A close-up photograph of a hand holding several pills. The hand is positioned in the center-right of the frame, with the palm facing upwards. There are four pills visible: two red and yellow capsules, one white round tablet, and one small orange round tablet. The background is blurred, showing other people's hands and what appears to be a medical setting. The overall image has a soft, slightly desaturated color palette.

Intellectual Property and Public Health

Reporting from the Indian Experience

Background

- TRIPS
 - Access to medicines (Doha and flexibilities)
 - India as ‘pharmacy of developing world’ is ground zero.
-

Increasing Use of TRIPS “Flexibilities” + Strong Patent Law in India Since 2001, 2005

TRIPS flexibilities before the grant of a patent:

- Pre-grant Patent Oppositions
- Patent exclusions and exemptions

TRIPS flexibilities in Enforcement of patents:

- Special courts
- Injunctions and other orders

TRIPS flexibilities after the grant of a patent:

- Compulsory Licenses

Working the patent system (national):

- Licenses
 - Patent office
-

THE THAI COMPULSORY LICENSES

2006-2007:

- Clopidogrel (Heart Disease)
- Efavirenz (HIV)
- Lopinavir/Ritonavir (HIV)

2008:

- Letrozole (Cancer)
- Docetaxil (Cancer)
- Erlotinib (Cancer)





1 April 2013

Health | Fri Aug 16, 2013 5:00am EDT

Bloomberg Businessweek

Roche gives up on India patent for breast cancer drug

ZURICH



India App Kale



A phial and pack of herceptin are seen in London June 9, 2006.

PHOTOS OF THE DAY



Our top photos from the last 24 hours. [Slide](#)

TRENDING ON REUTERS

So everything is fine?

ONE DOES NOT SIMPLY



TAKE IT FROM MORDOR

Implementing TRIPS Flexibilities – A Reality Check: Litigation

- Novartis v. India
 - Roche v. Cipla
 - Bayer v. India
 - Pfizer v. Philippines
 - Pharma v. South Africa
 - Pharma v. Brazil
 - Pharma v. Argentina
-

Implementing TRIPS Flexibilities – A Reality Check: Lobbying, Trainings, Etc.

- US and EU/MNC organised trainings:
 - Training of judges
 - Training of patent examiners, officers
 - Training of customs officials, police
 - Lobbying with law and policy makers
 - Trade sanction threats: USTR, Special 301
-

Lobbying and Training

Pfizer tie-up for India meet a mistake: US patent office

JOE C MATHEW
New Delhi, 17 March

The United States Patent and Trademark Office (USPTO) said it made a "mistake" by allowing US-based drug maker Pfizer to co-sponsor a public discussion programme on sensitive issues related to intellectual property rights in India last year.

In response to a blog post that talked about a "USPTO-Pfizer collaboration

US patent office to train Indian judges on IPR-related issues

JOE C MATHEW
New Delhi, 13 September

THE United States Patent and Trademark Office (USPTO) will train Indian law enforcement officials and members of the judiciary on issues related to intellectual property rights (IPR) from this week.

The five-day workshop, beginning September 15, will be held in Mumbai in association with the Maharashtra Judicial Academy. It would have a three-day session on IPR and a two-day training session on digital piracy, an academy official said.

This is the first time the state judicial academy is joining hands with USPTO to conduct refresher and training programmes for members of the judiciary.

"The IPR session is planned for district and session judges. For digital piracy workshop, public prosecutors, CBI officials and law enforcers, including police personnel, will be included," the official added.

The academy, the first of its kind in Maharashtra, was opened two years ago to train the judicial members in the state.

USPTO, an agency under the US government's department of commerce, runs similar training programmes world over primarily through its Global Intellectual Property Academy.

IPR violations is one of the major concerns of the US

and is a key reason for keeping India, among several other nations, in the US government's "priority watch list" that indicates the level of IPR protection offered by the trading partners.

The Special 301 Report of the Office of the United States Trade Representative released in May complained that India continued to have a weak legal framework, and an ineffective IPR enforcement system. The report wanted India to take action on its draft optical disc law and combat widespread optical disc piracy.

THE FIVE-DAY WORKSHOP, BEGINNING SEPTEMBER 15, will be held in Mumbai in association with the Maharashtra Judicial Academy. It will have a three-day session on IPR and a two-day training session on digital piracy

It had also sought improvement of India's IPR regime by providing for stronger patent protection, to address concerns such as provisions of India's patent law that limit the patentability of potentially beneficial innovations, such as temperature-stable forms of a drug or new means of drug delivery.

It also wanted India to take steps to improve the efficiency of judicial proceedings, and strengthen its criminal enforcement regime, by encouraging the imposition of deterrent-level sentences for IPR violations and by giving prosecution of IPR offences a greater priority.

The Special 301 Report has stated that the US looks forward to increased engagement with India to address these and other matters.



SC judge under attack from health activists

TNN | Sep 6, 2011, 08.28 AM IST

NEW DELHI: Two years ago, Justice Markandeya Katju of the Supreme Court had withdrawn from hearing a patent dispute vitally concerning pharmaceutical majors. Justice Dalveer Bhandari, the head of the bench that has since been dealing with the case, is now under attack, this time from health activists.

Though he did not himself give any reason for it, Katju's recusal in 2009 from the appeal filed by Novartis was then widely attributed to an article written by him in a legal journal conceding, much to the embarrassment of multinational companies, that "many of the medical drugs available in the market are too costly for the poor people in India" and that "ways and means should therefore be thought out for making these drugs available to the masses at affordable prices".

In what seems virtually a reversal of the situation, the health activists demanded on Monday, on the eve of the next hearing of the case, that the government should seek Justice Bhandari's recusal as he had participated in at least two international conferences for judges organized by the US-based Intellectual Property Owners Association (IPOA), whose members include Novartis, among a host of pharmaceutical and IT giants.

In a victory for U.S. pharma, India pledges to abandon compulsory licensing, trade group says

by Tracy Staton | Mar 8, 2016 11:26am



Has India given up the compulsory license fight? According to a U.S. trade group, officials have privately promised not to grant any more of the licenses, which force branded drugmakers to allow generics companies to knock off their on-patent drugs.

As *Reuters* reports, the U.S.-India Business Council assured the U.S. Trade Representative that it's no longer open to compulsory license requests from domestic drugmakers. The disclosure came in a USIBC submission to the trade rep, which is working on an annual report about international trade barriers.

Under Indian law--and World Health Organization protocols--the government is allowed to open the door to early generic competition when a medicine is too pricey for local use, but important to public health.



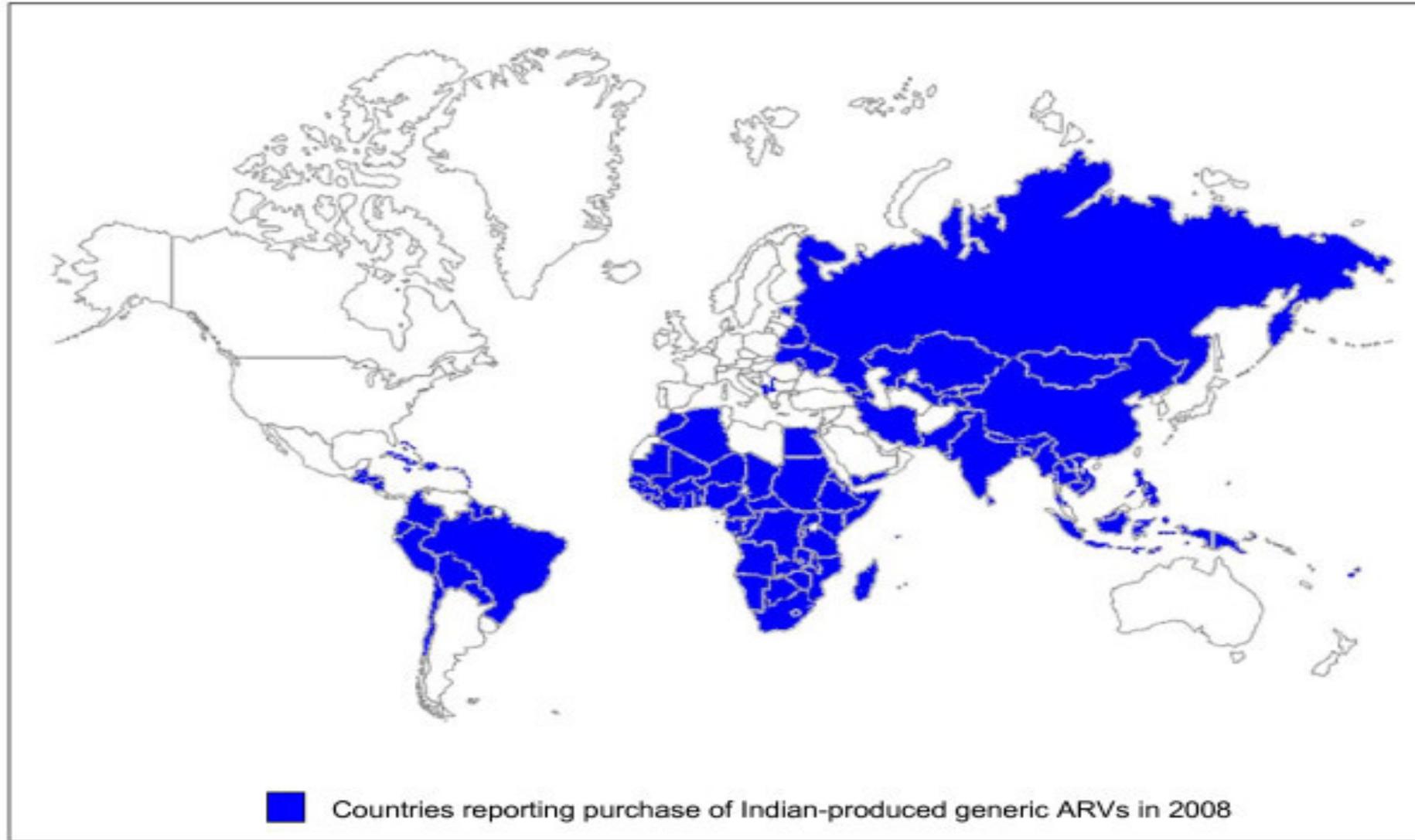
The threat of compulsory licensing became all too real in 2012, when

Indian Generic Industry: Merged and Acquired

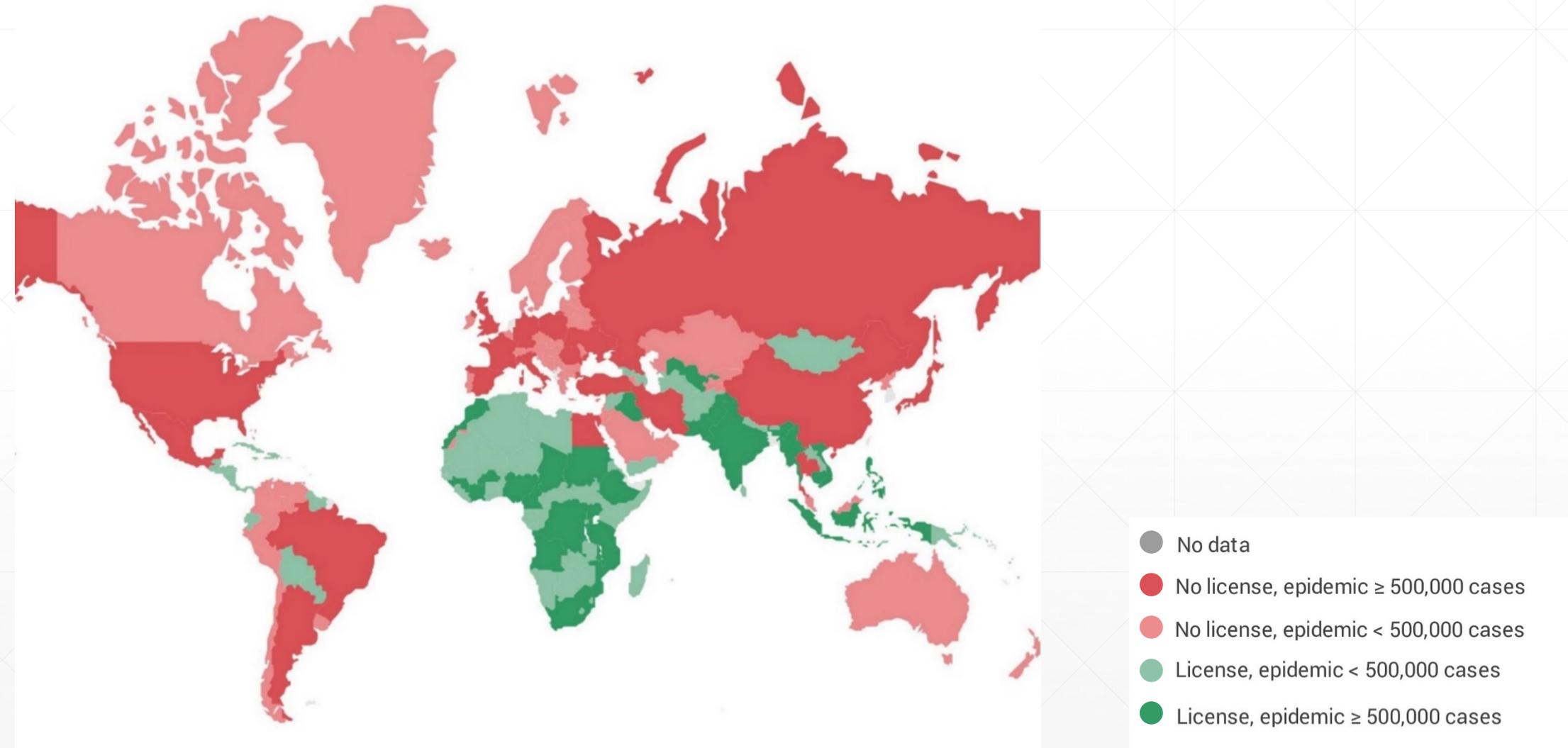
Target company	Acquirer	Country of origin	Year	Amount (USD)
Matrix lab	Mylan Inc	US	August 2006	\$736 million
Dabur Pharma	Fresenius Kabi	Singapore	April 20, 2008	\$219 million
Ranbaxy Laboratories Limited	Daiichi Sankyo	Japan	June 11, 2008	\$4.6 billion
Shantha Biotech	Sanofi Aventis	France	July 27, 2009	\$783 million
Orchid Chemicals (injectible business)	Hospira	US	December 16, 2009	\$400 million
Piramal Healthcare (domestic formulation)	Abbott Laboratories	US	21 May 2010	\$ 3.72 billion

Source: compiled from various news reports

India: “Pharmacy of the Developing World” (Original Reach)



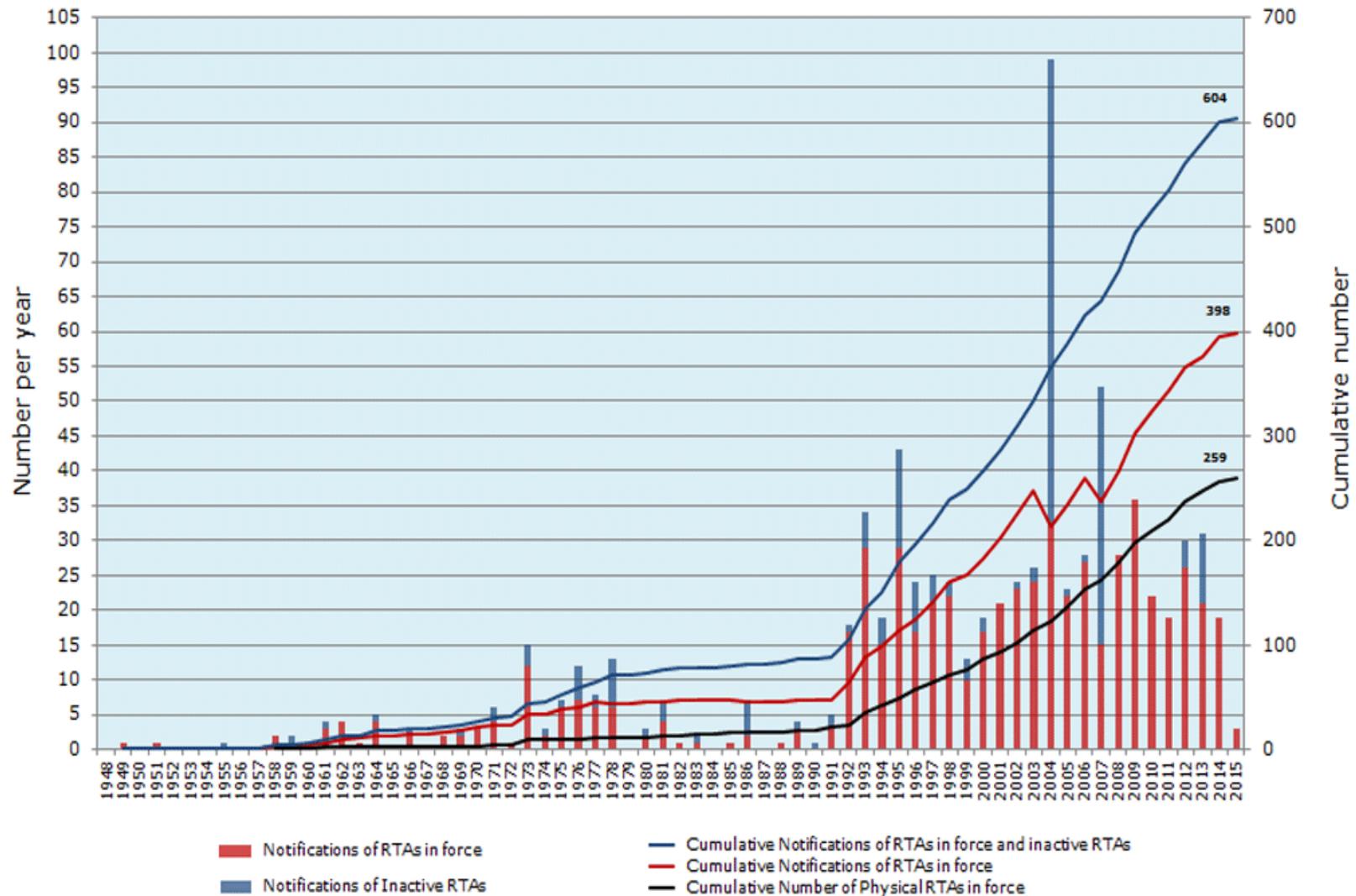
Curtailed Reach



FTAs:

- IP: Demands for provisions well beyond TRIPS i.e. TRIPS-PLUS.
 - Investment: Allowing companies to sue governments in private arbitration for pro-health policies.
 - Restrictions on using health safeguards; no protections of domestic industry from takeovers; decreased revenues for government health programmes?
-

Free Trade Agreements in Force



Patent Term Extension – Delays in Patent Grants

TRIPS:

- Patents only have to be for 20 years

TRIPS+:

- Patent term extension for patent office delays
 - Patent term extension for marketing approval delays
 - A study in Thailand in 2010 concluded that spending on medicines would increase by \$822 million if the patent term extension was 5 years.
-

Data Exclusivity: Creating an Entirely New Monopoly on Medicines

- Data exclusivity -> ☹ Even if patent is rejected, clinical trials data cannot be used to show bio equivalence. Hence non challengeable monopoly.
 - Jordan (2012):
 - 110 new drugs registered in Jordan between 2000 and 2004
 - No Patents but over 70% had no competition because of DE
-

Intellectual Property Enforcement

TRIPS:

- Patents are private rights
- Person who infringes to be sued
- Customs officials should be empowered to act on imports of goods infringing trademarks and copyright

TRIPS+:

- Patent enforcement to be paid by tax payer money – drug regulator, police, customs, judges
 - “Third party liability”
 - EU seizures (patents, in-transit, exports)
-

Intellectual Property as Investment

TRIPS:

- Treaty between two countries – if one country sues the other (WTO – EU v. Canada)
- For companies, they sue governments in local courts (Novartis case)

TRIPS+:

- Companies sue governments for treaty violation
 - International arbitration
 - Includes intellectual property as investment
 - Arbitration panels do not look at human rights or constitutional rights
 - Awards against governments in the 100s of millions of dollars
-

Theory: Weak Basis for Increasing IP Restrictions in Developing Countries

- Growth, depends on knowledge. (since Solow, 1958)
 - For developing countries, the most important determinant of growth is the pace of closing the knowledge gap.
 - Knowledge is a good that is inherently non-rival.
 - Implication: global social welfare maximizer would minimize impediments to knowledge transfer.
 - Abolish intellectual property restrictions that hamper such transfers especially when the knowledge has already been produced.
 - Argument about ‘absorptive capacity’ overstated. Indian generics producing drugs for 40 years before originator in India
 - But—returns to IP large. IP royalties to US from developing countries -> USAID transfers to developing countries.
-

Innovation, Intellectual Property, and Development:

A BETTER SET OF APPROACHES
FOR THE 21st CENTURY.

Dean Baker, Arjun Jayadev
and Joseph Stiglitz

July 2017

accessibsa.org

