Medicines, vaccines and biological products: the concerns over TPP on medicine and health system

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Article 18.18: Types of Signs Registrable as Trademarks

No Party shall require, as a condition of registration, that a sign be visually perceptible, nor shall a Party deny registration of a trademark only on the ground that the sign of which it is composed is a sound. Additionally, each Party shall make best efforts to register scent marks. A Party may require a concise and accurate description, or graphical representation, or both, as applicable, of the trademark.

สรุป สามารถจดเครื่องหมายการค้าของกลิ่นและเสียงได้

Article 18.37: Patentable Subject Matter

Each Party confirms that patents are available for inventions claimed as at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product.

Note: A18.50 para2 …..new indication, new formulation or new method of administration

สรุป สามารถจดสิทธิบัตร

📖การใช้ใหม่ของสารเก่า (ข้อบ่งใช้)

📖วิธีการใหม่ของการใช้สารเก่า (สูตรใหม่)

📖ขบวนการใหม่ของการใช้สารเก่า (วิธีการให้ยา)

Article 18.43: Amendments, Corrections and Observations

Each Party shall provide a patent applicant with at least one opportunity to make amendments, corrections and observations in connection with its application.

สรุป

แก้ในเนื้อหา แก้คำผิด และตั้งข้อสังเกต ได้อย่างน้อย 1 ครั้ง

Article 18.46: Patent Term Adjustment for Patent Office Delays

For the purposes of this article, an unreasonable delay at least shall include a delay in the issuance of a patent of more than 5 years from the date of filing …, or 3 years after a request for examination …, whatever is later.

สรุป

ต้องชดเชยอายุสิทธิบัตรจากการจดสิทธิบัตรล่าช้า

Article 18.48: Patent Term Adjustment for Unreasonable Curtailment

With respect to a pharmaceutical product that is subject to a patent, each Party shall make available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.

สรุป

ต้องชดเชยอายุสิทธิบัตรจากการขึ้นทะเบียนตำรับยาล่าช้า

Article 18.50: Protection of Undisclosed Test or Other Data

1. (a) If a Party requires, as a condition for granting marketing approval for a new pharmaceutical product, the submission of undisclosed test or other data concerning the safety and efficacy of the product, that Party shall not permit third persons, without the consent of the person that previously submitted such information, to market the same or a similar product … for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of the Party.

สรุป

ให้การผูกขาดข้อมูลการขึ้นทะเบียนยาเจ้าแรกอย่างน้อย 5 ปี

Article 18.50: Protection of Undisclosed Test or Other Data

2. Each Party shall:
(a) apply paragraph 1, *mutatis mutandis*, for a period of at least three years with respect to new clinical information submitted as required in support of a marketing approval of a previously approved pharmaceutical product covering a new indication, new formulation or new method of administration; or, alternatively,

สรุป
ให้การผูกขาดข้อมูลการขึ้นทะเบียนยาต่ออีกอย่างน้อย 3 ปี
สำหรับข้อบ่งใช้ใหม่ สูตรใหม่ หรือวิธีการให้ยาใหม่

Article 18.50: Protection of Undisclosed Test or Other Data

3. …, a Party may take measures to protect public health in accordance with:
(a) the Declaration on TRIPS and Public Health;
(b) any waiver of any provision of the TRIPS Agreement granted by WTO Members in accordance with the WTO Agreement to implement the Declaration on TRIPS and Public Health and that is in force between the Parties; or
(c) any amendment of the TRIPS Agreement to implement the Declaration on TRIPS and Public Health that enters into force with respect to the Parties.

สรุป
TRIPS ไม่กล่าวถึงข้อยืดหยุ่นในการขึ้นทะเบียนยา นั่นคือ การผูกขาดข้อมูลยา เป็นการผูกขาดตลาดอย่างสมบูรณ์

What is the result of article 18.50

EXISTING SYSTEM

POST-MARKET SURVEILLANCE

ORIGINALS
-SUBMIT UNDISCLOSED
(SAFETY & EFFICACY DATA)

GENERICS
-SUBMIT BIOEQUIVALENT STUDY

EFFICACY & SAFETY DATA are well known

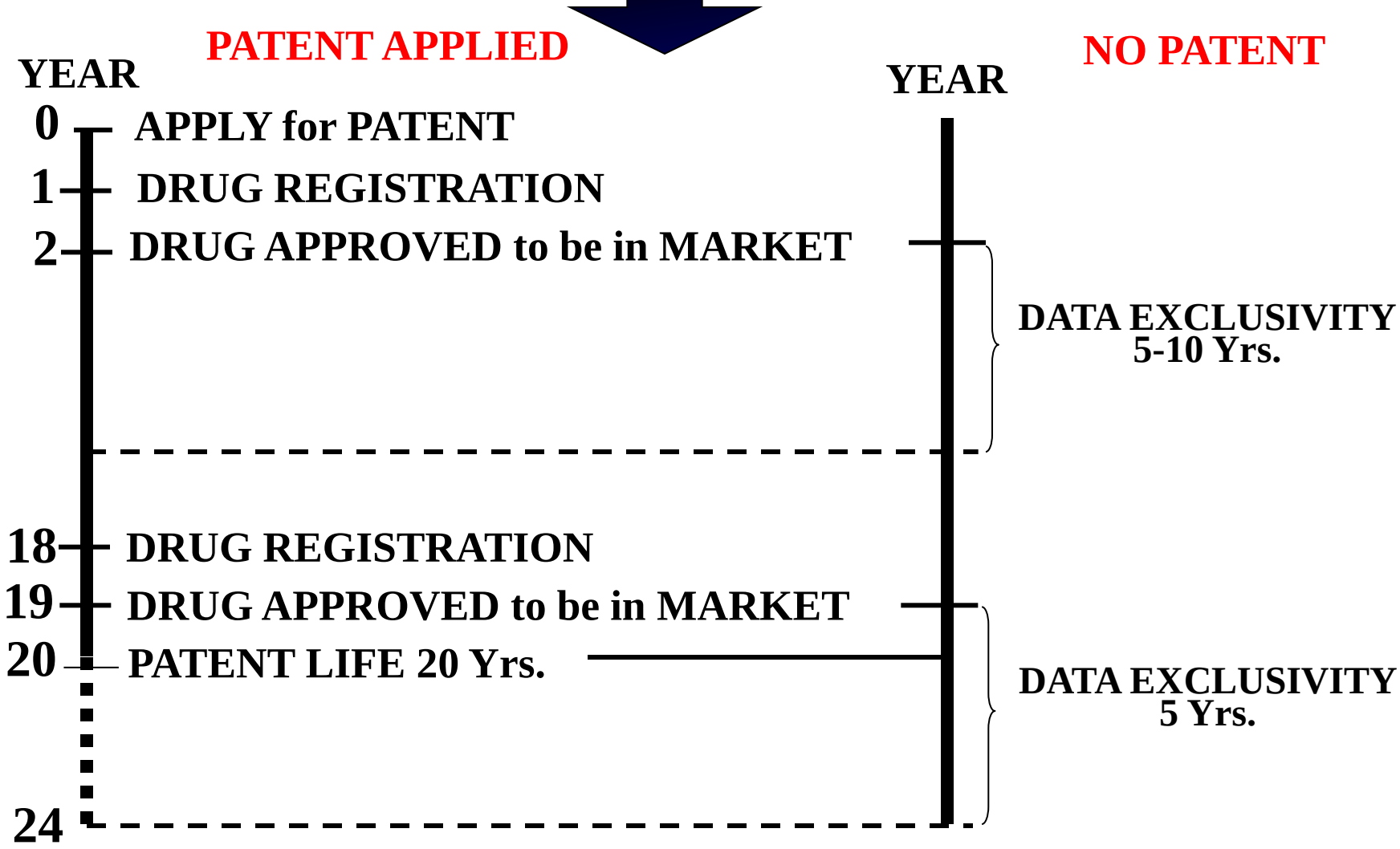
TPP

POST-MARKET SURVEILLANCE

ORIGINALS
-SUBMIT UNDISCLOSED
(SAFETY & EFFICACY DATA)

GENERICS
1. **SUBMIT SAFETY & EFFICACY DATA or**
2. **DE + SUBMIT BIOEQUIVALENT STUDY**

DATA EXCLUSIVITY & PATENT



Article 18.51: Biologics

1(a) With respect to the first marketing approval … a new pharm. product that is or contains a biologic, provide effective market protection through … (Protection of Undisclosed Test or Other Data), for a period of at least 8 years from the date of first marketing approval

3 …the Parties shall consult after 10 years from the date of entry into force of this Agreement, or as otherwise decided by the Commission, to review the period of exclusivity …

สรุป

📖**การผูกขาดข้อมูลยา 8 ปี**

📖 **ให้มีการทบทวนเวลาผูกขาดหลังจากใช้ข้อตกลงนี้แล้ว 10 ปี**

Article 18.52: Definition of New Pharmaceutical Product

For the purposes of Article 18.50.1 (Protection of Undisclosed Test or Other Data), a new pharmaceutical product means a pharmaceutical product that does not contain a chemical entity that has been previously approved in that Party.

สรุป

การผูกขาดข้อมูลยาในยาทุกตัวที่เข้ามาในประเทศ ไม่ใช่สารโมเลกุลใหม่ เท่านั้น

Article 18.53: Measures Relating to the Marketing of Certain Pharmaceutical Products

1. If a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting the safety and efficacy information,…, that Party shall provide:
(a) a system to **provide notice** to a patent holder or to allow for a patent holder to be notified prior to the marketing …;
(b) **adequate time** and opportunity for such a patent holder to seek, prior to the marketing of an allegedly infringing product, available remedies in subparagraph (c); and
(c) procedures, such as judicial or administrative proceedings, and **expeditious remedies**,

สรุป ถ้ามีการขอขึ้นทะเบียนยาสามัญ อย.
1.ทำระบบการแจ้งเจ้าของสิทธิบัตร
2.ให้เวลาเจ้าของสิทธิบัตรตรวจสอบการละเมิดสิทธิบัตรก่อน
3.ทำแนวปฏิบัติ เช่น มาตรการทางกฎหมายหรือมาตรการบริหาร และเยียวยาอย่างเร่งด่วน

Article 18.54: Alteration of Period of Protection

Subject to Article 18.50.3 (Protection of Undisclosed Test or Other Data), if a product is subject to a system of marketing approval in the territory of a Party pursuant to Article 18.47 (Protection of Undisclosed Test or Other Data for Agricultural Chemical Products), Article 18.50 or Article 18.51 (Biologics) and is also covered by a patent in the territory of that Party, the Party shall not alter the period of protection that it provides pursuant to Article 18.47, Article 18.50 or Article 18.51 in the event that the patent protection terminates on a date earlier than the end of the period of protection specified in Article 18.47, Article 18.50 or Article 18.51.

สรุป

ช่วงเวลาผูกขาดต่างๆ ไม่เกี่ยวกัน นับเวลาที่ยาวที่สุด

Articles in TPP which impact to A2M

Article 18.37: Patentable Subject Matter

- New uses of a known product
- New methods of using a known product
- New processes of using a known product

Article 18.43: Amendments, Corrections and Observations:

- At least one opportunity to make amendment…

Article 18.50: Protection of Undisclosed Test or Other Data (for chemical entity)

- DE at least 5 years for new pharmaceutical product
- DE at least 3 years for new indication, new formulation or new method of administration

Article 18.46 &18.48: Patent Term Adjustment

- Patent office delay
- FDA delay

Article 18.51: Biologics

- DE at least at least 8 years for a new pharm. product that is or contains a biologics

Article 18.53: Measures Relating to the Marketing of Certain Pharmaceutical Products

- a notice system to a patent holder prior to marketing approval of such product
- adequate time for a patent holder to seek, prior to the marketing of an allegedly infringe product
- procedure, such as judicial or administrative proceedings, and expeditious remedies

Article 18.52 Definition of New Pharmaceutical Product

- a new pharmaceutical product means a pharmaceutical product that does not contain a chemical entity that has been previously approved in that Party

Article 18.54: Alteration of Period of Protection

No alteration of DE period, even that the patent protection terminates.

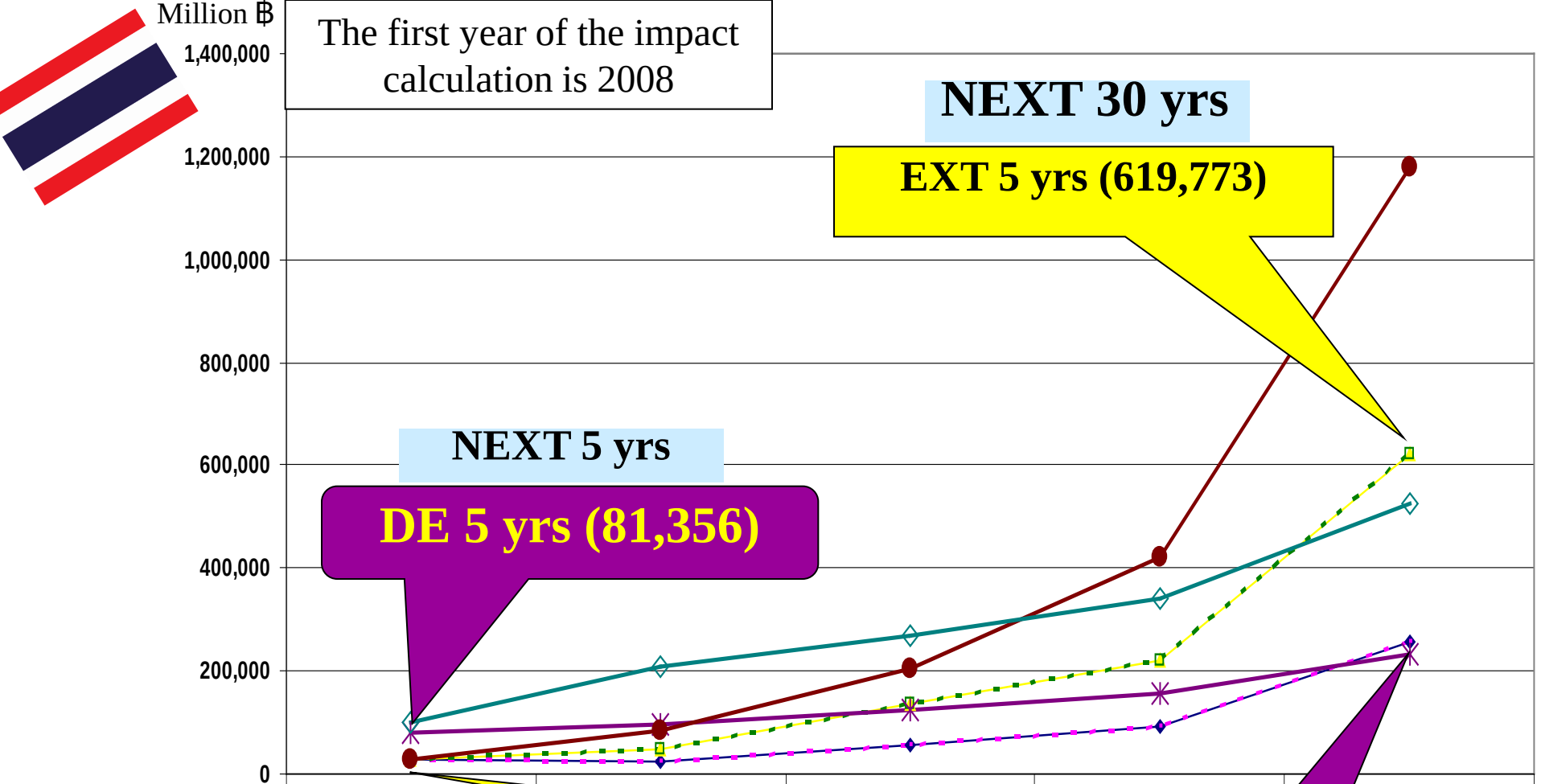
Economic Impact of Longer Market Exclusivity

- Two studies:
  - Chutima Akaleephan *et al* (2005)
    - Price*quantity approach
  - Nusaraporn Kessomboon *et al* (2010)
    - Rovira J, 2007 Model of Impact of Changes in Intellectual Property Rights (MICIPR) developed by Joan Rovira and jointly produced by the World Health Organization and the PanAmerican Health Organization (WHO/ PAHO Region)
    - Ref: "Impact on Access to Medicines from TRIPs-Plus: A Case Study of Thai-US FTA" Southeast Asian J Trop Med Public Health, Vol 41 No. 3 May 2010

Forecasted additional expense from ME extension (m USD)

source: Chutima Akaleephan, International Health Policy Program, 2005

Years of extension	Additional expense per item		Additional expense of 60 items (1 year)	
	min	max	min	max
1	0.1	1.1	6.4	65.9
2	0.6	2.5	34.2	152.4
3	1.1	4.7	64.8	279.2
4	1.7	7.2	103.9	431.0
5	2.5	12.0	151.7	722.5
6	3.4	19.2	204.5	1151.9
7	4.5	29.3	272.3	1755.9
8	6.7	43.2	403.3	2593.9
9	9.4	62.3	565.0	3737.2
10	13.9	90.2	836.7	5411.4



	next 5 years (2556)	next 10 years (2561)	next 15 years (2566)	next 20 years (2571)	next 30 years (2581)
ขยายอายุจากล่าช้า 2 ปี	27,883			91,249	255,324
ขยายอายุจากผูกโยง 2 ปี	27,883		55,236	91,249	255,324
ขยายอายุจากล่าช้า 5 ปี	27,883	40,494	136,922	221,50	619,773
ขยายอายุจากผูกโยง 5 ปี	27,883	46,494	136,922	22	619,773
ผูกขาดข้อมูลยา 5 ปี	81,356	97,442			233,447
ขยายอายุจากล่าช้า 10 ปี	27,883	83,960			1,180,399
ผูกขาดข้อมูลยา 10 ปี	99,163	206,688	269		525,049