

# *EFTA-Thailand FTA: Access to medicines and TRIPS*



Dr. Jiraporn Limpananont

- 📖 Social Pharmacy Research Unit (SPRU)  
Faculty of Pharm. Sciences,  
CHULALONGKORN UNIVERSITY
- 📖 FTA Watch  
Coalition of Thai NGO working on FTA

# Overview Presentation



- 📖 HIV Situation & ARVs Demand
- 📖 IPRs Protection in Thailand
- 📖 IPRs Protection & Access to Medicines
- 📖 EFTA-Thailand FTA & Access to Medicines
- 📖 FTA & Right to Health



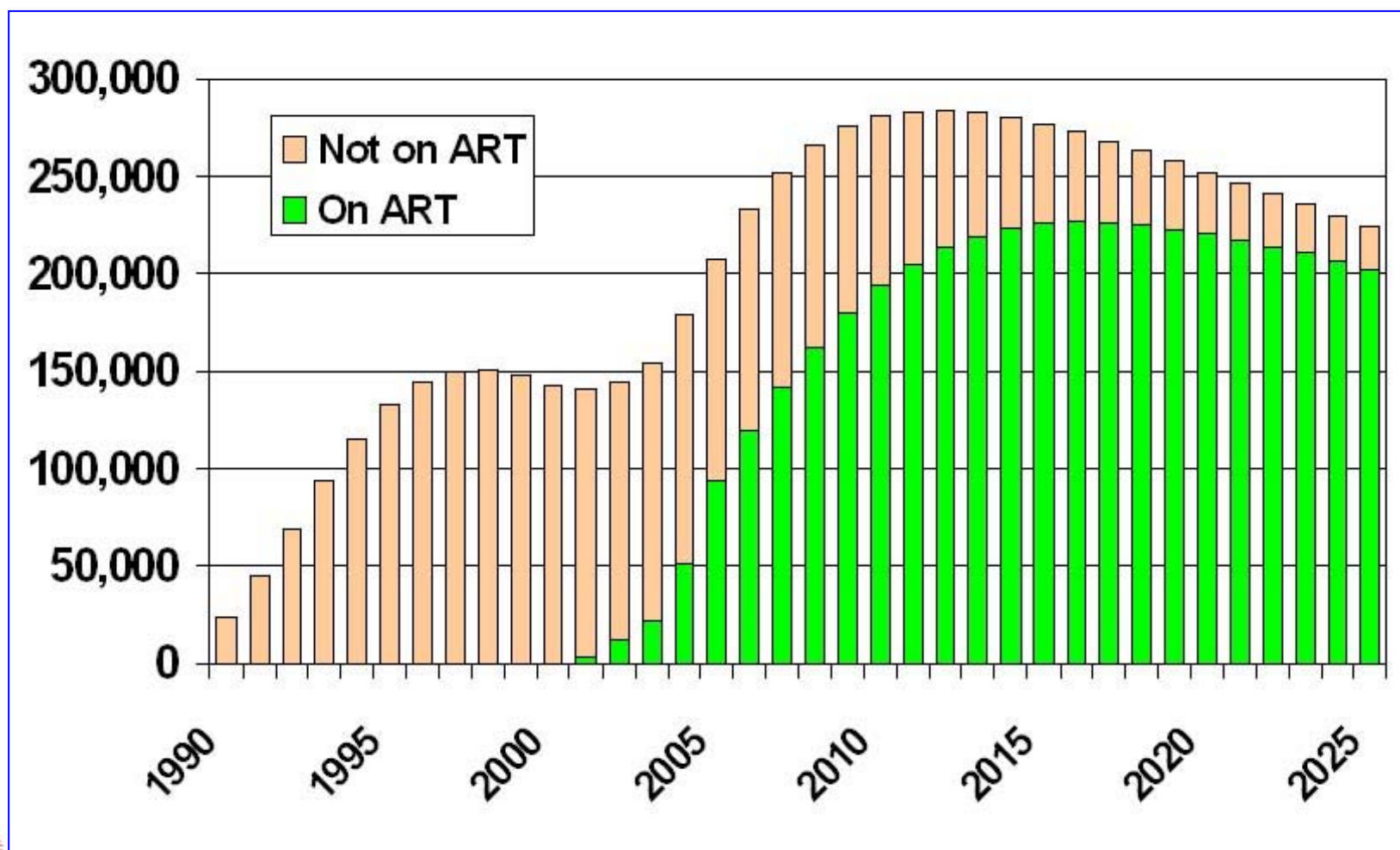
# HIV Situation & ARVs Demand



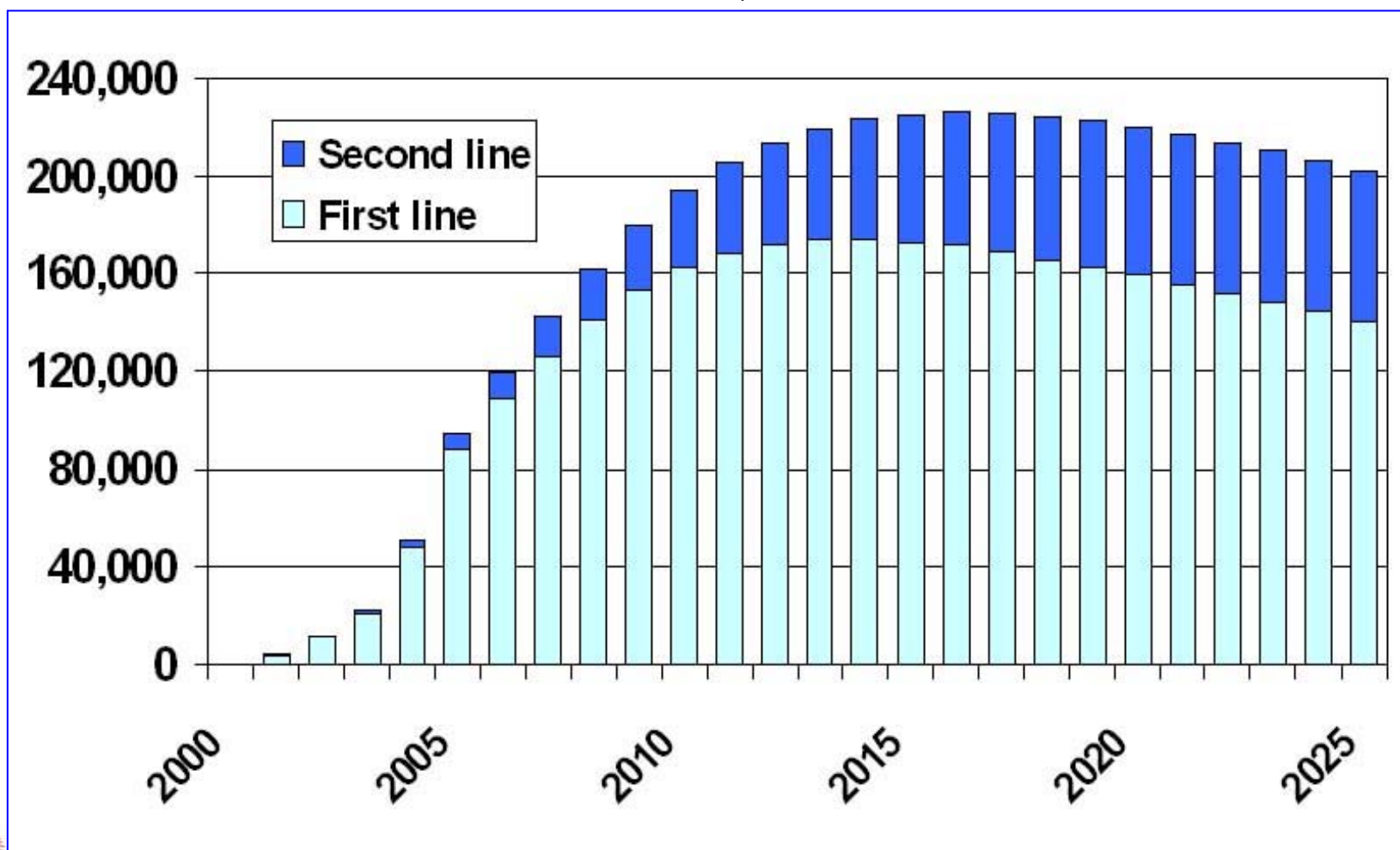
- 📖 Untill 2005, HIV infected 1,070,000 adults
- 📖 510,000 died
- 📖 560,000 HIV+ and AIDS
  
- 📖 in 2006 new infections 17,000
- 📖 37,000 HIV+ and AIDS
  
- 📖 The government policy is to provide the ARVs for the fiscal year 2005 is 80,000 cases
- 📖 GPO-vir as the first line ARVs



# Estimated number of HIV+ people on ARVs treatment upto 2025



# Estimated number of people need first and second line ARVs



# NATIONAL DRUG PATENT SYSTEM



TNCs or BIG DRUG CORPORATIONS

BILATERAL  
TRADE NEGOTIATION

WTO

TRIPS

LOCAL MANUFACTURING  
DEVELOPMENT

NOVELTY  
(EVER-GREENING PATENT)

PRICE



# IPRs Protection in Thailand



- 📖 Drug Patent Situation in Thailand
- 📖 Impact in Access to Medicines in Thailand



# Drug Patent Situation in Thailand



## RESULTS:

☞ 98% PATENTEES WERE FOREIGNERS

☞ Patent Granting Process Took 7-8 years

✎ Filing date to Publishing date      1-1.5   Yrs

✎ Publishing date to Exam date      4-5   Yrs

✎ Exam date to Patent issued date      1.5-2   Yrs

☞ The number of new drugs still on-patent up to July 2003 was 215 drugs out of 966 drugs (22.4%) and the remaining patent life were 7.5 to 18.2 years.





# DAILY COST of ARVS THERAPY

REGIMEN	2001	2002	2003	2004		
	B/G	B/G	B/G	B/G	B(฿)	G(฿)
GPO-VIR30		10.90	10.95	10.95	438	40
d4T+3TC+NVP	2.98	7.65	7.68	7.68	438	57
AZT+3TC+NVP	2.67	5.65	5.99	5.99	443	74
d4T+3TC+EFV	2.30	3.86	3.57	3.57	495	138
AZT+3TC+EFV	2.12	3.19	3.21	3.21	498	155
AZT+3TC+RTV+IDV	1.92	2.64	2.79	2.79	535	192
d4T+3TC+RTV+IDV	2.05	2.92	3.03	3.03	530	175
d4T+ddI+NVP	2.93	4.06	4.08	4.08	347	85
AZT+3TC+IDV	1.73	2.99	3.60	3.60	252	70
AZT+ddI+RTV+IDV	1.77	1.94	2.02	2.02	444	220
AZT+3TC+RTV+SQV	1.50	1.77	1.77	1.77	791	448

# TRIPs Plus of EFTA-Thailand FTAs



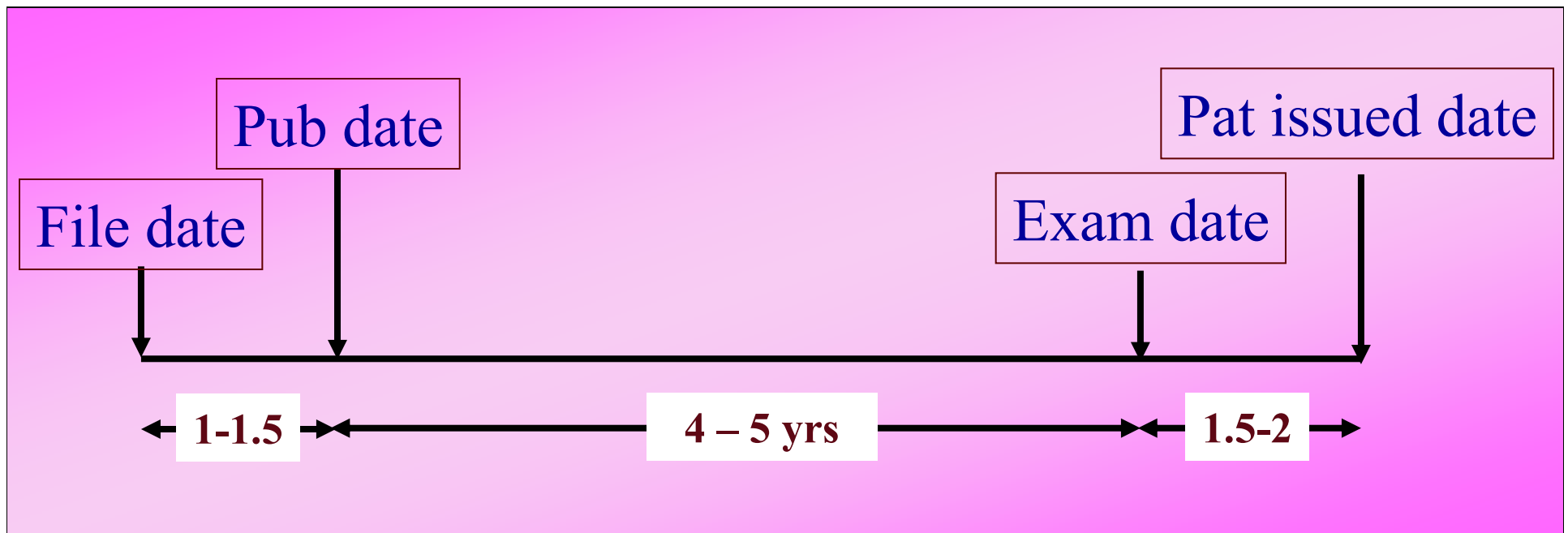
-  Extension of Patent Term
-  Data Exclusivity



# Patent Granting Process



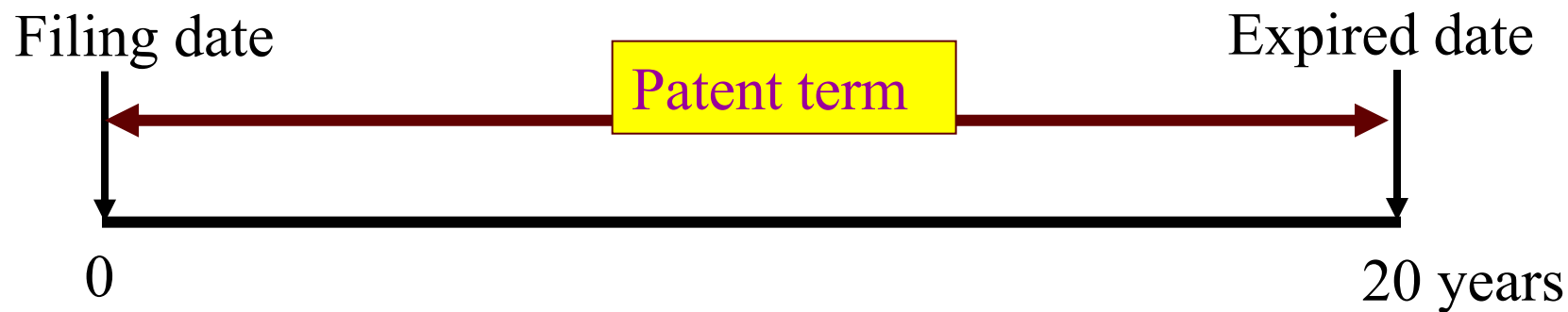
📖 Filing date to Publishing date	1-1.5	Yrs
📖 Publishing date to Exam date	4-5	Yrs
📖 Exam date to Patent issued date	1.5-2	Yrs
Total	7-8	Yrs



# Extension of patent term



- 📖 **Unreasonable request:**
- ☞ to compensate for up-front administrative or regulatory delays in granting the original patent



## 2. Data Exclusivity

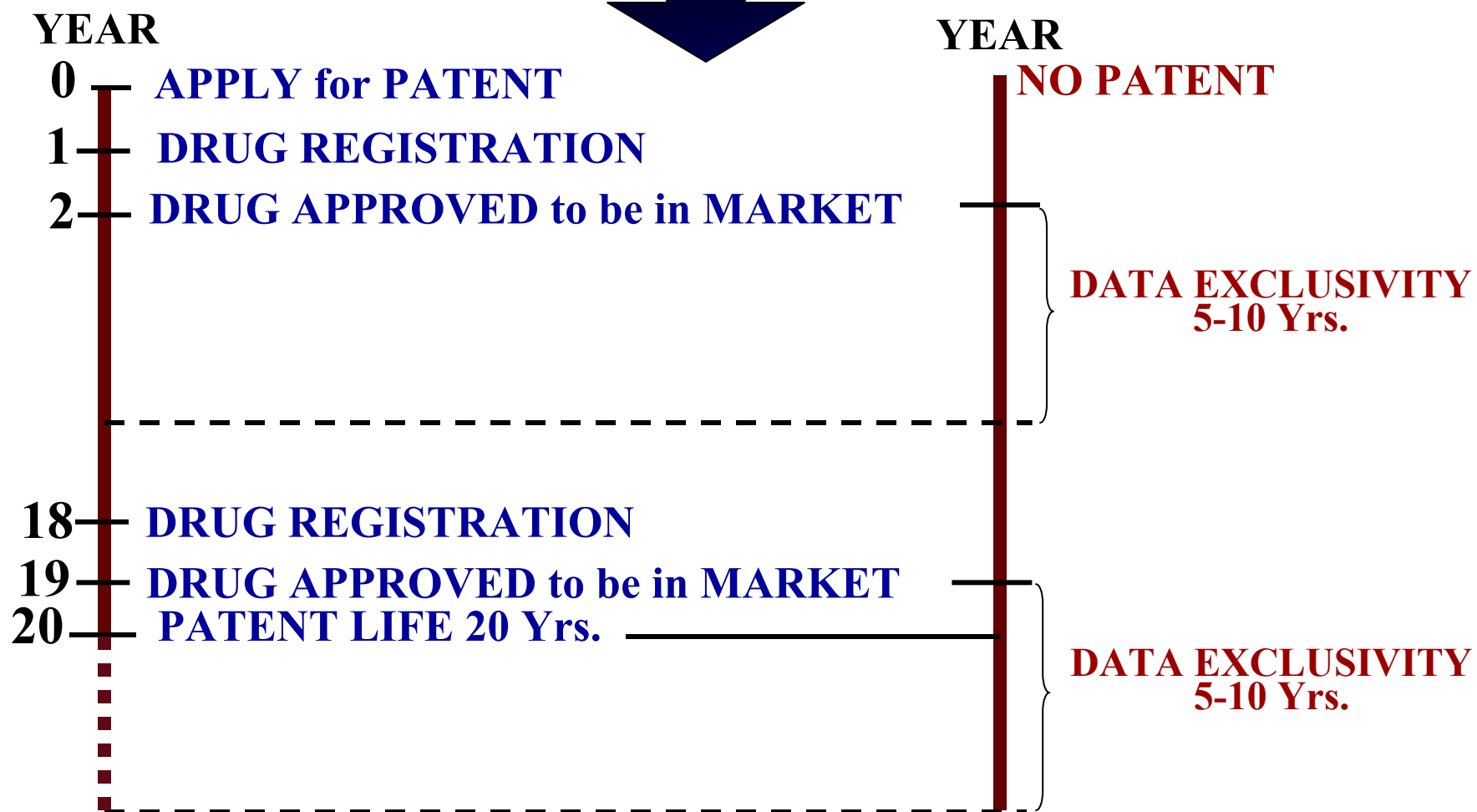


Test Data Protection	VN	JD	S G	Chi li	Mo roc co	Au	CA FT A	B R
-TRIPs std		X						
-Data Exclusivity								
-“reasonable period”	X							
- 5 yrs			X	X	X	X	X	X
-Plus 3 yrs Data Exclusivity by new clinical info.						X	X	X

In this period no any flexibility in TRIPs can be applied



# DATA EXCLUSIVITY & PATENT



# Thai Trade Secret Act 2002



📖 Art. 15: As a condition in law requiring of the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, to the government agency, the origination of which involves a considerable effort and they are declared to be protected, the government agency must protect such data from disclosure and against unfair commercial use.



# TRIPS Article 39.3



- 📖 As a condition of approving the marketing of
  - ➡ pharmaceutical or agri. chemical products
  - ➡ new chemical entities
  - ➡ undisclosed test or other data
- 📖 protect such data against
  - ➡ disclosure
  - ➡ unfair commercial use





# unfair commercial use



📖 **GENERIC DRUG REGISTRATION IS USED/RELIED ON UNDISCLOSED DATA OF ORIGINAL DRUG?**

👉 **NO**

**POST-MARKET SURVEILLANCE**



**ORIGINALS**

**-SUBMIT UNDISCLOSED  
(SAFETY & EFFICACY DATA)**



**GENERICS**

**-SUBMIT BIOEQUIVALENT  
STUDY**



# Conclusion



## Strengthen IPRs to TRIPs Plus

- High drug price > Inaccessibility to drug
- Obstacle to Thai Drug Industry to develop

## Data Protection

- Thai drug registration process comply to TRIPs

## Extension of Patent Term

- Propose for the Technological Co-operation System instead of extension of patent term





*THANKS*

*ขอขอบคุณค่ะ*