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INTERNATIONAL INTELLECTUAL PROPERTY TRAINING INSTITUTE
KOREAN INTELLECTUAL PROPERTY OFFICE

WORLD INTELLECTUAL PROPERTY ORGANIZATION
GENEVA

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WIPO ASIAN REGIONAL TRAINING COURSE FOR INTELLECTUAL PROPERTY TRAINERS AND INSTRUCTORS

organized by
the World Intellectual Property Organization (WIPO)

in cooperation with
the International Intellectual Property Training Institute (IIPTI)

and
the Korean Intellectual Property Office (KIPO)

and with the assistance of
the Japan Patent Office (JPO)

Daeduk, Daejeon, Republic of Korea, March 18 to 22, 2002

INTELLECTUAL PROPERTY (IP) TODAY; RECENT DEVELOPMENTS, CURRENT AND EMERGING ISSUES

INTELLECTUAL PROPERTY (IP) PROTECTION AND BIOTECHNOLOGY

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Intellectual Property (IP) Protection and Biotechnology

WIPO Asian Regional Training Course for
Trainers and Instructors of Intellectual Property
Daejeon, Republic of Korea,
March 18 -22, 2002

Mi-Chung Ahn, Ph.D.
Korean Intellectual Property Office (KIPO)

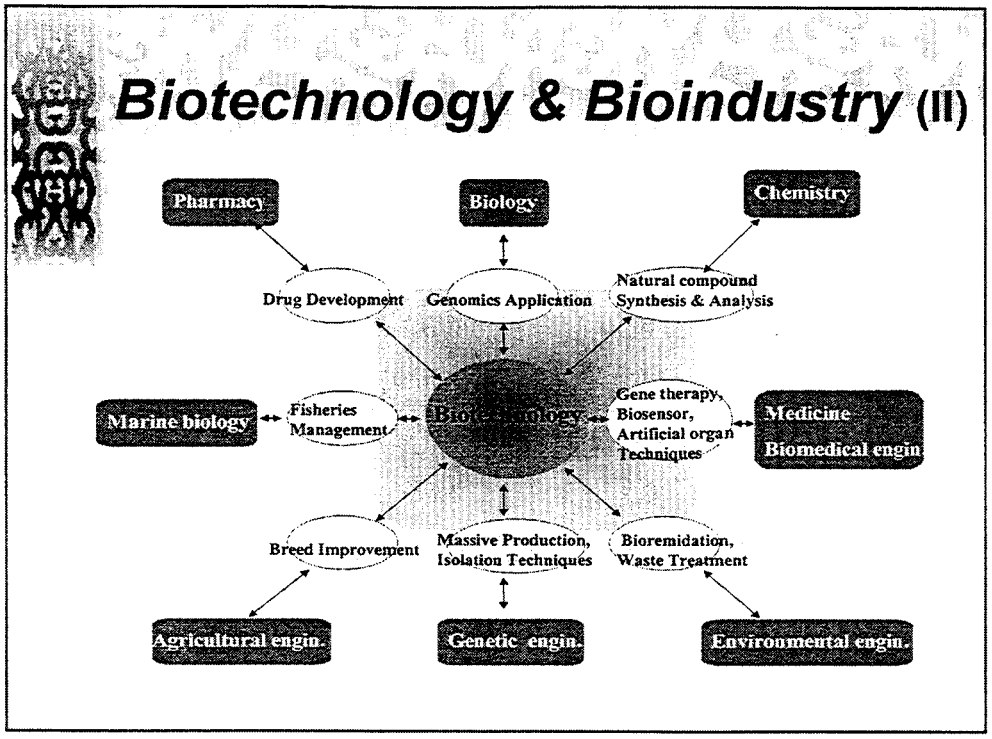
Biotechnology & Bioindustry (I)

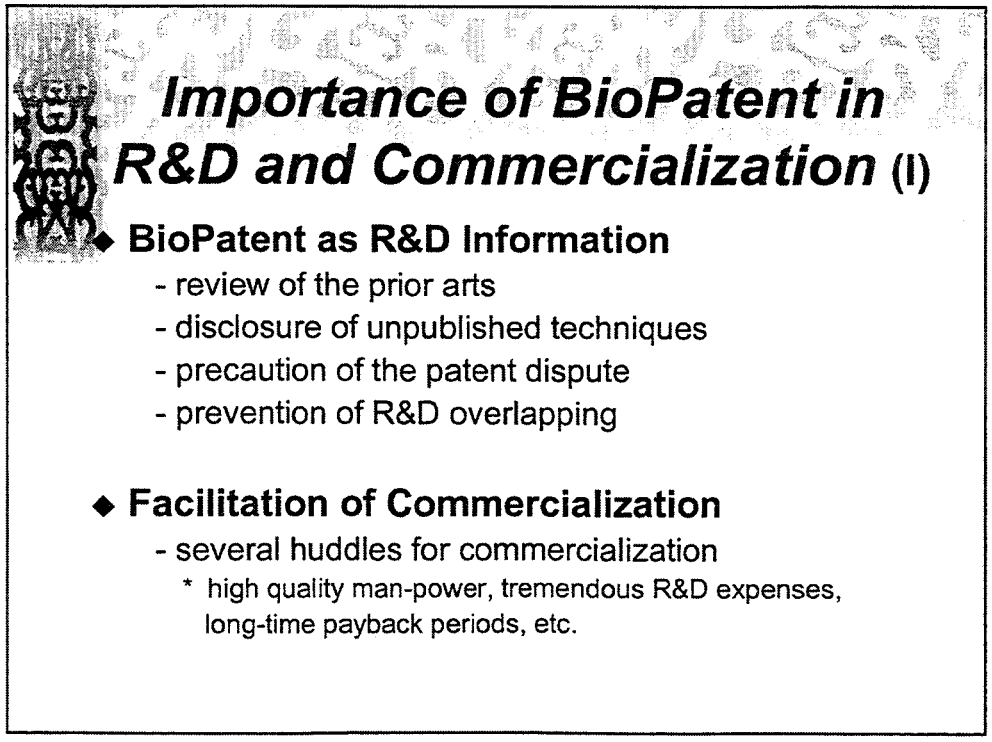
- **What is Biotechnology ?**

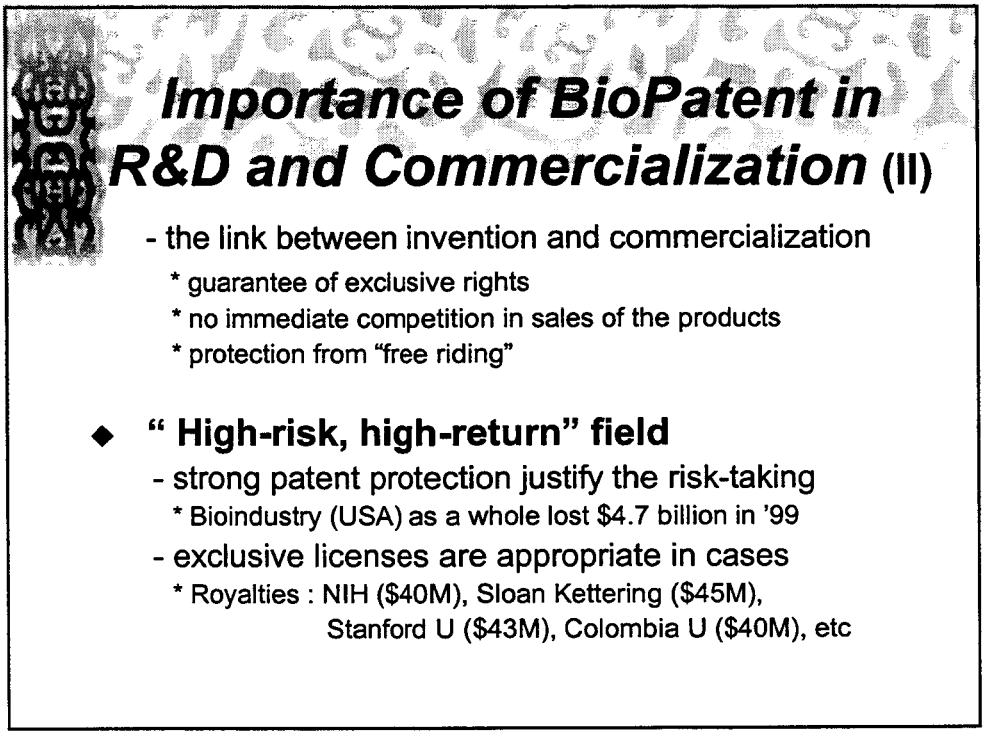
"bio" : the use of biological process
"technology": to solve problems or make useful products

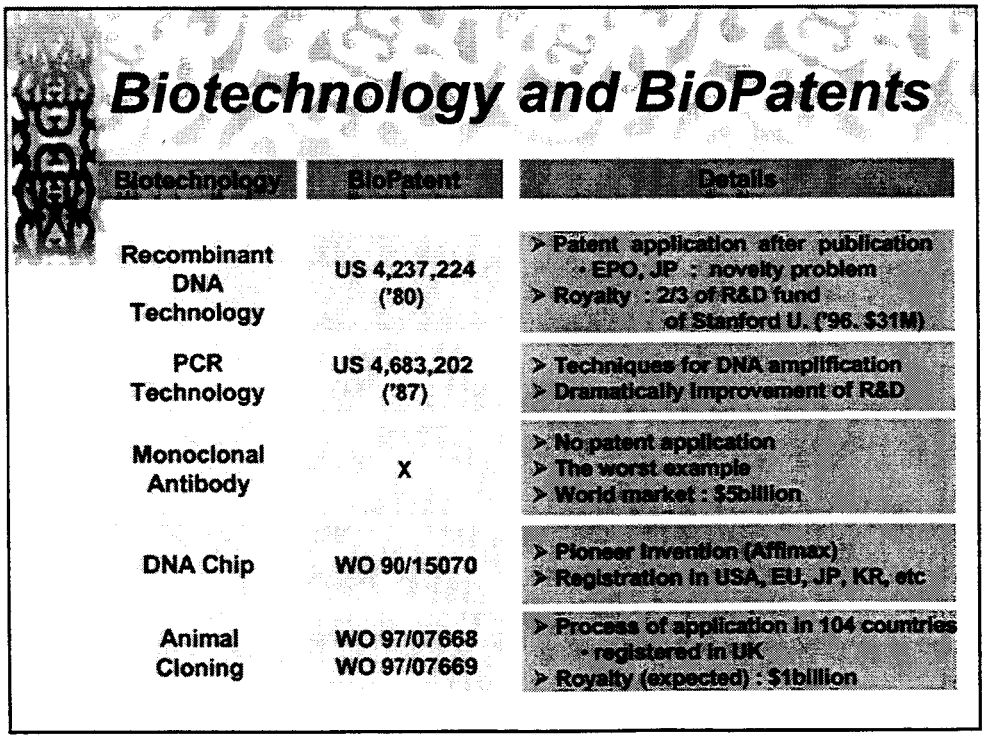
- the use of cellular and molecular processes to solve problems or make products

; *the application of several discrete fields of biological and chemical science to make commercial and industrial products*


Biotechnology & Bioindustry (II)
Pharmacy
Biology
Chemistry
Drug Development
Genomics Application
Natural compound Synthesis & Analysis
Marine biology
Fisheries Management
Gene therapy, Biosensor, Artificial organ Techniques
Medicine Biomedical engin
Breed Improvement
Massive Production, Isolation Techniques
Bioremidation, Waste Treatment
Agricultural engin.
Genetic engin.
Environmental engin.


Importance of BioPatent in R&D and Commercialization (I)
◆ BioPatent as R&D Information
- review of the prior arts
- disclosure of unpublished techniques
- precaution of the patent dispute
- prevention of R&D overlapping
◆ Facilitation of Commercialization
- several huddles for commercialization
* high quality man-power, tremendous R&D expenses, long-time payback periods, etc.


Importance of BioPatent in R&D and Commercialization (II)
- the link between invention and commercialization
* guarantee of exclusive rights
* no immediate competition in sales of the products
* protection from "free riding"
◆ " High-risk, high-return" field
- strong patent protection justify the risk-taking
* Bioindustry (USA) as a whole lost $4.7 billion in '99
- exclusive licenses are appropriate in cases
* Royalties : NIH ($40M), Sloan Kettering ($45M),
Stanford U ($43M), Colombia U ($40M), etc


Biotechnology and BioPatents
Biotechnology
BioPatent
Details
Recombinant DNA Technology
US 4,237,224 ('80)
> Patent application after publication
• EPO, JP : novelty problem
> Royalty : 2/3 of R&D fund of Stanford U. ('96, $31M)
PCR Technology
US 4,683,202 ('87)
> Techniques for DNA amplification
> Dramatically improvement of R&D
Monoclonal Antibody
X
> No patent application
> The worst example
> World market : $5billion
DNA Chip
WO 90/15070
> Pioneer invention (Affimax)
> Registration in USA, EU, JP, KR, etc
Animal Cloning
WO 97/07668
WO 97/07669
> Process of application in 104 countries
• registered in UK
> Royalty (expected) : $1billion

Patentability of Biotech-related Inventions (I)

Basic Patent Law Requirements

- Novelty, Inventive steps, Industrial applicability
- Disclosure Requirements : Enablement, Written Description,,,

◆ **As a Patentable Invention?** (35 U.S.C § 101)

- " ~ any new and useful **process, machine, manufacture,** or **composition of matter,** or any new and useful improvement,~ "

Biotech. inventions generally fall within the categories of "manufactures" or "composition of matter"

Patentability of Biotech-related Inventions (II)

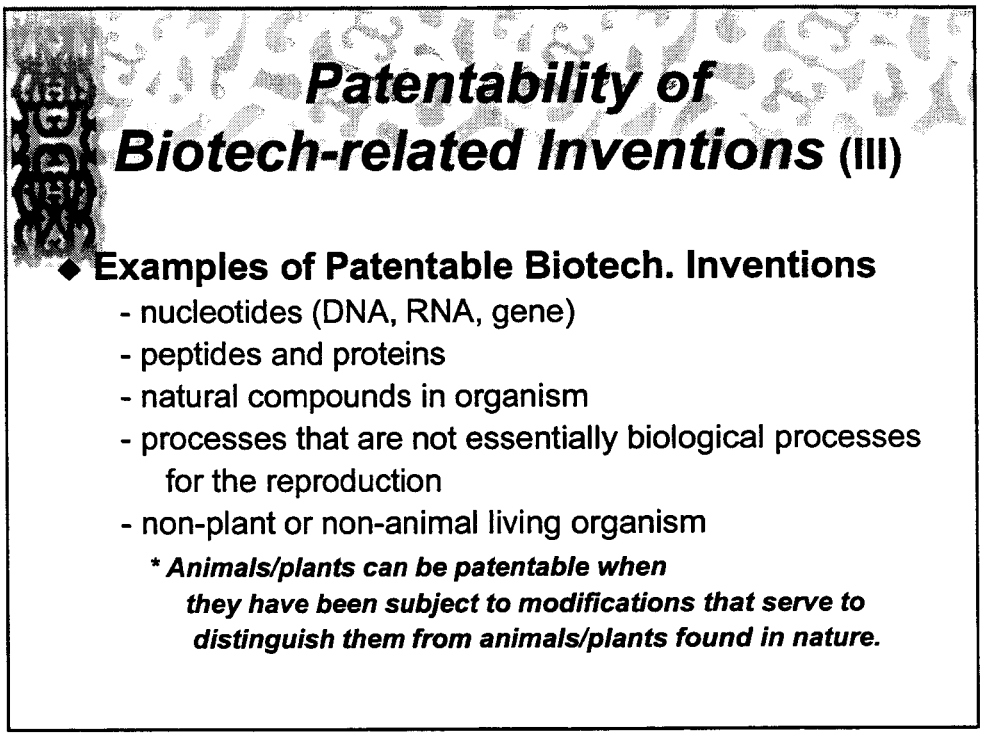
Exclusions of Patentable Inventions under TRIPs

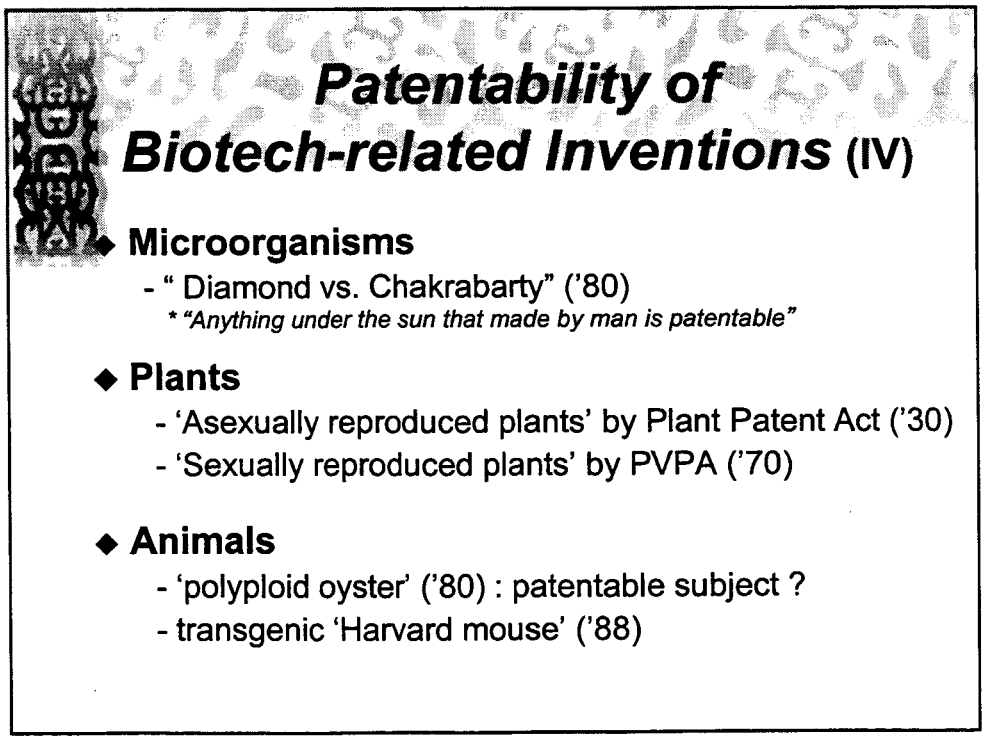
- **Art. 27.2** : *"to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment"*

- **Art. 27.3(a)** : *"diagnostic, therapeutic and surgical methods for the treatment of humans or animals"*

- **Art. 27.3(b)** : *"plants and animals other than micro-organism, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes"*

  * **However, plant varieties should be protected either by patents or by an effective *sui generis* system or by any combination thereof.**

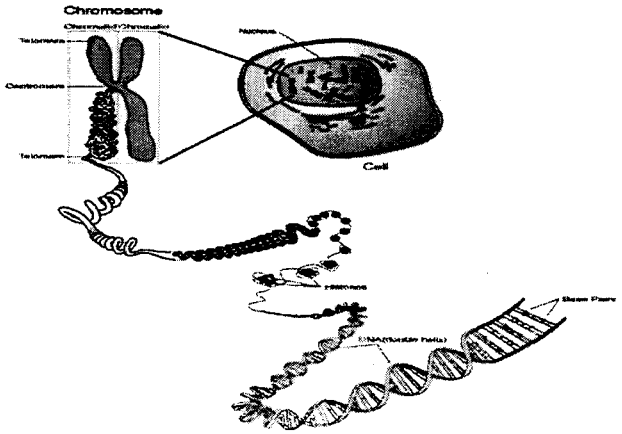

Patentability of
Biotech-related Inventions (III)
◆ Examples of Patentable Biotech. Inventions
- nucleotides (DNA, RNA, gene)
- peptides and proteins
- natural compounds in organism
- processes that are not essentially biological processes for the reproduction
- non-plant or non-animal living organism
* Animals/plants can be patentable when they have been subject to modifications that serve to distinguish them from animals/plants found in nature.


Patentability of
Biotech-related Inventions (IV)
◆ Microorganisms
- " Diamond vs. Chakrabarty" ('80)
* "Anything under the sun that made by man is patentable"
◆ Plants
- 'Asexually reproduced plants' by Plant Patent Act ('30)
- 'Sexually reproduced plants' by PVPA ('70)
◆ Animals
- 'polyploid oyster' ('80) : patentable subject ?
- transgenic 'Harvard mouse' ('88)

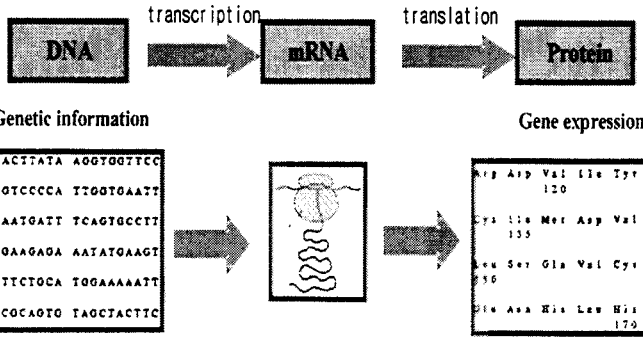
Patentability of Gene-related Inventions (I)

What is a gene ?

- the fundamental physical and functional unit of heredity



Patentability of Gene-related Inventions (II)

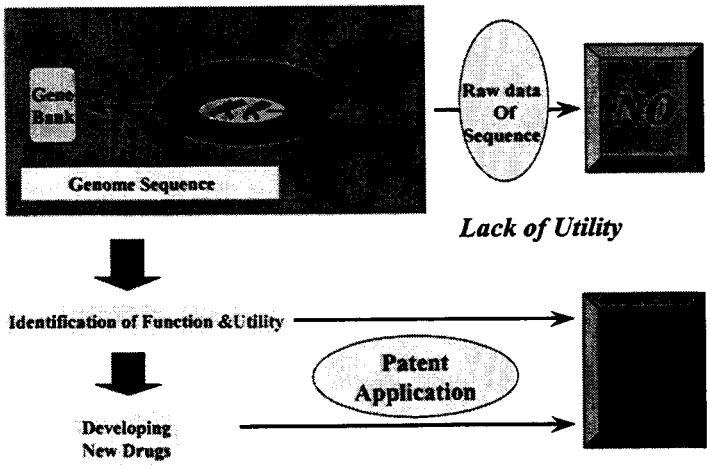


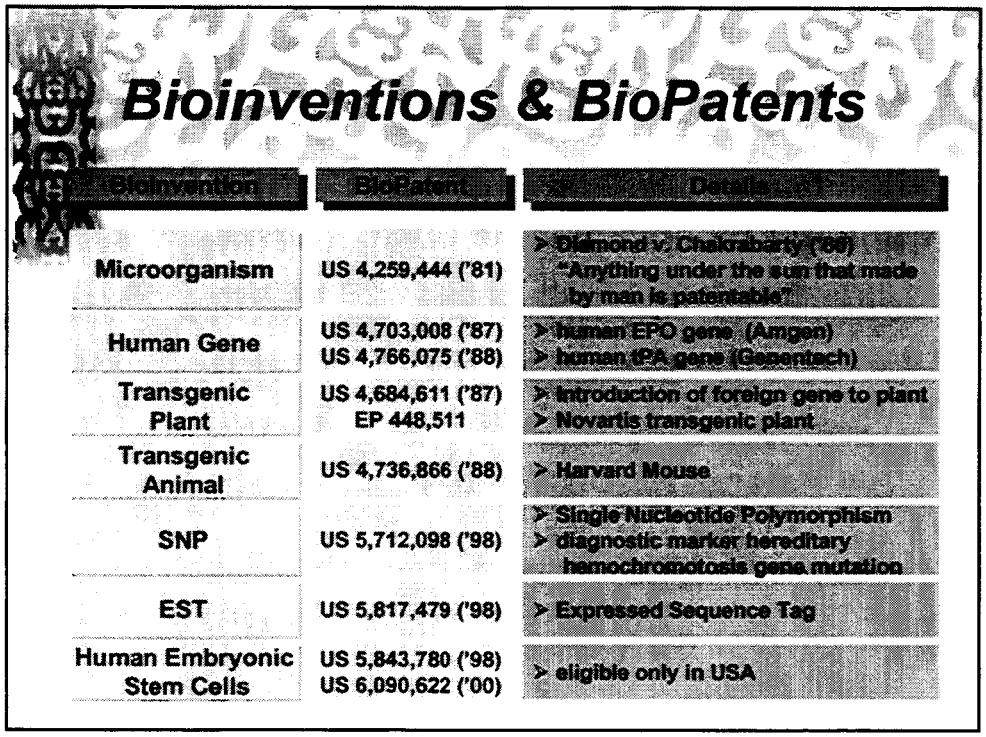
DNA is a chemical,
when placed in an appropriate environment,
will direct the synthesis of particular & specific proteins

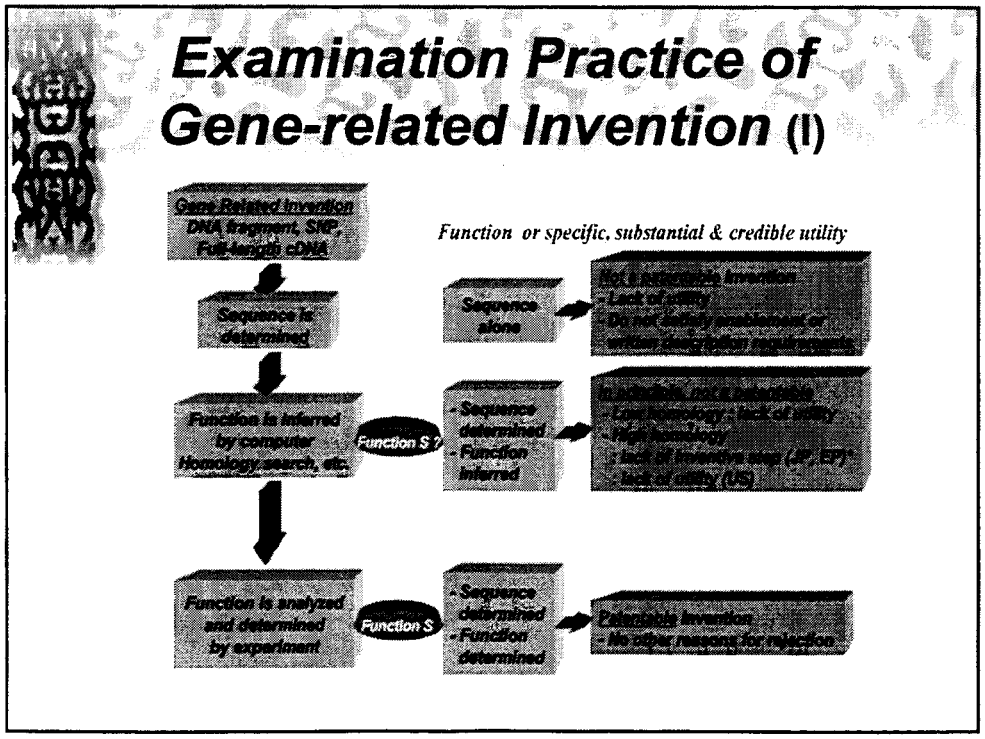
Patentability of Gene-related Inventions (III)

- **Are patents granted on an individual's gene?**
  - **No**, patents do not provide any right to a person or the genes in his or her body.
    Patents are granted on "isolated"gene products which has real world applicability.
- **Patents for DNA fragment ?**
  - **Yes**, if the research discerns the role of the gene,
    ESTs (expressed sequence tags) or
    SNP (single nucleotide polymorphism)
    in potential commercial application.

Patentability of Gene-related Inventions (IV)




Bioinventions & BioPatents
Bioinvention
BioPatent
Details
Microorganism
US 4,259,444 ('81)
> Diamond v. Chakrabarty ('80)
"Anything under the sun that made by man is patentable"
Human Gene
US 4,703,008 ('87)
US 4,766,075 ('88)
> human EPO gene (Amgen)
> human tPA gene (Genentech)
Transgenic Plant
US 4,684,611 ('87)
EP 448,511
> introduction of foreign gene to plant
> Novartis transgenic plant
Transgenic Animal
US 4,736,866 ('88)
> Harvard Mouse
SNP
US 5,712,098 ('98)
> Single Nucleotide Polymorphism
> diagnostic marker hereditary hemochromotosis gene mutation
EST
US 5,817,479 ('98)
> Expressed Sequence Tag
Human Embryonic Stem Cells
US 5,843,780 ('98)
US 6,090,622 ('00)
> eligible only in USA


Examination Practice of Gene-related Invention (I)
Gene Related Invention
DNA fragment, SNP, Full-length cDNA
Function or specific, substantial & credible utility
Sequence is determined
Sequence alone
Function is inferred by computer Homology search, etc.
Function S'
- Sequence determined
- Function inferred
- Lack of utility
Function is analyzed and determined by experiment
Function S
- Sequence determined
- Function determined
Patentable invention
- No other reasons for rejection

Examination Practice of Gene-related Invention (II)

Credible Utility

- An asserted utility is credible **unless** the logic underlying the assertion is seriously flawed, or the facts upon which the assertion is based are inconsistently with the logic underlying the assertion.
  * *polynucleotides used as probe or marker : credible*
  * *protein as an antitumor agent without working examples : not credible*

◆ Specific Utility (vs. general utility)

- The subject matter claimed should be specific.
  * *polynucleotides used as probe or marker in the absence of particular gene or chromosome target : not specific*

Examination Practice of Gene-related Invention (III)

◆ Substantial Utility

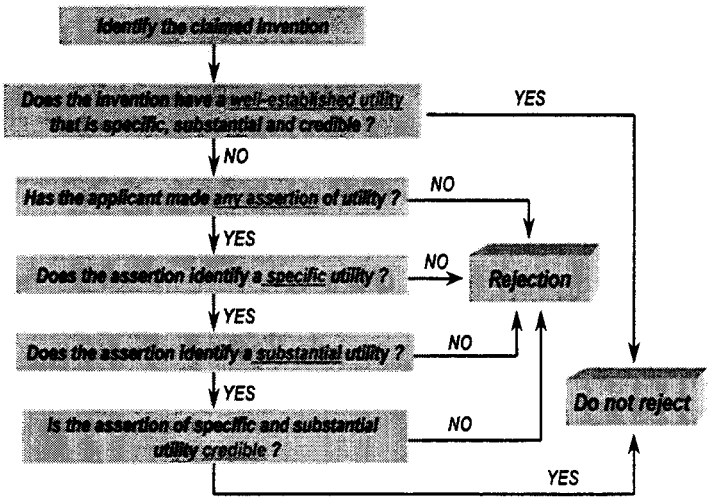
- If the invention requires or constitute carrying out further research to identify or reasonably confirm a real world use, it does not have a substantial utility.
  * *basic research just for the properties of the claimed product itself , or a method for treating an unspecified disease : not substantial*

◆ If credible, specific & substantial ,

"Well-Established Utility"

* **Throw-Away Utility : neither specific nor substantial**
  Transgenic mice as snake food,
  Recombinant protein as animal food supplements, etc

Examination Practice of Gene-related Invention (IV)



Examination Practice of Gene-related Invention (V)

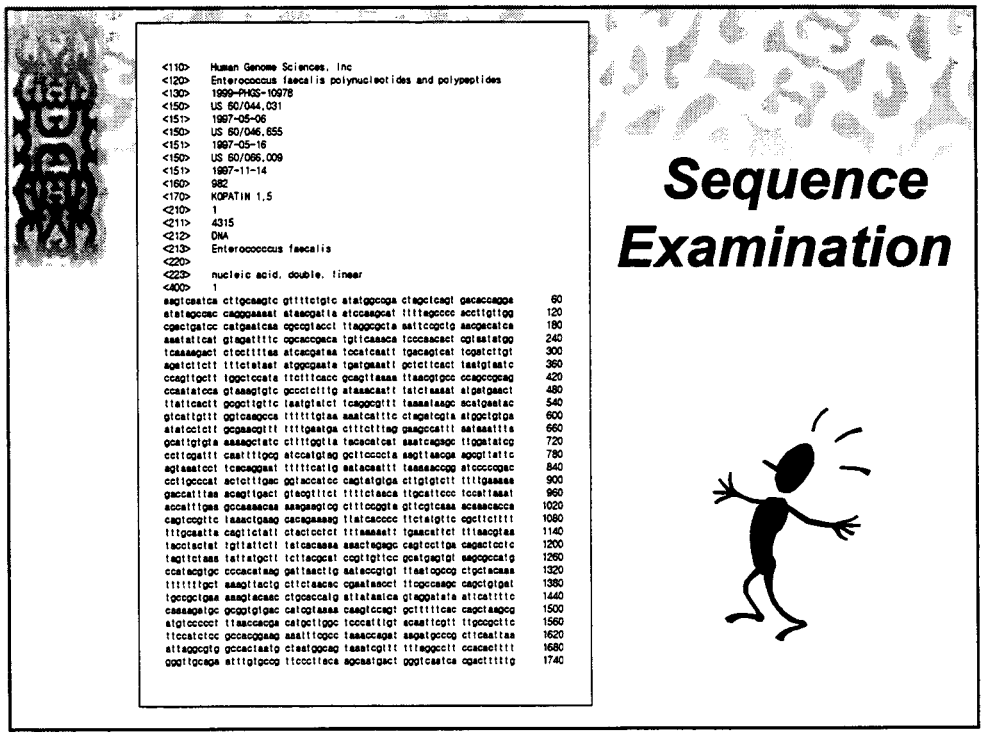
Example of Utility Examination

Claim : The isolated protein consisting of the amino acid sequence set forth in SEQ ID. No. 1

Specification : Asserted utility curing Alzheimer's disease (but no working examples)

ANALYSIS

- It is not an well-established utility since there is no evidence for the activity of the claimed protein.
- Then, does it have an asserted utility ? Yes
  - Is the asserted utility specific and substantial ? Yes
  - Is the asserted utility credible ? No


Sequence Examination
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<120> Enterococcus faecalis polynucleotides and polypeptides
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<151> 1997-05-16
<150> US 60/066,009
<151> 1997-11-14
<160> 982
<170> KOPATIN 1.5
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<211> 4315
<212> DNA
<213> Enterococcus faecalis
<220>
<223> nucleic acid, double, linear
<400> 1
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atatagccac cagggaaaat ataacgatta atccaagcat ttttagcccc accttgttgg 120
cgactgatcc catgaatcaa cgccgtacct ttaggcgcta aattccgctg aacgacatca 180
aaatattcat gtagattttc cgcaccgaca tgttcaaaca tcccaacact cgtaatatgg 240
tcaaaagact ctcctttttaa atcacgataa tccatcaatt tgacagtcat tcgatcttgt 300
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gtcattgttt ggtcaagcca ttttttgtaa aaatcatttc ctagatcgta atggctgtga 600
atatcctctt gcgaaacgttt ttttgaatga ctttctttag gaagccattt aataaattta 660
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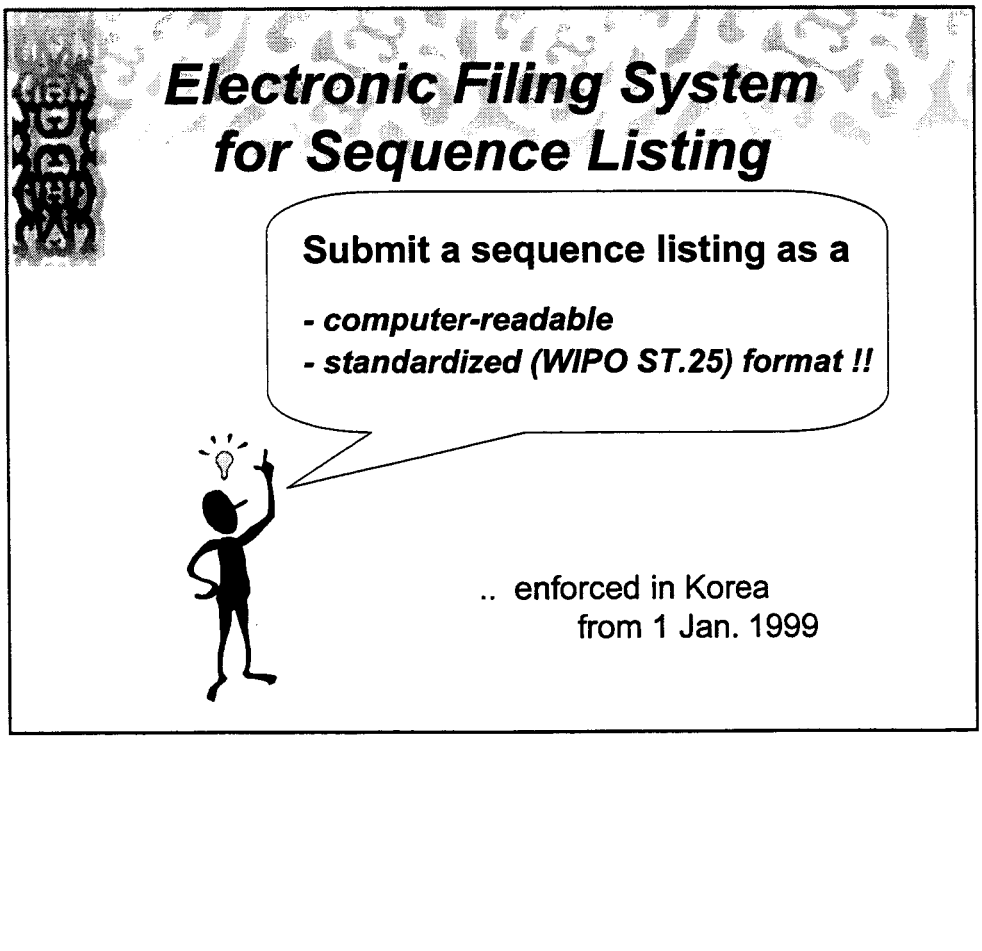

Electronic Filing System for Sequence Listing
Submit a sequence listing as a
- computer-readable
- standardized (WIPO ST.25) format !!
.. enforced in Korea
from 1 Jan. 1999

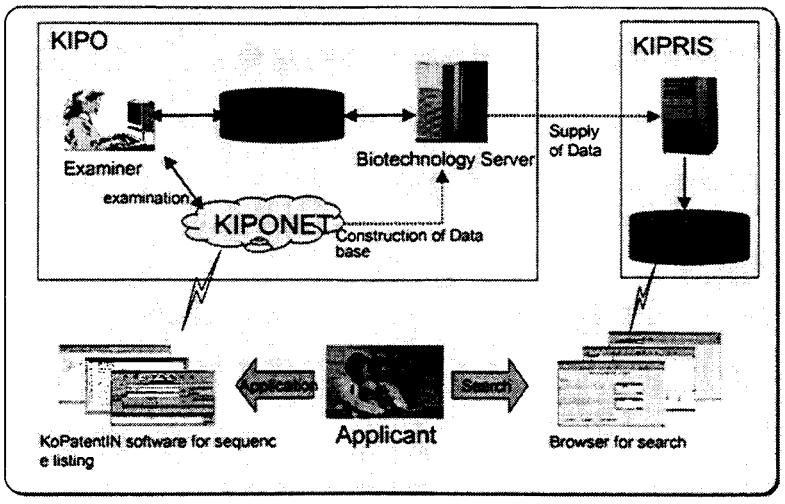
Examples of Application containing Large-sized Sequence Listing

- Application No. 10-2000-07005552
  Applicant : Genset, France
  Size of Sequence Listing: 5.4MB
  (A4 3,000 pages)

- Application No. 10-1999-07010172
  Applicant : Human Genome Sciences, US
  Size of Sequence Listing: 4.2MB

- Applicant: Helix, Japan
  Size of Sequence Listing: 26MB
  (A4 14,500 pages)

Biotechnology Patent Sequence Search System (BioPass) in Korea

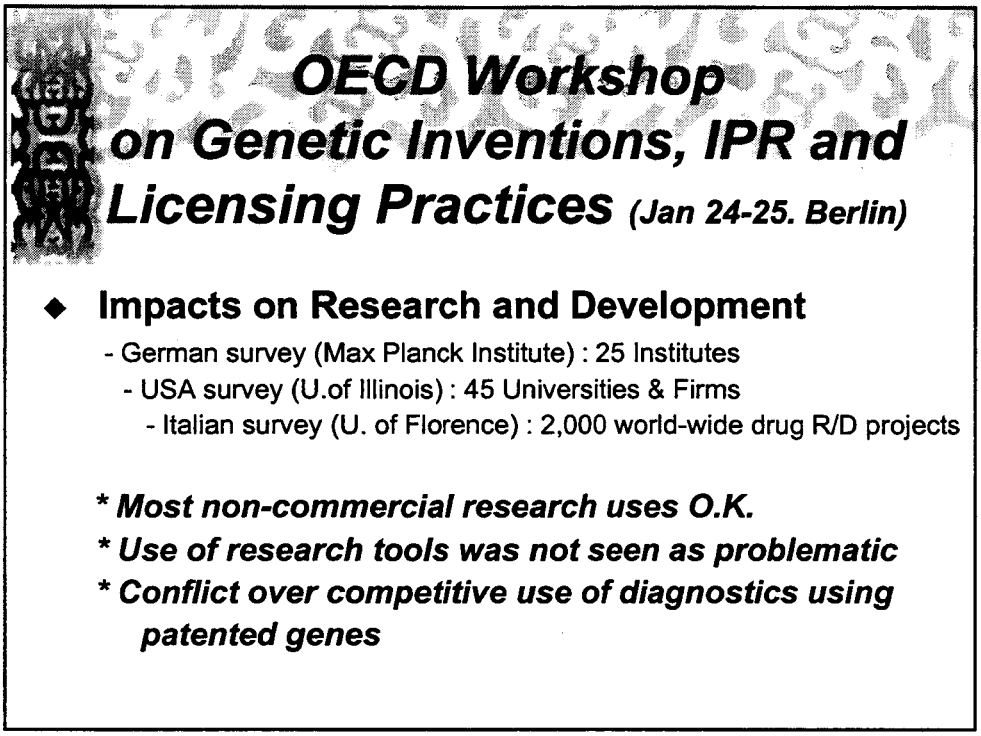


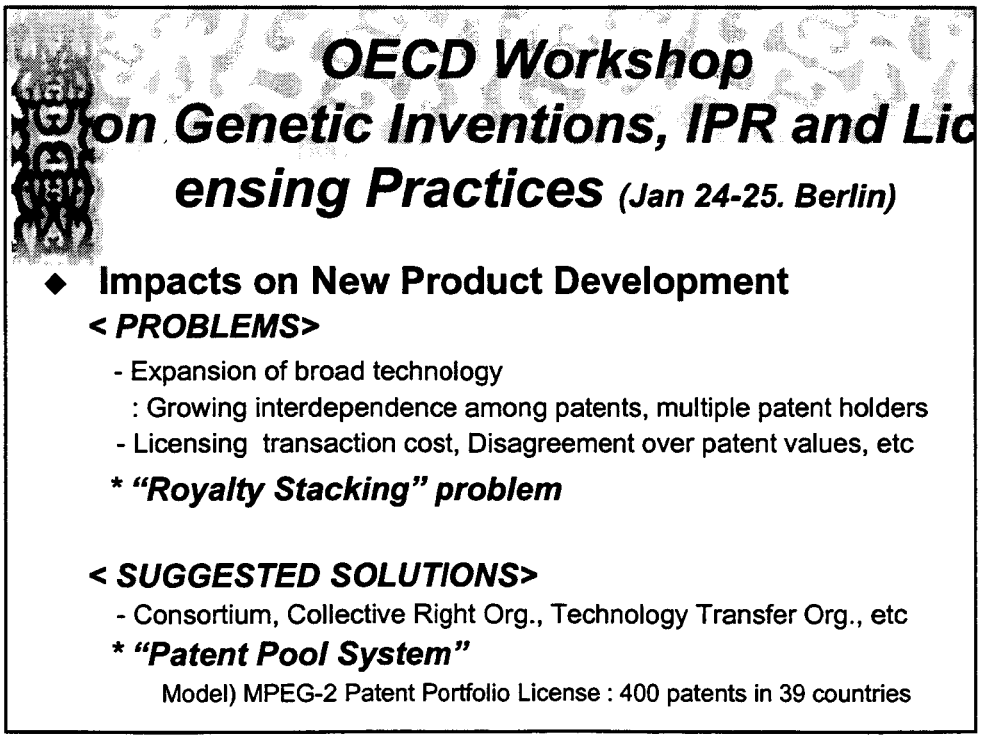
Summary of BioPatentability in Korea, US, EPO & Japan

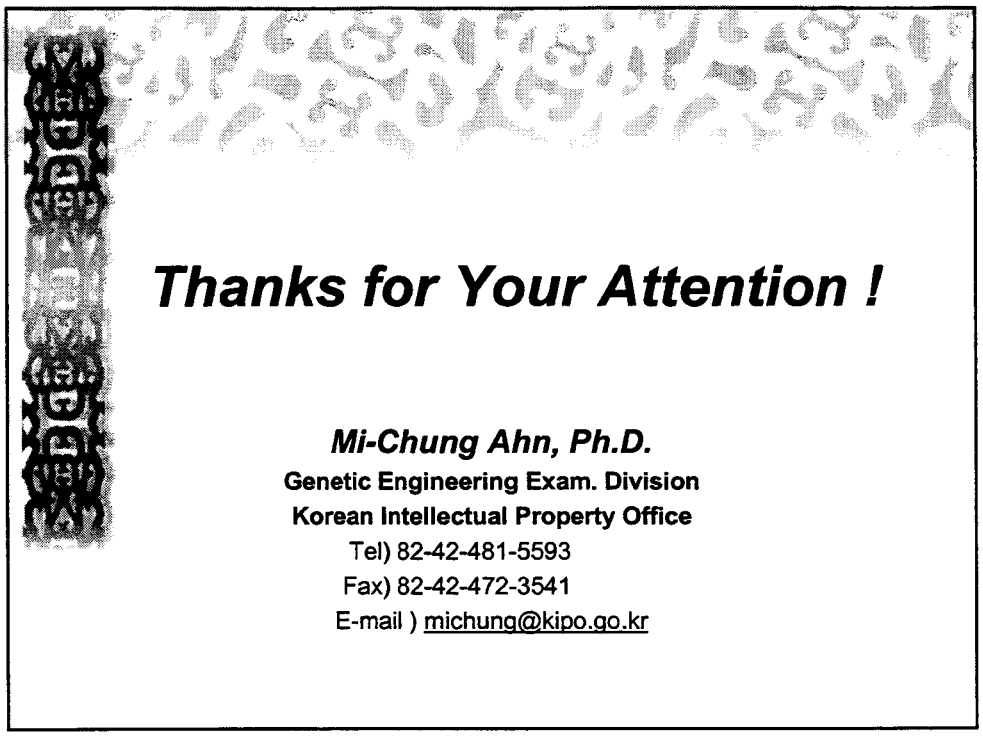
Subject matter	KR	US	EPO	JP
Gene	Yes	Yes	Yes	Yes
DNA fragment	Yes (with indication of a function and utility)			
Protein	Yes	Yes	Yes	Yes
Microorganism	Yes	Yes	Yes	Yes
Animal	Yes	Yes	Yes except Varieties	Yes
Plant	Only a variety which reproduces asexually	Yes	Yes except Varieties	Yes
Part of human body	No	No	No	No
Human ES cell	No	Yes	No	No
Surgical Treatment/ Diagnosis Method	Yes (animal) No (human)	Yes	No	Yes (animal) No (human)

Recent Emerging Issues on BioPatent

- **Traditional Knowledge & Genetic Resources**
  - Definition, Scope of Protection, *sui generis* System, etc
  - Access and Benefit Sharing (ABS)
- **Impacts on Research and Development**
- **Impacts on New Product Development**


OECD Workshop
on Genetic Inventions, IPR and
Licensing Practices (Jan 24-25. Berlin)
◆ Impacts on Research and Development
- German survey (Max Planck Institute) : 25 Institutes
- USA survey (U.of Illinois) : 45 Universities & Firms
- Italian survey (U. of Florence) : 2,000 world-wide drug R/D projects
* Most non-commercial research uses O.K.
* Use of research tools was not seen as problematic
* Conflict over competitive use of diagnostics using patented genes


OECD Workshop
on Genetic Inventions, IPR and Lic
ensing Practices (Jan 24-25. Berlin)
◆ Impacts on New Product Development
< PROBLEMS>
- Expansion of broad technology
: Growing interdependence among patents, multiple patent holders
- Licensing transaction cost, Disagreement over patent values, etc
* "Royalty Stacking" problem
< SUGGESTED SOLUTIONS>
- Consortium, Collective Right Org., Technology Transfer Org., etc
* "Patent Pool System"
Model) MPEG-2 Patent Portfolio License : 400 patents in 39 countries



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