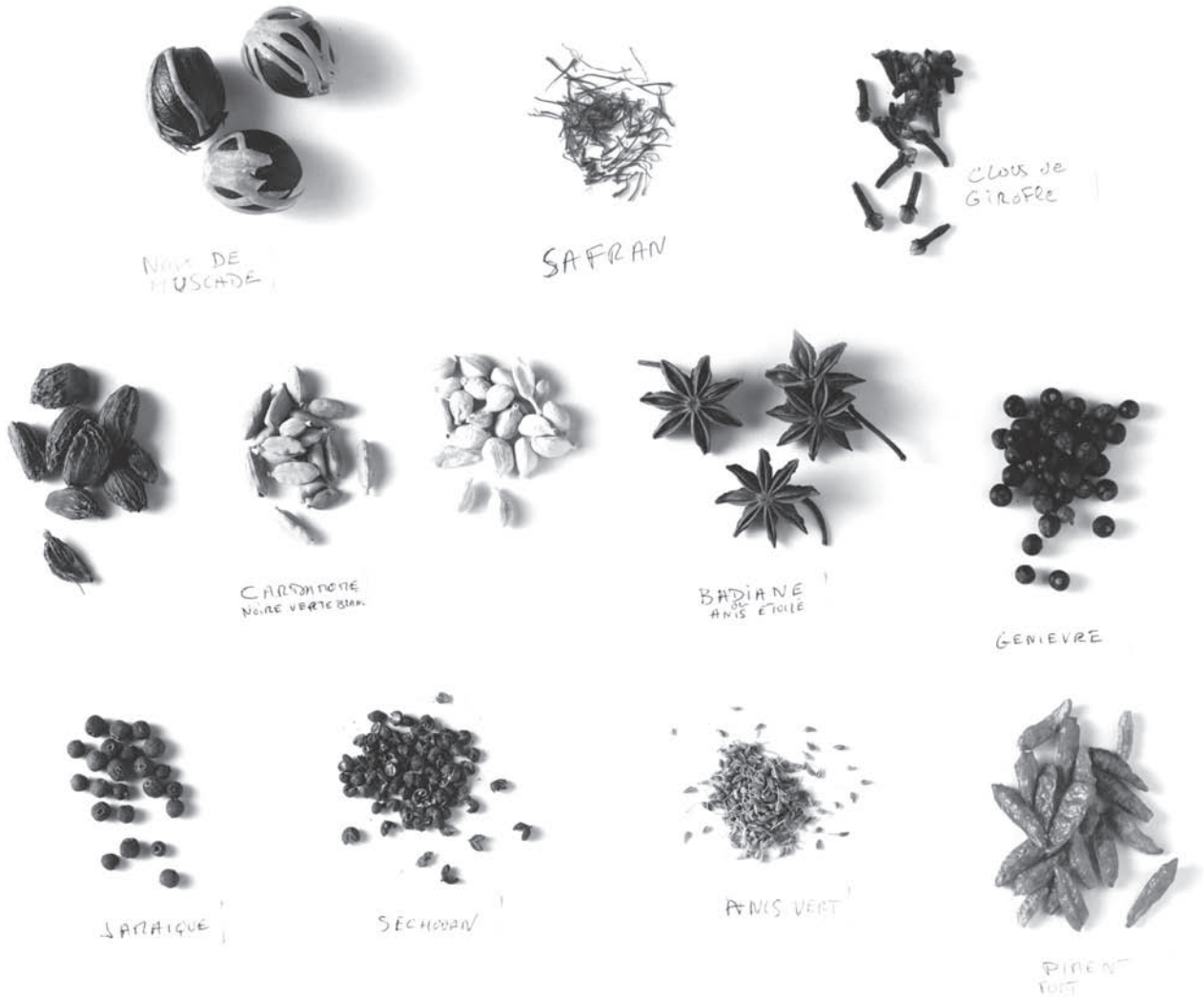


제4차
한국 ABS포럼

일시 | 2012년 12월 7일(금) 14:00~17:30

장소 | 건설공제조합 2층 중회의실

주관 | 한국 ABS포럼

주최 | 환경부 국립생물자원관

후원 | koreaBio 한국바이오협회

초대의 글

한국 ABS포럼이 국립생물자원관 및 한국환경정책평가연구원 후원으로 “유전자원접근 및 이익공유(ABS) 체제의 적절한 이행 방안 모색”을 주제로 국제심포지움을 개최합니다.

이 심포지움은 ABS에 관한 나고야의정서의 이행상황을 점검하고, 국내 이행에 있어서의 여러 문제점을 검토하며, 지속가능발전이라는 전세계적 과제에 기여할 수 있는 적절한 이행 방안을 모색하고자 하는데 목적이 있습니다. 논의의 초점은 의정서 이행관련 해석상의 이슈, 향후 각종 관련 연구의 방향, 그리고 기술적 지원 및 훈련 활동에 관한 논의에 기여하기 위해 법적, 정책적 및 실무적 문제점들에 맞추고자 합니다. ABS 관련 산업과 연구기관의 시각 또한 필수적으로 논의하고자 합니다. 많은 분들의 참석과 열띤 토론 바랍니다.

2012년 12월

한국 ABS포럼 회장, 이화여대 교수 **최원목**

행사 일정

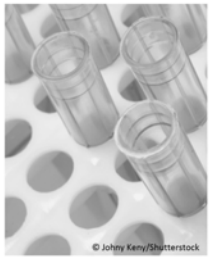
시간	주제	발표자	사회자
14:00~14:20 (20)	등록		
14:20~14:40 (20)	개회사 및 축사	국립생물자원관장	
14:40~15:40 (60)	**[제1세션]** ABS체제 개관 및 국내 이행에의 시사점	Olivier Rukundo	이병희
	[제2세션] 나고야의정서 체제에 관한 산업 및 연구기관의 시각	손미원	
15:40~16:00 (20)	휴식		
16:00~17:30 (90)	**[제3세션]** 한국의 나고야의정서 이행전략	박원석	
	[제4세션] 토론 및 질의응답	박용하 오명석 오선영 장성현 장호민 최재용	최원목

시간	주제	발표자	사회자
14:00~14:20	Registration		
14:20~14:40	Opening Remarks and Congratulatory Address	President NIBR	
14:40~15:40	**[Session 1]** Overview of the ABS System and its Implication at the National Level	Olivier Rukundo	Lee, Byoung-Hee
	[Session 2] Industry and Researching Community Perspectives and Disclosure	Son, Mi Won	
15:40~16:00	coffee break		
16:00~17:30	**[Session 3]** Implementation Strategies for Nagoya Protocol – Korea's Perspective	Park, Won Seok	
	[Session 4] Discussion	Park, Yong-Ha Jang, Ho Min Jang, Sung Hyun Oh, Myung Seok Oh, Sun Young Choi, Jaey Yong	Choi, Won-Mog

목 차

1. Overview of the ABS System and its Implication at the National Level

Olivier Rukundo



The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization

Olivier Rukundo
Programme officer, Nagoya Protocol Unit
Secretariat of the Convention on Biological Diversity

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CBD

Background

- After six years of intense negotiations, the Protocol was adopted, in October 2010 at COP 10 in Nagoya Japan.
- The Nagoya Protocol is a landmark agreement in the international governance of biodiversity.
  - Operationalizes the third objective of the CBD
  - Provides a clear framework aiming to bring **equity** between biodiversity-rich countries and the users of the genetic resources, while creating a win-win situation for the benefit of all parties involved.

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The Nagoya Protocol on Access and Benefit-sharing: Background

To further implement one of the CBD's three objectives:

- Conservation of biological diversity
- Sustainable use of its components
- **Fair and equitable sharing of benefits arising from the use of genetic resources**

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The Nagoya Protocol: Principles

Fundamental principles of ABS

- **Sovereign rights** of States over their natural resources
- Access to genetic resources is subject to the prior informed consent (PIC) of the provider country
- Users and providers must reach an agreement (mutually agreed terms) on the sharing of benefits that may result from their use

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The Nagoya Protocol: Objective

The fair and equitable sharing of the benefits arising from the utilization of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity

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The Nagoya Protocol: Scope

- Genetic resources within the scope of Article 15 CBD and the benefits arising from the utilization of such resources
- Traditional knowledge associated with genetic resources within the scope of the CBD and the benefits arising from the utilization of such knowledge
- Importance of UTILIZATION in art.2 of the Protocol.

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Core elements: Access

Obligation to establish ABS measures at national level providing for:

- Legal certainty, clarity and transparency.
- Fair and non-arbitrary rules and procedures.
- Clear rules and procedures for prior informed consent and mutually agreed terms.
- Issuance of a permit or equivalent as evidence that PIC was obtained and MAT were established.

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Core elements: Access

Obligation to establish:

- A national focal point :
  - Make information on **procedures** for obtaining prior informed consent and mutually agreed terms available.
  - **Liaise** with the Secretariat
- One or more competent national authorities:
  - **Grant access** to genetic resources
  - **Advising** on applicable procedures.

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Core elements: Fair and equitable sharing

Obligation to take measures:

For benefits arising from the utilization of genetic resources, as well as subsequent applications and commercialization, to be shared with provider country. Benefits to be shared are subject to mutually agreed terms (MAT).

Benefits may be monetary and non-monetary

- **benefits:** Access fees, milestone payments, licence fees, royalties, transfer of technology, sharing results of research, effective participation in research

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Core elements: compliance

Compliance obligations ensuring benefit-sharing

- Obligation to comply with **national ABS legislation and regulatory requirements** as well as with **mutually agreed terms** (MAT)
- Obligation to monitor the utilization of the genetic resources, including by:
  - Designation of effective **check points**
  - Establishment of an **internationally recognized certificate of compliance** as evidence that PIC was obtained and MAT established

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Core elements: traditional knowledge

- Indigenous and local communities rely on genetic resources and have helped preserve and maintain biodiversity over centuries
- Traditional knowledge related to biological resources can be an important source of information for identifying new uses of genetic resources

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Core elements: traditional knowledge

The Protocol aims to ensure that:

- Indigenous and local communities obtain a fair share of benefits from the use of their:
  - **Traditional knowledge** associated to genetic resources
  - **Genetic resources**, in cases where they have established rights to grant access to them, in accordance with national legislation
- Access will be subject to their prior informed consent, taking into account their customary laws and procedures

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The Nagoya Protocol: Opportunities

A global multilateral benefit-sharing mechanism

- To be further considered for benefits derived from the use of genetic resources and traditional knowledge that
  - Occur in **transboundary** situations, or
  - For which **prior informed consent cannot be granted or obtained**.

- Benefits from the mechanism are to be used to support the conservation and sustainable use of biodiversity globally.

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The Nagoya Protocol: Challenges and opportunities

- Protocol provides flexibility: challenge is to determine best approach to implement the Protocol in order to meet common objectives while taking into account national interests.
- Need for coherent national implementation to ensure functionality of the emerging framework, avoiding ad hoc approaches adding bureaucracy and inefficiency to detriment of providers and users.
- Goodwill and collaborative approaches required amongst Parties and stakeholders to make Protocol work, combined with genuine will to seek technical solutions to key outstanding issues.

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The Nagoya Protocol: Challenges and opportunities

- It contains a number of innovations which can contribute to greater legal certainty in ABS implementation
- It provides the basis for a functional international system of ABS provided that appropriate measures are adopted by countries for its implementation
- Success of Protocol will depend on a shared vision and willingness of Parties to build bridges and collaborate to achieve successful implementation

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Support for the early entry into force of the Protocol

GEF Medium-Sized Project implemented by UNEP and executed by SCBD, including:

Awareness-raising activities:

- **Briefings of parliamentarians** (e.g. IPU General Assembly, Asia Pacific Parliamentary Forum, Commonwealth Parliamentary Association, Pan African Parliament)
- **Briefings of UN missions** (e.g. New York, Geneva, Rome)
- **Briefings of relevant international organisations** (e.g. WIPO, ITPGRFA, CGRFA)
- **Briefings of ILCs and relevant stakeholders** (e.g. UNPFII, business community, research community)

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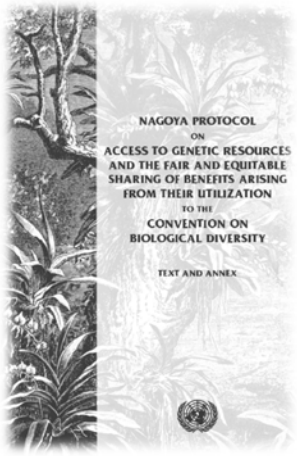
Status: Signature and ratification

- Protocol was open for signature from 2 February 2011 to 1 February 2012
- 9 Parties have ratified the Protocol (Ethiopia, Fiji Gabon, India, Jordan, Lao PDR, Mexico, Rwanda, Seychelles) and 92 Parties have signed
- Entry into force 90 days after the date of deposit of the 50th instrument of ratification (entry into force of the Protocol expected by COP 12)



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Africa (31)		Asia/Pacific (16)	CEE (11)	GRULAC (15)	WEOG (19)	
Algeria	Kenya	Bangladesh	Bulgaria	Antigua and Barbuda	Australia	Ireland
Benin	Madagascar	Bhutan	Czech Republic	Argentina	Austria	Italy
Burkina Faso	Mali	Cambodia	Hungary	Brazil	Belgium	Luxembourg
		***Fiji**				
Cape Verde	Mauritania	Cyprus	Lithuania	Colombia	Denmark	Netherlands
Central African Republic	Morocco	***India**	Poland	Costa Rica	European Union	Norway
Chad	Mozambique	Indonesia	Republic of Moldova	Dominican Republic	Finland	Portugal
Congo	Niger	Japan	Romania	Ecuador	France	Spain
Côte d'Ivoire	Nigeria	***Jordan**	Serbia	El Salvador	Germany	Sweden
Congo (Democratic Republic of)	***Rwanda**	Lebanon	Slovenia	Grenada	Greece	Switzerland
Djibouti	Senegal	***Lao PDR**	Tajikistan	Guatemala		UK
Egypt		Micronesia (Federated States of)				
*** Ethiopia**	***Seychelles**	Mongolia	Ukraine	Honduras		
***Gabon**	Somalia	Palau		***Mexico**		
Ghana	South Africa	Republic of Korea		Panama		
Guinea	Sudan	Thailand		Peru		
Guinea-Bissau	Togo	Vanuatu		Uruguay	*** Ratified**	
	Tunisia	Yemen				

Progress towards the implementation of the Nagoya Protocol

National level developments

Several Parties have initiated national-level processes towards the adoption and/or revision of national measures to meet the obligations set out in the Nagoya Protocol (Bangladesh, Brazil, Costa Rica Japan, Namibia, Norway, Nigeria, Switzerland, South Africa, Thailand)

Regional Initiatives:

- Commission of Central African Forests (COMIFAC): sub-regional ABS Strategy of the COMIFAC Countries
- EU Commission's legislative proposal on implementing the Nagoya Protocol in the Union

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Thank you for your attention!

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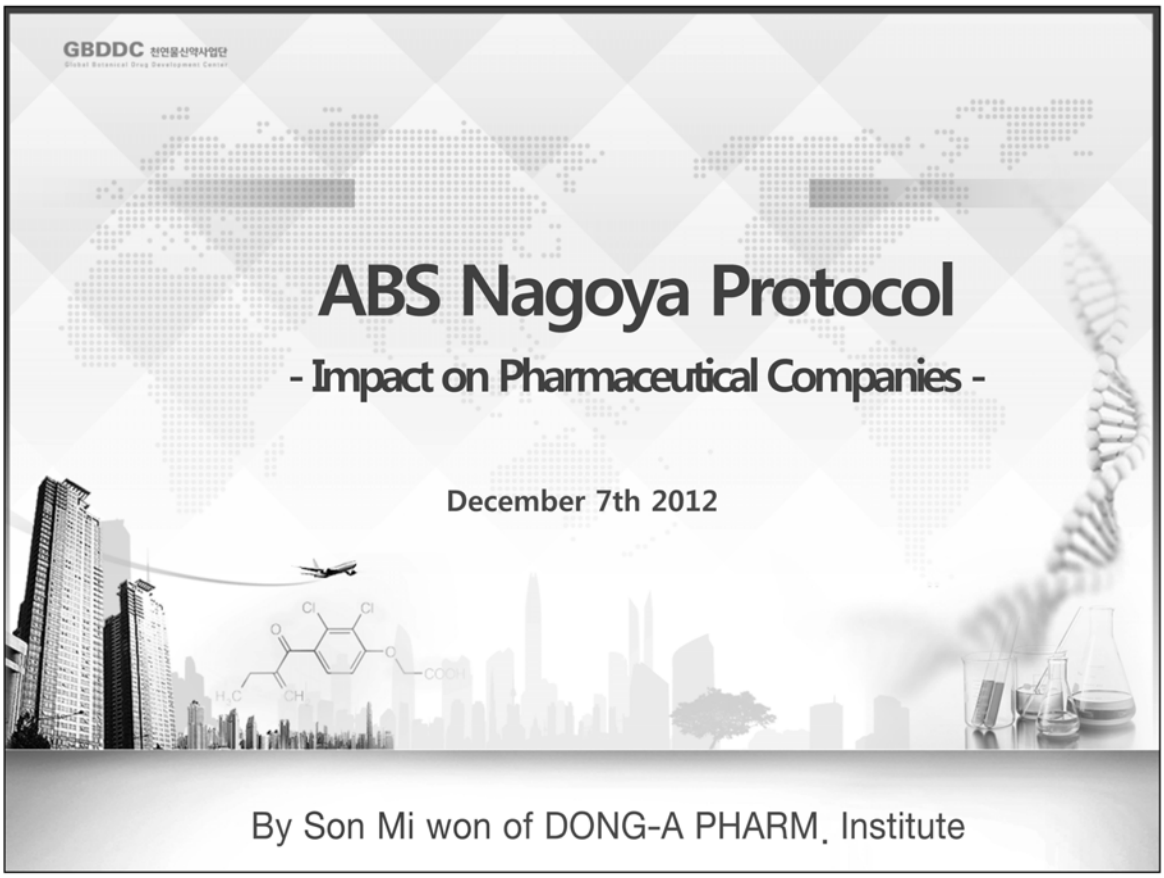
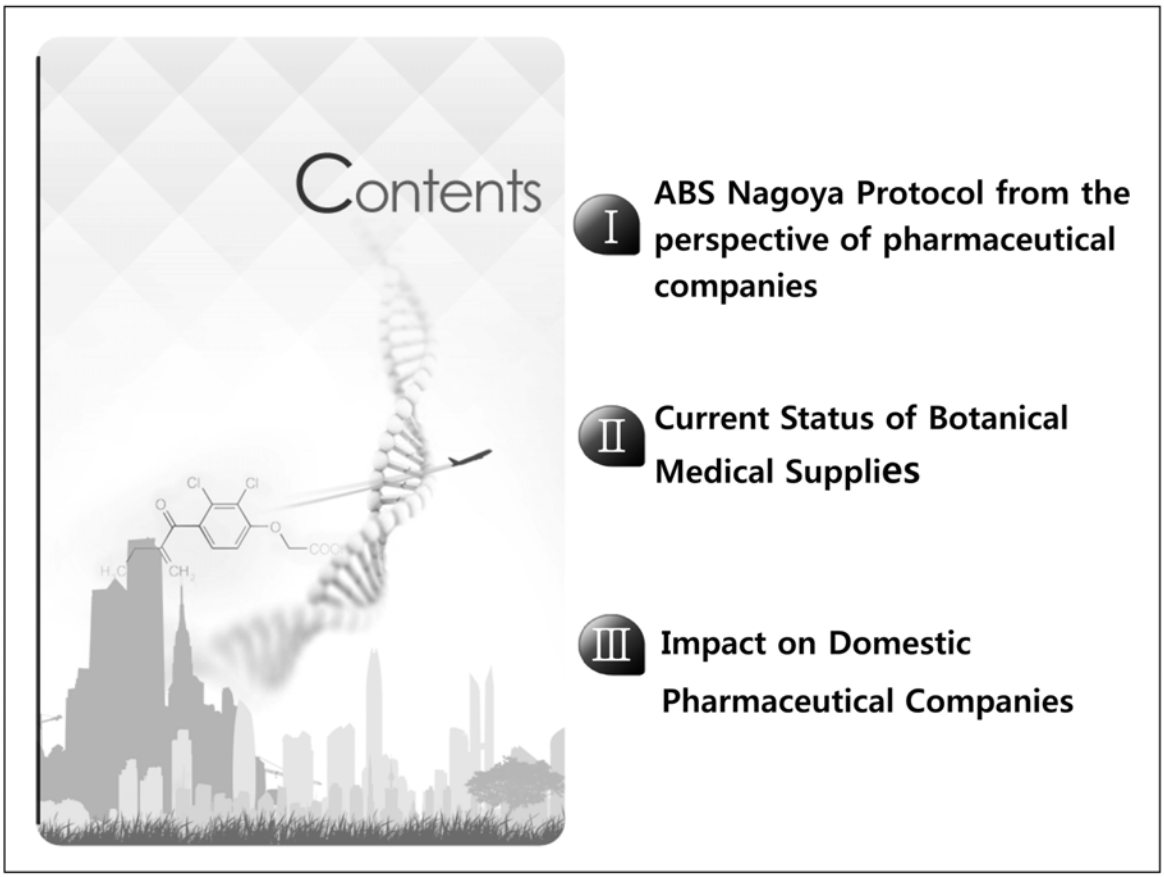
2. Industry and Researching Community Perspectives and Disclosure

Son, Mi Won


GBDDC
ABS Nagoya Protocol
- Impact on Pharmaceutical Companies -
December 7th 2012
By Son Mi won of DONG-A PHARM. Institute


Contents
I ABS Nagoya Protocol from the perspective of pharmaceutical companies
II Current Status of Botanical Medical Supplies
III Impact on Domestic Pharmaceutical Companies

I

ABS Nagoya Protocol from the Perspective of Pharmaceutical Companies

BackGround of ABS Discussion

Change in Perception on the Utilization and Development of Bio-genetic Resources

Convention on Biological Diversity (**'92**)

Common Assets for Mankind

Recognition of Sovereignty in Biogenetic Resources

Demand equal distribution of profits when using biogenetic resources

Developing countries claimed that they didn't get their fair share of profits and even were hurt from providing their biological resources to developed ones.

The Republic of Korea

Demand transparent and definite proceedings of using biogenetic resources

Developing countries demand the faire distribution of profits and transparent and definite legal procedurals as time and cost increase due to unclear process.

4

Core Issues of ABS Nagoya Protocoal

Issue	Main Contents	
	User Nations of Genetic Resources	Supplier Nations of Genetic Reosurces
Scope of Application	• After the Protocol taking into effect. • Include resources found on their territorie.s • Exclude derivatives.	• Before the Protocol taking into effect. • Include resources found outside their territories, such as Antarctica. • Include derivatives.
Sharing Profits	• Private Contract	• Share Profits through legislation.
Accessing Process	• Come up with a transparent accessing process. • Provide relevant information fully to people who want to access.	• Be Passive in coming up with an accessing. process • Be Reluctant to apply a streamlined accessing process to non-profit research works and an emergency.
Compliance	• Utilize existing judicial systems.	• Demand the introduction of stronger surveillance and tracking systems.

5

Main Contents of Nagoya Protocol-Application Score

➢ **Related regulations: Article 3 (Scope & Coverage)**

- Profits derived from biogenetic resources and their use within the scope and coverage descried in Article **15 of the Protocol**
- Profits derived from the **traditional knowledge** of biological resources and **its use** within the scope and coverage under the Convention

➢ **Main issues of the negotiations**

Developing Countries	Developed Countries
They claim retroactive application to profits from the use of biogenetic resources generated before the effectuation of the Protocol.	**They insist that profits from the use of biogen etic resources generated after the effectuation of the Protocol should be shared.**

- Article 15 is described in the Convention on Biological Diversity entered into force in 1993.
- Discussion on muti-national profit sharing systems.

6

Main Contents of Nagoya Protocol-Derivatives

➢ Related regulation: Article 2, 3, 5, 15, Article 2 of the CBD

- 'The use of **biogenetic resources' refers to R&D activities on biochemical and genetic composition of genetic materials including the application of bioengineering described** in Article 2 of the CBD.
- 'Derivatives' mean biochemical compounds naturally accrued from metabolism and gene expre ssion of organism or biogenetic materials even though they do not have genetic functions.

➢ Main issues of the negotiations

Developing Countries	Developed Countries
They claim that the use of derivatives should be included in profit sharing.	**They insist that derivatives should be excluded.**

- Biodiversity use is mostly related to derivatives from biogenetic resources such as plant extracts, rather than biogenetic resources themselves.

7

Main Contents of Nagoya Protocol-Others

➢ Nations eligible for Profit Sharing

- Related Regulations: the first and second clause of Article 5
- Profits, which are generated from commercialization and the second use of biogenetic resources, are fairly shared by the countries of origin of genetic resources.
- 'Profit Sharing' should comply with mutually agreed contracts.
  - ❖ Nations eligible for profit sharing should be worded as the country of origin of genetic resources.

8

ABS Infringement Cases

1) The case of Hoodia Gorofonii, an anorexigenic agent of traditional plant of Bushman in South Africa

- The CSIR, applied the patent on anorexigenic ingredients from Hoo-dia gorofonii, the n granted the right of use to Phytopharm and signed a licensing agreement with Pfize r & Unilever.
- At the insistence of "the rights over traditional knowledge" by a South African lawyer, Bushman was rewarded in return for giving upon the patent licensing.

2) The case of Maca Plant in Peru

- Maca, called as natural viagra, is a plant grown in Peru.
- The US Patent Office recognized the patent of the extracted material of MacaPure hel -d by US company Pure World Botanicals. However, Peruvian famers opposed the deci sion.
- Peru has made a law to share profits with the Peruvian government and its local com munities when medicine is developed by using its indigenous animals and plants.

9

ABS Measures to Deal with Risks

1) Olympus is developing an optical instrument by using firefly in Malaysia

✓ ABS measures to deal with risks

-Japan has laws barring the shipment of genetic resources of living organism.

-Financial profits are shared.

-Technology is transferred

-Patent application and intellectual property rights are shared.

Sharing Intellectual Property Rights

2) Mercian is developing a new drug using micro-organism in Indonesia.

✓ Micro-organism is provided by jointly exploring these resources.

✓ Only extracts (in the form of undiluted chemical) are taken out of the country of origin.

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II

Current Status of Botanical Medicine

High Value Added New Drugs

The World' s Top 10 Pharmaceutical Companies' Blockbusters

Ranking	Pharm.	Sales Results(2009)	Growth Rates comparing with2008	R&D Budget	Top-products	Indicant	Sales Volume
1	Pfizer	$45.45	3%	$7.85	Lipitor	Cholesterol	$11.43
					Lyrica	Epilepsy/neuropathy	$2.84
					Celebrex	Arthritis	$2.38
					Lantus	Diabetes	$4.30
2	Sanofi-Aventis	$40.87	1%	$6.39	Lovenox	Thrombosis	
					Plavix	Heart attack, storoke	
3	Novartis	$38.46	8%	$7.47	Diovan	Hypertension	
					Gleevec	Chronic myeloid leukemia	
					Zometa	Bone metastasis	
4	GlaxoSmithKline	$36.75	3%	$6.18	Seretide/Advair	Asthma, COPD	
					Valtrex	Herpes	
					Flovent	Respiratory	$1.21
5	Roche/Genentech	$36.02	8%	$2.80	Avastin	oncology	$5.47
					MabThera/Rituxan	Rheumatoid arthritis	$5.62
					Herceptin	Breast cancer	$4.86
6	AstraZeneca	$31.91	4%	$4.41	Nexium	Peptic ulcer, acid reflux	$4.96
					Seroquel	Anti-psychotic	$4.87
					Crestor	Cholesterol management	$4.50
7	Merck & Co	$26.93	4%	$5.85	Singulair	Asthma	$4.66
					Cozaar/Hyzaar	Hypertension	$3.56
					Zetia/Vytorin	Cholesterol management	$2.44
8	Johnson & Johnson	$22.52	8%	$4.59	Remicade	Rheumatoid arthritis	$4.30
					Procrit/Eprex	Anemia	$2.25
					Levaquin	Anti-infective	$1.55
9	Eli Lilly & Co	$20.63	5%	$4.33	Zyprexa	Schizophrenia	$4.92
					Cymbalta	Diabetic peripheral neuropathic pain	$3.08
					Humalog	Diabetes	$1.96
10	Bristol-Myers Squibb	$18.81	6%	$3.65	Plavix	Platelet inhibitor	$6.15
					Ability	Schizophrenia	$2.59
					Reyataz	HIV/AIDS	$1.40

$11.43
$2.84
$2.38

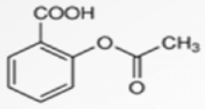
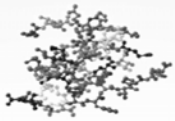
Blockbuster Medicine with High Sales Volume

Pfizer	Eight Blockbuster medicines consisting of 80% of the total sales
GlaxoSmithKline	Eight representing of 55% of the sale
Merck	Five representing of 68% of the sale
Johnson & Johnson	Five representing of 57% of the sale

Research on Botanical Drug

Types and characteristics of New Drug

Source: Daewoo Research center

Chemical Drug	Protein Drug	Botanical Drug
		
○ Market size $700b ○ Growth rate: 7% ○ Market: Worldwide ○ Manufacture: Organic synthesis	○ Market size: $63b ○ Growth rate: 18% ○ Market: Worldwide ○ Manufacture: Cell culture	○ Market size : $10b ○ Growth rate : 10% ○ Market : Asia, Europe ○ Manufacure: Extraction

Major botanical & botanical-derived drugs on the market

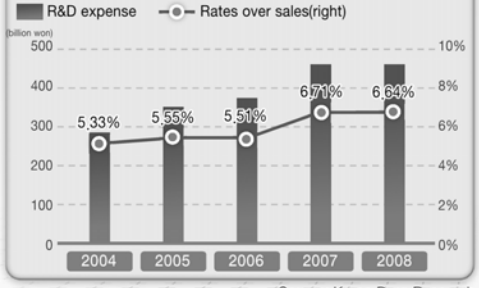
Taxol (BMS)	Bark of Yew (Taxus), Anticancer agent, $1.2b in annual sales
Compactin (San-kyo)	Microorganism, Hypolipidemic agent , ¥100b in annual sales
Tamiflu (Roche)	Fruit of Illicium verum, Influenza, 〉$2.9b (2009)
Tebonin (Schwabe)	Gingko leaf, Blood flow enhancer,, $20b in annual sales
Psyllium ex.	Seed of *Plantago asiatica*, Digestive, $300m in annual sales

13

Current Investment Status of Domestic R&D

International Pharmaceutical Companies R&D Expenses in 2008

Total R&D Expenses of 26 domestic pharmaceutical companies



Source: Korea Drug Research Association

Breakthrough methods for limited R&D expenses

US$8.7billion

R&D expenses for new drugs of Roche

US$400million

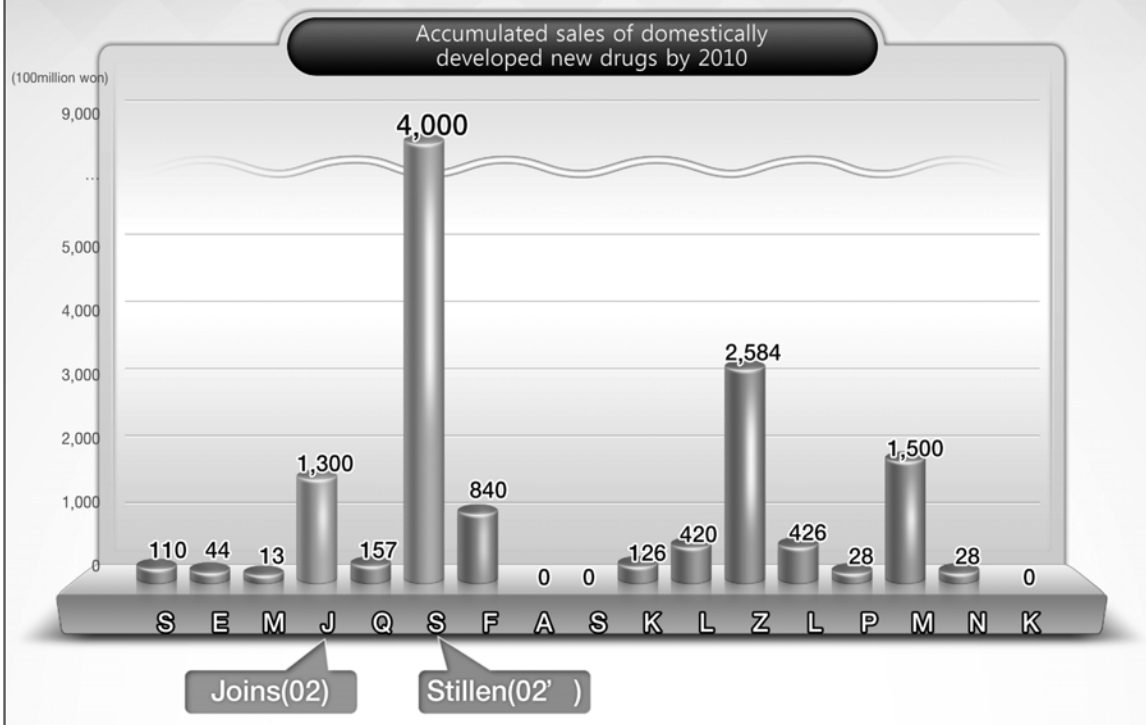
Total R&D expenses for new drugs of the domestic Pharmaceuticals

Global blockbuster drugs are developed by utilizing top-rated native natural resources and boosting researches on botanical medicines, which are highly efficient in investment.

Enhancing competiveness in overseas' market with domestic technology

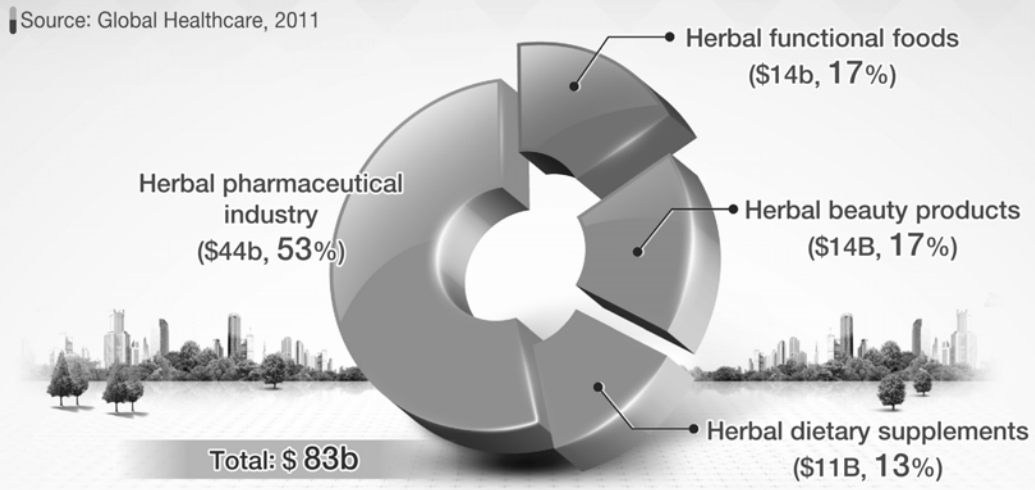
14

Competitiveness of Botanical Drugs: commercially successful R&D efforts



15

Global Trend in Botanical(Herbal) Products



- Global market for botanical drug
  2011: $164b ➜ 2017: $278b ➜ 2023: $423b (WHO)
- Botanical industry sales are expected to reach $5t by 2050 (World Bank)

16

Current State of the Domestic Market and Prospects

Market Size of Botanical Drugs

- The domestic market size of botanical drugs is about 500billion won including 190billion won in herbal me dici-ne.
- Economically viable products among domestically developed ones are only a few, such as Stillen, Joins, and Prospan.

Sales Volume of Domestic Botanical drug Market (unit: 100million won)

(source: IMS)

Domestic Pharmaceuticals	Products	Indicants	2011
Dong-A Pharmacy	Stillen	Gastritis	662
SK Chemical	Joins	Arthritis	246
Ahngook pharm	Prospan	Phlegm	232
SK Chemical	Ginexin	Blood circulation	181

Development Status

- The total 48 clinical tests were ongoing in 2011.

Reference Policies on Boosting and Developing Domestic Botanical Drugs

- The Ministry of Knowledge Economy
  : Projects for developing global-led botanical medicines
- The Ministry of Health and Welfare
  : Establishing plans on boosting R&D of botanical medicines

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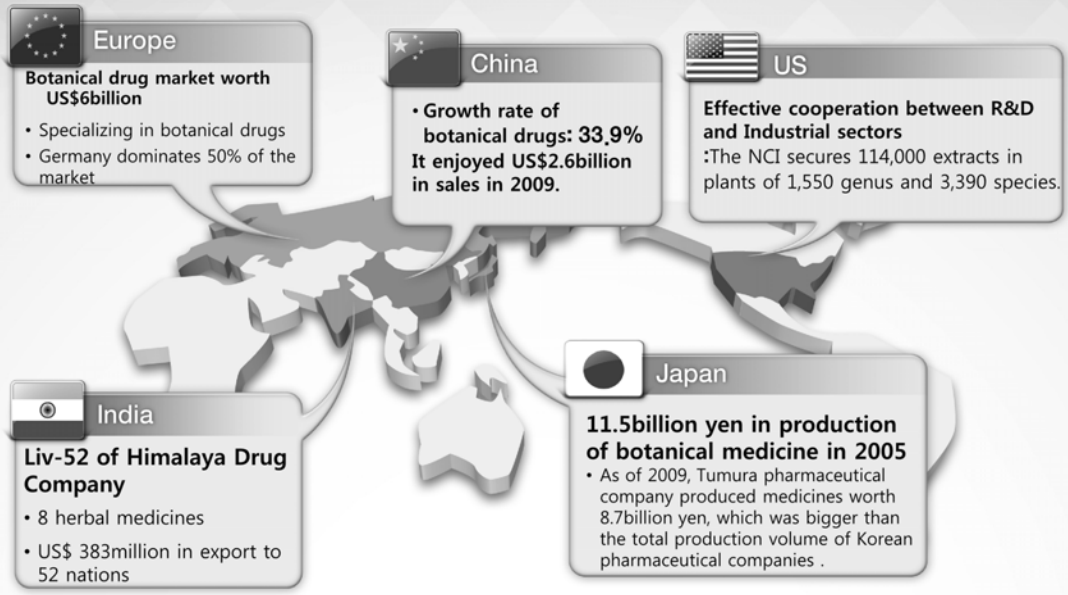
Global Market Status of Botanical Drugs



[The development of botanical drugs overseas mainly focuses on anti-cancer and arthritis.]

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Definition & Characteristics of Botanical Medicines

Definition

- **Botanical medicine is one being made with natu ral resources based on modern medical science.**

cf) Chemical (synthetic) medicine:
is one being made with synthetic products.

The need for developing botanical new drugs

The need for safe and effective multiple targeting botanical new drugs

Characteristics

- **Developing economically viable blockbuster drugs**
  → Less cost and time for development
- **Higher success rates for developing blockbuster drugs than other ones**

cf) The success rate of chemical drugs is 1/10,000.

Increase in chronic and intractable diseases
Cancer, gastrointestinal and inflammatory diseases

Increase in senile disorder due to aging population
Arthritis and neuropathy diseases

Increase in disease related to western diet and life style such as adult disease and obesity
High blood pressure, hyperlipidemia, cardio vascular diseases

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Development Status of Domestic Botanical Medicine

Sales Volum in Botanical Medicines of domestic pharmaceutical companies

(100million won)

Company	Product (major component)	Indicant	2008	2009 (2010)	Note
Dong-A	Stillen (mugwort)	Gastritis	607	836 (877)	The highest sales in domestically made new drugs
SK Chemicals	Joins (C.florida, Trichosanthis, Thesium)	Arthritis	150	263 (261)	
Angook	Prospan (Ivy Leaf)	Phlegm	523	406	
Huons	Salsarazine (18 kinds of plants such as Korean angelica root and peony)	Abdominal obesity	70	100	Prescription from Tonguibogam
Guju	Apitoxin (melissotherapy)	Arthritis	5	16	
Kwang Dong	PyunJaHwan Pill (Pyrite nodule, ox bezoar)	Hepatitis, ophthalmi-a	1	1.3	Adopting Chinese prescription
YuYu	Tanamin D (gingko leaf	Blood circulation	350	80	Independent development No pay
SK Chemicals	Gynexin (gingko leaf)	Blood circulation	500	125	Independent development No pay

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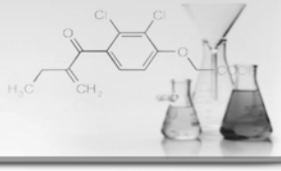
Development Status of Domestic Botanical Medicine

- Measures to boost R&D efforts in botanical medicine (2001) and nurture oriental medicine (2004)
- The approval number of clinical trial of botanical drugs has increased since 2008
- 60 newly licensed botanical medicines in 2010
  - 52 cases in arthritis (70%)
  - 4 cases in improving blood circulation (7%)
  - 4 cases in treating gastrointestinal disorders(7%)



Current status of clinical trials planning for botanical drugs('06~'10)

Classification	2007	2008	2009	2010	2011
First trial	1	-	1	-	1
Second trial	6	4	7	10	21
Third trial	2	4	5	7	18
Clinical trials by researchers	-	-	2	5	5
Total	9	8	15	22	47

Source: Korea Food and Drug Administration

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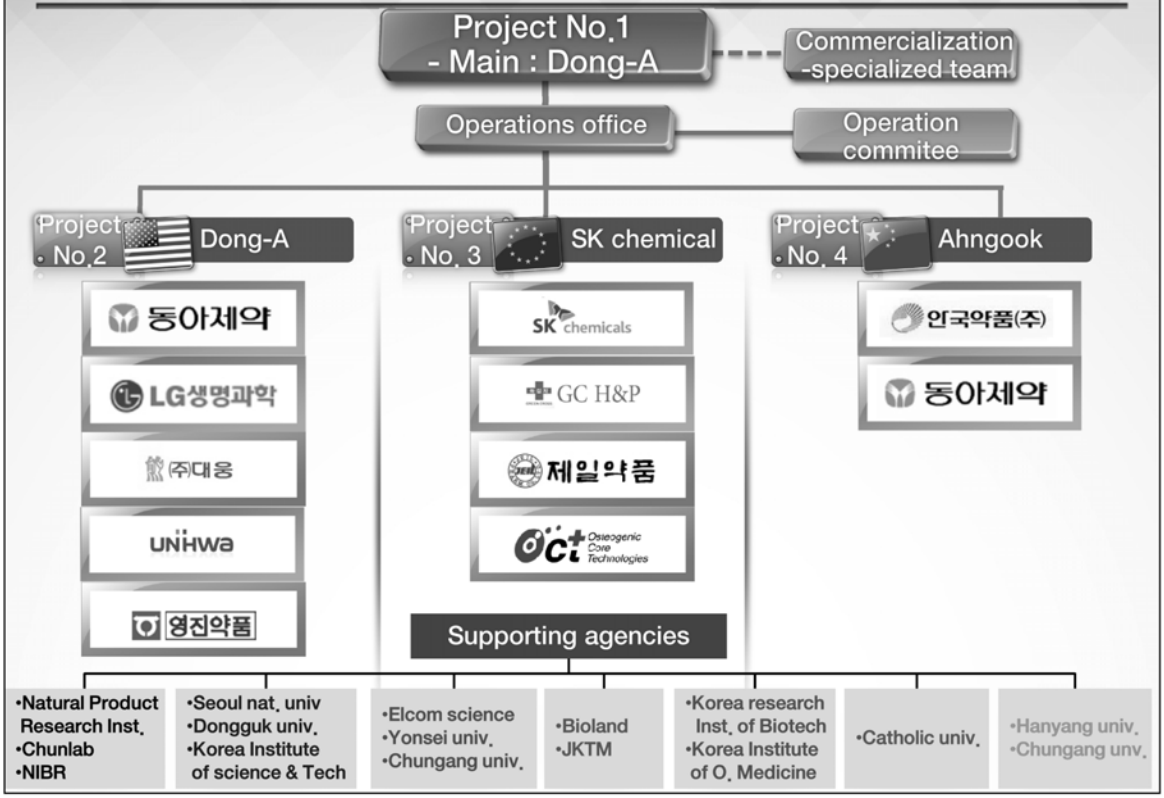
1. Introduction - Organizational chart



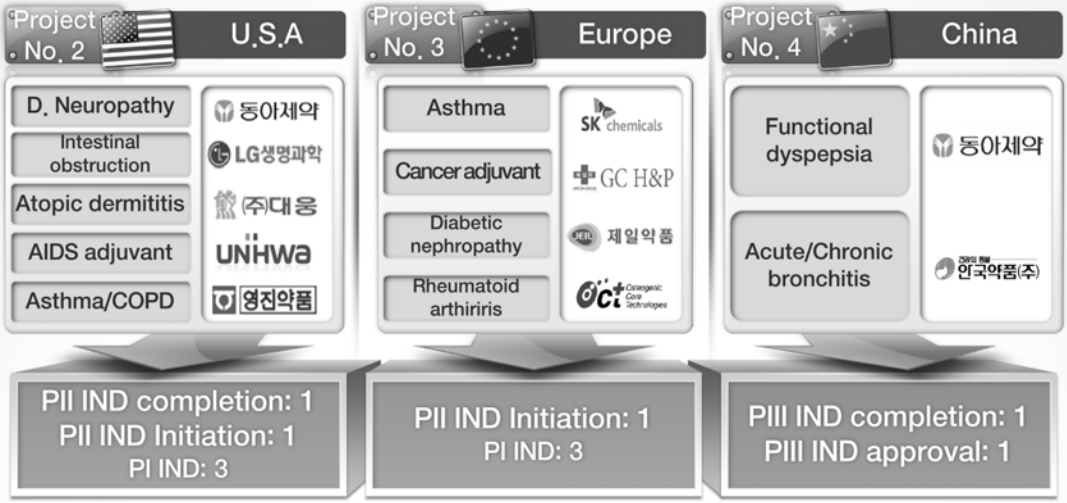
1. Introduction - Business Goals

Our final goal

Establishment of global-standard botanical drug development system

- For the development of blockbuster drug worth more than $1B in annual sales

Goals (in terms of R&D)



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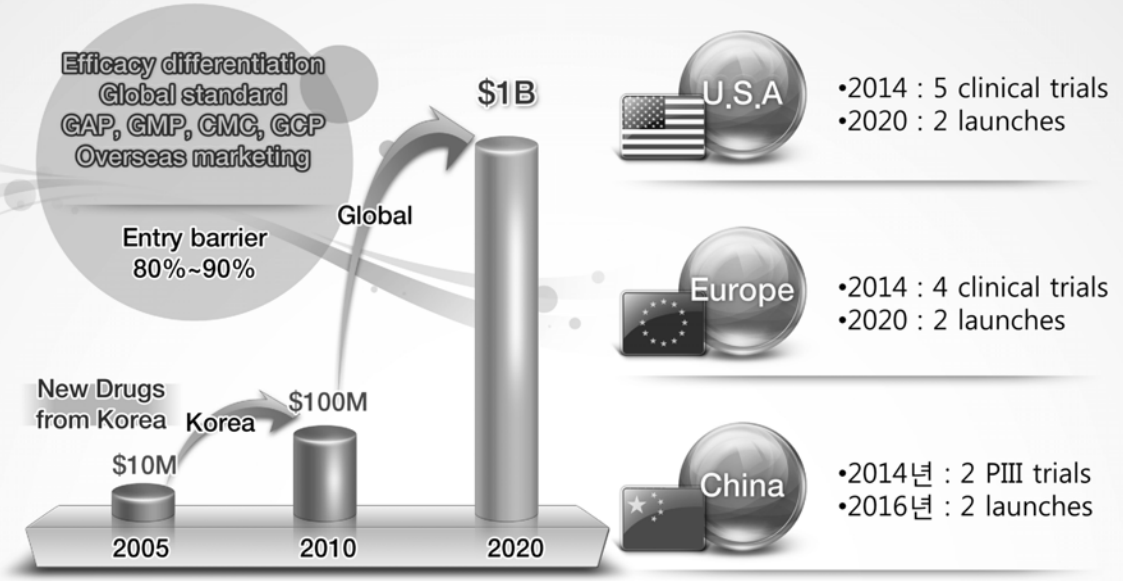
1. Introduction- Expected outcomes

Economic factor

Early goal accomplishments & fast market entry → market preoccupancy, securing the initiative



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3. Development status - U.S.A

Dong-A : Diabetic neuropathy

- Strong analgesic effect & regeneration of nerve
- Under PII in Korea
- Phase II IND submission by early 2013

LG Life science : Intestinal obstruction

- Under P II in Korea
- Phase I IND submission by 2013

Daewoong : Atopic dermitiitis

- Alleviation of pruritus , Anti-inflammatory effect
- Formulation will be decided based on skin irritation test & skin transparency test
- Phase I IND submission by 2013

Un-Hwa : AIDS adjuvant

- Cultured ginseng radix - lyophilized 100%)
- FDA pre-IND meeting done, PII IND submission within 2012
- Under construction of cGMP facility for manufacture

Yungjin : Asthma/COPD

- Formulation will be decided after discussion with CRO
- FDA pre-IND meeting (2012. 6. 29)

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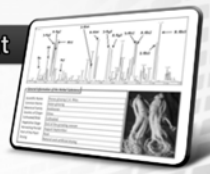
3. Development status - Europe

SK chemical : Asthma

- Oral botanical drug with multi-function
- PII clinical trial completed in Dec, 2011 in Korea.
- Pre-clinical study in E.U: 4 weeks repeated dose toxicity in non-rodent completed

GCH&P : Cancer adjuvant



- Synergistic effect with anti-cancer agent & lessen side effect
- GMP-certified manufacture of materials: by Indena (CMO)
- PI IND submission in 2013

Je-il : Diabetic nephropathy

- Meeting Unmet needs
- Pre-clinical study done, GAP for raw material certified

Oscotec : Rheumatoid arthritis

- High safety profile & ensured efficacy
- Under API manufacture of in europe, formulation study

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3. Development status - China

Ahngook : Bronchitis

- 2011.10.1:Launch in Korea $30M in sales in 9 months
- Selection of CRO for bridging study & developing clinical protocol
- SFDA IND submission in August

Dong-A : Functional dyspepsia

- 2011.12.1: Launch in Korea (Motilitone)
- Organization of Korea-China advisory board meeting based on ANMA for development of clinical protocol
- Under development of CTD data, SFDA IND submission in September

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III

Impact on Domestic Pharmaceutical Companies

Current Status

Problems

✓Korea pays annually 1.5trillion won in royalty abroad to use biological resources.

✓Pharmaceutical, cosmetic and bio companies, which heavily depend on overseas market for their product materi als, are expected to suffer a heavy blow by the effectuation of the Nagoya Protocol.

Global market size for biogenetic resources

Related Sector	Market Size (Billion $)
Medicine and medical supplies	75-150
Botanical derived products	20-40
Agricultural Products	300-450
Horticulture and foliage plants	16-19
Agricultural Pesticide	0.6-3
Bio related products	60-120
Cosmetics	2.8-2.8

There need for more understanding of biodiversity, measures to deal with The Nagoya Protocol and create opportunities.

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Current Status

Market size of bio industry

- ✓ The bio industry using bio resources generates 700trillion won in profit annually.
- ✓ In 2015, the market will reach 3700 trillion won, 8 times greater than that of the carbon market.

Bio industry in Korea

- ✓ The National Environmental Research Complex under the Ministry of Environment works on finding native living organism.
- ✓ Of 100,000 species of our native living organism, 37,000 species have been discove red.
- ➔ The number is only half of 70,000~80,000 species found on British and Japan, which are similar to Korea in terms of territorial size and natural environment.

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Threats

✓ Companies that produce products made from imported botanical products incl uding medical plants will suffer when the Nagoya Protocol comes into effect.
➔ Botanical new drugs, herbal medicine, oriental medicine

Company	Product	Ingredients
Dong-A	Stillen	Extracts from mugwort
Dong-A	Motiliton	Extracts from tuberous plant such as seeds of morning glory
Green cross	Sinbaro	Black beans, Eucommia bark, Acanthopanax, etc.
SK Chemical	Joins	C.florida, Tichosanthis, Thesium

Most ingredients are imported from China.

✓ It is likely that companies using overseas' resources experience li mited access to overseas' resources due to rising prices in royalty to them.

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Opportunity

Securing Native Resources

- ✓ Securing native resources in advance and finding resources that have differentiated effects
- ✓ Securing resources for medicines from crude drugs (resources overlapped with those of China and Japan)
- ✓ Using patent rights and the order of priority of ABS rights
- ✓ Using derivatives that are not protected by the patent law

Utilizing Overseas' Resources

- ✓ Working on Joint development of overseas' bio resources
- ✓ Coming up with measures to reduce extra cost on using overseas' resources after the Protocol comes into effect
- ✓ Preparing for possible problems such as a lawsuit arising from the lack of understanding of the ABS

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THANK YOU
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3. Implementation Strategies for Nagoya Protocol - Korea's Perspective

Park, Won Seok

Implementation Strategies for Nagoya Protocol -Korea's Perspective-

Won Seok Park, *S.J.D.*
Professor of Law
School of Law
Chung-Ang University

Scope of Presentation

I. General Introduction to Nagoya Protocol

II. Current Status of Korea's ABS Laws

III. Proposals for Implementing Nagoya Protocol in Korea

I. GENERTAL INTRODUCTION TO NAGOYA PROTOCOL

- **A Masterpiece in Creative Ambiguity,**

  or

- **A Worstpiece in Ambiguous Creativity?**

SCOPE OF APPLICATION: Derivatives Included?

- **CBD**
  - **Sharing of Benefits Arising out of Utilization of GR**
  - **Definition of Genetic Resources: any Material of Plant, Animal, Microbial or other Origin Containing Functional Units of Heredity**

- **Nagoya Protocol**
  - **Utilization of GR or Traditional Knowledge**

DEFINITIONS OF GR & DR

-Utilization of GR: Conduct Research & Development on Genetic and/or Biochemical Composition of GR

Cf) EU: Use of GR-Same as Nagoya Protocol

-Derivatives: naturally occurring biochemical compound resulting from genetic expression or metabolism of BR or GR, even if they do not have functional units of heredity

Cf) EU: No Definition on Derivatives

-No Definition on Utilization of TK associated with GR

Cf) EU: TK Held by ILC that is Relevant for the use of GR and that is as Such Described in the MAT Applying to the Use of GR

Entry into Force for PIC & MAT

- CBD Art. 15.5
  - Access to GR shall be subject to PIC of CP providing such GR, unless otherwise determined by that Party.
  - CBD HAS already required PIC, unless otherwise determined.
  - Then, How can it be otherwise determined? or How can PIC be relinquished or ignored or considered to be relinquished?

ENTRY OF FORCE FOR PIC/MAT

-If there is no ABS Law or requirements,
IMPLIED GIVING UP?

- Nagoya Protocol: No Retrospective Effect
  -No Definition on Access in NP

  c.f.) EU: Acquisition of GR or of TK in a Party to NP in Accordance with Applicable Domestic ABS Legislation or Regulatory Requirement of <u>That Party</u>

ENTRY OF FORCE FOR PIC/MAT

- Art. 6.1: Subject to sovereign rights over GR and domestic ABS legislation or regulatory requirements, access to GR shall be subject to PIC of

  - Providing Country that is Country of Origin of such Resources <u>or</u>
  - Providing Party that has acquired in accordance with CBD,

ENTRY OF FORCE FOR PIC/MAT

- Art. 6.3: Party requiring PIC shall take measures to
(a) provide for legal certainty, clarity and transparency of ABS law or reg. req.
(b) fair and non-arbitrary accessing rules,
(c) PIC application information---

Possible Interpretation:
PIC only after ABS Law or Requirement is enacted. Access to TK associated with GR

- PIC shall be obtained from ILC,
not its Government

c.f.) Access to GR under ILC's Established Jurisdiction

- Relevant Issues:
No PIC, No MAT?
PIC without MAT?
MAT without PIC?

BENEFIT SHARING OF GR

- Scope of Benefit-Sharing
-Benefits from utilization of GR as well as subsequent applications and commercialization

-Monetary and Non-monetary benefits included (Annex)

-Fair and Equitable Sharing? Determined by MAT

- With Whom
-Providing Party that is COOR OR
-Party that has acquired GR in accordance with CBD
or
-ILC, if established in accordance with domestic legislation

BENEFIT SHARING OF GR

- **Method of BS**
  -Mutually Agreed Terms

- **Timing of BS of GR**
  -At the time of establishment of PIC
  Requirements after entry into force of and accession to CBD

BENEFIT SHARING OF TK

- **Scope of Benefit-Sharing**
  -Benefits from utilization of TK
  -Excluding subsequent applications and Commercialization? NO
  -Monetary and Non-monetary benefits included (Annex)
- **With Whom**
  -ILC, regardless of established rights
- **Method of BS**
  Mutually Agreed Terms

BENEFIT SHARING OF TK

- **Timing of BS of TK**
  -Only after entry into force of and accession to Nagoya Protocol, b/c no mandatory requirement under CBD art. 8(j)-encouraging clause

- **Practical Issues**
  -Whether "processed materials" are also subject to PIC and MAT? YES.
  Cf) EU: Due Diligence Rule Applies

  -Country of Origin of materials?
  -Legitimate provider of such materials under CBD?

II. KOREA'S CURRENT ABS POLICY

-Biodiversity Conservation and Use Act-

- **No Special ABS Law until as of Dec. 2012**

- **Relevant Regulations requiring PIC**

Biodiversity Conservation and Use Act

- **Biodiversity Conservation and Use Act(BCUA)**
  -Basic Law for ABS legislation

  -Scope of application: Biological Resources (not Genetic Resources)

  -PIC applies only to BR designated by Minister of Environment according to Presidential decree when taken abroad(Art. 11)

Biodiversity Conservation and Use Act

-Discretionary Prohibition on Taking Abroad

a. Extremely Exceptional Population in Natural Habitat

b. Threatened to Cause Significant Loss to National Interests

c. Possessing Figurative /Genetic Properties with High Economic Value

d. Threatened with its Survival if Taken Abroad (Art. 11.3)

Biodiversity Conservation and Use Act

- Revocation of PIC for Taking Abroad
  (i) Approval with false or other inappropriate representation, (ii) Unapproved use (Art. 12)

-Filing of Accessing BR: foreigners(natural, legal entity, international organization) accessing BR for their utilization

- National contracting with foreigner for utilization of BR(Art. 13)

III. PROPOSALS FOR IMPLEMENTING NAGOYA PROTOCOL IN KOREA

- **Providing Country v.**

  User Country v.

  Extreme User Country
  (No PIC & MAT required)

- **Reasonable User Country**

PROPOSALS for Implementation

- **Competent National Authority**
  -grant access or issue written evidence or permit
  -advise on procedures for PIC and MAT

(Korea's Choice)
-Single or Multiple?
-not agreed among governmental entities
-possibly multiple, depending on characteristics or end-uses of BR

PROPOSALS for Implementation

- **CHECK POINT(S)**
  -(Functions) monitor and enhance transparency about Utilization of foreign GR within its jurisdiction

-would collect or receive information related to PIC, source of GR, establishment of MAT, Utilization of foreign GR
(BUT NOT MANDATORY)

Cf) EU: Mandatory Recording of Source of GR & TK as well as Subsequent Users for 20 Years

PROPOSALS for Implementation

- **ABS Clearing House**
  -"information sharing" House
  -provide any information required by NP and COP/MOP decisions
  -ABS measures
  -information on national focal point and competent national authority
  -permits or equivalents
  -Other non-mandatory information such as those above of ILC, model contractual clause, monitoring methods and tools, etc.

Thank you


MEMO


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