



## Thai CSOs' Advocacy on IPR and Access to Medicines

IPHU Training

Bangkok

10<sup>th</sup> December 2022

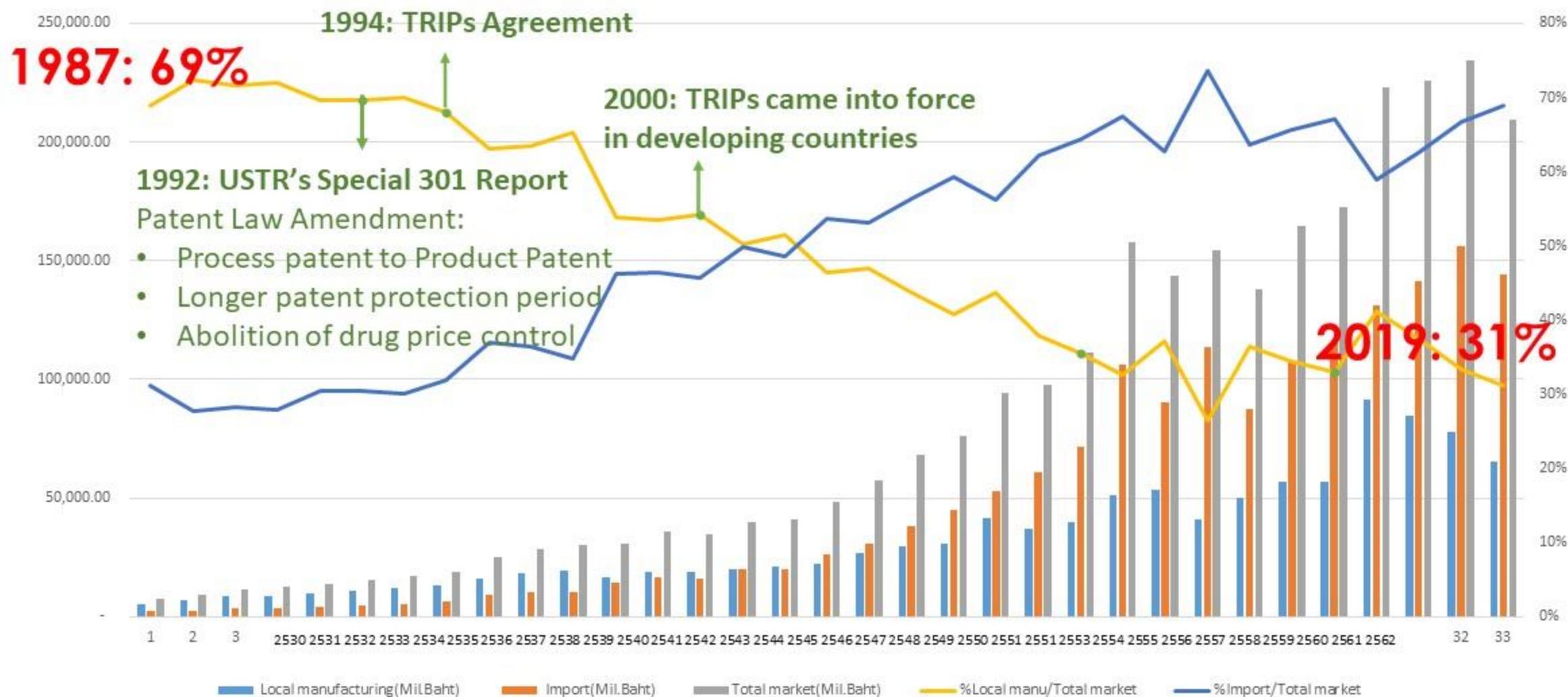
By Chalernsak Kittitrakul



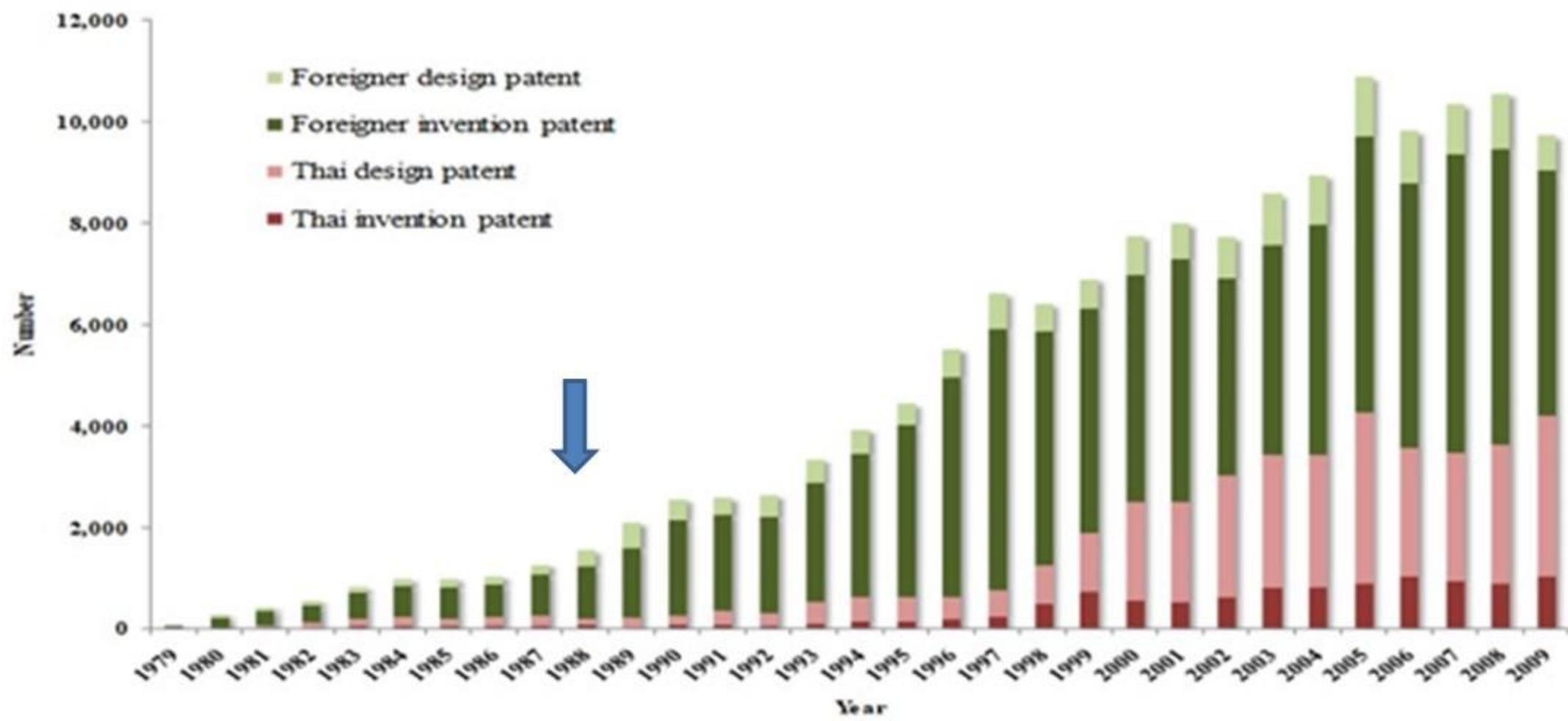


# What Happened Before & After TRIPs

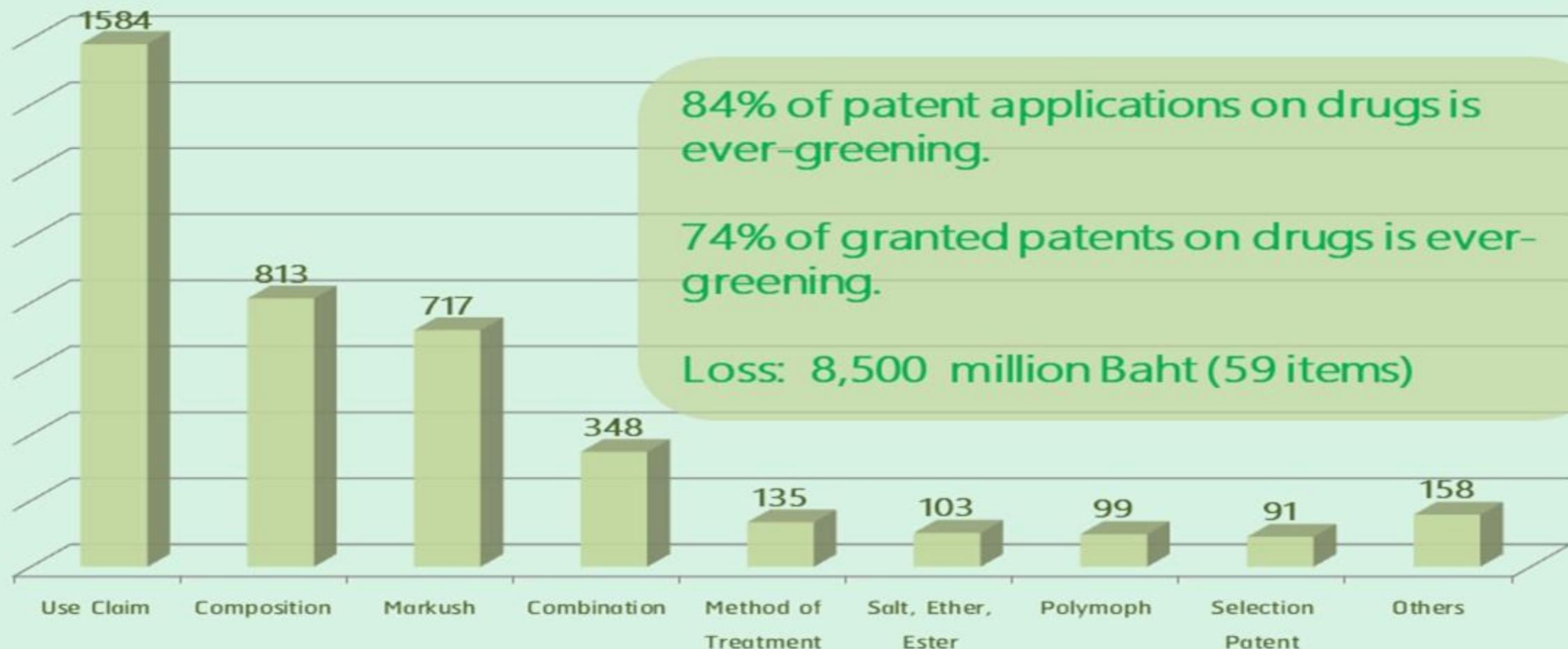
## Local Manufacturing and Import of Pharmaceutical Product 1987-2019 (source: Thai FDA)



# Number of patent applications by type and country in Thailand from 1979-2009



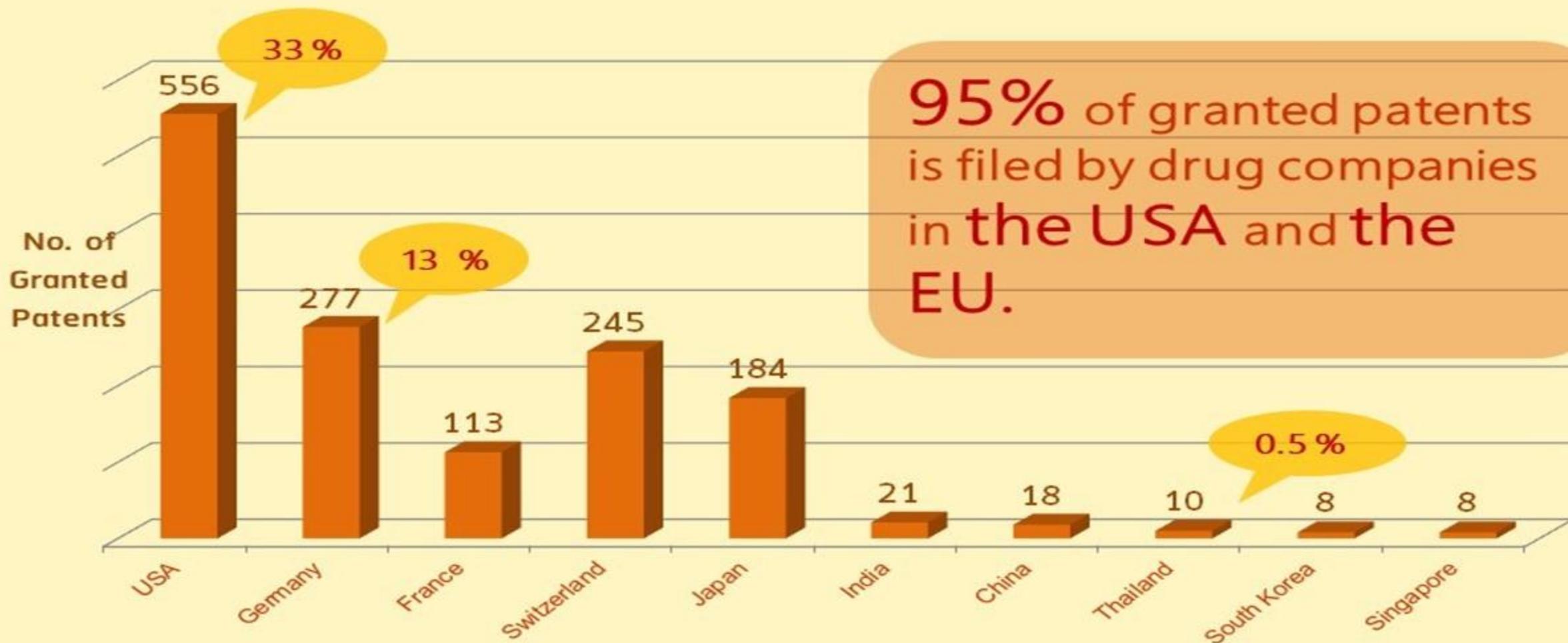
# Types and Quantity of Ever-greening Patents on Medicines (1999 – 2010)



Data Source: <http://kb.hsri.or.th/dspace/handle/11228/3750?locale-attribute=th>

# Who Benefits?

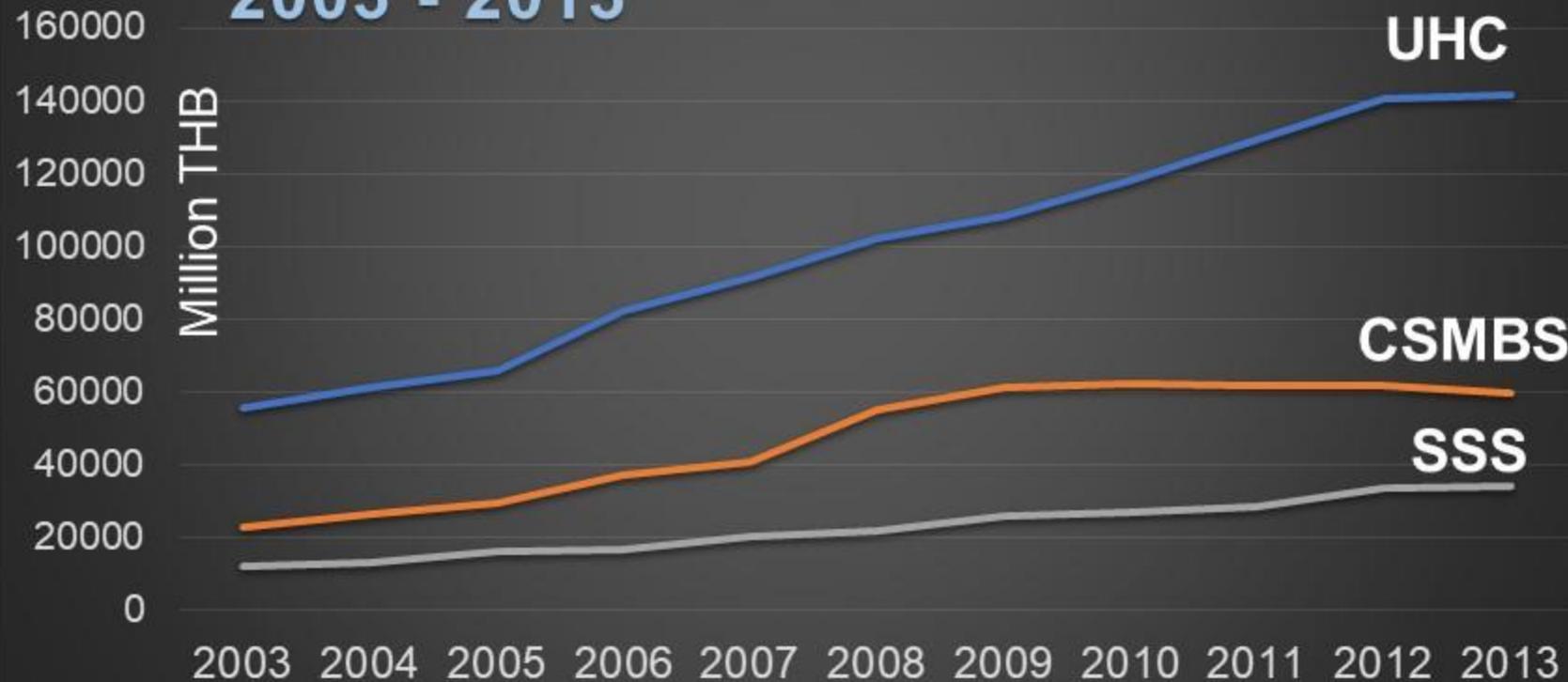
Nationality of Drug Patent Applicants in Thailand (1999 -2010)



Data Source: <http://kb.hsri.or.th/dspace/handle/11228/3750?locale-attribute=th>

# Thailand's Health Insurance Schemes

## Expenses of the National Health Insurance Schemes 2003 - 2013



Total Population:  
**66.2 million**

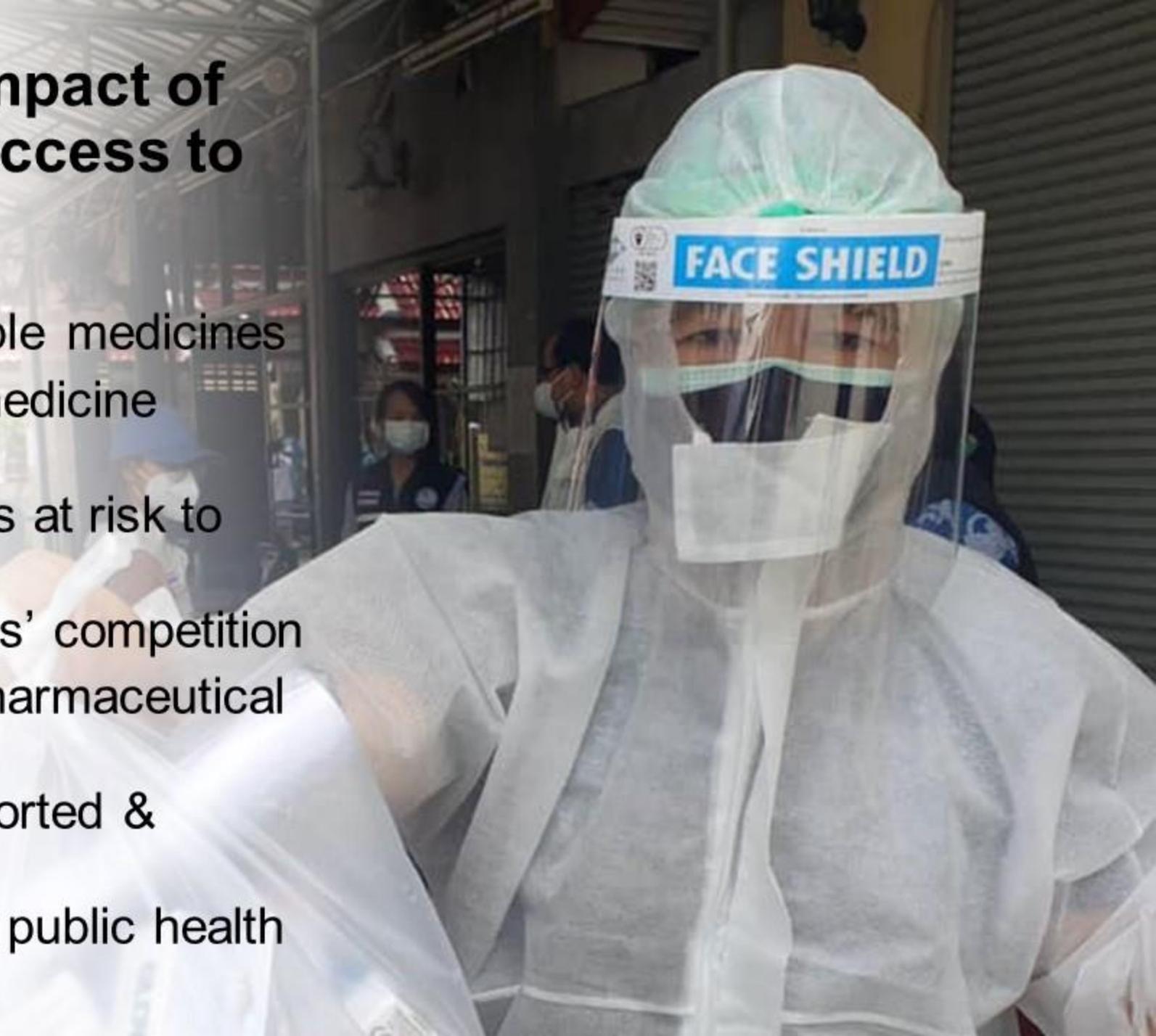
Health Insurance  
Schemes in Thailand

- **75% UHC**
- **15% SSS**
- **8% CSMBS**
- **2% uninsured**

**Almost 50% of  
the UHC budget  
is for the  
medicine  
expenditure**

# Concerns over the Impact of FTAs Undermining Access to Essential Medicines

- Lack of access to affordable medicines
- Increase in the national medicine expenses
- Health insurance schemes at risk to collapse
- Delay of generic medicines' competition
- Regression of the local pharmaceutical industry
- More dependency on imported & patented medicines
- Restrictions on the use of public health safeguard policies

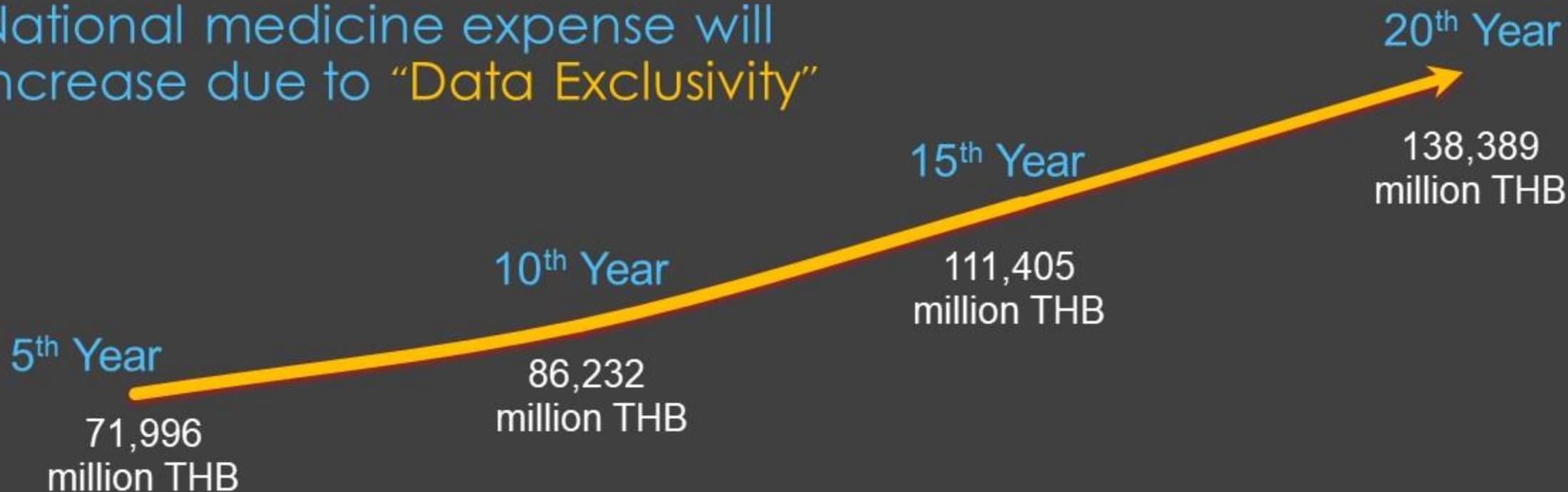


# Provisions Threatening Access to Medicines and Public Health

- 
- A woman wearing a white t-shirt and a black hat is speaking into a microphone at a protest. Behind her is a large banner with the text 'NO TRIPS+' in red and black. The banner also has Thai text. The woman's t-shirt has Thai text on it, including 'ขอสงวนสิทธิ์ใน' and 'พร้อมสิทธิในปัญญา' and 'ตามต่อเรื่อง'.
- Data Exclusivity
  - Patent Term Extensions
  - Extended Patentability Scope
  - Patent Linkage
  - Restrictions on Compulsory Licenses
  - Restrictions on Parallel Imports
  - Investment Rules
  - IP Enforcement and Border Measure

# Impact of Data Exclusivity

National medicine expense will increase due to "Data Exclusivity"

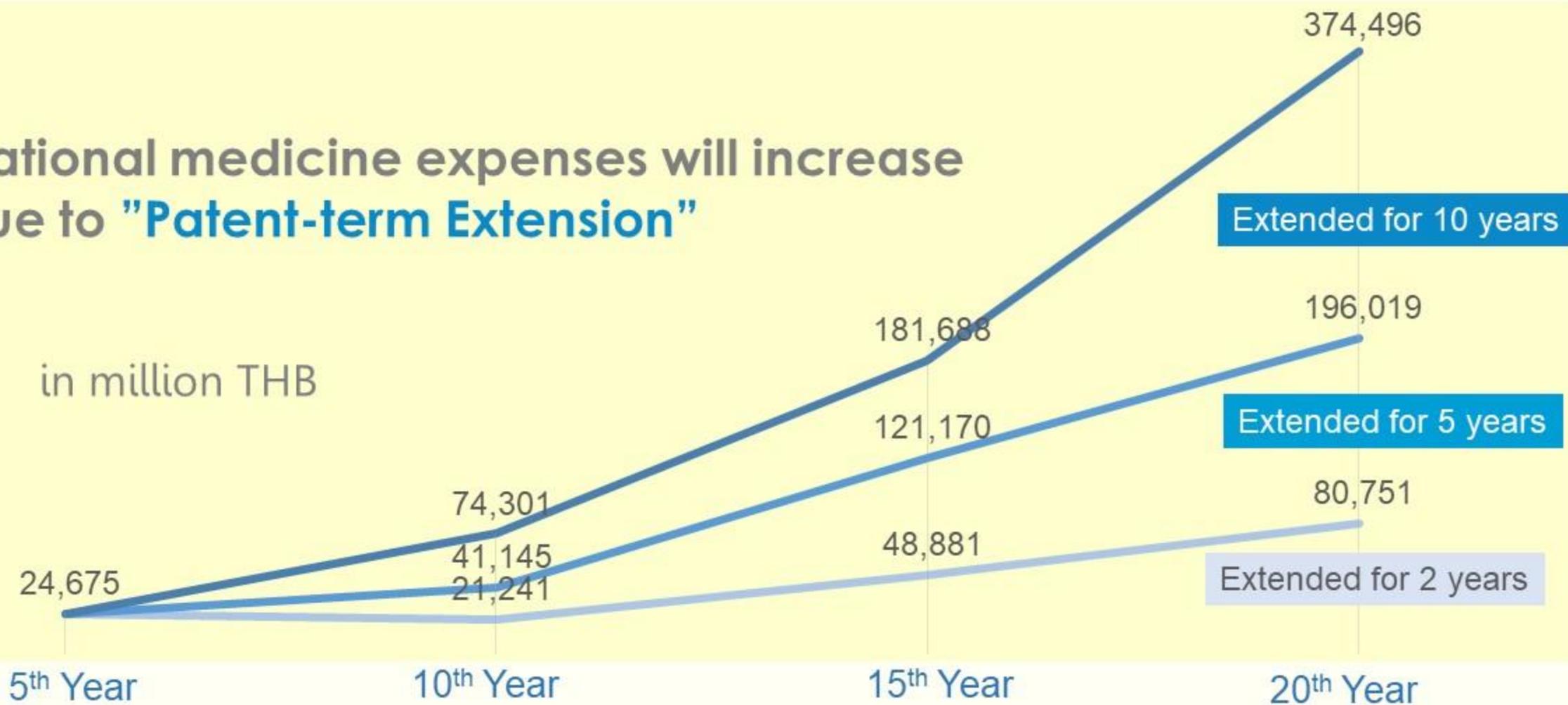


Thailand will have an increase of medicine expenses at least **72,000 million THB** if it amends its laws to have "Data Exclusivity" in compliance with TRIPs+ FTAs.

Thailand's medicine expenditure will increase at least **THB 24,700 million** up to **THB 374,500 million** if it amends its laws to have "Patent-term Extension" in compliance with TRIPs + FTAs.

## National medicine expenses will increase due to "Patent-term Extension"

in million THB

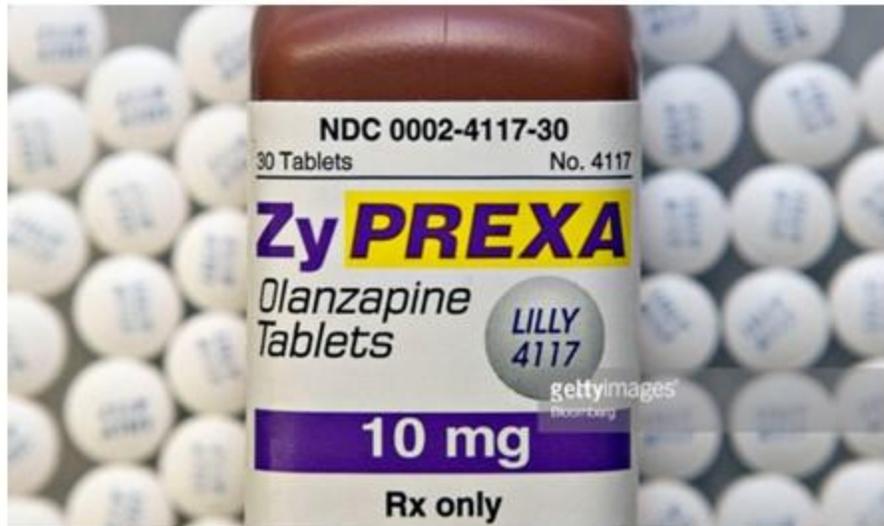




## CPTPP's Impact on Thailand's Medicine Expenses and Local Pharmaceutical Industry by 2047

	<b>Patent Linkage</b>	<b>Government Procurement</b>	<b>Patent Linkage &amp; Gov't Procurement</b>
Increase in the National Medicine Expenses	385,950 million THB	137,383 million THB	384,573 million THB
Dependency on Imported Medicines	Increase from 76% to 89%	Increase from 71% to 75%	Increase from 71% to 89%
Decrease in the Market Value of the Local Pharmaceutical Industry	99,246 million THB	13,505 million THB	103,289 million THB

# ISDS & Access to Medicines



## Eli Lilly VS Canadian Government (2013 - 2017)

- Using the Investment Chapter under NAFTA
- Canada's IP court had decision to reject patent applications filed for:
  - **Atomoxetine** (for ADHD treatment)
  - **Olanzapine** (for treatment of schizophrenia and bi-polar)
- Claiming compensation of CAD 500 million
- Decision: Canadian Government won the case in 2017



EU Hands off Our Medicines  
สหภาพยุโรปหยุดแย่งยาจากเราเสียที

สหภาพยุโรป  
ต้องไม่เอาเปรียบคนไทย

EU หยุดเอาเปรียบคนไทย  
ไม่เอาทริปส์

EUROPE!  
สหภาพยุโรป  
หยุด

ไทย-อียู FTA  
ยาแพง  
เหี้ยมถูก

EUROPE!  
HANDS OFF  
OUR  
MEDICINE  
สหภาพยุโรป  
หยุด

EUROPE!  
สหภาพยุโรป  
หยุด

EUROPE EUROPE!  
หยุด  
เหมือนบ้านไทย  
ไม่เอาทริปส์ พัด

EUROPE EUROPE!  
หยุด  
เหมือนบ้านไทย  
ไม่เอาทริปส์ พัด

NO TRIPs+  
ทรัพย์สินทางปัญญา  
ห้ามต่ออายุ

NO  
ทริปส์

EU = Hypocrite  
EU หน้าดีใจ หลัง หลอกลวงคนไทย  
EU = PHARMA'S Poodle

EU - the Nobel Peace Laureate  
- is killing people.

## Thai-US Free Trade Agreement Talks Spark Protests

By Sai Silp Monday, January 9, 2006

About 10,000 demonstrators protested in Chiang Mai today against the proposed Free Trade Agreement between Thailand and the United States being discussed this week in the northern Thai city.

The protesters handed in a letter at the US consulate in Chiang Mai, calling for an end to the talks and complaining that the proposed agreement would harm the Thai people.



The current talks—which continue until Friday—are the sixth round of the negotiations, which cover the full range of trade areas.

COMMENTS (0)  
RECOMMEND (134)  
FACEBOOK  
TWITTER  
PLUSONE  
MORE  
E-MAIL  
PRINT  
TEXT SIZE

# Why We Need Health Impact Assessment?

## From Thailand-USA FTA Negotiation to Section 190 of Constitution 2007

### Problems of FTA Negotiations:

- Lack of transparency
- Lack of people's participation
- Extensive and severe impact
- Complicated and comprehensive

Thailand-USA FTA Negotiation 2004 – 2006  
(Suspended)

# Prices of Medicines before and after the implementation of compulsory licenses

Medicine	Before (Original)	After (Generic)	Reduction in %
Efavirenz	\$ 37/month	\$ 18.50/month	50%
Lopinavir/Ritonavir	\$ 330/month	\$ 97/month	70%
Clopidogrel	\$ 2/pill	\$ 0.08/pill	96%
Docetaxel	\$ 714/injection	\$ 114/injection	84%
Letrozole	\$ 7/pill	\$ 0.2/pill	97%
Erlotinib	\$ 78/pill	\$ 21/pill	73%
Imatinib	\$ 26/pill	\$ 2/pill	92%

# Patent Oppositions in 2014 - 2022

No.	Disease	Medicines	Thai PA Number	Date of Opposition	Type of Opposition	Status
1	HCV	Sofosbuvir	1001000775	15-Dec-14	TPO	Pending
2	HIV	Raltegravir	1201001892	23-Sep-15	PO	Reject 22 May 2019
						Appeal 1 Aug 2019
						Reject 28 Sep 2020
3	HCV	Sofosbuvir	0801001634	30-Aug-16	PO	Pending
4	HCV	Sofosbuvir	0401001521	3-Oct-16	TPO	Pending
5	HCV	Sofosbuvir	1201005189	23-Dec-16	PO	Pending
6	HIV	DTG/ABC/3TC	1201003753	15-Mar-17	TPO	Pending
7	HCV	Sofosbuvir	1401002830	11-Apr-17	PO	Pending
8	HIV	TAF	1401000784	8-Feb-18	TPO	Pending
9	HCV	Sofosbuvir/Ledipasvir	1401001362	23-Apr-18	PO	Pending
10	TB	Rifapentine	16010000296	18-Dec-19	TPO	Abandoned 18 Feb 2020
11	TB	Bedaquiline	0501002434	24-Mar-20	TPO	Pending
12	TB	Bedaquiline	0701006189	17-Apr-20	TPO	Pending
13	TB	Bedaquiline	0501005795	5-May-20	TPO	Pending
14	COVID 19	Favipiravir	1101001988	17-Jul-20	TPO	Reject 5 May 2021
						Appeal 1 Jul 2021
15	TB	Bedaquiline	1701004168	30-Nov-20	TPO	Pending
16	HCV	Glecaprevir	1301001445	12-Jan-21	TPO	Pending
17	COVID 19	Favipiravir	1301001720	7-May-21	TPO	Pending
18	COVID 19	Remdesivir	1701002360	4-Jan-21	TPO	Pending
19	COVID 19	Remdesivir	0901001785	20-Jul-21	TPO	Pending
20	HIV	Doravirine	1201004874	13-Aug-21	TPO	Pending
21	TB	Telacebec	1201004783	12-Jan-22	TPO	Granted 28 Feb 2022
22	TB	Rifapentine	1301000834	11-Mar-22	TPO	Pending
23	HCV	Pibrentasvir	1301001948	6-Jul-21	TPO	Pending
24	HCV	Glecaprevir/Pibrentasvir	1801000311	8-Jul-21	TPO	Pending

- **HIV:** 4 oppositions  
4 drugs
- **HCV:** 9 oppositions  
5 drugs
- **TB:** 7 oppositions  
3 drugs
- **COVID 19:** 4 oppositions  
2 drugs

**Total: 24**

- **Pre-grant: 5**
  - Rejected: 1
- **Third Party Observation: 19**
  - Rejected: 1
  - Abandoned 1
  - Granted 1

# Generics' Competition: Lower Prices & More Access



- Patent application 1101001988 (tablet formulation)
  - Opposed in July 2020, rejected in May 2021 and appealed in July 2021
- Procurement in Oct 2020 to Jan 2022
  - Original: 18 million tablets (USD 1.73/tablet or USD 87/treatment)
  - Generic from China: 103 million tablets (USD 0.94/tablet or USD 47/treatment)
  - Generic from India: 8 million tablets (USD 0.94/tablet or USD 47/treatment)
  - Generic in Thailand: 8 million tablets (USD 0.48/tablet or USD 24/treatment)

**Cost-savings of  
Favipiravir's Procurement  
USD 16.4 million**



# Local Production & Access to Optimal Treatment

## Molnupiravir

- 7 million tablets of generic imported from India since May 2022.
- Local generic is filed for FDA's approval in Oct 2022.

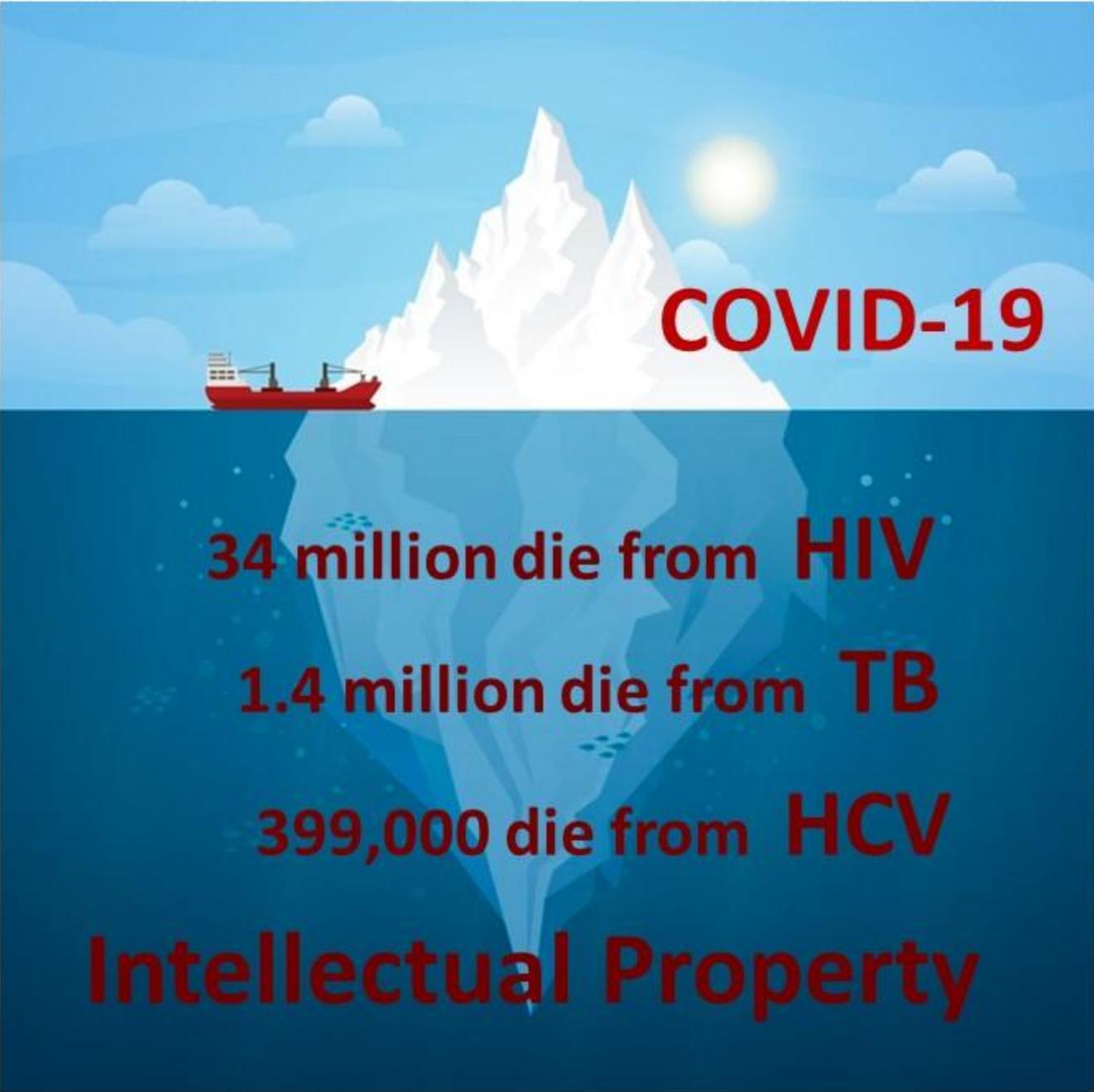
## Sofosbuvir/Velpatasvir (SOF/VEL)

- Pan-genotypic HCV DAAs are included in the national treatment guideline and the UHC.
- Local generic SOF/VEL is being launched in Dec 2022.

## Tenofovir/Lamivudine/Dolutegravir (TLD)

- TLD is included in the national treatment guideline as the first-line regimen to replace TLE in Jan 2022
- Generic versions are imported and locally produced and procured at the same price as TLE (USD 24/person/month)



An illustration of an iceberg floating in the ocean. The tip of the iceberg is above the water line, and the much larger base is submerged. A red cargo ship is visible on the left side of the water. The sky is blue with a sun and clouds. The text 'COVID-19' is written in red on the tip of the iceberg. Below the water line, the text '34 million die from HIV', '1.4 million die from TB', and '399,000 die from HCV' is written in red. At the bottom of the iceberg, the text 'Intellectual Property' is written in red.

**COVID-19**

**34 million die from HIV**

**1.4 million die from TB**

**399,000 die from HCV**

**Intellectual Property**

A background of various medical icons in white outline, including pills, syringes, and a heart, set against a light blue background.

# **Iceberg of Inequality Medicines**



make  
**medicines**  
affordable  
END UNFAIR MONOPOLIES