UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT

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TPP Chapter 18 – Intellectual Property and Medicines

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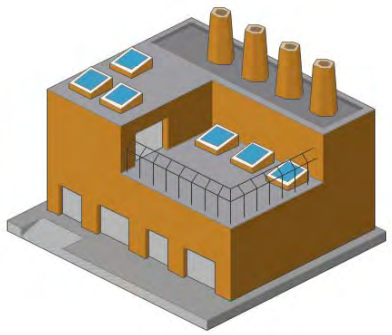

Caveats

- Impact assessment is largely hypothetical – TPP is not yet in force
- Lawyer's bias – identifying risk factors from the existing legal text doesn't necessarily mean the risks will always materialize
- Decision on accession is Thailand's to make – UNCTAD officially neither supports nor opposes, but we want to make sure country equipped to make informed policy choice

Understanding The TRIPS Agreement

- Basic Agreement of World Trade Organization (WTO)
- Establishes Minimum Standards of Intellectual Property Protection for All WTO Members
- Covers Patents, Trademarks, Copyrights, GIs, and other IP Rights
- Negotiating History of the TRIPS Agreement – The TRIPS Agreement and Policy Space (Flexibilities)

Patents

- Basic Criteria – Patents Available for All Inventions (Products and Processes)
  - Novelty
  - Inventive Step (Non-Obvious)
  - Industrial Application
- Exclusive Rights to Patent Owner of Technology for 20 Years from Date Application Filed with Patent Office
- Made Patents Available for Medicines

In-Built Patent Flexibilities in TRIPS: Health

- Countries Left Discretion to Decide
  - What is an invention?
  - What constitutes novelty?
  - What do we mean by inventive step?
- Determine Key Exceptions and Limitations
  - Regulatory Review Exception
  - Research and Experimentation
  - Medical Treatment
- Compulsory/Government-Use Licenses

Effect of TRIPS-Plus Provisions

- Curtails Available Flexibilities – Requires Signatory to Change Laws to Comply with New Standards
- TPP Chapter 18 – Intellectual Property
  - Makes it easier to obtain patents on medicines
  - Prolongs exclusive rights over patented medicines
  - Makes it easier for patent owners to enforce rights
- Many Preferential Trade and Investment Agreements Contain TRIPS-plus Provisions

How Does TPP Change Patentability Criteria?

- Must Make Patentable at Least One of the Following:
  - New Uses of a Known Product
  - New Methods of Using a Known Product
  - New Processes of Using a Known Product
- Prior Disclosures by Patent Applicant or Someone who Obtained Info from Applicant Directly or Indirectly Cannot be used to Assess Novelty or Inventive Step
- Requires Parties to Become a Party to UPOV 1991 Instead of *Sui Generis* Plant Variety Protection Law

What Didn't Change from TRIPS Standards

- Still permits TPP Parties to maintain a requirement that patents on pharmaceutical products show enhanced efficacy (as in the Indian Patent Act, section 3(d))
- Still permits TPP Parties to maintain a Regulatory Review Exception
- Still permits TPP Parties to maintain Exception for Medical Treatments
- Still permits TPP Parties to Issue Most Compulsory and Government-Use Licenses (Chapter 9 includes a Safe Harbor provision and reference to Doha Declaration)
  - However, Adequacy of Compensation Could Potentially be Subject to Review under ISDS

How Does TPP Change the Period of Exclusivity under TRIPS?

- Five-Year Exclusive Right to Undisclosed Test Data Submitted to Drug Regulatory Authority; Eight Years for Biologics
- TPP Members Must Adjust The Term of the Patent for 'Unreasonable Delays' in the Issuance of Patents over Pharmaceutical Products
  - 'Unreasonable' not defined under Article 18.48, even though defined from Article 18.46 (delay attributable to the Patent Office)

How Does TPP Make it Easier for Patent Owners to Enforce Rights over Pharmaceutical Patents?

- Patent Linkage – Marketing Authorization by Drug Regulatory Authority Linked to Patent Status
  - Effect on Bolar Exception Not Clear
- Border Measures - No Explicit Safe Harbor for Certain Off-Patent Medicines In Transit, i.e., Potentially Subject to Seizure

Transition Periods

- In-Built for Negotiating Countries
  - Ex. Vietnam Granted 10 yr. Reprieve from Application of Test Data Exclusivity, 3 yr. Reprieve from Application of Patent Linkage
- Not Clear What Happens for Acceding Countries – Ref. Chapter 30

Considerations Along Pharma Value Chain

- Underlying TPP Is Concept of GVCs. Is There a Point Along Value Chain Where Thai Pharmaceutical Firms or GPO Can Be Competitive?
- What Benefits for Thai Consumers?
- How Widely Available is Health Insurance in Thailand and What Is the Impact of National Health Insurance on Medicines?
- Value Chains May Differ for Patented Chemical Entities, Biologics, Generics, Biosimilars and Traditional Medicines

Consideration from Health Perspective

- Health Security – Extent to Which Thailand Wants to Protect Itself from Potential Stock Outs, Maintain Ability to Manufacture Medicines Locally
- Goal of Universal Access Reaffirmed with SDGs, Human Rights Conventions and Forthcoming Report of UN Secretary-General on Access to Medicines
  - SDG Targets Make Specific Reference to TRIPS Flexibilities

Thank You