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10 Reasons Why Intellectual Property (IP) Should Be Kept Out of the Trans-Atlantic Free Trade Agreement (TAFTA or T-TIP)

The US and EU hold the world's largest bilateral economic partnership. As recognized by the OECD, this alignment of economic power is seen by industry and government representatives as an opportunity to set what they consider a "gold standard" for IP rules which, over time, developing countries will most likely be pressed to adopt.

Consumers should not be excluded from secretive negotiations that can compromise access to health, cultural participation, and free expression. Because the inclusion of IP in TAFTA would likely result in political compromises that fail to adequately account for consumer interests, 45 civil society organizations from the US and EU have signed a Civil Society Declaration asking negotiators to keep IP Out of TAFTA. ***Here's why:***

1. The European Parliament voted overwhelmingly against the ACTA in 2012.

TAFTA must not be used to increase criminal penalties for infringement.

ACTA (Anti-Counterfeiting Trade Agreement) sought to impose criminal penalties for actions that previously incurred only civil liability, while lowering the threshold for criminal behavior. Overreaching enforcement provisions can chill speech and inhibit generic competition.

2. Making genes patentable would raise the cost of diagnostic tests and cancer research.

Patentable subject matter should not be expanded to allow monopolies on products of nature.

[US] The Supreme Court recently ruled in *Myriad* that isolated DNA is not patentable subject matter.

[EU] The EU Biotechnology Directive allows isolated DNA to be patented.

3. Making medical procedures patentable would raise the cost of healthcare services.

Patentable subject matter should not be expanded to allow monopolies on medical knowledge.

[US] Although medical procedures are patentable, physicians are granted limited immunity from infringement liability for using methods that don't involve patented devices or biotechnology.

[EU] European Patent Convention Article 53 excludes medical procedures (including methods of using devices) performed on humans from patentable subject matter.

4. Harmonizing regulatory exclusivity could result in longer pharmaceutical monopolies.

Data and market exclusivity regimes should remain flexible for future revisions.

[US] DRUGS: 5 yrs. data exclusivity; BIOLOGICS: 4 yrs. data exclusivity + 8 yrs. market exclusivity. Obama's proposed 2012 budget recommended reducing the exclusivity term for biologics.

[EU] DRUGS & BIOLOGICS: 8 yrs. data exclusivity + 2 yrs. market exclusivity.

5. Linking pharmaceutical patents to regulatory approval would impede generic competition.

Patent linkage delays generic availability and keeps drug costs high.

[US] Patent linkage for pharmaceutical products is statutorily required by the Hatch-Waxman Act.

[EU] EU Directive 01/83/EC takes a strong position against patent linkage. The EC recently issued a Reasoned Opinion calling on Italy to eliminate patent linkage.

Patent linkage serves as an impetus to move "payments for delay" behind closed doors.

[US] Patent linkage has led to reverse payment settlements, in which brand name companies settle legal challenges to their patents by paying generic competitors to delay market entry.

[EU] The EU Competition Commission recently fined nine pharmaceutical companies a total of 146 million Euros for paying generic companies to delay entry.

6. ***Imposing indirect infringement liability on ISPs would significantly raise the costs of providing internet services that facilitate freedom of speech and access to information.***

Internet Serve Providers (ISPs) should not be liable for infringing content.

[US] FTAs include provisions that call for incentives for ISPs to cooperate with copyright owners.

[EU] FTAs include provisions that safeguard ISPs from unlimited liability.

7. ***Strict compliance with the copyright three-step test would raise costs for consumers.***

As formulas and rigid rules are foreign to the common law tradition and statutory formulation of fair use, the U.S. should not agree to the three-step test despite being noncompliant with it.

[US] In 2000, the EU challenged the US's exemption of small businesses from public transmission licensing requirements under the Fairness in Music Licensing Act. A WTO Dispute Settlement Body found the US to be noncompliant with the three-step test. Many US FTAs require the three step test. If narrowly interpreted, these provisions could contradict certain user-friendly applications of fair use, such as the Supreme Court's *Sony* ruling regarding time-shifting (recording) of TV programs for personal use.

[EU] All member states, except for the UK, Ireland and Cyprus, strictly adhere to the three-step test.

8. ***Protecting facts in databases would inhibit access to knowledge.***

Compilations of facts should remain in the public domain.

[EU] The Database Directive grants sui generis copyright protections to compilations of facts.

[US] The Supreme Court's *Feist* ruling found the copyrighting of databases to be unconstitutional.

9. ***Requiring libraries to pay lending royalties would inhibit access to culture and knowledge.***

Public libraries should not have to pay royalties to lend books.

[US] Libraries are permitted to lend books for free under the first sale doctrine.

[EU] The EU Rental Directive requires libraries to pay royalties to authors.

10. ***Harmonizing approaches to geographical indications (GIs) would be near impossible.***

In 2005, the US challenged the EU before a WTO Dispute Settlement Body claiming that the EU's laws impermissibly discriminated against foreign products and provided insufficient protection to foreign trademark owners.

[US] A "first in time, first in right" principle protects GIs through the trademark system in the absence of any special registration or certification requirements. The US's anti-counterfeiting policies treat GIs within the framework of trademark law, without any criminal penalties.

[EU] A more restrictive GI regime seeks increased protection through a mandatory multilateral system of registration and enforcement. The EU enforces a strict anti-counterfeiting regime that separately applies to GIs and trademarks.

The US and EU have conflicting policies in many realms of IP. Each party supports more stringent policies in certain realms. There is a considerable risk that substantive IP negotiations may lead to worse anti-consumer standards in both the US and EU. An IP chapter in TAFTA would essentially serve as a forum for powerful lobbies in the US and EU to continue pushing for maximalist global IP standards that fail to account for the public interest.

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