

Managing Intellectual Property Rights for Better Transfer and Commercialization of Agricultural Technologies

H S Chawla[†]

Genetics & Plant Breeding Department, G B Pant University of Agriculture & Technology, Pantnagar 263 145

Received 27 January 2007, revised 21 March 2007

Intellectual property rights (IPR) have become important in the face of changing trade environment and collapsing of geographical barriers to trade among nations due to globalization. Patent policies have historically been enacted to further national interests. Thus, developing countries in Asia must establish their own IPR regime, which is compatible with the framework of their constitution and as per the TRIPS regulations. Recent developments in agricultural technologies and biotechnology have opened new doors for seed developers and marketers. However, innovations in agricultural technologies and agricultural biotechnology cannot be treated at par in investments in R&D and innovation risks. The revolution in biotechnology and intellectual property protection began in the developed world. The benefits of agricultural biotechnology will proliferate in the developing countries only if they understand and manage IPR properly. When the rights to existing patents are needed to practice a technology, dominant and overlapping patent claims must be examined because it can affect the right to use downstream innovations. Hence, management and commercialization of these technologies must be considered seriously by developing countries in Asia, as the perceptions by publicly-funded institutions are not only driven by economic considerations but also depend on considerations of social obligations, political objectives and will of a nation. In the agricultural research sector, public research institutions have the responsibility to see research through to commercialization since the negative effects of IPR have been most apparent in the agricultural sector. Various options for licensing of agricultural technologies and incentive schemes for innovation related researches have been discussed in the paper.

Keywords: Patenting, agricultural biotechnology, seed patenting, licensing, commercialization, technology valuation

Asia, the earth's largest continent has a land area of 3.18 billion hectares and home to 3.8 billion people or about 60% of the world's population. It is the most rapidly growing region of the world economy today and according to the report of UNESCO, the region provides 35.6% share to the world's gross domestic product in 2002.¹ The GDP growth of Asia in 2004 is nearly 5 %, higher than that of North America (4.1%), Europe (2.3%) and Africa (4.4%). Agriculture is of great importance to countries in Asia and contributed about 18 % to Asia's GDP in 2004. Research in agricultural technologies during twentieth century witnessed an all round progress in meeting the food and other livelihood needs of the growing population and development of human societies.

Role of IPR in Development

The advent of the new knowledge economy places a tag of urgency on understanding and managing knowledge-based assets such as innovations and know-how. The time for grasping knowledge has

become an important parameter for determining the success of an institution, enterprise, government and industry; shorter the time better are the chances of success. IPR have become important in the face of changing trade environment, which is characterized by the following features, namely, global competition, high innovation risks, short product cycle, need for rapid changes in technology, high investments in R&D, production and marketing and need for highly skilled human resources. Geographical barriers to trade among nations are collapsing due to globalization to a system of multilateral trade and new emerging economic order. It is therefore, quite obvious that the complexities of global trade would be on the increase as more and more variables are introduced leading to uncertainties. Many products and technologies will be simultaneously marketed and utilized in many countries. With the opening up of trade in goods and services, IPR have become more susceptible to infringement leading to inadequate returns to the creators of knowledge.

Knowing that the cost of introducing a new drug into the market may cost a company anywhere

[†]Email: chawlahs_patent@yahoo.com;
chawlahs_pantnagar@rediffmail.com

between \$300 million to \$600 million along with all the associated risks at the developmental stage, no company will like to risk its intellectual property becoming a public property without adequate returns. Recent developments in agricultural technologies have also opened new doors for seed developers and marketers. Seed industry is now a global \$15 billion industry.² However, innovations in agricultural technologies except for agricultural biotechnology cannot be treated at par with the drug discovery molecules. Further, agricultural technologies are livelihood technologies and IPR protection on these technologies by developing countries must be considered seriously. Thus, creating, obtaining, protecting and managing intellectual property must become a corporate activity in the same manner as raising of resources and funds. The knowledge revolution will demand a special pedestal for intellectual property and treatment in the overall decision making process. It is also important to realize that each product is an amalgamation of many different areas of science and technologies. In the face of the competition, being experienced by the global community, many industries are joining hands for sharing their expertise in order to respond to market demands quickly and keeping the prices competitive. Therefore, all publicly-funded institutions and agencies will have to come to terms with new ground realities and should take positive steps in the direction of research to generate and protect more intellectual property rights, and manage them efficiently.

Seed Industry and Patentability Issues

For thousand of years farmers are saving the seeds with most beneficial characteristics to replant the next season crop. It is believed that more than 80% farmers in developing nations rely on saved seeds for the next harvest.² This is an integral part of agriculture because seeds reproduce themselves indefinitely. Farmers used to replant, sell and share seeds because plant breeding was natural and considered as common property. Seeds were not seen as a commodity and hence there was little or no private investment. The United States agricultural industry was built upon sharing the seeds from around the world.² Until recently, there was a Jeffersonian tradition in US of sharing and importing genetic seed material. The term Jeffersonian refers to Thomas Jefferson's vision of United States as an agrarian republic composed of independent farmers. The Federal Government supported seed collection, sharing and also established

a distribution programme of free seeds. In 1879, it distributed over 1.1 billion seed packets and one third of USDA budget was allocated to seed collection and free distribution. Although free seed distribution was beneficial for Federal Government but it ran counter to the private seed industry. With the development of seed hybridization techniques for creating new varieties companies were able to control replanting of seeds. Therefore, farmers had to purchase new seeds annually because the second generation of hybrid seeds was not as good for high yield planting. Seed development started moving from public to private sector. Under the pressure of American Seed Trade Association (ASTA) Federal Government repealed the free seed distribution programme in 1924. Ultimately, US Plant Patent Act of 1930 (PPA) granted property rights for privately developed plant varieties of asexually reproducing plants. These rights were extended to new and distinct asexually reproducing varieties for a period of seventeen years. This legislation departed from the US Patent law because living things could receive a plant patent under a more lenient standard than the traditional utility patent requirements of being useful, non-obvious and novel. The protection provided by PPA continued to encourage the privatization of seed industry, even though seeds were not included under the PPA. Advances in breeding technology provided the momentum for the 1970 Plant Variety Protection Act (PVPA).³ The PVPA provided protection for sexual reproduction in plants, including seed germination. With this Act, most commercial crops were now protected by patent laws for seventeen years but it was limited by two major exemptions: seed saving by farmers and for research purposes. Under the PVPA 'brown bag' exemption, farmers could continue to save, replant and resell protected seeds to other farmers.

The process of seed commodification was completed 5 years later when US Board of Patent Appeals and Interferences reversed the US Patent & Trademark Office (USPTO) decision in *Ex Parte Hibberd* case. It dealt with patenting of maize plant technologies that included seeds and allowed plant patents to be included under the broad category of utility patents.⁴ In *Hibberd*, the claimant made over 260 separate claims for a single item that included DNA sequences and genes. After *Hibberd*, the USPTO granted over 1800 expansive utility patents for germplasm. The common law right of saving seeds was further eroded by *Asgrow Seed v Winterboer*.⁵ Thus,

the seed saving exemption was limited to farmers for replanting in their own farms.

Another decision in a case of *JEM AG Supply v Pioneer Hi-Bred International*, Pioneer Hi-Bred, a large seed company, sued a small Iowa seed supply company, Farm Advantage, for violating patents on hybrid corn seed. Justice Thomas, writing for the majority, concluded that newly developed plant breeds are covered by utility patents and that neither the PPA nor the PVPA can limit the scope of a utility patent.⁶

System for Protection of Plant Breeder's Rights

An International Convention of the Union for the Protection of New Varieties of Plants; original in French 'Union Internationale Pour la Protection des Obtentions Vegetales' (UPOV) was signed in Paris in 1961 and it entered into force in 1968. The UPOV aimed to ensure protection of Plant Breeder's Rights (PBRs) by the grant of an exclusive right on the protected new plant variety on the basis of a set of uniform and clearly defined principles. The UPOV Act was revised in 1972, 1978 and 1991. The 1991 Act came into force in April 1998. Some countries have ratified the 1991 Act whereas other the 1978 Act.⁷ Under the UPOV a plant variety qualifies for protection when it meets the essential criteria, (i) distinctness, (ii) uniformity, (iii) stability, (iv) novelty (new in the commercial sense) and an unique and unambiguous denomination (name of the new variety). Application for its protection can be filed in any other UPOV member country.

As per the 1991 Act of UPOV, such protection is to be granted to new varieties of all genera and species of plants, for a period of 25 years for all trees and vines and for 20 years for all other plants. The protection granted for the new variety authorizes the breeder with the exclusive right to commercially exploit the variety by direct sale or by licensing to others for sale. Nevertheless, the UPOV Act, 1991 provides that the breeder of an Essentially Derived Variety (EDV) will have to get authorization of the breeder of the original variety for the commercial exploitation of the new variety.⁸ UPOV Act, 1991 deprives farmers of its right to use, reuse, their produce as seed and the right to dispose of their farm produce. Farmers rights were available to the farmers in the UPOV Act, 1978 but UPOV Act, 1991 deprives farmers of their rights to reuse their produce as a seed. Although farmers are broadly exempted from the breeders monopoly for non-commercial use of their

produce from a protected variety including propagating another crop from harvested material on their own farm.⁹

Though several countries are following the UPOV system, those joined UPOV before 1999 could join under the less strict UPOV Act, 1978 (e.g. China) but countries joining now have to do that under the UPOV Act, 1991 (e.g. Korea, Singapore). Most of the developing countries have opted for the development of their own *sui generis* system. India and Thailand have enacted a *sui generis* system of plant variety protection known as 'Protection of Plant Varieties and Farmers' Rights' (PPV&FR) Act, 2001¹⁰ and Plant Variety Protection (PVP) Act, 1999, respectively. Acts of both the countries are TRIPS compliant. Most of the PVP laws in Asia have taken the UPOV Act, 1978 as a basis and many have added articles to cater for farmers' rights (e.g. India), or for the protection of public and local varieties (e.g. Thailand). The Acts of both the countries grant plant breeders protection against unauthorized use of their new plant varieties and other plant varieties which are under cultivation. Regulation and criteria used in Thailand's PVP Act and Indian PPV&FR Act for registering new varieties in order to provide plant breeder's protection is in line with UPOV guidance. The varieties have to be distinct, uniform, stable and not exploited for a certain time before the date of application for registration.

International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) 2001, enforced on 29 June 2004, known as seed treaty, aims at the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of benefits arising out of their use, in harmony with CBD.¹¹ It recognizes the role of indigenous communities and farmers of all regions of the world in conservation and development of plant genetic resources. The treaty also recognizes the farmer's right to save, use, exchange and sell farm saved seeds/propagating materials. The Article 12 of the treaty says that contracting parties agree for facilitated access to plant genetic resources for food and agriculture under the multilateral system. Access shall be provided solely for the purpose of utilization and conservation for research breeding and training for food and agriculture but does not include chemical, pharmaceutical and/or other non food/feed industrial use. The recipient shall not claim any IP or other rights. However, access to plant genetic resources for food and agriculture protected by

intellectual and other property rights shall be consistent with the relevant international agreements. Article 13 of the treaty says that the benefits accruing therefrom shall be shared fairly and equitably. However, no explicit directive in context of IPR has been mentioned for the farmers whose genetic resources have been utilized.

Agricultural Biotechnology and Patenting

Biotechnology is the synergistic union of the biological sciences and the technologically based industrial arts. It means any technological application that uses biological system, living organisms or derivatives thereof to make or modify products or processes for specific use. Although TRIPS did not specifically mention biotechnology as patentable, but Article 27, particularly its definition of patent, and the international evolution of the term biotechnology may have resulted to the patentability of biotechnology. TRIPS says 'patents shall be available for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application' and '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'.

Biotechnology has enormous economic potential. There are vast benefits, more productive harvests, improved food quality and decreased dependence on environmentally dangerous chemicals and pesticides. Increased investments and unprecedented returns on these investments in agricultural biotechnology have brought issues of IP protection to the forefront. Genetic engineering is one example of a biotechnological technique by which new transgenic varieties are created. Genomics is coming in a big way and by unraveling the genetic sequence information one can manipulate the genomes at will and in future it is expected that it will help in enhancing the agricultural productivity. Patent laws in most of the countries were tuned for non-biological material. In biotechnology, the basic aspect is biological material or biological process or biological product with industrial application. The issue of whether living organisms, such as, microorganisms, plants or animals, or naturally occurring DNA substance, cloning and bioinformatics may constitute the subject of an invention is very controversial and nations have enacted legislations as per their needs and in conformity with TRIPS regulations.

Nevertheless, gene sequences, transformation procedures, expressed sequence tags, cloning of animals, procedures and products, bioinformatic tools, methods of bioinformatics have a direct relevance in enhancing agricultural productivity.

Status of Biotech Crops

The revolution in biotechnology and intellectual property protection began in the developed world. Will the benefits of agricultural biotechnology proliferate globally? In the international agricultural research community, the belief is that patents have been hindering access to important biotechnologies for developing countries. A survey report says that US patents adversely affect the ability of researchers to access and use specific gene traits, transformation tools, transformation marker systems and genetically modified germplasm for developing country purposes.¹² It has been reported that 'National agricultural research systems and CGIAR institutions could jeopardize their funding if they violated US patents to develop useful applications of biotechnology'. This 'violation' indicates that the reach of US patents in the non-profit sector can extend well beyond the geographic bounds of their legal, if not political, reality, and certainly beyond the scope of protection recognized by well informed private firms. There are stories of donations of intellectual property rights for technologies patented in Europe, USA and other industrialized countries, such as 'Golden rice', virus resistant potatoes, sweet potatoes and yams for use by farmers in developing countries. The example of Golden rice shows that patented technologies need not necessarily be a barrier. Golden rice production technology is governed by more than 70 patents of which 15 are process patents. Kryder reports that few or no relevant IPR existed in most of the developing countries among the top 15 importers or producers of rice.¹³ Innovators have generally not filed or unable to file for patent protection in developing countries. Also modern biotechnology has been applied predominantly at the pre-commercialization stages of research. Patent holders typically have little or no incentive to constrain this type of activity. Prior to commercialization, little or no recoverable damages are generated.

Agriculture related IPR Management

Presently, aims of publicly funded institutions such as universities, colleges, autonomous bodies and public sector undertakings are multifaceted which are not purely driven by economic considerations but by

considerations of social obligations, political objectives and will of a nation. This approach has helped in creating a pool of highly educated people and also building an inherent strength in research and development in agriculture related technologies as well as in basic industries. However, this system has bred complacency, which blunts the spirit of innovation and fire for being ahead of others.

Management of IPR requires capacity building in Asian countries as per their needs.¹⁵ Capacity building is never monolithic in nature but a multidimensional and complex activity. Capacity building should be in all the areas viz. IPR management, information and documentation, patent search and analysis, techno-legal drafting of patent applications, patent litigation, licensing, valuation and negotiating IP licensing deals. No exercise at a national level can succeed if all or most of the players from innovators to entrepreneurs, scientists to students, NGOs to farmers are not engaged in the activity. IPR are often considered synonym of patents or at best patents, trademark and copyrights. Sometimes people even use word 'patent' as a substitute for 'protect'. There is a need to adopt different means for awareness such as contact programmes, workshops, trainings, print media, bulletins, internet, videos, etc. Awareness by itself is of little use if the State does not create and provide suitable systems to enable scientists, technologists, industrialists, farmers to protect their rights. These means would be in terms of technical guidance, financial support, legal help and other facilitation steps. Capacity building has to be multifaceted at the national level, regional level and at multi-country level, which are in the same stages of development so as to remain ahead, or at par in the knowledge race.

Government departments and various funding agencies for R&D must spell out in their policy decision who will be the owner of IP generated by their funding and how to move about for commercialization. The universities, industries whether public or private, must have their IPR policies. The development of skills and competence to manage IPRs and to leverage its influence should be given a major thrust. This area calls for significant technological insights and legal expertise and should be handled differently from the present, and with high priority. Efforts should be made for synergism between industry and scientific research by creating autonomous technology transfer organization as an

associate organization of universities and national laboratories to facilitate the transfer of know-how generated to industry.

Technology Transfer: Licensing and Commercialization

Licensing, the right granted by an owner of an asset to another to use that asset while continuing to retain ownership of that asset, is an important way of creating value with these assets. Licensing creates an income source, disseminates the technology to a wider group of users and potential developers and acts as a catalyst for further development and commercialization. The word 'license' simply means permission granted by the owner of the intellectual property rights to another to use it on agreed terms and conditions, for a defined purpose, in a defined territory and for an agreed period of time. Licensing of intellectual property is often considered in three broad categories, namely, technology licenses, publishing and entertainment licenses, and trademark and merchandising licenses. Licensing of inventions related to biotechnology come under technology licenses. Protected plant variety licensing will be altogether a different one where the buyers are poor farmers. For agricultural biotechnology, companies that continue to provide better products and services at lower price will be competitive, profitable and maintain an edge in a market economy that is globalized, fast moving and demanding.

The traditional drivers of economic growth: land, labour and capital, are no longer sufficient to provide necessary competitive advantage that makes the difference between companies that are otherwise very similar to one another. The answer lies in new or improved technology. Given the intangible character of technology, its use by one does not detract from its use by another. In other words, it can be used simultaneously by many users for the same or different purposes without impacting in any way on its quality or functionality. Therefore, the owner of technology could potentially license the use of his technology to as many licensees as he wishes, maximizing the earning potential of his technology constrained only by the terms of the agreements that he enters into with the potential licensees. In a sense, one technology could become the basis for a whole range of related or unrelated products and services made by one or many enterprises in a potentially large number of locations in one or many countries.

In selling or buying rights to the intellectual property in technology (where the legal transaction is called an 'assignment'), the ownership rights for that technology pass from seller to buyer and it is a one-time activity. The technology is bought or sold for an agreed price. There will be only a few continuing obligations in the relationship between the seller (assignor) and the buyer (assignee). Frequently, such transactions involve a one-time transfer of funds, but financial compensation might also be entirely or partially deferred and may depend on many factors or contingencies (such as the success of the commercialization). A technology owner, who has no experience in bringing a product to market and who is not interested in being involved in such day-to-day matters as technology at work, may consider that the ideal solution would be to find a buyer for the technology and to complete the whole transaction at one time. In contrast, a licensing agreement transfers from the licensor to licensee the right to use the intellectual property in the technology and to make, use and sell products embodying the technology, in a specified manner for a specific time in a specified region. In other words, the licensor continues to have the proprietary rights over the technology and has only given a defined right to the use of that technology. In the field of biotechnology where transfer of technology alone may not be sufficient to practice the invention, the right to use (but not own) certain tangible property, usually biological material, may also be transferred through a patent license agreement. Licensing, therefore, entails very different legal and practical consequences to those of a sale or assignment. It also serves very different business purposes. If these purposes are not relevant for the parties then licensing is not the strategy to adopt.¹⁶

Due diligence is a necessary step before embarking on any business transaction, which may include agreements on a multitude of other issues that generally linked to, but may separate from the agreement to license technology. The technology may be protected by one or more patents, copyright, trademark or trade secret. All of these issues may merit different agreements or perhaps constitute different parts of a single agreement. In these situations patent information on technological activity must be gathered from all the sources because technical solution to the problem may be found in a totally different technical field. If the technology is not protected and is in public domain then there is no

issue of licensing of IPRs. If the technology has been protected then validity in the country and its maintenance must be looked for. It is worth mentioning that only some 5 million patents are in force out of 42 million patent documents. On an average for any one invention a patent application is filed in only four countries, which means there is a good possibility that a particular invention protected by a patent in one country may not be protected in many, most or all countries of interest to a prospective licensee.¹⁶

In the agricultural research sector, public research institutions have the responsibility to see research through to commercialization in all but the few lucrative markets that attract the bulk of private-sector attention. Negative effects of IPR on non-profit 'commercialization' of innovations have until now been most apparent in the agricultural sector, and in non-profit institutions such as medical centres where clinical researchers wish to use patented diagnostic tools to treat patients, for a fee, as part of their research programme. It is the effect of IPR on the mission of these integrated enterprises, rather than on the environment perceived by the bench scientist, that is the key issue for the prospects for biotechnology innovations for agriculture in developing countries.¹⁴

The number of biotechnology innovations developed by public and non-profit agriculture which have reached commercialization point are small. In USA and some other developed countries, there is some evidence that university research projects designed to produce new crops with modern biotechnology have been shut down because of refusal of IPR-holders to permit commercialization of varieties incorporating their intellectual property. For example, researchers from the University of California are using a patented promoter of Life Science Corporation in the development of tomato variety genetically engineered to express endoglucanase gene to retard softening and improved shelf life characteristics.¹⁷ In another example, development of fungus-resistant strawberry at the University of California was blocked by lack of access to the necessary *Agrobacterium* transformation technologies. In the development of herbicide tolerant barley, the owner of the relevant herbicide tolerance patent refused to negotiate commercialization rights, and indeed refused to discuss developing the germplasm itself.¹⁴ Likewise, similar reports of impediments to commercialization, in the form of

refusal of freedom to operate, have been encountered in development of herbicide tolerant turf grass at the University of Michigan¹⁸ and herbicide tolerant lupin in Australia.¹⁹ The main point of these examples is not that they would all have been commercially successful given freedom to operate, but that freedom to operate was in these cases a serious barrier to a system of non-profit innovation that has responsibility for development to the point where they were made available to farmers in the field. Why do these happen? Wright and Pardey had analysed that in economic terms, the 'transaction costs' must have been too high or perhaps the public-sector negotiators had unrealistic expectations regarding private sector largesse. It might be that the owner of key IPR is concerned with protecting itself from liability or from damage to its reputation due to misuse beyond its control. In some cases, the expected financial gains, given the size of the market, might have been less than the cost in time and money to the IPR owner (public or private) of making and enforcing an agreement or perhaps the patent holder saw no reason to help out a potential competitor, for little financial return, in a market that could one day be of financial interest to the patentee.¹⁴

There are evidences from surveys and case studies that there is a strong prima facie case for significant blocking effect of intellectual property claims in public/non-profit agricultural research that yields commercially attractive results. There have been cases in which US patents, later invalidated, have been used to hold up commercialization of products from developing countries. For example, yellow bean (enola bean) patented by a Colorado firm demanding licenses from importers of similar Mexican beans, Del Monte Fresh Produce warning against working on Pineapple plant material, though variety in question was not patented.¹⁴ These examples show that, even before TRIPS had its full impact, confused perceptions of geographic scope of patents, its validity etc. may have a plausible discouraging effect.

When the rights to existing patents are needed to practice a technology, the dominant and overlapping patents claims must be examined because it can affect the right to use downstream innovations. For example, Monsanto claim to the plant transformation method using *Agrobacterium* means that a previous patent US 6,369,298, a patent assigned to Pioneer Hi-Bred International blocks all patents in which the claims specifically depend on this transformation method.

Valuation of Technology

Unlike tangible property, which has well recognized means of establishing a value and thus a price, there is no easy way to determine the value of intangibles. However, as with any other transaction, a price must be established. Valuation of technology is a difficult exercise and often a subjective one. Valuing a technology becomes important when the potential licensee has recognized the need for new and most appropriate technology, identified the potential licensor and decided that a license arrangement is the most appropriate business strategy. Broadly, the worth of an IP/technology will be derived from the likely benefits that would accrue to its end-users, and the price will be determined from the extent of the benefits that the R & D agencies would deem to appropriate. Several methods can be used to value a technology.¹⁶ A valuation may be subjective and depends on the data that is used in the valuation model, the valuations derived from each of the criteria will not be the same. One of the approaches is cost approach. The licensor's investment in the technology is represented by those costs associated with developing, protecting and commercializing the technology. The goal should be for both the licensor and licensee to have a realistic understanding of the licensor's investment and its relevance to the payments to be made to the licensor by the licensee. Income approach is another strategy for valuation of technology. Successful technology licensing means, for the licensee, increased profits because of the use of IPR protected technology. Some licensing professionals start their valuation calculations with a rule of thumb, according to which the licensor should receive around one quarter to one third of the benefits accruing to the licensee. Third approach for valuation of technology is market approach. It follows that comparable market transactions are a convenient and useful way of determining the value of asset in anticipation of negotiating a purchase or sale. An early survey by the Biotechnology Licensing Committee of the Licensing Executives Society (LES) reported that following ranges for non-exclusive licenses²⁰ were considered representative for:

- Research reagents (e.g. expression vector, cell culture), 1-5% of net sales.
- Diagnostic products (e.g. monoclonal antibodies, DNA probes), 1-5% of net sales.
- Therapeutic products (e.g. monoclonal antibodies), 5-10% of net sales.
- Vaccines, 5-10% of net sales.

- Animal health products, 3-6% of net sales.
- Plant/agriculture products, 3-5% of net sales.

Usefulness of market approach is often very limited. Generalizations, surveys and industry norms at least provide a starting point. What can be much more useful, however is knowledge of a comparable licensing arrangement in the same industry which could provide another basis or check for a particular valuation of a particular technology.

The Indian Council of Agricultural Research (ICAR), New Delhi, has released guidelines on IP Management and suggested following factors to be considered for agricultural technologies concerning SMEs and farmers with small and medium holdings in determining/assessing the worth of an IP/technology/know how and in fixing its price.²¹

- Expected adoption level and expected benefits accruing to the end-users. For high adoption rate and/or per unit benefit, higher will be the price e.g. the price of tomato seed may be higher than that of watermelon or amaranth seeds. Similarly, price of a rice hybrid gaining popularity over a large area could be higher than a conventional rice variety.
- Proportion of the benefits appropriated by the commercializing agency, where applicable: Higher are the benefits appropriated, higher will be the price, e.g., ready-mix baby food or other nutraceuticals.
- Cost associated with up scaling/commercialization of IP: Higher is the cost of up scaling, lower will be the price, e.g., those plant based agro-chemicals or bio-agents that essentially need up-scaling to develop commercial product.
- Impact on innovation market: Lower price may be charged for the IP/technology which can increase competitiveness of the innovation market, e.g., indigenously adapted, modified laser leveler.
- End-users and impacts of IP: Low price may be charged for IP benefiting disadvantaged social groups (poor people, women, tribals, etc.) or increasing sustainability of natural resources, or protecting environment, e.g., varieties of underutilized crops and minor millets, and small tools for agricultural operations and harvesting/threshing like tubular maize sheller.

Institutions may take several different price norms in the market as basis for fixing the price of their IP. They may also consider fixing price cluster of technologies (e.g., hybrids, bio fertilizers, machinery, etc.) rather than fixing individual cases; with a provision for different methodologies for different clusters. The institutions, instead of fixing one-time price for the IP, can consider reviewing the price periodically; say once in three years, e.g., for breeder seed of vegetable and flower crops, nevertheless, if affirmative, this clause may be incorporated in the licensing contract/ agreement.²¹

Licensing Agreement

Every license agreement is unique, reflecting the particular needs and expectations of the licensor and licensee. An infinite variety of agreements are possible, limited only by the needs of the parties and by the parameters of the relevant laws and regulations. However, certain issues are fundamental to the success of an agreement,

- (i) License is the outcome of a business strategy and is a business relationship. Both the licensor and licensee must carefully consider whether entering into one or more licensing agreements fits into the business plan of the company, whether the expected revenues would be sufficient to justify the costs involved in engaging licensing activity and whether the financial terms make sense to both the parties.
- (ii) A license agreement is a contract which means that legal requirements for a binding and enforceable contract are necessary.
- (iii) The subject matter is intellectual property, which the licensor grants the licensee the right to use. Therefore, without intellectual property, there is no technology licensing.
- (iv) For effectively using the licensed technology a licensee has to access other technologies owned by another, which are proprietary.

In these situations the licensee is obliged to obtain the rights to use the technology(ies) from the owner of the intellectual property right through a licensing agreement, which may be on a royalty free basis or negotiated on the basis of fair, reasonable and non-discriminatory terms.

Many license agreements involve a combination of one or more types of intellectual property. For example, patents and know-how license agreement, use of a trademark along with rights to make, use,

sell, distribute and/or import a patented invention, a license may not mention a specific patent by number, but rather provide the specifications of a product and grant all IPRs necessary to manufacture and sell such a product. An agreement can include additional rights for carrying out further research or development or the provision of technical assistance.²¹

Subject matter is the first section of the license agreement. It may include creations such as inventions, confidential information, the creativity expressed, business identifiers, etc. If license agreement involves computer software, then there may be specific clauses specifying the permitted use or application and requiring confidentiality to be maintained. Prior to and during negotiations for a licensing agreement the licensor may have to disclose information which is considered confidential and should not be used or disclosed by the potential licensee. For example in the development of hybrid variety parental lines involved, male sterile lines, source of male sterility, etc. In the development of transgenic variety the concentration of growth regulators for regeneration of an explant, transformation protocol, use of specific promoter sequence or codon modification in the gene sequence for better expression of a gene. For the purpose of protecting the licensor's rights the following agreements can be signed prior to negotiations:

- (i) Confidentiality or secrecy agreement.
- (ii) Letters of intent or memoranda of understanding.
- (iii) Standstill and related agreements.
- (iv) Research agreement.

Clauses on confidentiality must also be included in the final licensing agreement.

The second section of a license agreement relates to the extent of the licensed rights. It refers to the scope of the right, being exclusive, sole or non-exclusive, and the geographic territory for which the license is granted. For agricultural technologies non-exclusive license is the preferred one. Licensor can maintain a better control over the technology and also by virtue of the fact that several licensees are using and exploiting the technology and it does not affect the livelihood and also remains competitive. The idea is that these can lead to wider adoption of technologies; maximizing research benefits to farmers and other end users. There may be flexibility in fixing the license fee. It may be low (e.g. Rs 2 lakhs) in first instance which may increase (to Rs 3-4 lakhs) in the

second instance in case of higher demand or *vice versa*. There is less likelihood that a single firm will have adequate capacity and marketing infrastructure to cover the entire country, including the remote and far-flung areas. Therefore, non-exclusive licenses by government agencies with respect to agricultural technologies on regional/area bases will enhance the local availability of the technology and reduce the transportation cost and thereby market-price. When the license is non-exclusive, the licensee may wish to include most favoured licensee clause in the agreement.

ICAR guidelines on IP Management have enumerated certain situations where exclusive license can be issued:

- (i) commercialization in foreign countries,
- (ii) difficult areas offering low incentives;
- (iii) commercialization requiring high development cost,
- (iv) exclusive license should cover only one territory while it is non-exclusive in another, etc.

The exclusivity may be limited to a field of use or period of time or linked to achievement of milestones.²¹ The duration, whether limited or indefinite, for which such licenses are issued, will depend upon market conditions. A specific sub-licensing clause shall be negotiated and incorporated particularly in the exclusive licenses, which may require other contracting parties to share a part of the license fee and/or royalty from the sub-licenses that they may enter into. In case a client insists on the exclusive license, (i) it should be negotiated at a high license fee and/or royalty offer, and (ii) negotiations should be made for offering such license for a limited period (3 or 5 years) after the expiry of which re-negotiations should re-occur to account for current demand/scope of IP.

Sometimes in an exclusive license, the licensee wishes to have the right to grant sub-licenses in his territory, which needs to be specifically negotiated and stated in the agreement and prior approval of licensor is required. Non-exclusive licensees are generally not granted the right to grant sub-licenses since a potential sub-licensee could seek a license directly from the licensor.

Agreement for joint commercialization of IP can be entered into by institutions in cases where (i) a close scientific supervision is required, (ii) commercialization is done using the institute resources; (iii)

technology is extended under scientist entrepreneurship; or (iv) any other such situation.

For commercialization of technology technical assistance in the form of documentation, data and expertise is transferred depending upon the technology. An important factor in commercial and financial considerations is the valuation of technology. Payments to the licensor for the acquisition and use of technology are usually classified as lump sums and royalties and many agreements contain both the types.

Asian countries economies are dependent upon agriculture and governments must consider the following with respect to commercialization of its plant varieties.²¹

- (i) Advance breeding material or parental lines shall not be transferred/ licensed on exclusive basis but these should be first registered with Bureaus of Plant Genetic Resources in their respective countries or at Asian regional bureaus before any transfer/licensing deal is to be negotiated/ entered into.
- (ii) Breeder seed: To maintain the quality of seed supplied to farmers either one time transfer or recurrent supply of breeder seed of every licensed variety will be a 'must' and the licensor institutions should ensure as per the terms of the licensing contract/agreement with the licensees.
- (iii) The license fee and/or sale price of breeder seed and royalty either on a fixed basis or through negotiations with the licensee, as appropriate, may be fixed for each variety considering the cost of seeking and maintaining the plant variety right, cost of production, handling and supply of breeder seed and other institutional costs on equitable basis.
- (ii) Financial support from the government for commercialization of indigenous technologies.
- (iii) Exemption from drug price control order—The production of bulk drugs based on indigenous R&D may be exempted from drug price control for a certain period of time from the date of commencement of commercial production.
- (iv) Weighted tax deduction on R&D expenditure—R&D expenditure should be available to companies engaged in the business of biotechnology, agricultural technologies, manufacture of agrochemicals, etc. The expenditure on scientific research shall include expenditure incurred on clinical trials, field trials, obtaining approvals from the regulatory authority of state/province and central governments and for filing a patent application.
- (v) Accelerated depreciation allowance—Depreciation allowance at a higher rate should be made available to the industries, which are involved in the manufacture of goods or products based on indigenous technologies.
- (vi) Tax holiday to R&D companies for some years, which are involved in the development of agri-technologies.
- (vii) Income tax relief on R&D expenditure.
- (viii) Tax deduction for sponsoring research.

Conclusion

IPR have been created to ensure protection against unfair trade practices. The driving force behind the formation of TRIPS was to curb international abuse of patented technology, infringement, and misappropriations. Patent policies have historically been enacted to further national interests. Developed countries like USA and European Union have taken a long time of 150 years to establish their patent regime and from free seed distribution by public sector to private sector. Thus, developing countries in Asia must establish their own IPR regime, which is compatible with the framework of their constitution. The potential influence of patents and other IP on agricultural research in developing countries is changing rapidly, to the degree that countries are achieving effective implementation of TRIPS and subsequent agreements. Researchers in these economically poorer but genetic resources rich parts

Incentives for Innovation related Researchers and Enterprises by Government Funding Agencies

An innovative industry can gain competitive advantage in the market if it develops the necessary expertise and skills in developing and manufacturing new products, which are patented. The following incentives would be extremely useful in promoting the culture of innovation and intellectual protection in industries and academic and R&D institutions.¹⁵

- (i) Excise duty waiver on patented products for a certain period of time from the date of commencement of commercial production.

of the world will continue to be responsible for the bulk agricultural research on non lucrative but staple and important livelihood crops. They have to confront the challenges of obtaining the necessary freedom to operate for bringing the products to market. Genetically rich Asian countries should not remain spectator to the changing world scenario, they should form an alliance for cooperation regarding DUS testing, sharing of data, buying/borrowing of test reports, use of reference varieties from other countries as is done by UPOV countries to save time and expenditure and more so utilize intellectual capital at the earliest for their population. Developing countries should be aware of the need for access to expertise in law, economics and management of intellectual property protection. Developing countries need to make educational investments required to establish domestic capacity so as to withstand the challenges of knowledge economy.

References

- 1 FAOSTAT data 2005, <http://www.faostat.org>.
- 2 Stein H, Intellectual property and genetically modified seeds: The United States, trade, and the developing world, *North Western Journal of Technology & Intellectual Property*, 3 (2) (2005) 161-173.
- 3 Plant Variety Protection Act, 7 USC § 2321, 2000.
- 4 *Ex Parte Hibberd*, 227 USPQ (BNA) 443 (1985).
- 5 *Asgrow Seed v Winterboer*, 513 US 179, 1995.
- 6 *JEM Ag Supply v Pioneer Hi-Bred International*, 534 US 124, 127, 2001.
- 7 UPOV: States Party to the Convention, <http://www.upov.org/en/pdf>.
- 8 Chawla H S, Patenting of biological material and biotechnology, *Journal of Intellectual Property Rights*, 10 (1) (2005) 44-51.
- 9 Kochhar S, System perspective for IPR protection in the plant kingdom, *Journal of Intellectual Property Rights*, 9 (4) (2004) 342-355.
- 10 The Protection of Plant Varieties and Farmers' Rights Act, 2001 and Rules (Universal Law Publishing Co, Delhi), 2002.
- 11 The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFRA), 2001, <http://www.fao.org/Legal/Treaties/html>.
- 12 Taylor M R and Cayford J, The US Patent system and developing country access to biotechnology: Does the balance need adjusting? Discussion paper, *Resources for the Future*, Washington, DC 2002.
- 13 Kryder D R, Kowalski S P and Krattiger A F, The intellectual and technical property components of Provitamin A Rice (Golden Rice): A preliminary Freedom-to-Operate Review, ISAAA Brief No. 20, 2000.
- 14 Wright B D and Pardey P G, Changing intellectual property regimes: Implications for developing country agriculture, *International Journal of Technology and Globalization*, 2 (1/2) (2006) 93-114.
- 15 Saha R, Management of intellectual property rights in India, paper presented at Workshop on IP Management in Public-Private Partnership, Manesar and Bangalore, 2006, 9-35.
- 16 Exchanging Value—Negotiating Technology Licenses, A Training Manual by World Intellectual Property Organization and International Trade Centre, WIPO Publication No. 906(E), 2005.
- 17 Wright B D, Public germplasm development at a crossroads: biotechnology and intellectual property, *California Agriculture*, 52 (6) (1998) 8–13.
- 18 Erbsch F H, Challenges of plant protection: How a semi-public agricultural research institution protects its new plant varieties and markets them, presented at the workshop on The Impact on Research and Development of *Sui Generis* Approaches to Plant Variety Protection of Rice in Developing Countries, International Rice Research Institute, Los Baños, The Philippines, 2000.
- 19 Lindner R, Prospects for public plant breeding in a small country, paper presented at the International Consortium on Agricultural Biotechnology Research Conference, Rome, 17-19th June 1999.
- 20 Hylton D and Bradin D, Intellectual Property of Biotech Companies: A Valuation Perspective, 2002, <http://faculty.fuqua.duke.edu/courses/mba/2001-2002>.
- 21 ICAR Guidelines for Intellectual Property Management and Technology Transfer/ Commercialization, ICAR, New Delhi, 2006.