CHAPTER I
INTRODUCTION

1. PRELUDE

1.1 Statement of the Problem:

The gradual but the vast increase in the reach and forms of transgovernmental regulations and administration designed to address the consequences of globalized interdependence in such fields as security, the conditions on development and financial assistance to developing countries, protection of human rights, environmental protection, banking and financial regulations, law enforcement, telecommunications, trade in products and services, intellectual property, labor standards, and cross-border movements of populations, including refugees, etc. have resulted in the emergence of regulatory regime at the global level for its administration. Thus, the emerging Global Regulatory Regime (GRR) is a necessary consequence of globalization, which warrants governance at the global level even in the absence of global government. Therefore, much of global governance can be understood as regulatory administration.1

As a result of globalization, various transnational systems of regulation or regulatory cooperation have been established through international treaties and more informal governmental networks of cooperation.

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1. During the 20th Century, the existing legal theories and practices within the International Law were under constant pressures to adjust to fast economic and political map, accompanied with or arising from the changing world economic landscape, regulated in corresponding modification of international relations regulations. There was a basic shift regarding the sources of law and methods of norm codification at the international level. International agreements were replaced with international treaties. Soon this became a new trend where international organizations and other informal governmental organizations took over an active role in method of enacting and implementing legal norms. See, H. Hillgenberrg, “A Fresh look at soft law”, 10(3) Eur. J. Int. Law 499(1999). See also, P.S.Muller, “Reflecting on Global Governance”, in Lederer, Muller(eds.) Challenging global governance: a critical Perspective, ELRC/CPOGG workshop at Harvard Law School. See also, K.N.Waltz, theory of International politics, (1079).
shifting many regulatory decisions from the national level to the global level. Further, much of the detail and implementation of such regulation is determined by transnational administrative bodies—including international organizations and informal groups of officials— that perform administrative functions but are not directly subject to control by national governments or domestic legal system or, in the case of treaty based regimes, the states party to the treaty. However these regulatory decisions may be implemented directly against private parties by the global regime or, more commonly, through implementing measures at the national level.

In international administration, formal inter-governmental organizations established by treaty or executive agreement are the main administrative actors. A central example is the U.N. Security Council and its committees, which adopt subsidiary legislation, take binding decisions related to particular countries (mostly in the form of sanctions), and even act directly on individuals through targeted sanctions and the associated listing of persons deemed to be responsible for threats to international peace. Similarly, the United Nations High Commissioner for Refugees has assumed numerous regulatory and other administrative tasks, such as conducting refugee status determinations and administering refugee camps in many countries. Other examples include the World Trade organization assessing global trade cooperation and implementation of the Agreements annexed to the WTO, violation by specific states of the standards it has adopted, the compliance mechanisms of the DSU and non-compliance by Parties to the Agreement.

In distributed administration, domestic regulatory agencies act as part of the global administrative space: they take decisions on issues of foreign or global concern. An example is in the exercise of extraterritorial
regulatory jurisdiction, in which one state seeks to regulate activity primarily occurring elsewhere. Generally, regulatory programs agreed to at the international level by states are effectuated through measures taken by governments at the domestic level to regulate private conduct. At times, some of the international bodies make decisions that have direct legal consequences for individuals or firms without any intervening role for national government action.

The above instances clearly illustrate that the regulatory regime evolved at the global level is very vast in its reach and form and is still expanding. One of the aims of global regulatory regime is to achieve desired changes in private conduct by imposing regulatory obligations on states and supervising the manner in which states regulate the private actors subject to their jurisdictions. This clearly indicates that the important regulatory functions are no longer exclusively domestic in character and have become significantly transnational, or global.

The rise of regulatory programs at the global level and their infusion into domestic counterparts means that the decisions of domestic administrators are increasingly constrained by substantive and procedural norms established at the global level; the formal need for domestic implementation thus no longer provides for meaningful independence of the domestic regime from the international realm. Thus, it has, among other things, turned so-called sovereign nation states into administrative agencies. States are seen as administrative units occupying ‘an intermediate position’ in the governance of the country. This global regulatory regime has affected the law and policy in India also. India has to made certain changes and amendments in its law & policy to fulfill its obligation under the current global regulatory regime.
WTO is one of the global regulatory regimes dealing with both
economics and law. Under this WTO regime the member country have to
give effect to the provision of WTO Agreement under their domestic
jurisdiction. To ensure the compliance with the WTO obligation
particularly in IPRS and agriculture, India has made major changes in its
law and policy. In IPRs and agriculture regime India has enacted Plant
variety protection and farmer’s Rights Act, Biological Diversity Act etc.
to fulfill its obligation under the WTO agreement. Therefore it becomes
necessary to undertake this topic to access the impact of this global
regulatory regime on law and policy in India in relation to IPRs and
agriculture.

1.1.1 TRIPS Agreement under WTO

The agreement on Trade Related aspects of Intellectual Property
Rights (TRIPs) was introduced into the Uruguay Round in 1986. It was
the result of intense negotiations and a compromise between different sets
of interests. TRIPs provide minimum national standards for levels of
protection to the creators of Intellectual property in various fields. Most
countries in the world are members of the World Trade Organization
(WTO) and are thus obliged to implement the WTO Agreement on
Trade Related Aspects of Intellectual Property Rights (TRIPS). TRIPS
Agreement under Article 27.3(b) imposes an obligation on all member
countries of the World Trade Organization (WTO) to protect plant
varieties either by patents or by a sui generis regime or by a combination
of both. The issue of plant variety protection is significant and can be

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2. One of the dominant players in setting up the TRIPS was the American biotechnological industry.
3. There are total 153 member’s countries in WTO. [http://www.wto.org/english/thewto_e/
whatis_e/tif_e/org6_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm) (visited on January 30, 2010).
4. An important objective of article 27.3(b) of the TRIPS Agreement is to provide an incentive to
   commercial plant breeders to develop new plant varieties.
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 (PGR) 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 interests and concerns.

India explored the sui generis option given in the TRIPS Agreement to fulfill its WTO obligation. India developed a regime for the protection of plant varieties known as the Protection of Plant Varieties and Farmer’s Rights Act (PPVFR). This is a unique legislation because it involves all the commercial actors involved in PGR management, i.e. breeders and farmers, in a comprehensive manner. Presently, India is also contemplating a new seed law (which is presently a bill and is yet to be passed by the Indian parliament), which, if enacted, will replace the existing Seeds Act 1996. The move towards enacting the new seeds law is important when seen in light of the PPVFR Act and India’s proposed membership of International Union for the Protection of Plant Varieties (UPOV)\(^5\). This objective can be appreciated in the context of attempts that have been made and are being made, nationally, regionally and globally, to expand intellectual property protection to agriculture.

Developments related to protection of plant variety are not new and date back to the 1920s and 1930s when many countries introduced legislation that evolved into a *sui generis* system of protection of plant varieties. This *sui generis* system of protection provided an intellectual property right in the form of plant breeders right (PBR) distinct from the patent regime\(^6\), which developed in some countries such as the United States. The US developed a Plant Patent Act 1930, which further spurred the expansion of intellectual property in Agriculture. The pressures of expanding intellectual property protection to agriculture globally increased and, eventually, this journey *via* the formation of UPOV reached an important destination, where providing plant variety protection was made mandatory for all WTO members through Article 27.3(b)\(^7\) of the TRIPS Agreement. This development had an important bearing on developing countries because these countries are now under a treaty obligation to provide plant variety protection under their domestic laws. Thus, the objective of Article 27.3(b) seems to be to boost the protection of plant varieties not necessarily through patents.

UPOV is an international organization that provides a model for *sui generis* plant variety protection, using whichever countries can provide protection for newly developed plant varieties without granting patents on newly developed varieties. The UPOV convention was initially negotiated and developed among the western European countries and the countries belonging to the Organization for Economic Cooperation and Development (OECD). As it is evident from the mission statement of UPOV, the central objective of UPOV is to provide and promote an

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\(^7\) Article 27.3(b) gives option to countries on how to provide plant variety protection and does not make it mandatory for countries to protect plant varieties protection through patents only.
effective system of plant variety protection with the aim of encouraging the development of new varieties of plants. Providing and promoting the protection of plant varieties may affect the rights and interests of other stakeholder such as farmers and their rights. The UPOV model also assumes importance in light of the obligation imposed by Article 27.3(b) of the TRIPS Agreement.

1.1.2 Article 27.3-(b) of TRIPS

Article 27.3 (b)\(^8\) of TRIPS is perhaps the most controversial clause of the entire WTO agreement. It requires members to provide for the patenting of micro-organisms and genetically engineered organisms (“non biological and microbiological processes”). It allows them to exclude from patentability, plants and animals and essentially biological processes for the production of plants and animals.

However, member shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof\(^9\). The limits to a *sui generis* system and the meaning of an ‘effective’ *sui generis* system are not explicitly defined in the text. In other words, countries have to introduce some sort of plant breeders’ rights. Article 27.3(b) represents a major new development in IPR law, since it blurs the distinction between “invention”, which are patentable under traditional patent law, and “discoveries”, which are not. The

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\(^8\) Article 27.3. Members may also exclude from patentability….(b) plants and animals other than microorganism, and essentially biological processes for the production of plants or animals other than non-biological and microbiological process. However, member shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provision of this paragraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

\(^9\) These provisions were to be reviewed after four years but no systematic review has been put into place at the WTO. TRIPS Article 27.3(b), which requires all WTO countries to provide some kind of intellectual property rights (IPR) on plant varieties, was up for review in 1999. Seattle intervened and the review did not materialize.
majority of the developing countries, during the TRIPS negotiations, objected to the notion of the patentability of biological resources.

1.1.3 Some Issues with Article 27.3(b)

There are two key issues involved with respect to the patenting of life forms and the protection of plant varieties. The first relates to the process of “bio-piracy”, that is the theft of traditional knowledge from the developing countries. The second aspect is the advent of biotechnology. The ability to identify, isolate, and move genetic materials across species types has aroused great commercial interest and investment in biotechnology. Genetically engineered crops and foods are being produced with the global market as their target, thus the need to obtain IPR protection for such “new” products.

The second important aspect of Article 27.3(b) is the protection of plant varieties. Countries must protect plant varieties through the patent system, or through the establishment of an effective **sui generis** (i.e., unique or of its own kind) system or by any combination of the two. Thus *Once again there is some conflicting distinction that can be drawn between patents and plant varieties from the scientific or legal perspectives. However, there is a history of plant variety protection, in order to protect the interests of commercial plant breeders, which sought protection for their crop varieties but found it difficult to meet the requirements of the patent system.*

1.1.4 Problems embedded in Art. 27.3(b)

There are some extraordinary problems with Article 27.3(b) of the TRIPS Agreement which are:

1- No parameter for what a ‘**sui generis**’ system can amount to.

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10. Examples of bio-piracy abound - the case of the US Patent on the use of turmeric for healing wounds is a well-known one.
2- No parameter for what is “effective.”
3- Many WTO members have expressed their view that genes and microbiological processes are not invention and therefore are not patentable subject matter.
4- With its lack of any benefit-sharing mechanism, TRIPS offers no remedy for the ongoing wave of bio-piracy and is perceived as exacerbating the problem.
5- There is a bias ingrained in TRIPS to protect breeders and biotechnologist at the expense of farmers and local communities.
6- Many Countries perceive a conflict between TRIPS and the rights and obligations that they previously acquired under the Convention on Biological Diversity (CBD).

In addition, there is evidence that plant variety laws inspired by the Union for the protection of new varieties of Plants (UPOV) have no positive impact on food security, a matter that the TRIPS Council has not looked into12. The issue of food security is directly linked to the PBR regime because a very strong PBR regime may reduce the farming community’s accessibility to seeds. This may push farmers to market each time they want to buy seeds and impede the age-old practice in developing countries where farmers freely exchange and sell seeds and breed new varieties.

Therefore an attempt is made to critically analyze the impact of global regulatory regime on laws and policy in India in IPRs and Agriculture. The regulatory regime available for the protection of plants

12. “Plant Varieties protection to Feed Africa?” Rhetoric versus reality”, GRAIN Barcelona (1999). Available at http:// www.grain.org/publications/reports/variety.html(visited on March 2, 2010). WTO members are now in the process of defining their positions regarding the future of these provisions. There are indications that a few members like the US would like the sui generis option to be eliminated altogether, while others, which include most developing countries, are preparing national legislation to implement it.
varieties both at national as well as international level has also been examined. But before analyzing these regulatory regimes an attempt is made to explain the structure of plant kingdom that is necessary in order to understand the scope and impact of IPRs in agriculture i.e. the plant variety and its protection.

1.2 Plant Kingdom

Living things are traditionally divided into two kingdoms, the animals and the plant kingdom. Plants are generally distinguished from animals by their source of nutrition, their structure and mobility. The plant kingdom is vast and has been classified into a ranking system containing many divisions and sub-divisions. The division which is most familiar to many people is the ‘species’, however, the species level comes quite low down the classification of the plant kingdom. The most commonly used ranks in classification of plants are (in descending order), Kingdom, Division, Class, Order, Family, Genus and Species. Thus, in general, each species belongs to a genus; each genus belongs to a family; each family belongs to an order; each order belongs to a class; each class belongs to a division and finally each division belongs to kingdom. These ranks are called taxonomic groups or “taxa” (singular: taxon) in short. For instance: the taxonomic classification of soft wheat is Division: Spermatophyte; Class: Liliopsida (Monocotyledonae); Order: Poales; Family: Poaceae; Genus: Triticum and Species: Triticum aestivum L. (Soft Wheat).

The rank of species, by which most plants are known, is probably the most important because it is the basis from which the classification is constructed. It denotes a group of organisms sharing a long number of heritable characteristics, which are reproductively isolated. Thus, plants
of different species such as rose, potato, wheat and apple cannot inter-breed by natural means. Although the rank of species is an important botanical classification, it is clear that the plants within a species can be very different. Not all species are grown and cultivated. However, only those species which are adaptable to the environment in which they are grown, which are suited to the cultivation practices and which can be cultivated unchanged for generations are employed. Therefore, the use of a more precisely defined group of plants, selected from within a species is called ‘plant variety.’

UPOV Convention defines ‘variety’ as “a plant grouping within a single botanical taxon of the lowest known rank.” However, the ‘variety’ must be recognizable by its characteristics, recognizably different from any other variety and remain unchanged through the process of propagation. However if a plant variety does not meet these criteria, it is not considered to be a variety even under UPOV.

1.2.1 Types of Plant Variety

Plant variety can be developed and have been developed (depending upon the physiology of the plants of each species and the ways in which the plants of the species can be reproduced) either by asexually reproduction or by sexually reproduction or by self-pollination or by cross pollination or by hybridizing a plant variety. ‘Asexually reproduced varieties’ are also known as ‘vegetatively’ reproduced varieties.’ This variety can be reproduced by using a part of a

14. Ibid. It states that “a plant grouping within a single botanical taxon of the lowest known rank which grouping, irrespective of whether the conditions for the grant of a breeder’s right are fully met, can be: (i) defined by the expression of the characteristics resulting from a given genotype or combination of genotypes; (ii) distinguished from any other plant grouping by the expression of at least one of the said characteristics, and (iii) considered as a unit with regard to its suitability for being propagated unchanged.”
plant as the basis for producing another complete plant. For instance: Rose varieties can be reproduced by propagating a bud or a cutting from a plant of the variety. Potato varieties, on the other hand are normally reproduced by propagating a tuber of the variety. Thus, asexual reproduction of plants involves regeneration of vegetative tissues or organs into self-supporting plants with properties similar to those of the source plant. These types of plant varieties are reproduced from a single parent, through processes such as grafting, budding, cutting, rooting and layering. It may occur either naturally or as a part of human plant breeding. Asexually reproduced plant is genetically identical to its parent plant.16

‘Sexually reproduced varieties’ are reproduced sexually that is by pollination of the female part of a flower (the stigma) by pollen from the male part of a flower (the another). Varieties of grasses and most vegetables and cereals are few examples of sexually reproduced varieties.

‘Self-pollinated varieties’ are of those species which will tolerate, through successive generations, the fertilization of the stigma by pollen from the another’s of the same flower or from another flower on the same plant without loss of vigor. For example wheat tolerates, through successive generations, the fertilization of the stigma by pollen from another’s of the same flower or from another flower on the same plant without loss of vigor. Plant varieties of such species can be based upon a single plant or on a small number of plants which will reproduce
themselves precisely through successive generations. All the plants of such variety will be genetically the same or very similar.

There are plant variety of many species which cannot adapt to self-fertilization or cannot tolerate self-fertilization through successive generations and will become less vigorous if forced to self-pollinate (they will suffer from ‘in-breeding depression’). In these plants, the female part of the flower must be fertilized by the pollen from another flower, or from a flower of another plant. Varieties of such species, known as ‘cross-pollinated varieties’ and the populations of such variety are based upon the controlled cross-pollination of a sufficient number of selected diverse, superior plants to secure enhanced performance without suffering in-breeding depression.

'Hybrids varieties’ are based upon the controlled cross-pollination of parent lines, so that the seed resulting from the cross-pollination inherits its genetic make-up from the parent lines. Such varieties will typically exhibit greater vigor (‘hybrid vigor’) than the parent lines on which they are based, resulting, for example, in plants with higher yields, better resistance to stress, etc. The same controlled cross-pollination must be repeated each time the seed of those varieties is produced. UPOV as well as TRIPS protects all plant varieties reproduced by either of the above mentioned methods. For, instance USA is protecting asexually reproduced variety specifically by Plant Patents, sexually produced varieties by *sui generis* form of plant variety protection (PVP) and all other plants and its varieties including sexually reproduced varieties by general/utility patent.
1.2.3 Evolution of Plant Breeding

The plant variety was for the first time got legal protection around 1960’s. But they were generated and created by farmers since time immemorial. Today’s development in agriculture sector is a result of thousands years man’s hard wok both by selecting suitable plants among thousands of others and making them more useful by using science. Thousand years back when humans first began to domesticate wild plants was a paradigm of phenotype. Early farmers identified plants having desirable physical characteristics e.g. high or stable yield, disease or insect resistance, non-shattering seeds, desirable appearance, taste, or other observable physical characteristics and selectively propagated those plants. Farmers also experimented with simple cross-fertilization, attempting to blend characteristics from desirable parents. These practices eventually resulted in the emergence of farmers varieties (landraces), plant populations that may have been genetically heterogeneous, but possessed at least enough distinguishing phenotypic features that they could be differentiated from other plant populations by observation. Farmers began to develop names and naming systems to identify plant populations, implicitly internalizing both the conceptualization of plant populations as varieties and the use of phenotypic distinctions to determine what constituted a variety.

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17. A phenotype is a plants set of observable characteristics, a product of the plants genes and its interaction with the environment. However, a genotype is a plants entire genetic makeup. Crop Science Society of America, Glossary of Crop Science Terms 52 (1992) defines phenotype’ as the “observable characteristics, resulting from the interaction between an organism’s genetic makeup and the environment.” Included within a plant’s phenotype are both its morphological characteristics (a reference to visible characteristics and their evolutionary history) and its physiological characteristics (a reference to the dynamic processes relating to plant characteristics).

18. J.R. Harlan, “Our Vanishing Genetic Resources” 188 Science 618 (1975) states that ‘Landraces’ have a certain genetic integrity. They are recognized morphologically, farmers have names for them and different landraces are understood to differ in adaptation to soil type, time of seeding, date of maturity, height, nutritive value, use and other properties.”
These practices and, with them, the paradigm of phenotype persisted well into the twentieth century. Even after the emergence of plant breeding as a formal scientific discipline in 1900’s, breeders rediscovered Mendel’s laws of genetic inheritance. They began to understand plant breeding as the work of selecting for genotypes, plant breeders remained dependent on viewing or measuring plants phenotypic attributes in selecting for desirable agronomic traits. Though, the paradigm of phenotype is still relevant for the conceptualization of plants as varieties based on phenotype is still well-entrenched, and plant breeders still selected cultivated forms. But the paradigm of genotype has taken all the limelight. In sum, the technological foundation on which PVP systems were designed is being entirely reconstituted. Genotype now predominates over phenotype.

The plant genotype revolves two principal points of departure from phenotype. Firstly, genotyping technologies make it possible to identify

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19. Mendel’s research was with plants and the principles of heredity i.e. some basic trait transfers from parent to children. The principle applies to people and other animals because the mechanisms of heredity are essentially the same for all complex life forms. Through the selective cross-breeding of common pea plants (Pisum sativum) over many generations, Mendel discovered that certain traits show up in offspring without any blending of parent characteristics. For instance, the pea’s flowers are purple or white—intermediate colors do not appear in the offspring of cross-pollinated pea plants. Mendel observed seven traits that are easily recognized and apparently only occur in one of two forms: (i) flower colour is purple or white; (ii) flower position is axil or terminal; (iii) stem length is long or short, (iv) seed shape is round or wrinkled, (v) seed colour is yellow or green, (vi) pod shape is inflated or constricted and (vii) pod colour is yellow or green.

20. A genotype is a plant’s entire genetic makeup. Crop Science Society of America, Glossary of Crop Science Terms 46 (1992) defines ‘genotype’ as “the entire genetic makeup of an individual or group.”

21. For example, breeders of hybrid crops have utilized, detailed knowledge of pedigrees and replicated yield trials of an array of early generation F1 hybrids to measure the genetic potential of segregates in breeding populations. However, all of these developments relied upon the plant’s physical appearance and thus remained, at best, indirect approaches to genotypic selection.

22. Indeed, indigenous naming systems based on phenotype still exist for important crops in many cultures. For example, the Aguarana Jivaro community in northern Peru has practice selection by phenotype. However, since 1970’s, advances in biotechnology have allowed plant breeders to move away from sole reliance on plant phenotypes and towards direct characterization and manipulation of plant genomes.

23. For our purposes, a paradigm of plant breeding is comprised of the systems, mechanisms, and techniques for (1) identifying plants (and, in particular, for distinguishing among similar plants), and (2) exercising control over the characteristics of identified plants as plants are bred from generation to generation.
and discriminate among plants directly by their DNA profiles or by other molecular characteristics, rather than indirectly by their phenotype alone. Effectively, this is an exercise in the genetic “fingerprinting” of plants, a task facilitated by technological advances in molecular marker systems. In fact, it is increasingly possible to re-conceptualize plants altogether, as genetic datasets, a conceptualization that may diverge radically from the variety rubric.24

Secondly, plant breeders are developing new molecular breeding methodologies, i.e. methodologies that operate at the level of DNA sequences to manipulate directly the plants genotype, rather than using phenotype as the sole reference point. Techniques such as marker-assisted selection (MAS) enhancing (or even displacing) the traditional phenotype based breeding methodologies that dominated commercial plant breeding when PVP systems were designed.25

1.2.4 The Need for New Plant Varieties

New plant varieties are required to have improved varieties which have brought tremendous progress in agricultural productivity in various parts of the world. With the introduction of technology, such new varieties can be developed which can produces improved yields, higher quality seeds having better resistance to plant pests and diseases. Moreover, the new varieties reduce the cost (in long run) which in turn

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25. Id. at 14. It is stated that “in the course of exploring these techniques, plant breeders are beginning to discard long-held assumptions about the relationships between phenotype and genotype. Discoveries in plant genomics have moved plant breeders away from a ‘one-gene, one-phenotype mentality’ towards a new appreciation of the complex relationship between genotype and phenotype, in which plant breeders recognize that plant physiology is dynamic and responsive to external factors such as environment, and expect to find intricate gene networks controlling ‘complex phenotypes.’”
will increase the productivity and product quality in agriculture, horticulture and forestry, whilst minimizing the pressure on the natural environment. Many other modern technologies of plant production need to be combined with high-performing varieties in order to deploy their full potential.

Secondly, to feed the growing population, such new varieties are required which can produce maximum grain with limited resources. The continuous rise in the world’s population has increased the need to create and develop new varieties manifold. In addition, the conversion of cultivating land into concrete jungles has worsened the situation. Thus, it is necessary ways to increase the output through higher yields and by less wastage which can compensate the ongoing shrinking agricultural land and other resources (such as ground water level). Thirdly, plant breeding has also wider economic and environmental benefits for developing countries and least developed countries (LDC’s). The development of new improved varieties with, for example, higher quality, increases their value and marketability of crops in the global market.

Fourthly, the breeding and exploitation of new varieties is a decisive factor in improving rural income and overall economic development specifically developing as well as LDC’s (if allowed reasonably). Lastly, to conserve wild species from extinction, one needs to develop new varieties and to protect the same. With the modernization of world, the coming generations are not very keen to protect and conserve their traditional knowledge, which their forefathers have done. Thus, in order to save wild species from extinction it is necessary to
acknowledge the efforts of communities (to protect the species) by allowing them to exploit the species and its recourses, economically.

The process of plant breeding is long and expensive; however, it can be very quick and easy to re-produce a variety. Breeders spend many years of their life, making substantial economic investment, in developing a new variety. The sustained breeding efforts are only possible if there is a chance to reward investment. Therefore, it is important to provide an effective system of PVP, with the aim of encouraging the development of new varieties of plants, for the benefit of society. The concept of owning plant varieties emerged internationally for the first time in the 1960’s. Though, Germany was the first country to have a national law acknowledging breeder’s contribution to the society (developing new plant variety) by granting him breeder’s rights to exploit his work for a fixed term. However, UPOV was the first international attempt to codify law on the subject.

In 1961, few European industrialized countries set up an agreement amongst them and adopted UPOV. The signatories to the Convention were required to provide *sui generis* form of protection by granting commercial breeder’s rights over genus or species of plants. Subsequent Acts of 1972, 1978 and 1991 of the UPOV brought various changes. TRIPS is important for the protection of plant varieties as it seek the member states to protect at least the plant varieties (if not the plant) either by patents or by effective *sui generis* form of protection or by combination of both. The CBD and the IUPGR though are not directly related to plant variety or its protection but are two important documents.

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26. The first law for the protection of plant breeding products in Germany was issued in 1953 named *the Law on Variety Protection and Seeds of Cultivated Plants, 1 BGBI 450.*
which talk of the protection of biological resources encompassed in plant varieties.\textsuperscript{27}

Europe has though expressly opted for \textit{sui generis} form of protection but is gradually shifting from their stand and now granting patents over the genetically modified plant varieties.\textsuperscript{28} USA on the other hand has opted for plant patents for asexually reproduced plant variety; plant variety protection for sexually reproduced ‘variety and utility patents for all variety including sexually reproduced variety (Diamond Case and J. E. M. Ag Supply, Inc.).\textsuperscript{29} India, has expressly excluded plants and its varieties from the patent regime. And taking the advantage of the provision of TRIPS, it has wisely introduced a \textit{sui generis} form of protection suiting its needs and the requirements.\textsuperscript{30} The laws of respective countries however, expressly and elaborately provided breeder’s rights for a fixed term.\textsuperscript{31}

1.2.5 Patents or \textit{Sui generis} System

Initially it was thought that plants and their varieties must be protected under patent. However, granting a patent over a natural product like any other mechanical products was not considered a good idea by the World leaders. Thus, it was decided that a special form of protection must be introduced for the protection of plant and its varieties. They called it \textit{sui generis} form of protection (also called as PVP system). \textit{Sui generis} is a Latin term. It means ‘unique’ or ‘special’ or ‘of its own kind’\textsuperscript{32} leaving

\textsuperscript{27} Chapter-3 discusses all the four international documents in detail.
\textsuperscript{28} Chapter-4 deals with the position in Europe with respect to plant varieties.
\textsuperscript{29} Chapter-5 deals with the position in USA with respect of plant varieties.
\textsuperscript{30} Chapter-6 deals with the Indian law on plant variety protection.
\textsuperscript{31} Chapter-7 has discussed breeder’s rights.
the *sui generis* system open to interpretation it offers a unique type of IPRs, which is different from the classical IPRs.

UPOV illustrates a *sui generis* form of protection in form of plant breeder’s rights. However, very few countries were favoring patents for plant and its varieties. Therefore TRIPS provides protection to plants by patents (including invention with respect to plants where the invention is new, involve an inventive step and are capable of industrial application) or by an “effective” *sui generis* system or by any combination of both. Thus under TRIPS, the member countries are left free to exclude plants from the patent regime. But then they have to protect plant varieties either by patents or by *sui generis* system or by combination of both. However, countries like USA is granting patents over plant varieties, India is protecting plant varieties by a *sui generis* form and Europe is granting patents over plants but protect plant varieties by *sui generis* system.

**1.3 Scope and Objectives of the Study:**

The scope of the study is limited to study and analyze the emergence and enormity of Global Regulatory Regime and its implications on various Law and Policy in relation to IPRs and Agriculture in India. An attempt will also be made to examine how far the global regulatory regime is compatible with law and Policy in India.

**1.4 Conceptual Framework:**

The conceptual framework of the topic will be drawn in the light of emerging issues and problems some of which are referred to in the statement of problem.

**1.5 Focus of the Present Study:**

The present study focuses on the need for bringing about harmony between Global Regulatory Regime and Law and Policy in relation to
IPRs and Agriculture in India. It also focuses on need for accommodating national concerns in IPRs and Agriculture in the discourses of global governance, in order to create equal and fair opportunities for all in this era of globalization to realize socio, economic and political justice.

1.6 Scheme of the Study

1.6.1 Chapter 2

Chapter 2 of the thesis deals with emergence of Global Regulatory Regime. In this chapter the historical development of GATT along with the other international organization is discussed. It also deals with various round of GATT/WTO negotiations which resulted in establishment of WTO. It also deals with the jurisprudence of dispute settlement system (DSU/DSB) of WTO. How DSU/DSB works and what is the jurisprudence behind that is also critically examined in detail. How DSU/DSB of WTO works as adjudicatory body and how it is effective is also examined. This chapter also analyses the relevant WTO cases related to intellectual property rights. It also deals with the evolution/emergence of TRIPS in multilateral trade negotiations. The emergence of the TRIPS Agreement during the Uruguay Round of Multilateral Trade Negotiations is dealt with in comprehensive manner. This chapter also deals with the TRIPS Agreement and farmer’s right. The protection of plant varieties under TRIPS Agreement through Art. 27.3 and their inclusion in TRIPS Agreement is also analyzed.

1.6.2 Chapter 3

Chapter 3 of the Thesis deals with the International regulatory regime regarding plant variety protection, Biological Diversity and farmers rights. The historical development of law relating to plant variety
protection is also discussed. The UPOV 1961, UPOV 1972, UPOV 1978 and UPOV 1991 are also discussed in detail in this thesis. The various provisions of UPOV relating to plant varieties and breeders rights are examined in comprehensive manner. The Convention on Biological Diversity (CBD) and its relationship with TRIPS agreement is also discussed. Various provisions of CBD regarding benefit sharing and prior informed consent, Access to and Transfer of Technology and the Bonn Guidelines on Access to genetic Resources and fair and Equitable sharing of the Benefits arising out of their utilization are also discussed. Article 27.3(b) of the TRIPS Agreement is analyzed in detail. What amounts to ‘effective protection’ along with review of Article 27.3(b) of TRIPS is also discussed.

1.6.3 Chapter 4

Chapter 4 of the thesis deals with plant variety protection in Europe. The European Patent Convention, The Biotechnological Directive, 1998 and the community Plant variety Rights, 1994 are discussed in this chapter. The patentability criteria, term of protection, procedure for filing application under EPC are also discussed. The scope of protection under CPVR, duration of CPVR, procedure for filing an application for CPVR and jurisdiction over CPVR are also discussed.

1.6.4 Chapter 5

Chapter 5 of the thesis deals with the laws for plant variety protection in the United States of America. It also deals with the history of evolution of laws on plant variety protection. Under this chapter all the three systems relating to plant varieties protection are discussed in detail. The Plant Patent Act, 1930 protects asexually reproduced varieties, The Plant Varieties Protection Act, 1970 protects sexually reproduced varieties and
the Patent Statute of 1952 grant utility patent. All these acts are analyzed in detail.

1.6.5 Chapter 6

Chapter 6 of the thesis deals with the Plant variety protection in India. For this purposes, this chapter examines the various provisions of Plant Variety Protection and Farmer’s Rights Act, 2001 of India. The Different kinds of varieties, definition of varieties, breeder’s rights, and farmer’s rights are also discussed in this chapter. The salient features of the PPVFR are also examined. This chapter also deals with the Biological Diversity Act 2002 of India. The Seed Bill is also critically examined. It also deals with the issue relating to India’s UPOV membership. The manner of sui generis system in PPVFR is also examined. Whether PPVFR provides an effective sui generis system for protection of plant variety protection in conformity to TRIPS is also examined on detail.

1.6.6 Chapter 7

Chapter 7 of the thesis deals with the Breeder’s rights in Europe, The USA and India. It also deals with scope of breeder’s rights, infringement provisions and remedy regarding breeder’s rights.

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