

TPP and the Conflict Over Drugs

TPP and Digital Trade

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Joe Stiglitz and Orrin Hatch hardly ever agree on anything...



Senator Orrin Hatch
R - Utah

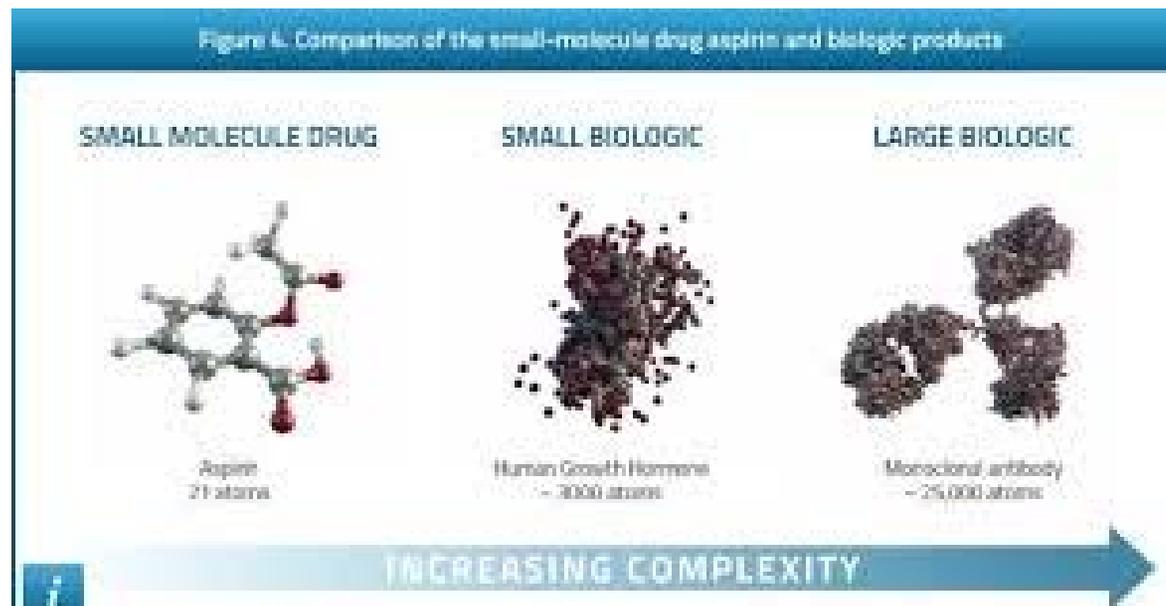


Professor Joseph Stiglitz
Columbia University

But they are united in their opposition to TPP's treatment of intellectual property rights for new drugs.

The main sticking point: longer data protection for biologics

- **Biologics are drugs based on biotechnology rather than chemistry.**
- **Industry wanted 12 years of data protection for biologics.**
- **NGOs and patient advocates wanted no more than 5.**
- **The compromise: 8 years of protection.**



The case for strengthening pharma IP

- **Pharma innovation is critical for human welfare.**
- **The American “pharmaceutical Marshall Plan” is coming to an (inevitable) end.**
- **Trade agreements are a forum in which nations can agree to divide the burden of funding new drug development more equitably.**



The National AIDS Memorial Quilt,
Washington, DC, 1992

A workable compromise on biologics

- **Will anything less than 12 years of data protection lead to an innovation apocalypse?**
- **No, because complexity cuts both ways.**
- **Biosimilars are likely to require (small scale) clinical trials.**
- **This means that biosimilar entry will be less frequent, less rapid, and will offer less of a discount than small molecule generic entry.**
- **Will anything more than 5 years of data protection lead to a catastrophic loss of access?**
- **No, because complexity cuts both ways.**
- **Biosimilar entry will be delayed by the need for clinical trials.**

TPP's other important pharma IP provisions

- Patent term extensions
- “Patent linkage”
- Data protection
- Patent and data protection for incremental innovation
- General legal provisions that strengthen the patent system

All of these provisions are part of the American “Hatch-Waxman” regulatory regime under which generic penetration has risen until it now exceeds 84%!

The TPP will not trade away our health!

- Most drugs available for treatment of disease are already generic – and therefore unaffected by TPP.
- Member states retain broad leeway to influence drug prices.
- Member states retain the right to employ compulsory licensing in the event of a public health emergency.
- Most of the controversial provisions were included in earlier TRIPs-Plus FTAs. These have had no statistically significant impact on imported drug prices, longevity, infant mortality, or the ratio of health expenditures to GDP.

**International flows of data are soaring,
even as growth in trade of physical
goods has sharply decelerated...**



Source: McKinsey Global Institute, 2016

The TPP and Digital Trade

- Recognizing the growing importance of digital trade, the TPP establishes new precedents for U.S. trade agreements.
- The TPP seeks to create an open market for digital goods and services.
- The TPP seeks to protect intellectual property, technology choice, and copyrights in a digital age.
- The TPP includes commitments to promote SME utilization of digital trade.
- The TPP seeks to protect data privacy but it does *not* try to standardize data privacy law across member states.
- Some new member states may require side agreements to reconcile free data flows with very different national privacy standards.