CHAPTER 7

Seeds, Plant Varieties and Intellectual Property Rights

Introduction

Granting IP rights over seeds has been a controversial issue, as, for many years seeds were considered as products of nature, and hence no IP protection could be granted. However today there are hundreds of patents on plant varieties and patents have been granted on plant parts, genes, traits etc. In this chapter the transformation of this product of nature into a patentable object is examined and the Article 27.3(b) is analyzed in detail in the context of the options available for developing countries in developing a sui generis system.[1]

Seeds were once outside the purview of industrial mode of production. But during the last hundred years or so there has been a sea change in this and today the very right of farmers' to save seeds and reuse them is under dispute. Plants can be considered as products of nature, only, and, if only, the contributions of farmers' are ignored. Farmers have over the ages have introduced thousands of varieties, created new ones and propagated them and plants have been taken across continents and have been integrated in to various cultures and nations. However plants could be multiplied and a handful of seeds are enough to (re)create plantations or fields filled with plants. This reproducibility is a feature that resisted commodification of germplasm/plant genetic resources for long.[2]

As pointed out earlier the colonial expansion and the transfer of exotic germplasm and introduction of new crops and varieties in distant lands went hand in hand. The colonial expansion also resulted in many other developments ranging from establishing botanical gardens in many places and Colombian exchanges which often resulted in genocides, destruction of native nations and cultures. Marx's observation on commodification are very

relevant here and seed/germplasm could not be commoditified till hybridization became a success[3]

Till this happened the seed industry could have little control supply and production of seeds. And with seeds the appropriability, became the problem. However the biological limitation was overcome by both scientific discoveries and by legal regimes that gave IP rights over plants and plant varieties. The agricultural mode of production in which seed is an important input could get fully integrated into the industrial mode of production only after this happened. About hundred years ago germplasm/seed was treated like a property in which the farmer had all the rights. It was considered as a resource but still it escaped full commodification, partly because it could be reproduced and that capacity to reproduce was beyond human intervention.[4] Scientific advancements made it possible to manipulate at the genomic and molecular level and the changes in the legal treatment of seeds and germplasm, which it self was necessitated because of the commercial importance of the scientific advancement and in the interests of agribusiness. Thus seeds became commodities over which IP rights could be established and enforced.

In this chapter USA is taken as a case study partly because of the availability of the literature on the subject, and partly to highlight the changes in laws and the decisions given in various cases. From this universal conclusions cannot be drawn for a good portion of the seeds and germplasm are yet to be commoditized and there are some circumstances that are unique to USA, still the developments in USA are relevant as they indicate how law and technology have interacted to create an IP regime on seeds and plant varieties.[5] At this juncture it is worth pointing out that although seed and germplasm can be considered as products of nature, they embody the collective wisdom and efforts of farmers and indigenous people. But these products of nature could be privatized and turned into commodities on

which IP rights could be obtained only the if legal discourse (i.e. laws, judgments) concurs that IP rights are applicable to them.

Till the late 1890s when the seed industry emerged stronger, the U.S government was sending seeds to farmers freely and the response of farmers was overwhelming. But in 1890s there were demands that this distribution should be stopped. The American Seed Trade Association was vocal in this. But the distribution continued. Yet important changes were occurring in plant sciences and the impacts of these were felt soon. With the rediscovery of Mendel's work in genetics, plant breeders had a better understanding about transmission of traits across generations.[6]

In the late 1890's some plant breeders in the public sector were experimenting in hybridization, although it became popular only in the 1930s. While improvements in scientific understanding enabled plant breeders to use the exotic germplasm with desired traits and carry out experiments to incorporate the needed traits in the varieties. Thus it was possible to improve existing varieties by back crossing with germplasm from other countries with desired traits. Although private sector was emerging as a major player laws relating to seed certification and the release of many varieties by the public sector restricted their market share and consequently they could not become the sole suppliers of seeds. But with the Congress removing the free seed supply program a major demand of the private sector was met in 1924. In the 1930s the research in public sector was strengthened and public sector plant breeding was using Mendelian genetics extensively.

Plant breeding was transformed in to a true scientific enterprise. In the 1930s two significant developments occurred. The private sector evinced interest in hybridization. The emphasis in public sector was more towards basic research than towards developing new varieties or open line hybrids. The hybrids produced high yields in the first time when cultivated, but for subsequent seasons the farmer had to buy seeds again to get the same or

higher yield. Thus through technology a biological barrier for appropriablity was overcome and the commodification of germplasm could be taken to next levels. With commodification comes the desire to control and stake claim for IP rights.[7]

Corn was hybridized first in the 1930s on a massive scale, and within three decades hybrids accounted for more than 85 % of the acreage planted.[8] Although farmers experimented through crossings and varietal improvement, the plant breeders had the advantage of the knowledge about Mendelian genetics and could use that to develop hybrids.[9] As farmers were producing for the market, commercial agriculture became the norm.[10] The shift in research and development in plant breeding from open pollinated varieties to hybrids resulted in public sector breeding programs developing more hybrids and true hybrids were appearing by 1920[11] .The seed companies in private sector who could not invest heavily in research and development relied on the public sector. However as public sector was still involved in seed production, not just plant breeding, the private sector had to contend with this competition. On the legal front demands from patents on plants were voiced in 1880s itself. The nurseries were vociferous.[12]

But for various reasons the demands could not be translated into a law. Only in 1930 the law, The Plant Patent Act was passed. The significant features of the Act were:

1. Patent like protection was given to asexually propagating species.
2. The protection was not available to staple crops (wheat, corn) and tuber propagated species (e.g. potato which was specifically excluded)
3. It specified that to get protection the asexually produced plant should be new and distinct.

Thus for the first time patent protection was extended to plants. Although Congress did not extend this protection to staple crops and tuber propagated species this law was a beginning in extending the boundaries of IP protection. Till then it was considered that

products of nature could not be patented except when it was isolated and purified. While the Act of 1930 thus opened up new vistas, hybridization was tried with other crops, and, although these were not as successful as in the case of corn companies had a new tool with them to help in commodification.

Plant breeders evinced interest in developing closed-line hybrids and the related knowledge (which lines were used and how) was held as a trade secret. Still public sector was competing with private sector and the private sector wanted public sector to concentrate on basic research only, so that, investment could be attracted to private sector seed development business. The public sector was needed as a resource provider, i.e. producing inbred line available for use. Even in the absence of patent production hybridization and holding the related knowledge as trade secret helped the private industry to consolidate its position and expand into new areas like vegetables.[13]

This leads to issues like social shaping of technology, deskilling and hybrid corn[14], the politics of artifacts and ideology and science. For obvious reasons this dissertation is not the place for an extensive analysis. It is suffice to say the account provided here is not based on any deterministic perspective as the interplay of various forces and changes in laws and the transformations these bring in is examined in this dissertation. Hybrids are important in the global seed business as sales of hybrids in various crops account for nearly 40 per cent of the global commercial seed business of about US$ 15 billion.[15] Thus within two decades the seed sector was transformed to a great extent, as by then the public sector had stopped competing and there was no public sector seed distribution too. In 1952 the PPA was transferred to separate section, from section governing utility patents. One major problem with hybrids is that they result in genetic uniformity and hence plants are vulnerable to epidemics. The uniformity in the cytoplasm in hybrids makes them susceptible and as a result an epidemic could result in significant loss of output.[16]

In 1961 the Union for Protection of New Varieties was established in Europe and this necessitated changes in the U.S law. The proposals put forth by the private industry were contested by the public sector plant breeders who were worried about the negative impacts of Plant Breeders' Rights (PBRs). Finally in 1970 The Plant Variety Protection Act was enacted. Under this protection is given if it is proved that the three criteria ("novelty," "uniformity," and "stability") were met and stability was meant to be consistent reproducibility. If the conditions are met, a certificate of protection would be given and this would give the holder the exclusive right to use the variety for seventeen years from the date of issue. Significantly PVPA also provided for exemptions to farmers and for research purposes.[17] For reasons of space the impact of PVPA on productivity, variety development and introduction and other related issues like its role in stimulating investment and innovation in plant breeding will not be examined in detail here. However whether PVPA really stimulated innovations worth the name is debatable.[18]

The PVPA was amended in 1994 to bring it in uniformity with UPOV 1991 rules. This resulted in the elimination of the farmers' exemption, i.e. farmers could no longer sell seed without a license from the owner of the variety but can save seed for their own replanting. It also introduced the concept of Essentially Derived Varieties which again was introduced in UPOV 1991 for the first time. Further it brought tuber crops also under protection and plant breeders' rights were extended to twenty years. Thus by this Act the farmer exemption was eliminated and the same was affirmed in *Asgrow vs. Winterborer.*

But a historic decision given by the U.S. Supreme Court in 1980 gave a new understanding about what could be patented. In *Diamond vs. Chakrabarty* the products of nature bar on patenting living products was overturned. The Court ruled that a human made microorganism is patentable subject matter as a "manufacture" or "composition of nature". Thus the majority opinion was the genetically modified microorganism was "not nature's

handiwork, but his own; accordingly it is patentable subject matter." This not only settled the issue but also overturned the opinion given in 1948 in *Funk Bros. Seed Co. v. Kalo Inoculant Co*[19].

But the majority opinion in *Diamond vs. Chakrabarty*, based on the premise that human agency made all the difference in transforming something occurring in nature. And hence the end product is not a product of nature but the outcome of handiwork of man and hence "'a live, human-made organism is patentable subject matter." In *Funk Brothers Seed Co* the Supreme Court held that combining bacteria was not an invention, but a discovery and observed "[it] is no more than the discovery of some of the handiwork of nature and hence is not patentable".

This radical concept of human agency as enunciated in *Diamond* raised many questions and the decision was widely debated, the reverberations of which are heard even today, particularly in the context of patenting genes.[20] In the context of agriculture the thousands of varieties of wheat, rice and other staple crops, apart from the variety of vegetables, fruits etc were not 'products of nature' but results of human intervention over thousands of years. Often these were done by farmers who collectively made this possible through exchange of seeds, experimentation, propagation, selection of varieties. In other words the exotic germplasm that transformed the agriculture in USA was the end result of handiwork of generations of farmers of distant lands. Are they eligible for protection, if so how. This reasoning is based on the idea of a single inventor or a genius who by his/her labor, skill and intelligence who brings to the world a useful product or a new idea or a work of art, broadly speaking. However this does not take into account collective innovations.

The significance of the decision for patents on plants was obvious but it was far from clear because of the two different acts and different types of protection. Hence Plant Variety Protection Office was not sure whether PVPA conferred protection concurrently with patents,

i.e. utility patents or exclusive of the utility patent. Although the judgment was very clear about patenting criteria the PVPA Office rejected applications for non-hybrid plants based on the reasoning or understanding on the separate protection regimes for plants.[21] But a ruling given in 1985 clarified the matter and that was further affirmed in another ruling given in 1987. In *Ex parte Hibberd* the issue was whether a patent could be issued on the tissue culture, seeds, and the whole plant of a maize line selected from that tissue culture, as applied by Dr. Kenneth Hibberd. The US PTO rejected the claim arguing that plants were covered under PVPA and PPA of 1930 and hence a utility patent claim was preempted. But the Appeals Board rejected this contention and gave the opinion that as long as the criteria for patents (i.e. novelty, utility and non-obviousness) were met, there was no bar in granting patents, and PVPA and PPA do not limit such claims. Thus the Board concluded that patents could be issued for all plants, including open-pollinated seeds, i.e. all plants and non-human animals. In *Ex parte Allen* the Board went a step ahead and ruled that a patent for genetically modified oyster could be granted and patent scope could be extended to new, nonhuman animal breeds. In 1988 a patent was issued on Oncomouse, popularly known as "Harvard Mouse", a genetically engineered mouse. Thus within a decade the patent landscape was transformed dramatically and all this was done without any change in the laws.

The expansion in the scope of patents and extension of IP protection for biological processes was not the result of any act passed by the Congress but by interpretations given by Courts and Appeals Board of US PTO. The utility patent offers a very strong protection when compared to Plant Breeders Rights. Further the breadth of the patent claim could include plants, modified genes, and seeds, and, hence the former differentiation between sexually reproducing and asexually reproducing was irrelevant .If the technology could result in anything that could meet the criteria for patentability anything under the sun could be protected. Without the permission of the patent holder, no body can make, sell or use of a

product covered by a utility patent. Thus farmers would be violating the law if they were to engage in selling or exchanging seeds for consideration, if the seeds were the outcome of a plant covered by a utility patent. In effect the farmers' exemption would no longer be applicable. And researchers also cannot claim any exemption. Under PVPA 1970, the owner of certificate protection may "exclude others from selling the variety, or offering it for sale, or reproducing it, or importing it, or exporting it, or using it in producing (as distinguished from developing) a hybrid or different variety there from". This is applicable in case of sexually propagated plants and the protection is valid for 18 years. But the PVPA also provided for what is known as farmers exemption and farmers are permitted to sell or exchange seeds and such sales are known as brown bag sales.

In 1983 the Fifth Circuit held in *Delta and Pine Land Co Vs. People Gin Co* (694 F.2d 1012 5th. Cir 1983) farmers exemption did not provide any scope for a middleman and sales should be made directly by one farmer to another farmer. It held that the Congress intended the exemption to be read narrowly.

In *Asgrow Seed Co. v. Winterboer* Asgrow sued Winterborers for violating the provisions of PVPA and contended that farmers do not have the right to sell the seeds to other farmers to be used in replanting and such brown bag sales are not valid. The Winterborers contended that it was legal as PVPA provided for an exemption. Companies like Asgrow were worried about such sales by farmers , Wintborers planted 256 acres of soyabean and sold the whole output to neighbors. They had bought the seed covered by certificate of protection issued under PVPA to Asgrow and sold the output at 50% of the seed price set by Asgrow. Hence Asgrow argued that their action infringed on the rights of Asgrow under 7 U.S.C. 2541(1), (3), and (6) of the PVPA . The Winterborers argued that since both the buyers and sellers were farmers such sales were permitted by the PVPA. The case was finally settled by Supreme Court, which held that the farmers' exemption did not cover the business

of selling protected seeds.[22] With this the idea of Farmers' Exemption was almost negated legally.

Thus the Asgrow case indicated that seeds are no longer goods that could be bought and sold without restrictions and seeds are covered by contractual obligations, including provisions on IP rights. This judgment thus restricted the rights of the farmers but the 1994 amendment to PVPA act eliminated the right to sell seeds to other farmers for replanting. Thus the farmers' exemption has become a very narrow exemption. In two subsequent cases, one in Canada the question of patent infringements and seeds was discussed and the rights of the patent holder were upheld.

In *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.* the latter alleged that the former had infringed on the patents on hybrid corn held by Pioneer by reselling them, and reselling amounted to violating the exclusive right of the patent holder to make, use and sell the seeds. But J.E.M. Ag Supply challenged this and questioned the legality of the PTO's policy of granting patents on seeds, since ex-parte Hibberd. It was argued that the mandate for this was not given by the Congress and as Congress had enacted two separate laws, one for sexually reproducing plants and other for asexually reproducing plants, and thereby did not extend patent rights on seeds and hybrid varieties. This was the first case in which the PTO's policy to grant patents on plants had been questioned. Much water has flown in Thames in the post ex-parte Hibberd and it has been pointed out in the judgment that more than 1800 patents had been issued since ex-parte Hibberd. The judgment delivered in the case has settled the issue and has affirmed that dual protection is permissible.

Justice Thomas in his judgment had pointed out the relevance of the judgment given in Chraborty for deciding the criteria for granting patents. He further dismissed the argument that Congress did not intend to grant patents on plants, nor he agreed with the view that double protection was not possible. Based on his reading of the legislative history and

decisions given by courts, he concurred with the view that patents on plants are valid and the Certificate of Protection and patent are complementary. The dissenting judges however opined that Congress did not intend to grant patents on plants and also questioned the relevance of the decision given in Chakraborty for this case. Justice Thomas had pointed out that since Ex-parte Hibberd more than 1800 patents on plants had been issued by PTO and in the absence of an intervention by Congress to over rule the issuance of such patents by PTO the seventeen patents issued to Pioneer Hi-Bred are valid. Such an interpretation raises some interesting questions. What exactly was the intention of the Congress when it passed PVPA with such an exemption and did the Congress really intend to provide both forms of protection without any exemption for research and to save the seeds. Judges have held divergent views on this.[23]

Both Charkrabaorty and Hibberd opened up new possibilities for patenting objects which were considered to be products of nature earlier and hence were excluded from patenting. If the former firmly laid the foundation stone for biotech patents, the latter made the grants of patents on plants a routine affair. Thus commodification of the germplasm is almost complete. In the fifteen years between Hibberd and J.E.M.Agro many changes have taken place – in law as well as in the seed industry.

Granting utility patents with strong IP rights had transformed seeds from a natural product to that of a manufactured product covered with licenses and agreements. The law makers severely restricted the rights of the farmers over the seeds. Judgments, laws and contracts stipulated by seed producers have thus reduced the farmer to the level of a user who has little freedom to decide on using the seeds. PVPA is perceived to offer a weak protection although it has some advantages. Still companies prefer utility patents as it provides better protection. The history of the legislation on plant varieties and studies on the impact of PVPA on stimulating innovation in plant breeding shows that PVPA had met with mixed success.

Till Chakraborty and the introduction of modern biotechnology in plant breeding it offered some protection although it was not very strong, but it had some advantages over trade secrets. But post Chkraborty and post hibberd the situation has changed. With availability of patents, companies need not prefer protection under PVPA but can opt for patents. Companies can enforce their rights by entering in to agreements with farmers However it is likely that PVPA will lose its importance as patents offer better protection and are more appropriate for genetically modified plants.[24] However PVPA is needed to give double protection and to fulfill the UPOV norms.

In the 1990s the use of patented seed systems enabled companies to produce seeds with specific traits and qualities and protect them under patent. Further the farmers who bought such seeds had to agree to some conditions, laid down in an agreement and had to pay technology fees also. Thus the farmers had to forego many rights which were taken granted before these agreements. In addition to this the seed companies also sued farmers for violations and demanded damages and farmers were charged with violation on IP rights. For example Monsanto marketed seeds that are resistant to Round Up, herbicide sold by Monsanto. The development of proprietary seed systems helped the companies to get stronger protection under patent rights. Moreover companies sued farmers, who were the users, and not competitors to the company in seed production. Thus the direction of technological development was further towards reducing the options available to the farmer. The consolidation in industry, technological trends and deployment, legislative changes and judicial pronouncements thus resulted in the complete transformation of seeds, from that of a 'product of nature' to one protected under patents.

At this juncture it can be pointed out using IP rights to commodify and control is possible because of the combination of many factors, including withdrawal of public sector from seed production and distribution, development of hybridization and later application of

biotechnology, changes in law and judicial interpretations. Thus the expansion of IP rights was made possible by expanding the coverage of existing rights, development of a new right (under PVPA) and by making available the dual protection. With many forces shaping the developments it would be naïve to believe that IP regime evolved independent of these factors. Rather the continuous interaction between various forces led to the creation of an IP regime which over the decades has evolved in a particular direction.

Hybridization ensured that farmers had to buy seeds to get higher yields, and genetic engineering of plants coupled with reduced rights for farmers ensured that farmers had little option except to buy seeds again and again. But in all these achieving 100 % control is difficult. Seeds sprout and it is difficult to ensure that all farmers do not violate agreements or contracts and if they have violated it takes time and energy to challenge them in the courts, apart from the expenses. So although in theory patents give full protection, there are 'leaks' in the system. To eliminate this some technologies like terminator, verminator were developed so seeds do not germinate naturally and the germination process is controlled through an external input.[25] This is a step towards the ultimate control over seeds and in turn making farmers totally dependent on input providers. Controlling the means of production is the objective and the continued use of IP rights for this is a part of the strategy. Hence IP rights cannot be viewed as isolated rights used only to safeguard the intellectual property interests. Rather they are intertwined inextricably with technology, business strategy and the objective of commodification of seed and germplasm.[26]

It has been argued that PVPA is losing its relevance and it has not been a major factor in stimulating innovation. There are many unresolved issues even after J.E.M. Agro vs. Pioneer. Although PVPA protection may continue, its importance will be less than that of patents.[27]

From the above analysis of plants and IP in USA it can be concluded, the basis of American agriculture was laid with exotic germplasm, which was obtained from many parts of the world, but developments in technology, legal system and judicial interpretations have only helped in commodification of seeds and consolidation of the rights of the breeder/seed companies. Thus with the availability of triple protection control over seed is almost complete. With increasing use of biotechnology in agriculture and spread of GM crops, it is most likely that patents would be the preferred form of protection. Thus stronger IP protection and commodification of germplasm are inseparable. Is this the only option?.

Prima facie it may appear that the issue of IPR plants is well settled. But it is not so, as argued elsewhere both in formulating a legislation as well as in defining the criteria of a plant or plant variety there is no consensus. The decisions given in Europe and USA vary considerably and as it has been shown elsewhere within USA also interpretations on patentability of plants and plant varieties have varied. Hence the IP issues on plants are not settled fully. If at all anything with application of biotechnology new questions have arisen. The case law at present indicates that issues relating to genetic pollution and IP rights are still debated.

Plants and Intellectual Property : TRIPS, UPOV, Sui Generis system

Under TRIPS Article 27(1) members must allow patent protection for inventions in all fields as long as the inventions are novel, involve an inventive step and Articles 27(2) and 27(3) indicate that there could be exceptions to the rule that patents should be available for inventions in all fields. According to Article 27(2) an exception can be provided if the inventions, commercial exploitation of which might be contrary to ordre public or morality. According to Article 27(3)(a) countries need not provide protection for diagnostic, therapeutic, and surgical methods for the treatment of humans and animals.

Article 27.3(b) states that members may exclude from patentability

'Plants and animals other than microorganisms, and essentially biological processes for the production of plants and animals other than non-biological, and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provision of this sub-paragraph shall be reviewed four years after the date of entry into force of the WTO Agreement.'

The TRIPS is silent about excluding human genetic material from patent protection, but only if patenting of that is considered to be against morality or order public it could be excluded.

But in case of plants TRIPS indicates that there can be no exception, and only the form of protection is to be decided. Providing protection for plants either through patents or plant varieties is very new. The UPOV itself is hardly fifty years old. But providing protection to plant varieties has been a contentious issue, as the history of IP in USA shows and the nature and scope of protection has undergone changes over the last few decades. In Europe also there has been an extensive debate on this.[28] Yet many countries in the North or developed nations had one form of protection or other even before joining WTO and agreeing to TRIPS.

The rules of UPOV have been the basis although countries had opted for stronger protection even before, revision of UPOV Convention in 1991. So the question has been more than one of which form of protection (e.g. patents, certificate of protection) than protection per se. As argued before, citing examples from the USA the scope of protection has only expanded over the years and the trend is towards offering double protection and patenting is preferred as it provides stronger protection. The strong protection has been made possible by effective deployment of technologies like hybridization and using genetic

engineering to produce seeds with specific traits. Thus for developed nations the TRIPS provisions on protection for plants is nothing new. Rather it is only an affirmation of the practice followed in the North. Since only a small percentage of the population is engaged in farming as the primary occupation, the expanding scope of IP rights did not provoke a very intense response, although there was opposition to the same. And farmers were used to hybrids and have been fully integrated into the industrial mode of production, in which seeds is yet another input.

In contrast many developing nations or South did not have scheme of offering protecting to plants in the past, nor had very well defined and elaborate IP regime as in the North. But they have no option but to change their IP regime to be made compatible with TRIPS. So the question before them is not whether to provide protection for plant varieties or not, but which option to choose. What is the exact/actual obligation for developing nations under Article 27(3) (b).

Article 1 of TRIPS does not stipulate any condition except the three (invention must be new, there should be an inventive step, and it should be capable of industrial application. According to Article 27 "Subject to the provisions of paragraphs 2 and 3, patents shall be available for any invention, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application. (For the purpose of this article the term "inventive step" and "capable of industrial application" may be deemed by a member to be synonymous with the terms "non-obvious" and "useful" respectively.

TRIPS does not give any further indication about the scope of these conditions. TRIPS mentions about inventive step and hence one can presume that it does not permit patents on discoveries. Paraphrasing what Justice Berger observed in Diamond Vs Chakraborty patentable subject matter includes "anything under the sun that is made by

man". But this distinction is not easy to define as the controversy over patenting 'products of nature', human genetic materials show. Further the countries vary in the treatment they accord to inventions and discoveries and hence there is no universal guideline to differentiate between both and nor the TRIPS offers one.[29]

Countries vary in the treatment of the patentable subject matter and this is more a question of level of technological development, judicial interpretation and legal regimes than the nature of invention or technology per se. So the criteria laid down in Article 27.1 should be construed as a bare minimum, but the question is whether even this is met in case of patents. Commentators have discussed in detail the indeterminacy in TRIPS and in the national laws that were amended to make them compatible with TRIPS.[30] Thus whether Computer Software or Business Methods are patentable or not is a question on which there is no consensus. In the context of TRIPS the absence of a definition for invention can be used to adopt a flexible approach by countries in differentiating what constitutes an invention and what is a discovery in biology related patent claims.[31]

TRIPS was not intended to address the divergent views on interpreting and applying the criteria for patentability. But as countries interpret the criteria differently and adopt different norms the question of a universal criteria is important. The blurring of boundaries between products of nature and invention on one hand, and, absence of global standards on invention , on the other hand have resulted in countries adopting norms as decided by their legislatures and courts has led a confusing, if not a chaotic situation. For example according to Section 161 of Plant Patent Act 1930

"[W]hoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedling other than a propagated plant or a plant found in an uncultivated state, may obtain a patent therefore , subject to the conditions and requirements of this title . (35 U.S.C 161-64)

It is not necessary that all nations should allow patents on such discoveries. A Member state could adopt stricter norms and thereby make it difficult to obtain patents on discoveries or products of nature. As long as countries adopt TRIPS consistent policies there need not be universal protection for all innovations in all countries.[32]

The provisions of Article 27(2) can be used to exclude some categories of plant genetic material from patent protection. But it would be necessary to prove that such a commercial exploitation is against morality or ordre public. However this would be very difficult for morality is not an issue of patent law, but public policy. [33]

Thus the question of using morality or ordre public is almost ruled out, except in cases where it could be conclusively proved that patenting the invention harms environment or is against morality. Morality will be a weak defense in case of plant genetic material as that would result in using Article 27(2) to defeat the requirements of Article 27.3(b). But the debate in academic circles on biotechnology, morality and patents continues.[34] A detailed analysis of this issue, i.e. patent, morality and TRIPS is beyond the scope of this chapter.

More important in the context of TRIPS is Member states cannot establish legal concepts of invention which exclude any living or non-living material from IP protection as novelty, non-obviousness and usefulness, i.e. the relevant requirements for patentability can be met by inventions relating to living material as well. However this is easier said than done for the countries define the criteria differently and in view of different interpretations on patentability, it can be argued that there is no necessity that all countries should allow patenting life forms. In case of patents on onco-mouse the courts in USA and Canada have given contradictory judgments. The Canadian Supreme Court has rejected the patent claim on oncomouse. Article 8 of TRIPS is not of any use and it has been discussed mostly in the context of access to medicines. [35]

So the developing nations have to evolve an appropriate strategy to ensure that they use the flexibility in TRIPS without violating it. Before designing an appropriate IP regime for plants the countries have to assess the pros and cons of such a regime. Developing nations are at different stages of industrial and scientific development and hence any IP regime that is not compatible with the development objectives will be self defeating. Moreover as countries move upwards on technological capability the IP regime which was appropriate in the past may not be appropriate to meet the needs of the future.

Thus Member States however much they differ on interpreting Article 27.3(b) have to provide IP protection to plants in one form or other or in more than one form.

Plant Variety Protection, Patents and UPOV

UPOV stipulates that variety should be Distinct, Uniform and Stable following repeated reproduction. The UPOV Convention provides protection to plant breeders if the variety in question could meet the above criteria. The rationale for giving protection under UPOV is different from the rationale under patents, which is, inventiveness. So, comparatively speaking, protection under UPOV is given for developing a distinct variety and whether that is novel or not is secondary. So there is no need to disclose how the variety was produced. Protection under UPOV differs from patent protection as the rationale are different. This is not a strong protection compared to patents as UPOV provided for exceptions, (research exemption for researchers/plant breeders, farmers exemption for using the seeds in replanting without additional payment). In case of patents, there is no need to undergo a trial before a patent is granted. But in case of plant varieties usually the practice is that a variety is subjected to tests and trails, usually two years before the protection is given. This is to ensure that the DUS criteria is met successfully. The UPOV Convention 1961 has undergone changes and it was revised in 1978 and in 1991.

Plant Varieties and Intellectual Property Rights

The obligation under 27.3(b) is for granting protection to plant varieties only. Hence defining plant variety is essential. But TRIPS does not elaborate on this. One can define plant variety in a scientific sense based on taxonomy or in a legal sense based on specific criteria to be met for protection. A plant variety can also be defined as a combination of both. According to UPOV article 1 plant variety has been defined as

"A plant grouping within a single botanical taxon of the lowest rank, which grouping, irrespective of whether the conditions for the grant of a breeder's right are fully met, can be - defined by the expression of the characteristics resulting from a given genotype or combination of genotypes, distinguished from any other plant grouping by the expression of at least one of the said characteristics and considered as a unit with regard to its suitability for being propagated unchanged".

Varieties that may fail in the DUS criteria may fall under this definition also. The term 'plant variety' is now defined in the new R. 23b (4) EPC as:

"any plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety are fully met, can be:

a. Defined by the expression of the characteristics that results from a given genotype or combination of genotypes,
b. Distinguished from any other plant grouping by the expression of at least one of the said characteristics, and
c. Considered as a unit with regard to its suitability for being propagated unchanged."

The divergence between the legal definition and scientific definition has been pointed by Leskin and Flinter.[36] The PVPA of 1970 offers protection to breeder "of any novel variety

of sexually reproduced plant (other than fungi, bacteria, or first generation hybrids) who has so reproduced the variety. The term "plant" in 35 U.S.C. Section 161 covers plants in the ordinary and common sense rather than the strict scientific sense.[37] Thus the term plant varieties can be defined in many ways, and what is important is that the legal criteria need not be based on any scientific criteria. This may sound very strange but it is true as it is the legal discourse that had tried to set the definitions in the context of IP rights and not on the basis of any sound scientific principle.

The rationale for this could be that patents are for encouraging innovation and to provide incentives to create new varieties. So applying very strict criteria based on science and taxonomy may not be suitable. In the context of USA the legislative history of both PVPA and Plant Patents Act indicates that the Congress was expanding the scope of IP protection and there were divergent views and hence a solution that is legally valid was to be found, even if that amounted to defining plant in ordinary and common sense. In case of Europe the situation is more complex and the developments could be read as the outcome of the negotiations between various interest groups and hence the legal domain of Plant Variety protection is a contested domain.[38] Thus the term 'plant varieties' is more a legal construct than a scientific fact. With the advent of biotechnology the legal construct has also undergone changes as protection has been claimed on genes, F1 hybrid plants.[39] Thus although there seem to be a wide scope for flexibility in defining plant varieties the countries have to be careful in that. Many countries are committed to recognizing farmers' rights and farmer varieties. At the same time if they choose the definition in UPOV Article 1, many farmer varieties may fail to meet these criteria. One option is to exclude wild varieties from protection and make the condition less stringent for farmers' varieties if some conditions are met. Plant varieties can also be defined in a broad sense with different definitions for different types of varieties. [40]

The PVPFR Act of India defines four types (New Variety, Extant variety, Farmers' Variety and Essentially Derived Variety) with different criteria, rights and durations.[41] The issue is when many types of varieties are defined, how interests of various stakeholders are balanced without creating ambiguity. The issue becomes complex as countries want to give maximum flexibility to farmers under farmers' rights and also want to encourage private sector investment in plant breeding by providing for Plant Breeders' Rights. The Plant Breeders' Rights and Farmers Rights need not necessarily be contradictory but expansion in the scope of one curtails the scope of the other. But at the same time extending protection to farmers' varieties is fraught with technical problems.

One major problem as it has been noted is that there is no universal standard or system to categorize a variety and here the law and science need not be compatible. Moreover the concept of novelty can be narrowly defined to include commercial novelty which may not be a substantial novelty if some stricter criteria were applied.

As impressive and useful as they might be, traditional farmers' varieties cannot typically meet the UPOV criteria of distinctness, uniformity and stability. In particular, they are rarely uniform. A peasant farmer depends on the stability and dependability of production offered by genetic heterogeneity. Uniformity in the field all too frequently means vulnerability to pest and disease attacks. Thus, while the intellectual property of modern plant breeders might be protected legally, the breeding work of farmers is not and cannot be through the same statutes or similar approaches.[42] On the other it has been pointed out that novelty is often commercial novelty.[43] So this dichotomy will continue to haunt any attempt to devise a comprehensive definition of variety and evolving uniform criteria. Thus the foundations of IP regimes on seeds and plant varieties are nebulous.

Sui Generis System

The options for a TRIPS compliant Sui Generis System can be as specified below:[44]

1) Exclude plants and plant varieties and set up a sui generis system which can be under patent law or a separate system
2) Cover plants and plant varieties under patentability
3) Provide for dual protection under patent law and under another system or law,
4) As in the USA
5) Exclude plant varieties only from patentability and establish a sui generis system.

Under this plants and parts of plants will be eligible for patents. Thus while plant varieties per se are not patentable, there is no bar on patenting genetically modified plants or their components there of. The European Patent Convention comes closer to this model.

However, whether the countries, should join UPOV or not depends on many factors. The major advantage is countries can readily use the rules and provisions of UPOV and need not extend protection to all varieties to begin. Countries can also opt for 1978 version to begin with, but sooner or later they have to adopt the 1991 version. In other words they should be prepared to provide stronger protection over a period of time, although they need not grant patents, to begin with [45]. The flexibility available in TRIPS should be made use of while designing a sui generis system. With respect to the specific obligation in article 27.3b, the following remain undefined in the TRIPS Agreement:

A plant variety, the requirements for protection, such as novelty, distinctness, uniformity and stability, the scope of protection, i.e. whether a right should extend to vegetative, reproductive and harvested material, or to the export of the protected material, the duration of the right and the relationship between a sui generis right and other IPR such as patents. [46]

But designing a sui generis system for its own sake is meaningless. For developing nations the sui generis system should be compatible with other laws and public policy. They should examine the options and there is no need that they should accept UPOV as the norm. The exact definition of sui generis system is not found in TRIPS. But it can be inferred.[47] . But there is no definition of 'effective' in the TRIPS Agreement nor the Agreement indicates that UPOV is the guiding principle. This could be traced to the negotiations that resulted in TRIPS.[48]

It has been argued that effective could be considered in a narrow sense, to require provision of a right that excludes other from doing certain acts, and/ or to allow remuneration to be earned in respect of certain acts.[49] Unless WTO's TRIPS Council or Dispute Settlement Body clarifies what is meant by 'effective' countries can interpret it in any way they like as long it does not violate TRIPS. On the other hand UPOV in many aspects provides more protection than TRIPS or Paris Convention although prima facie it may appear that the exemptions weaken the protection under UPOV. In TRIPS Plus agreements countries are urge to provide stronger protection with very few exceptions and are required to offer patenting of life forms also.[50] This is 'effective' protection from the perspective of USA and EU. But even commentators who argue that UPOV model can be taken as an effective protection agree that TRIPS does not mandate UPOV or UPOV based one as the norm.[51] But as it has been shown in the USA there was much debate on extending IP protection to plants and some exceptions were made in PVPA also, apart from providing exemptions to farmers and researchers. However in the changing IP landscape patents are preferred to mere Plant Breeders Rights or a combination of both is sought. The UPOV also allows dual protection. Hence in USA, Europe effective protection means dual protection with virtually no exemption. So countries joining UPOV now, although may start with a sui generis system

and applying protection to a limited number of varieties may have little option later. But they still can have farmers' exemption which is very limited. [52]

Many countries are introducing protection for plant varieties for the first time now. Even countries like India and China which have intentions to join UPOV have not decided to restrict farmers' rights. Regarding implementation of 27.3(b) countries have expressed their reservations in WTO. So at the initial stages, developing countries will not restrict farmers' rights. As argued elsewhere the nation states are the ones who will be implementing Farmers Rights in the context of IUPGR. Hence although countries may join UPOV they may have legislations that still permit farmers' rights. But the question is whether they can do so in the long run. For example China introduced laws for 'protection of new varieties of plants' in 1997 and joined UPOV Convention of 1978. With China joining WTO it will have to implement the relevant provision of TRIPS sooner or later. But as discussed earlier it will have to provide a sui generic system.

So there is a strong need to evolve a non UPOV perspective on extending IP rights on plants. But as indicated earlier what constitutes an effective system is not clear. At this juncture it is worth pointing out that the UPOV system was designed to meet primarily the needs of nations in Europe and USA. The similarities in the issues relating to access to medicines and seeds are striking. In both these cases the developing nations can afford to affirm to the demands of developed nations only by discarding the interests of a large section of the population.

It is argued that a sui generis system can be devised by using the flexibility in TRIPS and by using the absence of a universally acceptable definition on plant varieties and on what constitutes novelty and invention.[53] The outlines of a system based on an open source perspective are given elsewhere is this dissertation. Ultimately the issues relating to seeds cannot be divorced from issues relating to role of private sector and public sector in seed

development and distribution, food security and access to essential inputs and the overall agricultural development policy.[54]

While national laws are necessary to protect the interests of the people and innovators, in the context of IPRs on plant varieties and seeds they alone are not sufficient. A solution at the international level, most probably a consensus on interpreting Article 27.3(b) and what are the elements of a sui generis protection is needed. [55]

Conclusion

In this chapter the evolution of IPR regime on plants and seeds in USA was discussed to argue that IP regimes could be viewed both as a result and as a contributory factor. It was pointed out that the technological trajectory and the interaction between IPRs and technology has resulted in almost total commodification of seeds and germplasm although that was not the only option available. It was pointed out that there are many ambiguities in defining a variety and the extent of IP rights over seeds and plants. It was also pointed out that the idea of sui generis system as specified in TRIPS is also ambiguous. Developing nations hence have to devise a suitable strategy so that while meeting the objectives of TRIPS they do not sacrifice interests of farmers and national agricultural development.

Notes and References

[1] A detailed analysis of the Indian Act on Plant Varieties Protection and Farmers' Rights is not given here as that forms part of a work in progress. Similarly this chapter does not provide an analysis of the relevant laws of various countries.

[2] In the words of Kloppenburg

"Plant germplasm is a resource that reproduces itself, and a single 'taking' of germplasm could provide the material base upon which whole new sectors of production could be elaborated." Kloppenburg (1988).

[3] Kloppenburg, P. 10,

[4] See the discussion in Fitzgerald, Deborah (1990), Kloppenburg (1988)

[5] Obviously the intention is not to given an extensive history of U.S agriculture and IP rights on seeds and plant varieties but to high light some important aspects relevant to the dissertation. Hence from the extensive literature available only a small portion has been cited in this chapter.

[6] See for an analysis Chapter 3 of Busch, Lawrence, Lacey, W.B. Burkhardt, J, Lacey, L. R (1991)

[7] Two plant breeders who experimented with hybridization wrote in 1919.

[Our method of producing hybrid corn] is the first time in agricultural history that a seedsman is enabled to gain the full benefit from a desirable origination of his own or something that he has purchased. The man who originates devices to open boxes of shoe polish or to autograph our camera negatives, is able to patent his product and gain the full reward for his inventiveness. The man who originates a new plant which may be of incalculable benefit to the whole country gets nothing - not even fame - for his pains, as the plants can be propagated by anyone... .the utilization of first generation hybrids enables the originator to keep the parental types and give out only the crossed seeds, which are less valuable for continued propagation" cited in Aoki (2003)

[8] As Kloppenburg points out

"Despite a reduction of 30 million acres on which grain corn was harvested between 1930 and 1965, the volume of production increased by over 2.3 billion bushels....and hybrid corn's 700 percent annual return on investment remains the much cited and archetypical example of the substantial returns society enjoys from agricultural research." Kloppenburg (1998) at P. 92.

[9] Fitzgerald, Deborah (1990) see Chapter 1)

[10] According to Fowler

"The rise of commercialized agriculture had created a concomitant need for control and predictability of elements of production (such as knowledge of and control of what varieties were being planted, and their characteristics), as well as for product differentiation--a situation which tended to enhance the value of and interest in specific, identifiable varieties of crops." Fowler, Cary (1994).

[11] Fitzgerald, Deborah (1990)

[12] . For a discussion on this, particularly the role of Luther Burbank see Kelves, Daniel, Bugos Glenn. E (1991), and, also Fowler (1994), Fowler (2000).

[13] Commenting on the impact of hybridization Nathan Busch writes

While all new seed varieties represented the intellectual property of the seed manufacturers, the hybrid seed represented, in addition, a means for protecting that intellectual capital. The introduction of hybrid seed, while not eliminating the need for legal intellectual property protection, certainly reduced the possibility that the farmer would be a direct competitor to the seed manufacturer. The introduction of hybridization technology also accompanied the movement from the dependence upon

a centralized public institution for germplasm maintenance to privatization of the seed and plant industry" Busch, Nathan. A (2002) at P 32.

"Hybrid corn expanded the sphere of commodity production by creating a new and extraordinary profitable commodity which could not have been produced by alternative breeding methods. In the early twentieth century, a strong social and ideological movement in favor of proprietary rights influenced breeding work" Lewontin, Richard C and Berlan, JeanPierre (1990).

See Berlan(2001) for a history of development of hybrids in USA and elsewhere.

[14] Fitzgerald, Deboarh (1992)

[15] Wijk, J. van (1994)

[16] "Genetic uniformity of hybrids may be a desired trait for many but it also makes the plants vulnerable. This became painfully clear in the USA in 1970. About 15 per cent of the maize crop in that year was lost to an epidemic of Southern Corn Leaf Blight. The epidemic was caused by the susceptibility of the cytoplasm incorporated into the maize lines to achieve male sterility. Because nearly every maize hybrid in the USA carried this cytoplasm, the epidemic swept maize fields in large parts of the country and would have been worse if the weather had been less unfavourable for the disease organism. The risk that uniformity in cytoplasm in hybrids causes an epidemic again is not just theoretical, *as in some crops the number of different cytoplasm types incorporated in the hybrids is extremely limited."* Wijk, J. van (1994)

(Emphasis added). See also Doyle, Jack (1986) for a discussion on this issue.

[17] According to one report

'In their original form, these acts offered relatively weak intellectual property protection for plant breeders. Courts interpreted the acts as only protecting exact copies of the varieties. Phenotype variations, or variations in plant appearance due to environmental conditions, were unlikely to be protected. Other plant breeders were also allowed to use the protected variety in their breeding programs. One concern was that this would not prevent "cosmetic breeding," in which economically insignificant changes are bred into a protected variety to claim a new variety. In addition, under the Plant Variety Protection Act, farmers were allowed to save seed for replanting and to sell part of their seed to other farmers. While these limitations helped assure the wide availability of new varieties, they also reduced the returns to private plant breeding and lowered the incentive for private companies to invest in varietal improvement. Fuglie, Keith, et.al.

(1996) at P.35.

[18] As Kloppenburg points out

"[and because] eligibility for protection under the PVPA requires no demonstration of economic utility over existing species means this fine-tuning can be used to create "pseudo-varieties." ... [and] the PVPA has not resulted in the development of private varieties significantly superior in yield or quality... .[but] has been associated with a proliferation of varieties and greater choice. But that choice is more apparent than real." (Kloppenburg (1998) at 144, 146).

Another scholar writes

"The commercial seed industry attributes the development of the private seed industry to a great extent to PVP, but clear evidence for this assumption is absent. The conclusions of the very few studies that have been carried out on the effects of PVP on R&D investment are modest. An American study concluded that the U.S. PVP Act has stimulated the development of new varieties of a few crops, such as wheat and soybean, but there is little evidence that it has affected the R&D output for most self-pollinating crops (Butler, 1996:28). Also the U.S. Plant Patent Act (which provides a PVP type of protection for non-sexually propagating plants) had little impact on private investment in fruit breeding because the Act allows only a very narrow product space, and because enforcement costs are high (Stallmann and Schmid, 1987). A recent study carried out in Argentina, where PVP has been enforced since 1990, concluded the system has presumably played a role in preventing a reduction in plant breeding in soybean and wheat, rather than stimulating additional R&D expenditure (Jaffé and van Wijk, 1995)"

Butler, L.J. (2000) .

Thus the effect of PVPA or Plant Patents Act is not clear or it is little evidence to conclude that these Acts played a major role in spurring innovation and investment in R&D.

[19] In that case Justice William O. Douglas observed

"Patents cannot issue for the discovery of the phenomena of nature. ... The qualities of these bacteria, like the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none."

[20] For example Berkowitz , Kevles (2002) 'Attempts patent human DNA rest legally on Diamond v. Chakrabarty ' P 75

[21] According to Kloppenburg

"In view of the implications of Chakrabarty, the Plant Variety Protection Office took the precaution of appending to its list of abandoned applications the warning that 'Varieties published in this list may possibly be protected under the Patent Act.' " (Kloppenburg 1998,P262)

[22] Noting the ambiguity in the provisions the Court held that the

"Farmers exemption ' for saved seed allowed farmers to sell only such seed as was saved to replant their own acreage and not to engage in the business of selling protected seeds" Merges, Robert P,. Menell, Peter.S, Lemley,Mark A (2003) at 315.

[23] Aoki points out

"Looked at critically, Justice Thomas' opinion appears to say that because the text of the PPA and the PVPA do not explicitly say that general utility patents can NOT be issued for germplasm, this constituted permission for the PTO to extend utility patent protection to asexually or sexually reproduced germplasm. As pointedly noted in the dissent by Justice Breyer, the majority opinion ignores the clear legislative history of the congressional understandings in the drafting of the PVPA. Justice Breyer points out how in 1968, Congress rejected the option of extending patents to seeds, and engaged in negotiations with the different parties involved (public breeders, the seed industry and farmers) in order to craft compromise draft legislation that ultimately became the PVPA, in order to grant a weaker form of intellectual property to plant breeders. Indeed, Justice Breyer argued that by providing exemptions for seed saving by farmers and research under the PVPA when no such exemptions exist under the general utility patent statute, Congressional intent to protect farmers would be rendered a nullity if the seed industry was able to concurrently seek utility patents along with PVPA certificates." Aoki (2003) at 302.

[24] "PVPA proponents presented the PVPA as a regime that would meet the lofty objective of providing patent-like protection in a specific technological area - plant innovation - by seeking to capture the social benefits of patent protection, but nevertheless, accomplishing this by striking a different balance between protected and permitted activities. Our thirty-year PVP experience suggests that narrow, Swiss-cheese like, intellectual property protection does not promote excludability and, consequently, does not permit appropriability. ... Indeed, the very existence of the PVPA may pose future political and legal problems by exerting pressure on the more robust utility patent protection regime for plants by, for example, creating opportunities for seeking heightened standards for non-obviousness for plant utility patents. There are very limited reasons that support retaining a PVP regime of protection." Janis, Kesan (2002a) at 777-778.

[25] For an analysis see Berlan, Jean-Pierre (2001), Pottage, Alain (2003)

[26] The technological trajectory reveals the intentions behind the commodification process.

Aoki points out

"Beginning with hybridization in the early twentieth century, and continuing through to Monsanto's Terminator technology at century's end, it has become increasingly easy for companies to sell the seed as a complete commodity, as well as retaining control over the means of production (the genetic enhancements safeguarded by seeds that grow but produce sterile seeds). Aoki (2003) P. 250).

[27] 'Utility patent protection will quickly emerge as the dominant form of IP protection for the domestic seed industry." Janis, Kesan (2002) at 1164

[28] See Funder (1999), Westerlund (2003) particularly Chapter 6 .

" ... the exclusion of plant varieties from patentability under EPC was historically explained by the system of special protection for plant breeding products which was developed at the same time as the EPO was negotiated ' Westlund P. 242

[29] As Carvolho points out

"The TRIPS Agreement does not prohibit WTO Members to grant patent protection for discoveries or for inventions that could be seen as mere reconstitutions of natural products and processes. Actually, several WTO Members accord a liberal treatment to inventions that seem more products of nature than products of human intervention, especially in the biotechnological field" (P 147). Carvalho 2002

[30] Shankar, Daya (2002)

[31] "The TRIPS Agreement contains no definition of invention and therefore leaves member countries relatively free to draw the line between patentable 'discoveries' and actual inventions in the biological patents thus allows countries considerable leeway in fashioning their policy options" UNCTAD (1996) P 34.

[32] "The mere fact that certain innovations have been granted patent protection in some member states does not imply an obligation for other member states to do the same if the TRIPS Agreement does not require them to do so" (Leskien and Flitner, 1997).

[33] The Board of Appeal of the European Patent Office has stated

The board defined the concept of "ordre public" as covering the protection of public security and the physical integrity of individuals as part of society. It also encompassed the protection of the environment. Accordingly, inventions the exploitation of which was likely to seriously prejudice the environment were to be excluded from patentability as being contrary to "ordre public". The concept of morality was related to the belief that some behaviour was right and acceptable whereas other behaviour was wrong, this belief being founded on the totality of the accepted norms which were deeply rooted in a particular culture. For the purposes of the EPC, the culture in question was the culture inherent in European society and civilisation. Accordingly, inventions the exploitation of which was not in conformity with the conventionally accepted standards of conduct pertaining to this culture were to be excluded from patentability as being contrary to morality. Thus, the question to be decided in respect of Art. 53(a) EPC was whether the exploitation of any of the claimed subject-matter was likely to seriously prejudice the environment or whether it related to a misuse or destructive use of plant biotechnological techniques. In the specific case the board held that, although the documents submitted by the appellant (opponent) provided evidence of possible hazards from the

application of genetic engineering techniques to plants, they did not lead to the definite conclusion that the exploitation of any of the claimed subject-matter would seriously prejudice the environment.

http://db1.european-patent-office.org/dwl/legal/case_law/clr_all_en.pdf P 32-33 last visited 12th April 2004.

[34] See Drahos, Peter (1999) See also Bagley, Margo A (2003b) for a discussion on morality and patent law in USA, Gitter, Donna M (2001) for case law relating to morality and patents see Visser, Dana (2000).

[35] It has been pointed out that there is no operational obligation under Article 8 (Watal, Jayashree 2001, pp292-94). The negotiating history also leads to a similar conclusion.(Greavis 1996).

[36] Leskin and Flinter 1997

[37] Chisum on Patents (www.lexis.com)

[38] Further as Rangenakar has argued

"In fact, the origins of the EPC reveal a compromise between lobby groups representing patent lawyers (i.e. AIPPI) and plant breeders (i.e. ASSINSEL), wherein a legal distinction was erected to separate the spheres of patents and PBRs in a manner to map the distinction between microbiological and biological, respectively. Patent challenges at the EPO suggest variations and changes in the interpretations of 'plant variety', which with the final passage of the Biotechnology Patent Directive (of 1998) could favour a narrow definition of plant variety, thus restricting the legal domain of PVP law." Rangnekar (2002) P 40. See Rangnekar (2004), Westlund (2002) also. See also Lacey, Hugh (2003).

[39] . For example US Patent 4629819 Claim No 1 is for 'F1 Generation hybrid corn DK524' Correa (2000) P. 183.

[40] For example The (draft) Thai plant variety gives four definitions for plant variety, wild plant variety, general domestic variety, and local domestic variety. Llewelyn, Margaret (2003) P. 322.

[41] Ramanna (2003). See also Lalitha (2004) for an analysis.

[42] Fowler (1997)

[43] See Rangenkar, Dwijen (2002), See Westlund (2002) also

"One difference is that under the 1978 Act, a breeder is entitled to protection through being the "discoverer" of the new plant variety, whereas under the 1991 Act, mere discovery is not sufficient. Nonetheless, the criteria for "novelty" appear to emphasise commercial considerations,[43] rather than testing for inventiveness. "Sampath, Padmashree Gehl, Tarasofsky, Richard. G (2002).

[44] Leskien and Flitner, 1997.

[45] (Crucible Group, 1999, pp63-65)

[46] IPGRI 1999

[47] "A sui generic mechanism is exactly that : a mechanism that draws some provisions and principles from existing regimes, adapting them to specific characteristics of its subject matter. The protection of lay out designs (topographies) of integrated circuits is also a sui generis mechanism that borrows provisions from both the copyright and industrial design systems Carvalho (2002) (P 180).

[48] "Unlike the other subjects under TRIPs, there is no mention of adherence to the pre-existing international convention, UPOV. One possible reason was that UPOV 1991 had not yet entered into force; a reference to UPOV 1978 was considered inadequate, while a reference to UPOV 1991 was considered premature. Another reason for this brevity of this provision is that there was no agreement among industrialised countries as to the details of an effective sui generis system of protection for plant varieties." (Watal 2001 P 140).

[49] Leskien and Flitner, 1997

[50] Morin (2003), www.grain.org

[51] "Presumably in the case of a sui generis system what was contemplated by a number of negotiators was a UPOV-type protection. It is safe to assume that a UPOV (1991)-compatible system would enjoy a presumption of the effectiveness required by this Article. Yet the Article as it stands does not mandate UPOV protection and WTO members are thus free to develop another type of effective protection". (P225 Gervais (2003)

[52] As Carvalho (2002) points out

"The exception must be confined within reasonable limits and provided the legitimate interests of the breeder are preserved". Further Carvalho points out the similarities of Article 30 of TRIPS and UPOV 1991 and argues that no exception that nullifies, right or rights, of the breeder is not permissible. This implies that farmers' rights on seeds are limited to their own use and farmers are not permitted to engage in producing and selling seeds to others.

[53] "The concept of plant variety is problematic, particularly because it is a legal definition with no clear foundation in biological science" P. 245

"Because of the criteria laid down for the variety concept, which must be applied to the biological reality, there is no clear-cut borderline between the subject matter protected by different systems" P. 244, Westlund (2002)

[54] See Rangnekar (2004), Cullet (2003)

[55] See Correa (2000) P 201 – 202 for a list of possible actions to be taken at the international level.