Chapter 7

Statutory provisions on IPR:

A journey from Paris to Marrakesh

Chapter 7

Statutory Provisions on IPR: A Journey from Paris to Marrakesh

Chapter 7

Statutory provisions on IPR: A journey from Paris to Marrakesh

---

The 'Patent' initially was issued by the King to his subjects, conferring certain rights and privileges on one or more persons in his kingdom. Later on inventions increased by leaps and bounds and the inventors and researchers became interested in securing their interest in their inventions. The industrial development of Europe led to overseas conquests. That in turn created a huge overseas market for new inventions but without financial returns to inventors and researchers. That was a cause of concern for these nations. For the first time, an International Convention on Intellectual Property was adopted in Paris in 1883 that covered all aspects of intellectual property sans copyright. The gap was filled by Berne Convention, 1886. In the recent past another convention for the establishment of World Intellectual Property Organisation (WIPO)[1] was signed in Stockholm in 1967. Further, GATT, 1947 was succeeded by WTO that came into being on the successful conclusion of the Uruguay Round in 1994 at Marrakesh, Morrocco. Twenty-eight multilateral agreements were signed by 124 member countries. TRIPs is one of them.

The last few years have seen a range of significant developments related to Intellectual Property Rights (IPRs) and biodiversity. At

---

[1] *WIPO is United Nations' specialized agency for intergovernmental co-operation in industrial property It carries out programmes in the field of intellectual property, for its protection and transfer of technology to developing countries*

least two major international agreements, both legally binding, deal with this issue: the Convention on Biological Diversity (CBD) and the Agreement on TRIPs of the WTO. In addition, the WIPO and other international institutions are increasingly becoming active on the subject.

At national levels, too, several countries (Costa Rica, Fiji, India, Mexico, Peru, Philippines) are coming up with legislation, or other measures, which respond to these treaties or deal with the issue of IPRs and biodiversity. Of particular interest to many countries, especially in the 'developing' world, are the following:

- Protecting indigenous knowledge from being "pirated" and used in IPR claims by industrial/commercial interests;

- Regulating access to biological resources so that historical "theft" of these resources by the more powerful sections of the global society can be stopped and communities/countries are able to gain control and benefits from their use.

These issues relate not just to IPR regimes but also to the new provisions of Access and Benefit-sharing which the CBD contains, and which are being followed up by several countries with appropriate domestic legislation.

Propelling the spurt in activity on this front are the IPR-related scandals that periodically shock the world, such as:

- The patenting of ancient herbal remedies, e.g. patent given to the healing properties of turmeric[2], known for centuries to Indians; or the patent on the sacred 'ayahuasca' plant, used for medicinal purposes by Amazon's indigenous peoples[3];

- The patenting of crop varieties which are similar to those grown for centuries in certain geographical areas, e.g. for varieties of Basmati rice by Rice-Tec Corporation in the US[4]; Rice-Tec even uses the term Basmati, long used to refer to aromatic rice grown in northern India and Pakistan, to describe its rice varieties;

- The patenting of human genetic material, e.g. on the human cell line of a Hagahai tribesman from Papua New Guinea[5];

- Specific varieties or breeds, e.g. on all transgenic cotton or soybean granted to the company Agracetus; and

- Patents on technologies that threaten farming systems worldwide, such as a US Patent granted for the Terminator Technology[6] for its potential of stopping plant regeneration after the first generation.

With the extension of the scope of IPRs, living things, including plants, animals and human beings fell under the scope of 'Patentability'. This forced the governments, specifically of

---

[2] *US Patent no 5401504 dt March 28, 1995 to Uni Of Mississippi Medical Centre*
[3] *US Patent no 5751 dt Sep 5, 1848*
[4] *US Patent no 5663484 dt. Sep 2, 1997 to Ricetec Inc*
[5] *US Patent No 5397696 dt March 14, 1995 to Health Dept of US*
[6] *US Patent no 5723765 dt March 3, 1998 to Delta & Pine Land Co , USA*

developing countries, which are rich in biodiversity to look afresh into the provisions of various international agreements related to intellectual property rights and biodiversity and to amend their local legislations to protect the overall interests of humankind. But unfortunately the interests of a handful of MNCs of the West got priority over the overall interests of humankind. 'Profit' presided over 'People'. This chapter is a modest attempt to discuss the various international agreements and local legislations and their impact on biodiversity. India, being a rich source of biodiversity and hence the most affected country, had to enact various legislations and to amend certain provisions related to IPRs, either to protect its own interests or under the pressure of WTO. The Biodiversity Act, 2002, Protection of Plant Varieties and Farmers' Rights, The Patent Amendment Act, are a few of them.

7.1 GATT, The Uruguay Round and the Dunkel Draft

In the early 1960s, the United States passed a law granting plant breeders the rights to patent seeds, thus preventing others from selling the same variety. Having made billions of dollars on seeds developed by farmers in other lands, seed companies are now taking the final step to ensure a never-ending source of revenue. They are trying to force all countries to recognize patents on seeds through a set of trade accords called the General Agreement on Tariffs and Trade. If they succeed, farmers will be forced to pay royalties to companies who hold patents on the genetic material they or their ancestors helped to shape.

In 1948, the General Agreement on Tariffs and Trade (GATT) was established as a multi-lateral treaty. The Uruguay Round of Multilateral Trade Negotiations (MTN) is the eighth in a series conducted in 1986, under the auspices of the GATT. A Trade Negotiations Committee was set up to monitor the overall negotiations. The then Director General of GATT, Arthur Dunkel was made the chairman of this committee at the official level. The Dunkel Draft is the outcome of this Round and is considered a global package of treaties to cover all sectors of economy. The negotiations included new areas like Trade Related Aspects of Intellectual Property Rights (TRIPs), Trade Related Investment Measures (TRIMs) etc.

The Dunkel Draft took the first step towards patenting of life forms through allowing the patentability of micro-organisms. For the time being it was decided that the essentially biological processes for the protection of plants or animals be excluded from patentability. The Indian Patents Act too excludes the essentially biological processes from patentability. The Dunkel Draft also required parties to provide protection to plant varieties, either with the help of patents or through an effective *'sui generis'* system or a combination thereof. Many developing countries, including India, do not offer such protection because it has grave implications for their agricultural sector; it facilitates the entry of transnational capital into that sector and the domination of that sector by such capital. The introduction of IPRs in the field of agriculture would, among other things, allow multinational corporations to monopolise seed trade, increase

seed prices, restrict the free flow of germplasm, introduce delays in the availability of new variety, and affect our capability to adapt them to local conditions.[7]

The Dunkel Draft proposed an extension of the fields of activity, to cover selected forms of life, which were hitherto not considered patentable by most countries. The TRIPs draft text mentions that plant variety protection or plant patents should be given. Again many developing countries do not give this sort of protection. This was an attempt to extend International Convention on Protection of New Varieties of Plants (UPOV Convention) to all countries. Article 27.3 of the TRIPs agreement stipulates that patents should be given to micro-organisms. This was the first step towards patenting life. For the time being, biotechnological inventions were excluded from patentability. This provision, according to the Dunkel Draft, was to be reviewed four years after the entry of the proposed agreement.

7.2 Trade-Related Aspects of Intellectual Property Rights (TRIPs) :

Trade-Related Aspects of Intellectual Property Rights (TRIPs) is a product of the last round of GATT negotiations, which took eight years to conclude (1986-1994). IPRs were an entirely new item on that negotiating agenda. It was the United States that argued for its inclusion under pressure from the pharmaceutical

[7] *Dhar Biswajit and Rao Niranjan C - 'The Dunkel Draft on TRIPs An assessment'*

industry, representatives of which drafted the basic language for discussion. The developing countries fought against the introduction of IPRs into the world trade talks. They argued that different economies need different tools to stimulate innovation and that imposing uniform rules to protect monopoly rights in the form of IPRs would benefit foreign multinationals more than their own industries. By reason or by coercion, the US won and TRIPs became the third pillar of the world trade regime along with the goods and services.

The whole matter of IPRs over life forms was particularly controversial. The US wanted full patent protection for all fields of technology but the Europeans prohibit patents on plant and animal varieties and essentially biological processes for the production of plants and animals, under the European Patent Convention (EPC). A compromise was reached: TRIPs would use the language of European law as a starting point. That language is embodied now in TRIPs article 27.3(b) under the proviso that countries would review the provision four years after the coming into force of the agreement i.e. in 1999.

The TRIPs agreement is one of the pillars of the global trade regime which is enforced through the World Trade Organisation (WTO). TRIPs defines minimum standards of protection of Intellectual Property Rights (IPR) in the 135 WTO member states. Section 5, devoted to patents, states that inventions in every field of technology should be patentable. This includes life forms.

The agreement covers five broad issues:

- How basic principles of the trading system and other international intellectual property agreements should be applied

- How to give adequate protection to Intellectual Property Rights

- How countries should enforce those rights adequately in their own territories

- How to settle disputes on intellectual property between members of the WTO

- Special transitional arrangements during the period when the new system is being introduced

The second part of the TRIPs agreement looks at different kinds of Intellectual Property Rights and how to protect them. The purpose is to ensure that adequate standards of protection exist in all member countries. Here the starting point is the obligations of the main international agreements of the WIPO that already existed before the WTO was created:

- The Paris Convention for the Protection of Industrial Property (patents, industrial designs, etc)

- The Berne Convention for the protection of Literary and Artistic Works (copyright).

The TRIPs Agreement requires Member countries to make patents available for any inventions, whether products or processes, in all fields of technology without discrimination,

subject to the normal tests of novelty, inventiveness and industrial applicability. It is also required that patents be available and patent rights enjoyable without discrimination as to the place of invention and whether products are imported or locally produced[8].

There are three permissible exceptions to the basic rule on patentability. One is for inventions contrary to *ordre public* or morality; this explicitly includes inventions dangerous to human, animal or plant life or health or seriously prejudicial to the environment. The use of this exception is subject to the condition that the commercial exploitation of the invention must also be prevented and this prevention must be necessary for the protection of *ordre public* or morality[9].

The second exception is that Members may exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals[10].

The third is that Members may exclude plants and animals other than micro-organisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, any country excluding plant varieties from patent protection must provide an effective *'sui generis'* system of protection. Moreover, the whole provision is

[8] *Article 27 1 of Trade Related Aspects of Intellectual Property Rights (TRIPs)*
[9] *Article 27 2, ibid*
[10] *Article 27 3(a), ibid*

subject to review four years after entry into force of the Agreement[11].

The exclusive rights that must be conferred by a product patent are the ones of making, using, offering for sale, selling, and importing for these purposes. Process patent protection must give rights not only over use of the process but also over products obtained directly by the process. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts[12].

Member countries 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[13].

Thus the agreement describes the minimum rights that a patent owner must enjoy. But it also allows certain exceptions. A patent owner could abuse his rights, for example by failing to supply the product on the market. To deal with that possibility, the agreement says governments can issue "compulsory licences", allowing a competitor to produce the product or use the process under licence. But this can only be done under certain

[11] *Article 27 3(b) of TRIPs*
[12] *Article 28, ibid*
[13] *Article 30, ibid*

conditions aimed at safeguarding the legitimate interests of the patent-holder.

If a patent is issued for a production process, then the rights must extend to the product directly obtained from the process. Under certain conditions alleged infringers may be ordered by a court to prove that they have not used the patented process.

The term of protection available shall not end before the expiration of a period of 20 years counted from the filing date[14].

An issue that has arisen recently is how to ensure that patent protection for pharmaceutical products does not prevent people in poor countries from having access to medicines — while at the same time maintaining the patent system's role in providing incentives for research and development into new medicines. Flexibilities such as compulsory licensing are written into the TRIPs Agreement, but some governments were unsure of how these would be interpreted, and how far their right to use them would be respected.

A large part of this was settled when WTO ministers issued a special declaration at the Doha Ministerial Conference in November 2001. They agreed that the TRIPs Agreement does not and should not prevent members from taking measures to protect public health. They underscored countries' ability to use

[14] *Article 33 of TRIPs*

the flexibilities that are built into the TRIPs Agreement. And they agreed to extend exemptions on pharmaceutical patent protection for least-developed countries until 2016. On one remaining question, they assigned further work to the TRIPs Council — to sort out how to provide extra flexibility, so that countries unable to produce pharmaceuticals domestically can import patented drugs made under compulsory licensing. A waiver providing this flexibility was agreed on 30 August 2003.

7.3 Transition arrangements under TRIPs

When the WTO agreements took effect on 1 January 1995, developed countries were given one year to ensure that their laws and practices conform with the TRIPs agreement. Developing countries and (under certain conditions) transition economies were given five years, until 2000. Least-developed countries have 11 years (earlier 10 years), until 2006 — now extended to 2013 for pharmaceutical patents.

If a developing country did not provide product patent protection in a particular area of technology when the TRIPs Agreement came into force (1 January 1995), it had up to 10 years to introduce the protection (this is now increased to 11 years). But for pharmaceutical and agricultural chemical products, the country had to accept the filing of patent applications from the beginning of the transitional period, though the patent did not need to be granted until the end of this period. If the government allowed the relevant pharmaceutical or agricultural chemical to be marketed during the transition period, it had to — subject to

certain conditions — provide an exclusive marketing right for the product for five years, or until a product patent was granted, whichever was shorter.

Subject to certain exceptions, the general rule is that obligations in the agreement apply to intellectual property rights that existed at the end of a country's transition period as well as to new ones.

7.4 Problems embedded in Art 27.3(b)

There is a broad consensus that TRIPs in its present form is unacceptable because it violates the fundamental rights of people. There is much that is wrong with TRIPs. It goes against all the rights and opportunities that have been granted to local communities in the CBD and it strikes at their ability to engage in sustainable development in a self reliant way. In short,

- The TRIPs Agreement hinders the preservation of and respect for the knowledge, innovations and practices of indigenous and local communities.
- The TRIPs Agreement hinders access to and the fair and equitable sharing of benefits arising from the utilisation of genetic resources. It enables biopiracy since it does not require disclosure of the source of biological materials which are sought to be patented.
- The TRIPs Agreement creates conditions that will hinder the transfer of technology to developing countries.
- The TRIPs Agreement is likely to be detrimental to the conservation and sustainable use of biological diversity.

There are extraordinary problems with Art. 27.3(b) of the TRIPs agreement:

- No parameters for what a *"sui generis"* system can amount to.
- No parameters for what is 'effective'.
- Many WTO members have expressed their view that genes and microbiological processes are not inventions and therefore are not patentable subject matter.
- With its lack of any benefit-sharing mechanism, TRIPs offers no remedy for the ongoing wave of bio-piracy and is perceived as exacerbating the problem.
- There is a bias ingrained in TRIPs to protect breeders and biotechnologists at the expense of farmers and local communities.
- Many countries perceive a conflict between TRIPs and the rights and obligations countries previously acquired under the CBD.
- Plant variety laws inspired by the Union for the Protection of New Varieties of Plants (UPOV) have no positive impact on food security, which is a matter that the TRIPs Council has not looked into.

7.5 1999 Review of Article 27.3(b) of TRIPs

Developing countries had positive hopes for the 1999 review of 27.3(b). The exercise was taking place one year before they were obliged to implement the provisions. This was important

because the provision itself was the source of tremendous uncertainty in the South.

Many people hoped that TRIPs could be clarified through the review and, if possible, amended to better suit the development interest of the South, particularly since Third World countries were hardly heard during the GATT negotiation itself.

The review of Article 27.3(b) began in 1999 as required by the TRIPs Agreement. During the review session in July 1999, India presented a paper outlining its basic analysis of Article 27.3(b) and the problems posed to developing countries. According to India, there are two dimensions to deal with: the need to reexamine whether patenting life is acceptable in terms of ethics; and the need to recognize not only formal systems of innovation but informal systems as well, especially with regard to biodiversity. In particular, India insisted on the need to reconcile TRIPs with the CBD. The developing countries supported India. The developed countries evaded India. Malaysia took the discussion a step further by asking the Secretariat to prepare a list of *'sui generis'* options outside of UPOV.

The topics raised in the TRIPs Council's discussions include:

- How to apply the existing TRIPs provisions on the issue whether to patent plants and animals or not, and whether they need to be modified
- The meaning of effective protection for new plant varieties (i.e. alternatives to patenting such as the 1978 and

1991 versions of UPOV). This has included the flexibility that should be available, for example to allow traditional farmers to continue to save and exchange seeds that they have harvested

- How to handle moral and ethical issues, e.g. to what extent invented life forms should be eligible for protection
- How to deal with the commercial use of traditional knowledge and genetic material by those other than the communities or countries where these originate, especially when these are the subject of patent applications
- How to ensure that the TRIPs Agreement and the CBD support each other

7.6 The Doha Mandate

The 2001 Doha Declaration made it clear that work in the TRIPs Council under the reviews (Article 27.3(b) or the whole of the TRIPs Agreement under Article 71.1) and on outstanding implementation issues should cover: the relationship between the TRIPs Agreement and the CBD; the protection of Traditional Knowledge and folklore; and other relevant new developments that member governments raise in the review of the TRIPs Agreement.

It adds that the TRIPs Council's work on these topics is to be guided by the TRIPs Agreement's objectives[15] and principles[16],

[15] *Article 7 of TRIPs*
[16] *Article 8, ibid*

and must take development issues fully into account. However, no conclusion has been arrived at for the protection of Traditional Knowledge and folklore till date and Article 27.3(b) is still the most controversial part of TRIPs.

7.7 The debate

The discussion in the TRIPs Council has gone into considerable detail with a number of ideas and proposals for dealing with these complex subjects.

- Disclosure as a TRIPs obligation: A group represented by Brazil and India and including Bolivia, Colombia, Cuba, Dominican Republic, Ecuador, Peru, Thailand, and supported by the African group and some other developing countries, wants to amend the TRIPs Agreement so that patent applicants are required to disclose the country of origin of genetic resources and traditional knowledge used in the inventions, evidence that they received "prior informed consent" (a term used in the Biological Diversity Convention), and evidence of "fair and equitable" benefit sharing.
- Disclosure through WIPO: Switzerland has proposed an amendment to the regulations of WIPO's Patent Cooperation Treaty (and, by reference, WIPO's Patent Law Treaty) so that domestic laws may ask inventors to disclose the source of genetic resources and traditional knowledge when they apply for patents. Failure to meet the requirement could hold up a patent being granted or,

when done with fraudulent intent, could entail a granted patent being invalidated.

- Disclosure, but outside patent law: The position of the European Union (EU) includes a proposal to examine a requirement that all patent applicants disclose the source or origin of genetic material, with legal consequences of not meeting this requirement lying outside the scope of patent law.
- Use of national legislation, including contracts rather than a disclosure obligation: The United States has argued that the Convention on Biological Diversity's objectives on access to genetic resources, and on benefit sharing, could best be achieved through national legislation and contractual arrangements based on the legislation, which could include commitments on disclosing of any commercial application of genetic resources or traditional knowledge.

The review process so far has generated no clarifications, no responses to precise proposals from the South, great delays in getting down to the substance of the discussion and general confusion at present about obligations and opportunities. The vast majority of developing countries which are members of WTO have been approaching their obligation to grant intellectual property rights over plant varieties through an effective *'sui generis'* system and not through patenting. The deadline to have such legislation in place was 1st January, 2000 for developing countries. Despite the threat of possible trade sanctions,

however, just a few managed to adopt such legislation. This does not mean that the countries are inactive on the legislative front. Many of them are in the process of drafting; others have final drafts under scrutiny by their national assemblies or are awaiting ministerial or cabinet approval for submission to parliament.

This review was slow in starting and has been languishing for years – with a clear North-South divide producing interesting discussions but no progress. One bold move came at the beginning of the review from the Africa Group, which said that all patenting of living matter should be banned worldwide under TRIPs, and that any regime for plant varieties should protect the rights of farmers and local communities. Another bold move came from the United States, which proposed that no kind of inventions at all should be excluded from patenting, not even plants and animals. Along these lines a stalemate soon resulted.

7.8 The African Model Law

Most of the member states of the Organisation of African Unity (OAU) (*The OAU has officially changed its name now to the African Union)* were deeply engaged in a process to develop national legislation based on a regional model law that was only finalized in November 2000.[17] The OAU model law covers not only breeders' rights but also farmers' rights, benefit-sharing and rules on access to genetic resources. The model law aims to

[17] *Source Genetic Resources Action International (GRAIN) June 2001*

balance the rights of farmers, plant breeders and local communities based on the explicit recognition that in Africa all parties have an important role to play in the conservation, improvement and sustainable use of biodiversity.

The model law has four components:

Access to biological resources-

Requires a permit and the prior informed consent of communities; payment of collecting fee; sharing of benefits from commercial products; etc.

Community Rights-

Inalienable and collective rights to: control access to resources and knowledge; partake 50% of any benefits handed to the government under the access regime; properly exercise their own intellectual rights; etc.

Farmers' Rights-

Protection for farmers' breeds and seeds according to criteria based on customary practices; the right to save, use, multiply and sell seeds, with the limitation that sale of material owned by a breeder should not be on a commercial scale; etc.

Plant Breeders' Rights-

Intellectual property over new varieties that are distinct, stable and sufficiently homogenous or a multiline; the exclusive right to sell and produce such varieties, etc.

Some of the crucial features of the model law are:

- Breeders' rights are subordinate to farmers' rights
- The law prohibits patent protection on any life form
- Strong support to the role of women

WIPO, in a four-page submission to the OAU, used a professorial and technical approach to clamp down on some of the core issues that the model law addresses. It also pinpoints numerous deficiencies in terms of how the model law scopes out the definition and operationality of community rights. Rather than helping to make these rights really work in the context of rural Africa, WIPO's solution is to make them fit into global IPR conventions.

If WIPO's contribution to the furtherance of the OAU process was misdirected and counter-productive, UPOV's input consisted of an iron-fisted bash on the whole initiative. UPOV officials even reworked more than 30 articles of the model law to suit the standards of their own convention! The whole problem with UPOV's approach to the model law is that it clearly considers its own convention to provide the one and only model for implementation of TRIPs.

7.9 TRIPs – Ethical, Social and Economical issues

Many religious and cultural traditions regard the extension of patents to living organisms as intrinsically wrong. Patenting of life forms "marks a significant further step in the larger process

of the commodification of life" and the "reduction of the value of life and nature to the merely economic". In particular, many groups worldwide are concerned that patents underpin developments in genetic engineering that risk disturbing a complex pattern of inter-relationships in the natural world that we still only partially understand.

Many opponents of patenting on life forms see this as an inappropriate extension of private ownership rights to resources that should be or were previously held in common. Western IP regimes, as an extension of an individualistic culture, generally make no allowances for the protection of communal rights and intergenerational innovation that are the hallmark of many developing country cultural traditions.

Another concern about patents on life forms is their effects on the flow of breeding materials- animals and plant germplasm. There is evidence that the strengthening of IPRs is leading to restrictions on the flow of germplasm (breeding materials) and so inhibiting the development of new plant varieties, particularly by the publicly funded institutions such as those supported internationally by the Consultative Group on International Agricultural Research (CGIAR). The seed industry itself is concerned about the reduced flow of germplasm.

In many cases governments have moved away from near-market research, which has immediate applicability on farms, to focus spending on basic research which underpins private R&D efforts.

In some countries resources have shifted into areas supporting agri-business and food processing which may have reduced rather than increased the rate of return to public sector research.[18]

The private sector naturally, invests in areas where it can hope for a return – with much work in agrochemicals over the years. Today, former agrochemical companies have expanded to become biotechnology/seed companies (or life-science companies including pharmaceuticals) moving downstream to add value to their products. This private proprietary science will focus on crops and innovations that will find rich markets and ignore those of interest to poor, small farmers.[19]

There are also fears that patents and Plant Variety Protection (PVP) will facilitate the commercialization of farming along the lines of farming systems in the industrialized countries and so rapidly undermine the whole base of small scale mixed subsistence and local market based product systems. If R&D produces varieties and methods most suitable for medium and large scale farmers, rather than products and methods geared to the needs of small farmers, many small farmers will be squeezed out. Such a result would probably greatly increase population movements to urban centres.

---

[18] *Alston, Pardey & Smith, FAO 1998*
[19] *Newsweek August 24, 1998*

7.10 TRIPs and its effect on Health Sector

Intellectual Property is fundamental to western notions of creativity and prosperity, and few would argue with its importance in the economics of the developed world. For some industries like pharmaceuticals, for example, IP protection is essential. But hotly debated is how well the IP system works in poor countries, where millions of people are dying of life-threatening diseases such as AIDS because they cannot afford the latest patented drugs.

Until the adoption of the TRIPs by the WTO, few poor countries had Intellectual Property laws, and countries like Thailand and India had spawned thriving generic drugs industries. Under the TRIPs rules, all WTO members must change their laws to conform to the strict American IP regimes (which extend patent rights for at least 20 years from the date the patent application was filed) – patent provisions the American pharmaceuticals industry was extremely influential in drawing up for the WTO.

It is debatable whether IP protection contributes to the research and development of drugs and vaccines that are of particular relevance to the third world, or whether developing countries can benefit from the TRIPs rules.

The HIV/AIDS epidemic is a classic example. The Joint United Nations Programme on HIV/AIDS recently estimated that a total of 42 million people are infected with HIV/AIDS, 95% of whom

live in developing countries. Existing treatments, which enable many people with HIV/AIDS in the US and other developed countries to live relatively healthy lives, cost about $12,000 a year and are unavailable to all but a relatively few people in Africa.[20]

Drug companies argue that if they can't get protection in poor countries for their inventions, then there is no incentive to research remedies for the diseases plaguing poor countries. However, the brutal facts of the market indicate there is little incentive anyway. These countries are not rich enough to buy the new remedies – the Southern African News Features reported that the entire combined purchasing power of South Asia and sub-Saharan Africa's health budgets is the same as the pharmaceutical drugs market in the United States just for the 15 million people who suffer from heart failure and angina.[21]

The Commission on Intellectual Property Rights (CIPR), set up by the British government to look into the issue of IP rights and the developing world, produced a study that strongly challenged one of the original arguments drug companies used in support of strong IP – that the lack of protection in poor countries would harm research and development. It is estimated that less than 5% of the money spent worldwide on pharmaceutical R&D is for diseases that predominantly affect developing countries.[22]

---

[20] *UN website on AIDS*
[21] *South African News Features website*
[22] *www iprcommission org*

Private industry is essential for pharmaceutical innovation, the report said, but industry research is driven by commercial considerations. If the effective demand in terms of market size is relatively small, even for common diseases such as tuberculosis and malaria, it is often not commercially worthwhile to devote significant resources to addressing the needs. Usually the large pharmaceutical companies are unwilling to pursue a line of research unless the potential outcome is a product with annual sales on the order of $1 billion.[23]

In 2002, the Commission report said, the total world drug market is valued at $406 billion, of which the developing world accounts for 20%.

"In short we do not think that the globalisation of IP protection will make a significant contribution to increasing R&D expenditure by the private sector relevant to the treatment of diseases that particularly affect developing countries. The only feasible way to do this is by increasing the quantity of international aid resources devoted to such R&D," the Commission's report said.

IP protection in poor countries would therefore seem of little value to the drug companies. But it comes into play anyway because of competition from generic industries in somewhat more advanced developing countries such as India and Brazil. By applying IP protection, drug companies can stop these countries

[23] *www iprcommission org*

from exporting cheap generic copies of patented medicines to the least developed countries such as Gabon and Senegal that have insufficient or no drug-manufacturing capacity at all.

It's generally agreed that the present TRIPs agreement favors commercial pharmaceutical companies, particularly in the United States, Japan, Switzerland, Germany and the United Kingdom; while for poor countries, it would bring few benefits.

In response to concerns like this, the WTO Ministerial Declaration on TRIPs and Public Health was thrashed out at a WTO meeting in Qatar. It was an effort among developing countries to clarify that TRIPs should not prevent member nations from taking measures to protect public health. Though it isn't a relaxation of the agreement, the message was that TRIPs is not always appropriate and that poor countries should be allowed to set up levels of IP protection that are right for them. Different countries should tailor their IP system to fit their particular circumstances, in line with their levels of scientific and technological development. Applied in the right way and at the right moment in development, IP protection should offer opportunities to poor people, not a threat to their health.

The South African Parliament passed the Medicines and Related Substances Control (Amendment) Act in 1997 that allows compulsory licensing and parallel importing of AIDS drugs and other drugs. Faced with 4.7 million South Africans suffering from AIDS and higher prices of drugs, this Act was meant to

make available drugs at affordable prices to them. This was opposed by the Pharmaceutical Manufacturers' Association of South Africa (PMASA), a body representing South African subsidiaries of 39 drug Transnational Corporations' (TNCs) association. The South African Government defended the Act on the ground that providing equal access to health care (which also means affordable drugs) is a constitutional obligation. Further, the government announced that it would use the provisions of this Act as per the rules of WTO.

The drug TNCs dropped the lawsuit unconditionally not because of a sudden change of heart or altruistic feelings towards the poor South Africans but because of a sustained campaign by a number of health activists and groups. They were successful in spreading the message across the world that drug TNCs have been putting profits before poor people's lives.

The drug TNCs opposed the Act tooth and nail on the grounds that it violates the TRIPs under the WTO agreement. But this position taken by the drug TNCs is erroneous because there are provisions within the TRIPs that allow governments to take special measures to protect the health of their citizens. Both compulsory licensing and parallel imports are allowed under the TRIPs. But the TNCs were apprehensive that if the South African law is allowed to retain its stand, other countries may be encouraged to enact similar legislation.

However, some middle-income developing countries, such as India and China, with their industrial-scale copying of other people's products, are sufficiently advanced to benefit from the sort of innovation that would be spurred by stronger patent protections. They should implement the IP protection required by TRIPs, for the sake of their own industry. But for the least developed countries, where life-threatening disease - not just AIDS, but malaria, TB and other scourges - are rampant, there have to be ways to bypass patents. These countries should be allowed to make cheap generic versions of patented drugs themselves.

7.11 The Convention on Biological Diversity – CBD

On 29th December, 1993, there came into force an international treaty of far reaching significance for the future of humanity's troubled relationship with the earth: The Convention on Biological Diversity.[24] As befits any treaty on biodiversity, a considerable part of the CBD is devoted to issues of conservation and linked up to these are aspects of sustainable use. For the first time in human history, an agreement has been reached to conserve the entire range of biodiversity. The convention recognizes, however, that it may not be possible to conserve everything; it therefore calls for identification and monitoring of important biodiversity components and activities that have negative effects on them. It lays stress on *in situ* conservation through protected areas, action against factors destroying

[24] *Source Conserving life Implications of the Biodiversity Convention for India, Kalpvriksha, 1994*

biodiversity, restoration of habitats and species and control of alien species. It also calls for the adoption of *ex situ* conservation measures.

The Convention contains about 40 Articles. The substantial parts, Articles 5 to 17, deal with various aspects of biodiversity: identification and monitoring, conservation in natural or human-modified surroundings, rational or substantial use, creation of awareness, impact assessments of activities likely to affect biodiversity, access to genetic material, safeguarding of relevant traditional knowledge and practices, sharing of benefits of biological resource use and exchange of information and technology between countries. Indeed, what makes this treaty especially significant is that it goes far beyond the scientific aspects of biodiversity conservation into the realm of national and international politics.

Three broad thrusts permeate the Convention:

- The conservation of biological diversity
- The sustainable use of biological resources and
- The equitable sharing of the benefits of such use

The legally binding CBD's aims are "the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies"[25].

[25] *Article 1 of Convention on Biological Diversity(CBD), 1993*

The Convention:

- Recognizes the sovereign rights of states over their biological and genetic resources[26]
- Stipulates that access to genetic resources can only occur on mutually agreed terms and with the 'prior and informed consent' of states, unless states have otherwise determined[27], but these rules do not apply to seed in gene banks collected prior to the date when the CBD came into force. Such *ex situ* collections are dealt with in International Undertaking on Plant Genetic Resources [for food and agriculture] (IU).
- Requires signatories to protect and promote the rights of communities, farmers and indigenous people vis-à-vis their customary use of biological resources and knowledge systems[28].
- Requires each party to endeavour to facilitate access by other parties for environmentally sound use[29].
- Requires transfer to be on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights[30] and aims to enable developing countries, which provide genetic resources, to have access to technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights[31].

---

[26] *Article 3 and Article 15 of CBD*
[27] *Article 15 5, ibid*
[28] *Article 8 (j) and Article 10, ibid*
[29] *Article 15 2, ibid*
[30] *Article 16 2, ibid*
[31] *Article 16 3, ibid*

- Requires the equitable sharing of benefits arising from the commercial use of communities' biological resources and local knowledge[32].
- Asserts that intellectual property rights must be supportive of and not run counter to the objectives of the CBD[33].

The Conference of the Parties (COP) to the CBD recognized "the special nature of biological diversity, its distinctive features and problems needing distinctive solutions" and supported the renegotiation of the International Undertaking on Plant Genetic Resources (IU) at Food and Agriculture Organisation of the United Nations (FAO). Like the TRIPs agreement, there are ambiguous or unclear elements in the CBD that make interpretation difficult.[34]

The Convention gives a glimmer of hope of reversing the trend towards patenting life forms and biotechnologies. In 1995, the parties to the Convention agreed to study the relationship between IPRs and biodiversity, and between the CBD and GATT. An overall attempt to be made to revoke clause 3(b) of Section 5 of the Dunkel Draft, on the patentability of plants, by using Article 22(1) of the Convention, which implies that other international agreements can be called to question if they involve " serious damage or threat to biological diversity."

---

[32] *Article 15 7, of CBD*
[33] *Article 16 5, ibid*
[34] *GAIA Foundation/Grain, "TRIPs v CBD" and CBD legal texts*

Indeed the Biodiversity Convention could become one of the South's few effective weapons against the increasingly monopolistic and north-dominated international trade regime being currently propagated, a regime which economically indebted nations like India are finding hard to resist. The South's biological resources are its great assets and can be used as a bargaining lever in a world that is otherwise so heavily stacked against it. But to do this will require an unprecedented show of solidarity among the gene-rich nations of the world.

Indian Perspective

The CBD evolved as a popular, global response to the pressure of US multinationals for 'access' to all the world's biological resources. The objective, therefore, was to conserve India's biodiversity and to protect people's (local communities) sovereign right to these resources and knowledge thereof and to give them the lion's share of the 'benefits' arising from the use of these resources. That was the objective of the CBD. That also has to be the raison d'etre and the purport of any new legislation in India, on the issue of protection, conservation and use of the country's rich biodiversity.

On December 11, 2002 India passed the Biodiversity Bill, which came into force after receiving an assent from the President of India and is known as Biodiversity Related Community Intellectual Rights Act. The Act provides for conservation of biological diversity, sustainable use of its components and equitable sharing of the benefits arising out of the use of

biological resources. For the regulation of biological diversity, a 'National Biodiversity Authority' has been established under the Act. The Biological Related Community Intellectual Rights Act expressly prohibits any person, who does not have the previous approval of the National Biodiversity Authority, from (i) obtaining any biological resource occurring in India or related knowledge for research or for commercial utilization or for bio-survey and bio-utilization (ii) transferring the results of any research relating to any biological resources occurring or obtained from India for monetary consideration or otherwise to any person or organization which is not Indian or which has any non-Indian participation in its share capital or management (iii) applying for any intellectual property right by whatever name, for any invention based on any research or information on a biological resource obtained from India, before making such application.

7.12 Union for the Protection of New Varieties of Plants (UPOV)

The International Union for the Protection of New Varieties of Plants (UPOV) is an intergovernmental organization with headquarters in Geneva (Switzerland). UPOV was established by the International Convention for the Protection of New Varieties of Plants under the umbrella of the World Intellectual Property Organization (WIPO). The Convention was adopted in Paris in 1961 and it was revised in 1972, 1978 and 1991. The objective of the Convention is the protection of new varieties of plants by an Intellectual Property Right. The system actually does nothing to

protect plant varieties. Instead, it gives patent-like rights to plant breeders, protecting them and their market shares. It gives plant breeders a legal monopoly over seeds and allows them to collect bigger profits from genetic innovations. By its very nature UPOV is intended to preserve and enlarge the interest of multinational seed corporations and the scientists/plant breeders who work for them.

UPOV has the scope and potential to restrict the age-old traditional right of the farmer to "plant back seeds". Restricting this right will be disastrous since 75% of the Indian farming community saves seeds to replant. UPOV openly declares that concern of farmers' rights is the business of Food and Agricultural Organization (FAO) and not of UPOV. Its logic is simple: The prey does not seek redress from the hunter.

The WTO TRIPs Agreement obliges all members to provide intellectual property protection for plant varieties at the national level, either through patents or "an effective *'sui generis'* system" or both (Art. 27.3b). Few countries have laws that explicitly provide for patents on plant varieties, while others permit it in practice. As patents block anyone but the patent-holder from not only making and selling but also using an invention, the patenting of plant varieties would severely affect plant breeding and agriculture at large.

TRIPs does not define "effective *'sui generis'* system" – the other option – for protection of plant varieties. Industrialised countries had the UPOV system in mind when TRIPs was drafted, but UPOV is not mentioned in the Agreement. This means that the jury is out on what is to be considered an "effective" system under TRIPs. The UPOV Convention is an international agreement that sets rules for patent-like monopoly rights over crop varieties. It is highly biased toward industrial farming conditions and the bulk of UPOV's members are rich countries of the North.

Developing country members of WTO – there are 69 – were supposed to have implemented Art. 27.3(b) of TRIPs by January 2000. Least-developed country members – there are 30 – had until January 2006 to implement it (which has been extended to 2016). And while a mandated review of the provisions of TRIPs Art. 27.3(b) is under way since 1999, it has not yet resulted in any concrete actions to change the Agreement, despite very clear proposals from the South on how to improve it.

Despite the threat of trade sanctions from unmet deadlines, less than half (43%) of the developing country members of WTO have implemented TRIPs Art. 27.3(b) at face value by enacting some form of plant variety protection law. This excludes the least-developed countries. Considered together, just a quarter of the WTO members from the South (26%) have PVP legislation in place.

Until recently, its membership was confined to industrialised countries. But in the last couple of years, there has been a flurry of countries falling into its net - some 44 including 14 from the South: The reason for this is WTO's controversial agreement on Trade- Related Aspects of Intellectual Property Rights (TRIPs), and in particular its Art. 27.3. This requires all member states to enforce intellectual property laws on micro-organisms and plant varieties. Micro-organisms must be patentable. Plant varieties must either be protected under patent laws, or an "effective *'sui generis'* system" or both. TRIPs provides no definition of what such a system is nor what would make it effective. Yet developing countries are obligated to put such systems in place by the end of this year - if they choose this as an alternative to patenting - and if they wish to avoid sanctions from other WTO members.

Country after country, the *'sui generis'* option in TRIPs is gradually being reduced to UPOV-type legislation. The main reason for this is direct pressure from industrialised countries to harmonise intellectual property laws worldwide – not only through global treaties, but also through regional and bilateral trade and investment agreements. This carries serious implications for sustainable agriculture and farmers' rights. Because accepting UPOV is the first step toward accepting full-fledged patents on life.

7.13 UPOV in India

Adopted at the Earth Conference (Rio, 1992), the CBD is a legally binding international environmental law. India has ratified the convention and therefore the CBD's provisions are binding on the country.

The CBD mandates that benefits arising from the utilization of knowledge and practices that are relevant for conservation and sustainable use of biological diversity should be equitably shared with the communities concerned — Article 8(j). This includes the contribution of the farming community to the critical foundational knowledge of agricultural biodiversity that led to development of new plant varieties.

Therefore, any patent regime or allied process relating to biological diversity, including agricultural biodiversity, should enlarge and promote the CBD objectives. UPOV represents just the opposite; it completely negates rights of the farming community.

It was in such a scenario and context that New Delhi was required under the TRIPs-WTO process to provide for protection of plant varieties either under an existing patent scheme like UPOV or under a *'sui generis'* system. As UPOV was in place and operational, the Government was initially inclined to joining it.

An alert civil society quickly pointed out the adverse impact of UPOV on the farming community if India were to join it. Instead, it emphasised the need to develop a *'sui generis'* system that would strive to balance the need for stimulation and incentives to research and development with the welfare of the farmers. It is in this context that various governments at the Centre during 1994-2001 tried hammering out a comprehensive legislation that would balance the needs and demands of breeders/scientists and farming communities. After a long gestation period the Protection of Plant Variety and Farmer's Rights Act (PVPFR) was enacted by Parliament.

The Plant Variety Protection and Farmers' Rights Act 2002 was formulated under the *'sui generis'* option. The PVPFR Act recognises the farmers' rights. Perhaps for the first time in the legislative history of the country, the farmer's right is recognised in an enactment. The Act goes beyond the farmer's right to save seeds and replant.

The Protection of Plant Varieties and Farmer's Rights (PVPFR) is broadly compliant, as it should be, with the FAO Global System and the CBD on the critical issue of the farmers' rights. The enactment was hailed by the civil society as a milestone in the long journey in the recognition of the farmers' rights in the Indian context.

The Union Cabinet's recent decision to join UPOV, after enacting the PVPFR Act, will undo all the expectant benefits and will be detrimental to the interest of the farming community. UPOV and the PVPFR cannot co-exist as they represent two irreconcilable viewpoints. Accession to UPOV demands that India have a pro-breeder and pro-patent plant varieties protection scheme. The present pro-farmer PVPFR Act will not be acceptable to UPOV. The farmers' rights are, once again, in jeopardy. The Indian farmer is back to square one.

A number of international NGOs are advising India against acceding to the UPOV regime protecting intellectual property rights to plant varieties, lest multinational corporations wrest control over seed supply away from the country's farmers.

Ashish Kothari of Kalpavriksh, who is a member of the drafting committee of India's Biodiversity Act, added that "The UPOV option is not suitable for India ... [because it ignores] the interests and rights of millions of farmers who have been breeding and developing seeds for thousands of years." According to Binu Thomas of ActionAid India, "Transnational corporations spend millions of dollars developing a few new plant varieties which they then have to get planted in millions of hectares to recoup their investment costs. Monopoly rights, like UPOV, fast-track this profit-seeking exercise for big corporations at the expense of the farmer's capacity to feed his or her own family."

Several leading international civil society groups have urged the Indian government to take the lead for developing countries by resisting pressure to join the International Union for the Protection of New Varieties of Plants (UPOV).

UPOV is a part of the World Intellectual Property Organization (WIPO) and its sheaf of intellectual property agreements. UPOV and WIPO, the NGOs have been charging, are ignoring developing-country or public interests and promoting corporate interests. Some of them note that the UK-appointed independent Commission on Intellectual Property Rights has been very critical not only of the World Trade Organization and its Agreement on TRIPs, but also of WIPO and its slew of agreements and efforts to use WIPO to harmonize (to the US and European) norms and standards everywhere.

According to Dr Suman Sahai of Gene Campaign, an Indian NGO the three groups are alarmed at India's decision to join UPOV. India had spent 7-8 years drafting a comprehensive law, with the active participation of civil society, on farmers' rights that does not comply with UPOV. The Indian law that went into effect in September 2001 was compliant with the WTO in respect of plant breeders' rights.

Dr Sahai said that the Indian law was the only law in the world that provided for comprehensive farmers' rights including the rights of farmers over seeds, as well as protection against bad seeds provided by breeders and the right to compensation.

Farmers were also protected from the so-called "terminator seed" technology.

Under UPOV, which originally was set up by the seed industry, there are no formulations for farmers' rights. If India joins UPOV, it would have to give up its existing national legislation and abide by UPOV's provisions.

Gene Campaign has filed a petition in an Indian court challenging UPOV and is seeking an injunction to ensure that the farmers are not required to forfeit any rights that have already been granted to them. The Indian government cannot take a decision on UPOV until the Indian court has decided the case, otherwise it would be tantamount to contempt of court.

Indian alternative

Dr Sahai ventured the opinion that UPOV has been very interested in getting India on board, since India would be the first Asian developing country to join UPOV. Moreover, UPOV has been willing to make an exception for India to join UPOV 1978 when other countries acceding for the first time are being asked to join UPOV 1991.

Rajeswari Kanniah of Consumers International, Asia Pacific Office, also said that India is the first Asian developing country that has gone to UPOV. India's joining UPOV could have "a domino effect" on nine other Asian developing countries that are

currently consulting UPOV on their national legislations. "If India caves in, all other nine countries may do so as well," she warned.

Kanniah also referred to a recent report by the independent Commission on Intellectual Property Rights that concluded that patents or the TRIPs provisions were not compatible with developing countries and that these countries should come up with their own *'sui generis'* laws for protecting plant varieties.
"If India joins UPOV, it could spell disaster for millions of the country's poorest farmers. India has the opportunity to act as a trailblazer for other developing countries who are also being forced to join," said Dr Sahai.

The NGOs urged India to resist pressure to adopt damaging international legislation that would shift control over seed production and supply away from farmers and into the hands of multinational corporations.

Various pressures are being applied to countries to join UPOV. The case of the Organization of African Unity (OAU) that came up with its own model law is an example. When the OAU approached WIPO for its opinion on the law, the OAU was told that its model law was not compatible with the TRIPs Agreement. When countries approach WIPO, headed by Dr Kamil Idris, over WTO-TRIPs issues about *'sui generis'* systems and plant breeders' rights, WIPO refers them to UPOV, which in turn gives them wrong advice and says that a *'sui generis'* system has to be UPOV's.

India's membership in UPOV could have a huge impact in a country where nearly 70% of people depend on agriculture to make a living. India is the only country in the world that gives farmers' rights the same recognition as those of plant breeders.

Many developing countries fear that patents on genetic resources for food and agriculture could potentially raise the cost of seed and agricultural inputs, making them unaffordable for small farmers in developing countries. Six multinationals control around 70% of the patents held in staple food crops. Thus, if seeds and agricultural inputs fall into the hands of private corporations, there will be less incentive for agricultural research.

This could also have implications for farmers' rights to save, use, exchange and sell seeds. For these reasons, most developing countries do not want patent protection for new plant varieties and are instead looking to develop and implement plant breeders' rights legislation, or a *'sui generis'* system, in line with Art 27.3b of the TRIPs Agreement.

The TRIPs Agreement itself makes no mention of UPOV and there is nothing in the TRIPs Agreement that would not allow the incorporation of farmers' rights into *'sui generis'* plant variety protection legislation, the NGOs say.

The three NGOs argue that UPOV is not suitable for farmers and food security in that it restricts farmers' rights to save, grow and

sell seed; reduces access to seed and genetic resources; makes seeds more expensive for small farmers; reduces plant varieties available for cultivation; favours large-scale industrialized agriculture over small-scale subsistence farming; allows large multinationals to monopolize the seed industry; and discounts the contribution of farmers in breeding and preserving plant varieties over generations.

The three organizations suggest that alternatives exist to UPOV and cite the model law drafted by the OAU and Gene Campaign's Convention on Farmers and Breeders (CoFaB). For domestic legislation, the groups say that India's Plant Variety Protection and Farmers Rights Act, 2001 could serve as a model for developing countries.

7.14 Indian Statutes on IPR

Various legislations / Bills have been enacted in India on Intellectual Property Rights, some of them to protect national interests and some under the pressure of WTO. The important legislations or bills are 1) The Indian Patents Act, 1970; 2) The Patent (Amendment) Acts, 1999, 2002 and 2005; 3) Protection of Plant Varieties and Farmers' Rights Act, 2001; and 4) Biodiversity Related Community Intellectual Rights Act, 2002.

The history of the Indian patent system can be summarized as follows –

1856 – The Act VI of 1856 on protection of inventions based on the British Patent Law of 1852. Certain exclusive

privileges granted to inventors of new manufacturers for a period of 14 years.

1859 - The Act modified as Act XV; patent monopolies called Exclusive Privileges (making, selling and using inventions in India and authorizing others to do so for 14 years from date of filing specification).

1872 - The Patents & Designs Protection Act.

1883 - The Protection of Inventions Act

1888 – Consolidated as the Inventions & Designs Act.

1911 - The Indian Patents & Designs Act.

1972 - The Patents Act (Act 39 of 1970) came into force on 20th April 1972.

1999 - On March 26, 1999 Patents (Amendment) Act, (1999) came into force from 01-01-1995.

2002 - The Patents (Amendment) Act 2002 came into force from 2oth may 2003.

2005 – The Patents (Amendment) Act 2005 came into force from 1st January 2005

The first real patent legislation in India was the "Act for granting exclusive privileges to inventors" – Act (XV of) 1859 which required "exclusive privileges" to have some utility, to not have been published or generally publicly known and not to be enlarged subsequently by amendment of specification. So as to ensure that English patent holders could acquire a right to Indian markets or manufacture, such patent holders could register their patents within twelve months of the registration in England. This was similar to the general transnational right to priority that was to become such an important part of the use of patents for world market domination under the Paris Convention, 1883. But, in this instance, it was more limited (it applied only to India and England) and one-sided in that it was an option available only to English patent holders.

The Patterns and Designs Protection Act 1872 included the protection of designs, which was not covered by the previous legislation; and inventions disclosed at exhibitions were protected for their novelty by the Inventions and Designs Act, 1888. The term "patents" was substituted for "exclusive privileges" in the Indian Patents and Designs Act 1911. Many amendments followed, like The Indian Patents and Designs (Amendment) Act 1920, The Indian Patents and Designs (Amendment) Act 1930, The Indian Patents and Designs (Amendment) Act 1945, The Indian Patents and Designs (Amendment) Act 1950 and The Indian Patents and Designs (Amendment) Act 1968. The new comprehensive Indian Patents Act 1970 was supposed to be a new beginning.

7.15 The Indian Patents Act, 1970

Section 83, Chapter XVI of the Indian Patents Act 1970 says: Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations:

a) that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay; and
b) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article.

There are two kinds of patents: process patents and product patents. A patent can be obtained for any invention, which is a new and useful art, process, method or manner of manufacture or a machine, apparatus or article of substance produced by manufacture, or the process of manufacture of an article or its improvement. The Act permits product patents for all inventions except food, medicines, drugs and substances produced by chemical processes. In these areas only process patents are available.

According to Indian Patents Act 1970, the following are not treated as patentable inventions:

(i) A method of agriculture or horticulture;

(ii) Any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products.

No patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable. The Act also does not mention anything about patenting biotechnology, and so in practice India does not grant patent in plants, animals and human beings. Other areas of process in biotechnology are prohibited in India.

Compulsory licensing

In most cases, under section 84(1) of the Act, a patentee is given exclusivity of his patent rights for a period of three years after the sealing of the patent. After these three years are over, any person may apply to the Controller of Patents for a compulsory license. It can be applied for and granted where the reasonable requirements of the public have not been satisfied and the invention is not available at a reasonable price.

Need for Amendments

Though protection was available to innovators for their invention in the country much earlier, a comprehensive Act on patents was enacted only in 1970. But The Dunkel Draft on TRIPs under the Uruguay Round Negotiations evoked considerable debate and apprehension in the country and also forced the legislators to

propose amendments in the 1970 Act. An impression was being created that India does not believe in the protection or enforcement of the entire gamut of intellectual property rights and that such protection is inimical to our interests. This is far from true. The Dunkel Draft on TRIPs covers seven areas of intellectual property rights, viz., copyright, trademarks, geographical indications, industrial designs, trade secrets, integrated circuits and patents. In six of these areas, excepting patents, the policies, laws and regulations already followed in India or proposed to be adopted were on par with those in the rest of the world, including the industrialized countries. Our administrative and judicial system for the enforcement of intellectual property rights is also comparable with the best in the world. As a matter of policy, India has not believed in the piracy or counterfeiting of intellectual property rights. It was only in the area of patents, and that too primarily in the area of pharmaceutical and agro-chemical patents, that there was a sharp divergence between the norms and standards advocated in the Dunkel Draft and The Indian Patents Act, 1970. The adoption of the Dunkel Draft required a comprehensive and fundamental revision of the Indian Patents Act 1970.

7.16 The Patents (Amendment) Act, 1999

In order to fulfill the obligations undertaken by India in the TRIPs Agreements and the WTO Agreement, the Patents (Amendment) Act 1999 was made law retrospectively with effect from 1st January 1995. The Act provided the provisions for Exclusive Marketing Rights (EMR) for the first time. However the amended

Act specifically provided that a method of agriculture or horticulture or a process for medical, surgical, curative, prophylactic or other treatment of human beings or animals or plants or relating to atomic energy; shall not be entitled for Exclusive Marketing Rights (EMR).

Justifying the amendments, the then ruling BJP government said that the amendments were necessary for aligning Indian law with the TRIPs agreement under the World Trade Organization of which this country is a member. It also said that they were necessary for a strengthened patents regime which would help Indian scientists and protect their inventions.

But the amendments went far beyond satisfying the WTO. It ignored provisions permitted by WTO to member countries to protect public health and nutrition in an apparent rush to accommodate TNCs through exclusive marketing rights (EMRs). This sentiment was also echoed by several environmental activists and eminent jurists. "This is an Act which bypasses the patent system to grant EMRs as a statutory right to pharmaceutical and agrichemical TNCs against patents held outside India," said Vandana Shiva chief of the Research Foundation for Science, Technology and Ecology (RFSTE).

"The public will have to pay enormous sums through imports of essential drugs over prolonged periods of time till other manufacturers break a monopoly. Needless to say it will be drugs required for national health programs and essential drugs

that will be the ones most neglected," said Justice Jeevan Reddy, Chairman of the Law Commission.

India's lax patent laws on pharmaceuticals have for nearly two decades allowed local manufacturers to sell generic drugs at about a third of the price of that even in neighboring countries. The new law automatically gives MNCs exclusive marketing rights (EMRs) at prices unaffordable for most Indians for drugs and agrichemicals for specified periods in India if they hold single patents in another country. Worse, they can claim EMRs on formulations based on herbs and plants that are traditionally used under the Ayurvedic system as medicines since ancient times and continue to be the mainstay of health care in India.

A TNC now has the liberty to claim EMRs on formulations based on ginger, pepper, neem, turmeric and hundreds of other plants by introducing minor modifications in the methods of their extraction and process and then claiming that they are inventions, whose medicinal properties have been known to every household in India since ages.

New laws should facilitate rather than hinder the people's ability to access basic resources and enable and protect food and health security.

The Patent (Second Amendment) Bill, 1999 was introduced in the Rajya Sabha on 20 December 1999 to bring about other changes in the patent regime in line with the TRIPs agreement. The Bill was referred to a Joint Parliamentary Committee of both the

Houses of Parliament. The Joint Parliamentary Committee finalized and adopted its report in the meeting held on 14 December 2001 with some changes and recommended that the Bill, as amended be passed. The Patents (Second Amendment) Bill 2002 was ultimately passed by Rajya Sabha on 9 May 2002 and same was passed by Lok Sabha on 14 May 2002. The Bill has received the assent of the President on 25 June 2002.

7.17 The Patent (Amendment) Act, 2002

The Patent Act 1970 was amended in 2002 with the objective of making India's intellectual property rights system TRIPs-compliance. India is one of the signatories of the TRIPs Agreement of the Final Act of the Uruguay Round of the multilateral trade negotiations. Accordingly, it has to give product patents to drugs & pharmaceuticals, agro-chemicals and processed food from 1st January 2005. Meanwhile, India has to grant exclusive marketing rights (EMR) to the products that have patents and marketing approvals anywhere in any convention country. India has recently brought out legislation to accept applications for granting product patents from 2005 through *mailbox (Applications for the grant of exclusive marketing rights for pharmaceutical products, upto 31.12.2004, Sec.5(2)of Patent Amendment Act 1999)* facility. Under Article 70 (8a) of the TRIPs agreement India is bound to provide mailbox facility to accept applications for product patents. An EMR can be granted if the following conditions are complied with: (i) application has been filed in India on or after 1.1.1995 (ii) the patent has been granted in a convention country (iii) marketing approval has

been granted in that country and (iv) marketing approval has been obtained in India.

7.18 Salient features of the Act

- **Patentable Subject Matter-**

  The Patent Act 2002 has made comprehensive amendments in Section 3 of the 1970 Act and has opened the door to provide for patenting microorganisms. However, traditional knowledge is protected from being patented.

- **Term of Patent**

  Section 52(1) of the Indian Patent Act 1970 has been amended and the new Act 2002 has extended the period of holding a patent to twenty years from the date of filing of the application for the patent.

- **Compulsory Licensing (CL)**

  The amended Act has elaborate provisions on compulsory licensing in Chapter XVI that stretches from section 82 to 94. Under section 84, at any time after the expiration of 3 years from the date of the sealing of a patent, any person interested may make an application to the Controller for grant of Compulsory license on patent on any of the following grounds-

  (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or

  (b) that the patented invention is not available to the public at a reasonably affordable price, or

(c) that the patented invention is not worked in the territory of India.

Under section 92, the amended Act specifically says that compulsory licensing can be granted in a national emergency, extreme urgency or public non-commercial use, which may arise or may be required as the case may be, due to a public health crisis. This includes procedures relating to AIDS and HIV, hepatitis, tuberculosis, malaria and other epidemics.

7.19 The Patents (Amendment) Act, 2005

The Indian Patent Act was further amended in 2005 and some of the important amendments of this Act with relation to biodiversity are as follows-

The Act allows indigenous manufacturers to manufacture patented products even after a patent is granted, in respect of mailbox applications, on payment of a reasonable royalty to the patent holder, if they have been producing and marketing the concerned product even before 1st January 2005. This ensures a level playing field for domestic players who have already made substantial investments and have been manufacturing the products for which applications for patents have been received in the mailbox.

However, the words 'significant' and 'reasonable' are very vague and could have been more clearly defined. The reasonable royalty rate should have been fixed as a particular percentage,

the norm being 4 %. For example in South Africa, Glaxo Smith Kline demanded a royalty of 25 % before the courts intervened.

The amended Act takes care of public interest by providing for both pre-grant and post-grant opposition avenues, and reduces the timeframe for grant of patents in a cost-effective manner. A patent can be opposed or revoked on the ground of non disclosure or wrongly mentioning the source of geographical origin of biological material used for invention, and also on anticipation of knowledge oral or otherwise available with any local or indigenous community in India or elsewhere.

In order to prevent "ever greening" of patents for pharmaceutical substances, provisions listing out exceptions to patentability (or what cannot be patented) have been suitably amended. This removes all ambiguity as to the scope of patentability since India is very rich in traditional knowledge and heritage. Clear-cut instructions regarding what cannot be patented would help in protecting traditional knowledge in the long run. The healing techniques of well established ethnic systems of medicines such as Ayurveda, Siddha and Unani system and their formulations are not patentable.

TRIPs allows domestic manufacturers to manufacture patented products within 3 years of their introduction under compulsory licensing. Conditions for obtaining compulsory license have been clarified in order to facilitate export of patented pharmaceutical products by Indian companies to countries that do not have

adequate production capacities. It will boost Indian drug manufacturers.

This amendment should have provided the facilitation of compulsory licensing even before the mandatory 3-yr period since MNC pharmaceuticals often refuse to deal with requests for compulsory licenses or demand high royalties, which would curb the abuse of patent rights by patentees.
With respect to exporting drugs to a country, which makes a request for a generic drug, the amendment no longer requires the importing country to issue a compulsory license. However, one question that arises is whether the procedure for the grant of the compulsory license for the domestic market will also be the same for compulsory licenses for export. It is quite possible to argue the procedure both ways, thus potentially delaying urgent new drugs that a developing or least developing country may require.

This amendment includes product patents in all fields of the technology including drugs, food and chemicals that were previously covered under process patents only.

Over a period of time Indian drug companies will lose the opportunity to develop processes for patent protected drugs in the country. Indian drug companies might become dependant on MNCs for technology to produce new drugs. However, among existing drugs say about 10 per cent of the marketed drugs are likely to become expensive due to amendments made in new Patents Act. However, the existing 90 per cent of the old

drugs will not be affected by this Act. While this is true, it must be understood that the rate of obsolescence of old drugs is extremely fast today. Technological dependence on MNCs will lead to establish their dominance over the Indian drug market. MNCs once again may start charging exorbitant prices for drugs in the Indian market.

The India government is going far beyond what is required under WTO rules. The amended Act extends patent protection to the new uses of the known drugs- a level of the protection, which is not required by the TRIPs agreement. This would increase the frivolous inventions just by increasing the slight efficacy.

Patent protection should be favoured which will make India an ideal center for research but the loopholes in the Act should be rectified to strike a balance between patent protection and biodiversity.

7.20 The Protection of Plant Varieties And Farmers' Rights Act, 2001

The Plant Variety Protection and Farmers' Rights Bill was passed by both houses of the Indian Parliament, ending a long and arduous struggle for the recognition of the rights of farmers in India's *'sui generis'* legislation. For the first time, India has now put in place a law to grant Plant Breeders' Rights (PBRs) on new varieties of seeds. What started as a Bill heavily loaded in favour of breeders and falling far short of protecting the rights of

farmers, has now got a reasonable section on Farmers' Rights. It was pointed out over and over again to successive governments who were under pressure from plant breeders' lobbies, that there was nothing in TRIPs or Article 27.3(b), that came in the way of granting Farmers' Rights, and that even if there were to be any restraint on the granting of Farmers' Rights, India's food security concerns would make it impossible to accept such a restriction. The Act recognises the farmer not just as a cultivator but also as a conserver of the agricultural gene pool and a breeder who has bred several successful varieties. It makes provisions for such farmers' varieties to be registered, with the help of NGOs so that they are protected against being scavenged by formal sector breeders. The final version of the clause on what constitutes a Farmers' Right [Section 39, clause (iv)], now reads:

The farmer "shall be deemed to be entitled to save, use, sow, re-sow, exchange, share or sell his farm produce including seed of a variety protected under this Act in the same manner as he was entitled to before the coming into force of this Act, with the exception of branded seeds.

This Act allows the farmer to sell seed in the way he has always done, with the restriction that this seed cannot be branded with the breeder's registered name. In this way, both farmers' and breeders' rights are protected. The breeder is rewarded for his innovation by having control of the commercial market place but without being able to threaten the farmers' ability to

independently engage in his livelihood, and supporting the livelihood of other farmers.

Apart from the right to sell non-branded seed of protected varieties, the rights of farmers and local communities are protected in other ways too. There are provisions for acknowledging the role of rural communities as contributors of land-races and farmer varieties in the breeding of new plant varieties. Breeders wanting to use farmers' varieties for creating Essentially Derived Varieties (EDVs) cannot do so without the express permission of the farmers involved in the conservation of such varieties.

The Protection of Plant Varieties and Farmers' Rights Act was enacted in 2001 with the objective of giving effect to article 27.3 (b) of the TRIPs Agreement and to protect farmers' rights for their contribution made at any time in conserving, improving and making available plant genetic resources for the development of new plant varieties and for the protection of Plant Breeders' Rights to stimulate investment for research and development, both in the public and private sector for development of new plant varieties.

The Act covers new varieties, extant varieties, farmers' varieties and essentially derived varieties of plants derived by breeders. Section 15 of the Act provides that the variety will be protected only if it confirms to the criteria of novelty, distinctiveness, uniformity and stability. This is similar to the provisions of

UPOV. The EDV category refers to those varieties where a single character has been changed in a variety which otherwise remains more or less identical to the parent variety. Most genetically modified (GM) varieties are EDVs. For example Bt. cotton is a cotton variety, identical to its parent except for the single difference of containing a bacterial gene from the Bacillus thuringensis. The Act has made elaborate provisions for guaranteeing rights of Farmers, Breeders and Researchers.

- Breeders' Rights:

Breeders' Rights extend to Seeds and / or Propagating material of the protected variety for: i) Production, ii) Selling, iii) Marketing, iv) Distribution, v) Export, vi) Import. However, if the breeders' variety is essentially derived from a farmers' variety, the breeder cannot give any authorisation without the consent of the farmers or communities from whose varieties the protected variety is derived.

- Farmers' Rights :

i) The farmer is entitled to save, use, sow, re-sow, exchange, share or sell his farm produce including seed in the same manner as he was entitled earlier (Seeds for sale should not be branded) (essentially corresponds to Farmers' privilege in UPOV 78)

ii) Full disclosure of the expected performance of the Seeds or planting material by the plant breeder. Where these fail to

perform in the manner claimed by the breeder, the farmer may claim compensation from the plant breeder.

The Act also provides reward for the farmer "who is engaged in the conservation and preservation of genetic resources of land races and wild relatives of economic plants and their improvement through selection and presentation".

- Researchers' Rights:

Researchers' Rights are recognised which grant them free and complete access to protected materials for research use in developing new varieties of plants. However, authorisation of the breeder is required "whose repeated use of such variety as parental line is necessary for commercial production of such other newly developed variety". This provision in effect uses the formulation provided for in UPOV 78 for breeder's exemption.

One of the essential features of this Act is 'Benefit sharing'. For Essentially Derived Varieties, NGOs or individuals can claim a share of benefits that may arise from its commercialisation on behalf of any village or local community. Any individual or NGO can make a claim on behalf of a village or local community for the contribution that they had made in the evolution of any variety registered under the Act.

The Protection of Plant Varieties and Farmers' Rights Act 2001 is an example of a masterpiece legislation cleverly drafted for the protection of the rich biodiversity, cultural heritage, traditional

knowledge and farmers' rights in the country. However, India's decision to join UPOV will undo the good effects of this Act, and the decision of the politicians of the country under the pressure of the West will be the most unfortunate thing for the biodiversity of the country and will have an adverse and long-lasting impact on Indian biodiversity.

A battle has emerged between Intellectual Property Rights and Biodiversity. The Protection of Plant Varieties and Farmers' Rights Act 2001 had raised hopes of putting an end to this bio-battle. But India's decision to join UPOV will force the enactment of new legislations and the amendment of the provisions of the existing ones, both at the national and international level, which is dealt with in the next chapter.

7.21 Biodiversity related Community Intellectual Rights Act, 2002

The Indian Biodiversity related Act known as Biodiversity Related Community Intellectual Rights Act came into force on December 11, 2002. The Act provides for conservation of biological diversity, sustainable use of its components and equitable sharing of the benefits arising out of the use of biological resources. A 'National Biodiversity Authority' has been established under the Act for the purpose of regulating biological diversity. The Biological Related Community Intellectual Rights Act expressly prohibits any person, who does not have the previous approval of the National Biodiversity Authority, from (i)

obtaining any biological resource occurring in India or related knowledge for research or for commercial utilization or for bio-survey and bio-utilization (ii) transferring the results of any research relating to any biological resources occurring or obtained from India for monetary consideration or otherwise to any person or organization which is not Indian or which has any non-Indian participation in its share capital or management (iii) applying for any intellectual property right by whatever name, for any invention based on any research or information on a biological resource obtained from India, before making such application.

The Biodiversity Act has come under criticism from leading environmental activists who say the legislation alienates indigenous farmers from their resources and facilitates "biopiracy." The Act effectively negates the basic objectives of the CBD and purports to appropriate these resources – and all knowledge thereto – by corporate bodies with the approval of the government. When it was passed on Dec 11, Union Environment and Forests Minister T.R. Baalu claimed that the legislation would regulate access to genetic resources and associated knowledge by foreign individuals and institutions and ensure equitable sharing of benefits arising out of the use of resources and knowledge with the country and its people.

The Act was to provide safeguards to protect the interests of local people, growers and cultivators of biological diversity, as well as

Indian researchers through a new National Biodiversity Authority (NBA), supported by state level boards and management committees that would regulate access to plant and animal genetic resources. "The NBA's approval will be required before obtaining any form of intellectual property rights on an invention based on a biological resource from India or on a traditional knowledge and it will deal with all cases of access by foreigners[35]"

Indian citizens and companies are allowed free access to biological resources within the country for research purposes but are barred from transferring findings to foreign entities without the NBA's approval. But all these provisions only succeed in burying biodiversity under a mountain of bureaucracy that can only serve to alienate ordinary farmers from their resources while making international bio-piracy easier.[36]

The Act seeks to deny the people the right to their local biological resources and compels all Indian citizens to obtain the permission of the NBA before even applying for a patent based on any research or information on Indian biological resources. Indian companies would now have to grease the palms of an expanding bureaucracy before even applying for a patent.

The only beneficiaries from the legislation would be the MNCs. "By excluding agriculture from the Act's purview, global corporations can still gain access to valuable biological resources." But an impoverished local farmer who allows his cow

---

[35] *Baalu T R Union Environment and Forests Minister, India*
[36] *Sahai Suman of the Gene Campaign and Shiva, Vandana of the RFSTE*

to graze freely on the commons could find himself penalized for inadvertently destroying a herb considered to be a valuable biological resource[37].

The natural fallout of the proposed legislation would be the appropriation of the rich biodiversity by MNCs (like Monsanto) through the connivance of government functionaries. The CBD purported to conserve the biodiversity of the world, for the benefit of local communities; and , as already stated, was evolved in response to the pressure of the MNCs for greater 'access' to the world's resources. Section 3 provides that non-citizens of India, non-residents as well as corporate bodies not registered in India, cannot obtain any biological resource occurring in India or knowledge associated thereto for research or for commercial utilization or for bio-survey and bio-utilisation.

Yet, this prohibition is neatly bypassed by s.5 which states that the above provisions "shall not apply to collaborative research projects...if such projects...

(a) conform to the policy guidelines issued by the Central Government in this behalf;

(b) be approved by the Central Government."

In other words, anything is possible with the approval and blessing of the government. "Collaborative research" between

[37] *Sahai Suman of the Gene Campaign and Shiva Vandana of the RFSTE*

American Multi-Nationals and some Indian institution would be promptly approved. In the past too, the fruits of research have gone to enrich the knowledge and the coffers of MNCs and most of these R&D facilities have been wound up. The MNCs have got what they wanted and they want to now focus their research activities in their own laboratories at home, with material already obtained[38].

The Act not only opens the door to collaborative research but also leaves the door wide open to MNCs to exploit the Indian farming community to the full. This implies that the global seed industry – Cargill, Monsanto and others – can freely claim patents or 'breeders' rights', take Indian seeds and tinker with them and with special 'exterminator pesticides' which wipe out all plants other than those based on specially-treated imported seeds, exploit the Indian farming community to maximize their profits to the detriment of the bulk of Indian farmers.

The Act is weak on the issue of intellectual property rights (IPR). All that is stipulated is that IPR applications will have to go through the NBA and in its confused way ends up running to the national and international campaigns against patents on life forms. Because there is no stricture on patents in the Act, the NBA could now actually give permission for someone to take a patent out on a rare species of, say, a turtle or a bee.

[38] *The Ford/Rockefeller Foundation Project in 1950*

In fact, the new law would undo protection against the patenting of life forms contained in earlier path-breaking legislation such as the Plant Variety Protection and Farmers' Rights Act (PPVFR) passed in 2001, though it does recognize breeder's rights which again benefit large seed transnational corporations. Benefits conferred by the PPVFR were afterwards whittled away by cabinet approval, without consulting Parliament of the provisions of the International Union for Protection of New Varieties of Plants (UPOV) of 1978, which legitimizes the interest of global seed giants.

The area on which the Biodiversity Act is silent is the very area at the centre of a raging global controversy, in which Indian civil society has been very vocal in protecting local communities from the damage inflicted by patents on biological resources and indigenous knowledge. The Act would actually discourage research with its "strong tangles of bureaucratic red tape."

Not only will research proposals now need to be vetted by the NBA but publications will also have to conform to government guidelines causing infinite delays at a time when scholars are already protesting the loss of valuable time because of cumbersome procedures. Local communities, in whose name the legislation was carried out, will actually have no say in the granting of patents on biological material or in deciding what will be 'equitable' when it comes to the sharing of benefits. This will now be decided by bureaucrats in the NBA.

While the Act could have been stronger it can be a step in the right direction provided clear and stringent rules are now framed under it. There needs to be "full involvement of the public" if the Act is to succeed in its stated aim. The legislation only provided the framework and that it was now up to the government and citizens to use it pro-actively.

India has documented over 45,000 species of flora and 75,000 known species of fauna and contains with its borders two of the world's 10 bio-geographic zones. The country is one of the world's 12 mega centres of biodiversity.[39] Contained within the subcontinent are tropical wet evergreen forests, deserts and alpine vegetation and vast coastal systems. Coupled with a corrupt and unaccountable bureaucracy and impoverished local populations, the region is nevertheless the repository of vast traditional knowledge and thus makes for bio-pirates' delight.

[39] *Kothari Ashish of Kalpvriksh, Understanding Biodiversity Life, Sustainability & Equity – Orient Longman India Ltd, 1997*