Lecture 7
International Organisations'positions & Intellectual Property Rights on GM foods

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International Scientific Community

Areas of Negotiations

in International Fora

on the Safe Use of GM Organisms

- **A. Food Safety**
- **B. Labelling**
- **C. Environmental Safety**

International Fora dealing with the safe use of Genetically Modified Organisms

A. Food Safety

- *Codex Alimentarius Commission (CAC)*

Task Force on Foods Derived from Biotechnology (CCFBT)

- *OECD :* Task Force for the Safety of Novel Foods and Feeds

B. Labelling

Codex Alimentarius Commission (CAC)

Committee on Food Labelling (CCFL)

International Fora dealing with the safe use of Genetically Modified Organisms

- **C. Environmental Safety**

- ***Convention on Biological Diversity (CBD)***

CBD
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United Nations Environment Programme

- ***OECD***

Working Group on the Harmonisation of Regulatory Oversight in Biotechnology

OECD

- ***WHO/EURO***

European Centre for Environment and Health

Agricultural Biotechnology Issues

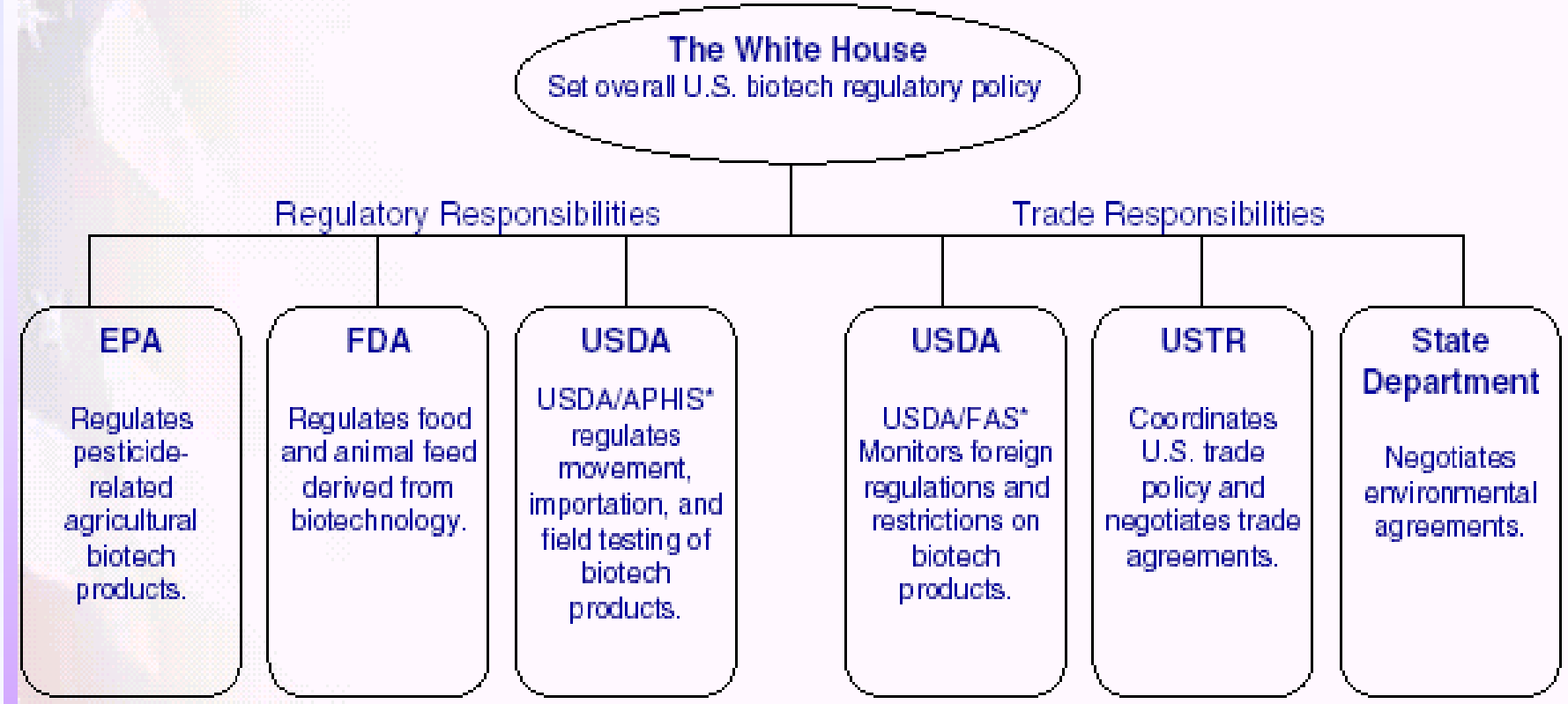
Discussions on biotechnology are taking place in Codex Alimentarius and the Biosafety Protocol. U.S. seeks to ensure guidelines set by these organizations are consistent with WTO disciplines.

Codex: Sets international food safety standards recognized under the WTO Sanitary and Phytosanitary (SPS) agreement. Active discussions related to biotech are taking place in several Codex committees. USDA manages overall U.S. participation in Codex. USDA and FDA lead U.S. delegations to Codex committees.

Biosafety Protocol: Environmental agreement under the U.N. Convention on Biological Diversity, covering the transshipment and use of living modified organisms. Protocol takes effect upon ratification by 50 countries. The United States has not ratified the Convention nor signed the Protocol. State Department represented U.S. interests at Biosafety Protocol negotiations.

WTO: Provides institutional framework for multilateral trade. Trade disciplines established under the SPS and Technical Barriers to Trade (TBT) agreements and the General Agreement on Tariffs and Trade (GATT) are related to biotech trade issues. USTR represents U.S. interests at WTO.

Agricultural Biotechnology and the U.S. Government



*APHIS: Animal and Plant Health Inspection Service; FAS: Foreign Agricultural Service.

USDA, FDA, EPA, State, and USTR all play a role in agricultural biotechnology trade.

International Developments Affecting Trade: Approval Process

ISSUE

Some foreign countries have not approved for marketing certain biotech products that have been approved in the United States. Resistance to new product approvals in the EU has affected U.S. exports and biotech trade in other parts of the world.

U.S. POSITION

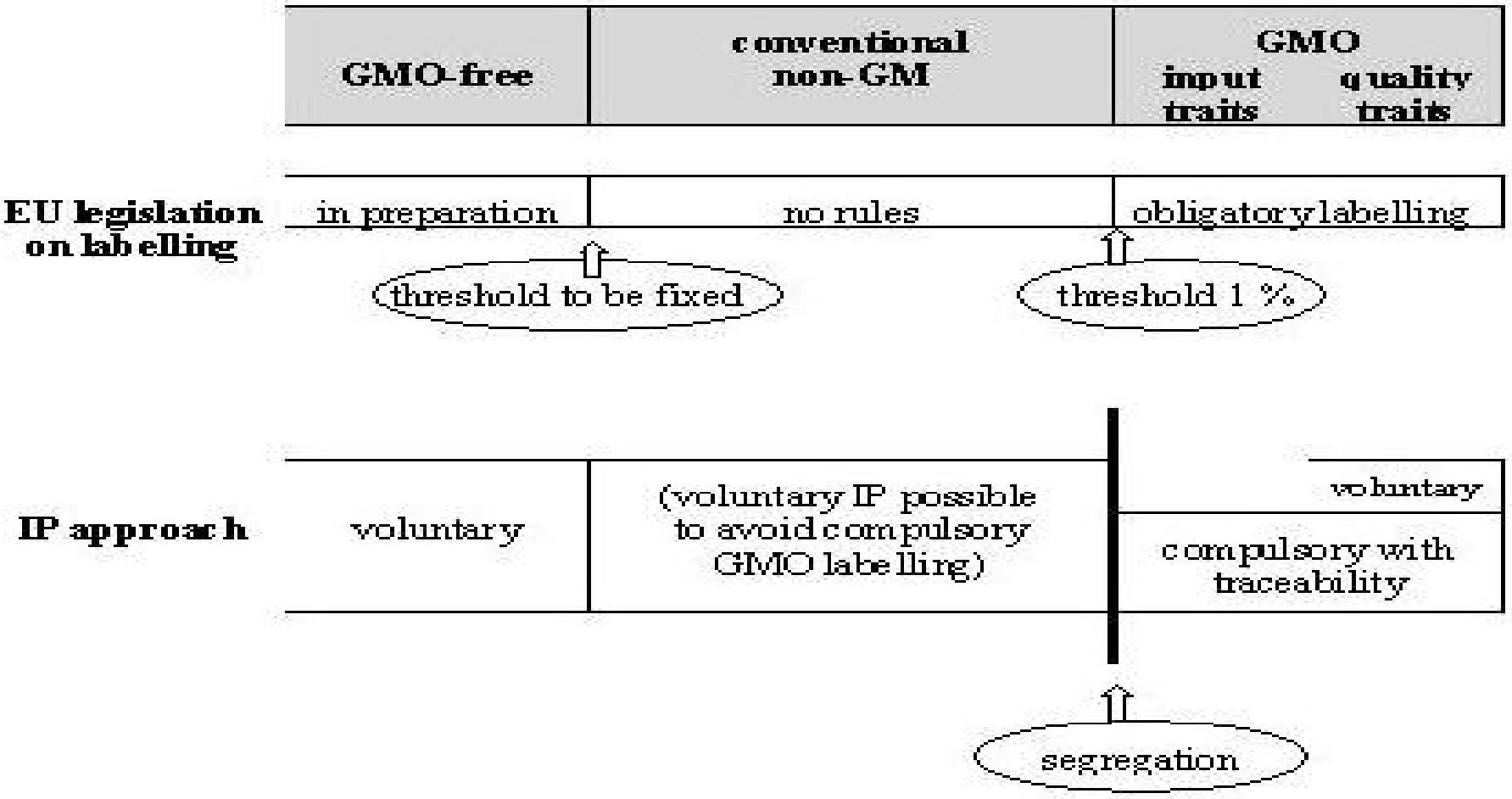
Product approval regulations must be clear, transparent, timely, science-based, and predictable. U.S. regulators have concluded that approved biotech foods on the market now are as safe as their conventional counterparts.

Ongoing Developments

- European Commission efforts to resume new biotech product approvals effectively blocked by six member states
- EU pushing for "precautionary principle" in various international organizations, including Codex and Biosafety Protocol
- Codex Ad Hoc Task Force on Biotechnology developing guidelines for analyzing risks of biotech foods

Photo source: USDA.

Issues in Labelling Requirements



IP: “Identity Preservation”

International Developments Affecting Trade: Labeling Requirements

ISSUE

Strict labeling requirements could impact U.S. exports because they could reduce consumer demand and increase costs.

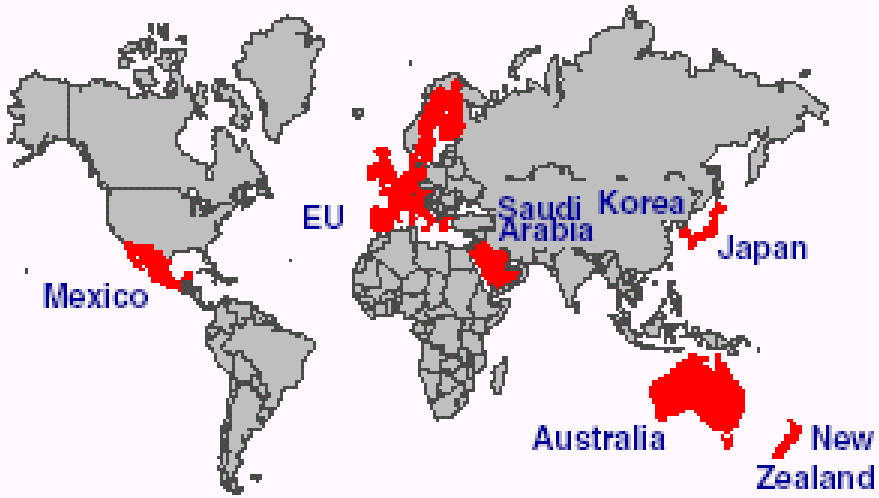
U.S. POSITION

Mandatory labeling should only be implemented when the new biotech product represents a significant change from the conventional variety or poses a threat to consumer safety. FDA has recently proposed voluntary labeling guidelines.

Ongoing Developments

- Various countries have taken action to enact mandatory labeling requirements (shaded areas on map)
- Codex Labeling Committee developing mandatory labeling guidelines
- Codex Ad Hoc Task Force on Animal Feeding considering biotech labeling for feed

Potential Markets Affected



International Developments Affecting Trade: Traceability Requirements

ISSUE

EU is pushing for traceability requirements to track biotech products throughout the production and distribution chains. However, the implementation cost to producers may be prohibitive.

U.S. POSITION

A costly and onerous traceability system is not justified because biotech products are not inherently less safe than other foods. U.S. officials have opposed traceability requirements in Codex.

Ongoing Developments

- EU developing new regulations on traceability and labeling for food and feed in conjunction with revised directive on biotech product approvals
- Codex Ad Hoc Task Force on Biotechnology divided on traceability guidelines
- Biosafety Protocol negotiations on documentation requirements may address traceability issue for bulk shipments

Photo source: USDA.

1998	October	EU approvals for agricultural biotech products come to a halt
1999	Nov/Dec	Ministerial Conference of World Trade Organization in Seattle -- U.S. and Canada propose a working group on biotechnology
2000	January	Agreement reached on Biosafety Protocol in Montreal
	March	1st meeting of Codex Ad Hoc Task Force on Biotech in Japan
	April	Codex Committee on General Principles meeting in France on risk analysis
	May	Codex Committee on Food Labeling meeting in Canada
	September	StarLink corn found in taco shells sold in the United States; delegation of U.S. agricultural and biotech companies visits Geneva to encourage discussions on biotech in WTO
	December	1st meeting of the interim intergovernmental committee for the Biosafety Protocol in France
2001	March	2nd meeting of Codex Ad Hoc Task Force on Biotech; 2nd meeting of Codex Ad Hoc Task Force on Animal Feeding; special session of WTO agriculture negotiations
	April	Codex Committee on General Principles meeting in France on risk analysis; labeling guidelines in Japan take effect
	May	Codex Committee on Food Labeling meeting in Canada
	June	G-8 Economic Summit; U.S.-EU Summit; special session of WTO agriculture negotiations
	July	Labeling guidelines in Korea take effect
	October	2nd meeting of the interim intergovernmental committee for the Biosafety Protocol in Canada
	November	WTO Ministerial in Qatar
2002	Summer	Mid-term report of Codex Ad Hoc Task Force on Biotech due
2003	Summer	Final reports of Codex Ad Hoc Task Forces on Biotech and Animal Feeding due

INTERNATIONAL LEGAL ISSUES

World Trade Organization's legal framework regarding trade in GM products include:

- **1.The Sanitary and Phytosanitary (SPS) Agreement,**
- **2. The Agreement on Technical Barriers to Trade (TBT) of the WTO**
- **3. The multilateral environmental agreement: The Convention on Biological Diversity, particularly its Cartagena Protocol on Biosafety.**

Stress in this area: Growing tensions between the need for fairness in international trade and the need to respond to domestic concerns about food and environmental safety.

1. The Sanitary and Phytosanitary Agreement

- The Sanitary and Phytosanitary Agreement, which concerns food safety and animal and plant health, says that WTO members have “the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health.” But those measures must be applied “only to the extent necessary to protect human, animal or plant life or health,” and must be “based on scientific principles.”
- The agreement also states that WTO members must “ensure that their SPS measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members,”
- Furthermore, those measures “shall not be applied in a manner which would constitute a disguised restriction on international trade.”
- The agreement suggests the use of international standards (CODEX)when possible.

2. The Agreement on Technical Barriers to Trade (TBT)

Currently, a review of available scientific evidence indicates that **GM foods have <u>not been found to be unsafe</u>** — **a double negative** that highlights the difficulties of balancing consumer concerns, science, and international law. In the absence of agreed-upon international standards:

- Some countries invoke the **"precautionary principle"** that allows them to set standards provisionally where relevant scientific evidence is lacking, although they are supposed to do the necessary research within a reasonable period of time.

- Other countries argue that the precautionary principle is being abused **in order to protect less efficient domestic producers from foreign competition, thus setting TBT's (Technical Barriers to Trade)**

The challenge lies in adequately addressing **both safety concerns** and **fairness in trade.**

3. The Convention on Biological Diversity, and Cartagena Protocol on Biosafety.

Due to extensive efforts of the international fora, in January 2000, the Cartagena Biosafety Protocol to the Convention on Biological Diversity was adopted , which (though not still in full force) intends to lay the foundation for a global system for assessing the impact of GMO's on biodiversity and exchanging information and to contribute to facilitating Worldwide understanding of the risk/benefit assessment of biotechnology.

Risk/benefit Assessment of GM foods and Market uncertainties:

Since the “risk-benefit analysis” of GM foods has not yet been properly communicated to consumers worldwide, especially those in developed countries react to GM foods.

If consumers decide that they do not want to consume GM goods, even regardless of the science, markets will have to adjust to satisfy their demands.

If these negative reactions persist, markets will adjust to different scenarios of prohibition, market segmentation, and product differentiation.

These market adjustments in developed countries will, in turn, have an impact on developing countries.

QUESTIONS CONCERNING THE ECONOMICS OF GM TRADE

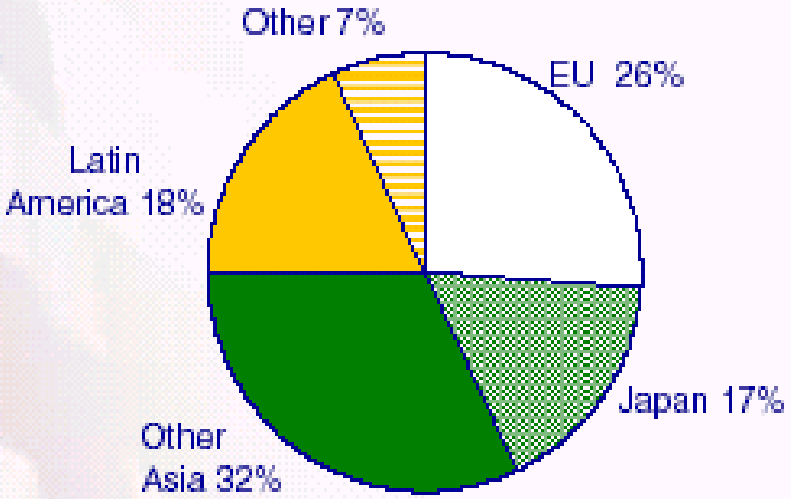
- What will happen if consumers in developed countries refuse to consume GM commodities?
- Can world markets adjust to a complete segmentation of the markets for GM and non-GM commodities?
- Will developing countries still benefit from these new technologies if world markets are completely segmented and if, in addition, some developed countries refuse to adopt the new technologies at all?

Major Exports Potentially Affected By Foreign Regulations

Corn and soy exports are most threatened by foreign regulations on biotech products. Because the U.S. grain handling system comingles biotech and conventional products, restrictions on biotech varieties affect nearly all exports of these commodities.

U.S. Soy and Corn Export Markets

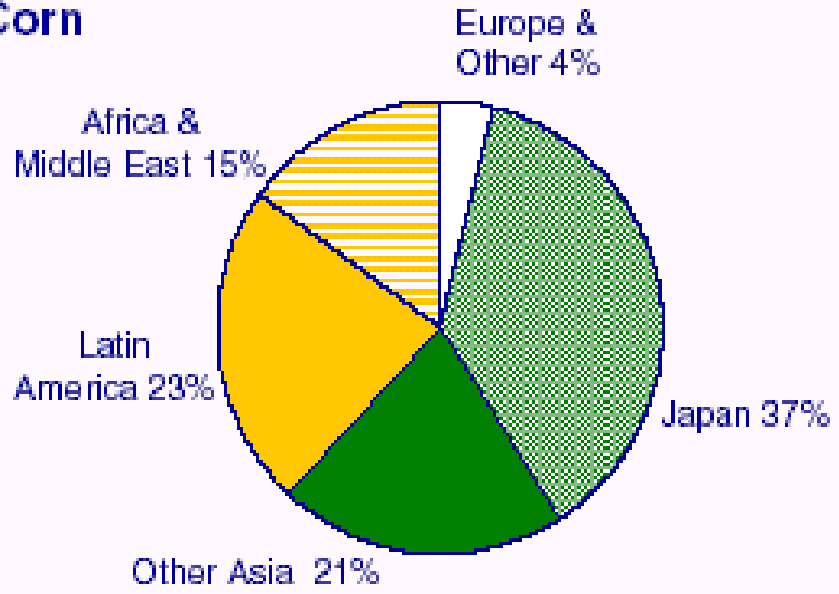
Soybeans



Total 1999 exports: $4.5 billion

Exports as percent of production: 29%

Corn



Total 1999 exports: $4.9 billion

Exports as percent of production: 18%

GM and Non-GM Soybeans and Maize

- In the world model, the two primary GM crops, soybeans and maize, are specified as either GM or non-GM. This GM and non-GM split is maintained throughout the entire processing chain: GM livestock and GM food processing industries use only GM intermediate inputs; likewise, non-GM livestock and non-GM food processing industries use only non-GM intermediate inputs.

- The underlying assumptions in the model are that developing countries will adopt the new technologies, to varying degrees, and that countries such as the United States will continue to use them, while Europe and Japan will not adopt them and will restrict their demand for such goods.

GM Trade

The empirical results indicate that global markets are able to adjust to this segregation in the sense that:

- **non-GM exports are diverted to the GM-intolerant regions,**
- **while GM-exports are diverted to the indifferent regions.**

Price differentials reflect cost differences in production and distribution with consumers who are indifferent benefiting from access to cheaper goods they find to be equivalent to non-GM goods, and producers benefiting from the higher productivity of GM crops.

The market results are analogous to what one would expect from increased consumer preferences in developed countries for organic foods. Such foods are more expensive to produce and command higher prices in the market.

Intellectual Property Rights

Intellectual property rights

- Intellectual property refers to products of the mind. Inventions, computer programs, publications, videotapes, and music are all examples of intellectual property.
- “Intellectual property rights” afford a time-limited legal protection to artistic, scientific, technological, or economic products. Copyrights, trademarks, design patents, utility patents, plant patents, plant breeders' rights, and trade secret laws are some of the ways of protecting intellectual property rights.
- The type of intellectual property to be protected and the legal and administrative system of the country where the right is being sought affect the extent of rights, such as the scope of the protection and the geographical limits to and duration of the rights.

Intellectual Property Protection

- In plant breeding, patents and plant breeders' rights have generally been the most important forms of intellectual property protection.

- As the biotechnological revolution unfolds, however, copyrights are becoming more important because the databases that hold information about plant genes can often be copyrighted. Such copyrights do not, however, affect trade in products developed using the protected information.
- U.S. state "trade secret laws" have been used to protect in-house breeding materials such as the inbred lines of maize used as parents of hybrids, but these laws do not protect against independent discovery or reverse engineering of products by their purchasers.

Patents afford stronger protection than “trade secret law” for innovation embodied in products.

Trademarks are used for the protection of brand names of biotechnologies, such as Monsanto's Roundup ReadyJ technology or Aventis's Liberty7 and LibertyLink7 technologies. Trademarks only protect the names and other symbols denoting products or technologies, not the technologies themselves.

PATENTS

- To be patentable, an invention must satisfy the criteria of: **novelty, nonobviousness, and utility or industrial application.**
- The **patent right** is generally considered the **most powerful** tool in the intellectual property system, enabling the patent holder to **exclude all others from making, using, selling the invention** in the country that granted the patent right or importing it into that country, if it is made elsewhere, for as long as the patent remains valid.
- In addition, an inventor is required to describe the invention to the **public in a manner sufficiently clear** and complete for the invention to be reproduced by another person skilled in the art.

PATENTS

- While many member countries of the World Trade Organization are still in the process of implementing a protection system for plants, the United States and Europe have led the way in allowing utility patents for plants, particularly for transgenic plants.

- In **1985**, the U.S. Patent Office Board of Appeals ruled that asexually and sexually propagated seeds, plants, and tissue culture **could be protected** by utility patents. More recently, the European Patent Office has held that transgenic methods and plants are not per se unpatentable.

PLANT BREEDERS' RIGHTS

- **Plant breeders' rights (PBRs), or plant variety protection, are a form of intellectual property protection for plants offered in most developed countries and a growing number of developing countries.**

- **The holder of a plant breeder's right has a legal monopoly over commercialization of that variety for a prescribed length of time, allowing the recovery of the cost of breeding commercially valuable new plant varieties.**

- **While countries differ in how they implement PBRs, the laws usually grant *protection to varieties that are novel, distinct, uniform, and stable*. Thus, the variety must not have been previously sold, be clearly distinguishable from previous varieties, be uniform, and breed true to type.**

PLANT BREEDERS' RIGHTS

- Although the details of protection vary from country to country, in general, the sale, reproduction, import, and export of new varieties of plants are encompassed. Exceptions may be made, however, for research, breeding of new varieties, and use of seed saved by a farmer for replanting.
- Moreover, in some countries, if a protected variety is used as the basis for a transgenic plant, the latter is covered by the plant breeder's right if it constitutes a variety "essentially derived" from the protected variety.

CONTRACTUAL AND TECHNOLOGICAL PROPRIETARY TOOLS

In addition to the legal protection afforded by patents and plant breeders' rights, contractual provisions may be used to extend or establish intellectual property rights. Such contracts include :

- Material transfer agreements between technology developers and third parties, which limit the transfer and use of materials such as vectors, genes, and plants developed by the transferor;
- Bag label contracts between the manufacturer and the buyer of seed, for example, which limit further uses of purchased material that would otherwise be allowable;
- Technology use agreements between technology suppliers and farmers, which typically control the right to plant a given seed on a specific area of land for a certain period of time; and
- Licenses between patent or property holder and licensee, which are negotiated grants of some or all of the holder's rights, such as allowing the use and sale of the technology.

OTHER TECHNICAL PROPRIETARY TOOLS

There are a number of genetic modification technologies that impose technical limits on farmers' use of seeds from their harvest to replant or to sell for replanting:

- The most common is production of hybrid crops that generally have a lower yield through loss of "hybrid vigor" if replanted.
- Modern alternatives include genetic use restriction technologies (GURT) that confer sterility on replanted seeds 'popularly dubbed terminator technologies' and
- Others allow reproduction but prevent expression of proprietary traits until the plant is treated with a specific chemical activator.

ADVANTAGES of PATENTING: THE RIGHTS TO RESEARCH

- The principal public policy rationale for intellectual property rights (IPRs) is that they provide direct socially beneficial incentives to innovate as well as facilitate further innovation by mandating public disclosure of the patented technology. When individuals or organizations know that legal protection will enable them to recoup their research investments, they have a stronger incentive to pursue such innovations.

- Countries with strong traditions of innovation have long histories of IPRs — **the United Kingdom awarded its first patent in 1449**, and **the authority for the U.S. patent system is present in that country's Constitution (1788)**.

ADVANTAGES of PATENTING:

- In the absence of protection, disclosed new ideas and information are entirely in the public domain, and an innovator's attempts to recoup investment or to profit commercially from an innovation may fail because of imitation. Knowing this, prospective inventors may underinvest in R&D, or inventors may exploit their inventions in secret.

- In addition, by clarifying rights to new ideas, intellectual property rights help reduce the costs that would otherwise be required to determine ownership of rights.

ADVANTAGES of PATENTING:

Intellectual property rights systems **require** **that the inventors and researchers seeking these rights must disclose the new knowledge they have obtained**. As new ideas are disseminated through publication, licensing, or other means, this information **stimulates further rounds of innovation** and technological advances.

Inherent in intellectual protection is a **tension** between **the goal of providing incentives for innovation** and **the goal of allowing innovators to build upon one another's work.** The broader the monopoly rights conferred, the larger the potential threat to the freedom to operate — the ability to practice or use an innovation.

Though there is no international patent, international treaties and organizations do play an important role in intellectual property rights: they make it easier to extend protection to multiple countries and provide a uniform, minimal set of laws and standards that apply to all subscribing countries.

Currently, in the fields of agriculture and agricultural biotechnology, the type and scope of protection varies greatly from country to country, especially between developed and developing countries.

THE CASE OF DEVELOPING COUNTRIES

Patents and other intellectual property rights are awarded by national governments, and the protection conferred extends only as far as the geographic boundaries of the country in which the right is awarded.

Therefore, agricultural researchers in many developing countries are freer to make use of innovations protected in the developed countries. This is because there is no such thing as an "international patent right." A patent or other intellectual property right awarded in, for example, the United States does not a priori confer property rights in the rest of the world. Thus, to obtain patent protection in several countries, innovators must apply for and gain rights in each.

Thus , anyone is free to make, use, or sell whatever technology or knowledge is available for crops in countries where that technology is not subject to intellectual property protection, irrespective of whether the crop is grown for subsistence or commercial use or whether the technology is protected elsewhere.

The Case of Less-developed Countries

- The recent " vitamin A rice innovation ("golden rice") reportedly requires permission to practice over 70 patent rights. The well-publicized donations by major corporations of their intellectual property relevant to vitamin A rice left a strong impression that the exercise of large numbers of crucial patent rights was being handed in favor of the poor in developing countries. In fact, in some major rice-consuming countries, there are no valid relevant patents, and in most, there are very few.
- Similarly, the well-publicized donations of virus-resistant technology for some noncommercial potato varieties in Mexico and for sweet potato in Africa apparently do not involve any patents relevant in the target countries.
- Finally, a survey reported widespread use of protected intellectual property by the centers of the CGIAR(Consultative Group on International Agricultural Research), in many cases without formal authorization from the patentees.

HOW PRODUCTION AND TRADE PATTERNS AFFECT INTELLECTUAL PROPERTY RIGHTS

Crop breeders in the developing world are free to produce crops as long as the inputs and processes used and the crop varieties grown are not protected under local intellectual property laws. But those crops cannot be legally exported to countries where they fall under intellectual property protection. In such cases the importer, not the breeder, may be infringing on intellectual property rights.

A recent IFPRI study looked at **production and trade data for 15 of the crops most important to research agencies operating in developing economies: rice, wheat, maize, soybeans, cassava, coconut, groundnuts, bananas, beans, potatoes, sorghum, lentils, millet, barley, and chickpeas.** As a group, the developing countries accounted for an average of **more than 65 percent** of the world's production of sorghum, beans, and lentils. For the rest of the 15 crops, they accounted for **more than 90 percent** of world production (and for quite a few of these crops, more than 98 percent). **The majority of these crops are never traded across international borders**

Of the 15 crops, soybeans, coconuts, bananas, lentils, and beans are the only ones for which more than 10 percent of developing-country production is exported. Just two crops (**soybeans and bananas) account for 64 percent by value of developing-country crop exports to the developed countries,** and just four countries (Argentina, Brazil, Costa Rica, and Ecuador) account for 42 percent of such trade in these two crops.

When exports of rice to developed countries (mostly from Thailand) and coconuts (mostly from the Philippines) are added into the soybean and banana exports, these four crops account for 80 percent of the total exports from developing to developed countries. Of these four crops, only rice and coconuts are staples in the exporting countries.

Freedom to operate

Freedom to operate depends upon specific circumstances. An investigation of the intellectual property rights show that these rights are mainly held in, and are therefore primarily relevant to, rich-country jurisdictions. Thus, for most of the crops that matter for food security in poor countries, researchers' freedom to operate is not obsructed — much of the needed technology is not regulated by intellectual property rights in developing countries and little of the developing-country production gets shipped into developed-countries where intellectual property rights may prevail.

This does not mean, however, that freedom to operate is not a problem for developing-country research on export-oriented cash crops such as horticultural products, tropical beverages like coffee or cocoa, or dessert bananas.

PROBLEMS of DEVELOPING COUNTRIES and FUTURE CONCERNS

Many developing countries lack the scientific skills to effectively access the rapidly advancing complex modern biotechnologies, whether they are protected by patents or not. As a matter of fact, most are not protected in these developing countries. Failure to invest in developing the domestic expertise needed to evaluate, access, and regulate the new technologies is currently a far greater constraint than freedom to operate.

Moving forward in the 21st Century, the intellectual property landscape will be altered by the Trade-Related Aspects of Intellectual Property (TRIPs) agreement, which introduced minimum standards for intellectual property rights for new technologies by which all members of the World Trade Organization must abide.

TRIPs requires that member states allow patents for inventions but with certain exceptions. The precise nature of these exceptions has yet to be resolved. **Members are not required to allow plants to be patented, but they are required to protect plant varieties, either through patents or through a sui generis system (such as plant-breeder rights), or through a combination of both systems**.

As developing countries come into compliance with the intellectual property rights provisions of the TRIPs agreement, the implementations of those provisions — both domestically and in export markets — will affect researchers' freedom to operate in future technologies of research and development.

Concluding Remarks

Over one-half of agricultural R&D in rich countries was done by private firms. Much of the know-how to improve crop varieties now reside in these corporations.

Institutional arrangements to facilitate effective partnerships between the public and private sectors in agricultural R&D are just beginning to emerge. These arrangements could help enable the sharing of expertise along with the products and processes to do the breeding , and, may be, help direct some private research toward poor peoples' crops.

To direct such private-public research toward the poorer parts of agriculture in developing countries, and to tap intellectual property on behalf of the world's poor could have profound long-term global development consequences.

Major Reference:

- **“Are Intellectual Property Rights Stifling Agricultural Biotechnology In Developing Countries?”**

  by Philip G. Pardey, Brian D. Wright, and Carol Nottenburg