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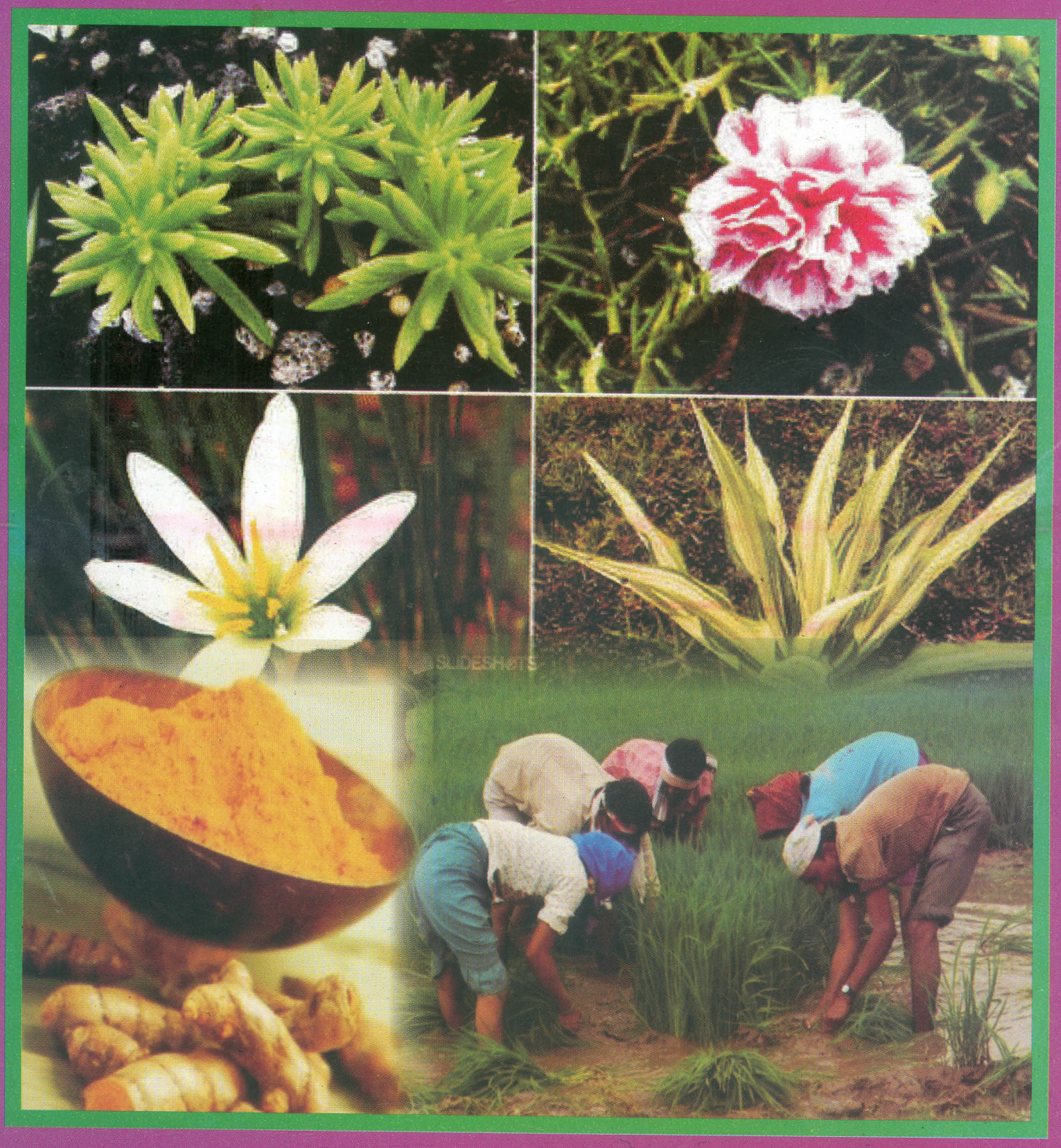
MIP-106
PLANT VARIETIES PROTECTION, BIOTECHNOLOGY AND TRADITIONAL KNOWLEDGE



International Conventions for the Protection of New Plant Varieties 1

"शिक्षा मानव को बन्धनों से मुक्त करती है और आज के युग में तो यह लोकतंत्र की भावना का आधार भी है। जन्म तथा अन्य कारणों से उत्पन्न जाति एवं वर्गगत विषमताओं को दूर करते हुए मनुष्य को इन सबसे ऊपर उठाती है।"

– इन्दिरा गांधी

"Education is a liberating force, and in our age it is also a democratising force, cutting across the barriers of caste and class, smoothing out inequalities imposed by birth and other circumstances."

–Indira Gandhi

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Plant Varieties Protection, Biotechnology and Traditional Knowledge

Block

1

INTERNATIOAL CONVENTIONS FOR THE PROTECTION OF NEW PLANT VARIETIES

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MIP-106 PLANT VARIETIES PROTECTION, BIOTECHNOLOGY AND TRADITIONAL KNOWLEDGE

The evolution of the Intellectual Property Right Regimes has always been influenced by the prevailing political and economic situations. Patent laws have traditionally exempted plants from the scope of protection. Thus plant variety protection or PVP, a form of IPRs for plant varieties has only recently gained momentum. Till 1990's PVP was exclusively a feature of the developed countries.

The form of intellectual property for protection of plant varieties is widely known as Plant Breeders Rights (PBRs). The PBR like any other IPR system allows the plant variety owner to prohibit specific unauthorized uses of the variety. This course will extensively deal with issues relating plant variety protection.

The Course consists of four blocks.

Block I – International Conventions for the Protection of New Plant Varieties
Block II – Protection of Plant Varieties, Farmers and Breeders Rights in India
Block III – Intellectual Property and Biotechnological Inventions
Block IV – Protection of Traditional Knowledge

In **Block 1** of this Course we will concentrate more on the objectives of plant varieties protection and the Plant Breeders Rights (PBRs)

In this Block issues like origin of plant breeding and crop development, approaches for development of new varieties, Plant Patents, Plant Breeders Rights and UPOV, a look on the background of CBD negotiation, biosafety issues, key provisions of the UPOV convention, DUS tests etc are extensively taken and explained.

Block 2 of this course concentrates on plant varieties and farmers rights, wherein topics like objectives of the PPV and FR Act are discussed and explained, other topics like conducting of the DUS tests, scope of breeders rights, procedures in enforcing PBRs, protection of plant varieties and farmers rights, rationale for farmers rights etc are explained.

Block 3 of this course extensively discusses issues based or Genetic resources and biotechnology. In this block major issues like biotechnology and law, biotechnology and ownership mandate of TRIPS Agreement, issues relating to IPR and technology, common inventions related to biotechnology, Indian scenario on this issue etc are discussed in details.

Block 4 of this course is exclusively dedicated to Traditional knowledge. This course explains topics related to the protection and the significance of traditional knowledge.

The efforts for the protection of traditional knowledge global issues for the protection of traditional knowledge and the Indian efforts towards the protection of Traditional Knowledge.

This course is of 4 credits
1 credit = 30 hrs of study
4 credit = 4 × 30 hrs = 120 hrs of study

Therefore learners are requested to dedicate 120 hrs of study in reading, discussing and studying the Course.

Good Luck and happy reading!

BLOCK 1 INTERNATIOAL CONVENTIONS FOR THE PROTECTION OF NEW PLANT VARIETIES

This Block concentrates on the International Convention for the protection of new plants. In this Block, major topics like plant variety, their classifications, and their naming are initially explained, then other sensitive issues like the origin of plant breeding, crop improvement, variety development and plant breeding, different approaches for the development of new varieties, modern techniques for crop improvement, etc are discussed and explained.

This Block consists of four units.

Unit 1 of this Block will try to explain the objectives of Plant Varieties Protection and Plant Breeders Rights (PBRs).

Unit 2 of this Block explains the topic like how the plant variety protection has evolved in the new era. Under the umbrella the TRIPS agreement has dealt with issues like the TRIPS obligation and IPR, the other topics like alternatives for protecting new plant varieties, it has also tried to explain the rationale for the sui-generis option. The Unit deals with other topics like alternatives for protecting new plant varieties etc.

Unit 3 of this Block concentrates on the topics and issues of background of CBD negotiation which deals with issues related to conservation, patents, prior informed consents etc. This unit deals with other sensitive issues like bio-safety issues, and the national response.

Unit 4 of this Block explains the key provisions of the UPOV convention, like the scope of plant breeders rights, varieties covered within the scope of the Plant Breeders Rights (PBRs), essentially derived varieties, duration of plant Breeders Rights, the DUS tests etc.

UNIT 1 OBJECTIVES OF PLANT VARIETIES PROTECTION AND PLANT BREEDERS' RIGHTS [PBRS]

Structure

1.1 INTRODUCTION

The evolution of the Intellectual Property Rights regimes has always been influenced by the prevailing political and economic situations. In addition, the area domain of the innovations that are intended to be protected has led to emergence of a family of IPR systems that are applicable for different types of intellectual creation. Patent laws have traditionally exempted plants from the scope of protection. In this context the Plant Variety Protection (PVP), a form of IPRs for plant varieties, is a relatively recent phenomenon in the long history of IPRs.

Till the early 1990s, PVP remained almost exclusively a feature of developed countries. The major water-shed period related to IPR protection for plant varieties resulted from the Uruguay Round of General Agreement on Tariffs and Trade (GATT) concluded on April 15, 1994 and known as the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement. During the negotiations, the developed countries and transnational corporations lobbied for expansion and introduction of uniform IPRs regimes for protection of plant varieties globally.

The implications of the extending regimes of IPRs, particularly in the developing countries, witnessed heated public debate at national and global forums that cut across wide range of sectors, such as food and nutritional security, biological diversity conservation and environment degradation, economic, social and cultural development and ethics and human rights. However, as acceptance of the TRIPS Agreement was one of the conditions of entry in the World Trade Organisation (WTO), many countries opted for the obligations of TRIPS to harness the benefits of WTO. The obligations included that the countries provide an "effective" system of plant variety protection within a specified time frame. This has significantly accelerated the spread of PVP systems across countries. The form of intellectual property for protection of plant varieties is known widely as plants breeders' rights (PBRs). The PBR like any other IPR system allows the plant variety owner to prohibit specific unauthorized uses of the variety.

The plant breeders' rights (PBRs), which are more comprehensive in the coverage of varieties to be granted legal protection, have a recent origin, even in the developed world. While there are universally accepted minimum standards for other forms of IPRs, most of the countries have opted for *sui generis* legislations that offer less stringent protection than patents.

PBR systems, like other IP systems, has three major components:

1) Definition/identification of protectable subject matter

2) Requirements that must be met to receive protection

3) Rights of the variety owner

Before we try to understand the details of legislations for obtaining PBR in subsequent Units; in this Unit the focus would be to understand the subject matter including what are plant varieties, basic principles involved in plant breeding and the need for separate PBR system.

1.2 OBJECTIVES

After completing the study of this unit, you should be able to:

- acquire a basic knowledge of taxonomy of plant variety;
- explain some of the key features of plant breeding;
- describe, the process involved in developing a new variety;
- explain the benefits of a PBR system.

1.3 PLANT VARIETY

It is well known that plants are a major source for human beings for their needs including food, fodder, fibre, fuel, shelter and products of industrial and pharmaceutical importance. In addition, the plants make tremendous indirect contribution in maintaining greater resilience in the ecosystems, and also in providing for recreational, inspirational and spiritual comforts to human beings.

1.3.1 Plant Classification

The plant kingdom is vast and throughout ages human beings have been interested in the study of plants. Various explorers discovered new lands and came across new plants of interest. Therefore, the need arose to describe, classify, identify, and names plants. Carolus Linnaeus, a Swedish physician and botanist, published in the mid 1700s, a two-volume work *Species Plantarum*. Linnaeus grouped the species according to their reproductive parts and classified them into many divisions and sub-divisions. A "Family" is a division within the plant kingdom, usually where the classification process takes on significance, as at this level, the similarity between plants is often easily recognisable by the layman. The Family is subdivided into "Genera", which are further subdivided into "Species".

An example would be of Family Solanaceae, the potato or nightshade family, which includes some 100 genera and nearly 2,500 species and includes major crop plants such as potatoes, tomatoes, bell peppers, eggplants, tobacco, and the garden petunia.

Although the rank of species is an important botanical classification, it is clear that the plants within a species can be very different. Farmers and growers need plants that are adapted to the growing conditions in their local environment and which are suited to the cultivation practices employed. Therefore, farmers and growers use a more precisely defined group of plants, selected from within a species, called a plant "variety". A case in point could be that in India, there are nearly 1000 mango varieties, which have specific ecogeographical requirements for optimum growth and fruiting. Some of the well-known commercial varieties include Dashehari, Langra, Chausa, Bombay Green and Fazri in north India; Banganapalli, Totapuri, Neelum, Pairi, Suvarnarekha, Mulgoa, Kalapadi and Rumani in south India; Alphonso, Kesar, Mankurad, Fernandin' and 'Vanraj' in western India and 'Langra', 'Fazri; 'Chausa', 'Zardalu', 'Himsagar' and 'Malda' in eastern India.

1.3.2 Naming of Plants

Further, it is important that the names of the plants are accurate and unambiguous. While most of us are much more comfortable referring to the plants by their common names, the problem is that these names are generally specific to a geographical region and therefore, not universally accurate. For example, eggplant, aubergine, melongene, guinea squash, berenjena, garden egg, egg apple, patlican, melanzane are some of the names by which the plant we call as brinjal is referred to. In contrast, the same plant has one scientific or botanical name: *Solanum melongena* acknowledged worldwide.

The major advantage of scientific naming of plants is that there is only one name per species which is recognised and documented worldwide and is same in any language. There are three basic rules pertaining to the scientific name, one it always has two parts, the Genus (capitalized first letter) and species (lower case). Second the order is genus first, species second, like Gupta Anil. And third both names are always set apart in the text – by underlining, italicizing, or boldfacing. The application of scientific names to plants is governed *International Code of Botanical Nomenclature (ICBN)* which provides a single set of rules, accepted and followed throughout the world, and periodically revised and updated.

1.4 ORIGIN OF PLANT BREEDING AND CROP IMPROVEMENT

In addition to the enormous genetic diversity between plant species resulting in the large number of plants we see, there also exists large genetic variability within a species. This genetic diversity is essential for any species to maintain its reproductive vitality, resistance to disease and ability to adapt to changing conditions. In the absence of this genetic diversity, it would not have been possible to identify plants that exhibit variation for the traits or plants of interest. It, therefore, formed the basis for genetic improvement both at the plant level through plant selection, and at the varietal level through varietal choice. The early farmers recognised that certain species were more suitable than others for their needs and that within populations, some plants were more suited to their specific requirements. The efforts resulted in developing combination of populations and growing environments that result in phenotypes that provided the optimal net benefit to the farmer.

As the improved crops were further carried and introduced to new locations, the natural inter-crosses with new wild populations provided opportunities for increase in genetic variation, through the interaction of the environment with the genotype (the genetic makeup) and the resultant expression of the genotypes in the form of the phenotypes (morphological appearance). Darwin had observed that in any population of plants or animals, individual members carried hereditary traits which are slightly different from one another. It is these traits which could give the member a better chance of adaptation. According to the theory proposed, these better adapted individuals would get more food, be healthier, live longer and, most importantly, have more mates in staying alive long enough to successfully reproduce and pass on their traits more frequently to the next generation. Further, with successive generations, traits become more obvious in the populations, and possibly after thousands of generations, form a new species.

The earlier crop improvement efforts were aimed at selecting the naturally occurring variants. Systematic plant breeding began by the end of the eighteenth century, when the innovative farmers realised that considerable further progress was possible by systematic selection.

1.4.1 Beginnings of Systematic Plant Breeding

The early plant breeders made conscious attempts to predict the performance of plants that could be expected from one generation to the next. Each year the best appearing individuals of a generation of plants in the field were selected and seeds for next sowing were collected from these superior individuals only. Practicing this selection for each subsequent generation, proportionately resulted in more superior individuals and after many generations of seed selection, a superior new variety of a plant species could be bred from the original inferior variety

Initial efforts to breed plants were somewhat of a hit or miss process as they were carried out without a clear understanding of the genetic mechanism involved in inheritance. The refinement in the selection process came when the importance of ancestry was realised. Mendel in 1866 worked with common pea plants (*Pisum sativum*) and selected seven traits that could be easily recognised and apparently occurred only in one of two forms, such as flower color (red versus white), plant height (tall versus dwarf), seed coat (smooth-coated seeds verses wrinkled seeds), pod length (long pods versus short pods), and so on. He observed that these traits show up in offspring without any blending of parent characteristics. Through the selective cross-breeding for over many generations he proposed the laws of heredity that explained the expression of the characteristics and their inheritance by later generations of plants.

1.4.2 Genotype and Phenotype

At the time that Mendel did his research, there was no knowledge of chromosomes, cell structure, fertilization, mitosis and meiosis, which is now common knowledge. Geneticists distinguish between genes and their expression, as genotype and phenotype. A genotype is the actual set of genes or genetic makeup of an organism whereas a phenotype is a measurable characteristic of an organism. Mendel's findings, therefore, show a remarkable use of observation and deduction which was quite ahead of his time and linked the, **genotype**, of the pea plants with resultant expression of the genetic structures as observed in its **phenotype**.

1.4.3 Mendelian Genetics

Since pea plants are capable of self fertilization, Mendel was able to produce true-breeding plants, that is, plants of the second generation had consistent traits with those of the first generation. A true-breeding tall plant for example would only produce tall offspring. He performed monohybrid crosses, meaning that the experiment was carried out between two strains of plants that differed only in one characteristic. For each of the seven phenotypes, he crossed parents of different phenotypes to see what resulted. He referred to the two parental plants as the parental generation (P generation) and the resulting offspring were called the first filial or F1 generation. He noticed

that by crossing pure tall plants with pure short plants, all the new pea plants in the F1 generation were tall. The one trait not expressed in the offspring (in this case short plant) he called a recessive trait. The following generation (F2) consistently has a 3:1 ratio of tall to short plants. He hypothesised that there is a 'factor' that makes pea plants tall and another factor that makes pea plants short; and when the factors are mixed, the tall factor seems to dominate the short factor. The individual inherits one such unit from each parent that are passed on to descendants unchanged; and a trait may not show up in an individual but can still be passed on to the next generation.

It was not until the early 20th century that the importance of Mendel's ideas was realised. In modern day genetics, we use "allele" (forms of expression) or "gene" instead of what Mendel called factors. An allele that can be suppressed during a generation is called a recessive allele, while one that is consistently expressed is a dominant allele. It is also now established that in diploid plants, there are 2 sets of chromosomes and for each gene, there is a pair of alleles (one in each chromosome). The plants or individuals who have two copies of the same gene, e.g. Round/Round or Wrinkled/Wrinkled are described as **Homozygous** and individuals which received a different type of gene from each parent, eg. Round/Wrinkled or Wrinkled/Round are described as **Heterozygous**. In this case, Round being the dominant trait, the phenotype of the plant would be Round, though the genotype Round/Wrinkled.

It is important to realise that, in this experiment, the starting parent plants were homozygous, that is to say, they each had two identical or alleles of the gene for the traits. The plants in the F1 generation were all heterozygous.

Further, after performing dihybrid crosses between plants that differed in two traits, such as seed color and pod color. Mendel formulated the principle of independent assortment.

Exercise:

Based on the expression of the characteristics and their inheritance by later generations of plants let us understand their applicability in plant breeding and variety devlopment. As a first step of selection process, let us identify heterozygous plants for two traits namely height and flower colour, for considering a 'dihybrid cross'.

Let us designate capital "T" for the dominant tall allele, and the lowercase "t" for the recessive short allele and capital "C" for the dominant coloured flowers allele, and the lowercase "c" for the recessive white flowers allele. As allele for tall plants and coloured flowers are dominant a tall plant would have the genetic expression 'TT' or 'Tt' while plants with coloured flowers would have the genetic expression 'CC' or 'Cc'.

The phenotype of the heterozygous plant will be tall with coloured flower as these are dominant traits and the genotype will be TtCc.

Self Assessment Question **(Spend 3 minutes)**

1) What type of gametes will this plant produce?

   i) Tt, Cc

   .....

ii) T,t,C,c

.....

iii) TT,tt,CC,cc

.....

iv) TC,Tc,tC,tc

.....

Since the gametes are TC, Tc, tC, tc and this is a self fertilization, the gamete types shall be the same for both parents. Let's see below the Punnett square, a diagram named after Reginald C. Punnett, used to predict an outcome of a particular cross or breeding experiment and represents visual representation of Mendelian inheritance.

		Male Gametes			
		¼ TC	¼ Tc	¼ tC	¼ tc
Female gametes	¼ TC	1/16 TTCC	1/16 TTCc	1/16 TtCC	1/16 TtCc
	¼ Tc	1/16 TTCc	1/16 TTcc	1/16 TtcC	1/16 Ttcc
	¼ tC	1/16 TtCC	1/16 tTCc	1/16 ttCC	1/16 ttCc
	¼ tc	1/16 TtCc	1/16 tTcc	1/16 ttcC	1/16 ttcc

As can be seen above, the genotype of the offsprings are TTCC, TTCc, TTcc, TtCC, Ttcc, TtCc, ttCC, ttCc, ttcc.

Self Assessment Question **(Spend 3 minutes)**

2) What would be the genotypes of plants with phenotypes as given below? (Remember tall and coloured flowers are dominant phenotypes)

i) Tall plants and coloured flowers:

.....

ii) Short plants and coloured flowers:

.....

iii) Tall plants and white flowers:

.....

iv) Short plants and white flowers:

.....

Let us now put the phenotypes in the Punnett square as below:

		Male gametes			
		¼ TC	¼ Tc	¼ tC	¼ tc
Female gametes	¼ TC	1/16 TTCC	1/16 TTCc	1/16 TtCC	1/16 TtCc
		 Tall colored	 Tall colored	 Tall colored	 Tall colored
	¼ Tc	1/16 TTCc	1/16 TTcc	1/16 TtcC	1/16 Ttcc
		 Tall colored	 Tall white	 Tall colored	 Tall white
	¼ tC	1/16 TtCC	1/16 tTCc	1/16 ttCC	1/16 ttCc
		 Tall colored	 Tall colored	 short colored	 short colored
	¼ tc	1/16 TtCc	1/16 tTcc	1/16 ttcC	1/16 ttcc
		 Tall colored	 Tall white	 Short colored	 Short white

Now let us count the number of plants with different phenotypes. You will find these are: Tall and Coloured flower = 9; Tall and white flower = 3; Short and coloured flower = 3; and short and white flowers = 1.

Therefore, it can be concluded that different pairs of alleles are passed to offspring independently of each other and the same ratio of 9:3:3:1 appeared among the offspring. Therefore, for example a pea plant's inheritance of the ability to produce tall plants instead of short ones does not make it more likely that it will also inherit the ability to produce coloured flowers seeds in contrast to white ones.

1.5 PLANT BREEDING AND VARIETY DEVELOPMENT

Plant breeders have played a pivotal role in improving the crops productivity, particularly as witnessed in the second half of the last century. The self-sufficiency in food grains achieved during the 'Green revolution' would not

have been possible without the huge genetic improvements made to the crops. Recent scientific and technological developments have allowed a greater rate of improvement. Today breeding has evolved as a sophisticated, high investment business and the breeding programmes plan and look years ahead to the needs of farmers, consumers and the environment. Plant breeding can directly improve the performance of crops in different ways. Some of the broader objectives are given below:

1.5.1 Increasing the Productive Yield

Developing crop varieties which convert more of their biomass into productive yield is the single biggest contributor to improved crop output.

1.5.2 Physical Characteristics

Changing a crop's physical structure can also contribute to increased yields; among the most spectacular development in crop improvement was transfer of dwarfing gene from Japanese wheat cultivar 'Norin 10' which began a new era in crop improvement with the development of dwarf varieties.

1.5.3 Pest and Disease Resistance

There are numerous examples of devastating plant disease impacts such as the epidemic caused by grassy stunt virus which destroyed more than 1,60,000 ha of rice in Asia or the famous Irish Potato Famine in 1845 that lasted for six years, and killed over a million men, women and children in Ireland and caused another million to flee the country. Therefore, selection and development of plant varieties that are resistant to pests and disease has been a major area of concern for plant breeders. While plant diseases can be partially controlled by use of agro-chemicals and by proper cultivation practices but incorporating inherent disease resistance in plant varieties remains the first choice for disease control.

1.5.4 Change in Maturity Duration

Plant breeding technology has brought major improvements in the uniformity with which crops ripen and are ready for harvest. While short duration crops reduce cost of crop production, uniform maturity makes improved ability for mechanized harvesting operations.

1.5.5 Desirable Agronomic Factors

Improving crops' ability to cope with a range of other agronomic factors is another important objective. For example, for fodder crops tallness and profuse branching are desirable traits for breeding new varieties.

1.5.6 Quality Improvement

Developments in plant breeding have brought significant gains in crop quality. This aspect is particularly important in horticultural crops. Many of horticultural crop cultivars (varieties) with unique qualities are admired, and appreciated so much so that they become the basis for entire industries. Examples include the 'Bartlett' ('Williams') pear which dominates fresh fruit production and is almost the only cultivar used for processing, 'Hayward' kiwifruit, 'Kerman' pistachio, 'Smooth Cayenne' pineapple (for processing), 'Clementine' mandarin, and 'Dwarf Cavendish' banana.

1.5.7 Wider Adaptation

The modern day intensive cropping systems require varieties that can be grown in all the seasons as well as in all the environments. Failure to maintain vigorous growth during periods of climate extremes, limits the usefulness of many crops. Varieties with traits of wider adaptability are desirable as the same crop variety can be grown in different conditions. Also one of the major challenges for the plant breeders today is incorporating traits in crops to adapt to significant impacts of climate change, while at the same time providing food for a growing population.

1.5.8 Improved Nutritional Aspect

At a fundamental level, food is viewed as a source of nutrition to meet daily requirements at a minimum in order to survive. There is now considerable evidence for substantial genetic variation within species for many of the health ameliorating properties. Consequently, plant breeders today are experimenting with opportunities to maximize the health ameliorating properties of different species through plant breeding. The aim is to develop functional foods which are modified food or food ingredient that may provide a health benefit beyond the traditional nutrients it contains; and developing plants with nutraceuticals or substances that may be considered a food or part of a food and provide health benefits, including the prevention and treatment of disease.

Self Assessment Question **(Spend 3 minutes)**

3) How society at large can benefit from plant breeding and development of new varieties of plants.

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1.6 APPROACHES FOR DEVELOPMENT OF NEW VARIETIES

Mendel's discovery was the beginning of modern science of genetics, the example given though may seem complicated, is among the simplest, from plant breeding point of view as it only covers two characteristics (height and flower color) controlled by two independent genes. As the science of plant breeding progressed, many exceptions to these rules were discovered. Many useful characteristics, such as yield and quality, for example, were found to be controlled by the interaction of very large numbers of genes, about inheritance of which was not much known. Thus, the development of new variety is a time-consuming, complex, costly, and skilled operation. Let us examine the general techniques to produce plant varieties.

1.6.1 Conventional Breeding

The finer techniques vary between crop species, but the scientific principles of plant breeding remain unchanged from Mendel's first discovery. Conventional plant breeding involves crossing carefully chosen parent plants, then selecting the best plants from the resulting offspring to be grown on for further selection. For example in crop cereals, hundreds of individual crosses are carried out by hand to create seed for the F1 generation. The resulting F1 plants are uniform, but in the following generation several hundred thousand different plants are produced. Because of the way genes works, the new combinations produced from each cross are not revealed until the second (F2) generation. It is this enormous diversity of new gene combinations which may hold the key to a successful new variety. The plant breeder's task is to select the plants most likely to meet his breeding objectives. Seed from the best of these F2 plants are grown on in small rows or plots and the best plants again selected – this process is repeated year after year until only the very best plants remain. As promising new lines emerge, tests are conducted on each plot to assess factors such as yield, disease resistance and quality. Once the best lines are purified to ensure that every plant has the same characteristics, the process of multiplying seed begins. Since each plant contains many thousands of genes, and the breeder is seeking to combine a range of traits in one plant, such as high yield, quality and resistance to disease, developing a successful variety is an extremely lengthy process – up to 12 years in the case of cereals, even longer for potatoes and horticultural crops.

Self Assessment Question **(Spend 3 minutes)**

4) Why is developing a plant variety takes long time?

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1.6.2 Hybrid Breeding

Hybrid seeds are an improvement over open pollinated seeds in terms of qualities. Hybrid seeds are developed by the hybridization or crossing of parent lines that are 'pure lines' produced through inbreeding. A critical requirement of hybrid production is that the parents be unidentical. It is this divergence of genotypes of the parents that expresses in hybrid vigour, or heterosis in the F1 hybrid seed. The emphasis for development of hybrid varieties has been in cross-pollinated crops such as maize, primarily because its male flowers (tassels) and female flowers (incipient ears) are separate and easy to handle, thus proving economical for the production of hybrid seed. However, commercial hybrids are now available for many crops, including self-pollinating species.

Self Assessment Question **(Spend 3 minutes)**

5) Why is the private seed sector a more active player in hybrid seed production?

i) Hybrids are easy to produce

ii) Seeds resulting from hybrids show an extremely poor ability to reliably reproduce the trait of interest in their progeny or next generation.

iii) The market for Hybrid seeds is much higher

iv) Hybrid seeds give more productivity

1.6.3 Modern Techniques for Crop Improvement

With increasing knowledge and improved technology, breeders have developed ways to enhance the speed, accuracy and scope of the breeding process. There are several ways to reduce the lengthy interval between the first cross of selected parents and establishing true breeding lines of promising new varieties. For example, maintaining parallel selection programmes in two different environments allows two generations to be produced each year. Latest developments in genetic science have greatly improved our understanding of how plants behave, offering additional ways to enhance the breeding process.

Interspecific and intergeneric hybrids produced from a cross of related species or genera often do not normally sexually reproduce with each other and plant breeders make use of tissue culture techniques to produce progeny from such crossings. For example, the cereal triticale is a wheat and rye hybrid. Failure to produce a hybrid may be due to pre- or post-fertilization incompatibility. In such cases the embryo resulting from an interspecific or intergeneric cross can sometimes be rescued and cultured to produce a whole plant; and the technique is known as Embryo Rescue.

Mutation Breeding makes use of mutagenic agents, such as radiation and certain chemicals, to induce mutations and generate genetic variations from which mutants with desirable traits to be bred with other cultivars may be selected. Single seed descent produces very small plants under restricted growth conditions. Large numbers of these plants are cultivated under controlled condition, with two or more generations produced in a year. In potatoes, mini-tuber breeding speeds up the slow multiplication process by producing miniature plants under greenhouse conditions.

1.6.4 Biotechnology and Plant Breeding

Revolution in plant breeding was witnessed with the discovery of new recombinant DNA techniques that allowed specific identification, isolation, and alteration of genes and their reintroduction into living organisms. Direct manipulation of DNA, or genetic engineering as it is called, is now regularly being used to complement classical plant breeding, to achieve useful practical outcomes in plant breeding. Genetic engineering and other molecular biology tools allowed the creation of several new methods such as DNA fingerprinting (DNA markers) that accelerate the relatively slow process of classical breeding. Marker assisted breeding is increasingly being used by the breeders to determine whether desired traits are present in a new variety at an early stage in the breeding programme.

The science of Genomics allows scientists to map the genetic makeup, or genome,

of crop species, and identify the exact position and function of individual genes. Genome mapping has revealed striking similarities in the genomes of different crop species, such as rice, wheat, barley and rye. This information is already helping to broaden the scope and precision of current breeding programmes.

The scope of plant breeding continues to expand in the twenty first century. Genomics, marker-assisted breeding, and RNA interference (RNAi), siRNA, cisgenics are increasingly effective in accelerating commercial breeding, identifying the functions of physiologically relevant genes, and in allowing crop traits to be modified.

1.6.5 Genetically Modified Plant Varieties

Genetic engineering techniques allows plant breeders to bring together in one plant useful genes from a wide range of living sources, not just from within the crop species or from closely related plants. In most cases the aim is to introduce a new trait to the plant which does not occur naturally in this species and therefore, cannot be incorporated in the variety through conventional breeding methods. It allows for the transfer of only one or a few desirable genes, thereby permitting breeders to develop crops with specific beneficial traits and reduced undesirable traits. The transgenic varieties have genes inserted into them that are derived from another species which can come even from across kingdoms. Some transgenic plant varieties – such as those with resistance to the herbicide Roundup and those producing the protein Bt – have great potential to reduce the amount of land needed for farming and also to reduce the use of chemical pesticides while reducing the incidence of pesticide resistance. Other technical strategies involving transgenic varieties being pursued include using genetically modified plants as the production platform to manufacture industrial enzymes for use in pre-processing feedstock for cellulosic fuel manufacture.

1.7 COMMERCIAL PLANT BREEDING

Plant breeding is one of the first things in commercial seed production which entails a series of quite distinct operations and responsibilities. These include source seed production, seed multiplication, quality control, compliance with regulatory requirements, and marketing. Large, modern commercial seed companies take responsibility for all of these operations in an integrated firm.

1.7.1 Maintaining Genetic Diversity

Genetic diversity is essential for any species to maintain its reproductive vitality, resistance to diseases and ability to adapt to changing conditions. Since the dawn of civilisation, economically useful plants have evolved thousands of locally adapted genotypes because of natural and human selection. These wild species, landraces or folk varieties have the genetic reservoir of useful genes adopted to low in-put conditions and conferring resistance to various biotic and abiotic factors.

One of the most important components of plant breeding programme is maintaining as extensive as possible gene pool from which new traits can be selected. In the absence of this genetic diversity, it will not be possible to identify plants that exhibit variation for the traits or plants of interest. Thus, the full spectrum of plant genetic resources of any crop consists of diverse type of

collections such as those derived from centers of diversity, those derived from centers of cultivation and those derived from breeding programmes. Some of the valuable genes found in plant genetic resources have provided tremendous boost to the crop improvement programmes. It is important to mention that the gene banks established across the globe conserve the valuable genetic diversity within past and present varieties, as well as landraces and wild relatives of cultivated crop species.

1.7.2 Notification of Variety

The developments in the seed industry in India, particularly in the last 30 years, are very significant. Introduction of New Seed Development Policy (1988 – 1989) transformed the very character of the seed industry and stimulated appreciable investments by private individuals, Indian Corporate and MNCs in the Indian seed sector.

Before commercialization of any new crop variety, each variety has to pass through a phase of evaluation. The breeders contribute their best entries on the basis of evaluation carried out in their local programmes for testing in the Initial Yield Evaluation Trial (IET) entries qualifying from yield, disease and quality point of view in IET/PYT are tested in the Advanced Varietal Trials (AVT) or Coordinated Varietal Trials (CVT). Successful varieties are identified for release and notification. The official trials are conducted, in most cases for a minimum of three years, to test each new variety for many characteristics which together determine its uniqueness, its genetic uniformity, and its value for cultivation and use (VCU). The proposal is then submitted for approval of the Central Sub-Committee on Crop Standards, Notification and release of varieties.

1.7.3 Genetically Modified Varieties

In addition to the tests described above, varieties produced using genetic modification must also pass through a separate process of regulatory scrutiny. The regulatory clearances of GEAC under Ministry of Environment and Forestry, Government of India is mandatory for conducting any genetically modified crops field trials in India, which specifies that no GM crops can be marketed until they have been assessed and approved in terms of human health, food safety and the environment. The cross-border movement of genetically modified organisms (GMOs) is regulated at a global level under the internationally agreed Biosafety Protocol.

1.7.4 Maintenance Breeding

Plant breeders are required to maintain the genetic purity of existing parental lines and pre-commercial seed supplies year by year for the varieties developed by them. Thus, the genetic identity and purity of the varieties and hybrids can be preserved against various factors affecting the genetic deterioration, viz., genetic erosion, admixtures, selective influence of pests and diseases etc. The initial handful of seeds obtained from selected individual plants of a particular variety, for the purposes of purifying and maintaining that variety, by the plant breeder who has developed the variety and its further multiplication under his own supervision, to provide Breeder's Seed constitutes the basis for all further seed production. The quality of the nucleus/breeder's seed determines the varietal purity of subsequently multiplied Foundation seed, which is further multiplied

and provided to farmer as certified seed. Unless the nucleus/ breeder's seed is of highest purity and quality, the seed multiplied from it cannot be regarded as of satisfactory genetic purity. It is, therefore, of utmost importance that the nucleus/ breeder's seed is maintained and produced in such a manner that satisfactory genetic purity, identity and the other good qualities of seed are not compromised.

1.7.5 Seed Certification

Seed of an approved variety can only be marketed if it meets strict quality criteria. Seed quality standards are laid down in Indian seed standards, and policed by agencies appointed by Government of India. The Indian seed certification system offers an independent assurance of quality to growers. Minimum standards apply for varietal identity, purity and germination capacity. In addition, strict limits apply to seed-borne diseases and the presence of physical impurities such as weed seeds. Seed certification underpins the health and purity status of the major arable crops in India. It offers an independent benchmark of quality on which buyers of seed and their customers depend.

1.8 RATIONALE FOR *SUI GENERIS* IPR REGIMES FOR PLANT VARIETIES

The origin of distinct form of IPR in the form of PBRs has been necessitated as the patent system is found to be ill-adapted to plant varieties. The rules of the system designed to protect industrial inventions to plant varieties, encounter technical difficulties.

1.8.1 Self-replicating Inventions

Plant innovation is borne in seeds whose very use demands multiplication. These products of innovation are biological products which at least in the case of self-pollinating plants can make hundreds of copies of themselves in the natural growth process. While from the standpoint of a producer of plant variety, this is a major cause of concern, the users of the technology (and potential 'copiers') are millions of individual farms whose compliance with any protection regime is difficult and expensive to monitor. Moreover, the user of the technology are farmers and farming communities which in many countries like India involves traditional cultural values that affects food security and the livelihood of the rural poor, thus making the imposition of any control a sensitive political issue.

1.8.2 Invention, Inventive Step and New Plant Variety

The inherent genetic diversity within a plant variety and the inevitable changes between generations create problems with the description of the 'invention'. Moreover, for producing new plant varieties, plant breeders rely on traditional breeding methods or standard genetic engineering techniques. These techniques are part of common knowledge, and it is obvious breeders rely on them to search and develop new plant varieties. It can be argued whether application of standard breeding methods constitute an inventive step. So even if these techniques required considerable effort and investment, the product they create may not amount to a patentable invention. In these situations PBR is more suited as it specifically protects the end product of the breeding process, that is, the new plant variety in itself.

1.8.3 The Criteria of Novelty

Patent protection of an industrial invention requires to be new, that is, it should not form part of the "state of the art". The novelty criterion of the patent system was difficult to maintain where the natural diversity of a plant variety is insufficiently known to the examiner. Also the patent application requires that the invention needs to be disclosed in such a way as to allow someone 'skilled in the art' to reproduce. Meeting this requirement is not possible in plant breeding; even if someone has access to the same parents and the same selection strategies it is impossible to breed the same variety.

1.8.4 Privileges Under PBR

The PBR system evolved in various countries in consideration of the rights of their citizens and the potential economic benefits in order to increase national welfare. Since the socio-political systems and the structure of industries differ widely, the optimum contribution to increased welfare may be achieved at different levels of protection. The concerns on food security and traditional systems have led to the establishment of exemptions in several countries. For example, many PBR legislations allow farmers to save, exchange and sell seed in accordance with local custom. Under patents, such actions would constitute infringement. Also, while the patent systems do allow some research on patented inventions, but the form and extent of research allowed is based on case law and so this is more difficult to assess; however, research use under PBR a more clear-cut process. Provisions of such privilege (where allowed) are generally considered to give holders of PBR certificates weaker protection than the patents. This helps explain why, where the choice is available, commercial breeders often prefer patents, or patents plus PBR, over PBR alone.

1.9 JUSTIFICATION OF PBRS

The primary justification for the establishment of PBRs like any other form of IPR is economic. As we have seen above, plant breeding has moved on from being purely an art (i.e., experience and good sense of selection) to become a science-based state-of-art technology enterprise.

The private sector involvement expanded with increasing application of practical biotechnological tools for developing new varieties and multi-fold increase in private investment resulted in pressures to expand PBRs in agriculture. This was primarily because these firms aimed to offer agricultural technology as an integrated package, in which improved varieties of planting material were the critical components. Offering a type of monopoly for the commercial exploitation of plant variety to the breeder is expected to earn back investment costs and provide an incentive for creating new varieties. The system can also offer additional, more widespread, economic benefits such as reducing transaction costs and clarifying ownership. This is important to provide the farmers and growers increased access to the best available overseas varieties.

The issue of PBR is significant and can be understood in two ways: first, in the narrow sense, where protection of plant variety is important to provide an incentive to commercial breeders for developing new plant varieties; and, second, in the broader sense, where plant variety protection has direct linkages with the rights of the farmers who have traditionally been breeding plant

varieties as per their local conditions, accessibility to Plant Genetic Resources and concerns related to food security. Farmers have played an important role in the conservation of PGR and will continue to do so in the future as well. Because of their enormous contributions in the past, present and future towards the conservation of PGR, farmers have an important stake in any legal regime on plant variety protection and such a regime should take into account their interests and concerns.

1.10 SUMMARY

- The plant breeders' rights (PBRs), providing intellectual protection to new plant varieties have a recent origin in the history of IPR accelerated across countries by the acceptance of the TRIPS Agreement.
- Taxonomists have described, classified, identified, and named plants from early days. While the rank of species a one of the basic units in botanical classification, the plants within a species can be very different. Farmers and growers use a more precisely defined group of plants, selected from within a species, called a plant "variety".
- The genetic variability within a species is essential to maintain its reproductive vitality, resistance to disease and ability to adapt to changing conditions. Systematic selection aimed at selecting the naturally occurring variants formed the basis for earlier crop improvement efforts.
- Mendel elucidated the genetic mechanism involved in inheritance and linked the **genotype**, of plants with resultant expression of the genetic structures as observed in its **phenotype**. This led to refinement in breeding techniques by crossing carefully chosen parent plants, then selecting the best plants from the resulting offspring to be grown on for further selection. As breeders aim to combine a range of traits such as high yield, quality and resistance to disease in one plant breeding of crops with better performance is an extremely lengthy process.
- The speed, accuracy and scope of the breeding process have been enhanced with the use of recombinant DNA techniques. The direct manipulation of DNA, or genetic engineering is now regularly being used to complement classical plant breeding. Further, the advancement in science of genomics has broadened the scope and precision in breeding and accelerated the pace of commercial breeding. These techniques allow plant breeders to develop transgenic varieties that have genes inserted into them that can be derived from a wide range of living sources across kingdoms.
- In addition to plant breeding commercial seed production entails operations and responsibilities such as source seed production, seed multiplication, quality control, compliance with regulatory requirements, and marketing etc.
- The PBRs have been necessitated as the existing patent systems are ill-adapted to plant varieties due to technical limitations in describing the invention, inventive step, and the criteria of novelty. This is largely because the plant variety inherently possesses genetic diversity which changes between generations; is self-replicating and developed through standard breeding/ genetic engineering techniques that are common knowledge. Further, the

concerns of food security and traditional systems require establishment of exemptions based on the socio-political systems in the country.

- The primary justification for the establishment of PBRs like any other form of IPR is economic. As plant breeding has moved on to become a science-based state-of-art technology enterprise, the private sector involvement and investment has expanded multi-fold. The PBRs are expected to earn back investment costs and provide an incentive for creating new varieties that is important to provide the farmers and growers increased access to the best available varieties.

1.11 TERMINAL QUESTIONS

1) How have development in biotechnology contributed to development of plant varieties?

2) Why is the patent regime not considered suitable for protecting plant varieties?

3) What is the justification for providing PBRs to plant breeders?

1.12 ANSWERS AND HINTS

Self Assessment Questions

1) i) Tt, Cc is wrong because no gamete will have two alleles of the same trait.

   ii) T,t,C,c is wrong as in this exercise two traits are being considered at the same time.

   iii) TT,tt,CC,cc is wrong as no gametes will have two alleles of the same trait

   iv) TC,Tc,tC,tc is the correct answer

2) i) Tall plants and coloured flowers: TTCC, TTCc, TtCC, TtCc

   ii) Short plants and coloured flowers: ttCc, ttCC

   iii) Tall plants and white flowers: TTcc, Ttcc

   iv) Short plants and white flowers: ttcc

3) The benefits generated by plant breeding are large, positive and widely distributed. The gains resulting from the development and adoption of new varieties of plants reach to both favoured and marginal environments, and benefits are broadly shared by producers and consumers. Examples include:

   i) Economic gain by providing better product quality and increasing the marketability of crops on the global market.

   ii) Increasing productivity, minimizing the use of land and other scarce resources and benefiting the environment.

   iii) Improving income of farmers and overall economic development.

4) The breeding of a plant variety takes place over many years. The first requirement is that the breeder must obtain a plant with a desirable expression of characteristics. This can be made from plant material which present variability or by creating it crossing selected plants to be used as parents. It is necessary to test hundreds, or even thousands plants. Finally, once a plant has been identified, its genetic structure has to be fixed to make out of it a uniform and stable plant variety.

5) Seeds resulting from hybrids show an extremely poor ability to reliably reproduce the trait of interest in their progeny. It, therefore, becomes necessary for the farmer to purchase new seed for subsequent plantings. Hybrid selection, therefore, becomes a way for the plant breeder to protect their varieties from exploitation as they are assured that the farmer or purchaser can only access the trait reliably for one generation. In addition to providing a tool for creating new plant varieties with attractive traits, hybrid technology provides technical protection of the intellectual property, i.e., the new commercial plant varieties.

Terminal Questions

1) Refer to Sub-section 1.6.4 and 1.6.5.

2) Refer to Section 1.8

3) Refer to Section 1.9 supplemented with information in Section 1.6

1.13 REFERENCES AND SUGGESTED READINGS

1) International Union for the Protection of Varieties of Plants, http://www.upov.int/

2) Norman Siebrasse (2010) Intellectual property protection for higher life forms: Current law and policy issues. The Integrated Assessment Journal Vol. 10, Iss. 1 (2010), Pp. 23-39.

3) Kesan JP. (2007) The Statutory Toolbox: Plants. In Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

UNIT 2 PLANT VARIETIES PROTECTION AND THE TRIPS OBLIGATION

Structure

2.1 INTRODUCTION

The issue of providing adequate incentives for innovations in plant breeding has been debated in the intellectual property community for at least a hundred years. As private companies have expanded their operations in plant breeding, pressures to expand IPP in agriculture have built up globally over the past few decades. The breeding activities which were largely carried out by the public sector have increasingly been taken up by private seed companies. The 1980s saw an unprecedented expansion of private sector operations as major transnational corporations like Unilever, ICI, Monsanto and Rohm and Haas, involved in the agrochemical industry, entered plant breeding. This was primarily because these firms aimed to offer agricultural technology as an integrated package, in which improved varieties of planting material were the critical components. Extending

IPRs to plant varieties was considered as the most effective way in which plant breeders could obtain returns on their investment.

The lack of fit between innovation related to plants and traditional intellectual property regimes has been an issue of global debate. Therefore, the late inclusion in the multilateral trade negotiations under the auspicious of GATT of the Trade Related Aspects of Intellectual Property Rights (TRIPs) was and still remains the most contentious area and largely debated all around the world.

TRIPS which now forms an integral and important agreement of WTO represents a significant step towards the adoption of a more globally harmonised IPR system while providing for a wider scope of protection and stronger rights for IPR owners. It also introduces into the IPR regime the obligation to provide Plant Breeders' Rights (PBRs). While many of the developed countries had experimented with one or the other kind of IPR system for the protection for plant varieties, such laws previously never existed in most of the developing countries.

In this Unit we first assess plant variety protection from an historical and comparative perspective, analysing the emergence of the concept of "breeders' rights" in the developed countries. We then delineate the essential requirements under the TRIPS agreement and its impact on the changing IPR legislations concerning plant variety protection.

2.2 OBJECTIVES

After completing the study of this unit, you should be able to:

- acquire a basic understanding of evolution of legislations related to PBRs;
- explain the obligations and options for plant variety protection under the TRIPs Agreement;
- explain the rationale of *Sui generis* system of PBRs; and
- differentiate between the requirements of protection of plant varieties under various IPR systems.

2.3 EVOLUTION OF PBRS

2.3.1 Initial Attempts

The growth of the commercial seed trade towards the end of the 19th century in several European countries witnessed the emergence of breeders associations that played a key role in the inclusion of agricultural innovations within the international regulatory regime. Further, impetus was provided by the formation of the International Bureau of the Union for the Protection of Industrial Property in 1883, and the signing of the Paris Convention for the Protection of Industrial Property in Paris, France, on March 20, 1883. The final Protocol of the Convention in Article 1(3) expanded the scope of protectable subject matter and stated:

> "*Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to*

agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour".

Initial efforts of providing protection for plant innovation were made by experimenting to fit them into traditional IPR systems regimes. Given the state of technology in 1883, the inclusion of these agricultural subjects within the Paris Convention was probably for the purpose of protecting trademarks and indications of source. To reward the creativity in breeding new crops more generic protection systems were experimented in Europe, such as concepts of seed registration and protected seals for seed from the original breeder (Germany) and monetary rewards (prizes) to breeders issued by farmers' organisations (Netherlands).

2.3.2 The U.S. Plant Patents Act

Despite the European initiatives to establish PBRs, the first explicit inclusion of biological agricultural innovations in an IP statute was in the U.S. Plant Patents Act of 1930. This Act recognised specifically that plant breeders create more than mere products of nature, and exempted plant patent applications from the enabling written description required of industrial inventions under patent law. It was the first attempt in the world to legislate for the protection of new plant cultivars, provided they were both "distinct and new". The statute did not define this requirement, although the Senate Committee report accompanying the Act stated that "in order for a new variety to be distinct it must have characteristics clearly distinguishable from those of existing varieties" and that it was not necessary for the new variety to constitute "a new species".

2.3.3 Establishment of UPOV

The Plant Patents Act gave impetus to the process of acceptance of IPR regimes for development of plant varieties. By the 1960's, some European countries enacted plant breeders' rights laws. The successful enactment of laws protecting the rights of breeders in countries such as the Netherlands and Germany, it was demonstrated that sexually reproduced varieties were uniform and stable enough to be included in these laws. In the United States the Plant Variety Protection (PVP) Act was enacted on December 24, 1970 to "encourage the development of novel varieties of sexually reproduced plants" by providing exclusive marketing rights to their developers.

The International Association of Plant Breeders for the Protection of Plant Varieties (ASSINSEL), the acronym derived from French for Association Internationale des Sélectionneurs pour la Protection de Obentions Végétales) was established in 1938 with the main objective for the adoption of an international convention for the protection of new varieties of plants. The active engagement of associations of the beneficiaries of protection, mainly the International Association for the Protection of Industrial Property (AIPPI) and the ASSINSEL lead to inspired advocacy for the creation of a new organisation for the promulgation of an international legal regime for the protection of plant varieties.

In 1957, the French Government held a conference in Paris concerned with the protection of new varieties in which 12 Western European countries that were known to have similar concerns on the subject were invited. The *Bureaux*

Internationaux Réunis de la Protection de la Propriété Intellectuelle (BIRPI), which subsequently became the International Bureau of the World Intellectual Property Organization (WIPO), and the Food and Agriculture Organization of the United Nations (FAO), attended as observers.

The Final Act, adopted on May 11, 1957 recognised the legitimacy of breeders' rights and established as the preconditions for protection, that a variety had to be distinct from pre-existing varieties and sufficiently homogenous and stable in its essential characteristics. It defined the rights of the breeder and acknowledged the principle of the independence of protection. The second session of the Conference was held in Paris from 21 November to 2 December, 1961. This led to the adoption of International Convention for the Protection of New Varieties of Plants or UPOV in its French acronym (*Union Internationale pour la Protection des Obtentions Végétales*) which came into force in 1968. The form of intellectual property created by UPOV is known widely, as plants breeders' rights (PBR). The UPOV was an attempt to harmonize the legal systems for the protection of plant varieties that were enacted in Europe from the 1940s onward. The UPOV system provides protocols for assessing and describing the unique characteristics of a new variety, ensuring that it is distinct, uniform and stable (DUS). The UPOV Convention, as amended in 1972, 1978 and 1991, forms the basis of existing national laws in UPOV-member States. We shall discuss the UPOV provisions in details in a separate Unit.

2.4 THE TRIPS AGREEMENT

2.4.1 TRIPS Obligations and IPR

The TRIPS Agreement Adopted in 1994 and administered by the World Trade Organization (WTO) is the first and only IPR treaty that seeks to establish universal, minimum standards of protection across the major fields of intellectual property, including patents, copyrights, trademarks, industrial designs, integrated circuits and trade secrets. Article 27 of the TRIPS Agreement defines the inventions which the member states are obliged to make eligible for patenting, and what they can exclude from patenting. Inventions that can be patented include both products and processes, and should generally cover all fields of technology.

Among the most debated provision is Article 27.3(b) (see Box 1) that allows member states to exclude some kinds of inventions from patenting, i.e. plants, animals and "essentially" biological processes. However, micro-organisms, and non-biological and microbiological processes have to be eligible for patents. In addition, plant varieties have to be eligible for protection either through patent protection or a *sui generis* system (created specifically for the purpose), or a combination of the two.

Box 1: TRIPS Article 27

Patentable Subject Matter

1) Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65,

paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2) Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3) Members may also exclude from patentability:

   a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

   b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Self Assessment Question **(Spend 2 minutes)**

1) The TRIPS Agreement requires that every member should: Choose any of the following:

   i) Compulsorily provide Patent protection to new plant varieties

   ii) Become member of UPOV convention

   iii) Provide an effective system for plant variety protection

   iv) Have no legislation for protection to new plant varieties

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2.4.2 Options for Protecting Plant Varieties

For other fields of intellectual property, such as patents, copyrights and trademarks, the TRIPS expressly requires WTO Members to comply with the standards of protection contained in preexisting IPR agreements, such as the Berne Convention for the Protection of Literary and Artistic Works and the Paris Convention for the Protection of Industrial Property. In sharp contrast, although the UPOV Acts have provided IPR protection for plant varieties, TRIPS Agreement does not mention the same for protection of plant varieties.

It is clear from Article 27.3(b) of TRIPS that member states are not obliged to provide for patent protection for plants and animals. However, they have to implement intellectual property protection for plant varieties. The policy options for protecting plant varieties would be as follows.

- To make provisions for the patent protection of plant varieties
- To join the UPOV Convention
- To provide for comparable *plant variety protection* (PVP) without formally joining the UPOV Convention.
- To devise a *sui generis* system which is better designed to suit national interests and to take into account the protection demands of informal and local communities.

2.4.3 Rationale for *Sui Géneris* Option

The question of *sui generis* intellectual property right protection for plant varieties has become the most debatable issue following the adoption of the TRIPS Agreement. The concept was introduced in the negotiations as a number of countries rejected the compulsory introduction of plant patents, and there was no universal acceptance on one specific alternative to patents. The fact that the interpretation of the concept of 'effective' *sui generis* system remains problematic, UPOV has advanced its system as the principal workable example of a *sui generis* PVP system in the debates. This has led some countries like the member states of the African Intellectual Property Organization to adopt the regime modeled after UPOV-1991 and at the same time to commit to join the UPOV Convention.

The TRIPS gives member states a wide margin of appreciation in determining how to implement their obligation to introduce plant variety protection. The developing countries while shaping their *sui generis* systems are confronted with far-reaching consequences that touch upon the whole spectrum of their socio-political situation. The TRIPS makes it possible to incorporate specific exceptions and limitations in national IPR laws provisions to suit their specific needs. The major issues that have influenced the development of *sui generis* system in various countries are as follows.

a) Conservation of genetic diversity

Concerns have been expressed regarding the consequences of according IPR to plant varieties on the plant genetic diversity. It is argued that the incentives provided by the IPRs would lead to more investments for private sector for creation of new plant varieties, thus leading to an increase in plant genetic diversity over time. The contrary view is that the spread of the commercial plant would result in the replacement, of the traditional varieties and landraces under cultivation and would reduce on-farm genetic diversity by limiting the choice only to certified varieties for cultivation which are more uniform and thus have high genetic vulnerability.

b) Farmers' privileges

The concept of farmers' rights was for the first time formally recognized by the FAO Conference in 1989. The farmers' rights are in contrast to the proprietary

rights of the breeders on new varieties. They are an acknowledgement of the large number of innovations and contribution made by farmers and communities for the preservation and improvement of plant genetic resources over thousands of years. Still today, there are numerous varieties called as farmers'/folk/ traditional/primitive varieties or landraces that have been developed and nurtured by innovative farmers or communities who have in their acumen selected or genetically manipulated them through intervention for specific traits. These farmers' varieties or landraces, have laid the foundation of all modern plant variety development programmes. While the breeders can claim IPRs on the varieties, the farmers' varieties and landraces may not have the same level of genetic and phenotypic homogeneity to meet the stringent requirements of IPR protection. Protecting the farmers' varieties and rewarding farmers for their contributions to plant genetic diversity, therefore, require different approaches.

Further, the farmers or communities in the developing countries mainly have decided which crops and varieties to grow and have carried over self-regenerated seeds for next season. The tradition of seed exchange with other farmers from the same or other communities always existed and resulted in enhancement and spread of the genetic diversity. Agriculture, particularly in the areas of crop diversity, therefore, developed as a dynamic system that integrated seed production, selection, storage and exchange. Even today these farmer-based systems of seed supply have been the mainstay in many countries and depending on the crop and country, 60-90% of the seed planted is farmer-produced and exchanged. Local varieties maintained by farmers occupy major part of the crop-land and diffusion of new varieties through exchange of seeds from farmer-to-farmer has been shown in many cases to be more effective than formal sector seed distribution. The restriction on saving seed in the IPR regimes creates a conflict that has to be resolved at the national level through appropriate exclusion of the rights of breeders in the national legislations.

c) Researchers' privileges

The scope of IPRs in plant varieties has been a concern even among the breeders. The issue is utilisation of legally protected varieties for developing still more new varieties. The breeders' exemption extends the scope of protection for a variety over the material of a newly developed cultivar which is derived from the original variety, as the protection is granted only for the specific variety as such and not the breeding method, nor crops' ingredients or particular traits. Therefore, if such privileges are incorporated in the national legislations, any breeder can follow new developments, without infringing the rights of the previous breeder. This freedom of operation does not permissible under a utility patent system.

2.5 ALTERNATIVES FOR PROTECTING NEW VARIETIES

2.5.1 Patent System

Under the TRIPs most member countries choose not to provide mechanisms under their national patent system in which an entity may claim that it has a legal right to intellectual property in plants and plant products. Thus, in most countries, inventions directed to plants or plant products such as seeds, are not eligible for a patent grant, but some (including the United States and Australia)

provide utility patents for use of plants and plant products, as long as the statutory requirement for patentability are met. While the patent legislation of each jurisdiction is different, the requirements and rights awarded to patentees are substantially similar. The issue of patenting here shall be discussed only from the limited perspective of protecting plant varieties and plant related inventions.

a) Patenting of plants in US and Australia

In the United States, the Utility Patent law designates four broad categories of patentable subject matter: composition, machines, articles of manufacture, and processes. Section 101 of Title 35 U.S.C. sets out the subject matter that can be patented:

> "*Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title*".

Plants and biological subject matter are not explicitly included. However, in 1980, the landmark Supreme Court decision of ***Diamond v. Chakraborty***, 447 U.S. 303 (1980), (see Box 2) construed Section 101 to encompass genetically modified organisms and suggested the possibility of securing utility patents on plants previously thought eligible solely for protection under the PVPA. This case undoubtedly helped to open the gates for ensuing patents for genetic engineered biological material and plant/plant varieties. Following this analysis by the Supreme Court of the scope of 35 U.S.C. 101, the Board of Patent Appeals and Interferences has determined that plant subject matter or an animal may be protected under 35 U.S.C. 101.

The first patent granted to a plant was to a corn plant which contained increased level of free tryptophan, an amino acid. The US Patent and Trademark Office had rejected the application on the ground that utility patent protection of plants was not available since these could be covered by the Plant Patent Act and the Plant Variety Protection Act. However, in 1985 case, known as the *Ex parte Hibberd*, 227 USPQ 443 (Bd. Pat. App. & Inter. 1985), the Board of Patent Appeals and Interferences held that plant subject matter may be the proper subject of a patent under 35 U.S.C. 101 even though such subject matter may be protected under the Plant Patent Act (35 U.S.C. 161 - 164) or the Plant Variety Protection Act (7 U.S.C. 2321 et seq.). Thus, the Board of Appeals concluded that genetically engineered plants seeds and plant tissue are patentable.

Box 2: *Diamond v. Chakraborty* (1980) 447 US 303

Respondent Chakraborty, a microbiologist, filed a patent application for a human-made genetically engineered bacterium that is capable of breaking down crude oil, which makes it valuable for the treatment of oil spills.

Chakraborty's patent claims were

1) process- method of producing the bacteria
2) an inoculum comprised of a carrier material floating on water.
3) The bacteria itself

The patent examiner allowed the first 2 claims but rejected the third on the basis that (1) microorganisms are "products of nature," and (2) that as living things they are not patentable subject matter under 35 U.S.C. § 101.

The Court of Customs and Patent Appeal reversed and awarded the patent.

The Supreme Court affirmed the decision holding that Chakraborty's microorganism is not a nature's handiwork but a product of human ingenuity having a distinct name, character and use and hence patentable under 35 U.S.C. § 101. The Supreme Court felt that genetically –engineered organisms fall within the definition of manufactured. Chakraborty's claim is not a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter.

Further, in the 2001 decision of ***J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.***, 534 U.S. 124 (2001) (Box 3), the Court conclusively held that sexually reproduced plants that are eligible for protection under the PVPA are also eligible for utility patents. As a result, plants are patentable subject matter (35 U.S.C. 101) in the US.

In Australia, the Patent Act (1990) allows all technologies to be patented (except 'human beings and the biological processes for their production') provided that there is an "invention", defined as 'an innovative idea which provides a practical solution to a technological problem'. In accordance the Patents Act 1990 (Cth), patent to be granted in respect of a plant should meet the general patentability criteria. Firstly, the invention must involve the intervention of a technologist applying their inventive ingenuity to produce something distinguishable from the natural source material. Secondly the plant variety, plant components, or plant materials must be new and novel when compared to what has been publicly available prior to the date of application. Lastly, the invention must be non-obvious to a person skilled in the art. This requirement has resulted in many new plant varieties failing to meet the patentability criteria, particularly when traditional and well-known breeding methods have been employed to develop the new plant.

Box 3: *J.E.M AG Supply, Inc. v. Pioneer Hi-Bred*

Pioneer Hi-Bred filed a patent infringement suit against J.E.M. Agricultural Supply (JEM). They were accused of infringing one or more of Pioneer's patents by making, using, selling, or offering to sell plaintiff's patented seed corn products. Defendants were not authorised Pioneer Sales Representatives and did not claim to have any contract with Pioneer to sell Pioneer's products. However, Farm Advantage purchased patented hybrid seeds from Pioneer and resold them. Defendants never repackaged or altered Pioneer's seed containers prior to reselling the seed to customers.

The defendants argued denying Pioneer's allegations and asserted, among other defenses, patent invalidity. Additionally, defendants counterclaimed asking the court for a judgment declaring all of Pioneer's patents-in-suit invalid. In their counterclaim, defendants asserted, *inter alia*, that sexually reproduced plants, such as plaintiff's patent-in-suit, were not patentable subject matter under Section 101 of the 1952 Patent Act. Defendants claimed

that the United States Patent and Trademark Office granted Pioneer's patents on the basis of an erroneous understanding of applicable law.

On December 10th, 2001, the US Supreme Court held that Utility patents may be issued for plants under 35 U.S.C. 101 despite distinct protections available under the Plant Variety Protection Act and the Plant Patent Act. Affirming the Federal Circuit's ruling by a majority vote, Justice Clarence Thomas explained that the broad scope of Section 101 was established in Diamond v. Charkraborty and that nothing in the PVPA or the PPA precluded granting utility patent coverage to plants.

b) Patenting plant varieties in EU

As seen above in the U.S. and Australia, individual plant varieties are patentable. In Europe, individual plant varieties *per se* are not patentable. However, a plant which is characterized by a particular gene (as opposed to its whole genome) is not included in the definition of a plant variety and is, therefore, patentable.

i) European Patent Convention

In Europe, patenting is controlled by the European Patent Convention (EPC) signed in 1973. Therefore, in addition or as an alternative to obtaining a patent through the patent office, in individual European countries, patent grants in nearly all European countries can be gained by filing patent application at the European Patent Office (EPO). Article 53(b) of the EPC stipulates that "*plant or animal varieties or essentially biological processes for the production of plants or animals*" are not patentable. This Article reflects the fact that some of the main countries of the EC, which are members nations of the UPOV Convention, had already stipulated a special law for the protection of new plant varieties in compliance with the provisions of the UPOV Convention.

This brings up the issue of the definitional distinction between plants and plant varieties. The first consideration of this issue by the Technical Board of Appeal of the EPO occurred in 1984 in the Ciba/Geigy determination. This case is related to claims directed to propagating materials and seedlings treated with a chemical agent to confer on the plant a degree of protection from the toxic side effects of certain herbicides. The Examination Division rejected these claims on the basis that plant varieties are excluded from patentable matters in Article 53(b) of the Patent Law. However, the Technical Board of Appeals of the EPO admitted these claims. Applying the definition of plant variety in the UPOV Convention, it held that new plant varieties excluded from patentable subject matters stipulated in Article 53(b) of the Patent Law are only those new plant varieties meeting the requirements of distinctness, uniformity and stability. In this case the claims covered merely the application of a chemical treatment and not plant varieties as such and that Article 53(b) should not be construed to exclude a cultivated plant that has been chemically treated. This approach was applied by the Technical Board of Appeal in the hybrid plant/LUBRIZOL case, where the Board held that "the term 'plant varieties' means a multiplicity of plants which are largely the same in their characteristics (i.e. homogeneity) and remain the same within specific tolerances after every propagation or every propagation cycle (i.e. 'stability')". The Board then ruled that the plant may be patentable, and that even if the invention is related to a breeding method using

classic mating, the invention may still be patentable provided that the invention is characterized by a technical feature not found in nature, such as a combination of special artificial processes to realise a high yield, since such a method is not an essential biological process.

ii) European Directive on Protection of Biotechnological Inventions

Since most of the biotechnological inventions are subject to possible self-replication, the impact of the concept of exhaustion of the right after the first sale had to be clarified. In order to avoid discrepancies among European Member States, it was proposed in 1988 to have a directive on that important subject. After 10 years of parliamentary debates, a consensus on the protection of biotechnological inventions was reached on July 6th, 1998, through the adoption of the Directive 98/44/EC of the European Parliament on the Legal Protection of Biotechnological Inventions. The Directive provides the framework for protecting biotechnological inventions by the memberstates. The objective of the Directive is to clarify the distinction between what is patentable and what is not and harmonize protection for biotechnological inventions (including plant protection) amongst the European Union members.

The European Biotechnology Directive permits the patentability of inventions concerning plants, where "the technical feasibility is not confined to a particular plant...variety". Patent claims can therefore be made in respect of plant groupings. A plant grouping which is characterized by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is not excluded from patentability even if it comprises new varieties of plants. Therefore, transgenic plants are patentable if they are not restricted to a specific plant variety, but represent a broader plant grouping. The European Directive considers plant cells to be "microbiological products" and as a result patentable.

This qualification was addressed by the Technical Board of Appeal in Novartis/ Transgenic Plant (Case G1/98). The original patent application by Ciba-Geigy (later on Novartis, now Syngenta) in 1991 concerned a patent containing claims to transgenic plants comprising in their genomes specific foreign genes, the expression of which resulted in the production of antipathologically active substances, and to methods of preparing such plants. The application by was rejected by the EPO, supported by the Technical Board of Appeal on the ground that Article 53(b) denied the patentability of an invention which could embrace plant varieties. The case was subsequently handed over to the EPO's highest chamber. In its decision of 20 December 1999, the Enlarged Board of Appeal indicated that it would favour the application because, in substance, it did not involve an application for a plant variety. This determination contains some useful guidance on the legal definition of plant varieties.

The Enlarged Board of Appeal noted that the definitions of plant variety in the UPOV Convention and the EC Regulation on Community Plant Variety Rights refer to "the entire constitution of a plant or a set of genetic information", whereas a plant defined by a single recombinant DNA sequence "is not an individual plant grouping to which an entire constitution can be attributed". It observed that the claimed transgenic plants in the application before they were defined by certain characteristics allowed the plants to inhibit the growth of plant pathogens.

No claim was made for anything resembling a plant variety. The tribunal noted that in the case of PVR an applicant had to develop a plant group, fulfilling in particular the requirements of homogeneity and stability, whereas in the case of a typical genetic engineering invention, a tool was provided whereby a desired property could be bestowed on plants by inserting a gene into the genome of a specific plant. It observed that the development of specific varieties was not necessarily the objective of inventors involved in genetic engineering.

c) Standards of patentability and the rights granted

The legal criteria for patentability are substantially similar across all jurisdictions. In order to show that the plant, plant technology or plant product of interest is an invention, the patent application must show:

1) novelty
2) non-obviousness, or an inventive step
3) usefulness (United States) or industrial applicability (Europe, Australia)
4) enablement
5) claim clarity
6) written description
7) best mode (United States only)

From the date that a patent is granted, the patent holder has the exclusive right to exploit the invention or authorize another person to do so until the patent expires. Patent rights grants the owner the right to exclude others from making, using, selling or offering for sale or importing the protected invention for a 20 year period from the earliest file date.

d) Invention vs discovery

Although the patent laws of some countries use the words 'invention' and 'discovery' synonymously, it is a universally accepted principle that discoveries in the strict sense of the word are not patentable. Natural source material should not be coverable by patents as exclusionary rights in any country in the world, because natural source material is not novel. Discoveries that fall under the laws of nature, physical phenomena, and abstract ideas have been held not patentable. The case ***Funk Brothers Seed Co. v. Kalo Inoculant Co.*** 333 U.S. 127 (1948) (Box 3) supports the discovery/invention dichotomy in the patentable subject matter enquiry.

e) Exemptions

Exemptions to patent infringement that are relevant to patenting of plants are provided in some jurisdictions. Experimental use exception allows researchers to use patented inventions for carrying out experiments without taking the licence from the patent holder. This includes both usage of patented invention as a research tool and experimenting on the patented invention to better it or otherwise. The US has an extremely narrow experimental use exception which terms any experiments for commercial purposes as patent infringement, except those for drug-regulatory purposes.

Box 4: Funk Brothers Seed Co. v. Kalo Inoculant Co.

Leguminous plants have the ability to take nitrogen from the air and fix it in the plant for conversion to organic nitrogenous compounds. However, capability depends on the presence of bacteria of the genus Rhizobium. which infect the roots of the plant and form nodules on them.

The general practice was to manufacture and sell inoculants with each package containing only one species of root nodule bacteria. The patent provided a mixed culture of Rhizobia capable of simultaneously inoculating the seeds of plants belonging to several cross-inoculation groups. Kalo exploited the claimed invention by providing a mixed culture of Rhizobia capable of inoculating plants belonging to several groups. The appellant Kalo brought a patent infringement suit, against the respondent Funk for selling similar packages. The respondent counter-claimed alleging the patent was invalid.

The Supreme Court clarified the requirements that a microorganism must meet in order to fall within the definition of patentable subject matter under § 101. The Court invalidated the claim on the ground that Kalo had merely discovered a natural phenomenon. The mere aggregation of species falls short of invention within the meaning of the patent statutes. The Court observed that the combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement in their utility and that each species had the same effect it always had. He who discovers an unknown phenomenon of nature has no claim to a monopoly.

In Australia, limited exemptions are defined within the legislation. The 'prior use' exemption allows someone who was utilizing the patented product or process before the priority date of a claim to continue using the patented product without infringement.

The EU Directive Article 11(1) and (2) provides a 'farmer's privilege' a particular right which limits the monopoly of a patent holder. According to this provision, when there has been a sale or any other commercialisation of a plant-propagating material to a farmer, the latter is allowed to use the products of his harvest for propagating or multiplying them. This means that the farmer is allowed to keep some seeds he would have produced to sow crops in the following year.

Self Assessment Question **(Spend 2 minutes)**

2) Mr Rao is an explorer. On an exploration trip, he discovers a plant which has not been documented in a flora. He wants to get a patent on it. In which country should he apply to get a patent?

   i) The United States

   ii) Germany

   iii) India

   iv) No country would grant him a patent

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2.5.2 Plant Patents

Specific plant patents are only available in a very few countries. As mentioned above, the first Plant Patent Act was enacted by the US congress in 1930. The Act had a limited coverage and patent protection applied only to asexually propagated fruit and ornamental species, because of the view that sexually reproduced varieties lacked stability. Asexually propagated plants are those that are reproduced by means other than from seeds, such as by the rooting of cuttings, by layering, budding, grafting, inarching, etc.

The Act, however, excluded tuber-propagated plants principally for political rather than technical reasons. The concern was that this would lead to monopolies in basic foodstuffs such as potatoes. This concern was reflected in the position of developing countries like India in explicitly excluding from patenting agriculture products.

The Act was subsequently amended to exclude plants found in an uncultivated state (i.e. wild plants). It has also been determined through case law that the term "plant" is defined by its lay rather than its scientific meaning, and hence bacteria are excluded.

While the patentability requirements are same as those for utility patents, the implementation of these requirements is less stringent. For example, the disclosure requirement for a plant patent would not be so demanding as to prevent protection, as per 35 U.S.C. § 162: "No plant patent shall be declared invalid for noncompliance with [the disclosure requirement for utility patents] if the description is as complete as is reasonably possible." It does however, require that the new variety be described as complete as reasonably possible.

Plant patents confer on the owner "the right to exclude others from asexually reproducing the plant, and from using, offering for sale, or selling the plant so reproduced, or any of its parts, throughout the United States, or from importing the plant so reproduced, or any parts thereof, into the United States." 35 U.S.C. § 163. The rights are granted for a period of 20 years. In contrast to utility patents, plant patents cover a single new plant and its asexually reproduced offspring only and the protection conferred is quite limited. As plant patents are granted on the entire plant, it follows that only one claim per plant patent is permitted.

The Plant Patent Act was amended on 27 October 1998 to extend the exclusive right to plant parts obtained from protected varieties but it is not applied retroactively. It is possible to obtain protection for the same plant both as a utility patent and a plant patent in the United States at the same time, provided that the requirements for patentability for both types of patents are fulfilled.

2.5.3 Plant Breeders' Rights and UPOV

The term Plant Breeders' Rights is synonymously used with Plant Variety Rights. The PBR like other IPRs allows the plant variety owner to prohibit specific unauthorised uses of the variety. As the PBR laws apply only to plants, they are considered as a class of *sui generis* systems.

PBR systems, like other IP systems, have three major components:

1) Definition/identification of protectable subject matter

2) Requirements that must be met to receive protection

3) Rights of the variety owner

PBRs, like patents and other forms of IP laws, are forms of national legislation. The signatories of WTO are committed to comply with the requirements of a harmonized minimum level of IP rights protection for plant varieties.

The UPOV Act adopts most of the international IPR obligations, including a definition of the applicable subject matter and protected material, eligibility requirements, exclusive rights, national treatment, reciprocity, terms of protection and exceptions and limitations to exclusive rights. The UPOV is an international agreement that provides a framework under which countries can implement a protection system that generally fulfils the TRIPS requirement. Though a 'treaty', countries are not obliged to join UPOV and membership is purely voluntary. However, many countries have joined UPOV and modelled their PBR legislations as per its framework. Details about the UPOV Convention and requirements for obtaining PBR are discussed in a separate Unit. While it is beyond the scope to discuss individual legislations on PBR available in different countries, few cases are discussed below as examples:

2.5.4 Plant Variety Protection Certificates (United States)

As seen above, in the United States plant varieties can be protected by patents and thus it is not technically obliged by the TRIPs Agreement to have additional protection for plant varieties. However, the US is also a UPOV member and implements the UPOV Convention by the Plant Variety Protection Act (1970). Changes to the Act made by Amendments in 1994 to comply with the 1991 UPOV Convention.

The Plant Variety Protection Act is administered by the U.S. Department of Agriculture, which issues Plant Variety Protection Certificates (PVPC) for qualifying plant varieties. The Act protects sexually reproduced plants, including first generation (F1) hybrids and tuber propagated plants (e.g. potato varieties). The requirements and term of this protection offered are exactly the same as those outlined in the UPOV Convention. It is obligatory to deposit seeds of the new variety with an authorised depositary, and in the case of F1 hybrids, seeds of the parents must also be deposited. There is a limited farmer's exemption and the protected seed may be "saved" for replanting on their own individual holdings provided that it is not sold to any third parties who use it for reproductive purposes.

Simultaneous protection both as a utility patent and a PVPC is also permitted. The choice is usually depends on the level of protection sought and the ability to satisfy the necessary requirements. Patent system is preferred in cases where comprehensive exclusive rights are desired.

2.5.5 Community Plant Variety Rights (European Union)

The Community Plant Variety Right (CPVR) is a form of intellectual property for the protection of plant variety rights created by EU legislation (Regulation 2100/94/EC), in 1995. The CPVR system is managed by the Community Plant Variety Office (CPVO) established to run the regime on granting plant variety right protection valid throughout the EU. Thus the CPVR enables

applicants, on the basis of one application, to be granted as a single IPR which is operative throughout all countries that are members of the EU. A CPVR can only be transferred or ceased within the EU Community on a uniform basis. That is, a CPVR can only be valid (or cancelled) across all EU countries, not selected individual countries. The CPVR system offers the member countries an alternative form of protection alongside the national plant protection legislation. However, protection for the same variety cannot be held under both the CPVR and the national system at the same time. In case a CPVR is granted in relation to a variety for which a national right has already been granted, the national right is suspended for the duration of the CPVR.

Self Assessment Question **(Spend 3 minutes)**

3) Ms Julie wishes to get CPVR granted in Germany. What should she do to register the variety for protection in France and Italy.

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2.5.6 Regulations on the Protection of New Varieties of Plants (People's Republic of China)

The Regulations on the Protection of New Varieties of Plants of China is a UPOV based system. It provides for rights in new varieties of plants, which are defined as 'a cultivated plant variety, or a developed one based on a discovered wild plant, which is new, distinct, uniform and stable, and whose denomination is adequately designated'. Article 24 of the Patent Act of the PRC explicitly rules out the grant of patents for 'animal and plant varieties'.

2.5.7 Protection of Plant Varieties and Farmers' Right Act (India)

India became a member of the World Trade Organization on January 1, 1995. As a member, India was then required to comply with the TRIPS Agreement, specifically, Article 27.3 (b) and enact legislation to protect plant varieties either by patents, or by an effective *sui generis* system.

India adopted the *sui generis* approach and legislated the 'Protection of Plant Varieties and Farmers' Right (PPVFR) Act 2001'. The *sui generis* option for the protection of plant varieties had three major advantages: a) flexibility, b) better protection of farmers' rights, and c) stronger researchers' exemptions meeting the social, ethical and cultural value of Indian ethos. The Act has been developed by integrating the rights of breeders, farmers and communities, and taking care of the concerns for equitable sharing of benefits. The PPVFR Act has been envisaged with the objective to stimulate the much-needed investment by the private sector in agriculture research and development, recognize and protect the rights of farmers in respect of their contribution in conserving, improving and making available plant genetic resources for development of new varieties. The details of the provisions shall be discussed in detail in other Unit.

2.6 REVIEW OF ARTICLE 27.3(B)

The Convention on Biological Diversity (CBD) was adopted in 1992 at Rio de Janeiro in Brazil. The objectives of this Conventio, 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 utilisation of genetic resources. The details of the CBD shall be discussed in a separate Unit.

It may, however, be mentioned that the TRIPS agreement is creating serious challenges to the successful implementation of the CBD, including in relation to access and benefit sharing, protection of traditional knowledge, technology transfer and the conservation and sustainable use of biological diversity. The relationship between TRIPs and CBD has given rise to many issues and many policy makers and members of civil society are concerned that the TRIPs agreement promotes private commercial interests at the expense of other important public policy objectives as, contained in the CBD.

As given in the Box 1 above, the TRIPS Agreement requires a review of Article 27.3(b). The Article specifically deals, with the issues of patentability of plant and animal inventions and protection of new plant varieties. However, Paragraph 19 of the 2001 Doha Declaration has provided additional focus on these issues and the TRIPS Council is to look intot the relationship between the TRIPS Agreement and CBD and on the issue of protection of traditional knowledge and folklore. Most recently discussed are the proposals on disclosing the source of biological material and associated traditional knowledge in patent applications. Till date the issue is under discussion, and as expected, e members' views continue to be divergent on the "practical and operational context" of the existing patent mechanisms for disclosing the origins of genetic material and any associated traditional knowledge used in inventions.

2.7 SUMMARY

- Providing Plant Breeders' Rights (PBRs) as incentive for innovations in plant breeding has been a global concern particularly with the expansion of operations by private companies in this sector. Initial efforts for providing PBR were made exploring the option of fitting them into traditional patent regimes; the first attempt was made in US through the U.S. Plant Patents Act of 1930.
- By the 1960's, many European countries had enacted PBR laws, which led to the adoption of International Convention for the Protection of New Varieties of Plants (UPOV) 1968 and amended in 1972, 1978 and 1991. It forms the basis of existing national laws in UPOV-member States.
- Pressures to expand IPR to plant varieties were witnessed during the TRIPS negotiations. TRIPS Article 27.3(b) obliges member states to provide PBRs either through patent protection or a *sui generis* system or a combination of the two. The options makes it possible for member states to incorporate specific exceptions and limitations in national PBR laws by incorporating concerns *inter alia* for conservation of genetic diversity, farmers' privileges and researchers' privileges, suiting their specific socio-political situation. The TRIPS Agreement also requires a review of Article 27.3(b).

- In most countries, inventions directed to plants or plant products such as seeds, are not eligible for a patent grant, but some (including the United States and Australia) provide utility patents provided the statutory requirement for patentability are met. In Europe, individual plant varieties *per se* are not patentable. However, a plant which is characterized by a particular gene is not included in the definition of a plant variety and is, therefore, patentable.
- In addition to patents in the US the Plant Variety Protection Act issues Plant Variety Protection Certificates (PVPC) for granting PBRs based on the UPOV 1991 Convention. In Europe the Community Plant Variety Right (CPVR) system grants plant variety right valid throughout the EU. While TRIPs Agreement does not mention the UPOV Acts the same have been advanced as the principal workable example of an 'effective *sui generis*' PVP system, and many countries have modeled their legislations after UPOV-1991 and/ or have joined the UPOV Convention.
- Adopting the *sui generis* approach, India has legislated the 'Protection of Plant Varieties and Farmers' Right (PPVFR) Act 2001'. The Act integrates the rights of breeders, farmers and communities, and incorporating concerns for equitable sharing of benefits.

2.8 TERMINAL QUESTION

1) Mention the pre-TRIPS attempts made by countries to provide intellectual property rights to plant breeders?
2) What are the options for member states to provide plant variety protection under TRIPS?
3) What are the alternatives available for seeking plant breeders rights taking USA, EU and India as examples?

2.9 ANSWERS AND HINTS

Self Assessment Questions

1) The correct answer is iii. Patent protection for Plant variety is an option but not obligatory. Similarly, UPOV is considered an effective *sui generis* system. TRIPs does not obligate member states to join UPOV. It only requires members to provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.
2) The correct answer is: iv. Patent laws in India and Germany (governed by European Patent Convention) consider plants as non patentable subject. While US patent law permits patenting of plant, in the present case the plant is as a natural source material and considered as a discovery, and thus is not novel.
3) The CPVR granted to Ms Julie would be operative throughout all the countries that are members of the EU. As France and Italy are members of the EU, therefore, she will automatically be granted protection in France and Italy and there is no need for her to register individually in these countries.

Terminal Questions

1) Refer to Section 2.3

2) Refer to Sub-section 2.4.1 and 2.4.2

3) Refer to Section 2.5

2.10 REFERENCES AND SUGGESTED READINGS

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DISCLAIMER: The material presented in this Unit is a simplified summary of important provisions of various legislations for study purposes only. It should not be construed as legal advice.

UNIT 3 OBLIGATIONS UNDER OTHER INTERNATIONAL INSTRUMENTS ON PLANT GENETIC RESOURCES

Structure

3.1 INTRODUCTION

Genetic resources have played a significant role in the development of humankind, by providing food, feed and fodder and also numerous medicines and industrial products. We have studied in Unit 1 that plant breeding is a process by which genes are recombined either through selection, crossing or other modern breeding techniques using genetic resources.

The full spectrum of plant genetic resources of any crop consists of diverse type of collections such as those derived from centers of diversity, those derived from centers of cultivation and those derived from breeding programmes. Some of the valuable genes found in PGRs have provided tremendous boost to the

crop improvement programmes. Emphasis on new breeding objectives, such as increased stress tolerance, biological efficiency with reduced inputs, mitigation of effects of climate change etc., also are necessitating plant breeders to look once again at genetic resources for new sources of genes regulating the various desirable traits.

The recent advancements in new technologies particularly biotechnology (including molecular biology and genetic engineering/metabolic engineering) have profoundly expanded the pool of genes potentially available for the breeding of new crop varieties, thereby increasing the value of the genetic resources. By and large the tropical and sub-tropical regions of the world, mainly comprising the developing nations are endowed with rich plant genetic diversity. However, all the countries are inter-dependent on their germplasm needs and no country can claim to be self-dependent for present or future on germplasm needs.

During the period from 1980's the economically advanced countries were not only developing capacity for deploying novel methods and techniques in genetic manipulation (biotechnology) but were also equipping themselves with legal instruments by unprecedented enhancement in the level, scope, territorial extent and role of intellectual property rights (IPR) that were now applicable to plants and plant products. The creation of new knowledge utilising living materials was, therefore, perceived as a means of generating commercial goods by converting them into useful value added products, production process and services.

This attracted large multinational corporations to undertake 'life science' research which was earlier largely a prerogative of the public sector institutions. The developing countries were, therefore, legitimately concerned that the transnational corporations would take a short-term, opportunistic view of genetic resources conservation, and exploit it for monopolizing the control and use of biologically derived materials, specifically through product or process patents or plant breeders' rights. The opportunity to transform the genetic resources from public to private goods would also lead to restricted exchange of genetic material (especially proprietary material) with public and private plant breeders.

These developments made conservation and use of crop germplasm highly politicized in recent years. Debates at national and global forum that cut across wide range of sectors, such as food and nutritional security, biological diversity conservation and environment degradation, economic, social and cultural development and ethics and human rights. Although the anthropocentric view of conservation of biodiversity was supposed to have encouraged the utilization of such resources for the benefit of humankind, the emerging IPR regimes and their intricate relationship seems to have had a contradictory effect. The world opinion today is clearly divided into two groups, one favouring a strictly regulated control of genetic resources and other advocating flexibility and limited control in access.

The complexities have largely emanated from two global developments, namely, the Convention on Biological Diversity (CBD) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) administered by the World Trade Organisation. These two developments have led to new dimensions of statutory provisions and regulatory obligations that make access and utilisation of genetic resources not as unrestricted as it used to be. In the earlier Unit we had studied the obligations under the TRIPS Agreement related

to genetic resources, in this Unit we would examine the obligations under the CBD. The focus shall be on the provisions of CBD specific to the biodiversity-related aspects of the global IPR regime.

3.2 OBJECTIVES

After completing the study of this unit, you should be able to:

- acquire a basic understanding of international concerns for conservation and utilisation of genetic resources;
- acquire a basic understanding the provisions of Convention of Biological Diversity, ITGRFA, Nagoya Protocol and Cartegena Protocol and analyse their implications on access and utilisation of genetic resources; and
- explain the obligatory requirements pertaining to access and utilisation of genetic resources as per the Biological Diversity Act, 2002.

3.3 BACKGROUND OF CBD NEGOTIATIONS

3.3.1 Issues related to Conservation

The tremendous value of the biological resources for the present and future generations and the threat to species and ecosystems has been a global concern in the last four decades. The first attempts were made to promote the development of an international convention on biological diversity when United Nations Environmental Programme (UNEP) convened an Ad-hoc Working Group of Experts on Biological Diversity in 1988 (later known as the Intergovernmental Negotiating Committee), to explore the need for an International Convention on Biological Diversity. In 1989, it established an Ad Hoc Working Group of Technical and Legal Experts, to prepare an international legal instrument for the conservation and sustainable use of biological diversity. The experts were to take into account "the need to share costs and benefits between developed and developing countries" as well as "ways and means to support innovation by local people".

By February 1991, the Ad Hoc Working Group had become known as the Intergovernmental Negotiating Committee. Its work culminated on 22 May 1992 with the Nairobi Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity.

3.3.2 Issues related to Patents

As we have studied in the earlier Unit, this period also witnessed implementation of expanded and reinforced IPR regimes applicable to life forms in the developing countries. Compounding the problem was the fact that the patenting standards in some countries were either too relaxed or low allowing protection for inventions involving biological resources which amounted to little more than discoveries. Patents had been granted for inventions that were either not novel or are not inventive if the traditional knowledge already in the public domain is taken into consideration.

A case in example is the US patent on "use of turmeric in wound healing" granted in 1995, which proved to be a landmark case of re-appropriation of

traditional knowledge. While the use of turmeric for healing wounds and rashes had been practised for thousands of years in traditional medical systems in India, it was for the first time that a patent was successfully challenged by providing documentary evidence including an ancient Sanskrit text and a paper published in 1953 in the Journal of the Indian Medical Association.

Subsequently, admitting their inability to refer to the existing prior art not accessible through digitized databases while examining novelty of an invention, the USPTO suggested access to a digital database of traditional knowledge, to ensure that no patent was issued on the same. This led to the initiative in the form of Traditional Knowledge Digital Library (TKDL) in India to transcribe available traditional knowledge in books on Ayurveda, Unani, Siddha and Yoga and document the same in electronic form. The information has been classified as per international patent classification systems, and agreements have been entered with leading international patent offices to give patent examiners access to the TKDL database for patent search and examinations purposes.

Another issue related to granting of patents in the developed countries was that patents sometimes contained claims which appeared to be excessively broad. A good example is the European patent EP 301749 granted in 1994 to the company Agracetus for "Particle-mediated transformation of soybean plants and lines". It was one of the first patents in Europe which covered genetically engineered plants. It covered plants treated with a 'gene-gun', a device that used an electronic accelerator to fire DNA coated microprojectiles (e.g. gold particles) into living cells to introduce new genes into these cells. Despite the scarce evidence for the technical feasibility of the procedure, Agracetus received an incredibly broad patent. Not only was the procedure for genetic modification patented, but also the application of this procedure to all kinds of plants. Even the seeds themselves were patented.

It was challenged by the NGOs "No Patents on Life" and ETC-Group (formerly RAFI). They were joined by agrochemical and seed industry giants who argued from the point of view of their own economical interests. These multinational corporations included Sandoz, Ciba Geigy, Monsanto, Dekalb, Pioneer Hi-Bred. In a hearing of the oppositions against the patent in 2003 at the European Patent Office (EPO), the oppositions were rejected, but some details in the patent had to be changed. However, in a public hearing at the board of appeal at the European Patent Office in May 2007, the patent was finally revoked. Reasons were that parts of the patent were not really new and other details were not described in a way that the invention could be really repeated by other experts.

The case study of this patent also reflects the development of international agrochemical and seed companies and the effects of their consolidation on access to technology. In this period Pioneer, the biggest seed company in the world, has been taken over by DuPont. Ciba Geigy and Sandoz merged to become Novartis whose seed division then separated under the name of Syngenta. Monsanto, on the other hand, bought the companies DeKalb and Agracetus and consequently was also able to acquire Agracetus' incredibly broad patent, thus making sure it would not be in danger of economic dependence through the patent. Ironically, Monsanto, that initially opposed the patent later defended the same patent against other companies. This confirmed the apprehensions, not only of the civil society and public sector organisations but also other new biotechnology firms as well

as seed companies that patent may lead to monopoly positions for companies or nations, thereby adversely affecting research and development in agriculture.

3.3.3 Objectives of the Convention on Biological Diversity

The Convention on Biological Diversity (CBD) was negotiated following unprecedented debates among the developed and developing countries on issues that included *inter alia* the questions of access to genetic resources, sharing of benefits accrued from their use, technology transfer and biosafety.

The CBD was signed by 150 countries at the United Nations Conference on Environment and Development in 1992 in Rio de Janeiro (the 'Earth Summit'), and entered into force on 29 December, 1993. There are currently 191 parties and the treaty has been ratified by 168 countries; notable exceptions include the USA.

The CBD for the first time affirmed the sovereign rights of nations over their biological resources and to exploit their own resources pursuant to their environmental policies. It has three main objectives;

i) conservation of biological diversity,

ii) the sustainable use of its components, and

iii) fair and equitable sharing of the benefits arising from the use of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies.

Self Assessment Question **(Spend 2 minutes)**

1) The CBD is often quoted to have caused a paradigm shift in the discipline of plant genetic resources. What was this shift?

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3.3.4 CBD and Issue of Access and Benefit Sharing

Implementation of the objectives of the CBD relies on the protection and use of knowledge, including knowledge of genetic material, knowledge of technology, or the knowledge of indigenous and local communities regarding biological diversity. Since most of the developing countries were rich in genetic resources, it was argued that they did not necessarily benefit equally from industrial, medical, agricultural, and other uses of genetic resources that take place with technologically advanced developed countries, which were equipped or were equipping themselves with legal instruments that expanded and reinforced the implementation of IPR regimes to life forms. Thus the commitment of the Parties to "fair and equitable sharing of the benefits arising out of the utilisation of genetic resources" was incorporated in the CBD objectives.

There are a range of Articles incorporated in the treaty that reflect the concern of Parties on the issues of access to genetic resources, access to and transfer of

technology, handling of biotechnology and distribution of its benefits (Box 1). It can be seen from these provision that CBD reflects not only the commitment of global community for conservation and sustainable use of biodiversity, but also makes the facilitated access to genetic resources by developing countries a two-way process by effectively linking it with equitable sharing of benefits. Technology flows are also founded on the principle of equity with the developing countries providing resources, and developed countries sharing and transferring technologies including biotechnologies and providing financial resources to help developing countries meet their commitments and realise benefits. The CBD incorporates two obligations in this regard: namely, for providing access on "Mutually Agreed Terms" (MAT) and "Prior Informed Consent" (PIC).

3.3.5 Mutually Agreed Terms and Material Transfer Agreements

The concept of MAT establishes a new participatory relationship among country of origin, provider and user of genetic resources. It is a contractual arrangement, executed on a bilateral basis that provides an opportunity for the providing country to negotiate a share of the benefits derived from the use of the genetic resources. It also provides an opportunity to the provider of the genetic resource to specify the permitted or prohibited uses of the genetic resources provided, including whether or not any IPR rights which may or may not be taken over the resource or its derivatives may be commercialised, and benefits that are to be shared.

It is increasingly becoming common to transfer the genetic resources accompanied by a Material Transfer Agreement (MTA). Such a document forms a contractual relationship between the provider and the recipient. It is common for MTA agreements to attach terms and conditions regarding both the approved use of genetic resources and the rights to ownership of such materials or their derivatives. MTA agreements can appear in a number of forms. While the most common is a conventional sheet of paper, it is also possible for the material to come with language included on the bag. The use of so-called bag-tag language is becoming increasingly common. At issue, however, is whether the "shipper" who applies the MTA language actually owns title to the materials and has the right to allocate ownership rights.

3.3.6 Prior Informed Consent

The PIC empowers the provider of genetic resource to establish an authority that can grant or refuse access following a request from the applicant as per the national legislation. The applicant is required to provide information concerning the genetic resources required, purpose for which required and any proposal for benefit sharing for the providing Party, giving it an opportunity to become an equal partner and monitoring the use. As part of the PIC procedure, the authority may consult indigenous and local communities or other stakeholders concerned before granting the access.

Box 1: Important provisions under CBD related to conservation, access and benefit sharing

General Measures (Article 6)

- Develop national strategies, plans or programmes for conservation and sustainable use of biological diversity;

- Integrate, as far as possible and as appropriate, the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies.

Conservation of biological diversity (Articles 8 and 9)

- Establish a system of protected areas or areas where special measures need to be taken to conserve biological diversity;
- Develop guidelines for the selection, establishment and management of protected areas;
- Promote the protection of ecosystems, natural habitats and the maintenance of viable populations of species in natural surroundings;
- Rehabilitate and restore degraded ecosystems and promote the recovery of threatened species;
- Regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology;
- Prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species;
- Respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities and with the approval and involvement promote their wider application and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices;
- Cooperate in providing financial and other support for *in situ* and *ex-situ* conservation particularly to developing countries;
- Adopt measures for the ex-situ conservation of components of biological diversity;
- Establish and maintain facilities for ex-situ conservation of and research on plants, animals and micro-organisms;
- Adopt measures for the recovery and rehabilitation of threatened species and for their reintroduction into their natural habitats;
- Regulate and manage collection of biological resources so as not to threaten ecosystems and in-situ populations of species.

Access and benefit sharing (Article 15)

- Authority to determine access to genetic resources rests with the national governments and is subject to national legislation;
- Create conditions to facilitate access for environmentally sound uses;
- Access subject to "prior informed consent" of resource provider and on "mutually agreed terms";
- Endeavor to develop and carry out scientific research based in genetic resources provided by other Contracting Parties with full participation of, and where possible in, such Contracting Parties;

- Take legislative, administrative or policy measures, as appropriate, with the aim of sharing in a fair and equitable way the results of research and developments and the benefits arising from the commercial or other utilisation of genetic resources.

Access to and transfer of technology (Article 16)

- Endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties. Access to and transfer of technology using genetic resources to countries providing the genetic resources.
- Take legislative, administrative or policy measures, as appropriate, with the aim that countries, which provide genetic resources are provided access to and transfer of technology on mutually agreed terms.
- Ensure that IPRs are supportive of and do not run counter to the implementation of the Convention objectives.

3.3.7 Implementation of Access and Benefit Sharing Provisions

Implementation of the CBD is a dynamic process and the Conference of the Parties (CoP) is the governing body of the Convention that takes decisions on outstanding issues at its periodic meetings. In order to facilitate better implementation of the CBD obligations with respect to access and benefit-sharing, Parties have undertaken several initiatives. The CBD constituted two Ad Hoc Open-ended Working Groups: one on Traditional Knowledge (COP IV/9/1998) and other on Access and Benefit Sharing (ABS) issues {COP V/6/2000); and one panel of experts on ABS (CBD/COP IV/8, 1998) with representation from diverse interest groups. The terms of references of these Working Groups and Expert Panel included mainly the development of a framework that would help assist Parties to develop national and regional regulations or guidelines on ABS, with special focus on evolving standards and principal elements of PIC, MAT, Material Transfer Agreements (MTA) and Monetary and Non-monetary Benefit Sharing Agreements.

One of the important outcomes of Sixth Meeting of the Conference of Parties held in April 2002 (COP VI/24/2002) in The Hague was adoption of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation.

a) The Bonn Guidelines

The Bonn Guidelines can be construed as the first affirmative step in operationalising the relevant CBD provisions with respect to ABS. These Guidelines are voluntary in nature and indicate procedures intended to provide the Parties and Stakeholders with a transparent framework to facilitate access to genetic resources through the practices and procedures of PIC of the country of origin as well as MAT, MTA, and other relevant agreements. The Guidelines assist in establishing and developing national access and benefit sharing regimes while promoting capacity building, transfer of technology and the provision of financial resources. They also seek to promote sustainable use of genetic

resources by promising to improve users' (commercial and non-commercial) access to valuable genetic resources in return for sharing the benefits with the countries of origin and with local and indigenous communities.

b) International regime on access and benefit-sharing

The World Summit on Sustainable Development held at Johannesburg, in September 2002, invited Parties to take appropriate steps

> *'to negotiate within the framework of the Convention on Biological Diversity [CBD], bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources'.*

Following it the Convention's Conference of the Parties at its seventh meeting, in 2004, (COP VII/19/2004) mandated its Ad Hoc Open-ended Working Group on ABS to elaborate and negotiate, together with the Working Group on Article 8(j), an international regime on access to genetic resources and benefit-sharing in order to effectively implement Article 15 and Article 8(j) of the CBD. Subsequently, discussions were held by the Working Group in the fifth and sixth meetings held in Montreal, Canada (8-12 October 2007) and in Geneva, Switzerland (21-25 January 2008) respectively.

Thereafter, recommendations on international regime on ABS were consolidated in Cali, Colombia by COP 9 (COP IX/12/2008). After six years of negotiations, the 'Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity' was adopted at the tenth meeting of the Conference of the Parties on 29 October 2010, in Nagoya, Japan. The Nagoya Protocol opened for signature by Parties to the Convention from 2 February 2011 until 1 February 2012 at the United Nations Headquarters in New York. The Protocol now has 61 signatories, but will enter into force 90 days after 50 countries, who are Parties to CBD, ratify the text.

The objective of the Nagoya Protocol is to promote sharing of the benefits arising from utilisation of genetic resources in a fair and equitable way, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components. The Protocol envisages the setting up of an international regime on access and benefit sharing of genetic resources, which will lay down the basic ground rules on how nations shall cooperate in obtaining genetic resources and sharing the benefits arising from their utilisation.

3.4 PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE

The CBD provisions encompass all biological resources, however, the plant genetic resources for food and agriculture (PGRFA), received special attention during the negotiations.

3.4.1 International Undertaking on Plant Genetic Resources

The first international and intergovernmental discussions on access to PGRFA were initiated in 1983 while negotiating the implementation of the International Undertaking on Plant Genetic Resources (IUPGR) at the Food and Agriculture Organization (FAO). It established the principle of plant genetic resources as the "common heritage of mankind" and consequently these resources were available without restriction. The Undertaking also raised apprehensions and issues for debate. While the multinational corporations and the developed countries raised the concern of IPR for the plant breeders, the developing countries raised objections against the inequitable and contradictory nature of free access to PGR. The Undertaking was thus clarified through various annexes stating that "free access" does not imply "free of charge". Also broad reference was made to farmer's rights and the compatibility of the Undertaking with the concept of sovereign rights over plant genetic resources was recognized.

During the pre-CBD period systematic explorations were conducted globally and samples of wild relatives, landraces and farmers' varieties were collected by scientists of the developed countries without any reciprocal benefit sharing or technology transfer arrangements. Many of these samples were conserved in the national and international gene-banks as *ex situ* collections. The recognition of the sovereign right of nations under CBD raised the two outstanding issues (i) facilitated access to the *ex situ* collections held world over prior to the CBD and (ii) the realization of farmers' rights enshrined in the revised agreed interpretation of the IUPGR.

Resolution 3 of the Final Act to the CBD referred these outstanding issues to be dealt with by the FAO's Global System on Plant Genetic Resources, of which the International Undertaking was the corner-stone. In November 1993 the FAO initiated the adaptation of the IUPGR in harmony with the CBD. In 1994, twelve Centers of the Consultative Group on International Agricultural Research, and subsequently other institutions, signed agreements with FAO, placing most of their collections (some 500,000 accessions) in the International Network. Through these agreements, the Centers accepted a number of responsibilities and obligations, in particular, to hold designated germplasm "in trust for the benefit of the international community", and "not to claim ownership, or seek intellectual property rights over the designated germplasm and related information".

After considering the negotiating texts in a series of sessions between 1994 and 1997, a simplified draft text concentrating on scope, availability of Plant Genetic Resources and Farmers' Rights was prepared. After sustained negotiations the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) was adopted on 3 November 2001.

3.4.2 International Treaty on Plant Genetic Resources for Food and Agriculture

The ITPGRFA provides a legal framework that not only recognizes the need for plant genetic resource conservation, sustainable agriculture and food security but also defines a regime for ABS linking it with IPRs (Box 2). It provides broad guidelines but entrusts the responsibility for realizing farmers' rights to memberstates. The specific obligations include the need to keep an inventory of PGRFA, promote their collection, promote farmers and local communities' efforts

to manage and conserve on-farm their PGRFA, promote *in situ* conservation of wild crop relatives and wild plants for food production, and cooperate to promote the development of an efficient and sustainable system of *ex situ* conservation.

In exercise of sovereign rights of nations over their PGRFA, the Treaty provides for a multilateral system (MS) covering a list of 35 food crops/group of crops and 29 forage crops/group of crops (provided as Annexure 1 of the ITPGRFA) selected on the criteria of food security and interdependence. The facilitated access to PGRFA shall be provided in pursuance of Standard Material Transfer Agreement (SMTA) adopted on 16 June 2006 by the Governing Body of ITPGRFA in their first meeting held at Madrid, Spain. The SMTA has 9 Articles including rights and obligations of the provider and the recipient under Articles 5 and 6 and contains the provisions of the Articles 12 and 13 and other relevant provisions of ITPGRFA as referred to in the Box 2. The conditions of SMTA shall apply to the transfer of PGRFA among the Contracting Parties and also to another person or entity, as well as to any subsequent transfers of these PGRFA.

The ITPGRFA includes ground-breaking, innovative provisions for monetary benefit-sharing as reflected in the SMTA. If a product that incorporates material from the MS is commercialised in such a way that is not "available without restriction to others for further research and breeding" a mandatory payment of 1.1% of the sales of the product(s) less 30% or alternatively at 0.5% of the sales of any products and of sales of other products that are PGRFA belonging to the same crop, into the mechanism established for this purpose. However, payment shall be voluntary if product(s) are available without restriction for further research and breeding.

Box 2:Important provisions under ITPRFA related to conservation, access and benefit sharing

Farmers rights (Article 9)

- to save, use, exchange and sell farm saved seed/propagating material
- protection of their traditional knowledge relevant to PGRs
- right to equitably participate in sharing benefits arising from the utilisation of PGRs
- right to participate in making decisions on matters related to conservation and sustainable use of PGRs.

Establishment of Multilateral system (MLS) (Article 10)

- Recognizes sovereign rights of states over their PGRFA
- Authority to determine access rests with states and is subject to national legislation

Coverage of MLS (Article 11)

- List of 35 crops/genepools and forages - Annex I
- PGRFA under "the management and control of the Contracting Parties and in the public domain"

- Includes Annex I genetic resources held by CGIAR and other international institutions
- Other holders of Annex I PGRFA (e.g. private sector) invited to include these in MLS

Guidelines for Facilitated Access to PGRFA (Article 12)

- Solely for the purpose of utilisation and conservation for research, breeding and training for food and agriculture
- Accorded expeditiously, with a minimal or no charge at all
- All available non-confidential descriptive information shall be made available
- No IPR or other rights so as to limit access shall be claimed over the PGRs or their genetic parts or components in the form received from the multilateral system
- Access to PGRs protected by IPR shall be consistent with international and national arrangements
- PGRs accessed under the multilateral system shall continue to be made available
- Access to PGRs in *in situ* conditions shall be provided subject to national legislation.

Benefit Sharing Mechanism (Article 13)

- Establish a Global Information System to facilitate exchange of information
- Facilitated access to technologies for the conservation, characterization, evaluation and use of PGRFA, subject to applicable IPRs.
- Technologies protected by IPRs particularly for use in conservation as well as for the benefit of farmers in developing countries should be transferred under 'fair and most favorable terms'.
- Establishing/strengthening/developing scientific and technical education and training, facilities for conservation and sustainable use of PGRs and carry out scientific research in the developing countries.
- Standard Material Transfer Agreement, for facilitated access to include a requirement that an equitable share of the benefits arising from the commercialization of product that incorporates material accessed through the Multilateral System will have to be paid to the Trust Account set up under the Treaty.
- The benefits that arise under the benefit sharing arrangements must be primarily directed to farmers who conserve and sustainably use PGRFA

3.5 BIOSAFETY ISSUES

Biotechnology has opened up multitude of opportunities for the scientists to alter the genetic structure of any organism, thereby developing a number of

genetically modified organisms and products from them. Notwithstanding the potential of biotechnology, the ecologists and environmentalists perceive the biosafety implications of the field release of transgenic crops among the major ecological risks.

They apprehend that large-scale adoption of transgenics may lead to monoculture and may lead to genetic erosion and genetic vulnerability to insect-pests and diseases, in the genetic diversity over a period of time. Further, the possible transfer of genes from herbicide-resistant transgenic crops to wild or weedy relatives may occur and create 'superweeds'. It may also lead to development of strains of insect-pests resistant to the genes of known sources of resistance, and genetic recombination may also lead to emergence of new virulent strains of virus, especially in transgenic plants engineered for viral resistance derived from viral genome. The possible environmental impact of any transgenic crop will vary depending on the crop's reproductive behaviour, the ecological system in which it is grown, its management strategy and the regulatory mechanism.

3.5.1 The Cartagena Protocol

Recognizing the potential risk arising from genetically modified organisms (GMOs), the CBD, in Article 19.3 provided for the Parties to consider the need for and modalities of a protocol to ensure safe transfer, handling and use of GMOs. In the second meeting of Conference of Parties (CoP) in November 1995 an open ended Ad-hoc Working Group to develop a protocol on biosafety through a negotiation process focusing on transboundary movement of LMOs was established. Six meetings of the Biosafety Working Group were held from June 1996 to February 1999. The sixth and the final meeting of the Working Group was followed by the Extraordinary meeting of the CoP held in Cartagena, Colombia in February 1999 for adopting the Protocol. After sustained negotiations the Cartagena Protocol on Biosafety was adopted in Montreal, Canada on June 29, 2000 and entered into force on 11 September, 2003. Later the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol was adopted on 15 October 2010, in Nagoya, Japan. India signed the Biosafety Protocol on 23 January 2001 and ratified the same on 5 September, 2002.

The Protocol is a legally binding instrument governing transfer of GMOs from one nation to another. It deals primarily with GMOs that are to be intentionally introduced into the environment (such as seeds, trees or fish) and with genetically modified farm commodities (such as corn and grain used for food, animal feed or processing).The objective of the Protocol is to contribute to adequate level of protection in the field of safe transfer, handling and use of GMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements (Article 1 of the Protocol, SCBD 2000).

The Protocol advocates adoption of the precautionary principle (Principle 15 of the Rio Declaration on Environment and Development) which is a moral and political principle indicating that lack of scientific certainty is no reason to postpone action to avoid potentially serious or irreversible harm to the environment, and the onus of proof falls on those who would advocate taking the action. An important feature of the Protocol is the procedure of "Advance

Informed Agreement" (AIA) that applies to the first intentional transboundary movement of GMOs for intentional introduction into the environment of the Party of import. It obliges the exporter to notify the competent national authority of the importing country and provide the necessary information such as modification introduced, the technique used and the resulting characteristics of the GMO, the regulatory status of the GMO in the country of export or any other details if required by the importing country to enable it to decide in favour of or against importing. This shall provide importing countries both the opportunity and the capacity to assess risks that may be associated with the GMO before agreeing to its import.

3.6 NATIONAL RESPONSE

3.6.1 Biological Diversity Act, 2002

The Government of India ratified the CBD on 18th February 1994. This required a national legislation for the sustainable management and conservation of India's natural resources. Accordingly, the Biological Diversity Act, 2002 (BD Act) was formulated after intensive consultation with various stakeholders. The Act aims to ensure conservation and sustainable use biological diversity; and to regulate access to biological resources of the country with the purpose of securing equitable share in benefits arising out of the use of biological resources and associated knowledge. The important provisions of the Act are given in Box 3:

Box 3: Important regulatory provisions of the Biological Diversity Act, 2002

Section 3. 1) No person referred to in sub-section (2) shall without previous approval of the National Biodiversity Authority obtain any biological resource occurring in India or knowledge associated thereto for research or for commercial utilisation or for bio-survey and bio-utilisation.

2) The persons who shall be required to take the approval of the National Biodiversity Authority under sub-section (1) are the following, namely:

a) a person who is not a citizen of India;

b) a citizen of India, who is a non-resident as defined in clause (30) of section 2 of the Income-tax Act, 1961;

c) a body corporate, association or organisation-

i) not incorporated or registered in India; or

ii) incorporated or registered in India under any law for the time being in force which has any non-Indian participation in its share capital or management. Results of research not to be transferred to certain persons without approval of National Biodiversity Authority.

Section 4. No person shall without the previous approval of the National Biodiversity Authority, transfer the results of any research relating to any biological resources occurring or obtained from India for monetary consideration or otherwise to any person who is not a citizen of India or a body corporate or organisation which is not registered or incorporated in India or which has any non-Indian participation in its share capital or management. Explanation—For the purposes of this section, "transfer" does not include publication of research papers or dissemination of knowledge in any seminar or workshop, if such publication is as per the guidelines issued by the Central Government.

Sections 3 and 4 not to apply to certain collaborative research projects.

Section 5. 1) The provisions of sections 3 and 4 shall not apply to collaborative research. projects involving transfer or exchange of biological resources or information relating thereto between institutions, including Government sponsored institutions of India, and such institutions in other countries, if such collaborative research projects satisfy the conditions specified in sub-section (3).

2) All collaborative research projects, other than those referred to in sub-section (1) which are based on agreements concluded before the commencement of this Act and in force.7 shall, to the extent the provisions of agreement are inconsistent with the provisions of this Act or any guidelines issued under clause (a) of sub-section (3), be void.

3) For the purposes of sub-section (1) collaborative research projects shall,-

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

b) be approved by the Central Government.

Section 6. 1) No person shall apply for any intellectual property right by whatever name called in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application:

a) Provided that if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the sealing of the patent by the patent authority concerned.

b) Provided further that the National Biodiversity Authority shall dispose of the application for permission made to it within a period of ninety days from the date of receipt thereof.

2) The National Biodiversity Authority may, while granting the approval under this section, impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilisation of such rights.

3) The provisions of this section shall not apply to any person making an application for any rights under any law relating to protection of plant varieties enacted by Parliament.

4) Where any right is granted under law referred to in sub-section (3), the concerned authority granting such right shall endorse a copy of such document granting the right to the National Biodiversity Authority.

Section 7. No person who is a citizen of India or a body corporate, association or organisation which is registered in India shall obtain any biological resource for commercial utilisation or bio-survey and bio-utilisation except after giving prior intimation to the State Biodiversity Board concerned:

a) Provided that the provisions of this section shall not apply to the local people and communities of the area, including growers and cultivators of biodiversity, and vaids and hakims, who have been practising indigenous medicine.

Some of the important definitions related to access, utilisation and benefit sharing in the Act are given below.

- **"benefit claimers"** means the conservers of biological resources, their by-products, creators and holders of knowledge and information relating to the use of such biological resources, innovations and practices associated with such use and application;
- **"biological resources"** means plants, animals and micro-organisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value but does not include human genetic material;
- **"bio-survey and bio-utilisation"** means survey or collection of species, subspecies, genes, components and extracts of biological resource for any purpose and includes characterization, inventorization and bioassay;
- **"commercial utilisation"** means end uses of biological resources for commercial utilization such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and genes used for improving crops and livestock through genetic intervention, but does not include conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping;
- **"fair and equitable benefit sharing"** means sharing of benefits as determined by the National Biodiversity Authority under Section 21;

- **"value added products"** means products which may contain portions or extracts of plants and animals in unrecognizable and physically inseparable form.

Self Assessment Question **(Spend 3 minutes)**

2) What are value added products? Give examples.

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a) Institutional mechanism

The act has created a three tier institutional mechanism comprising National Biodiversity Authority, State Biodiversity Boards and Biodiversity Management Committees.

i) National Biodiversity Authority (NBA)

The National Biodiversity Authority was established under Sub-section (1) (4) of Section 8 of the Biological Diversity Act, 2002, by Government of India in October, 2003 at Chennai, Tamil Nadu. The Authority comprises a Chairperson, 10 Ex-officio and 5 Non-official members. The NBA has been charged with the overall responsibility of implementing the Act and regulates the requests for access to bio-resources and associated traditional knowledge in partnership with the State Biodiversity Boards and the Biodiversity Management Committees at the local level. As per the Act NBA shall perform the following functions:

1) Regulate activities referred to in Sections 3, 4 and 6 and by regulations issue guidelines for access to biological resources and for fair and equitable benefit sharing.

2) Grant approval to foreigners/non-resident Indians and foreign companies, for obtaining any biological resource (Section 3); for transferring the results of any research (Section 4); for seeking IPR rights on biological resources and associated traditional knowledge obtained from India (Section 6).

3) Develop and issue guidelines for facilitating access to biological resources and for fair and equitable benefit sharing under Section 21.

4) Advise the Central Government on matters relating to the conservation of biodiversity, sustainable use of its components and equitable sharing of benefits arising out of the utilisation of biological resources; including notifications of threatened species (Section 38); designating institutions as repositories for different categories of biological resources (Section 39) and exempt certain biological resources, normally traded as commodities (Section 40).

5) Advise the State Governments in the selection of areas of biodiversity importance to be notified under Section 37(1) as heritage sites and measures for the management of such heritage sites.

6) Grant approval to certain persons seeking transfer of already accessed biological resource/associated traditional knowledge as per Section 20.

7) To determine and impose terms of equitable benefit sharing, arising out of the use of accessed biological resources and associated traditional knowledge (Section 21).

8) To take any necessary action on behalf of the Government of India to oppose the grant of IPR in any country outside India on any biological resource obtained from India or knowledge associated with such biological resource which is derived from India.

ii) State Biodiversity Boards (SBB)

The Act requires under Section 22(2) that the State Biodiversity Boards are to be established. Accordingly, so far 25 States have established the SBBs. The SSBs deal with all matters relating to access to bio-resources by Indians for commercial purposes. It has the authority to restrict any activity which violates the objectives of conservation, sustainable use and equitable sharing of benefits.

iii) Biodiversity Management Committees (BMCs)

Under Section 41, the Act requires, Institutions of local self government to set up Biodiversity Management Committees in their respective areas. The mandate of the BMCs is conservation, sustainable use, documentation of biodiversity and chronicling of knowledge relating to biodiversity. The task of setting up of BMCs remains a challenge although some states have gone ahead notably in this direction and 31,542 BMCs have already been constituted. The provision of mandatory consultation of BMCs by the NBA and SBBs would ensure formalisation of PIC by the communities and active involvement of the local and traditional communities in all decision making processes related to biological diversity and traditional knowledge.

The main function of BMC is to prepare Peoples' Biodiversity Registers (PBR) in consultation with the local people. The register shall contain comprehensive information on availability and knowledge of local biological resources or any other traditional knowledge associated with them. Establishment of comprehensive PBRs would not only help to inventorize and document the local biological and genetic resources, but also to conserve and sustainably use the bio-cultural diversity for rewarding income generation.

b) Regulating access to biological resources and associated knowledge

The important provisions related to the regulations for access to biological resources and traditional knowledge are given in Box 3. The Act accordingly, stipulates norms for access and differentiates the applicants in two categories.

i) Persons who are citizens of India: Access to bio-resources for research is unrestricted and free. However, Section 7 states that no person, who is a citizen of India or a body corporate, association or organisation which is registered in India, shall obtain any biological resource for commercial utilisation, or bio-survey and bio-utilisation for commercial use except after giving prior intimation to the concerned State Biodiversity Board and adhering to its directives.

ii) Persons who are not citizens of India non-resident Indians, and body corporate, association or organisation – not incorporated or registered in India; or incorporated or registered in India but having any non-Indian participation in its share capital or management.

Prior approval of NBA is required by the applicants of the second category (non-Indians) to access India's bio-resources and associated TK for research and commercial use or engaging in bio-survey and bio-utilisation activities (Section 3 read with Section 19). They are also required to seek prior approval of the NBA for transferring research results abroad (Section 4), for applying for IPR (Section 6) and also for third party transfer of the granted approval (Section 20).

Self Assessment Question **(Spend 3 minutes)**

3) An Indian industry wants to obtain the biological resources for commercial purposes. Does it require prior approval of the NBA?

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c) Exemptions under the Act

The following exemptions have been provided under the BD Act to promote *bona fide* use of bioresources for research and non-commercial use:

- Under Section 5 of the BD Act, Section 3 (access to bio-resource) and Section 4 (transfer of research results) shall not apply to the approved collaborative research projects. Guidelines on collaborative research projects involving transfer or exchange of biological resources or information relating thereto between institutions, including government sponsored institutions of India and such institutions in other countries, have been issued by the Ministry of Environment and Forests (MoEF) vide its notification dated 8 November, 2006.
- Provision of Section 6 shall not apply to any person making an application for any right under the Protection of Plant Varieties and Farmers' Rights Act, 2001. Where any right is granted under this law, the concerned authority granting such right shall endorse a copy of such document (granting the right) to the NBA.
- Provisions of Section 7 (prior intimation to SBB for commercial use) shall not apply to local people and communities including village healers/vaids, farmers and other traditional growers and also to Indian users of these bio-resources for research.
- Normally traded commodities, 190 bio-resources as notified by the MoEF vide its notification dated 26 October, 2009, subject to the clarification issued on 16 February, 2010, would be exempted from purview of this Act provided they are traded as commodities.

d) Criteria for benefit sharing

The Act, according to Section 21 (1) insist that the NBA while granting approvals ensure, *inter alia,* equitable sharing of benefits arising out of the use of accessed biological resources, their by-products, innovations and practices associated with their use and applications and knowledge relating thereto in accordance with mutually agreed terms and conditions between the person applying for such approval, local bodies concerned and the benefit claimers.

The NBA is yet to develop and notify guidelines for imposing terms for fair and equitable benefit sharing. Presently the NBA has constituted an Expert Committee on ABS which has developed working guidelines and recommendions regarding benefit sharing on a case-by-case basis. The benefit sharing can be given effect in all or any of the following manners:

a) grant of joint ownership of intellectual property rights to the NBA, or where benefit claimers are identified, to such benefit claimers;

b) transfer of technology;

c) location of production, research and development units in such areas which will c)facilitate better living standards to the benefit claimers;

d) association of Indian scientists, benefit claimers and the local people with research and development in biological resources and bio-survey and bio-utilisation;

e) setting up of venture capital fund for aiding the cause of benefit claimers;

f) payment of monetary compensation and other non-monetary benefits to the benefit claimers as the NBA may deem fit.

Every determination of benefit sharing or order made by the NBA or a SBB under this Act or the order made by the High Court in any appeal against any determination or order of the by the NBA or a SBB shall, on a certificate issued by any officer of the NBA or a SBB or the Registrar of the High Court, as the case may be, be deemed to be decree of the civil court and shall be executed in the same manner as a decree of that court.

e) Designated National Repository

As per the provision of Section 39, the Central Government may in consultation with the NBA designate institutions as repositories under this Act for different categories of biological resources. The repositories shall keep in safe custody the biological material including voucher specimens deposited with them. Any new taxon discovered shall be notified to the repositories or any institution designated for this purpose and deposit the voucher specimens with such repository or institution. The DNR consists of service providers and repositories of preserved specimen consisting of all fauna, herbarium (dried plant material for research), the living cells, genomes of organism, and information relating to heredity and the functions of biological systems. DNRs also contain collections of culturable organisms (e.g. micro-organisms, plant, animal and human cells), replicable parts of these (e.g. genomes, plasmids, viruses, cDNAs), viable but not yet culturable organisms, cells and tissues, as well as databases containing molecular, physiological and structural information relevant to these collections and related bioinformatics. The NBA has prepared guidelines on DNR and it is in the process of notification.

f) Restrictions for access to biological resources

Under Rule 16 the Act imposes certain restrictions on NBA's approval on requests related to access to biological resources and traditional knowledge if the request is on:

i) endangered taxa

ii) endemic and rare species

iii) likely adverse effects on the livelihood of the local people

iv) adverse environmental impact which may be difficult to control and mitigate

v) cause genetic erosion or adversely affect ecosystem function

vi) purpose contrary to national interests and other related international agreements to which India is party

Self Assessment Question **(Spend 3 minutes)**

4) Mr John from Mississippi University wants to work on a species that is mentioned in the Red Data Book. He applies to the NBA for granting approval. Can he get the approval?

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g) Revocation of access or approval

Revocation of access or approval granted to an applicant will be done only on the basis of any complaint or *suo moto* under the following conditions: (i) violation of the provisions of the Act or conditions on which the approval was granted (ii) non-compliance of the terms of the agreement (iii) failure to comply with any of the conditions of access granted (iv) on account of overriding public interest or for protection of environment and conservation of biodiversity (Rule 15, Sub rule 1). After having withdrawn the access permit, the Authority is required to send an order of revocation to the concerned BMC and the SBB for prohibiting the access and to assess the damage, if any, caused and steps to recover the damages.

h) Biodiversity funds

The BD Act provides for setting up of biodiversity funds at national, state and local levels.

National Biodiversity Fund: The amount realised by the NBA through grants and loans, fees, royalties and other sources shall be credited to the National Biodiversity Fund, which is used for the following purposes:

- Channeling benefits to the 'benefit claimers'.
- Helping the conservers and developers of biological resources/ local communities in support of their on location efforts towards conservation and sustainable use.

- conservation of biological resources and development of areas from where such biological resources or knowledge associated thereto has been accessed;
- socio-economic development of the areas in consultation with the local bodies concerned

State Biodiversity Fund: The amount realised by the SBB through grants and loans made to SBB or made by NBA, or from such other sources as may be decided upon by the State Government shall be credited to the State Biodiversity Fund. The State Biodiversity Fund shall be used for:

- the management and conservation of heritage sites;
- compensating or rehabilitating any section of the people economically affected by restriction imposed under Section 37;
- conservation of biological resources;
- socio-economic development of areas from where such biological resources or knowledge associated thereto has been accessed subject to any approval granted under Section 24, in consultation with the local bodies concerned.

Local Biodiversity Fund: The grants and loans made by the State Government, NBA, SBB or amount received by BMC as fees or other sources shall be credited thereto the Local Biodiversity Fund at every area notified by the State Government where any institution of self-government is functioning. The fund shall be applied for conservation of biodiversity in the areas falling within the jurisdiction of the concerned local body and for the benefit of the community in so far such use is consistent with conservation of biodiversity.

i) Penalties

The offences under this Act are cognizable and non-bailable. Contravention or attempts to contravention or abetting the contravention of the provisions of Section 3, Section 4, or Section 6 shall be punishable with imprisonment for a term extendable to five years, or with fine extenable to ten lakh rupees. In case where the damage caused exceeds ten lakhs such fine may be commensurate with the damage caused, or with both. Contravention or attempts to contravention or abetting the contravention of the provisions of Section 7 or any order made under Section 24(1) shall be punishable with imprisonment for a term which may extend to three years, or with fine which may extend to five lakh rupees, or with both.

If a person contravenes any direction given or order made by the Central Government, the State Government, the NBA or the SBB for which no punishment has been separately provided under this Act, he shall be punished with a fine which may extend to one lakh rupees and in case of a second or subsequent offence, with fine which may extend to two lakh rupees and in the case of continuous contravention with additional fine which may extend to two lakh rupees everyday during which the default continues.

3.6.2 Protection of Plant Varieties and Farmers' Rights Act

The Protection of Plant Varieties and Farmer's Rights (PPVFR) Act, 2001 of India (PPVFR) deals with the protection of plant breeders rights over the new varieties developed as per the requirement of TRIPS, while the Biological Diversity Act legislated in response to CBD. In order to incorporate the concerns

of CBD particularly on equitable benefit sharing, efforts have been made to harmonize both the legislations.

Section 6(3) of the Biological Diversity Act requires prior approval of NBA before applying any IPR for any invention based on any research or information on a biological resource obtained from India. This provides NBA the opportunity to realise equitable sharing of benefits arising out of the use of biological resources and knowledge. However, an exemption has been provided for applicants seeking protection of varieties under the PPVFRA as this legislation also has a provision for benefit sharing; only that the Authority under the PPVFRA legislation is required to endorse a copy of the right granted under this Act to the NBA.

Keeping in line with the spirit of the CBD provisions, the PPVFR Act also provides for protection of farmer's varieties and creation of national gene fund for promoting conservation of local varieties.

3.6.3 Patent Act

Section 6 (1) of the BD Act links to the requirement under Section 10 (4) of the Patents (Amendment) Act, 2002 that requires mandatory disclosure in patent applicatios the source and geographical origin of biological material and traditional knowledge used in invention. It also provides for pre- and post-grant opposition of applications and revocation of granted patents on grounds of nondisclosure or wrongful disclosure. A sample of the bioresource is also required to be deposited in the designated national repository.

3.6.4 The Biosafety Regulatory Framework

Genetically modified organisms are regulated in India under the purview of the Indian Environment (Protection) Act 1986. The broad definition of "environmental pollutant" was used by the Ministry of Environment and Forests in 1989 to issue rules to govern use of genetically engineered organisms under the EP Act. The 1989 "Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells" (henceforth 1989 Rules) provide the legal framework for regulation of GMOs in India. Since the 1989 Rules call for guidelines to be developed to give them effect, biosafety guidelines were issued by the Department of Biotechnology under the Ministry of Science and Technology. These Rules are notified with the purpose of protecting the environment, nature and health from the application of gene technology and micro-organisms. These Rules cover industries, hospitals, research institutions and other establishments that handle micro-organisms or are engaged in genetic engineering. The application of these rules extends, not only to the genetically engineered organisms, etc. but also to any substance, products and foodstuffs containing such cell organisms or tissues. More specifically, the Rules cover storage and handling of hazardous organisms. As per these Rules, Review Committee on Genetic Manipulation (RCGM) established under the Department of Biotechnology supervises research activities including small scale field trials. Approvals for large scale releases and commercialization of GMOs are given by the Genetic Engineering Approval Committee (GEAC). In addition to these two committees under the Government of India, the 1989 Rules provide for establishing the State Biotechnology Coordination Committees and District level committees for monitoring. The Rules also mandate that every institution

engaged in GMO research establish an Institutional Biosafety Committee to oversee such research.

Self Assessment Question **(Spend 3 minutes)**

5) Prof Verma, a plant breeder, has developed a transgenic variety by incorporating into a existing wheat variety, a disease resistant gene isolated from bacteria. What additional formalities will be required before the variety is released for commercial purposes?

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3.7 SUMMARY

- The Convention on Biological Diversity (CBD) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) have led to new dimensions of statutory provisions and regulatory obligations for access and utilisation of genetic resources.
- The CBD entered into force on 29 December, 1993; and affirmed the sovereign rights of nations over their biological resources. The main objectives are, (i) conservation of biological diversity; (ii) sustainable use of its components, and; (iii) fair and equitable sharing of the benefits arising from the use of genetic resources. In this regard the CBD incorporates two obligations: namely, for providing access on "Mutually Agreed Terms" (MAT) and "Prior Informed Consent" (PIC).
- Implementation of the CBD is a dynamic process and the Conference of the Parties (CoP) is the governing body of the Convention that takes decisions on outstanding issues. To facilitate implementation of CBD obligations with respect to access and benefit-sharing several initiatives including the Bonn Guidelines were taken, culminating in adoption of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization on 29 October 2010.
- The CBD provisions encompass all biological resources, however, the plant genetic resources for food and agriculture (PGRFA) received special attention. The negotiations on two outstanding issues, (i) the facilitated access to the *ex situ* collections held prior to CBD and (ii) the realization of farmers' rights, culminated with the adoption of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) on 3 November 2001. The Treaty provides for a multilateral system (MS) for facilitated access to PGRFA covering a list of 35 food crops/group of crops and 29 forage crops/group of crops in pursuance of standard material transfer agreement (SMTA) which includes provisions for monetary benefit-sharing.
- The Cartagena Protocol on Biosafety was adopted on June 29, 2000 recognising the potential risk arising from genetically modified organisms

(GMOs), and entered into force on September 11, 2003. Later the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol was adopted on 15 October 2010. The Protocol governs transfer of GMOs to ensure adequate level of protection in the field of safe transfer, handling and use of GMOs against any adverse effects on conservation and sustainable use of biological diversity, specifically focusing on transboundary movements.

- In India the Biological Diversity Act, 2002 came in force since April 15, 2003. The Act regulates access to genetic resources and associated knowledge; and equitable sharing of benefits arising out of their use. To achieve this it establishes the National Biodiversity Authority (NBA), the State Biodiversity Boards (SBB) and the Biodiversity Management Committee (BMC). Further, the PPVFR Act provides for protection of farmer's varieties and creation of national gene fund for promoting conservation of local varieties. The Patents (Amendment) Act, 2002 requires mandatory disclosure in patent application of the source and geographical origin of biological material and traditional knowledge used in invention and deposition of a sample of the bioresource in the designated national repository. Genetically modified organisms are regulated in India under the purview of the Indian Environment (Protection) Act 1986.

3.8 TERMINAL QUESTIONS

1) How does the provisions of Mutually Agreed Terms and Prior Informed Consent enshrined in CBD address the issues of access to genetic resources and sharing of benefits from their utilization?

2) What are potential biosafety implications of genetically modified organisms and how does CBD addresses it?

3) What are the important regulatory provisions of the Biological Diversity Act, 2002 with reference to access and utilization of biological resources?

3.9 ANSWERS AND HINTS

Self Assessment Questions

1) The plant genetic resources (PGRs), prior to CBD were considered as a common heritage of mankind and consequently were available without restriction. The recognition of sovereign rights of countries, over their genetic resources under the CBD caused a paradigm shift in the legal perception and triggered very significant changes in the international policy frameworks for access to these resources.

2) Value added product implies products containing portions/extracts of plants and animals in unrecognizable and physically inseparable form. For example: drugs such as toxicol, cosmetic creams using turmeric etc.,

3) No. NBA regulates the access of genetic resources for non-Indian persons. However, the Indian industry is required to give prior intimation to the concerned SBB about obtaining the biological resources for commercial purposes. The SBB will have the power to prohibit or restrict any such

activity, which violates the objectives of conservation, sustainable use and equitable sharing of benefits.

4) No. The Red Data Book is the State document established for documenting rare and endangered species that exist within the territory of the state or country. As the species is mentioned in this book, he cannot be granted permission for access.

5) The genetically engineered variety will have to be tested for environment and bio-safety before its commercial release, as per the regulations and guidelines of the Environment Protection Act (EPA), 1986.

Terminal Questions

1) Refer to Sub-section 3.3.5 and 3.3.6

2) Refer to Section 3.5

3) Refer to Box 2 supplemented with information in Sub-section 3.6.1.2 and 3.6.1.3

3.10 REFERENCES AND SUGGESTED READINGS

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9) Walker, Simon. 2001. *The TRIPS Agreement, Sustainable Development and the Public Interest: Discussion Paper*. IUCN, Gland, Switzerland and Cambridge, UK and CIEL, Geneva, Switzerland. 60pp.

DISCLAIMER: The material presented in this Unit is a simplified summary of important provisions of various legislations for study purposes only. It should not be construed as legal advice.

UNIT 4 THE INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS

Structure

4.1 INTRODUCTION

The first inclusion of biological agricultural innovations in an IP statute was in the U.S. Plant Patents Act of 1930, which created a *sui generis* system confining protection to a sexually reproduced plants. During this period IP protection of plant varieties was uncommon in most of the countries. The International Association for the Protection of Intellectual Property (AIPPI), which largely comprises lawyers with a pro-industry stance; and the International Association of Plant Breeders (ASSINSEL) took the strategic view that the lack of IP norms specifically for plants needed to be resolved internationally.

The associations called for a conference to consider the possibility of developing a new international instrument for protecting plant varieties. Consequently in February 1957, the French government issued invitations to 12 western European countries4 to attend a diplomatic conference in Paris in May of that year to consider establishing such a system. Participation was limited by the French to those states who were known to have similar concerns on this subject. The conclusions of the 1957 Paris conference were set down in its Final Act, adopted in May 1957. At the second session of the conference, held in Paris in late 1961, the International Convention for the Protection of New Varieties of Plants, or *Union pour la Protection des Obtentions Végétales* (UPOV), was adopted in December 1961. It entered into force in 1968 once it had been ratified by three countries, which then formed the Union. It took seven years for the Convention to enter into force because few countries had a PVP system, and ratification required a national PVP system to be in place. UPOV was revised in 1972, 1978 and 1991. The 1991 revision entered into force in 1998.

In its early years, the Convention applied exclusively to European countries as it was largely conceived and designed by and for European commercial breeding interests, balancing these interests with those of European farmers. The same European breeding interests continue to be intimately involved in the operations of the Convention and of the Union today, and have also played important role in encouraging more countries – from all regions – to join UPOV.

Neither UPOV nor TRIPS preclude non-UPOV members adopting non-UPOV PVP regimes. But while some non- UPOV *sui generis* systems have been established in recent years, developing countries are more often opting for UPOV membership than exploring other approaches. In the last decade, developing countries have often agreed to apply for UPOV membership – or adopt UPOV 1991 compatible legislation – through their trade or investment agreements with the United States, the European Union, Japan or the European Free Trade Association. In addition, technical assistance programmes can result in PVP rules that may comply with UPOV, but are not necessarily adapted to local conditions or to the needs of all stakeholders. In this Unit we will analyse the UPOV provisions specifically as enshrined in the 1991 Act (Convention).

4.2 OBJECTIVES

After completing the study of this unit, you should be able to:

- acquire a basic understanding of UPOV Convention;
- analyse the requirements for protection of new varieties of plants;
- explain briefly the underlying principle of the DUS criteria as it applies to plant varieties; and
- describe the acts covered by the scope of the breeder's right which require the authorisation of the breeders.

4.3 KEY PROVISIONS OF THE UPOV CONVENTION

The Convention's provisions are extremely detailed and specific. To be eligible for protection, plant varieties must be novel, distinct, uniform and stable (the 'DUS criteria').

4.3.1 Scope of Plant Breeders' Rights

In most countries, the implementation of the UPOV Convention and the rights granted under the PBRs are conferred by domestic legislation. The PBR like the other IPRs permits the owner of the right to exclude others from performing certain acts. It should, however, be emphasized that the breeders' right does not give a breeder the right to grow or commercialize the variety. Based on propagating material, UPOV Convention (Article 14(1)) specifies the following acts in relation to propagating material of the plant varietywhich require the prior authorisation of the breeder:

- Production or reproduction (multiplication)
- Conditioning for the purpose of propagation
- Offering for sale
- Selling or other marketing
- Exporting
- Importing
- Stocking for any of the above purposes

The UPOV Convention, in its Article 14(2), extends the breeder's right to harvested material,

- If the material is obtained through the unauthorised use of propagating material, and
- If the breeder has not had reasonable opportunity to exercise his right in relation to the propagating material

In the absence of the extension of the right to harvested material, the material of a protected variety could be exported from country A, without the authorisation of the title holder, to country B, where plant breeders' rights are not available. The material could then be freely reproduced in country B to produce cut flowers

(harvested material), which were exported back to country A. If cut flowers did not fall within the scope of the breeder's right, the breeder could not do anything to stop this practice. The result would be that the breeder would go unrewarded and would lose his breeding investment.

Article 14(3) provides for an optional provision to extend the scope of the breeder's right to products made directly from harvested material, where this has been obtained through the unauthorised use of harvested material of the protected variety which has itself been obtained from unauthorised propagating material, unless the breeder has had reasonable opportunity to exercise his right in relation to the harvested material.

The provisions under Article 14(2) and (3) constitute what has been called a "cascade". The notion of "cascade" implies that breeders can only exercise their right in relation to the harvested material if they have not been able to exercise their right in relation to the propagating material.

4.3.2 Varieties Covered within the Scope of the PBRs

As stated in Article 14.5 of the 1991 UPOV Act, in addition to the protected variety itself, the scope of breeder's right also applies to: (i) varieties which are not clearly distinguishable from the protected variety (ii) varieties whose production requires the repeated use of the protected variety and (iii) essentially derived varieties

Varieties which are not clearly distinguishable from the protected variety fall within the scope of the breeder's right and the breeder's authorisation is required as indicated in Articles 14(1),14(2), 14(3) and 14(4) as explained above.

Varieties whose production requires repeated use of the protected variety cover, in particular, varieties which are used to produce hybrid varieties. For example, some varieties such as "inbred lines" have been specifically bred to be used as parents for the production of hybrid varieties in crops, which in general perform better because of a phenomenon known as the "hybrid vigor". However, to produce seed of the F1 hybrid 'C', it is necessary to repeat the cycle described above (i.e. to cross the female parent A by the male parent B). If seed harvested from hybrid variety C is grown, the crop will not resemble variety C but rather a segregated mixture. Hybrid C is a different variety from both its parents.

As the production of variety C requires the repeated use of variety A (and variety B), the acts included in Article 14(1), (2), (3) and (4) concerning the F1 hybrid variety C require the authorisation of the title holder of variety A.

The provision of Article 14(5)(a)(iii) means that anyone using a protected variety as a parent to produce and commercialize a hybrid requires the authorisation of the titleholder of the protected variety to use it for that purpose. It should also be recalled that where the hybrid variety is protected, commercialization of the hybrid would also require the authorisation of the breeder of the hybrid variety itself (Article 14(1) to (4) applies in respect of the protected hybrid variety).

4.3.3 Essentially Derived Varieties

The concept of essential derivation is embodied in Article 14(5) and is designed to ensure that the Convention continues to provide an adequate incentive for plant breeding. Under this provision, a variety which is essentially derived from

a protected variety and which fulfils the normal protection criteria of novelty, distinctness, uniformity and stability, may be the subject of protection but cannot be exploited without the authorisation of the breeder of the protected variety. Simply stated, a variety ("B") is essentially derived from another variety ("A") when it (B) is predominantly derived from that variety (A), and except for the differences which result from the act of derivation, it (B) conforms to that variety (A) in the expression of the essential characteristics that result from the genotype or combination of genotypes of that variety (A). Accordingly, for practical purposes, varieties will only be essentially derived when they are developed in such a way that they retain virtually the whole genetic structure of the earlier variety. The 1991 Act contains a detailed definition of essential derivation in Article 14(5)(b) as mentioned below.

"14 (b) For the purposes of subparagraph (a)(i), a variety shall be deemed to be essentially derived from another variety ("the initial variety") when

i) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety,

ii) it is clearly distinguishable from the initial variety and

iii) except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety".

The UPOV Convention does not require the granting authority to assess whether a protected variety is essentially derived or not. However, Article 14(5)(c) lists some ways in which an essentially derived variety may be obtained:

> *"14 (c) Essentially derived varieties may be obtained for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering".*

But this is not an exhaustive list as essentially derived varieties could be obtained by other methods too.

Self Assessment Question **(Spend 3 minutes)**

1) Variety A is a protected variety. Is it required to seek the authorisation of the titleholder of A in order to breed a variety which is essentially derived from A.?

   a) Yes

   b) No

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4.3.4 Duration of Plant Breeders' Rights

The minimum period of protection (Article 19) provided by legislation implementing UPOV 1991, is to be 25 years in the case of trees and vines and 20 years for any other plant type. This duration period commences on the date of grant of PBRs in the variety. Where a plant variety is declared to be essentially derived from an initial variety, the total duration of protection for the dependent or essentially derived variety generally can last for no longer than the duration of the protection of the initial variety.

The mandatory DUS test examinations could take a significant time (usually one or two years). For the period between the filing or publication of the application and the granting of the PBRs the UPOV Convention (Article 13) requires to provide measures designed to safeguard the interests of the breeder. Such measures shall have the effect that the holder of a breeder's right shall at least be entitled to equitable remuneration from any person who, during the said period, has carried out acts which, once the right is granted, require the breeder's authorisation. This provisional protection takes effect only if protection is granted, i.e., if the application is rejected, provisional protection is not available.

4.3.5 Exploitation of Protected Varieties

Protection of a variety is independent of the measures regulating the production, certification and marketing of material of varieties. Irrespective of whether a variety is protected or not, there may be provisions of legislation to be met before a variety can be released onto the market; e.g., environmental legislation (e.g., concerning the release of genetically modified varieties) and/or variety registration requirements involving a minimum level of agronomic performance, (e.g., yield, disease-resistance).

Thus it would be possible to have the following situation:

Variety A: protected, and can be grown

Variety B: protected, but cannot be grown because of other legislation (e.g., environmental legislation)

Variety C: not protected, and can be grown

Variety D: not protected and cannot be grown because of other (non-PVP) legislation (e.g., variety registration, environmental legislation)

4.3.6 Exceptions to PBR

Article 15 of the UPOV Act provides exceptions to the breeders' right. Under compulsory exceptions it includes:

i) acts done privately and for non-commercial purposes,

ii) acts done for experimental purposes and

iii) acts done for the purpose of breeding other varieties

A provision for optional exception (see Article 15(2)) has been provided to address farm-saved seed (the "farmer's privilege"). The member countries can within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in

order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety.

Exceptions are provided for both private and for non-commercial purposes. The seed saved by a farmer from harvested material and treated for the purpose of sowing a crop on that farmer's own land is considered not to be an infringement by legislation based on UPOV 1991.Legislation may also provide that PBRs are not infringed when propagating material is used as a food, food ingredient, or fuel, or for any other purpose not leading to or involving the production or reproduction of propagating material. Also, it may be provided that PBRs are exhausted following the sale of propagating material by a grantee unless there is a multiplication of the material after the sale.

4.4 REQUIREMENTS FOR PROTECTION OF NEW PLANT VARIETIES

If a legal right is to be granted in respect of a variety and if that right is subsequently to be effectively enforced, the identity of the variety must be well established and maintained during the whole period of protection. The UPOV Convention has established certain criteria which should be satisfied before protection of a plant variety /or granting the breeder's right. The criteria for protection of a variety are as following (Article 5):

The variety should not be sold or commercialized during a specified period before filing of the variety, i.e. it should be 'new'(Novelty)

The variety should be clearly distinct from the other variety or should not be same, i.e.,'distinct'

The variety should be uniform in appearance - 'uniform'

The variety should not be segregated, it should be stable generation after generation, i.e., 'stable'

The variety should be designated by denomination in accordance with the applicant complying with the formalities provided for by the laws and rule of the Government with whose authority the application has been filed and that he deposit the required fees.

Therefore, Article 5 accordingly establishes distinctness, uniformity and stability (DUS) as criteria to be satisfied. The conditions are specifically based on the nature of variety and breeding methods by which the variety developed. These conditions are necessary for the grant of effective rights of the breeder for long time subject to the varieties should be well established and reproducible. However, the grant of protection *shall not be subject to any further conditions*, provided that the applicant complies with all the formalities and pays the required fees (Article 5). The requirements for these criteria are given below:

Self Assessment Question **(Spend 3 minutes)**

2) Does the UPOV Convention allow a variety to be refused protection because it is genetically modified?

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4.4.1 Variety Denomination

The UPOV Convention requires that the member-states shall designate the variety under their national laws by a denomination destined to be its generic designation. The denomination must enable the variety to be identified. Therefore special rules have to be fulfilled. Free use of the denomination even after the expiration of the protection must be ensured. A variety denomination must be suitable as a generic designation and must enable the variety to be identified; it must not be liable to mislead or to cause confusion concerning the characteristics, value or identity of the variety or the identity of the breeder. If the breeder fails to provide a suitable variety denomination, the application will be rejected.

Variety denomination requirements are dealt with in Article 20 (Box 1) of the UPOV Convention.

Box 1:

CHAPTER VI

Article 20

Variety Denomination

(1) [*Designation of varieties by denominations; use of the denomination*] *(a)* The variety shall be designated by a denomination which will be its generic designation.

(b) Each Contracting Party shall ensure that, subject to paragraph (4), no rights in the designation registered as the denomination of the variety shall hamper the free use of the denomination in connection with the variety, even after the expiration of the breeder's right.

[*Characteristics of the denomination*] The denomination must enable the variety to be identified. It may not consist solely of figures except where this is an established practice for designating varieties. It must not be liable to mislead or to cause confusion concerning the characteristics, value or identity of the variety or the identity of the breeder. In particular, it must be different from every denomination which designates, in the territory of any Contracting Party, an existing variety of the same plant species or of a closely related species.

[*Registration of the denomination*] The denomination of the variety shall be submitted by the breeder to the authority. If it is found that the denomination does not satisfy the requirements of paragraph (2), the authority shall refuse to register it and shall require the breeder to propose another denomination within a prescribed period. The denomination shall be registered by the authority at the same time as the breeder's right is granted.

[*Prior rights of third persons*] Prior rights of third persons shall not be affected. If, by reason of a prior right, the use of the denomination of a variety is forbidden to a person who, in accordance with the provisions of paragraph (7), is obliged to use it, the authority shall require the breeder to submit another denomination for the variety.

(5) [*Same denomination in all Contracting Parties*] A variety must be submitted to all Contracting Parties under the same denomination. The authority of each Contracting Party shall register the denomination so submitted, unless it considers the denomination unsuitable within its territory. In the latter case, it shall require the breeder to submit another.

(6) [*Information among the authorities of Contracting Parties*] The authority of a Contracting Party shall ensure that the authorities of all the other Contracting Parties are informed of matters concerning variety denominations, in particular the submission, registration and cancellation of denominations. Any authority may address its observations, if any, on the registration of a denomination to the authority which communicated that denomination.

(7) [*Obligation to use the denomination*] Any person who, within the territory of one of the Contracting Parties, offers for sale or markets propagating material of a variety protected within the said territory shall be obliged to use the denomination of that variety, even after the expiration of the breeder's right in that variety, except where, in accordance with the provisions of paragraph (4), prior rights prevent such use.

(8) [*Indications used in association with denominations*] When a variety is offered for sale or marketed, it shall be permitted to associate a trademark, trade name or other similar indication with a registered variety denomination. If such an indication is so associated, the denomination must nevertheless be easily recognisable.

4.4.2 Novelty

The variety is to be known as new if at the time of filing of application for the protection it is ensured that the propagating or harvested material of the variety has not been sold or otherwise disposed of to others, by or with the consent of the breeder, for purposes of use of the variety. Novelty is defined in Article 6 of the UPOV Convention (Box 2). The grace period provided under Article 6(1)(i) and (ii) for selling or disposing of the variety in the territory of the Contracting Party where the application is filed and in other territories without affecting the novelty have been established in recognition of the lengthy nature of the evaluation by the breeder of the variety in each territory in order to take a decision to seek protection. The longer period for trees and vines takes into consideration the slower growth and longer evaluation needed for these types of plants.

Box 2:
Article 6
Novelty

(1) [*Criteria*] The variety shall be deemed to be new if, at the date of filing of the application for a breeder's right, propagating or harvested material of the variety has not been sold or otherwise disposed of to others, by or with the consent of the breeder, for purposes of exploitation of the variety

(i) in the territory of the Contracting Party in which the application has been filed earlier than one year before that date and

(ii) in a territory other than that of the Contracting Party in which the application has been filed earlier than four years or, in the case of trees or of vines, earlier than six years before the said date.

(2) [*Varieties of recent creation*] Where a Contracting Party applies this Convention to a plant genus or species to which it did not previously apply this Convention or an earlier Act, it may consider a variety of recent creation existing at the date of such extension of protection to satisfy the condition of novelty defined in paragraph (1) even where the sale or disposal to others described in that paragraph took place earlier than the time limits defined in that paragraph.

(3) [*"Territory" in certain cases*] For the purposes of paragraph (1), all the Contracting Parties which are memberStates of one and the same intergovernmental organisation may act jointly, where the regulations of that organisation so require, to assimilate acts done on the territories of the States members of that organisation to acts done on their own territories and, should they do so, shall notify the Secretary-General accordingly.

4.4.3 The DUS Criteria

According to the UPOV 1991 Act, protection can only be granted in respect to a new plant variety after examination of the variety has shown that it is Distinct (D), Uniform (U) and Stable (S). According to this DUS criteria, to qualify for protection a variety is to be distinct from any other variety whose existence is a matter of common knowledge and that it is sufficiently uniform and stable. Article 12 clarifies that, "*In the course of the examination, the authority may grow the variety or carry out other necessary tests, cause the growing of the variety or the carrying out of other necessary tests, or take into account the results of growing tests or other trials which have already been carried out.*"

The UPOV has established specific Test Guidelines Procedures or "the TGP documents" to set out the principles which are used in the examination of DUS fora particular species, or other group(s) of varieties. This ensures an agreed and harmonized approach for the examination of new varieties and facilitates cooperation in DUS testing and also helps to provide effective protection through the development of harmonized, internationally recognized descriptions of protected varieties.

4.4.4 Distinctness

Article 7 of the UPOV Convention sets the requirement of distinctness (Box 3).

Box 3:

Article 7

Distinctness

The variety shall be deemed to be distinct if it is clearly distinguishable from any other variety whose existence is a matter of common knowledge at the time of the filing of the application. In particular, the filing of an application for the granting of a breeder's right or for the entering of another variety in an official register of varieties, in any country, shall be deemed to render that other variety a matter of common knowledge from the date of the application, provided that the application leads to the granting of a breeder's right or to the entering of the said other variety in the official register of varieties, as the case may be.

Accordingly, a variety must be clearly distinguishable from any other variety whose existence is a matter of common knowledge. A variety of common knowledge should satisfy the definition of a variety but it may not necessarily have to fulfil the DUS criteria. Specific aspects that may be considered to establish common knowledge include, among others:

a) commercialization of propagating or harvested material of the variety, or publishing a detailed description;

b) the filing of an application for the grant of a breeder's right or for the entering of a variety in an official register of varieties, in any country, which is deemed to render that variety a matter of common knowledge from the date of the application, provided that the application leads to the grant of a breeder's right or to the entering of the variety in the official register of varieties, as the case may be;

c) existence of living plant material in publicly accessible plant collections.

The common knowledge is not restricted to national or geographical borders.

The definition of a variety as per the UPOV Act (Article 1(vi)) makes it clear that it is a plant grouping that can be "*defined by the expression of the characteristics resulting from a given genotype or combination of genotypes*" and can be "*distinguished from any other plant grouping by the expression of at least one of the said characteristics*". Thus the Convention establishes that a variety is defined by its characteristics and that those characteristics are therefore are the basis on which a variety can be examined for DUS. The "General Introduction to the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions of New Varieties of Plants" (document TG/1/3) states the "Criteria for Distinctness Using Characteristics".

In the absence of any elaboration in the UPOV Convention on the term "clearly distinguishable, the document TG/1/3 provides the basis for the use of characteristics to clearly distinguish varieties. A variety may be considered to be clearly distinguishable if the difference in characteristics is consistent and clear.

Ensuring that a difference in characteristics, observed in a growing trial, is sufficiently consistent requires examining the characteristic on at least two independent occasions. This can be achieved in both annual and perennial

varieties by observations made on plantings in two different seasons or, in the case of other perennial varieties, by observations made in two different seasons after a single planting. Guidance on the possible use of other approaches, such as two different environments in the same year, is explored in document TGP/9, "Examining Distinctness". However, if the growing conditions of the crop are controlled, such as in a greenhouse with regulated temperature and light, it may not be necessary to observe two growing cycles. The individual Test Guidelines specify whether several independent growing cycles are required to show sufficient consistency, or whether, for certain species, the growing test could be made in one growing cycle.

Determining clear differences between two varieties depends on many factors, and should consider, in particular, the type of expression of the characteristic being examined, i.e., whether it is expressed in a qualitative, quantitative, or pseudo-qualitative manner.

The qualitative characteristics are not influenced by environment and comprise characters expressed in discontinuous states. For example the sex of plant can be described in four different states namely 1) dioecious female; 2) dioecious male; 3) monoecious unisexual and 4) monoecious hermaphrodite. These states are self-explanatory and independently meaningful. All states are necessary to describe the full range of the characteristic, and every form of expression can be described by a single state. The order of states is not important.

The quantitative characteristics are those where the expression covers the full range of variation from one extreme to the other. The expression can be recorded on a one-dimensional, continuous or discrete, linear scale.The range of expression is divided into a number of states for the purpose of description. For example length of stem can be recorded as very short 1) short 3) medium 5) long 7) very long 9) The division seeks to provide, as far as is practical, an even distribution across the scale. The Test Guidelines do not specify the difference needed for distinctness. The states of expression should, however, be meaningful for DUS assessment.

In the case of "pseudo-qualitative characteristics", the range of expression is at least partly continuous, but varies in more than one dimension (e.g. shape: ovate 1) elliptic 2) circular 3) obovate 4)) and cannot be adequately described by just defining two ends of a linear range. In a similar way to qualitative (discontinuous) characteristics, each individual state of expression needs to be identified to adequately describe the range of the characteristic.

4.4.5 Uniformity

Article 8 of the UPOV Convention defines that a "*variety shall be deemed to be uniform if, subject to the variation that may be expected from the particular features of its propagation, it is sufficiently uniform in its relevant characteristics*".The notion of uniformity ensures that the variety can be defined as far as is it necessary for the purpose of protection. This is indicated by the notion of sufficiently uniform, i.e., the criterion for uniformity does not seek absolute uniformity.

The UPOV Convention links the uniformity requirement for a variety to the particular features of its propagation. This means that the level of uniformity required for truly self-pollinated varieties, mainly self-pollinated varieties,

inbred lines of hybrid varieties, vegetatively propagated varieties, cross-pollinated varieties, mainly cross-pollinated varieties, synthetic varieties and hybrid varieties will, in general, be different. Furthermore, it relates only to the characteristics which are relevant for the protection of the variety.

Self Assessment Question **(Spend 3 minutes)**

3) Should all protected varieties have the same level of uniformity?

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4.4.6 Stability

Article 9 of the UPOV Convention defines that a "*variety shall be deemed to be stable if its relevant characteristics remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle*". As with the uniformity requirement, the criterion for stability has been developed to establish the identity of the variety as the subject matter of protection. Thus, the criterion for stability relates only to the relevant characteristics of a variety.

4.5 THE DUS TESTS

The examination, or "DUS Test," is based mainly on growing tests that involve the growing of a variety in a way which ensures the expression of the relevant characteristics of the variety. The basic principles which are used in the examination of DUS that have been developed by UPOV include TG/1/3: "General Introduction to the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions of New Varieties of Plants (referred to as "the General Introduction") and the associated series of documents specifying Test Guidelines' Procedures (referred to as "the TGP documents").

The identification of those principles facilitates best practices on the basis of proven experience and enables harmonised examination of new plant varieties by the members of the Union. The General Introduction and the associated TGP documents are kept under review by the Technical Committee. In addition, UPOV has developed "Guidelines for the Conduct of Tests for Distinctness, Uniformity and Stability," or "Test Guidelines", for many individual species or other variety groupings. The purpose of these Test Guidelines is to elaborate certain of the principles contained in the General Introduction, and the associated TGP documents, into detailed practical guidance for the harmonized examination of DUS and, in particular, to identify appropriate characteristics for the examination of DUS and production of harmonized variety descriptions. The individual Test Guidelines are prepared by the appropriate Technical Working Party, comprising government appointed experts from each member of the Union with invited experts from other interested States and observer organisations; and approved by the Technical Committee. The Test Guidelines adopted by the

UPOV are available in electronic format in the four UPOV languages at the UPOV website: http://www.upov.int/en/publications/tg-rom/tg_index_latin.htm.

Although the Test Guidelines provide detailed practical guidance on certain aspects of the DUS test and, in particular, identify appropriate characteristics, there are certain general aspects that apply across all Test Guidelines which it would not be appropriate to reproduce in all the individual Test Guidelines. Therefore, the use of the UPOV Test Guidelines should be made in conjunction with the General Introduction (document TG/1/3). The General Introductio, also provides guidance in the case Test Guidelines for the species or variety grouping concerned are absent.

4.5.1 Characteristics in DUS Testing

The basic requirements that a characteristic should fulfil before it is used for DUS testing or producing a variety description are that its expression:

a) results from a given genotype or combination of genotypes: The characteristic should be an expression of the variety genotype and not influenced by environment, for example, short stature due to drought conditions is not the right character to choose.

b) is sufficiently consistent and repeatable in a particular environment: The characteristic should show the same differences when varieties are grown in the same location the following year. While it is possible that some characteristics may only be expressed in a particular environment, such characters can also be used if the differences in that particular environmen, or condition, are consistent.

c) exhibits sufficient variation between varieties to be able to establish distinctness: Since the characteristic is to be used to clearly distinguish varieties, there should be some variation for the same between the varieties. For example, if all the varieties have white flowers it will not be possible to differentiate any variety by the colour of the flower. However, if the flower colour of varieties can be white, red or yellow, flower colour would be a good characteristic for DUS test.

d) is capable of precise definition and recognition: the characteristic should be clearly defined to be assessed, as far as possible, in an objective way.

e) allows uniformity requirements to be fulfilled.

f) allows stability requirements to be fulfilled, meaning that it produces consistent and repeatable results after repeated propagation or, where appropriate, at the end of each cycle of propagation.

It should be noted that there is no requirement for a characteristic to have any intrinsic commercial value or merit. However, if a characteristic that is of commercial value or merit satisfies all the criteria for inclusion it may be considered in the normal way.

4.5.2 Technical Cooperation under UPOV

a) Cooperation between Testing Authorities

Cooperation with other members of the Union can reduce the overall time,

expense and the number of examiners involved in the DUS tests, and minimize the work involved in the maintenance of variety collections. The 'centralized' testing system is the ultimate form of international cooperation. At regional or global basis, the entire examination is carried out by one authority on behalf of other members of the Union. Some countries do no DUS examinations, and benefit from the exchange of examination results among UPOV members. The Office of UPOV hopes this will get easier once there is a full harmonisation of examination procedures amongst members. It is by no means a simple matter for a country to set up a PVP system from scratch including running the field trials.

The technical cooperation and services to members available from UPOV, including from the various Technical Committees, and through the Office's practice of putting countries directly in touch with each other, to learn from each other, plays a useful role. Nevertheless, concerns have been expressed that this harmonisation contributes to a creeping PVP rule uniformity that may not suit many developing countries.

b) Cooperation with Breeders

In most countries, variety testing is done by an official authority, although the breeders participate in the growing tests to varying degrees. The cooperation with breeder is always supported by UPOV even under the strict system of government-conducted testing. Some members of the Union have a system whereby breeders are asked to perform the whole test. They are required to conduct the DUS test and produce a test report. The decision on DUS may be based entirely on the test report supplied by the breeder although the member of the Union may verify the results.

The UPOV Office also provides assistance and advice to countries wishing to join UPOV, on occasion through WIPO technical assistance processes. Rather than assessing the countries' specific needs and advising on how UPOV could best be applied to the applicants' circumstances, the advice tends to consist of providing applicant countries with the model UPOV legislation.25 This is almost identical to the text of the UPOV Convention itself. Interestingly, recent draft legislation proposed through WIPO technical assistance contains a chapter on implementation, including provisions on enforcement and supervision that are not in the UPOV Convention itself.

Self Assessment Question **(Spend 3 minutes)**

4) What information/documents are available to the UPOV member states for providing guidance in conducting the DUS examination?

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4.6 APPLICATION FOR PLANT BREEDERS' RIGHT

The UPOV Convention provides an international legal framework for the

protection of new varieties of plants. National treatment defined in Article 4 of the UPOV Convention puts nationals and residents of a UPOV member at the same level. This is an important benefit of UPOV membership and gives the advantage to the breeders to file applications in the territory of any UPOV member and to be treated in the same way as nationals of the territory where the application is being filed.

4.6.1 Filing of Applications

Provisions for the filing of applications for plant breeders' rights are contained in Article 10 of the 1991 UPOV Act. The UPOV Convention makes no restrictions on the place of the first application. The breeder may choose the Contracting Party where he wishes to file his first application for a breeder's right. The UPOV Convention allows breeders to file subsequent applications for the granting of a breeder's right without having to wait to be granted a breeder's right by the UPOV member where the first application was filed. The UPOV Convention provides for "independence" of the protection, making the granting or rejection of a breeder's right by a UPOV member independent of the granting or rejection of the breeder's right on the same variety by another UPOV member.

4.6.2 Right of Priority

Article 11 of the UPOV Convention provides for a right of priority of one year, based upon an earlier application for the same variety with another UPOV member; hence a subsequent application is treated as if it was filed on the date of the earlier application. Thus, the examination of subsequent applications will relate to the filing date of the first application. Other benefits of the right of priority are that, in relation to subsequent applications, the breeder has at least three months to send the relevant documents and can defer the examination for up to two years after the expiration of the priority period. It is important to note that, in order to benefit from the right of priority based upon the first application, the breeder must claim it in the subsequent applications. Should the breeder fail to do so, the subsequent application will be considered as filed on the application date of that subsequent application.

4.6.3 Form of Application and Fee

The form of application for PBRs will be prescribed by the national legislation. It will provide that an application must contain:

- the name and address of the applicant
- the name and address of the agent, if any, making the application on the applicant's behalf
- a statement to that effect if the applicant is the breeder of the variety
- if the applicant is not the breeder of the variety, details of the applicant's right to make the application
- a brief description, with a photograph, if appropriate, of a plant of the variety sufficient to establish a *prima facie* case that the variety is distinct from other varieties of common knowledge
- the name, and any proposed synonym, for the variety
- particulars of the location at which and the manner in which the variety was

bred, including particulars of the names by which the variety is known and sold in the country and particulars of any PBRs granted in the country or in another country that is a signatory to the UPOV Convention

- particulars of any application for, or grants of, rights of any kind in the variety in any other country
- the name of an approved person who will verify the particulars of the application and who will supervise any test growing of the variety required under Section 37 of the Act and who will verify a detailed description of the variety; and
- such other particulars, if any, as are required by the approved form.

4.6.4 Acceptance or Rejection

The authority or official that is responsible for the administration of the relevant law will be required to decide, as soon as is practicable after an application is filed, whether to accept or reject the application. Where the authority or official is satisfied that the application is prior in time to any other application and that it complies with the requirements of the legislation and establishes a *prima facie* case for treating the plant variety as distinct from other varieties, the application must be accepted. Upon acceptance, the applicant must be notified that the application has been accepted and public notice of the acceptance must also be given. Similar notification obligations apply when an application is rejected.

4.6.5 Detailed Description of the Plant Variety

Whenever it is practical, but not later than 12 months after an application has been accepted, or within such further period granted by the authority or official, the applicant is usually required to give a detailed description of the plant variety to which the application relates. Failure to supply this description will result in the application being deemed to have been withdrawn. The detailed description must be in writing and in an approved form, containing particulars of:

1) the characteristics that distinguish the plant variety from other varieties, the existence of which is deemed a matter of common knowledge
2) any test growing carried out
3) any test growing outside the country that tends to establish that the variety will, if grown in the country, be distinct, uniform and stable; and
4) other such particulars that may be prescribed.

4.6.6 Objection to an Application for PBRs

The administering authority is usually obliged to give public notice of the detailed description as soon as is practicable after it has been received. A person may object to an application for PBRs if they can establish that their commercial interests would be affected by the grant of PBRs to the applicant and that the authority cannot be satisfied that the various substantive requirements of the law have been met by an applicant The objection must set out the particulars of the manner in which the person believes his or her commercial interests would be affected and the reasons why the person considers that the authority cannot be satisfied that the various substantive requirements of the law have been met.

4.6.7 Inspection of Application and Objections

A person may, at any reasonable time, inspect an application for PBRs over a plant variety, or an objection lodged in respect to that application. Upon payment of a prescribed fee, a copy of an application or an objection to an application is to be provided.

4.6.8 Provisional Protection

Where an application for PBRs is accepted, the applicant is taken to be the grantee of that right from the date the application is received until the application is disposed of. During this period of provisional protection, the applicant is prevented from commencing any infringement action with respect to the PBRs, until such time as the application is finally resolved in the applicant's favour.

4.6.9 Declarations of Essential Derivation

Where a person is the grantee of PBRs over a particular plant variety (the initial variety) and another person is the grantee of, or has applied for, PBRs in another variety (the second variety), the grantee of PBRs in the initial variety may seek a declaration that the second variety is an essentially derived variety of the initial variety. A plant variety is defined to be an essentially derived variety of another plant variety if:

1) it is predominantly derived from the other plant variety
2) it retains the essential characteristics that result from the genotype or combination of genotypes of that other variety; and
3) it does not exhibit any important (as distinct from cosmetic) features that differentiate it from that other variety.

The application for essential derivation must be in an approved form and contain such information relevant to establishing a *prima facie* case of essential derivation. If the authority is satisfied, or not satisfied, as the case may be, that a *prima facie* case has or has not been established, the applicant and the grantee of PBRs in the second variety must be informed and provided an opportunity to rebut the *prima facie* case. The authority may order a test growing in order to rebut a *prima facie* case of essential derivation.

4.6.10 Grant of PBRs

When an application for PBRs in a plant variety is accepted, the authority must grant the right to the applicant after it is satisfied that:

1) There is such a variety
2) The variety is registrable under the law
3) The applicant is entitled to make the application
4) The grant of that right is not prohibited by the law
5) The right has not been granted to another person
6) The name of the variety complies with Section 27
7) Propagating material of the variety has been deposited for storage, at the

expense of the applicant, in a genetic resource centre approved by the authority

8) A satisfactory specimen plant must be supplied to a prescribed herbarium; and

9) All fees have been paid.

PBRs are granted by the issue of a certificate in approved form.

4.6.11 Revocation

There may be provision for the revocation of PBRs, or a declaration that a plant variety is essentially derived from another plant variety, if the authority becomes satisfied that the facts had existed that, if known before the grant of the right or the making of the declaration, would have resulted in the refusal to grant the right or make the declaration. Revocation may also result from a failure to pay prescribed fees. Within a prescribed number of days of the decision to revoke, the grantee or transferee of PBRs may be provided with particulars of the grounds of proposed revocation.

Applications for revocation may be made by a person whose interests are affected by the grant of PBRs over a plant variety or by a declaration of essential derivation. In the event of revocation or surrender of PBRs, particulars of revocation or surrender will usually be entered in the PBRs Register and published.

4.7 COMPULSORY LICENSING

National laws usually require the grantee of PBRs in a plant variety to take all reasonable steps to ensure reasonable public access to that plant variety. This requirement is considered to be satisfied if propagating material of reasonable quality is available to the public at reasonable prices, or as gifts to the public, in sufficient quantities to meet the demand. Article 17 provides for Restrictions on the Exercise of the Breeder's Right for reasons of public interest. However, permission to license a third party to sell propagating material, or to produce propagating material of plants of that variety for sale, during such period as the authority considers appropriate shall be done on such terms and conditions that ensure the breeder equitable remuneration.

4.8 ENFORCEMENT REMEDIES

Generally speaking, PBRs in a plant variety are infringed by an unauthorized person by:

1) performing acts that are included in the PBRs

2) claiming the right to perform one of those acts; and

3) using the name of a registered variety in relation to another plant or another plant variety.

The UPOV 1991 Act in Article 30 requires that the members states shall adopt all measures necessary for the implementation of the Convention and in

particular, provide for appropriate legal remedies for the effective enforcement of breeders' rights;

The enforcement measures considered, could be provided through civil, custom, and criminal remedies. The Civil remedies may include measures to prevent or stop an infringement of the breeder's right, and/or to preserve evidence, take measures to allow a civil action to prohibit the committing, or continuation of the committing, of an infringement of the breeder's right and measures to provide adequate damages to compensate the loss suffered by the holder of the breeder's right and to constitute a deterrent to further infringements. The customs measures could include suspension by the customs authorities of the release into free circulation, forfeiture, seizure or destruction of material which has been produced in contravention of the breeder's right; and measures to allow the suspension by the customs authorities of the release of the infringing material destined for exportation. The criminal measures could include criminal actions and penalties in cases of violation of the breeder's right on a commercial scale.

4.9 ADMINISTRATION

Most laws provide for the establishment of the Office of the Registrar of Plant Breeders' Rights, which is responsible for the general administration of the Act and for the maintenance of the Register of Plant Varieties. The office of the Registrar will usually issue an official Plant Varieties Journal in which all public notices are to be published.

4.10 FEATURES INTRODUCED BY THE 1991 ACT

As compared to the previous versions of the Convention,UPOV 1991 extends the scope of the breeders' rights in certain ways. One is that it limits 'farmers' privilege': UPOV1978 refers to the right of farmers to use seed harvested from protected varieties for private and non-commercial purposes (this is what is usually referred to as 'farmers'privilege'). Most parties to UPOV 1978 uphold this. UPOV 1991 does so too by specifying that the breeder's right in relation to a variety may be restricted 'in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting ... the protected variety'. However, under the 1991 Act, the State party must take measures to safeguard 'the legitimate interests of the breeder', which in the European Union is interpreted as 'to ensure that the breeder receives equitable remuneration'. At present the strength of the 'farmers' privilege' varies quite widely from country to country. Some countries, like France, has no 'farmers' privilege' at all (with the exception, in France, of tender wheat), while the USA until 1990s allowed farmers even to sell protected seed to other farmers.

UPOV 1991 also introduced other changes to PVP. Notable amongst these is the fact that the duration of PVP is lengthened (to 20 years, and 25 years for trees and vines) and that that all plant species must be covered.Another significant change is that patents on plant production processes, plants, seeds or genes relating to a PVP-protected variety are allowed – in other words 'double protection' of the same variety by PVP and patent is permitted.

New adherents to UPOV cannot choose but must join UPOV 1991, whereas

UPOV 1978 continues to apply to members that joined prior to 1999 and have not 'upgraded'to the 1991 Act.

4.11 MEMBERSHIP OF UPOV

UPOV's initial gradual expansion may have served a useful purpose for the older (read: European) members of the Union. A more rapid expansion in its first two decades might have led to the entry of 'outsiders' who may then have worked to change the culture in certain ways,such as by pushing UPOV to accept a broader range of national PVP regimes. It is plausible that UPOV's long consolidation period made it easier to absorb the recent membership expansion without threatening the leadership or culture of the established custodians. Indeed despite UPOV's membership having more than doubled in the last 15 years, with the concerns and characteristics of the new members being very different from those of the older members.

Prospective UPOV members are required to request an analysis of their law or draft law from the UPOV Council before they can join. If the law is deemed compliant with the UPOV and has entered into force (but not necessarily been technically implemented), the Government or Intergovernmental organisation can proceed to ratify the Convention, thereby becoming an UPOV member. If modifications are deemed by the Council or Office as necessary for compliance, these must be effected before ratification is allowed.

Obviously, this enables existing members of UPOV (as well as the UPOV Office and other observers) to request fairly strict conformity of new members, and may quite possibly give them a degree of leverage over the legislatures of applicant countries. The UPOV Office plays an essential role in 'guiding' the aspiring member through the membership procedure including the assessment of 'conformity' of its law with the UPOV Convention and prepares the recommendation on this matter to the Council.

A range of factors encourage countries to seek membership of UPOV. These include the possibility of accessing improved seeds and diversifying the seeds available within the country. Another reason that many developing countries often give is that UPOV membership can contribute to attracting foreign investment in the agricultural sector.

4.12 UPOV AND WIPO

UPOV is legally separate from the World Intellectual Property Organization (WIPO), and is not part of the United Nations. Despite UPOV's formal separation from WIPO,the two have a close relationship. The UPOV Office is located in the WIPO building in Geneva, where UPOV meetings are also held. WIPO's Director-General is the Secretary-General of UPOV with the power to approve the appointment of the UPOV's Vice Secretary-General. The latter oversees the day to day operations of the UPOV.

WIPO regularly provides opportunities to make UPOV better known. The present relationship between WIPO and UPOV is defined by the 1982 WIPO/UPOV Agreement. Much of the Agreement concerns the various administrative and practical tasks that WIPO must undertake for UPOV. UPOV is required to pay

WIPO '*for any service rendered to, and any expenditure incurred on behalf of, UPOV.*'The Agreement affirms the 'complete independence'of WIPO's International Bureau and the UPOV Office in respect of the exercise of their functions.

4.13 SUMMARY

- International Convention for the Protection of New Varieties of Plants, or *Union pour la Protection des Obtentions Végétales* (UPOV), is an intergovernmental organisation with headquarters in Geneva. The Convention was adopted in December 1961 and entered into force in 1968; and further revised in 1972, 1978 and 1991. The 1991 revision entered into force in 1998. Initially adopted mainly by European countries, many countries post TRIPS, are more often opting for UPOV membership or adopting UPOV 1991 compatible legislation. The purpose of the UPOV is to ensure that the member States acknowledge the achievements of breeders of new plant varieties provide Plant Breeders' Rights (PBRs) based on a set of uniform and clearly defined principles.
- The UPOV Convention offers member States the possibility of taking national circumstances into account in their domestic legislation. The minimum scope of PBRs requires prior authorization of the right holder for the production for purposes of commercial marketing, the offering for sale and the marketing of propagating material of the protected variety.
- In addition to the protected variety itself, the scope of breeder's right also applies to: (i) varieties which are not clearly distinguishable from the protected variety (ii) varieties whose production requires the repeated use of the protected variety and (iii) essentially derived varieties. However, authorisation is not required for acts done for private and for non-commercial including research purposes for breeding other varieties. Optional provision is provided to permit farmers the use of propagating purposes, on their own holdings. The minimum period of protection provided by UPOV 1991, is 25 years in the case of trees and vines and 20 years for any other plant type.
- The eligibility criteria for protection, requires varieties to be new i.e., they must not have been commercialized prior to certain dates established by reference to the date of the application for protection. Further "DUS Test," based mainly on growing out tests is conducted to establish that the variety is (i) distinct from existing, commonly known varieties, (ii) sufficiently homogeneous, (iii) and stable.
- A detailed set of general principles for conducting the DUS test and specific guidelines have been developed by UPOV. The cooperation between member States allows for conducting tests which are accepted others member States, thus minimizing the cost of operating their protection systems and facilitating breeders to obtain protection in several countries at relatively low cost.
- The UPOV member States and the UPOV Secretariat maintain contacts with and provide legal, administrative and technical assistance to the governments.

4.14 TERMINAL QUESTIONS

1) What is the scope PBRs and period of protection under the UPOV?

2) What are the provisions for providing exceptions to PBRs which member states can include in their national legislations that provide plant variety protection?

3) What are the requirements for protection of new plant varieties under UPOV?

4.15 ANSWERS AND HINTS

Self Assessment Questions

1) b) The use of a protected variety for the purposes of breeding other varieties is not covered by the plant breeder's right (see Article 15(1)(iii)).

2) No. Under the UPOV Convention, no further requirements can be requested for protection than those stated in Article 5. Furthermore, Article 18 states that "[the] breeder's right shall be independent of any measure taken by a Contracting Party to regulate within its territory the production, certification and marketing of material of varieties or the importing or exporting of such materials [....]." In that respect, it is also important to note that the grant of protection does not grant the right to commercialize a plant variety.

3) The criterion for uniformity is subject to the variation that may be expected from the particular features of the propagation of the variety. Therefore, the level of uniformity required for varieties such as inbreds, synthetic varieties and hybrid varieties will, in general, be different.

4) The information/documents available on the UPOV website include:

- The General Introduction to the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions of New Varieties of Plants (document TG/1/3) and its associated documents (TGP documents) which are available on the UPOV website.
- The "Guidelines for the Conduct of Tests for Distinctness, Uniformity and Stability" or "Test Guidelines" which are available on the UPOV website.

Terminal Questions

1) Refer to Sub-section 4.3.1, 4.3.2, 4.3.3 and 4.3.4

2) Refer to Sub-section 4.3.6

3) Refer to Section 4.4

4.16 REFERENCES AND SUGGESTED READINGS

1) Graham Dutfield (2011) Food, Biological Diversity and Intellectual Property: The Role of the International Union for the Protection of New Varieties of Plants (UPOV) Quaker United Nations Office, Global Economic Issue Publications Intellectual Property Issue Paper Number 9 February 2011.

2) www.quno.org/economicissues/food-sustainability/foodLinks.htm#QUNOPUB

3) http://www.upov.int/edocs/infdocs/en/upov_inf_12_1.pdf

4) UPOV General Introduction to the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions of New Varieties of Plants TG/1/3April 19, 2002

5) http://www.upov.int/en/publications/tg-rom/tg001/tg_1_3.pdf

6) http://www.upov.int/en/publications/pdf/upov_exn_enf_1.pdf

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