

BICnews

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INTELLECTUAL PROPERTY RIGHTS or IPRs...

Biotechnology has an essential proprietary nature. Unlike the agricultural sciences in the past, which have come out of publicly supported labs, recent inventions are locked into patents and other private intellectual property rights (IPRs). This edition of BICnews focuses on IPR and other related issues.



WHAT ARE IPRs?

According to the World Trade Organisation, intellectual property rights (IPRs) are the rights given to people over the creations of their minds. They include trademarks, patents, copyrights, trade secrets, as well as plant variety protection. Of this, patents and plant variety protection are the most relevant forms of intellectual property protection in plant breeding. These rights are granted by state authority for certain products of intellectual effort and ingenuity.

A patent is an exclusive right given to an inventor to exclude all others from

making, using, selling or offering to sell the invention in the country that granted the patent right, and importing it into that country. In agricultural biotechnology, patents may cover, for example, plant transformation methods, vectors, genes, etc. and in countries that allow patenting of higher life forms, transgenic plants or animals.

Patents are the most critical form of protection for agricultural biotechnology and are considered to be the most powerful in the IP system. Patents have a specific life-span,

generally about 20 years, and are country specific.

Plant Breeder's Right (PBRs) are used to protect new varieties of plants by giving exclusive commercial rights for about 20-25 years to market a new variety or its reproductive material. The variety must be novel, distinct, uniform, and stable. This protection prevents anyone from growing or selling the variety without the owner's permission. Exceptions may be made, however, for both research and use of seed saved by a farmer for replanting.



Why IPRs are important

IPRs are necessary evils. Without patents, much innovative research would not be done. Biotechnology industry is characterized by high R&D and regulatory costs and high risk. Public and private sectors must typically invest several million dollars to discover a novel gene and to learn how to use it. An assurance that the discoverers will have a protected right to recoup this investment is essential. IPRs free man's creativity and give him protection for the fruits of his creativity. They allow the inventor to restrict the use of the intellectual property, i.e., no one is allowed to use, manufacture, grow, sell or offer to sell the invention without permission. IPR also promotes innovation to occur at any level in any part of an organization.

Photo courtesy of NASA

IPRS AND DEVELOPING COUNTRIES

Patents, plant breeder's rights and trademarks are awarded by national governments, and the protection is valid only in countries in which they are issued. Thus, to obtain protection in several countries, rights must be applied for and awarded in each. On the other hand, copyright and trade secrets are not country specific. At present, many key technologies used in the development of agri-biotech products appear to be unprotected in developing countries. For example, patents for the most widely used promoter, the CaMV 35S promoter, have been granted only in the United States and Europe (and the only pending application is in Japan). Thus, there are no IP restrictions in developing countries on the use of this tool in research and development at present.

Furthermore, anyone is free to use technologies in crops developed, produced, and consumed in countries where the technology is not subject to local IP protection. IP problems, however, may arise when these crops are subsequently exported to countries in which the technologies are protected by IPRs. The development time should also be taken into consideration since patents might be issued in the country by the time the product

is developed. It is therefore necessary for scientists in developing countries to be aware of the IP issues and develop strategic plans in handling these IP concerns.

Photo courtesy of USDA



New plant variety can be protected by Plant Breeder's Right

PROMOTING TRANSFER OF AGRI-BIOTECH TO DEVELOPING COUNTRIES

Crops grown for subsistence use in developing countries and the technologies that are used to develop such crops are clearly of little commercial interest to the private sector. Thus, donating proprietary technologies to develop such crops is a

realistic possibility, and in fact is already happening. However, developing country scientists must remember that technology transfer involves a lot more than simply signing a license or a material transfer agreement for a product. Both

technology donor and recipient must be aware of the IPR issues involved in the technology and there will often be a need for partnerships in which there is mutual trust among all parties.

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WHAT CAN YOU PATENT?

Which biotech products can or cannot be patented is a delicate issue. By definition, patents cannot be granted for substances that exist in nature or traditional knowledge taken as it is, as these do not fulfill the criterion of novelty. However, the following are considered novel and are patentable:

- New or newly isolated nucleic acids and proteins
- Plasmids/phages/microorganisms bearing nucleic acid constructs
- Genetically modified plants, seeds, plant parts, organisms and animals
- Methods of preparation/manipulation/treatment
- Protein/peptide therapeutics
- Cell-based therapies (stem cells, T-cells)
- Experimental tools - transgenic animals, cell lines
- Gene probes for diseased state (diagnostic and prognostics) e.g. cancer gene mutation
- Known nucleic acids and proteins to which useful alterations have been made
- New uses
- Nucleic acid constructs
- Vaccines
- Tissue engineering
- Gene therapies/gene medicines
- Assays for drug discovery
- Antibodies

IPR -CONTROVERSIES

To many environmental and social activists, IPRs embody the evil of appropriating nature and living things for profit. Hence IPRs have been the centre of many controversies, often due to the lack of understanding of the issues involved.

Among the issues are IPR infringement on traditional knowledge or indigenous communities' ability to use traditional products which have been patented.

Another controversial issue is the sharing of benefits derived from cash-poor but natural resource-rich nations with cash-rich resource-poor countries. Unfair extraction of natural resources from biodiversity-rich countries have led to charges of biopiracy, where beneficial and useful products were extracted and patented without the host country's knowledge or consent. Several developing countries in the tropics have succeeded in fostering positive exchanges between developed and developing countries in biodiversity development using novel mechanisms.

The following are two case studies of the facts behind these controversies.

The Neem Controversy

Neem (*Azadirachta indica*) is a tree from India and other parts of South and Southeast Asia. Its natural medicinal pesticide and fertilizer properties has attracted a considerable amount of international interest.

Many neem products have received patents. But the most controversial patents are those granted to the US company WR Grace & Co for extraction and storage processes.

They are:

• **US patent No. 4946681** granted in 1990 for improving the storage stability of neem seed extracts containing azadirachtin (a substance obtained from *Azadirachta* (neem)). (The inventor is named as James F Walter of Ashton, Maryland.)

• **US patent 5124349**, 1994 for storage of stable insecticidal composition

comprising neem seed extract. The major contribution was increasing the shelf-life stability of azadirachtin solution. (Four people are named as the inventors.)

The WR Grace patents provoked a national outcry in India. Under pressure from the NGOs, the Indian government filed a complaint to the US Patent Office accusing WR Grace of copying an Indian invention. However, in the end, the government withdrew its complaint as it realized that the US-based company had in fact created a new invention for the neem extraction process, and the patent was not based on traditional knowledge. Only these specific newly invented processes are covered by the patents. Farmers always have and will continue to be free to use neem in traditional ways.

INBIO, Costa Rica

IPRs can be employed efficiently and successfully to benefit both the research and local community. One such case is the work of The Instituto Nacional de Biodiversidad (INBIO) in Costa Rica. INBio's Bioprospecting Program uses information generated by the national biodiversity inventory to carry out research that adds value and knowledge to existing resources.

INBio's strategy has been focused on developing a diversified portfolio of bioprospecting research agreements promoting innovation, learning, and an increase in national scientific capacity.

Each agreement has its corresponding work plan and research budget that establishes a 10% donation to the Ministerio del Ambiente y Energía (MINAE) (Ministry of the Environment and Energy), which helps cover direct biodiversity conservation costs. Furthermore, it contributes to increasing services, species identification, sample collection and preparation, collection records, information management, training, management, etc. If other benefits are derived from the process due to the

discovery of a successful product, 50 % of INBio's royalties will be donated to the Sistema Nacional de Areas de Conservación (National System of Conservation Areas) through the Ministerio del Ambiente y Energía (MINAE), and the rest will be invested in continuing the process and other INBio activities.

In prospecting, the processes are executed in conjunction with research centers, universities, and national and international companies. This network of associations makes state-of-the-art technologies available and provides the opportunity to rapidly and efficiently train Costa Rican scientists as well as laboratory and field personnel. At the same time, this type of collaboration generates financial resources that are used to fund the country's conservation activities, and also other research projects oriented towards satisfying the demands of users who contribute to the country's sustainable development.



Promoting transfer of Agri-Biotech to developing countries

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Developing countries frequently lack the required IP management capacity and resources to perform product clearance analyses and evaluations that facilitate the legitimate import, use and/or export of technologically advanced products. Thus, to help transfer of appropriate agri-biotech to developing countries, capacity building in IPR management is vital from both the donor and the recipient side.

The International Service for the Acquisition of Agri-biotech Applications (ISAAA), a not for profit international organisation that delivers the benefits of new agricultural biotechnologies to the poor in developing countries, has brokered several technology transfer applications from institutions in developed countries to developing countries. ISAAA has facilitated training fellowships for scientists to learn from donor institutions, who shared both technology and training.

In addition to the technical training and

development, ISAAA also conducts training workshops in intellectual property and technology transfer management providing scientists with essential tools to conduct licensing negotiations for the use of patented technologies used to develop their products. These negotiations are important as the products would eventually be commercialised and may then be subject to IPR regulations. Capacity building in IPR management might involve the following:

- s Educate research staff and research administrators on the basic principles of IPR management.
- s Use different patent databases as well as scientific databases as information sources.
- s Remain aware of the complexity of germ-plasm issues.

- s Stress the importance of good laboratory records.
- s Document what comes in and goes out of the lab.
- s Establish clear lines of responsibility for negotiating, reviewing and signing Material Transfer Agreements (MTAs) and licenses.
- s Manage and organize licenses and MTAs and the various documents and correspondence associated with them.



Photo courtesy of ISAAA

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GLOSSARY

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