Chapter 10

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The international patent system has evolved around two basic objectives. First, it seeks to recognize the efforts of the inventor. Second, it attempts to balance the interest of the inventor with public interest. The process of evolution of the patent system has furthermore established the fact that there is a close correlation between the level of the economic, industrial and technological development of a country on the one hand, and the nature and extent of patent protection granted by it on the other.

The earliest known patent law, the Venetian Patent Act, 1474 had laid emphasis on the promotion of social interest by providing for the working of the patented invention within a prescribed time. Even in England, the first modern patent legislation, the Statute of Monopolies, 1623, provided that the right of the inventor was merely granted in the interests of society. Subsequently, during the years of industrial revolution, the widening of markets, the expansion of the scope and volume of international trade, and the accompanying possibilities of economic advancement led to increased understanding of both the need for and the monopolistic and restrictive aspects of the patent system. The territorial application of the patent laws during this period hindered the effective movement and assimilation of new technological developments transcending State boundaries. With a view to facilitating a uniform structure of patent laws some countries took the initiative to evolve an international patent system which finally culminated in the adoption of the Paris Convention for the Protection of Industrial Property in 1883.
The evolutionary process of the Paris Convention shows that the dominant economic interests in the international system shaped the contents of patent norms. Some of these interests dominated the revision conferences of the Paris Convention for nearly one hundred years. These were mainly profit maximization by extending the life of exclusive grants i.e., patents; and monopolization of technological knowledge by restricting its dissemination. The implications flowing from the domination of these interests in the evolution of the Paris Convention could also be identified: firstly, the focus shifted from the greater dissemination of inventive activity to the creation of exclusive monopolistic rights (countries which possessed the technological and industrial base supported this); secondly, there was a gradual weakening of the strict requirements of "working". Even the "compulsory licensing" provisions were subjected to certain conditions in the revision conferences of the Paris Convention.

The end of colonialism and the birth of a number of new States saw the law relating to patents critiqued from the standpoint of the developing countries. During the seventies, these countries succeeded in convincing the developed countries to agree to the revision of the Paris Convention with a view to accommodating the concerns of the developing countries and their patent holders.

The Diplomatic Conference convened to revise the Paris Convention in 1980 failed to reach any firm conclusions. Rapid technological developments made the developed countries to rethink their position. On the other hand, the developing countries failed to foresee the possibility of negotiating in a completely different forum, the GATT.
When this was proposed, the developing countries, while accepting the growing inevitability of the interrelationship between technology, trade and IPRs, argued that GATT was not the proper forum for negotiating the linkages, leave aside a uniform global regime for IPRs.

For developing countries the acquisition of new and high technology was crucial to enable them to leapfrog their economic advancement. The acquisition of these technologies by the developing countries, notably in the areas of biotechnology, agriculture and informatics, opened up the possibilities of a technological leap with the help of "reverse engineering". In other words, the developing countries' response to protection of IPRs was shaped by factors such as the objective of self-reliance, the narrowing of the technological gap, the reduction of dependency, protection of traditional practices and methods and a more active participation in the process of technological change.

In so far as the developed countries were concerned, one way of stopping the diffusion of technology was a hard IPRs regime. They were willing to use any means to achieve this goal. The US Government, while proclaiming GATT-based multilateral negotiations as its preferred strategy for resolving trade problems, undertook an intense programme of direct bilateral negotiations coupled with the threat or use of unilateral economic coercion to protect the interests of technology holders. The Omnibus Trade and Competitiveness Act, 1988 authorised the USTR to identify "priority" countries that
denied "adequate" and "effective" protection of IPRs. It also provided for the initiation of unilateral sanctions after a brief period of watching and assessment.

India and Brazil were placed by the USTR in the "Priority Watch List" countries. They were pressurized to improve the patent protection for all classes of inventions, and in this context, to take part constructively in the GATT negotiations. The threat comprised of the initiation of retaliatory measures by clamping-down tariff or quantitative or other restrictions on products imported into the US. However, the reform of domestic patent laws in response to bilateral pressures hardly constituted a rational approach towards the concerns of the developing countries. Ironically, the US itself is resisting certain changes in its patent laws. It has called into question the WIPO's Draft Harmonization Treaty as it is unable to accept the relinquishment of its first-to-invent principle in favour of first-to-file principle. The US reluctance shows that the essential ingredients of any patent system reflect the peculiar needs of the society which shapes it.

The essential features of law of patents are territorial in nature. And these features are clearly reflected in the national patent legislations. Although the patent laws of various countries provide more or less uniform standards while defining the patentable subject matter, a degree of variation may arise in the emphasis accorded to each criterion of patentability involving considerable amount of subjectivity. The subjectivity factor may arise at different levels of the domestic patent system. For instance, it varies with the competence and effectiveness of patent agents who describe the invention in the patent
specification, patent examiners who examine them, and finally the patent offices and courts which look into the patent's legal validity. So, the substantive conditions of patentability, namely, novelty, inventiveness and industrial applicability, are considered within the domestic legal set up, taking into account all these subjective factors at various levels.

Despite this, the TRIPs negotiations seek to outline a uniform criterion of patentability. Developed countries generally favour the availability of patents in any technological field provided the invention is new, useful, and unobvious product or process. India opposed this formulation. It did not concur with the rationale to stipulate uniform criteria for non-patentable inventions applicable both to developed and developing countries alike or to restrict the freedom of developing countries to exclude any specific sector or product from patentability. These ideas, however, did not get adequate response and support from other major developing countries, particularly Brazil and the Republic of Korea. The silence could perhaps be attributed to the threat of bilateral pressure held out by the U.S.

Article 27 of the Agreement on TRIPs enumerates as many as five crucial components of the patentability criterion, disregarding in the process the views of developing countries. These five components are: (a) availability of patents for all kinds of inventions; (b) patents granted in all fields of technology, whether products or processes; (c) inventions to be patentable should fulfil the criteria of novelty, inventiveness and industrial applicability; (d) patents should be available and patent rights
enjoyable without discrimination as to the place of invention, and the field of technology; and (e) patents to be granted irrespective of products importation or local production.

The interests and priorities of developing countries will be severely affected if patents are to be granted in all fields of technology whether products or processes. If patents are not worked sufficiently within a reasonable stipulated period, the basic objective of the patent system itself will be defeated. Until very recently, many of the developed countries granted only process patents in pharmaceutical and chemical sectors so as to achieve faster economic growth and to provide health care to all. Developing countries adopted this technique and were successful in maintaining the prices of the drugs at a reasonably lower level. India was one of them. IPA provides for the exclusion of certain sectors, including food and pharmaceutical, from product patenting. Canada, Australia, New Zealand and certain other developed countries provided for these exclusions until as recently as the 1980s.

For developing countries the actual working of the patent grant is crucial for acquisition of the latest technological developments. Section 83 of the IPA, accordingly, provides that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale, without undue delay. Further, it also provides that patents are not granted merely to enable patentees to enjoy monopoly for the importation of the patented article. The "working" of a patent grant after the expiry of a reasonable period has a unique role to play in the creation of knowledge and its sustenance. When a patent is worked sufficiently, it adds value to the existing state of
the art in any country. Therefore, to equate working of the patented invention with the importation of the patented product defeats the very purpose and objective of the patent system. Compulsory licensing, for this reason, offers an appropriate solution as it harmonizes public interest on the one hand and the patentee's rights on the other. It is considered as an instrument which enables the society to exercise its legitimate right to benefit from patented technology. In addition, developing countries consider compulsory or non-voluntary licensing as a tool to facilitate technology transfer and to balance the patentee's interests and the user's interests by preventing the patentee's abuse of his exclusive right.

For developed countries, on the other hand, the introduction of compulsory licensing system is a limitation on the enjoyment of the patentee's rights. Article 31 of the TRIPs Agreement embodies their view and is accordingly entitled: "Other Use Without Authorization of the Right Holder". This is the TRIPs text's equivalent of compulsory licensing. It could be described as compulsory licensing without teeth. Because, the authorization of the use is restricted by specific conditions such as the proposed user should make efforts to obtain authorization on reasonable terms; that the authorization of the use should be considered on individual merits; that the use should be limited to the purpose for which it was authorized; that the use should be non-exclusive, and non-assignable; that such use should be authorized predominantly for the supply of domestic market; and that there should be a judicial review of the authorization itself.
Most of these conditions for the authorization of the use as formulated in Article 31 of the TRIPs Agreement will go against the interests of developing countries. Indian Patents Act (IPA), for example, provides for the compulsory licensing in section 84 on the grounds that "the reasonable requirements of the public have not been satisfied or that the patented invention is not available to the public at a reasonable price". The grounds envisaged in the Indian Law will have to be considerably diluted to bring it into conformity with the TRIPs Agreement. The provisions relating to "licences of right" in Section 87 of IPA, on the other hand, do not conform with the TRIPs formulations. Such unilateral authorizations, with "deemed endorsements" go against Article 31 and will have to be deleted from IPA.

Similarly, the implications arising out of Article 34 of the TRIPs Agreement concerning the "reversal of burden of proof" are far-reaching, particularly in the context of a developing country. It authorises the judicial authorities to order the defendant to prove that the process to obtain an identical product is different from the patented process. To obtain a certain product, an inventor may employ different processes, without infringing patented processes. The pharmaceutical sector, for instance, in many developing countries including India has evolved through this mechanism and registered considerable success in providing drugs and other essential medicines to the people at reasonably low prices. Even the word "identical" used in Article 34 is very broad and is not strictly amenable to objective assessment. So, the extension of the right of the process patentees to cover identical products rules out the development of substitute products. More significantly, this provision has been inserted keeping in view
biotechnological processes where a particular form of gene splicing at least in theory could yield more than one product. And these products evolved from the biotechnological inventions exhibit largely identical features with slight variations in their structure and operation.

The term of protection for patented invention is a crucial element in any patent legislation. In the past it was left to individual countries to decide on the term of protection. However, the Agreement on TRIPs now provides for a twenty year term from the filing date. Developed countries justified the long patent term by citing long delays involved in securing marketing and environmental approvals. The uniform term of twenty years is iniquitous for it delays the access of developing countries to new and emerging technologies, retarding their industrial capabilities. In other words, a shorter duration of patent protection could have been more in tune with the interests of the developing countries. In respect of areas like electronics, robotics, cybernetics and communications where technological developments are extremely fast, the twenty year term is a technological nonsense.

The so-called "transitional arrangements" in the Agreement on TRIPs provides the developing countries a "concession" of ten years in applying its provisions. But these arrangements become ineffective with the inclusion of "classical pipeline protection". "Pipeline Protection" provides that patent applications in the field of pharmaceutical and agricultural chemical products should be allowed to be filed in developing countries as soon as the Agreement enters into force. While receiving these applications, Article 70
provides that the criteria of patentability as embodied in the Agreement is to be considered. This is not all: paragraph (9) of Article 70 authorises the granting of "exclusive marketing rights" (EMRs) for a period of five years after obtaining marketing approval to the product for which a patent is applied. By virtue of this provision, the patent applications in the pharmaceutical agricultural and chemical sectors will have to be examined after five years for granting only the product patents. The provision for EMRs is only a clever technique to extend product patent regime forthwith to all the developing country members.

The implications of this are equally far-reaching. After examination for patentability, for instance, if the patent applications fail, there is no way to roll back the already granted "exclusive rights". Assuming that "marketing approval" could partially replace the "patentability" criterion, the question remains whether it is possible to assess objectively the criterion of "marketing approval" in any given country. Marketing approval techniques differ from country to country. The granting of EMRs is sure to strengthen the monopoly rights of the pharmaceutical MNCs, and, consequently, could lead to an increase in the prices of drugs. The Indian Patents (Amendment) Ordinance, 1994, promulgated with a view to meeting India's obligations under the WTO, however, lapsed on 26 March 1995 and the bill seeking to replace it was facing rough weather in Parliament till the closure of the 1995 monsoon session.

The exclusionary provisions in paragraph 3 of Article 27 of the Agreement on TRIPs has given rise to a complex web of issues relating to patenting of life-forms. It
specifically excludes the patenting of plants and animals, the diagnostic, therapeutic and surgical methods for the treatment of humans or animals. It also excludes essentially biological processes for the production of plants or animals. On the other hand, it does not exclude the patenting of micro-organisms and non-biological or micro-biological processes for the production of plants or animals. Further, it also provides that plant varieties should be protected either by patents or by an effective *sui generis* system or any combination thereof.

The US has been granting patents to plants since 1930s with the enactment of its Plant Patent Act, 1930. Micro-organisms, on the other hand, gained legal recognition in the US much later with the decision of the Supreme Court in *Diamond Vs. Chakrabarty*. The Court in this case allowed the patenting of human-made micro-organisms which had been genetically engineered in laboratory conditions. In other words, it should have been a hitherto unknown natural phenomenon, a non-naturally occurring manufacture or composition of matter, a product of human ingenuity. However, it did not conclusively answer the question whether micro-organisms that occur in nature should be protected and if so in what circumstances? The American Supreme Court merely stated that such micro-organisms were not suitable for intended use in their natural form. The EPC, on the other hand, allowed patenting of micro-organisms, but excluded in Article 52 (EPC) any discovery to be patented. The Common Position adopted by the EC in February 1994 clarified that while determining this exclusion human intervention and its effect on the result obtained should be taken into account.
On the other hand, considerable uncertainty prevails as regards the patentability of animals originated through a non-biological process. The EPO dealt with this aspect in *In re President and Fellows of Harvard College* which is also known as "Onco-mouse Case". This case had before it the issue of the patentability of a "transgenic non-human mammalian animal whose germ cells and somatic cells contained an activated oncogene sequence". The introduction of an oncogene into an animal by technical means was considered to be a "non-biological process" and the patentability of the product of such a process was allowed. Even then, this case raised a number of issues which called for much greater consideration. For instance, it raised the issue of "sufficiency of disclosure" in such cases. It also noted that the patenting of such inventions should be dependent on a careful weighing up of the suffering of animals and possible risks to the environment.

The issue relating to disclosures and environmental risks are likely to affect the future growth of biotechnology in the developing countries. At the same time these issues also constitute the primary limitations in the patentability of life-forms. For a very long time, living things were considered unpateentable as they were not amenable to accurate written description for an adequate disclosure. The standards of disclosure requirements have been summed up in Article 29 of the Agreement on TRIPs. It requires the disclosure of an invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and also to indicate the best mode for carrying out the invention. This provision incorporates both the European and American approaches in this regard. The "best mode requirement" emanates from Article 112 of the US patent law. Although the legal requirement is clear, the problem arises at the
level of description. How can one conclusively decide that an invention or a discovery relating to living matter is sufficiently disclosed? This question is sought to be answered in cases relating to genetic engineering and biotechnology.

The basic element of a sufficient disclosure requires that at least one specific way should be clearly indicated enabling the person skilled in the art to carry out the invention. If this requirement is fulfilled, then the non-availability of some particular variants or unsuitability of some unspecified variants of a functionally defined component feature of the invention would be immaterial to sufficiency as long as there are suitable variants known to the skilled person through the disclosure or common general knowledge which provide the same effect for the invention. The disclosure need not necessarily include specific instructions as to how all possible component variants within the functional definitions should be obtained. In cases where the basic ingredients constituting the patentable subject matter are not readily available, the adequacy of disclosure is to be measured by the process of "repeatability". It requires that the skilled person be able to carry out the steps described in the specification independently and produce identical products.

The disclosure requirements for micro-organisms, on the other hand, are quite different. Micro-organisms pose formidable difficulties in meeting the requirements of written description. Consequently, it is mandatory to deposit the sample of the micro-organism in an authorized institution. For instance, the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent
Procedure provides for the setting up of international depository authorities with which microorganisms can be deposited.

While considering the disclosure requirements, developing countries should exercise caution to exclude particularly broad claims made in the patent specifications. Such broad claims will affect the overall research efforts undertaken by them in the arena of biotechnological inventions. For example, in 1994 India summarily revoked the controversial process patent on genetically-engineered cotton seed granted to the Agracetus Inc., a subsidiary of a US MNC. The scope of coverage of the patent grant was reported to be unprecedented. The broad scope of biotechnological inventions has also raised issues relating to ethics and the risks directed towards environment. The efforts to patent human genes has, for example, raised many ethical issues. The stakes in unravelling the human genome would concern all of us as this information is in all of us. Similarly the genetic manipulation of life, if related to the environment, might entail unforeseeable and irreversible adverse effects.

In the scheme of protecting life-forms, plant varieties fall into a different category. The Agreement on TRIPs seeks to protect it either by patents or by an effective *sui generis* system. A *sui generis* system simply means a unique system, not classifiable with others. The trend in many developing countries, including India favour this method of protection.

There is, however, the apprehension that UPOV Convention provides the model for a *sui generis* approach by laying down the minimum standards of protection that a
national system should afford. If the UPOV Convention is to be taken as a model the main issue is whether to incorporate UPOV Convention as revised in 1978 or UPOV Convention as revised in 1991. The 1978 UPOV text grants "Breeder's exemption" which allows other plant breeders to use protected variety for breeding purposes. The other exemption relates to farmers i.e., allowing farmers to use seeds from their harvests to plant the next crop, even if the "variety" is protected. On the other hand, the 1991 UPOV text brings in stringent PBRs. In other words, it seeks to impose on the breeders, irrespective of their country of origin, an obligation to pay a licence fee to the PBR-holders if the new variety bears any similarity to the protected variety, even if the new variety has been bred for different traits. If this formulation is accepted, farmers in developing countries and particularly the Indian farmers who traditionally seek to save or exchange seeds for the next cultivation season will have to do so only after paying the prescribed amount of license fee. Considering this, India should model its PBR system in line with the provisions of the 1978 UPOV text, incorporating "farmer's privileges" and of "researcher's exemption" unambiguously and modifying them as necessary to suit its needs.

In India, for instance, a Plant Varieties Act has been on the anvil since 1993. Although the features of the draft legislation have some similarity with the provisions of 1978 UPOV text, the main objective seems to be to take into account Indian conditions.

However, the proposed sui generis system in the draft Plant Varieties Act, 1993 exhibits a very conservative approach while setting up an institutional framework. India
seeks to exercise maximum control on the germplasm protection and on the rights granted to plant breeders. In other words, there is too much centralization and the role of farmers and the local communities in preserving the germplasms have not been sufficiently recognized. Instead, the draft Indian legislation could have taken a lead in creating an entirely unique *sui generis* system by recognising and vesting rights of the germplasm protection in the local communities. These ideas have been reflected in the views expressed by some Indian experts also.

The area relating to the patenting of seeds and genes has been grossly misunderstood in the Indian context. In India, particularly among the farming communities, the idea has gained currency that once a seed is patented, the farmer loses the right to modify, to retain or use his seeds. It should be noted that in India seeds cannot be patented as products. The issue at stake is the patenting of the gene which constitutes the main traits of the seed. In the normal course farmers need have no fear in cultivating the known traditional varieties of seeds.

The patenting of seeds and genes has also raised other crucial issues such as the survival of domestic agro-based industries in the event of an onslaught by the MNCs. The immediate concern of the MNCs is stated to be "assembly of genetic technology" i.e. to acquire control over as many genes and other life-forms as possible so that the future research orientation could be regulated. This, however, could be achieved only through patenting. In this sense, patenting is crucial for these MNCs.
Another area which is of critical importance to developing countries including India relates to software development. The issues relating to the patentability of software-related inventions have been posing difficult problems. Until recently, there was a consensus that the software-related inventions should be protected by copyright law, because, the software-related inventions are in the form of instructions and cannot normally be categorized as inventions. One reason attributed to the existing consensus regarding the copyright protection for computer software was mainly on account of fears that the developing countries may not otherwise agree to provide adequate and effective levels of protection. A number of national legislations, therefore, contain express provisions excluding computer software from patent protection.

It has, however, been argued that in cases where computer programme or software forms an integral part of a process, the software could be considered as forming part of the process and the patent protection could be accorded subject to the fulfilment of patentability criteria. Uncertainty exists as regards the protection of commands of a language in a computer software. There is also a *sui generis* approach which was initially considered by the WIPO. The *sui generis* approach to software protection envisages an independent system of protection, a protection different from copyrights and patents.

Developing countries should seriously consider the possibilities of protecting software-related inventions by a *sui generis* system. Software inventions are generally easily copiable and possess a very high rate of diffusion and dissemination. In view of
this, the extent of protection and mode of working within a definite time frame has assumed lesser importance.

Finally, it should be stated that the evolving regime of IPRs has been raising many important issues which directly concern the developing countries. With the setting up of WTO and the binding dispute settlement mechanism the future of international trading system will be more iniquitous towards developing countries. In other words, the Final Act Embodying the Results of Uruguay Round Multilateral Trade Negotiations envisages not only increased obligations on the developing countries, but also admits of no derogations therefrom. If there are any derogations, the dispute settlement mechanism provides a stringent process of resolution sanctioned by "cross-sector retaliations".

Furthermore, the nature and scope of obligations under the Agreement on TRIPs mandatorily confer an obligation on the Members to give effect to its provisions. In other words, the Agreement on TRIPs places limits on the options of the States to defend their national interests. By treating IPRs as essentially "private rights", the Agreement transforms the overall policy approach towards the rights conferred. It also shifts the emphasis from the existing mode of protection which attempts to harmonize public interest and private gains. The definition of patentability criteria, for instance, reflects this change clearly. The options before the developing countries have been curtailed by such provisions as "pipeline protection", "exclusive marketing rights" and the dilution of the provisions relating to licensing.
In this macro-level view, the thesis had made a modest attempt to identify and place the various issues concerning patents in their proper perspective particularly taking into account the priorities of developing countries. It is hoped that some of these issues identified and the concerns expressed herein will be given the consideration that they merit.