

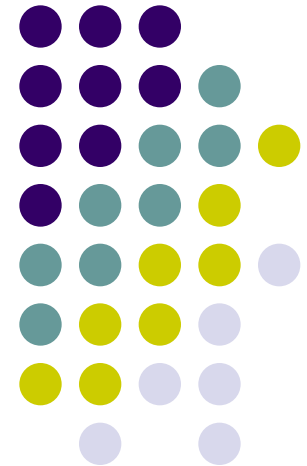


# The Intersection of ISDS and TRIPS Flexibilities

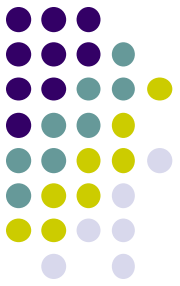


Cynthia M. Ho

XIXth EIPIN Congress  
Enforcing IP in Trade & Investment  
Agreements  
April 25, 2018



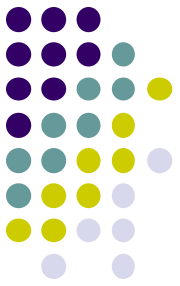
# Investor State Disputes & TRIPS Issues



*Lilly*



# A shift



# TRIPS

- WTO countries (besides LDC) generally **must grant patents** on “inventions” in all fields of **technologies** if they are “new,” “useful/industrial application,” and have an “inventive step”



- TRIPS preserves flexibilities on patentability, and exceptions to patents



# Since TRIPS

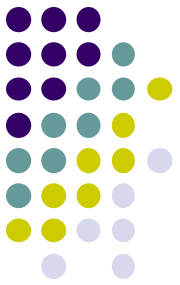
- DSU – should be sole forum to adjudicate WTO/TRIPS issues
- Domestic Discretion subject to challenge at WTO
  - Canada- Generic Med
    - Art. 30 "limited exception" narrow
    - Reg Rev exception ok; Stockpiling invalid



## ● TRIPS-Plus

- Free Trade Agreements
- WIPO – SPLT attempt

- Investor States Disputes re: TRIPS?



# TRIPS flexibilities

- Long recommended by policy makers. but not always used



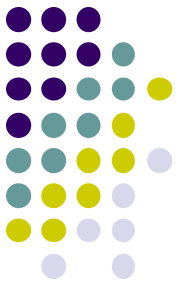
- Are they realistic in light of ISDS?
  - UN 2016 Report cites *Eli Lilly v. Canada* in 2 FNs
    - example of “undue political and economic pressure” against government action to protect public health
    - trade agreements should not interfere with health policies; recommends *future* agreements not do so
  - Recommends use of flexibilities without recognition of possible ISDS challenge



# ISDS & TRIPS – key dates



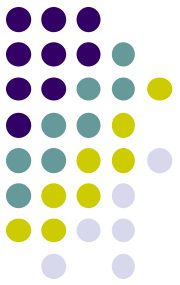
- 1994 – Canada considers plain packaging,
  - RJ Reynolds claims expro → No regulation
- 2003 – WHO Framework Convention
- 2008/09 – Uruguay regulations
  
- 2010 – PMI v. Uruguay ISDS initiated
- 2011 – PMI v. Australia ISDS initiated
- 2012 – Ukraine – WTO req. consultations
  - [Jones Day recommends ISDS](#)
- 2013 – Eli Lilly v. Canada ISDS initiated



# Overview

- Overview
  - Key investment claims
- Comparison
  - IP issues
  - Facts
- Details
  - Tobacco Regulation & TM
  - Canada's "promise doctrine" (interpretation of industrial application) & patents





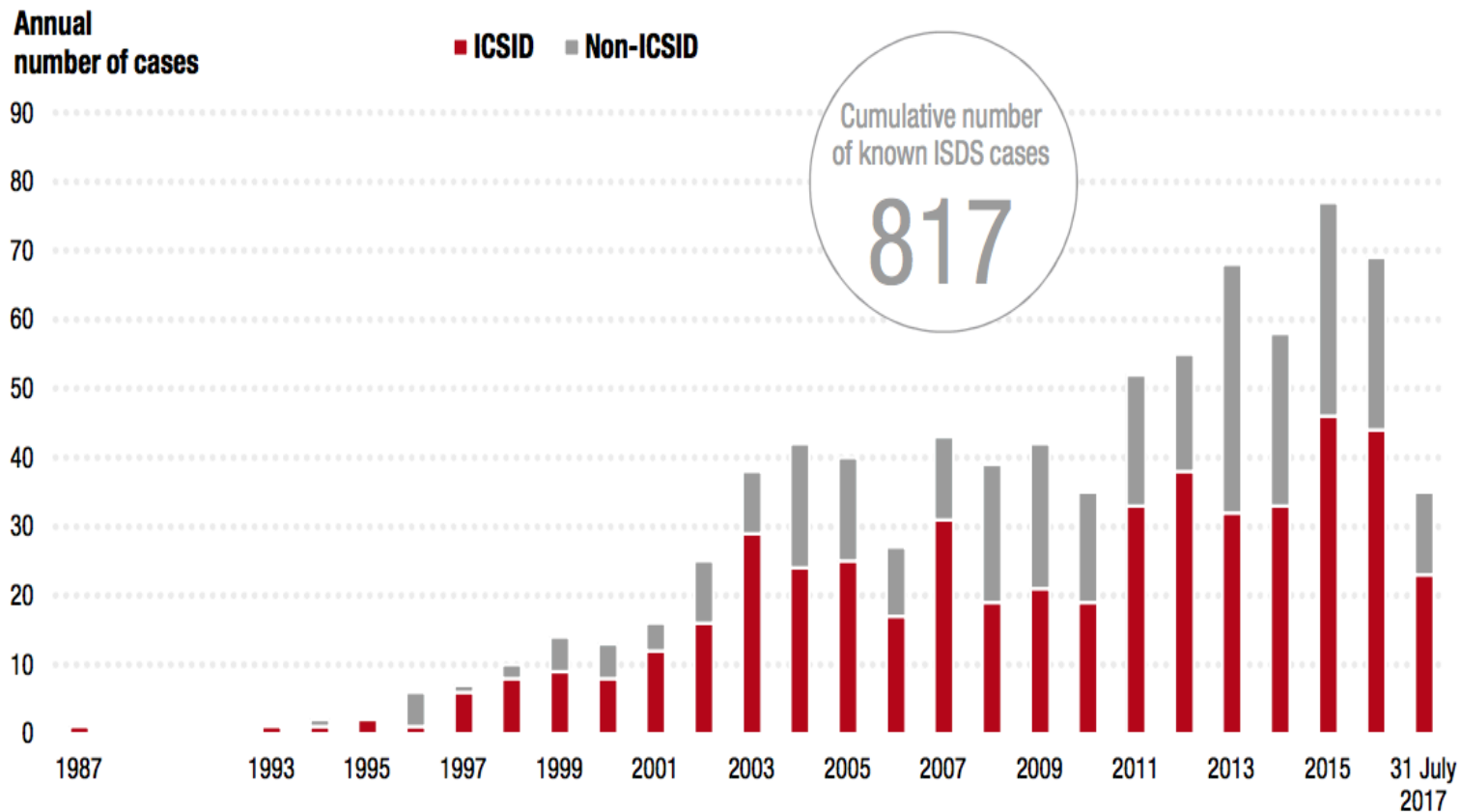
# Key Investment Claims

- Expropriation
  - Roughly analogous to domestic taking, although can be broader
- FET
  - No domestic analog
  - Originally: Egregious and shocking
  - Since 2003:
    - "legitimate expectation" focus

# Known ISDS Disputes – Historical Perspective



Figure 1. Trends in known treaty-based ISDS cases, 1987–31 July 2017



# Comparison of IP at issue



## Philip Morris



- IP: Trademark
  - Right to *exclude* use by competitors *if* confusion; **no affirmative right to use**
- Philip Morris TM Status:
  - Valid; use constrained – same as all other tobacco companies
  - *Unjustifiably* encumbered?

## Eli Lilly

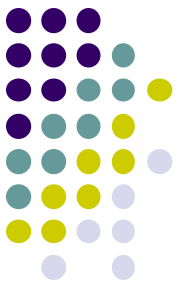
An ophthalmologically acceptable non-steroidal anti-inflammatory drug formulation, comprising:

an ophthalmologically acceptable non-steroidal anti-inflammatory carboxyl group-containing drug in an effective amount for ophthalmic treatment between 0.001% and 10.00% wt/vol;

a quaternary ammonium preservative in an antimicrobially effective amount between 0.001% and 1.0% wt/vol;

an ethoxylated alkyl phenol that conforms generally to the formula:  $C_6H_{11}C_6H_4(OCH_2-CH_2)_nOH$  where  $n$  has an average value of 40  $[O_{40}]$  in a stabilizing amount between 0.001% and 1.0% wt/vol; and an aqueous vehicle q.s. to 100%.

- IP: Patent
  - Right to *exclude* identical; **no affirmative right to use**
- Eli Lilly Patent Status:
  - 2 patents Invalidated (permissible under TRIPs and domestic law)
  - “useful” undefined



# Facts for Expro/FET Claims

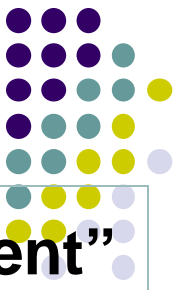
## Philip Morris

- Challenged domestic law
  - tobacco *regulatory* laws that limit use of trademarks
  - Compliance with TRIPS (Australia only)

## Eli Lilly

- Challenged domestic law
  - Canada's patent law "promise" *common law* doctrine
    - arguably changed since NAFTA
    - impermissible retroactive application?

# Typical analysis



## Expropriation

- *Sole Effect*
- Other factors
  - **State interest**
    - Reduce Smoking
    - Access to cheap medicine?
  - **Legitimate expectations**
    - TRIPS
    - No change in law

## “Fair and Equitable Treatment”

- “stable legal and business env”
- Investors “legitimate expectations” defeated *if* specific state representation that investor relied upon
  - Is patent a specific representation that it will remain valid?
    - “[W]e assume contracts are valid ... because they really are. ... And here we’re in a different universe ... you could flip a coin as to whether a patent is valid.” (Justice Kagan)

# PMI v. Tobacco Reg (& TM)



- Uruguay
  - 80/20
  - SPR



Warnings on cigarette packets in Uruguay.

- Australia
  - “plain package”

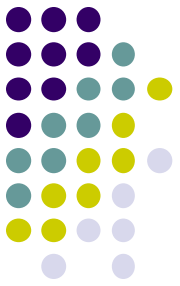


# TRIPS – TM provisions



- Art 20: Trademark use “shall not be unjustifiably encumbered by special requirements
- Art 15.4: nature of goods “shall in no case form an obstacle to registration” (*implicit assumption of use*) despite Art. 16 only providing negative right and Art. 17 permitting “limited exceptions”

# ISDS v. WTO



## Direct Conflict

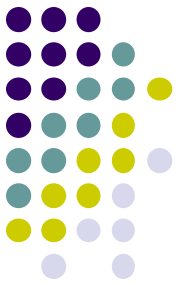
- Different interpretation of TRIPS
- Why?
  - Not all IP scholars agree
  - IP policy not familiar to commercial arbitrators
  - No way to reconcile different interpretations

## Implicit Conflict

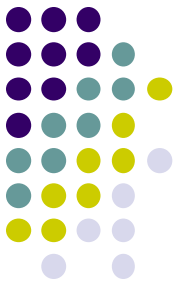
- Investment claim without regard to compliance with TRIPS under either
  - Expropriation
  - FET



# PMI v. Uruguay



- Goals:
  - Repeal regulations
  - Suspend application
  - \$\$\$\$\$\$\$\$\$\$



# Uruguay ISDS - Positives

- Funded by billionaire Bloomberg
- Interpretation of TRIPS art.20
- Reliance on amici
- Expropriation
  - compensation unnec for bona fide nondiscrim reg consistent with police power
- FET
  - *Majority* says regulations not arbitrary

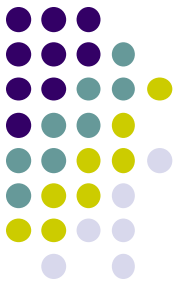
# Uruguay ISDS issues



- FET not unanimous
  - Unique law problematic to dissent
- Future tribunals need not follow
- Application to Eli Lilly & Beyond
  - Not all IP regulations fall within police power
    - Law at issue was public health regulation for issue with global consensus
    - No consensus on limiting patent rights to promote access to medicine or limiting unnec patents

# ISDS & WTO

## -Australia case



- Allege FET violation for violating TRIPS
- Simultaneous ISDS and WTO cases
  - Possible Conflict in TRIPS interpretation averted



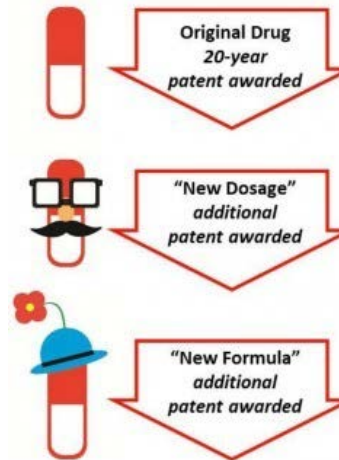
# Eli Lilly's challenge to TRIPS flexibilities



Invalidated patents for violating Canadian law on utility

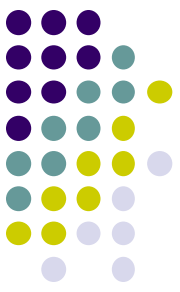


How Does Evergreening Restrict Access to Medicines?



Affordable Generics Delayed

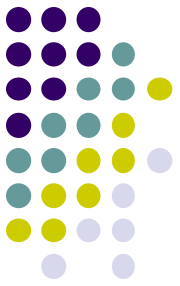
# Cause for concern despite Canada “win”



- Tribunal said *case was not frivolous*
  - Some experts/amici supported Eli Lilly
- Tribunal did not question that IP rights invalidated by court consistent with domestic law (and TRIPS) can constitute investment claim
- Canada “wins” because Eli Lilly failed to show *dramatic* change to the law as prereq for both claims
- Case is NOT predictive
- Not all amici briefs accepted

# ISDS threat to TRIPS

## - Eli Lilly case



### Direct Conflict

- N/A
- No WTO case despite PhRMA lobbying

### Implicit Conflict

- Chilling effect on TRIPS patent flexibilities to define key undefined terms
  - Revoked patent as expropriation
  - Expansive FET interpretation
    - Issued patent as “promise” valid forever
    - “legitimate expectation” laws will not change
- Country could be liable for \$\$\$\$\$ despite full TRIPS compliance

# Big Picture Issues

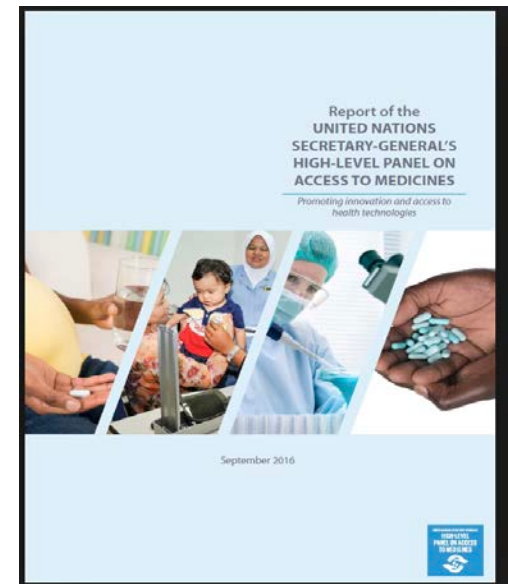


- Chilling effect on TRIPS flexibilities
- ISDS to enforce/promote IP
  - Disrupts WTO/DSU as sole forum to assess TRIPS issues
  - Commercial lawyers to assess TRIPS
  - Actual conflict in TRIPS interpretation



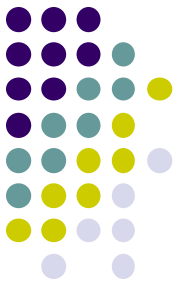
## DECLARATION ON PATENT PROTECTION

### Regulatory Sovereignty under TRIPS





# Recent "wins" are little solace



- Colombia (Novartis)

- ISDS threat after *suggested compulsory license* for cancer drug sold at nearly double GNI

- Legal claim = ?

- What result if

- Below public radar &
- NO consensus?



- Ukraine (Sovaldi)

- \$800 million ISDS claim for approving generic version of Hepatitis C treatment

- Legal claim = ?



# Domestic Laws at Risk?

- Patents

- Compulsory license, or possibility
- Other Patentability Criteria
  - India 3d etc- no patent if similar to known drug unless “increased efficacy”



- Regulatory Laws

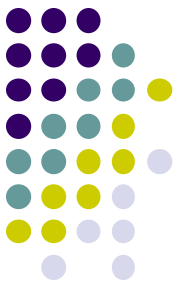
- Data exclusivity issues
- Required data transparency



# Big Picture Problems



- Chilling effect on TRIPS flexibilities due to threat of ISDS, or existing/potential decisions
  - Commercial lawyer adjudicators + most agreements focused on promoting only investments fail to recognize IP is social policy not just for creators; even newer agreements may not emphasize IP policy
- Disrupts WTO Dispute settlement forum as intended sole interpreter of WTO disputes
- ISDS controversy/proposals tend *not* to focus on IP issues in particular



# Additional:

- [Sovereignty Under Siege: Corporate Challenges to Domestic IP Decisions \(2014\)](#)
- [A Collision Course Between TRIPS Flexibilities and Investor-State Proceedings \(2017\)](#)
- [Regime Shift of IP Law Making and Enforcement from the WTO to the International Investment Regime \(2017\)](#)
- TRIPS Flexibilities Under Threat from Investment Disputes, IP-Watch, April 27, 2017, republished at [bilaterals.org](http://bilaterals.org)

# Thanks!

