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Beijing, July 23 to 27, 2001

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

(II) PATENTABILITY OF BIOTECHNOLOGY-RELATED INVENTIONS

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Biotechnological Inventions : Emerging Issues & Scope of Patentability

WIPO Asian Regional Training Course for
Trainers and Instructors of Intellectual Property
Beijing, China, July 23 ~ July 27, 2001

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

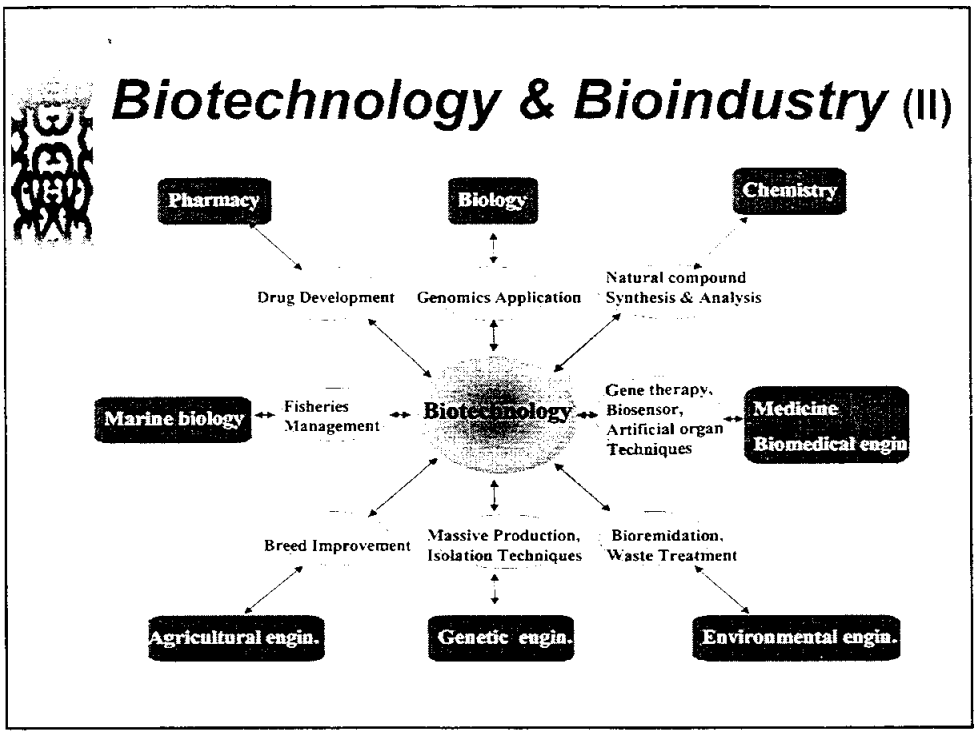
Biotechnology & Bioindustry (I)

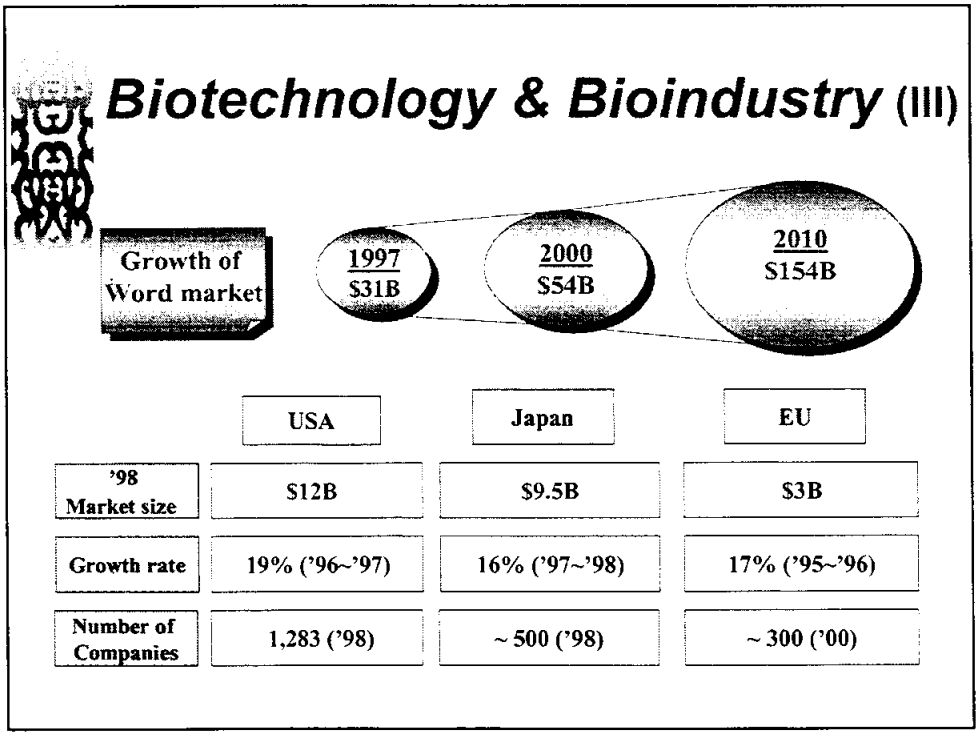
What is Biotechnology ?

"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 co mmercial and industrial products*





	USA	Japan	EU
'98 Market size	$12B	$9.5B	$3B
Growth rate	19% ('96~'97)	16% ('97~'98)	17% ('95~'96)
Number of Companies	1,283 ('98)	~ 500 ('98)	~ 300 ('00)

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- disclosure of unpublished techniques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)

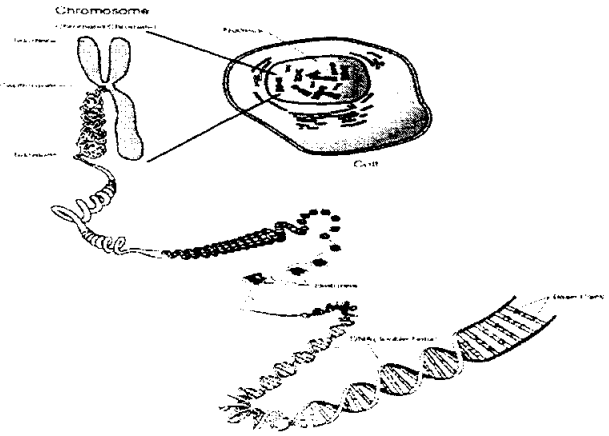
Animals

- 'polyploid oyster' ('80) : patentable subject ?
- transgenic 'Harvard mouse' ('88)

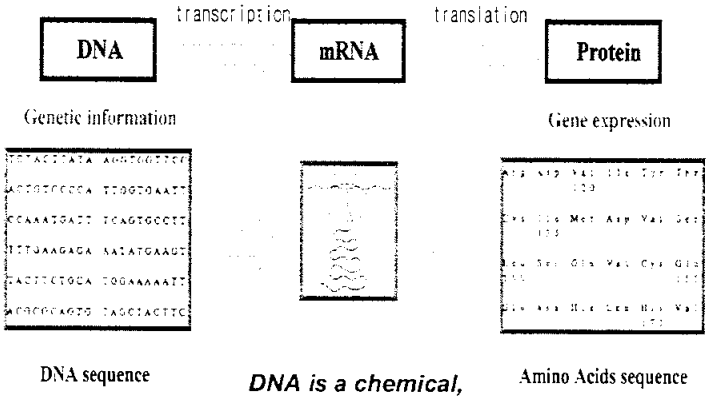
Patentability of Gene-related Inventions (I)

What is a gene ?

- the fundamental physical and functional unit of heredity



Patentability of Gene-related Inventions (II)

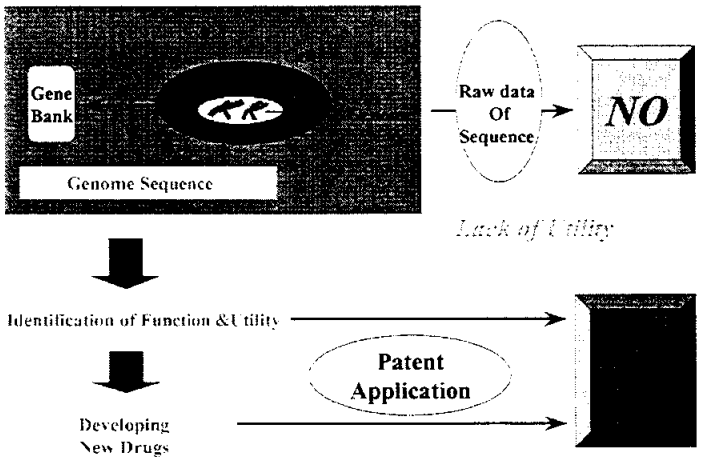


DNA is a chemical,
when placed in an appropriate environment,
will direct the synthesis of particular & specific proteins

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.

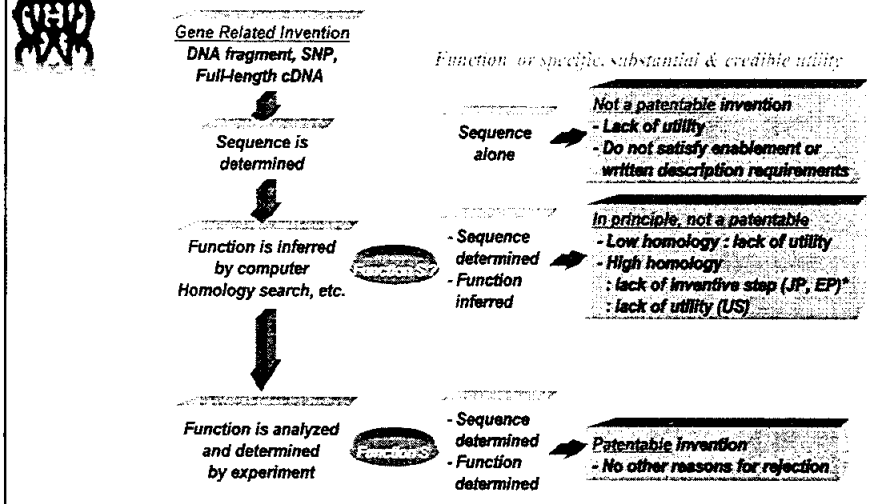
Patentability of Gene-related Inventions (IV)



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)



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

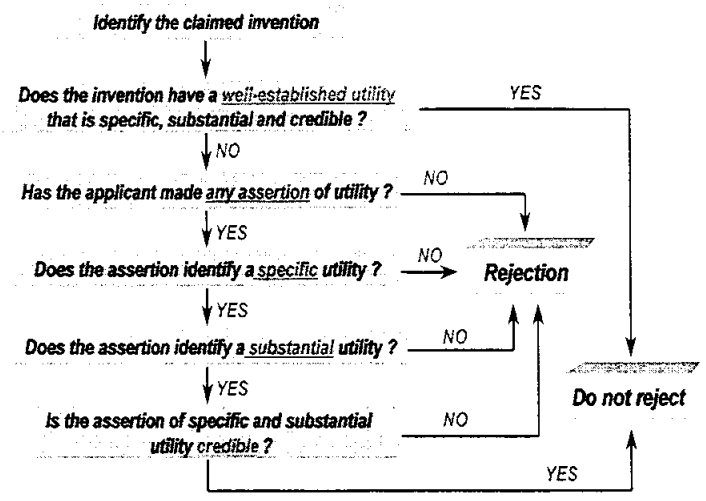
- If the invention requires or constitute carrying out further research to identify or reasonably confirm a real world use, it does not have a substantial utility.
  * *basic research just for the properties of the claimed product itself , or a method for treating an unspecified disease : not substantial*

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

Brief Outlook of Bioindustry in Korea (I)

Current situation ('99)

- Market size : $560M (1.2% of World Market)
- Annual Growth Rate : 30% ('94 ~'99)
- Number of Companies : ~ 250

Government Efforts

- "Genetic Engineering Promotion Law" ('83)
- "Biotech 2000 Program" ('93)
  * National Biotechnology Development Program

Brief Outlook of Bioindustry in Korea (II)

- **Government's budget for biotechnology**
  - $178M in year 2000
  - an 33% increase over the previous year.

- **Goal for year 2010**
  - 6.5% of World Market
  - Number of Companies : 1,200
  - Intellectual Properties : 10,000

Trend in Applications & Registrations of BioPatent

1. Applications

(Unit : Number of Applications)

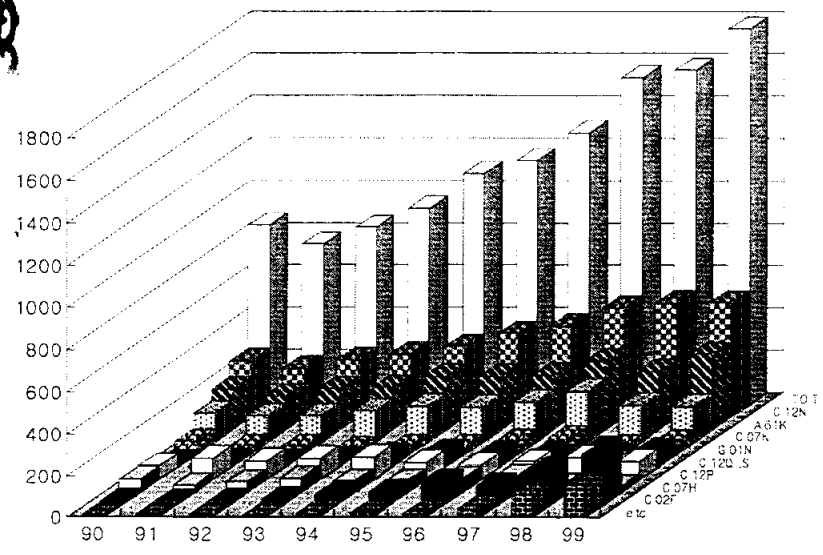
	'97	'98	'99	2000(1st half)
Koreans	596	823	959	281
Foreigners	948	756	817	434
Total	1,544	1,579	1,776	715

2. Registrations

(Unit : Number of Registrations)

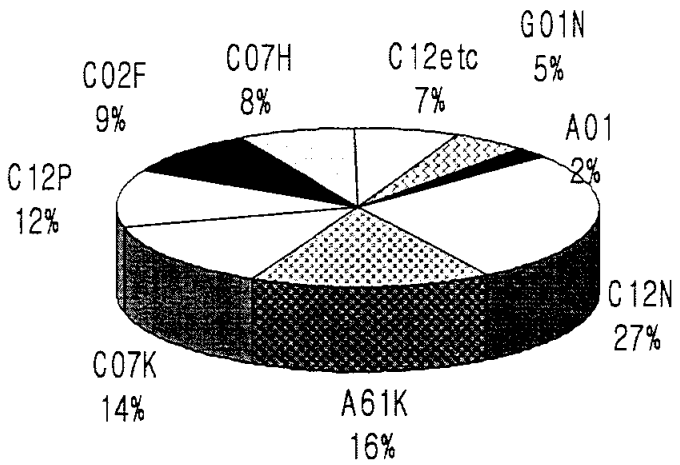
	'97	'98	'99	2000(1st half)
Koreans	286	690	667	257
Foreigners	315	492	584	183
Total	601	1,182	1,251	440

Major IPCs of BioPatent Applications



Major IPC of BioPatent Registrations

(1990-2000.11 : total 5,385)



BioPatent Examination System in Korea

- **Genetic Engineering Examination Division**
  - Pharmaceutical Exam. Div. / Agricultural Forestry & Fishery Exam. Div.
- **Patent Exam. Guideline for Biotech. Inventions** (1998)
  - It is amended to reinforce specific standards for the product of HGP. The amended one is enforced from January, 2001.
- **Depository System for Biological Materials**
- **Electronic Filing System for Sequence Listing**
- **Biotechnology Patent Sequence Search System (BioPASS)**

Deposit of Biological Materials for patent applications

- **Microorganisms became patentable subject matter : 1987. 7. 1.**
- **Entered into Budapest Treaty : 1988. 3. 28 .**

3 International Depositary Authorities in Korea

Name of IDAs	KCTC Korean Collection for Type Cultures	KCCM Korean Culture Center of Microorganisms	KCLRF Korean Cell Line Research Foundation
Year acquired IDA Status	1989	1989	1993
Number of Deposits	1,950	1,489	26
Number of samples furnished	132	38	30

Substance Patent & Patentable Subject Matter

Permission of Substance patent (1987. 7. 1)

- Chemical substances, Pharmaceuticals
- Microorganisms

Expansion of Patentable subject matter (1990. 9. 1)

- Foods or Food stuff

Unpatentable Inventions (present)

- *The inventions liable to contravene public order, morality or public health shall not be patented* (Patent Law Article 32)

Plant Patent

Patent Law Article 31 (Patent for Plant Invention)

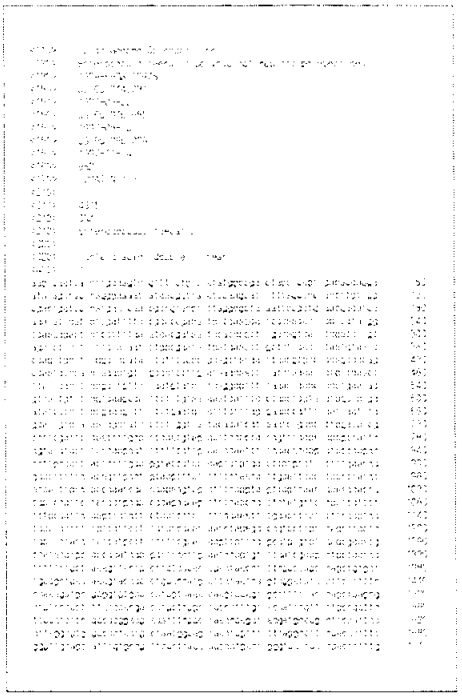
- *Any person who invents a variety of plant which reproduces itself asexually may obtain a plant patent therefore.*
  : Similar to US plant patent law (introduced to Korea in 1946)

Seed Industry Law (Plant variety protection law)

- Enforced on December 31, 1997 : UR/TRIPs 27.3(b)
- Species eligible for protection : 57 species (2000)
- Examination Authority : National Seed Management Office

Animal Patent

- **Animal Patent Stipulation in Exam. Guideline (1998)**
  - Not liable to contravene public order, morality or public health
  - Require the deposit of fertilized eggs
- **Examples of Animal Patents**
  - Transgenic Mouse Deficient in T Cell (2000)
  - Transgenic Mouse Inducing Diabetes (2000)
- **Patent Applications of Animal cloning**
  - 2 patent applications related with "Dolly" from UK (1998)
  - Seoul National University : 10 applications



Sequence Examination

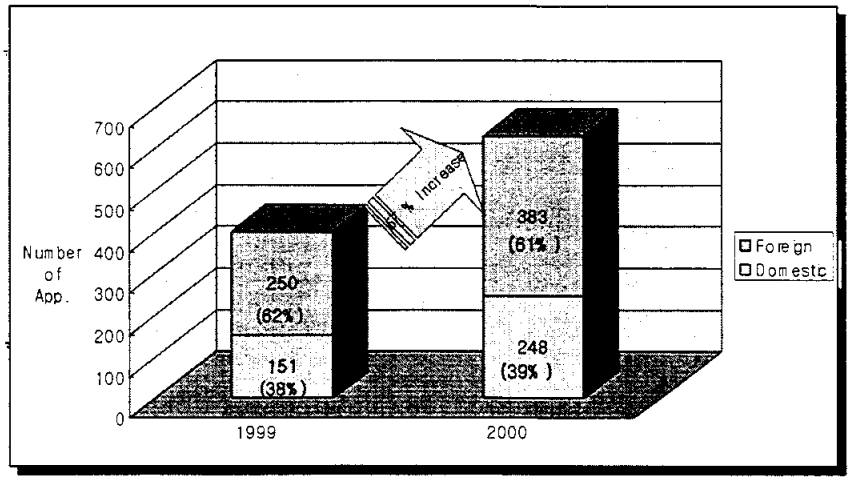
Electronic Filing System for Sequence Listing

Submit a sequence listing as a

- ***computer-readable***
- ***standardized (WIPO ST.25) format !!***

.. enforced from 1 Jan. 1999

Recent status of Applications containing Sequence Listing



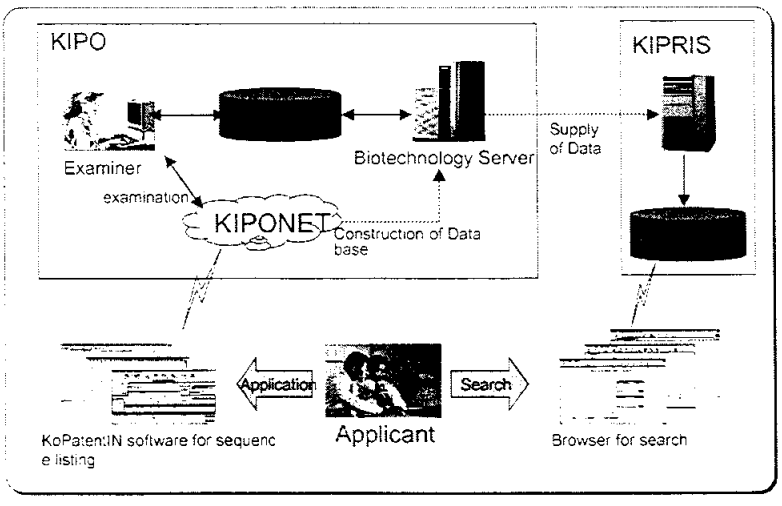
Examples of Application containing Large-sized Sequ ence Listing

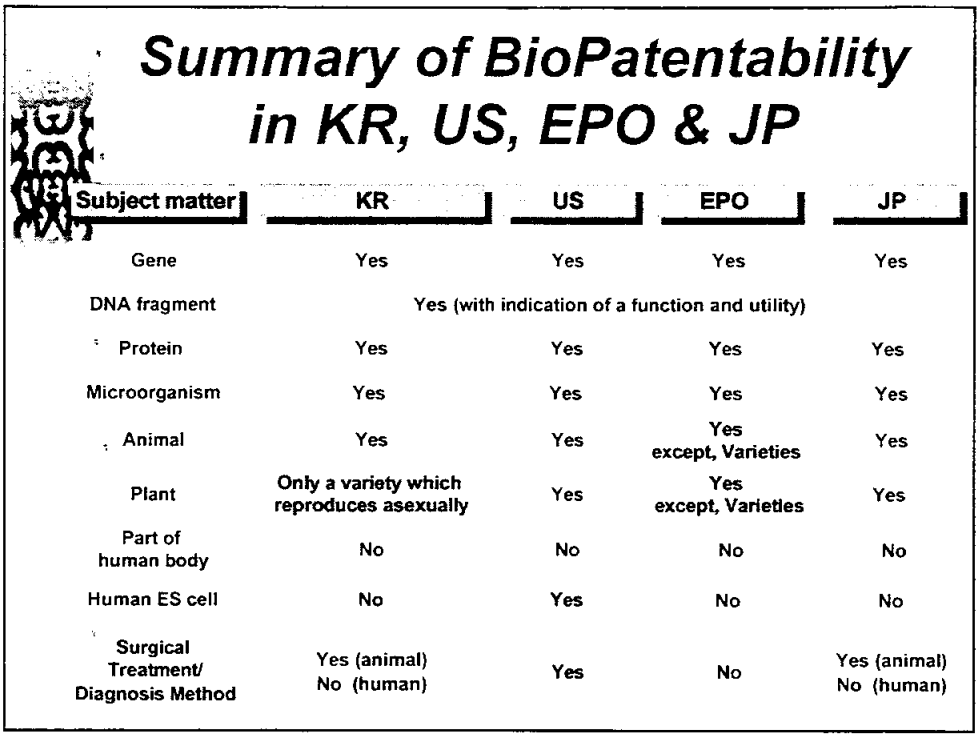
- Application No. 10-2000-07005552
  Applicant : Genset, France
  Size of Sequence Listing: 5.4MB
  (A4 3,000 pages)

  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)





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