Chapter 14

Biotechnology Regulation

Biotechnology Regulation

- Coordinated Framework for Regulation of Biotechnology
- Basic federal policy for regulating the development and introduction of products derived from biotechnology
- A key principle of the framework is that genetically engineered products would continue to be regulated according to their characteristics and unique features, and not according to their method of production

APHIS

- Animal and Plant Health Inspection Service
- Protect agriculture product from pests and disease in USA
- Provide permits for developing and field testing genetically engineered plants
- Provide safeguards
- Permitting process of field trials

Environmental Protection Agency (EPA)

- Responsibility ranged from protecting endangered species to establishing emission standards of car
- Regulating pesticides and herbicides
- Issued Experimental Use Permit (EUP)
  - Eg. pesticidal protein and plant
  - No unreasonable adverse effect
  - Must meet same standard as chemical pesticide used

Criteria for permit testing

- Produce unexpected genetic effects
- Have higher than normal levels of toxicants
- Has altered level of essential nutrients
- Chemical composition different from normal existing products

- The product contain protein that cause allergic
- Adversely impact current clinically useful antibiotics
- Plants developed to make specialty nonfood substance: Engineered plants to produce pharamceutical products
- Issue specific to animal feed: the product composition (nutrient and toxins) is differently from similar products used for feed

Field trials and EPA

- Ice minus bacteria to protect plant (strawberry) in freezing conditions
- Potential treat of Bt corn and monarch butterfly

Food and Drug Administration (FDA)

- Safe for food and the medicine were safe and effective
- As consultant for new product or additive
- Advice on testing practices
- Focus on whatever the new product has any unexpected undesirable effect
- Grant generally-recognized as safe (GRAS) such as Chymosin in cheese & Flav Savr tomato

Good Laboratory Practice (GLP) and Good Clinical Practice (GCP)

- To govern clinical study of pharmaceutical product
- GLP require testing laboratories follow the SOP, have adequate facilities, provide animal care, record data properly and conduct valid toxicity test
- GCP protect the rights and safety of human research participants and ensure the clinical experiments

Labeling the biotechnology product

- Contain GMO
- Food labels must include ingredients information and any claims by manufacturer
- Special label for safety such as protein and traces of peanut (risk of allergic to consumer)
- Eg:Use of BST in milk production

Fluvirin Failure

- Vaccine of flu
- Found bacterial contamination, *Serratia* sp in some lots of the vaccine
- FDA sent 20 listed violation by the Chiron Company at 2004 and closed
- FDA encourage drug company to:
  - Do clinical trial: doses versus patient data, side effects etc

Patents

- Exclusive right granted to anyone who invents any new, useful, and non-obvious process, machine, article of manufacture, or composition of matter, or any new and useful improvement thereof, and claims that right in a formal patent application

- A patent application must include one or more claims defining the invention which must be new, non-obvious, and useful or industrially applicable
- The exclusive right granted to a patentee in most countries is the right to prevent others from making, using, selling, or distributing the patented invention without permission

Type of patents

- 1. Utility
  - The most common
  - The most difficult
  - Includes the functional characteristics of machines, electronic device, manufacturing process, chemical compounds, composition of medical treatment and manufactured articles
  - How to make and use the invention include drawing
  - Duration of patents : 20 years

- 2. Design
  - Protect the shape as well as the ornamental or artistic features of an articles
  - Eg; unique shape of bottle or grill of the auto mobile
  - Duration: 14 years
- 3. Plant
  - Protect the invention or the discovery of a distinct and new plant variety via asexual reproductive methods
  - Duration: 20 years

Important of patent

- Exclusive right to the inventors
- The patentee discloses the invention and provide information that expand the existing technical knowledge base
- Others can not imitate. Can be use for improvement
- Provide effective incentive foe creativity and invention : commercialize and profits
- Strong incentives for continuous R&D

Enforcement

- Patents can generally only be enforced through civil lawsuits
- Typically, the patent owner will seek monetary compensation for past infringement, and will seek an injuction prohibiting the defendant from engaging in future acts of infringement.

Basic requirement for patents

- 1. Novel
- 2. Nonobvious
- 3. Must have some utility

Value of patents in Biotechnology industry

- To invent in the first place
- To disclose the invention once made
- To invest the sums necessary to experiment, produce and market the invention
- To design around and improve upon earlier patents
- For biotechnology industries, strong pattern means strong business

- Patents provide incentives for economically efficient R&D
- A study conducted annually by the IPTS shows that the 2,000 largest global companies invested more than 430 billion euros in 2008 in their R&D departments
- If the investments can be considered as inputs of R&D, patents are the outputs

- Patents facilitate and encourage disclosure of innovations into the public domain for common good
- Ifinventors did not have the legal protection of patents, in many cases, they would prefer or tend to keep their inventions secret

Guidelines for patenting

- 1. Keep good records
  - Keep detail notes
  - Sign, dated and witness by individual who is not directly involved in the research
  - Note should contain all the conceptual idea and supportive data

  - 2. Do your homework
  - Monitor through the trade literature, potential competitor, publish patent and issued patent

Patent DNA sequencing

- A product must have some utility
- Patent on gene sequence must be specific
- Specific utility: A researchers must know exactly what the DNA sequences does, define precisely
- Substantial utility: A real-world use
- Credible utility: The researchers must convince the patent office