

Ensuring Safety and Access

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April 2014

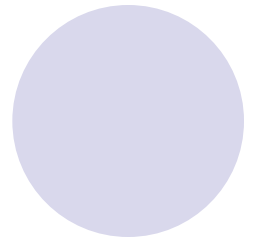
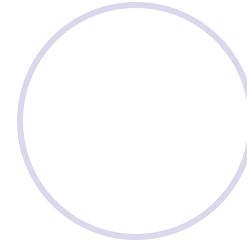
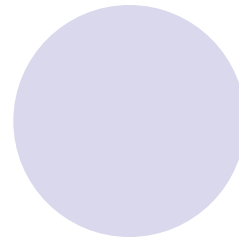
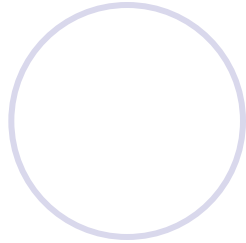
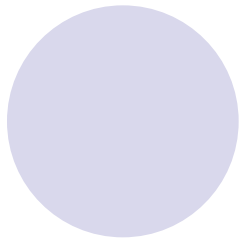
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Thinking Usefully About Counterfeits

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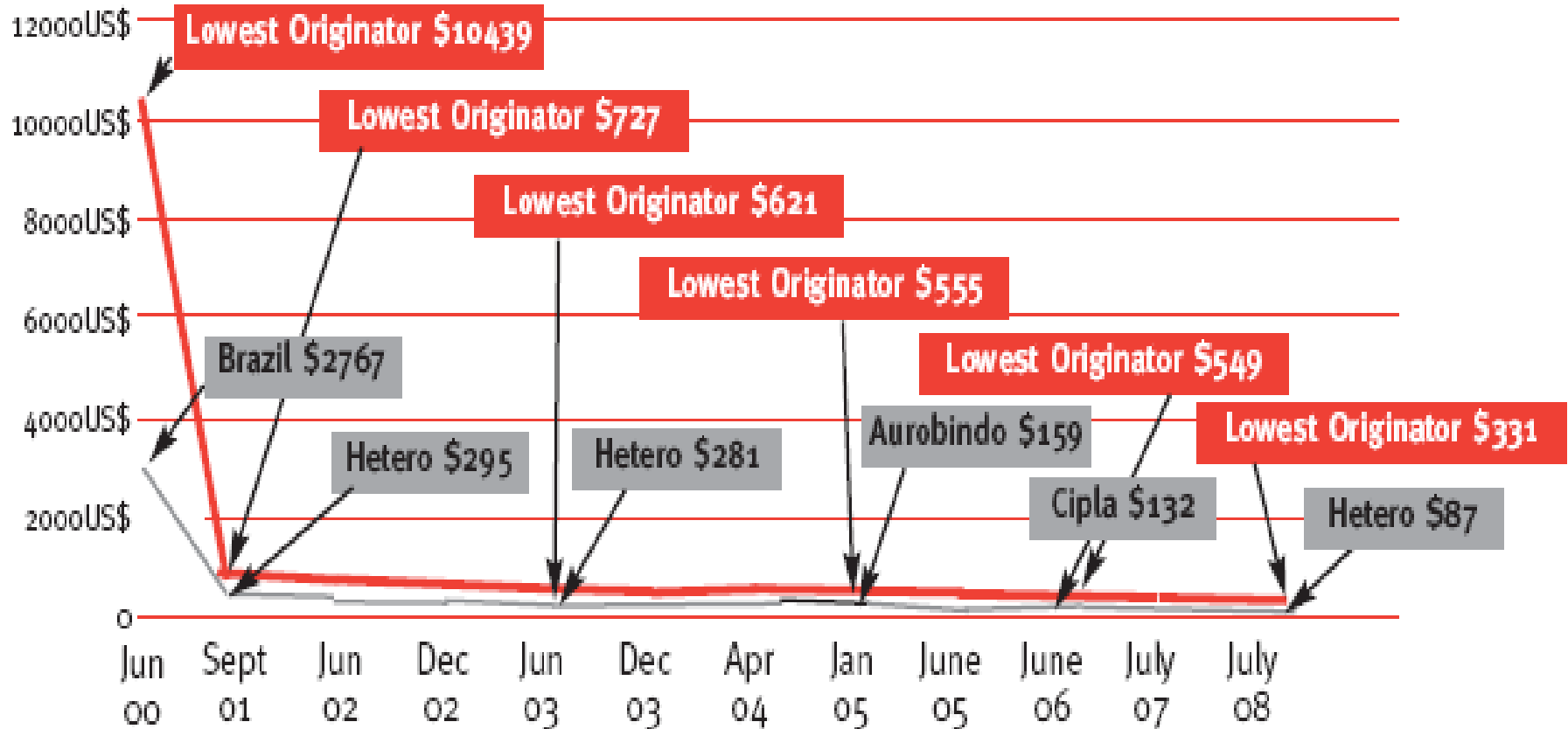
Counterfeit

Anti-Counterfeiting Policy & Public Health

- ***Two major public health interests implicated:***
 - **Safety**
 - To what extent does the policy stop unsafe products?
 - **Access**
 - Does the policy compromise access to quality medicines?
- ***Access and safety are complementary goals:***
 - We must ensure both - and each depends on the other.
 - Inconsistent access drives the market for falsified and counterfeit medicines.
 - Price is a factor.

Competition and Access

(Medicines Sans Frontieres)



Questions:

- **How do we best protect the public from unsafe medicines - including but not limited to falsified medicines?**
- **How do we distinguish between commercial and health interests, for the greatest health benefit?**

Consumer interest:

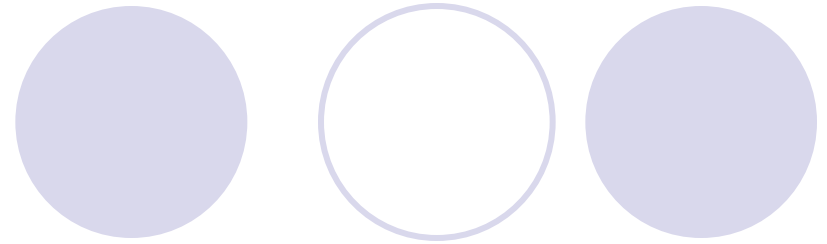
Innovation + Access & Rational Use



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Protecting Health, Safety and Democracy

Access concern:



- **Some commercially interested “anti-counterfeiting” measures block generic competition, without safety benefit.**
- **Many initiatives worldwide protect patent monopolies and other commercial interests under guise of fighting counterfeits and piracy.**
 - *See Susan Sell, “The Global IP Upward Ratchet.”*
 - *See Kevin Outterson, “Import Safety Rules.”*
 - *See Essential Action, “Survey of Anti-Counterfeiting Measures”*
- **Examples**



**Fight
Counterfeits
Not Generic
Drugs**

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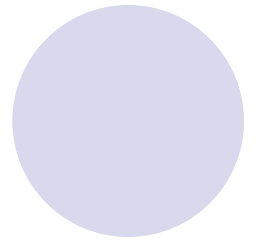
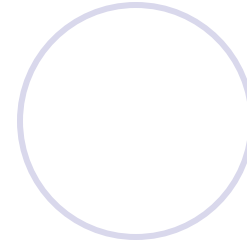
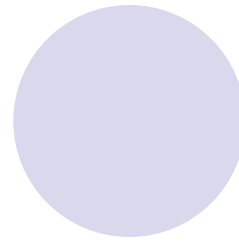
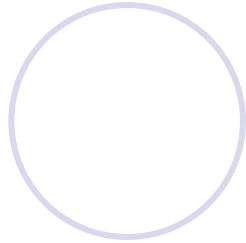
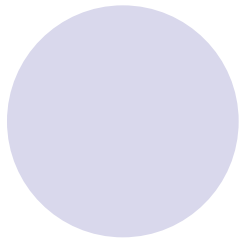
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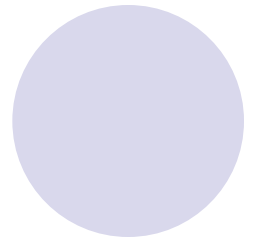
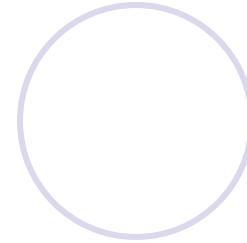
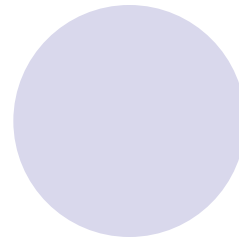
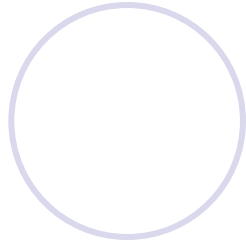
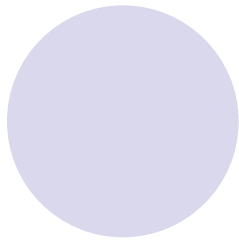
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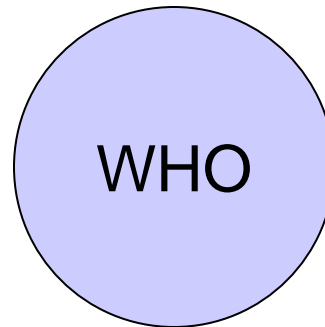
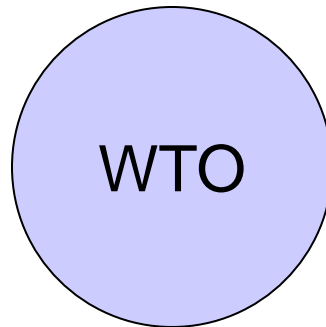
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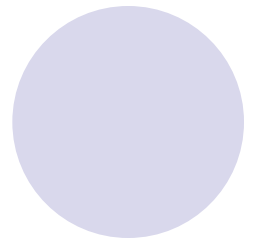
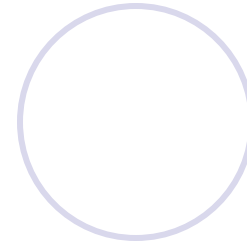
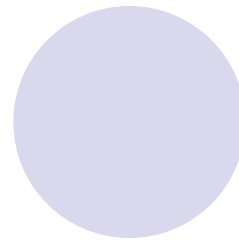
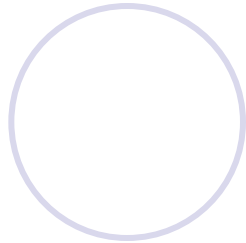
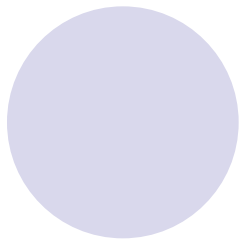


Counterfeit

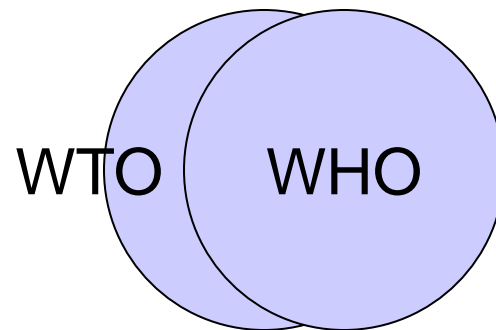


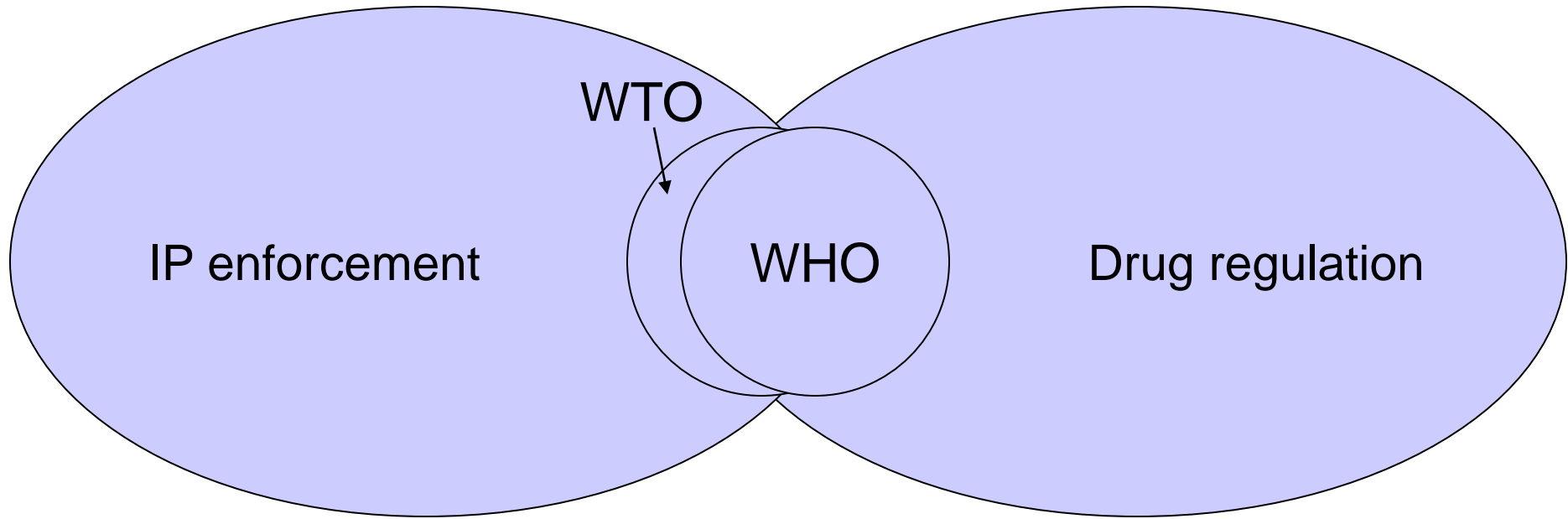
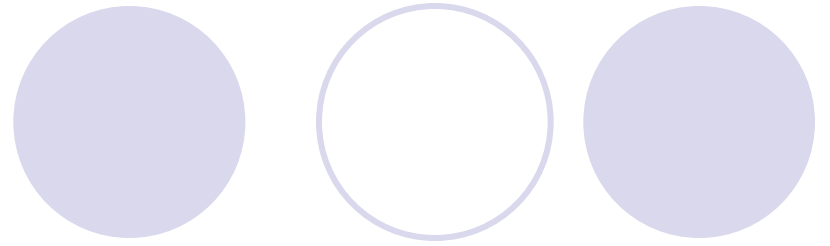
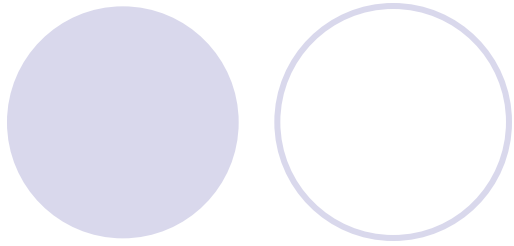
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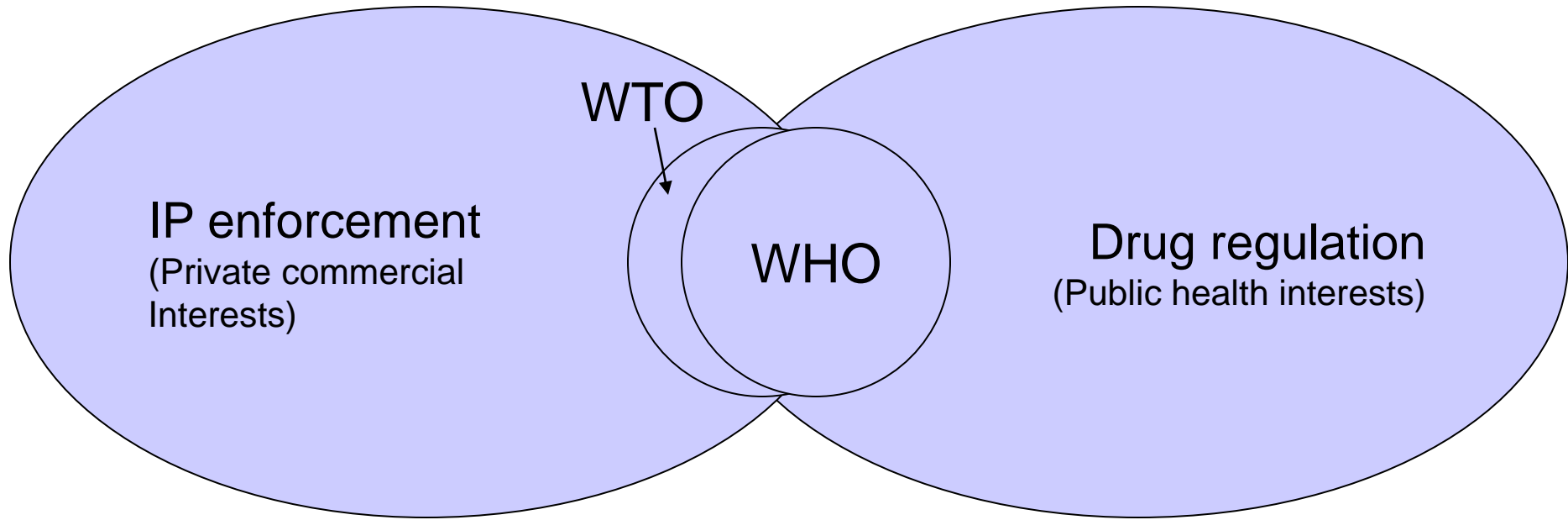
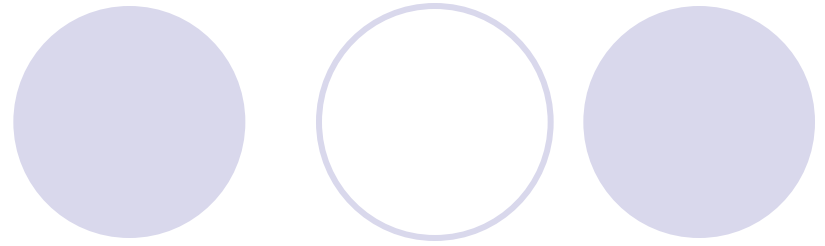
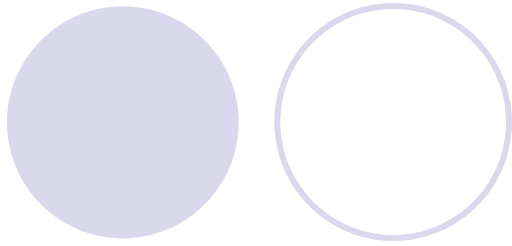




Counterfeit







“Intellectual Property” as “Anti-Counterfeiting”?

- **Anti-Counterfeiting Trade Agreement (ACTA)**
- **Objective:**
 - **“Establish, among nations committed to strong IPR [intellectual property rights] protection, a common standard for IPR enforcement to combat global infringements of IPR particularly in the context of counterfeiting and piracy.”**
 - **“Border Measures”**
 - **Authority at customs – acting on its own initiative or on request of a title holder – to seize medicine shipments.**
 - **Entitlement to injunctions**

Seizing Generic Medicines in Transit?

- **European Customs Regulation 1383/2003**
 - **Multiple instances of generics seized by customs authorities while en route from India to Latin America and Africa**
 - **Holder of any intellectual property right could request detention of generic medicines in transit – even when no right in country of origin or destination**
 - **Customs authority to act on its own**



SEIZED
BY
BIG
PHARMA

EU SEIZED BY BIG PHARMA

EU
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PATENT
ON AIDS
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EU
SEIZED
BY
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PHARMA

SHARE
ON YOU
EU

EU
SEIZED
BY
BIG
PHARMA

EU
SEIZED
BY
BIG
PHARMA

The 2011
Big Pharma
Law By

LIVES BEFORE PROFIT

Intl AIDS Conference Vienna 2010





Prison Time for Selling Generics?

- **East Africa Anti-Counterfeiting Bills**

- **Model legislation shopped to Anglophone countries**
- **Baroness Lynda Chalker & Investment Climate Facility**
- **Kenya, Uganda, Tanzania, Rwanda, Ghana ...**
- **May have criminalized selling generics if a patent related to the drug was claimed anywhere in the world**
- **Became law in Kenya; ultimately defeated through lengthy legal battle by health groups at Kenya Supreme Court**

THE ANTI—COUNTERFEIT BILL, 2008

“counterfeiting” means taking the following actions without the authority of the owner of any intellectual property right subsisting in Kenya or elsewhere in respect of protected goods—

Penalties.

35. (1) A person convicted of an offence under section 32, shall be liable—

- (a) in the case of a first conviction, to imprisonment for a term not exceeding five years, or to a fine, in respect of each article or item involved in the particular act of dealing in counterfeit goods to which the offence relates, not less than three times the value of the prevailing retail price of the goods, or both;

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“Counterfeits” conflation

Private rights

TM

- Infringement
- counterfeiting (WTO)

©

- unauthorized copy
- piracy

Patents

- infringement

Public health

- Counterfeit medicine = deliberately mislabeled (WHO)

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Fallacy #1: Any infringement can be loosely considered a fraudulent & “counterfeit” good.

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Counterfeits endanger public health.

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Fallacy #1: Any infringement can be loosely considered a fraudulent & “counterfeit” good.

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“Counterfeits” conflation

- TM © patents
- All “intellectual property rights.”
- *Fallacy #1: Any infringement can be loosely considered a fraudulent & “counterfeit” good.*
- *Fallacy #2: Similar remedies can be applied in similar manners and degrees for infringement of the distinct rights.*
- *Medical counterfeits (criminally falsified medicines) endanger public health & safety (true).*
↓
- *Fallacy #3: Tougher enforcement of (all) IPRs is a necessary, (primary) and effective means to fight fraud & protect health & safety.*

Promoting Drug Monopolies as Health Measures?

- **Many USG initiatives tasked with “anti-counterfeiting” are IP / business promotion offices**
 - **Messages:**
 - “IP Crime,” “IP Theft,” “Fight Fakes,” etc.
 - **Protect your people by adopting our commerce/IP rules**
 - **Offices include:**
 - **US Patent & Trademark Office**
 - **White House “IP Czar”: Office of IP Enforcement Coordinator**
 - **Dept. of State Office of IP Enforcement**
- **Private initiatives: US Chamber of Commerce**

Business or Health?



Top 10 Ways to Protect Yourself From Counterfeiting and Piracy



Counterfeiting and piracy cost the U.S. economy between \$200 billion and \$250 billion per year, are responsible for the loss of 750,000 American jobs, and pose a threat to health and safety. From DVDs and CDs, shampoo, and batteries to car parts, prescription drugs and electrical equipment, every product in every industry is vulnerable.

There are costs ...

Misdirecting resources?

- **Consumers most comprehensively protected by direct regulatory and consumer protection frameworks (coupled appropriately with law enforcement)**
- **Opportunity cost**



Trends

- **Some titular anti-counterfeiting initiatives focus on IP enforcement, rather than public safety.**
 - ACTA, East African Anticounterfeiting Bills.
- **Some monopoly expansion measures advanced in part on public health & safety rationales.**
 - EC Regulation 1383/2003, IPEC, USPTO/Intellectual Property Academies
- **Some health framework anti-counterfeiting initiatives risk incorporating IP enforcement agenda**
- **In each case, potential public health costs.**

Fraud & Unsafe Industry Practices

- **Off-label promotion**
- **Failure to disclose safety & efficacy data**
 - **Vioxx & heart attacks, Paxil & suicide risk, Tamiflu efficacy**
 - ***See eg* Public Citizen Health Research Group, Peter Doshi at Hopkins**
- **Corruption**
 - **USDoJ: Pfizer bribed officials in 4 countries (\$15m)**
- **Dirty plants**
 - **Glaxo \$750m to settle USG allegations it knowingly sold contaminated products, etc.**

Public Citizen: Pharma Industry is Biggest Defrauder of Fed Government under False Claims Act, 2010

- **Pharmaceutical cases accounted for at least 25% of False Claims Act payouts over the past decade, compared with 11% by the defense industry**
- **More than one-half of the industry's fines were paid by four companies – GlaxoSmithKline, Pfizer, Eli Lilly and Schering-Plough**
- **“Desperate to maintain their high margin of profit in the face of a dwindling number of important new drugs, these figures show that the industry has engaged in such activities as dangerous, illegal promotion for unapproved uses of drugs and deliberately overcharging vital government health programs, such as Medicare and Medicaid.”**

--Sidney Wolfe, director of the Health Research Group, Public Citizen



“According to the Center for Responsive Politics, the pharmaceutical and health-care-product industries, combined with [other health-related] organizations, have spent \$5.36 billion since 1998 on lobbying in Washington. That dwarfs the \$1.53 billion spent by the defense and aerospace industries and the \$1.3 billion spent by oil and gas interests over the same period. That’s right: the health-care-industrial complex spends more than three times what the military-industrial complex spends in Washington.”

-Steven Brill, *Bitter Pill: Why Medical Bills are Killing Us*

Foreign drugs categorically unsafe?

- **Canada**

- **Reimportation debate**

- **NABP application to control “.pharmacy”; exclude foreign pharmacies selling to US consumers**

- **India**

- **Major manufacturing country**

- **Many good drugs, many firms w/GMP – others not.**

- **Better enforcement; more oversight critical.**

- **But why prejudice entire supply?**

- **Most API for branded & generic drugs sourced from India and China.**

Questions:

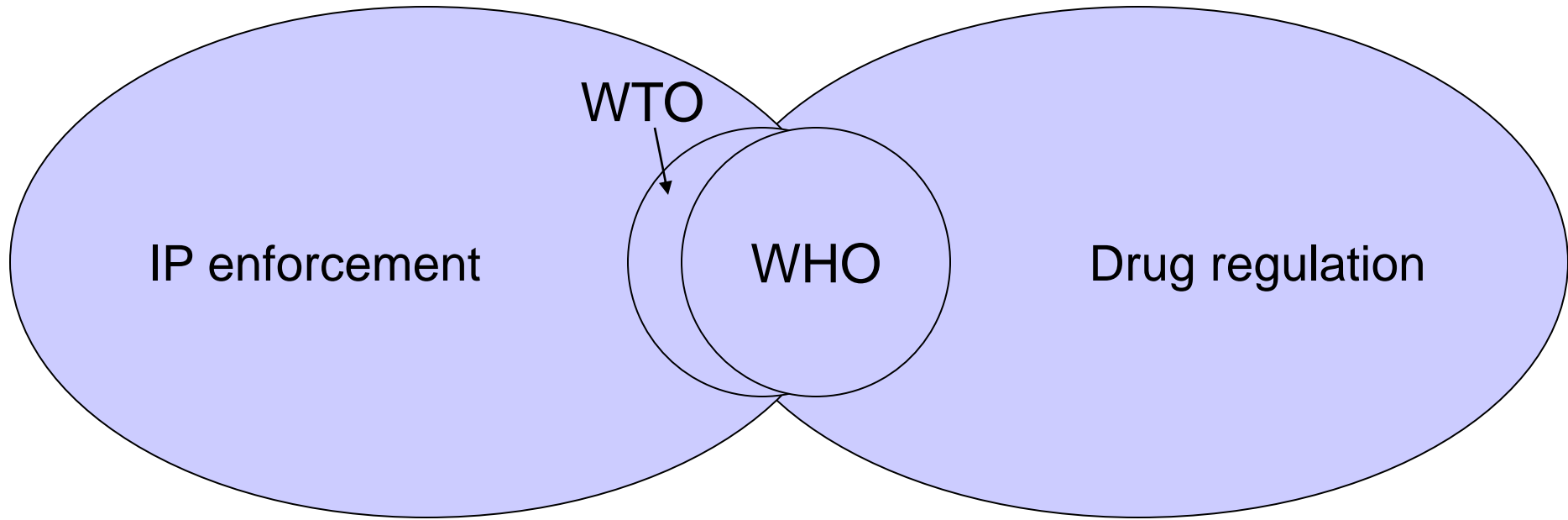
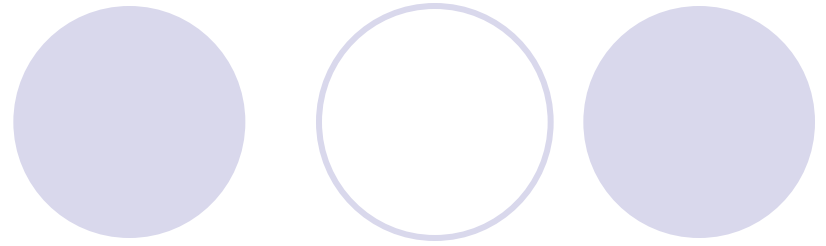
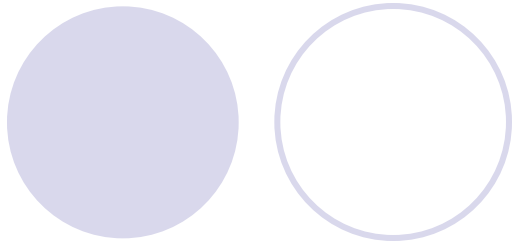
- **How do we best protect the public from unsafe medicines - including but not limited to falsified medicines?**
- **How do we separate commercial interests from health interests?**

Consumer interest:

Innovation + Access & Rational Use

Positive Agenda

- **IP measures of appropriate scope, proportionate penalties, and procedural safeguards**
- **Positive agenda on medicines quality assurance and rational use**
 - **Strengthen DRAs & law enforcement**
 - **Combat pharmaceutical fraud**
 - **Disclosure requirements**
 - **Access to medicines**
 - **International cooperation**
 - **Private sector accountability**
 - **Public participation**



Lessons

- **Distinguish between health and commercial concerns**
- **Ask, “which frame governs here”? Quality control and regulatory measures? Or commercial and IP concerns?**
- ***Much progress in recent years.***
 - ***See eg Institute of Medicine report.***
- **Medicine access and quality are complementary goals; we should seek solutions that advance both.**

Ensuring Quality and Access

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