration.		Yes	
Other TRIPS+		Criminal Sanctions for some patent infringements.			
MISCELLANEOUS					
Protection of undisclosed information		5 years protection of data from date of authorisation.	Intend allowing second generic applicant to rely on data submitted by first applicant.		
Utility models			Yes		
COPYRIGHT					
Fair use provisions including educational material		Yes. Making sufficient copies to satisfy educational needs without undermining normal exploitation of material.	Limited specific fair use for educational purposes		Any use in an approved educational institution for the purposes of that institution provided such copies are subsequently destroyed
Technology circumvention rules (DCMA)					Act includes specific sanctions against importation or possession of anti piracy device. Prescribed use of holograms and registration of producers of CDs and films.

Other				Had 25 years for software but international treaties take precedent	Provides for protection of folklore – administered by Nigerian Copyright Commission.
PLANTS AND PLANT GENETIC RESOURCES					
Access legislation for genetic resources				.	
Plant Variety Legislation		YES. Appears to be based on UPOV 1991 – EDV protected.	Protects rain-fed as well as cultivated varieties	UPOV 91 consistent law passed in 1996	
Plant variety right exceptions		Limited farmers' rights to save seed.	No clear farmer's right.		
Source of information	WIPO IP Law Series	WTO notifications	WTO notifications	WTO notifications	WTO notifications
Laws	IP Law 82-001 1982	1999 Patent Law as amended	2001 Patent law	Patent law 17/97	Patent law of 1971, which is similar to UK law. Copyright law as amended in 1999

Table 3. Africa Data 2

Country					
	Egypt	**South Africa**	**Madagascar**	**Botswana**	**Namibia**
Membership of international or regional treaties/bodies					
WTO Member	1995	1995	1995	1995	1995
Paris	1951	1947	1963	1998	---
Berne	1977	1928	1966	1998	1990
UPOV (1978 or 1991 Act)	---	1977 (Making amendments to comply with 1991 Act)	---	---	---
WC Treaties	---	---	---	To be ratified in 2002	
CBD (ratified)	1994	1994	1994	1995r	1997
Member of regional body	---	---	---	ARIPO	---
PATENTS					
Search & Examination	Yes	Examination before publication	Search and examination, search provided by applicant. Examination to patentable subject matter and clarity only.	Certain categories of invention can be excluded from examination vis-à-vis novelty & inventive step.	
Novelty	Absolute?	Absolute	Absolute	Absolute	
Exhaustion regime	International	Section 15C of Medicines Act 1997 provides for international exhaustion for medicines.	National	National	National
Early working (Bolar exception)	Yes	Not specifically provided (Almost certainly no).	Not specifically provided	Not specifically provided	
Compulsory licensing	Yes including failure to work domestically.	To remedy abuse including – not working, demand not being met on reasonable terms	Not working, refusal to grant reasonable licences, not satisfying market.	For failure to supply or to supply on reasonable terms.	Not worked or insufficiently worked.
Government use				Yes	Yes, in the interests of national security
2nd Medical use	Excluded	Specifically allowed.	Not specifically excluded		
Disclosure requirements Foreign filings and search & exam reports		Not required		Upon request.	Upon request
Disclosure requirements (origin of material)	Yes	Apparently no	Not explicitly required	No	
Best Mode		Yes	Yes	No	No
Multiple independent claims		Yes	Yes	Yes	Yes
Grace Period		Disclosure through trials or experimentation by patentee	6 months – exhibitions only	12 months	12 Months
Patents on parts of human	Excluded	Not specifically excluded	Not specifically excluded	Not specifically excluded	Not specifically excluded

body include gene sequences					
Patents on plants and animals	Excluded	Plant and Animal Varieties excluded	No plant or animal varieties	Not specifically excluded	No plant or animal varieties. Draft access legislation says no person shall apply for patents on life forms or biological processes
General exceptions		No exceptions to rights other than in respect of vessels temporarily entering territory	Presidential decree excluding from patentability (provisionally or definitively) certain categories of invention as required by vital interests including public health.		
Research exceptions		No	Rights extend only to acts carried out for industrial and commercial purposes.	Experimentation relating to the invention	Acts done for scientific research.
Pharmaceutical products	No	Yes	No but see comment below.	Not specifically excluded	
Improvement patents		Yes	Yes		
MISCELLANEOUS					
Protection of undisclosed information	Provided but would not prevent regulatory authority, when examining second pharmaceutical application, from relying on previously submitted data.	No specific legislation- unclear whether second applicant can rely on prior data.		Not provided	
Utility models				Yes	
Other	Draft law did consider referring patent applications to Health Ministry but this has apparently been dropped.				
COPYRIGHT					
Fair use provisions including educational material		As Berne Article 10.			
Reverse engineering of software		Not allowed			
Other	70 year protection for literary works such a computer programs				
PLANTS AND PLANT GENETIC RESOURCES					
Access legislation for genetic resources					
Plant Variety Legislation	Yes. Requires breeder to reveal details of source of material and also provide sufficient proof that the country of origin of these resources agrees on him	Yes – compatible with UPOV 1991			

	conducting the activities that led to the development of the variety. This obligation also includes the genetic information and the related experiences of the local communities that were of use to the breeder's efforts in developing the new plant variety.				
Plant variety right exceptions	Allows farms to save and exchange seed.	Allows farmer to save seed. Private and non commercial uses and research to produce new variety.			
Source of information	WTO notifications	WTO notifications	WTO Notifications. Statement to WTO says Article 27(1) takes precedence over Article 8.	WTO notifications	WTO notifications
Laws	New draft IP law , 2000 PVR law.	Patents Act 1978 as amended by IP Act 1997 and Medicines Act 1997. Copyright Act 1978	Ordinance No 89-019 of July 1989. Decree No 92-993 as last amended by Decree 95-057 (1995) WIPO IPLT	IP Act 1996 Copyright Act 2000	

Table 4. Asia Data

Country							
	India	**Pakistan**	**Sri Lanka**	**Philippines**	**Malaysia**	**Vietnam**	**China**
Membership of international or regional treaties/bodies							
WTO Member	1995	1995	1995	1995	1995	---	2001
Paris	1998		1952	1965	1989	1949	1985
Berne	1928	1948	1959	1951	1990	---	1992
UPOV (1978 or 1991 Act)	---	---	---	---	---	---	1999 (78)
WC Treaties	---						
CBD	1994	1994	1994	1993	1994	1994	1993
Member of regional body	UCC	UCC	UCC	APEC, ASEAN	APEC, ASEAN	APEC, ASEAN	APEC
PATENTS							
Search & Examination	Yes	No clear substantive examination. Opposition period is however provided.	Grant published	Substantive examination after grant.	Grant published. Applicant may request modified sub exam when he has a granted patent for the same invention elsewhere (<70% of normal cost.		Substantive examination after publication
Novelty	Absolute (for inventive step use only in India is considered)	Absolute	Relative – oral and use only in Sri Lanka.	Absolute	Absolute –including oral & use disclosure worldwide	Absolute	Relative. Local public use only taken into account.
Exhaustion regime	International	Unclear. Law refers to products put on the market.	International	National	International		Appears international
Early working (Bolar)	Yes – within 3 years of end of patent life	Not explicitly allowed	Not specifically allowed	Not specifically allowed	Yes		Not specifically provided
Compulsory licensing	Failure to work in India. Public requirement not met or not met on reasonable terms	For reasons of public interest including health. To remedy anti-competitive practice	No provision.	For reasons of public interest and to remedy anti competitive practices. Non working.	Demand not being met or being met on unreasonable terms.		Failure to obtain reasonable licence. Public interest, national emergency or extraordinary situation.
Government use	Yes			As above.	Yes		
2nd Medical use	Specifically excluded		Not specifically excluded.	Not specifically excluded.	Yes SS14(4)	Yes	Allowed
Disclosure	Required	May be requested	May be requested	May be requested	May be required		May be requested

requirements Foreign filings and search & exam reports							
Disclosure requirements (origin of material)	Yes. Section 25-ground for opposition		No		Apparently not.		
Best Mode	No?	No	Yes	No	Yes		No
Multiple independent claims	Yes	Yes	Yes	Yes	Yes		Yes
Grace Period	6 months for exhibitions and papers before learned societies.	12 months	12 Months	12 Months	12 Months		6 Months – exhibitions only.
Patents on parts of human body include gene sequences	Mere discovery of any living thing or non living substance occurring in nature excluded.	Not specifically excluded	Not specifically excluded	Not specifically excluded.	Not specifically excluded		Yes
Patents on plants and animals	No	No	Specifically excluded	Plant varieties and animal breeds excluded.	Plant and animal varieties excluded	Plant and animal varieties excluded (US Agreement requires inventions covering more than one variety to be patentable).	Plant and animal varieties excluded
General exceptions		Limited to experimental use.		Private and non-commercial. Experiments relating to patented invention.	Rights extend only to acts done for industrial or commercial purposes.		
Research exceptions	Experimental and research uses including teaching		Scientific research allowed.		See above		Use solely for experimental or research purposes allowed.
Pharmaceutical products	No. Mailbox provisions apply.	Not until 2005. Mailbox provisions apply.	Yes		Yes	Yes	Yes
Improvement patents		Yes – life dependent on main patent.					
Differential Fee Structure				50% reduction for small entities.			
MISCELLANEOUS							
Protection of undisclosed information			Article 39(3) wording in proposed legislation.	Data apparently protected against use by second applicant.	By common law. Would apparently prevent second applicant using previously submitted test data.	Protected. (US agree prevents second applicant from relying on previously submitted data.)	

Protection of Community IP Rights				Specific legislation provided protection in perpetuity for Community based innovations. Commercial users of the innovation must pay at least 50% of net sales to the Community.			
Utility models				Yes	Yes		
Other TRIPS+					Malaysia has an Optical Discs Act 2000 for licencing manufacturers of optical discs. Offences punishable by fines and/or prison terms up to six years		
COPYRIGHT							
Fair use provisions including educational material		Limited fair use for educational needs including incorporation in a collection of short passages and performance or reproduction not using a printing process	Broad to include multiple copies for classroom use provided that it constitutes fair use (effect on market is considered).		Limited fair use for educational.		
Reverse engineering of software	May be adapted to enable use with a computer		May be adapted to enable use with a computer	Decompilation of computer programs to achieve inter-operability may constitute fair use.	Would not appear to be allowed for commercial purposes.		
Exhaustion regime	international		Appears national,		National.		
Technology circumvention rules (DMCA)						Required under bilateral agreement	
Other			Folklore defined.				
PLANTS AND PLANT GENETIC RESOURCES							
Access legislation for genetic resources	Draft legislation requires patent applicant to seek consent of National Biodiversity Authority before patent based on GM obtained from			Yes. Act does not however appear to impose any requirements on patent applicants or authorities. Act does require PIC and			

	India.			benefit sharing.			
Plant Variety Legislation	Provides for benefit sharing claims by communities and NGO;s. Applicant must disclose details of Community based genetic material used to develop the protected variety.	Provides protection for EDV.	Sui-generis system being prepared. Will protect EDV. Exceptions cover private and research. Farmers' exception may be provided for certain varieties to enable limited use of farm saved seed. National Exhaustion regime.	Sui-generis system providing protection for EDV. Plant Variety Act 2000	Being drafted	UPOV consistent legislation issued in 2001. (US Agreement calls for either UPOV 78 or 91 standard).,	Yes.
Plant variety right exceptions	Broad research exemption. Broad farmers' rights. Payment from central gene fund available to local conserves of biological resources.	Broad farmers' rights to cover traditional saving, exchanging and selling. Broad research exception. National Exhaustion .		Small farmers can save and exchange seeds. Broad research exemption but not covering EDV.			Rights extend only to production or selling for commercial purposes.
Source of information	WTO notifications Grain Website	WTO notifications Grain Website	WTO notifications	WTO notifications	WTO notifications		
Laws	PPV & FR Bill 2000.	PBR ordinance 2000	Code of IP 79 as amended including draft amendments notified to WTO.	IP Code No 8293	Patent Act 1983 as amended (2000)	Government decree of 96	Patents Act 2000, PVR Law
Bilateral Agreements						US – Vietnam Agreement - TRIPS Plus –	

Table 5. South America and Caribbean Data 1

Country					
	ARGENTINA	**BOLIVIA**	**BRAZIL**	**CHILE**	**COLOMBIA**
Membership of international or regional treaties/bodies					
WTO Member	1995	1995	1995	1995	2000
Paris	1967	1993	1884	1991	---
Berne	1967	1993	1922	1970	1988
UPOV (1978 or 1991 Act)	1994 (78)	---	1999 (78)	1996 (78)	1996(78)
WCT				Legislation recently passed	Implemented 2000
CBD	1994	1994	1994	1994	1994
Member of regional body	Mercosur, UCC	Andean Community, UCC	Mercosur, UCC	APEC,UCC	Andean Community, UCC.
PATENTS					
Search & Examination	Yes after publication,	Yes after publication. Art 46 provides that national office may accept results of another office as sufficient to satisfy patentability requirements.	Yes after publication		
Novelty	Absolute		Absolute		
Exhaustion regime	International and apparently includes broad definition of consent to cover countries not providing patent protection and patents put on market via compulsory licences. (cross reference to compatibility with TRIPs Agreement).	International	National but Paragraph 3 - If a compulsory license is granted on the grounds of abuse of economic power, a period of time, limited by provisions of art 74, shall be secured to a licensee to import the subject matter of the license, provided it has been placed on the market directly by the patent owner or with his consent.		
Early working (Bolar)	Not explicit.	Not explicit.	Yes		
Compulsory licensing	Yes. Failure to obtain licence under reasonable terms. Failure to work. Remedy uncompetitive practice including excessive prices.	Non exploitation. In public interest or for an emergency or national security consideration. Anti competitive behaviour.	In an abusive manner of if he uses it to abuse economic power I - failure to exploit the object of the patent within the Brazilian territory for failure to manufacture the product or failure to fully use a patented process, except in case of economic unfeasibility, in which case importing shall be	On grounds of a monopolistic abuse of a patent	

			admitted; or II - marketing that does not satisfy the needs of the market.		
2nd Medical use	Not explicitly excluded.	Excluded	Not explicitly excluded.	Excluded in new draft law	
Disclosure requirements Foreign filings and search & exam reports	May be requested	Required	Required		
Disclosure requirements (origin of material)		Yes. Art 26(h) & in relation to traditional knowledge, (i).On pain of being declared abandoned.	Patent right may be in jeopardy if means to obtain the subject matter are illegal. See below.		
Best Mode	Yes	Yes Art 28(e)	Yes		
Multiple independent claims	Possibly.	Yes	Yes		
Grace Period	12 Months for exhibitions.	12 Months	12 Months		
Patents on parts of human body include gene sequences	Biological and genetic material existing in nature or its replications excluded.	Excluded are any living thing, either complete or partial as found in nature, natural biological processes and biological material, as existing in nature, or able to be separated, including the genome or germ plasm of any living thing. Art15(b). Artificially created genes patentable.	Natural living beings, biological material including genome or germ plasm of any natural living being when found in nature or isolated therefrom.	Not explicitly excluded.	
Patents on plants and animals	All classes of living matter and substances excluded.	No. Art 20(c)	See above.	Plant Varieties and Animal Races excluded	
General exceptions	Article 30 type wording.			Business methods explicitly excluded	
Research exceptions	Private & non commercial research	Private & non commercial research. Experiments with subject matter and acts carried out exclusively for the purposes of teaching or scientific or academic research.	UK but with experimental purposes, if related to studies or scientific or technological researches.	Experimental or teaching purpose related uses allowed.	
Pharmaceutical products	Yes as from end of 2000.. Article 70.8 Mailbox provision provided.	Yes	As from 2004. mailbox in operation. Patent applications have to be passed by Health Ministry.		
Improvement patents	Yes. Duration dependent on life of patent on which they depend		Yes		
MISCELLANEOUS					
Protection of undisclosed information	Apparently allows second applicant to rely on previously	Yes. TRIPS 39 type wording		Authorisation for second product not possible until	

	submitted data lacking – subject of DSP			patent has expired however previously submitted information by first applicant can be relied on by later applicants.	
Utility models	Yes. Termed design patents – requires local novelty only.	Yes	yes		
COPYRIGHT					
Fair use provisions including educational material	Limited use (incorporation and performance) for educational purposes.	Art 32 of Decision 351 provides for use of copyrights works for teaching.			
Reverse engineering of software	Does not appear to be explicitly allowed. Note Government apparently considering switching to open source software.			Would not appear to be allowed.	
PLANTS AND PLANT GENETIC RESOURCES					
Access legislation for genetic resources		Yes. Decision 391	Draft legislation provides The rights upon genetic resources and derived products obtained or used in violation of this Act shall not be recognized, and the certificates of intellectual property or similar certificates upon such resources or derived products or upon products or processes resulting from access under such circumstances shall not be considered valid. Also The depositors of intellectual creations subject to protection by copyright, industrial property, crops or any other mode of intellectual property, being based on any genetic resources or traditional knowledge, as well as those based on the cultural or artistic traditions of local communities or indigenous populations, must present a certificate of approval by the communities or populations, to be obtained		

			before requesting legal protection of the creation and in compliance with the laws of the country of origin of the genetic resource or of the traditional knowledge.		
Plant variety right exceptions	UPOV 78		Protection extends to EDV but exceptions are broad covering farm saved seed, material and seed share initiatives among rural farmers.	UPOV 78	
Source of information	WTO Notifications	WTO Notifications	WTO Notifications	WTO Notifications	WTO Notifications
Laws	Law 24481 as amended . 1996	Andean Decisions 486 and 391.	Law 9.279 amended 2001	Law 19.039	Law

Table 6. South America and Caribbean Data 2

Country							
	COSTA RICA	**GUATAMALA**	**HONDURAS**	**NICARAGUA**	**PERU**	**URUGUAY**	**EL SALVADOR**
Membership of international or regional treaties/bodies							
WTO Member	1995	1995	1995	1995	1995	1995	1995
Paris	1995	1998	1994	1996	1995	1967	1994
Berne	1978	1997	1990		1988	1967	1994
UPOV (1978 or 1991 Act)	---	---	---	2001 (78)	---	1994 (78)	---
WC Treaties		Approved shortly.					
CBD	1994	1995	1995	1995	1993	1993	1994
Member of regional body	UCC	Central American Convention, UCC	---	Central American Convention, UCC	Andean Community, APEC, UCC	Mercosur	
PATENTS							
Search & Examination	After Publication	After Publication				Substantive examination after publication which may resort to docs from corresponding filings and may request advice from other authorities.	Substantive examination after publication. Office may request advice from any other national or international organisation.
Novelty	Absolute. Any disclosure anywhere	Absolute. Any disclosure anywhere	Absolute. Any disclosure anywhere	Absolute. Any disclosure anywhere		Absolute	Absolute
Exhaustion regime	International		International		International	International	National
Early working (Bolar)	Specifically allowed.	Not apparently allowed.	Not explicitly allowed.			Acts made with experimental aims including preparing for future exploitation with 1 year of patent expiry allowed.	Not specifically provided.
Compulsory licensing	Failure to exploit, public interest, anticompetitive practices	On grounds of national emergency, public health or public non commercial use. Also anti competitive practices.	Public health, public interest, national emergency, national security or nutrition.			For failure to work, in public interest including public health emergency and to remedy unfair competition or abuse of rights – latter would include fixing of prices in excess of international mean of	For reason of emergency or national security

						the patented product.	
2nd Medical use						Specifically excluded	
Disclosure requirements Foreign filings and search & exam reports	May be requested.	May be requested.				May be required	May be requested.
Disclosure requirements (origin of material)	In draft biodiversity law although this has not apparently entered into effect.	No					
Best Mode		Yes	Yes			Apparently not.	
Multiple independent claims						Yes	
Grace Period	12 Months	12 Months	12 Months			12 Months	12 Months
Patents on parts of human body include gene sequences	Draft biodiversity law excludes patents on DNA	Not explicitly excluded although legislation provides morality exclusion- never enacted. Gene sequences patentable.		Genetic sequences patentable – unclear whether applies to human		Biological genetic material as existing in nature excluded.	Not specifically excluded
Patents on plants and animals	No	Yes but not as they occur in nature	Plant varieties and species, Animal Breeds and species excluded. Also biological material existing as in nature	Not Animals		Excluded	Not specifically excluded
General exceptions	Private and non-commercial and experimentation relating to subject matter.	Rights do not appear to extend to farm saved seed or livestock. First generation protection only.				Actions targeted to educational as well as scientific or academic research.	Experimental, scientific, academic or educational research for non-gainful purposes.
Research exceptions	See above.	Private and non commercial. Educational, scientific and academic investigation.	Rights extend only to commercial acts			Private and non commercial	Private and non commercial and non profit making purposes
Pharmaceutical products	Yes. Was previously 1 year now 20 years.	Yes	Yes	Yes		Yes as of 1 Nov 2001. Law also provides pipeline protection for pharmaceuticals	
Other TRIPS+							Have ratified WIPO Copyright Treaties.
MISCELLANEOUS							
Protection of	Not decided yet	Test data w.r.t new	Test data protected	Test data w.r.t new			Unclear whether

undisclosed information	however indication is that second user will be able to rely on previously submitted data.	chemical components protected for 15 years against use by anyone including other applicant.	against disclosure and unfair use although exceptions including in relation to protection of the public.	chemical components protected . Can not be supplied to second user. exceptions including in relation to protection of the public			second applicant can rely on previously submitted data.
Utility models						Yes	Yes
COPYRIGHT							
Fair use provisions including educational material		Yes as provided by Art 10 Berne	Yes.				Limited reproductive right for teaching use of short fragments of a work for educational purposes
Reverse engineering of software							
Other		Copyright protection of 75 years. Also database protection.	Copyright protection of 75 years. Also database	Copyright protection of 70 years. Also database			
PLANTS AND PLANT GENETIC RESOURCES							
Access legislation for genetic resources							
Plant Variety Legislation	Pending based on UPOV 91 however CR believes implementation not required before 2005	Plant varieties protected under modified patent system.	Pending based on UPOV 91	Yes			
Plant variety right exceptions		Farmers' right provided under patent law.					
Source of information	WTO notifications	WTO notifications	WTO notifications	WTO notifications	WTO notifications	WTO notifications	WTO Notifications
Laws	Law 6867 of 1983 as amended (2000)	IP law 57/2000	Decree 12-99E	Law 354 - 2000		Law 17.164	Decree 604 of 1993.

Table 7. South America and Caribbean Data 3

	Country							
	Trinidad & Tobago	**St Lucia**	**Barbados**	**Jamaica (legislation pending)**	**Suriname**	Antigua and Barbuda	Dominican Republic	Dominica
Membership of international or regional treaties/bodies								
WTO Member	1995	1995	1995	1995	1995	1995	1995	
Paris	1964	1995	1985	1999	1975	2000	1890	
Berne	1988	1993	1983	1994	1977	2000	1997	
UPOV (1978 or 1991 Act)	1995 (78)	---	---	---	---	---	---	---
WC Treaties						---	---	---
CBD	1996	1993	1993	1995	1996	1993	1996	1994
Member of regional body	CARICOM	CARICOM	CARICOM	CARICOM	CARICOM	---	UCC	---
PATENTS								
Patent Office	Yes	Yes	Yes – able to subcontract examination	Registrar of Companies	Yes			
Search & Examination	Yes (subcontract)		Yes – published at grant.		Office may rely on other reports or commission its own search and examination..			Examination.
Novelty	Absolute	Absolute	Absolute		Absolute	Absolute. Any disclosure written or oral in anywhere in the world.	Absolute. Any disclosure written or oral in anywhere in the world.	Absolute
Exhaustion regime	National		National		National	National	International	National
Early working (Bolar)	Not explicitly.		Not explicitly		Not explicitly allowed	Not explicitly	Yes[17]	Not specifically
Compulsory licensing	Yes – sufficiency only	Yes –sufficiency, unreasonable terms, dependent patent. Would appear to require local working other than food or medicines where importation equals local working.	Yes – national security, national health, national nutrition, for other public interests		Yes- insufficiently exploited.	Yes. Non or insufficient exploitation	Yes. Grounds unclear but might be broad eg failure to offer reasonable licences.	Public interest or to remedy anti competitive practice.

[17] Article 30(g)[exceptions] those uses which are necessary to obtain sanitary approval and to market a product after the patent protecting it has expired.

Government use	Yes with remuneration	Yes	Yes		Yes in public interest or to remedy anti-competitive practice.	In public interest and to remedy anti competitive practice		
2nd Medical use	Yes				Not specifically excluded		Exclude from patentability products or processes already patented, put to a use different from that contemplated in the initial patent	Specifically allowed[18]
Disclosure requirements Foreign filings and search & exam reports	Yes	No	Yes. Extensive information may be requested		If requested	May be requested		May be requested.
Disclosure requirements (origin of material)			Not explicit.			Apparently not.		
Best Mode	No		No		No			No
Multiple independent claims	Yes		Yes		Yes			Yes
Grace Period	12 months		12 Months		12 Months	12 months		12 months
Patents on parts of human body include gene sequences	Not specifically excluded	Not specifically excluded	Not specifically excluded.		Not specifically excluded	Not specifically excluded although may be covered by general morality clause.	Not specifically excluded although making known something already existing in nature is unpatentable.	Apparently allowed
Patents on plants and animals	Not specifically excluded.	Not specifically excluded	Not on animal or plant varieties	Plants and animals specifically excluded	Not specifically excluded	Plants and animals Specifically excluded as are also plant varieties.	Plants and animals excluded. Also any kind of living matter and substances pre-existing in nature	Allowed
General exceptions	Private and non commercial						Exclusively for purposes of teaching or scientific or	Experimental purposes only.

[18] Although methods of treatment are specifically excluded, Section 9(4) of Patent Act 1999 provides that in the case of an invention consisting of a substance or composition for use in a method of treatment of the human or animal body.., the fact that the substance forms part of the prior art shall not prevent the invention from being taken to be new if the use of the substance in any such method does not form part of the prior art.

							academic research;	
Research exceptions	Experimentation relating to the subject matter of the invention		For scientific research.		Experimentation relating to the subject matter of the invention.	Experimental purposes relating to the invention	Private and non commercial and also experimental use.	Experimental use only.
Pharmaceutical products	Yes	Yes	Yes	Yes		Yes	Yes	Apparently not.
MISCELLANEOUS								
Protection of undisclosed information		As TRIPS 39.3	As TRIPS 39.3	No specific protection available.	No protection currently available.	As Article 39. Second user prevented from relying on that data for period determined by Court but not normally less than 5 years.	Previously filed data can not be disclosed to the second applicant but would appear that second applicant can "rely" on that data.	No provisions.
Comments						All laws currently in draft		
COPYRIGHT								
Fair use provisions including educational material	Limited fair use providing single copies for personal use, reproduction of short parts and reprographic reproduction in isolated instances.	Limited fair use for educational purposes including reprographic copies but no more than 1% of a work/quarter.	Limited exceptions covering copying other than by a reproductive process.					50 year protection for software.
Reverse engineering of software	Adaptation allowed only for use of the program for the purposes intended.							
Berne exceptions for developing countries								Reproduction solely for face to face teaching purposes except certain works specifically produced for such purposes
Other			Provides for protection of					

			folklore originating in Barbados. Rights extend in perpetuity and allow crown to prevent importation of copies of folklore.					
PLANTS AND PLANT GENETIC RESOURCES								
Access legislation for genetic resources							Law on environmental and natural resources includes provisions on access.	
Plant Variety Legislation	1997 Act	Legislation Pending.	2001 Act – protection also to EDV	Legislation pending.			Yes. UPOV compatible.	Yes
Plant variety right exceptions	Rights extend to commercial production. Use to develop new varieties allowed.		Minister may provide for farm saved exception.					
Source of information	WTO notifications	WTO notifications	WTO Notifications	WTO notifications	WTO Notifications	WTO notifications	WTO notifications	WTO Notification.
Laws	Patents Act 1996 Copyright Act 1997 Plant varieties Act 1997	Patents Act 2001 Copyright Act 1995 as amended	Patents Act 1981 and Patents Bill 2001 Copyright Act 1998 Plant Breeders Bill 2001	Draft Patents and Designs Act 2001 Copyright Act 1993	Draft IP Legislation	Patents Bill 2001 Copyright Bill Unfair competition Bill	Patent Law 1911 as amended.	1999 Patents Act Draft Copyright Bill
Bilateral Agreements	EU-ACP US-T&T IPR Agreement 1994			US-Jamaica IPR Agreement 1994				