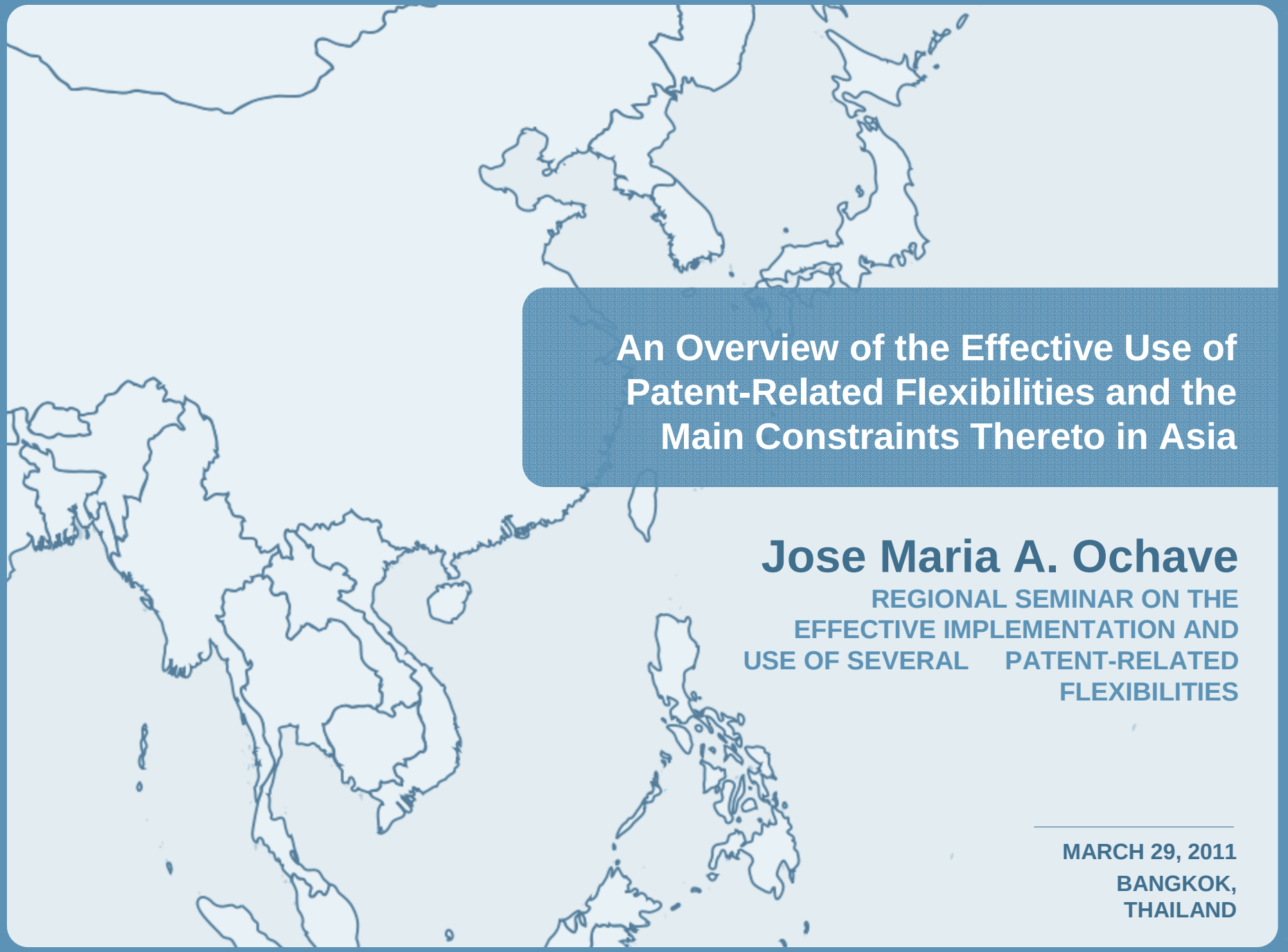
DEPARTMENT OF INTELLECTUAL PROPERTY
MINISTRY OF COMMERCE

OMPI
ORGANIZACIÓN MUNDIAL DE LA PROPIEDAD INTELECTUAL

Regional Seminar on the Effective Implementation and Use of Several Patent-Related Flexibilities

Topic 5: An Overview on the Use of Patent Related Flexibilities and Main Constraints thereof within the Asian Region

Bangkok, Thailand
March 29 to 31, 2011



An Overview of the Effective Use of Patent-Related Flexibilities and the Main Constraints Thereto in Asia

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REGIONAL SEMINAR ON THE EFFECTIVE IMPLEMENTATION AND USE OF SEVERAL PATENT-RELATED FLEXIBILITIES

MARCH 29, 2011

BANGKOK, THAILAND

OUTLINE

An Overview of the Effective Use of Patent-Related Flexibilities and the Main Constraints Thereto in Asia

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4. **Effective Use of the Flexibilities: Country Examples**
5. **Common Elements in Effective Use**
6. **Constraints to Effective Use**
   - In incorporating into national law
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7. **Points for Further Discussion**

Introduction

An Overview of the Effective Use of Patent-Related Flexibilities and the Main Constraints Thereto in As

INTRODUCTION

Access to Essential Medicines in Asia

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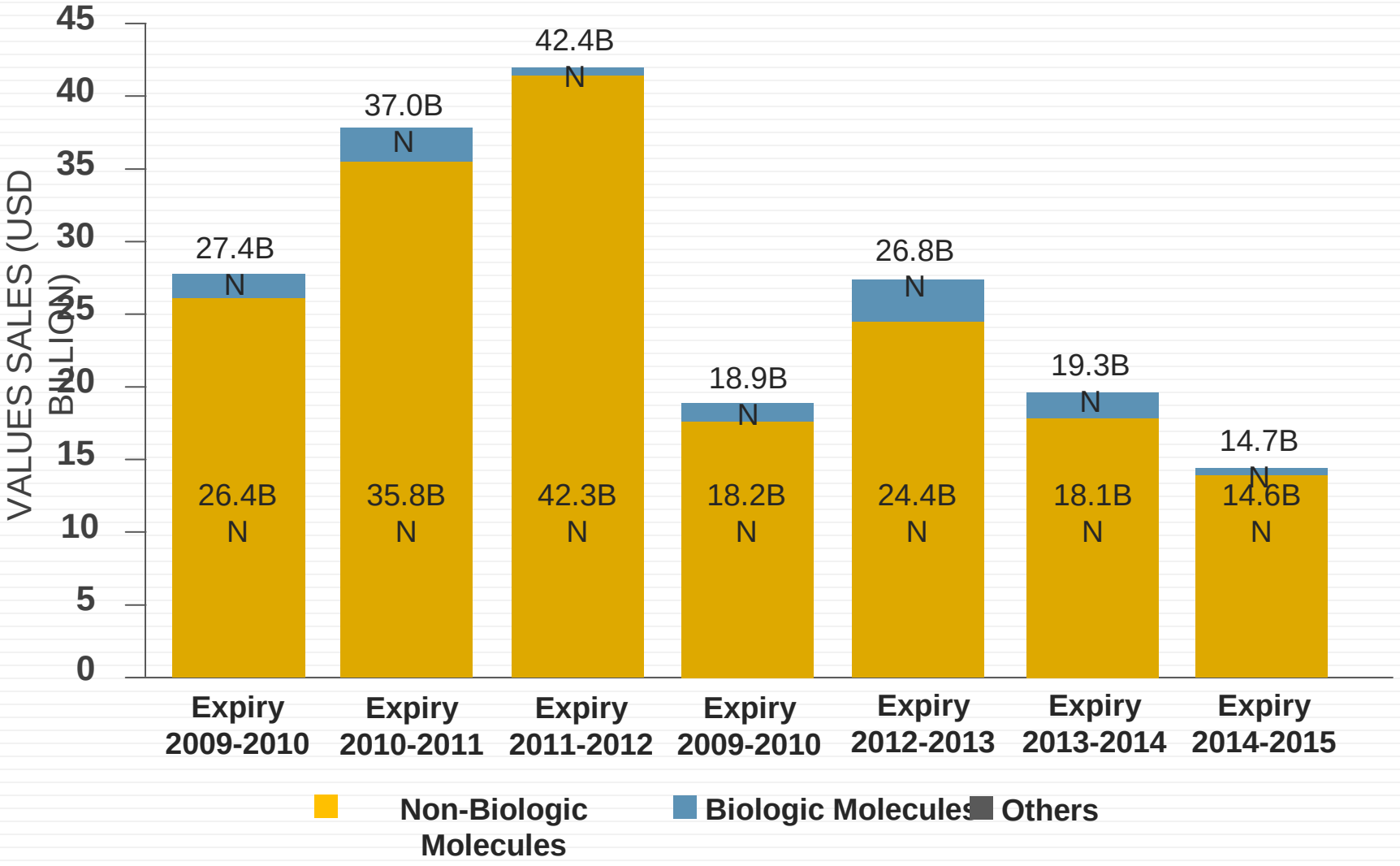
- As of September 2010, the Asian pharmaceutical market is at USD 158 Bio, or around 20% of global sales of USD 780 Bio. It is expected to grow faster than the rest of the world. By 2014, the Asian pharma market will be at USD 221 Bio (8.8% growth) vis-à-vis USD 691 Bio for rest of the world (2.7% growth). [IMS 2010]
- Considerable out-of-pocket spend for health relative to developed countries.
- Healthcare policies and systems vary significantly from one country to another. No such thing as an Asian Model.
- Patent-related flexibilities are not the only policy instruments available to governments in expanding access to essential medicines. Price control; drug price referencing; generics labeling; generics substitution; Essential Drugs List; requirement of local manufacture; discount schemes.

The Patent cliff – 18.6bn sales revenues of patent protected medicines is likely to be exposed to generic competition between 2010-2016

Biologics/Non-biologics: Global sales value of patent losses



Source: IMS Health MIDAS Market Segmentation MAT Sept 2009 – Market Segmentation Countries only.

INTRODUCTION

Patent-Related Flexibilities

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- "Flexibilities" means that "there are different options through which TRIPS obligations can be transposed into national law so that national interests are accommodated and yet TRIPS provisions and principles are complied with."CDIP/5/4 Rev
- **Categories of flexibilities:**
  1. Flexibilities in the process of acquisition of the right.
  2. Flexibilities in defining the scope of the right. ←
  3. Flexibilities when enforcing the right

INTRODUCTION

Flexibilities in Defining the Scope of Right

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1. Exhaustion of rights/Parallel Importation
2. Regulatory review exemption
3. Research exemption
4. Compulsory licensing and Government Use

Pharmaceuticals 10

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PHARMACEUTICALS 101

The Pharmaceutical Value Chain

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1. **Sourcing/Manufacturing the product**
   - If sourced as finished product, identification and negotiations with the source
   - If manufactured, identification of API and excipients source and manufacturing. Formulation R&D, conduct of validation batches and stability testing.
2. **Packaging** (primary/secondary)
3. **Product registration with drug regulatory authorities**
4. **Marketing and Promotions**
5. **Distribution**
6. **Sale to channels** (drugstores, hospitals, doctors, government)

PHARMACEUTICALS 101

Categories of Generics

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- **Generic drug – a copy of the originator's drug whose patent has expired.** It must be identical or within an acceptable bioequivalent range to the originator's drug with respect to pharmacokinetic and pharmacodynamic properties. Identical in dose, strength, route of administration, safety, efficacy and intended use.
- **Categories of Generics:**
  1. Commodity generics – usually an unbranded generic version of easy to produce small molecules originator brands.
     - Unbranded generic – sold by their International Nonproprietary Name. US and UK have well-developed unbranded generics.
     - Branded generics – off-patent prescription drugs sold under a brand. Favored in Japan and France and in emerging markets like China and India.

Categories of Generics

2. Specialty generics – generic products that have one or more competitive barriers to market entry, e.g., difficulty in sourcing raw material, complex formulation or development characteristics, or special handling requirements. Includes modified release and oncology products, products with niche markets, and sterile drugs administered by injection or infusion.

3. Supergenerics ("incrementally modified drug") - improved version of an original drug which has lost product patent protection but usually with other patents protecting the formulation or composition of the drug in the new improved formulation or delivery system. Nature of improvement includes new drug delivery, manufacturing or reformulation technology. Types: (i) new dose forms; (ii) new synergistic combinations of generic single entity formulations; (iii) new salts; (iv) new use

Categories of Generics

4. Biogenerics, biosimilars and follow-on biologics – officially-approved subsequent versions of originator's biopharmaceutical products made by a different company. Biologics have high molecular weight and often sensitive to manufacturing process. Biosimilar manufacturer will usually not have access to originator's molecular clone or original cell bank nor to exact fermentation and purification process.

Source: Buggle, Irene (2010). Market Opportunities for Supergenerics: Regulatory Issues

Context of Exercis
of the Flexibilities

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Flexibilities and the Main Constraints Thereto in A**

A. Sources of Healthcare Funding

1. **Government**

   (United Kingdom, Germany, Thailand, Taiwan)

2. **Insurance**

   (United States)

3. **Out-of-pocket**

   (India, Philippines, Indonesia)

B. Architecture of the Pharmaceutical Sector

1. Relative strength of the various players in the market (government, doctors, hospitals, third-party payors, pharmaceutical companies, distributors, wholesalers)
2. Point of Care and Point of Sale dynamics. Separation of prescribing and dispensing.
3. Originator companies vis-à-vis generic companies.
4. Local companies vis-à-vis multinational companies.
5. Existence of competing healthcare products (e.g., herbals, traditional medicines).
6. Manufacturers vis-à-vis traders.
7. Historical/political issues relating to pharmaceutical source countries.

C. Pharmaceutical Manufacturing Capability

1. No manufacturing and entirely dependent on imported finished medicines
2. Manufacture of finished formulations from imported active pharmaceutical ingredients
   - Sterile or Non-sterile
3. Development and manufacture of super generics
4. Manufacture of synthetic active pharmaceutical ingredients
5. Development and manufacture of biosimilars
6. Development and manufacture of new chemical entities

Effective use of the Flexibilities

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EFFECTIVE USE OF THE FLEXIBILITIES

Indonesia

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The Context:

- **Healthcare system based mainly on out-of-pocket payments.** Less than half of the population is covered by any health insurance scheme. Public sector employees entitled to benefits under Askes scheme, while some private sector employees have company health insurance plans. Medical care for the poor is through Jamkemas, but it has been problematic in terms of implementation and funding.
- **Malaria has been successfully controlled.** Confirmed malaria cases fell from 31.09 per 1000 in 2000 to 19.67 in 2007. Dengue, however, is on the rise. Prevalence of TB has been reduced through better detection and treatment. HIV/AIDS growing rapidly.

EFFECTIVE USE OF THE FLEXIBILITIES

Indonesia

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- **Government is promoting low-cost medicines.** No direct price control in the private sector. Prices in the public sector are controlled through the Essential Drug List System. Generic substitution expected under Government Regulation No. 51 (issued September 2009), which allows pharmacist to substitute the prescribed product provided approval is obtained from the "doctor and/or the patient".
- **Decree 1010. Issued in November 2008.** Provides that:
  - MNCs which do not own manufacturing facilities in Indonesia are classified as wholesalers. As such they may not register new drugs for import from abroad or renew registrations. Instead, initial registration may be made by a manufacturer.
  - Imported medicines may only be registered with written approval from the overseas manufacturer, who must agree to transfer technology so that within five years the medicine may be produced in Indonesia. Not applicable to patented products..
- **Local manufacturers account for more than 70% of sales.** Kalbe Pharma, Sanbe, and Dexa Medica comprise 23.5% of the market. The government has majority ownership of 4 manufacturing companies, PT Kimia Farma, PT Indofarma, PT Phapros and PT Biofarma. Biofarma specializes in vaccines and exports 80% of its business.

EFFECTIVE USE OF THE FLEXIBILITIES

Indonesia

An Overview of the Effective Use of Patent-Related Flexibilities and the Main Constraints Thereto in Asia

Use of Flexibilities:

- Compulsory licensing confined to HIV/AIDS antiretrovirals for use in emergency public health programs. On October 5, 2004, Indonesia issued a compulsory license to manufacture generic versions of lamivudine and nevirapine, until the end of the patent term in 2011 and 2012, respectively. The license is for government use, and includes a royalty rate of 0.5% of the net selling value.

  No CL of other patented products based on cost.

- Grants regulatory review exemption. No data exclusivity and patent linkage. PhRMA recommended relisting of Indonesia on the Priority Watch List because of these.

EFFECTIVE USE OF THE FLEXIBILITIES

Philippines

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THE CONTEXT:

- **Healthcare system consists of mixture of public and private healthcare providers.** Expanding public health sector although funds continue to be inadequate. Population still largely depends on our-of-pocket spending for medical treatment. About 65% of healthcare provision is funded by the private sector, of which 84% is our-of-pocket. For pharmaceuticals, it is 90%.
- **Government committed to increase from 20% to 85% of the population who can purchase medicines.** Child health is below regional standards and maternal mortality remains high. Main causes of adult death are heart disease, cerebrovascular disease, cancer, TB, chronic lower respiratory diseases and diabetes mellitus. Philippines has 9th highest TB incidence in the world and second highest in the Western Pacific Region.

EFFECTIVE USE OF THE FLEXIBILITIES

Philippines

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- **Government efforts to reduce medicine costs culminated in R.A. 9502 (Cheaper Medicines Act).** Various discount schemes soon followed, e.g., senior citizens discount, persons with disabilities discount. Government social health insurance for indigents will be expanded. PITC has authority to do parallel importation.
- **Prescribing is generally separate from dispensing, with most of the sales coming from drugstores.** However, dispensing doctors are on the rise.
- **Around 65% in value is MNCs, but generics are rising rapidly.** Biggest pharma company is a local company.

EFFECTIVE USE OF THE FLEXIBILITIES

Philippines

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Use of Flexibilities:

- **Enacted Cheaper Medicines Law**, amending the patent law, and which provided: (i) exclusion of "frivolous patents" from patentability; (ii) adoption of international exhaustion; (iii) allowance of regulatory review exemption; (iv) prohibition of TROs and injunctions against parallel importation; and (v) rejection of data exclusivity. PhRMA expressed concern that the compulsory license provision is discriminatory since it applies only to medicines.
- **Grants regulatory review exemption.** No data exclusivity and patent linkage. Allows parallel importation.

EFFECTIVE USE OF THE FLEXIBILITIES

Thailand

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THE CONTEXT:

- **National Health Security Act 2002 mandates universal access to essential medicines for all Thais.** The public health insurance schemes are: (1) Civil Servant Medical Benefit Scheme, for 5 million civil servants, public employees and their dependents, paid from general tax revenue and based on fee-for-service; (ii) Social Security Scheme, for 8.5 million private employees and temporary public employees paid by contributions from employers, employees and government on an equal basis and based on contract capitation; and (iii) Universal Coverage or Gold Card Scheme, for 48.5 million people, financed from general tax revenue and based on contract capitation. Government also committed since October 2003 to policy of universal access to ARVs for AIDs patients.
- **Healthcare is mainly funded by the government (66.3% in 2007).**Funding per capita for the UC scheme almost doubled since 2002, but funds still lower than requested amount.

EFFECTIVE USE OF THE FLEXIBILITIES

Thailand

An Overview of the Effective Use of Patent-Related Flexibilities and the Main Constraints Thereto in Asia

- **Industry estimates that as much as 70-75% of CSMBS spending goes to medicines.** Cost of medicines significantly increased due to expansion of UC scheme.
- **Health indicators improved since UC was introduced, but incidence of cardiovascular disease, cancer and mental illness is rising.** Number of deaths from cancer is rising steadily at 50,000 a year while 34,000 deaths are due to the circulatory system, over 18,000 to heart disease and over 12,000 to cerebrovascular disease.
- **MNCs hold majority of Thai pharma market in USD sales.** Leading five MNCs (Pfizer, Sanofi, Novartis, AstraZeneca and GSK) accounting for 30% of the market. Only two generic manufacturers, e.g., Siam Pharmaceuticals and GPO, are in the top ten, catering mostly to the government market. Global generic companies like Sandoz and Ranbaxy are also present.
- **Prescribing is largely determined by benefits offered by the insurance schemes and patient's ability to pay out-of-pocket.** Doctors in private practice dispense medicines. Public hospitals obliged to use generics and drugs from GPO. NCEs rarely prescribed in the government sector until after 2-3 years from approval as they undergo safety monitoring programme. Prescribing is not separated from dispensing.

EFFECTIVE USE OF THE FLEXIBILITIES

Thailand

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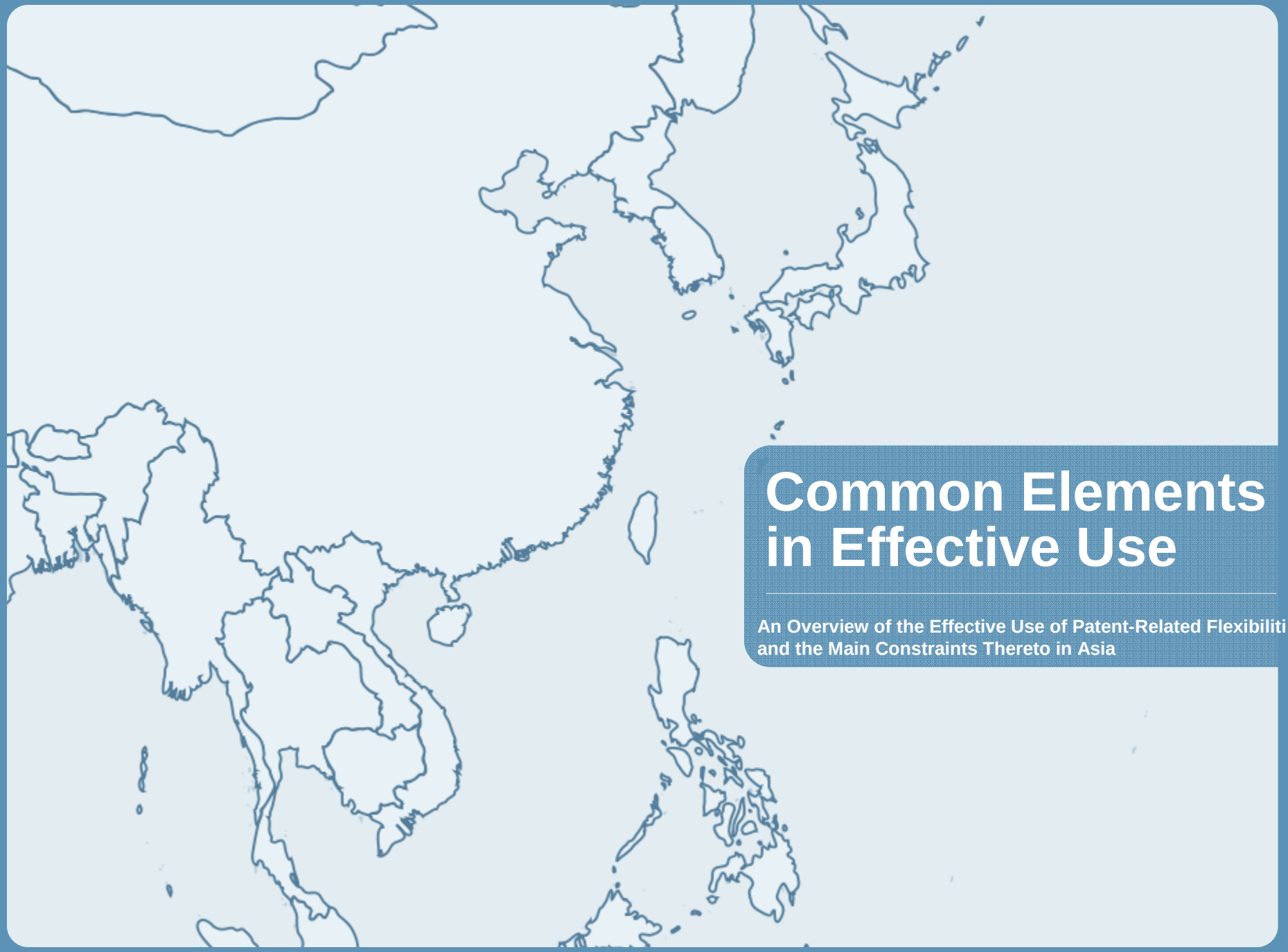
Use of Flexibilities:

- Compulsory licensing policy first announced by military-appointed interim government in late 2006. Licenses were eventually issued in 2008
  - Included for compulsory licensing were: 4 anti-cancer drugs, 2 ARVs and 1 cardiovascular drug
    - Taxotere™ (docetaxel), Femara™ (letrozole), Tarceva ™ (erlotinib) and Glivec ™ (imatinib)
    - Stocrin™ (efavirenz) and Kaletra ™ (lopinavir + ritonavir)
    - Plavix ™ (clopidogrel)
- Grants regulatory review exemption. No data exclusivity and patent linkage. PhRMA argues that the Trade Secrets Act of 2002 are not satisfactory in protecting data exclusivity (e.g., it only applies to NCEs and does not apply to those not patented in Thailand.)
- Thailand is in the US Priority Watch List.



Common Elements in Effective Use

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Common Elements in Effective Use

An Overview of the Effective Use of Patent-Related Flexibilities and the Main Constraints Thereto in Asia

- **Effective Use:** achievement of the desired policy outcomes
- **Elements:**
  1. Recognition of escalating healthcare costs.
  2. Political necessity to address the access to essential medicines issue. Existence of public debate.
  3. Understanding by health authorities of public health flexibilities in the TRIPS agreement.
  4. Ability of government to withstand pressures from patent holders and their respective governments.
  5. Capacity to manufacture or import the products.
  6. Infrastructure to effectively distribute and encourage the use and consumption of the products.

Constraints to Effective Use

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CONSTRAINTS TO EFFECTIVE USE

Incorporating into National Law

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1. Lack of technical expertise
2. Information asymmetry between patent holders and the public health sector
3. Inability to access information on the effective use of TRIPS flexibilities
4. Public failure to understand the correlation between patents and medicines access
5. Inadequate participation of Health Ministries in trade negotiations and decision-making

Implementing the Supporting Policies and Measures

In General

1. Availability of other policy interventions to quickly address insufficient access to essential medicines.
2. Absence of public or private sector entity to effectively champion the use of the TRIPS flexibilities.
3. Market preference for originator's branded products.
4. Absence or inadequacy of competition law. Anti-competitive acts in the marketing, promotion, distribution and sale of pharmaceutical products.
5. Inefficiencies in government procurement, marketing, and distribution system.
6. Pressures from trade partners
   - Free Trade Agreements
   - Sec. 301 of the US Trade Act

Parallel Importation

1. Universal pricing of patented products.
2. Existence of therapeutic substitutes.
3. Limited, if not absence of, source of cost-effective, good quality, available pharmaceutical product.
   - Source countries are now within the TRIPS patent regime (e.g., Italy, Spain, Greece, Argentina, Korea, India, Brazil, Taiwan, and China).
   - No supply security due to use of mere consolidators.
   - Difficulty in sourcing biosimilars.
   - Price premium of supergenerics.
4. Market limitations
   - Transfer price and capacity to pay
   - Minimum order quantities

Implementing the Supporting Policies and Measures

Parallel Importation

5. Absence of technical dossiers to secure product registration and marketing authorization
6. Importing country requirements on product packaging and labeling.
7. Lack of facilities or expertise to review safety, quality and efficacy of pharmaceutical products and to conduct post-marketing surveillance.
8. Marketing and promotion counter-measures by patent holders.
9. High risk of substandard or counterfeit medicines.

Regulatory Review Exemption

1. Insufficient knowledge of the patent system by drug regulatory authorities.
2. *De facto* patent linkage due to threats of suit against the drug regulatory authorities.
3. Protectionist research and quality standards setting.
4. Data exclusivity.

Research Exemption

1. Limited or no research & development capacity.
2. Inefficient allocation of R&D resources.
3. Weak linkage between academic research institutions and industry.
4. Focus on profitable lifestyle diseases.
5. Rapid growth in the non-regulated natural products market.

Implementing the Supporting Policies and Measures

Compulsory Licensing

1. Determination of the ground for CL is essentially political.
2. Legal uncertainty due to protracted legal process.
3. Availability of lower-cost therapeutic alternatives for many diseases.
4. Insufficient or no pharmaceutical manufacturing capability.
5. Limited or no source of cost-effective, good quality API or finished formulation.
6. Strategic threats and litigation by patent holders and pressures from their home governments.

Implementing the Supporting Policies and Measures

7. Limited distribution, mostly through government hospitals or clinics.
8. In the case of Para. 6 compulsory licensing:
   - Determination of ground depends upon the eligible importing Member (EIM)
   - Regulatory requirements of EIM
   - Healthcare sector acceptance of products from exporting country

Defending Against TRIPS Plus Pressures

1. **Pressures by key trade partners.**
   - Viet Nam and Cambodia entered into bilateral agreements with US containing data protection.
2. **Protracted period to realize the benefits of TRIPS flexibilities.**
3. **Inadequate participation of Health Ministries in trade negotiations and decision-making.**

Concluding Remarks

An Overview of the Effective Use of Patent-Related Flexibilities and the Main Constraints Thereto in Asia

Concluding Remarks

An Overview of the Effective Use of Patent-Related Flexibilities and the Main Constraints Thereto in Asia

1. The TRIPS Agreement contains several flexibilities to help countries address their public health concerns.
2. A number of countries have made use of these flexibilities as one of several policy instruments to address the access to essential medicines problem.
3. While the TRIPS Agreement provides for them, the use of these flexibilities have always been attended by controversies. Hence, their effective use depends partly on political will and the capability of the health infrastructure to deliver on the policy promise.

Thank you

An Overview of the Effective Use of Patent-Related Flexibilities and the Main Constraints Thereto in Asia