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CIPA 2017 AGM

March 3, 2017



Outline

About Shadow Regulation

Introduction

Why Shadow Regulation for Pharmaceuticals?

Defeating Shadow Regulation

Examples

How Can Industry Agreements be Done Well?

Conclusion





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Summary of project

This project aims to call out the misuse of closed and opaque voluntary agreements* to regulate Internet content in areas such as:

- Intellectual property
- "Hate speech"
- Terrorism
- Child online protection

* Codes, principles, standards, MOUs





Outline of the project

Critical agenda

Existing codes, MOUs and standards lack transparency and participation and bypass democratic processes.

Positive agenda

Any agreement intended to address a problem should be developed in an inclusive, balanced, accountable way.





Voluntary agreements are not all bad

Good things about voluntary agreements

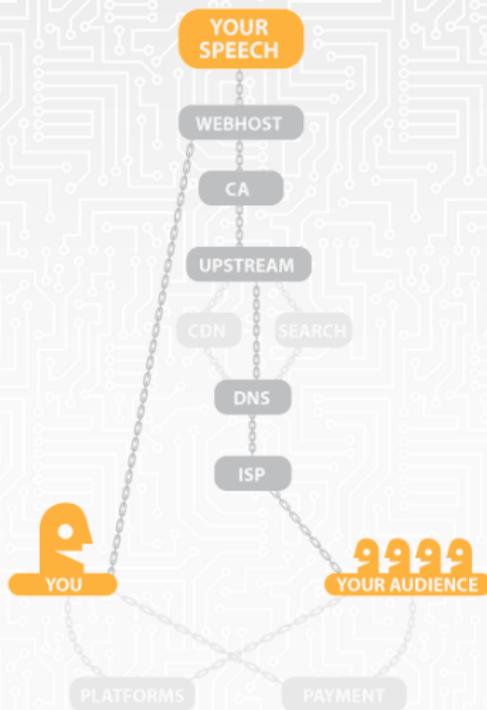
- Internet is based on voluntary adoption of standards
- More flexible, faster, and cheaper than regulation
- Can be cross-jurisdictional and non-governmental

Bad things about voluntary agreements

- Used by governments to abdicate their responsibilities
- Industry writing the rules to govern itself
- Lack of transparency, accountability, and participation



How Does Shadow Regulation Work Online?





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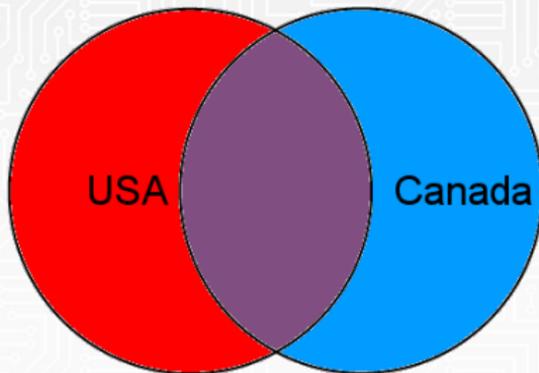
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Parallel importation of pharmaceuticals

For branded drugs under patent in both countries

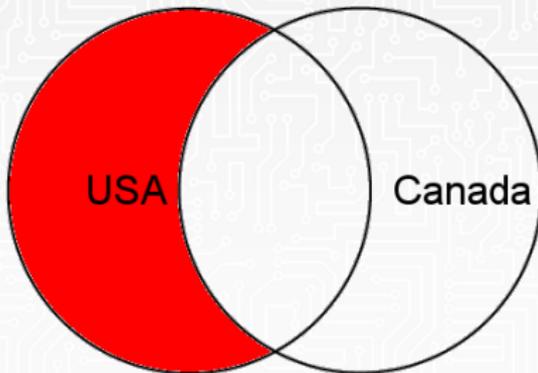
- Canadian exporter must comply with Canadian patent
- U.S. courts accept national exhaustion of patent rights
 - But this only affects the importer *not* the exporter
- Personal use imports low enforcement priority for CBP



Parallel importation of pharmaceuticals

For branded drugs under patent in the USA only

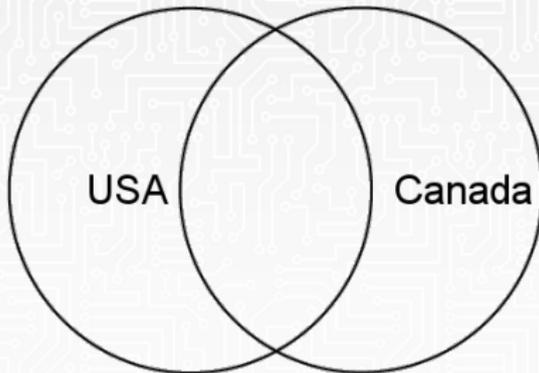
- U.S. patents not enforceable against foreign exporters
 - Unless there is a U.S. FTA that requires otherwise
 - eg. Australia, Singapore, Morocco (but not NAFTA)



Parallel importation of pharmaceuticals

For drugs that are under patent in neither country

- Possible breach of exporter's contract with its supplier
- Breach of FDA rules (not enforceable against exporter)
- Exporter must comply with Canadian licensure rules





Examples of Shadow Regulation for Pharmaceuticals

The basic problem for big pharma:

American patent and licensure rules aren't extra-territorial

Their solution:

- LegitScript
- Center for Safe Internet Pharmacies
- .pharmacy domain
- Healthy Domains Initiative





HDI on Online Pharmacies

Streamlining complaint handling from illegal or “rogue” online pharmacies

These measures are designed to enhance registry and registrar capability to field, evaluate and handle complaints regarding online outlets suspected of being unlicensed pharmacies or otherwise distributing harmful or counterfeit medication.





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- We identified the genesis of the plan in a proposal by the Public Interest Registry (PIR)
 - PIR is accountable to the Internet Society (ISOC) which is on record opposing Internet censorship
 - From 13 February we fomented disagreement with the plan amongst ISOC members



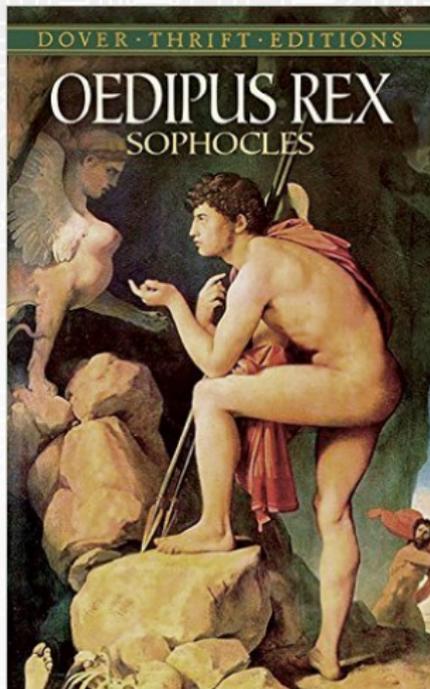


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- ISOC withdrew PIR's plan on 23 February
- HDI made a similar announcement the next day



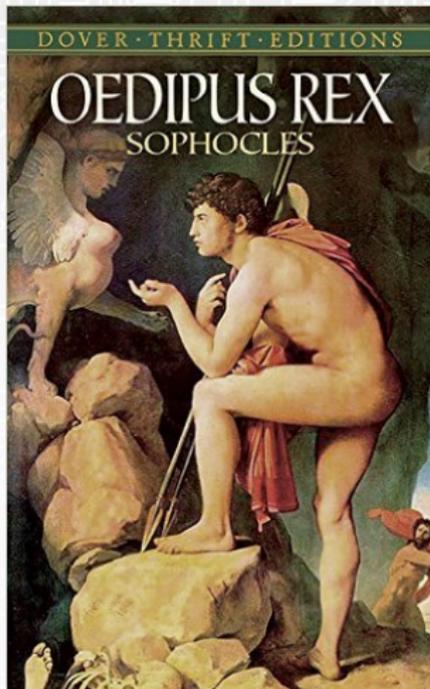
Defeating PayPal's censorship of books



- In February 2012, PayPal threatened to ban booksellers if they sold books describing rape, incest, or bestiality



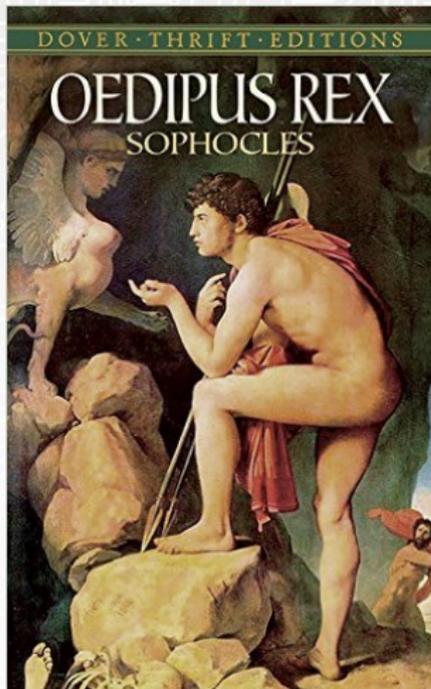
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- One week later, PayPal reversed its position





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BEYOND REGULATION: *Reaching Solutions that Work for Users*

Not every problem on the Internet calls for cross-border rules or principles. If a group or process proposes to address such a problem that way, they should demonstrate at the outset why solutions can't be found at the local level or by directly empowering users. Then, they should comply with these criteria:



INCLUSION

We need to make sure that all stakeholders who are affected by Internet policies have not only the opportunity, but also the resources, to be heard.



BALANCE

Reaching the optimal solution requires letting the best ideas rise to the top, even if governments and corporations don't always get their way.



ACCOUNTABILITY

Institutions and stakeholders who participate in crafting rules, standards or principles for the Internet must be transparent and deserving of our trust.

Even if a just process has been followed, that doesn't mean users will accept the outcome. But if they do—voluntarily—that's good evidence of a successful solution. If the solution also needs to be formally enacted or enforced by an empowered body, there should be a clear way forward to make that happen, with equally clear limits.



Beyond Regulation

Is there a need for cross-border rules or principles, that can't be met at the local level or by user empowerment? If so:

- **Inclusion**

- Are the right stakeholders participating?

- **Balance**

- How is their participation balanced?

- **Accountability**

- How are the body and its stakeholders accountable to each other for their roles in the process?

Is the body an empowered space? If not, how (if at all) are its recommendations formally institutionalized?





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- Inclusion of diverse stakeholders produces **more inclusive, better informed** outcomes
- CIPA is targeted for Shadow Regulation because **patent and prescription drug laws are not global**
- The most effective weapons against it are **sunlight, shame and a strong coalition**

