



Thai CSOs' Advocacy on IPR and Access to Medicines

IPHU Training

Bangkok

10th December 2022

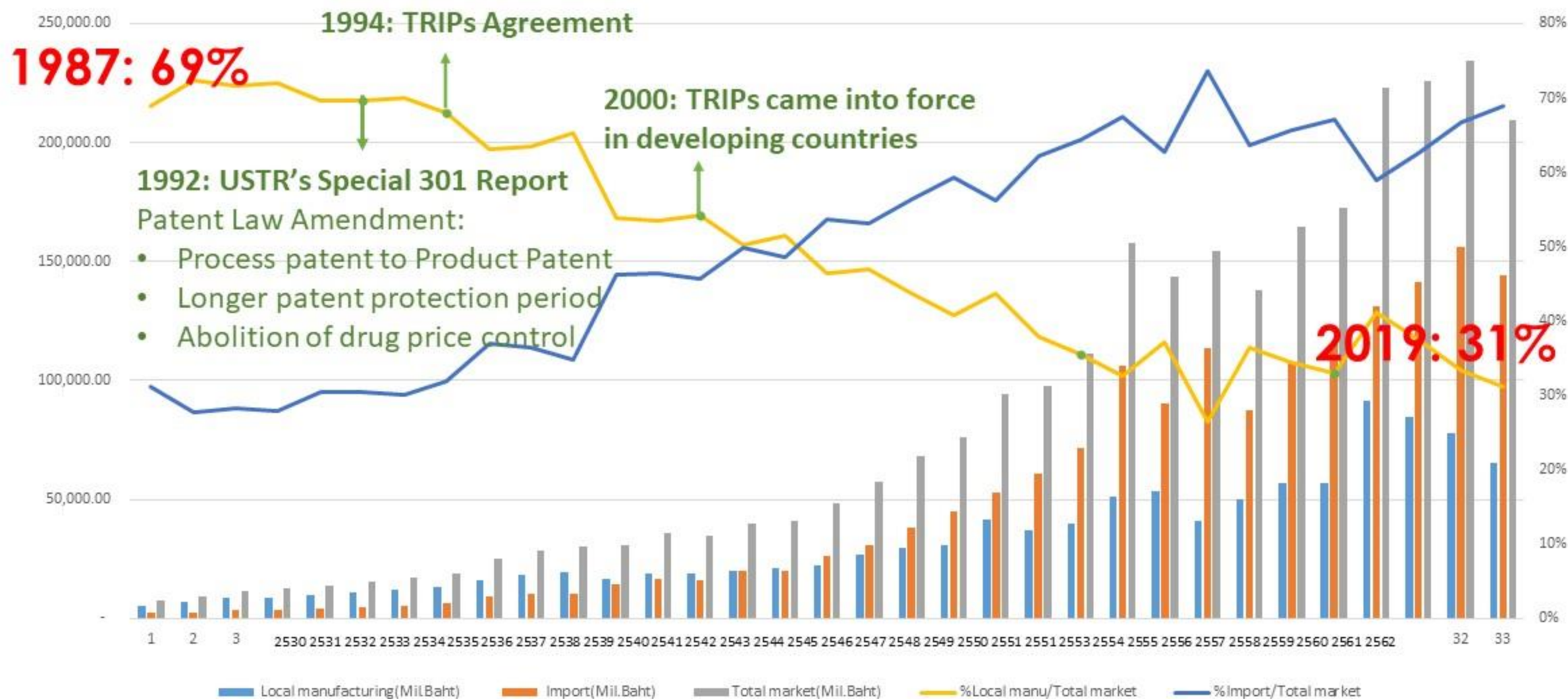
By Chalernsak Kittitrakul



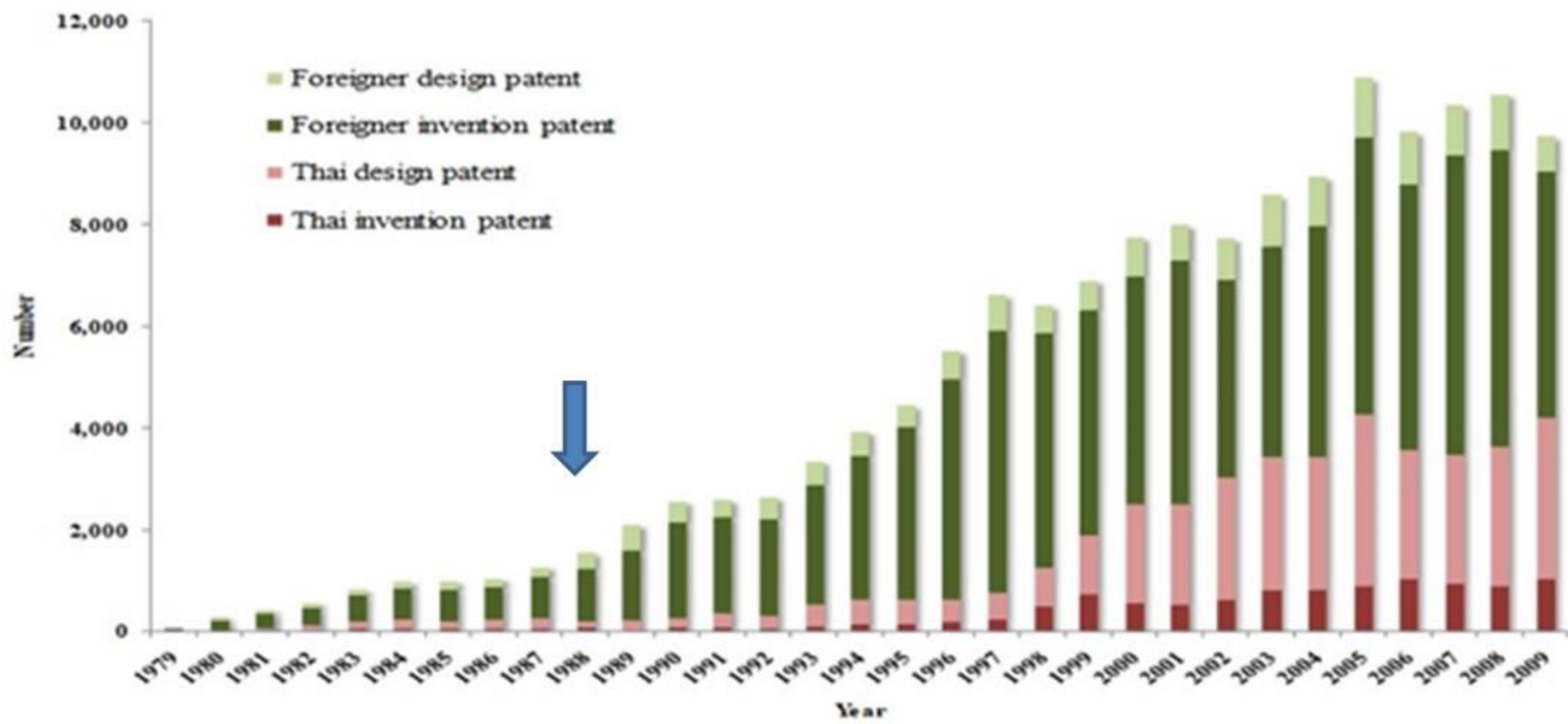


What Happened Before & After TRIPs

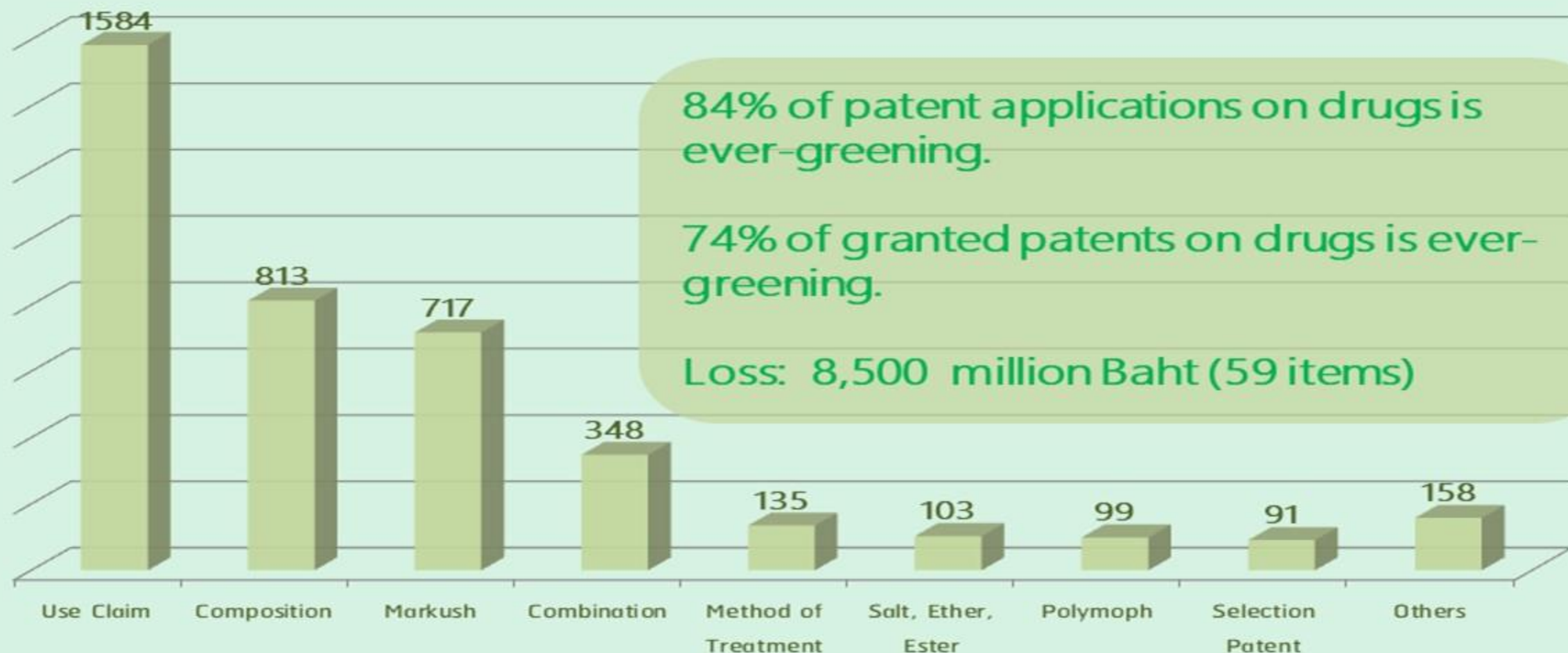
Local Manufacturing and Import of Pharmaceutical Product
1987-2019 (source: Thai FDA)



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



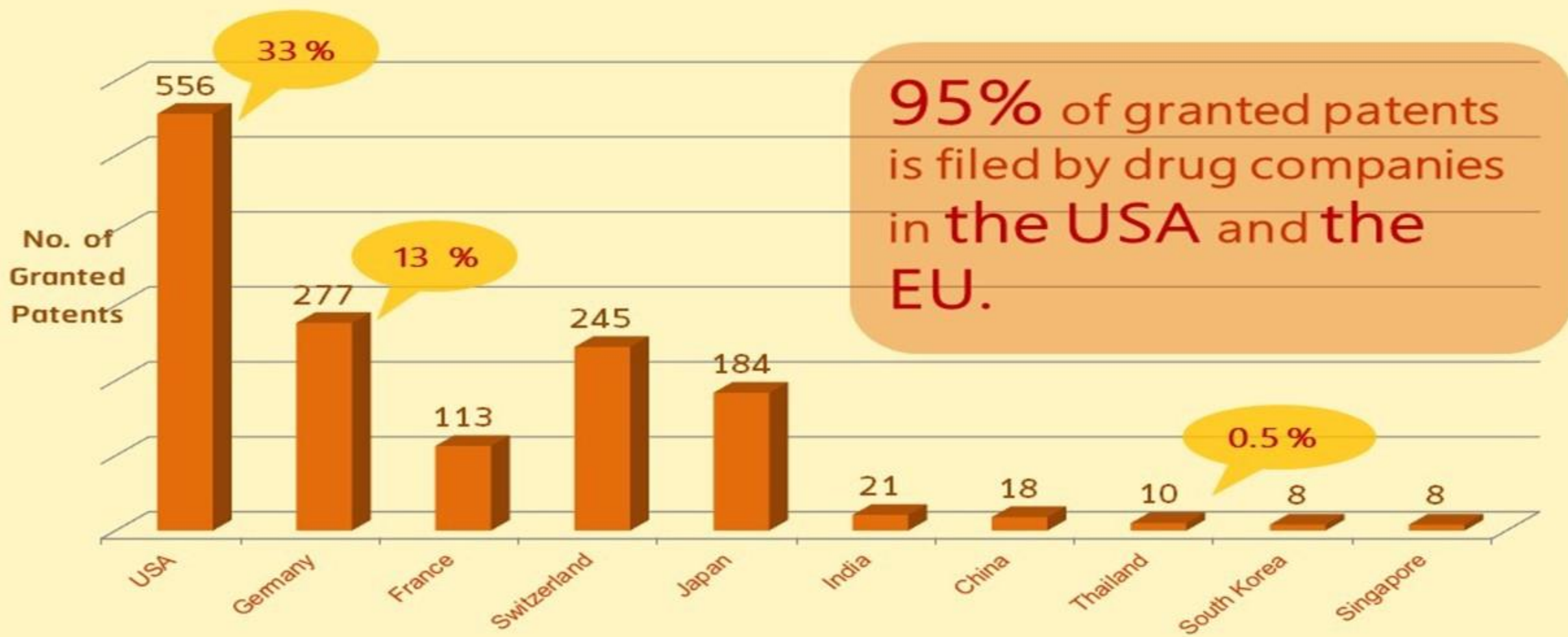
Types and Quantity of Ever-greening Patents on Medicines (1999 – 2010)



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

Who Benefits?

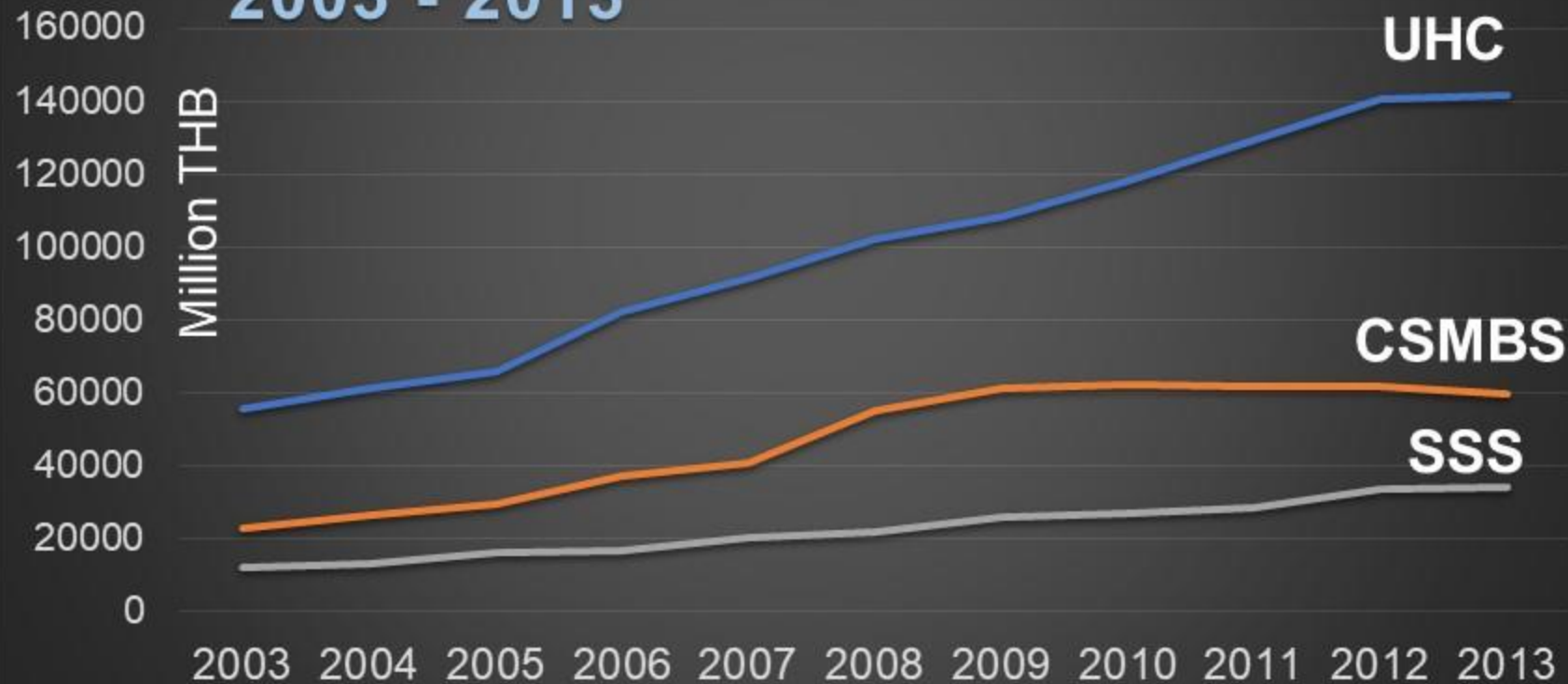
Nationality of Drug Patent Applicants in Thailand (1999 -2010)



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

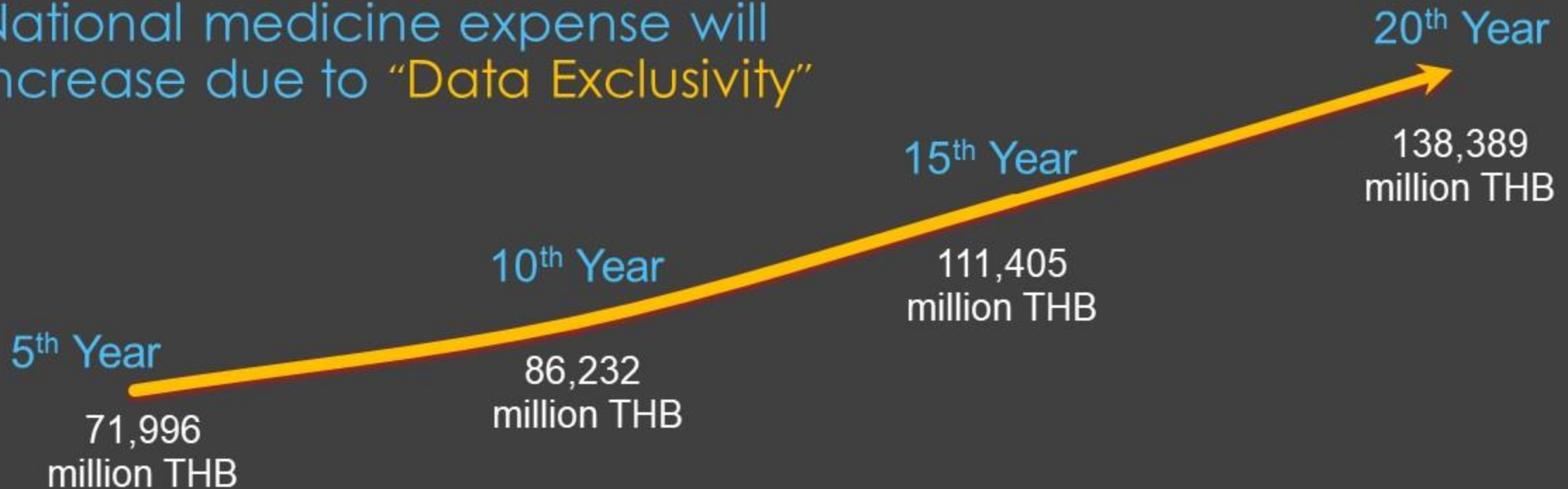


Provisions Threatening Access to Medicines and Public Health

- 
- A woman wearing a white t-shirt and a black bucket hat is speaking into a microphone. The t-shirt has Thai text on it, including 'สิทธิผู้บริโภค' (Consumer Rights) and 'พร้อมสู้กับปัญหา' (Ready to fight the problem). Behind her is a large yellow and black banner with the word 'TRIPS' in large red letters and a red cross symbol. There is also Thai text on the banner, including 'สิทธิผู้บริโภค' and 'พร้อมสู้กับปัญหา'.
- 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"

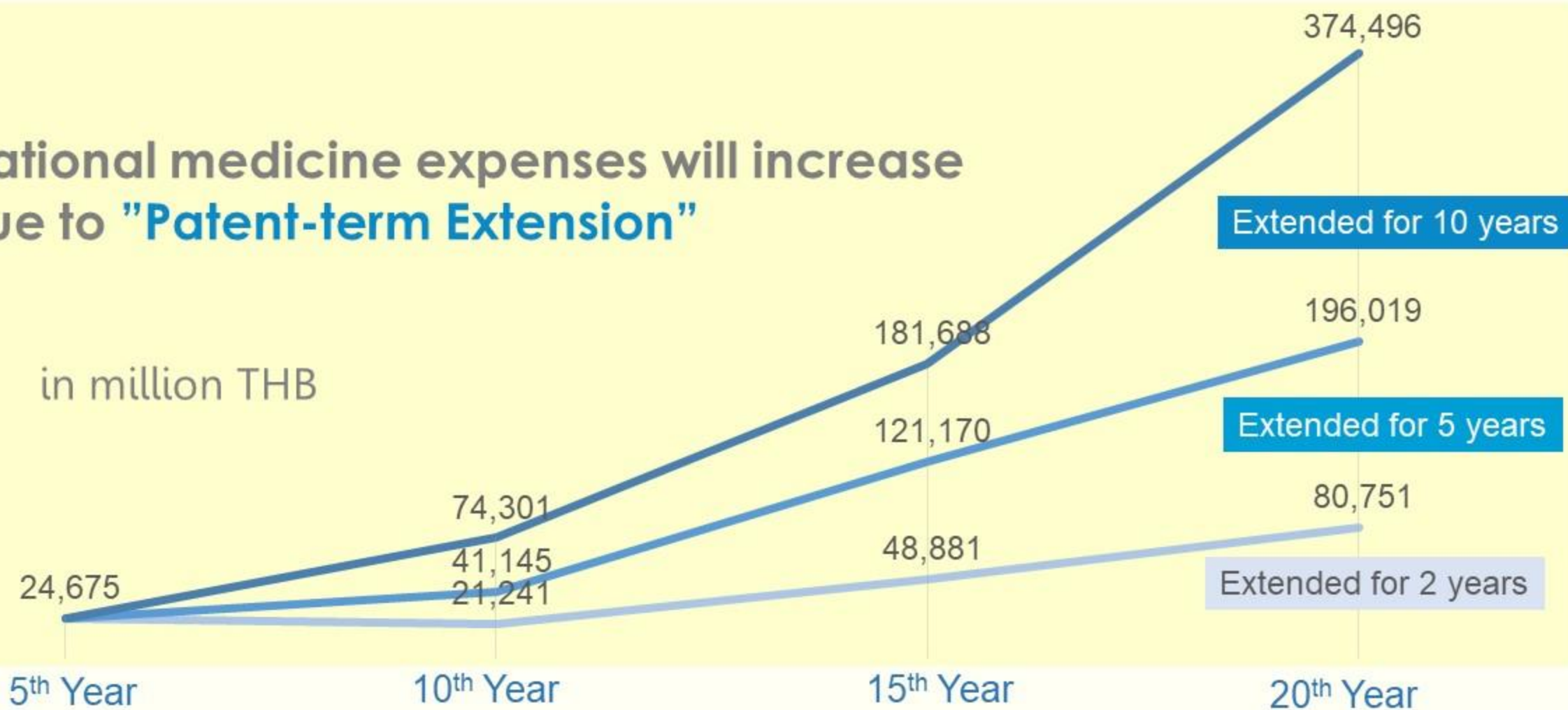


Thailand will have an increase of medicine expenses at least **72,000 million THB** if it amends its laws to have "Data Exclusivity" in compliance with TRIPs+ FTAs.

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

	Patent Linkage	Government Procurement	Patent Linkage & Gov't Procurement
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

“Health Impact Assessment of Policies Related to Local Pharmaceutical Industry Development towards Technology Readiness and Access to Medicines” by HIAPP, 26 May 2021

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

ต้องไม่ยอมลดกลไกการคุ้มครองยาทำลายชีวิต

EU หยุดแย่งยาจากคนไทย ไม่เอาทริปส์

EUROPE!

สหภาพยุโรป
หยุดแย่งยาจากเราเสียที!!!

ไทย-อียู FTA

ยาแพง

เหี้ยมถูก

EUROPE!

HANDS
OFF
OUR
MEDICINE
สหภาพยุโรป
หยุดแย่งยาจากเราเสียที!!!

EUROPE!

สหภาพยุโรป
หยุดแย่งยาจากเราเสียที!!!

EUROPE EUROPE!

หยุด
เหมือนบ้านไทย
ไม่เอาทริปส์ พัด

NO TRIPs+

ทรัพย์สินทางปัญญา
ห้ามดัดแปลง

NO
TRIPs

EU = Hypocrite
EU หน้าไหว้ หลังหลอก
EU = PHARMA'S Poodle

EU - the Nobel Peace Laureate
- is killing people.

Why We Need Health Impact Assessment?

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

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



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

- 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)

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)





The image features a large iceberg floating in a blue sea under a blue sky with a sun and clouds. A small red ship is visible on the left. The top of the iceberg is above the water line, while the vast majority of the iceberg is submerged below the surface. The text 'COVID-19' is written in red on the visible tip. 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 very bottom, the words 'Intellectual Property' are written in red. The background of the right side of the image is white with faint, repeating outlines of various medical supplies like pills, bottles, and syringes.

COVID-19

34 million die from HIV

1.4 million die from TB

399,000 die from HCV

Intellectual Property

Iceberg of Inequality Medicines



make
medicines
affordable
END UNFAIR MONOPOLIES