

TAFTA/TTIP & Consumer Concerns: Access to Knowledge and Health

Knowledge Ecology International
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What Will Be Proposed?

- Minimum IP standards already exist in various international agreements
- Lack of transparency in negotiating texts and positions
 - No upwards harmonization of IP chapter?
- Prior FTAs demonstrate trend of pushing for stronger IP rights for rightholders without corresponding balance for consumers
 - US-Korea
 - EU-Korea
 - TPP

ACTA

- Never submitted to U.S. Congress for ratification
- Final vote in EU 478-396-165 abstentions



Access to Knowledge

- Locking in lengthy copyright terms (life plus seventy years)
 - Time to rethink?
 - Maria Pallante
 - UK Hargreaves Report
- Three-step test
 - Many existing L&Es under international law do not have to comply with the three-step test (Berne Exceptions)
 - Numerous US examples arguably do not comply (fair use, compulsory licensing of sound recording)
 - Fair use industries' contribution to economy
- Orphan Works

Orphan Works

- Long copyright terms exacerbate orphan works problem, where the rightholder is difficult or impossible to locate
- Efforts to support solutions to orphan works problem
 - U.S. Senate proposal in 2008: Shawn Bentley Orphan Works Act (solution relies on limitations on damages and injunctions)
 - European Parliament set out Directive 2012/28/EU in October 2012 permitting uses of orphan works for certain organizations (effort toward digitization and cross-border access for works in these organizations' collections)

Patent Linkage

- Can delay entry of generics into the market
- Exists in the US but not implemented in the EU
 - EC formally requested Italy to remove patent linkage because “As a result of this law, and of the lengthy procedure to secure the authorisation for marketing, manufacturers of generic products are placed at a disadvantage on the market”
- Controversial
 - Potential for abuse: weak/non-germane patents asserted in linkage process
 - Pay-for-delay agreements
 - FDA conceded it “does not have the expertise to review patent information. The agency believes that its resources would be better utilized in reviewing applications rather than reviewing patent claims.”

Gene Patents and Scope of Patentability

- No reason to expand scope of patentability, particularly where courts currently determining appropriate practice and application of patent rights and considering limitations on certain categories
- Gene patents important in diagnostic tests and research and development
 - BRCA gene patent case study in US: prevented secondary, confirmatory testing, high cost not covered by all insurance companies; mistakes in test developed by exclusive licensee, Myriad; hindered research and development
 - *Myriad* case resulted in Supreme Court rejection of isolated DNA
- *Myriad* case in the U.S. resulted in Supreme Court rejection of isolated DNA, but left open the potential possibility of patents on cDNA
- EU Biotechnology Directive allows isolated DNA to be patented, but several countries adopted compulsory licenses to weaken the patent monopoly over genes