

Access and IP enforcement
or
A positive agenda on medicine
quality, safety & efficacy

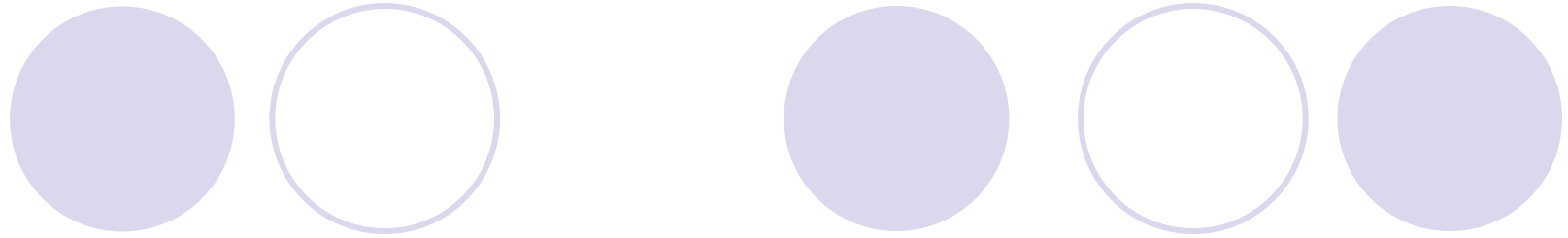
Peter Maybarduk
Public Citizen

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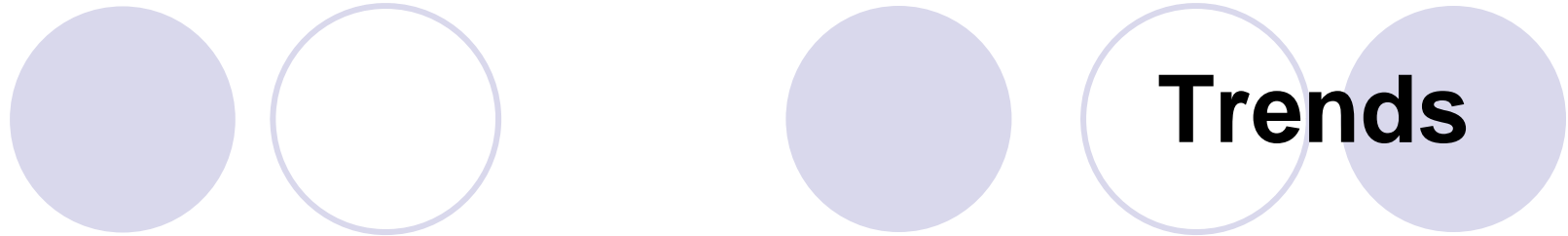
June 2010

Questions:

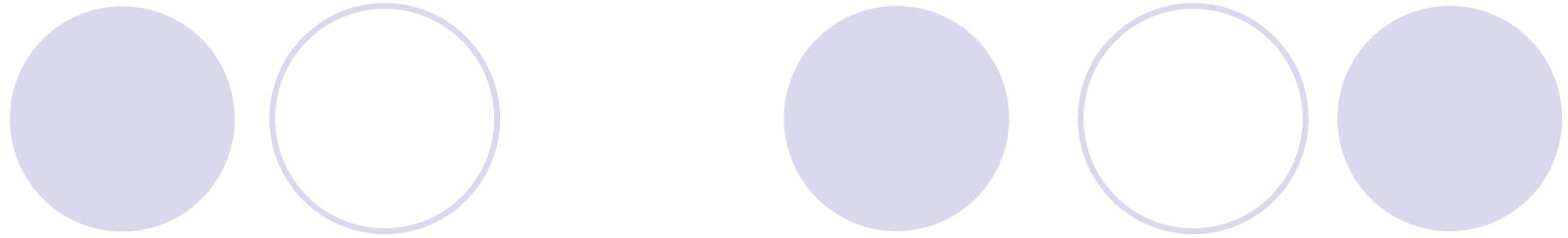
- How do we best protect the public from unsafe medicines - including but not limited to falsified medicines?
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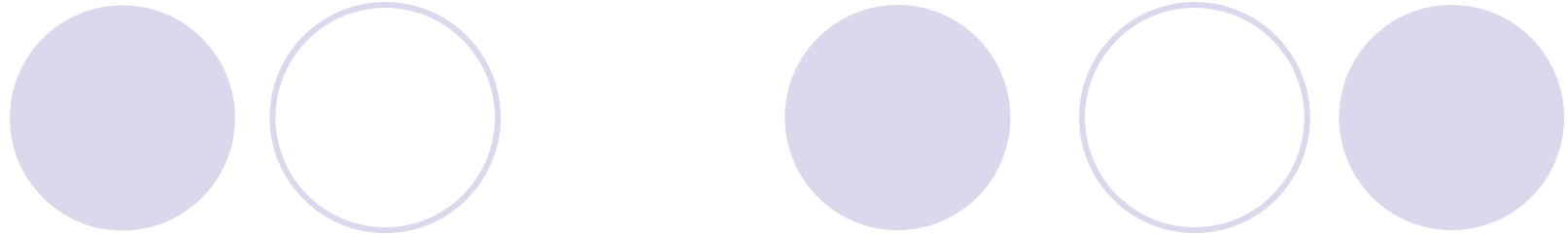
Counterfeit



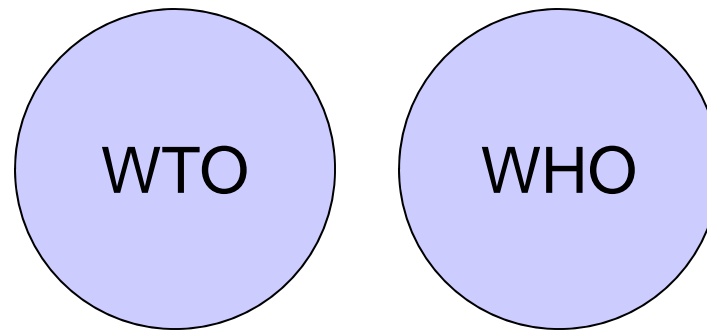
- Some titular anti-counterfeiting initiatives focus squarely and broadly on IP enforcement, not directly on public safety.
 - ACTA, EAC
- Some TRIPS+ enforcement measures advanced in part on public health & safety rationales.
 - EC Council Reg 1383/2003 (*cue Prof Flynn*), US interagency effort
- Some health framework anti-counterfeiting initiatives risk incorporating IP enforcement agenda
 - WHO IMPACT (joint venture with IFPMA)
- In each case, potential public health costs.

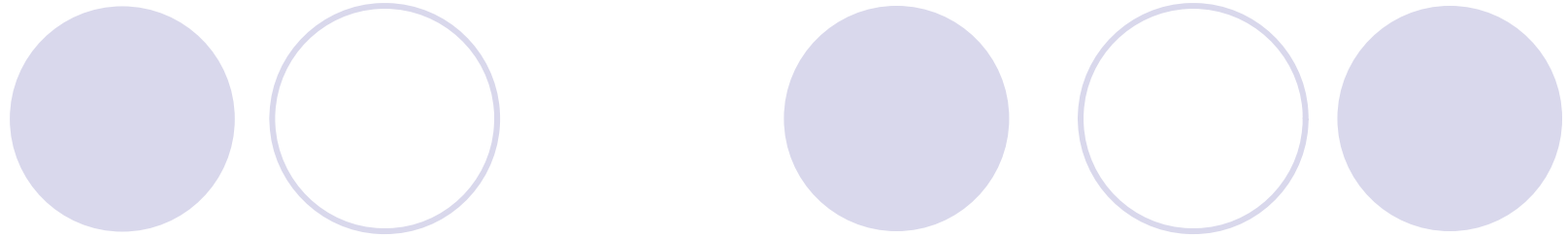


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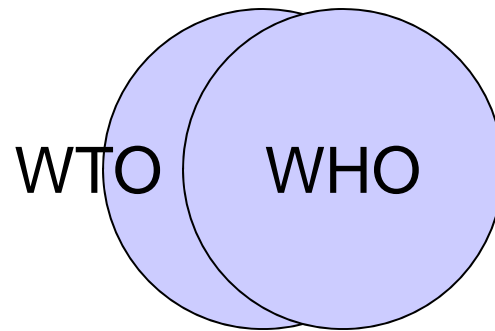


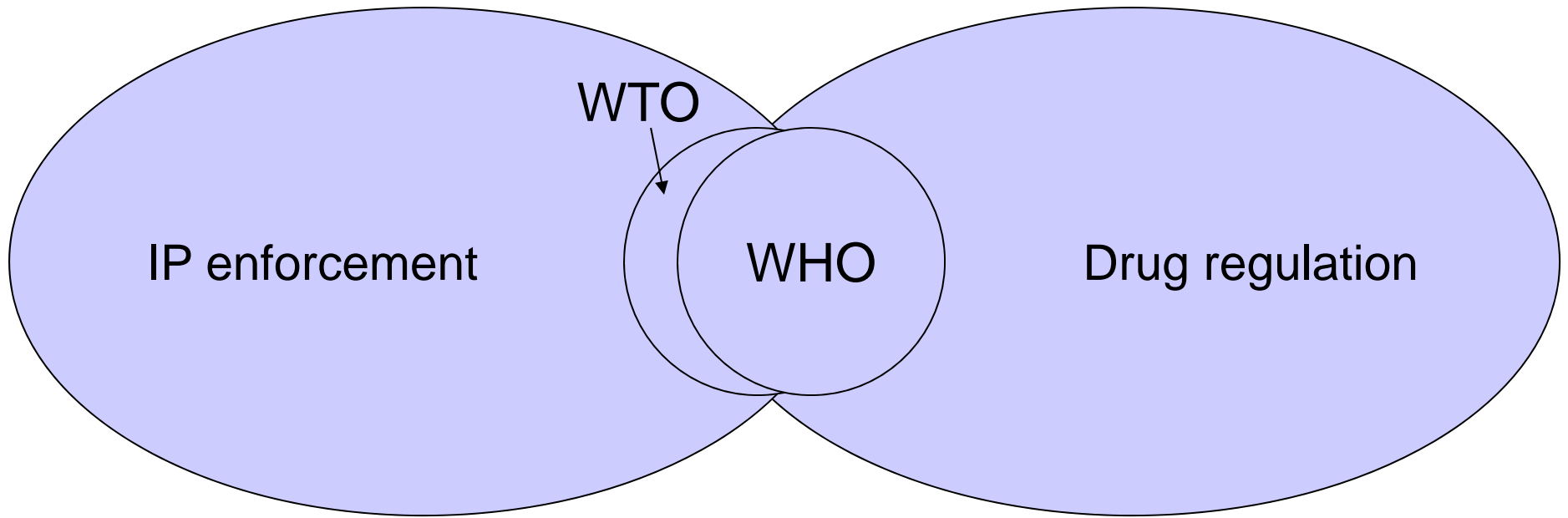
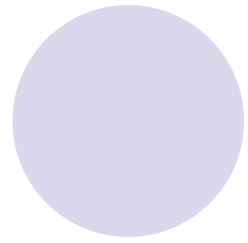
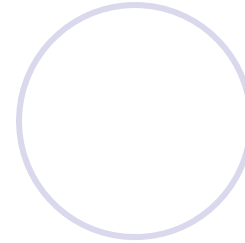
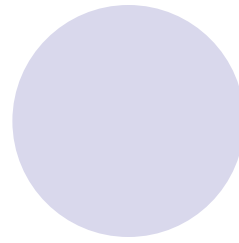
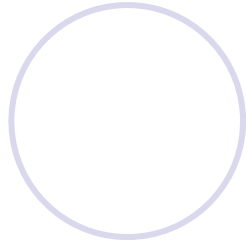
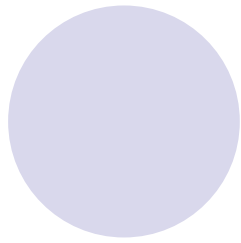
Counterfeit





Counterfeit





“Counterfeits” confusion

Private rights

TM

- misappropriation
- counterfeiting (WTO)

©

- unauthorized copy
- piracy

Patents

- infringement

Public health

- Counterfeit medicine = deliberately mislabeled (WHO)

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Counterfeits endanger public health.

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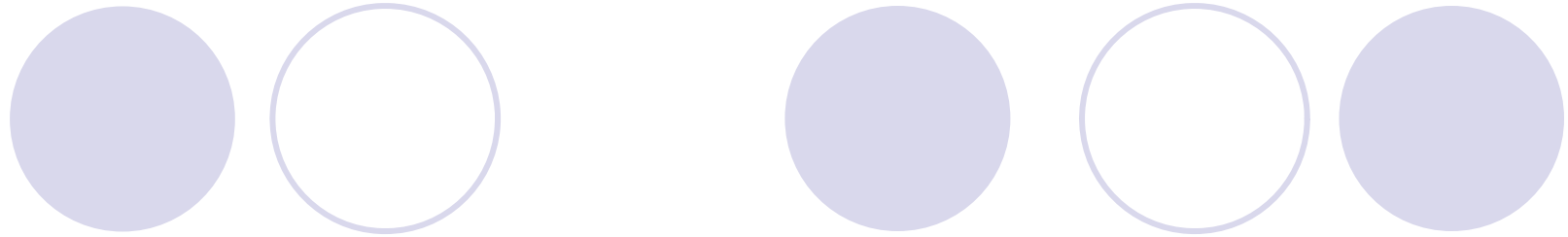


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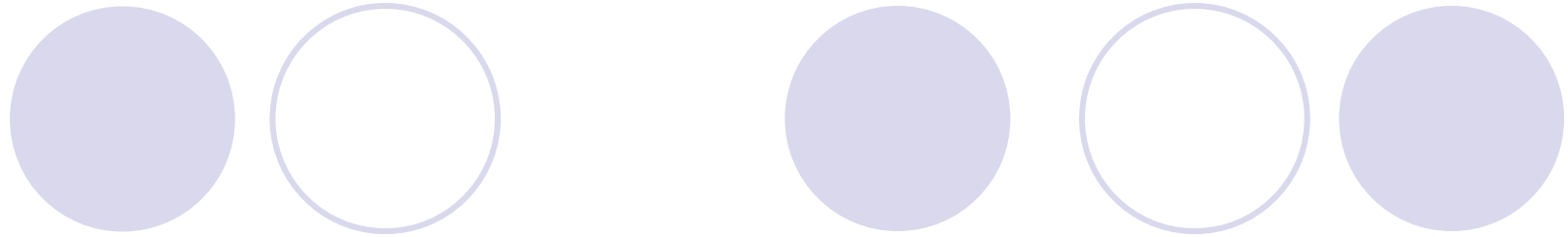
Protecting Health, Safety and Democracy

“Counterfeits” confusion

- 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 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.*

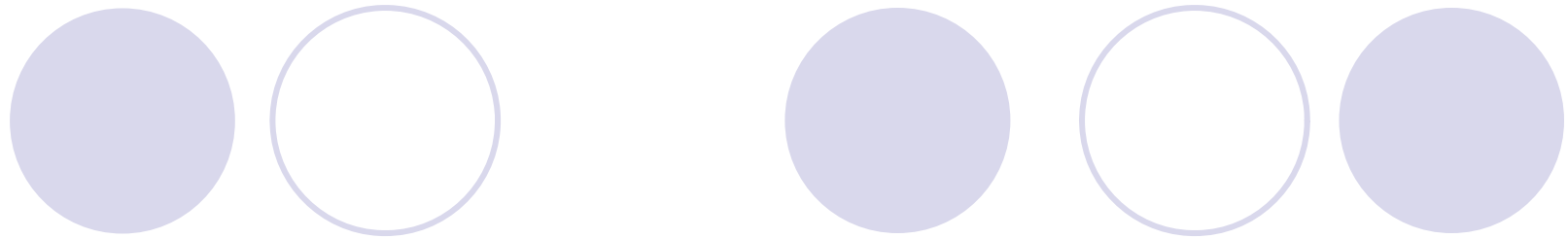


IP enforcement agenda



IP enforcement agenda

- Border measures
- Remedies
- Law enforcement
- Public investment
- Criminal penalties
- International enforcement
- Legal / political culture



Risks for access

Other public costs



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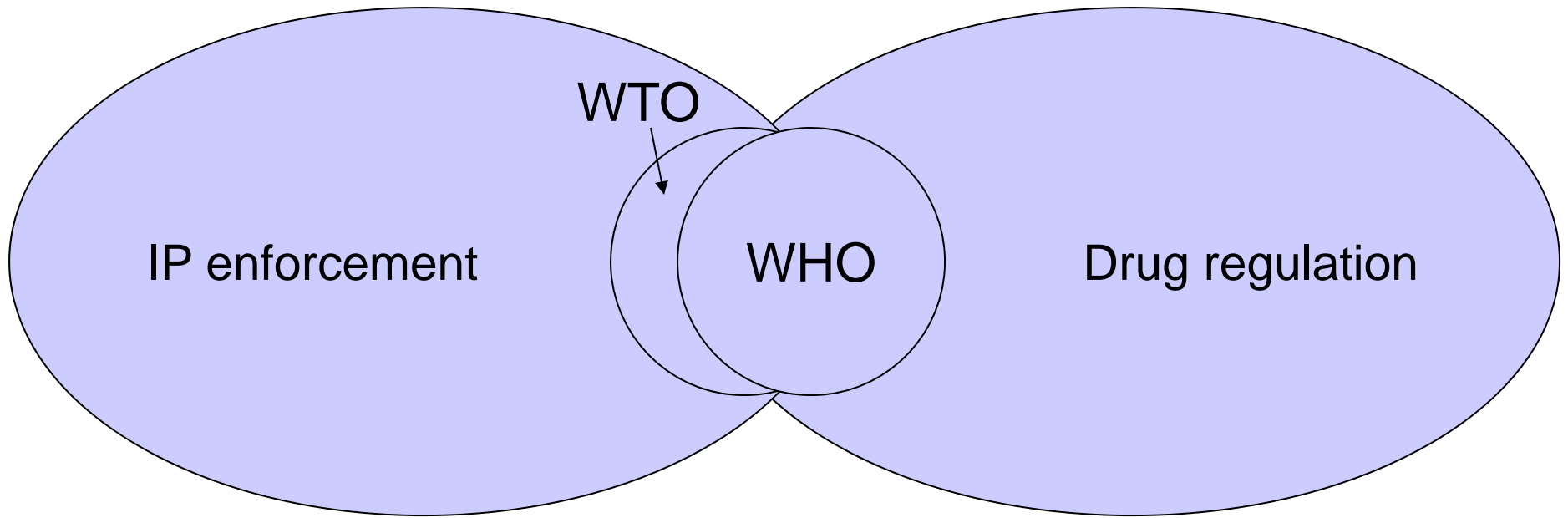
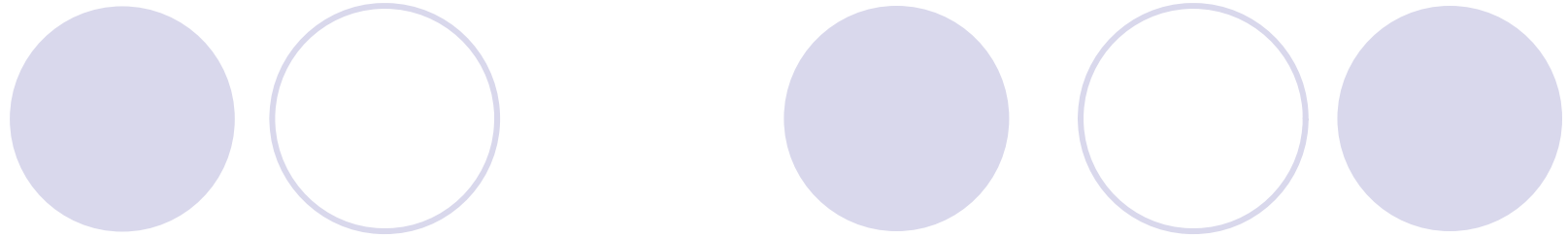
- Restraints on free movement of generics
- Chilling effects
- Limitations on flexibilities

Other public costs

- Public investment
- Opportunity cost - law enforcement
- Opportunity cost - health
- Innovation cost

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