

Regulation, Patents, and Diagnostics

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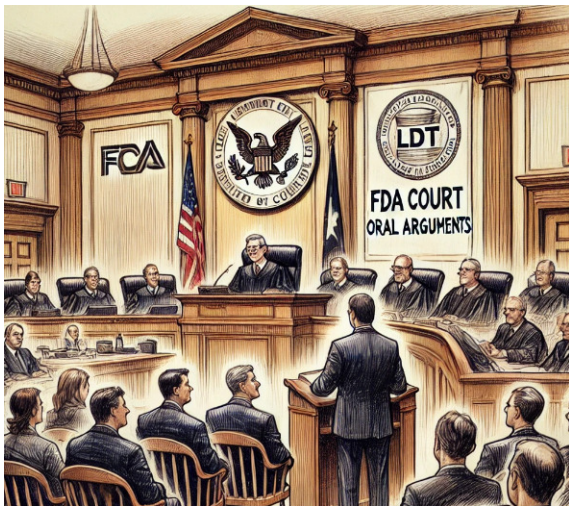
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Two Lawsuits



(I assume that this particularly awful graphic of a six-eyed chief justice was AI-generated.)

Discoveries in Health Policy,

<https://www.discoveriesinhealthpolicy.com/2025/02/acla-vs-fda-on-ldt-hearing-in-texas.html>.

In This Talk

- ▶ Two stories
- ▶ A theory
- ▶ Balancing
- ▶ A win-win?

Molecular Diagnostics



Ricardipus, https://commons.wikimedia.org/wiki/File:Affymetrix_5.0_microarray.jpg.

Two Regimes

| Laboratory-developed tests (LDTs) | Commercial tests |
|--|--------------------------|
| CMS (CLIA) | FDA (medical devices) |
| Per laboratory | Per test |
| Proficiency and accreditation | Safety and effectiveness |
| Low cost | High cost |

AMP v. Myriad



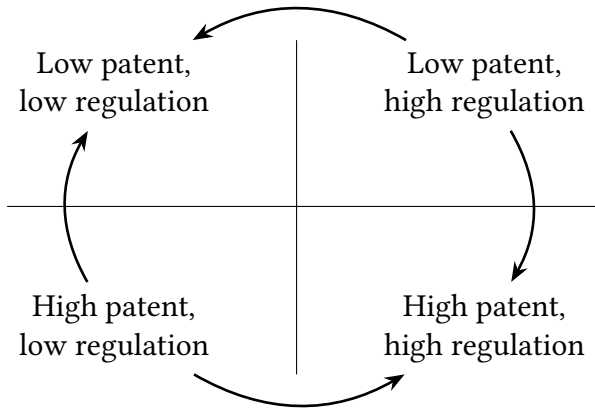
SHYCITYNikon, End Patents of Life Forms, <https://www.flickr.com/photos/kgnixer/7227341916/>.

Barriers to Entry



PantheraLeo1359531,
https://commons.wikimedia.org/wiki/File:Hinweis_Abstrichstelle_Hof_20200407_08.jpg.

Equilibria



Pros and Cons

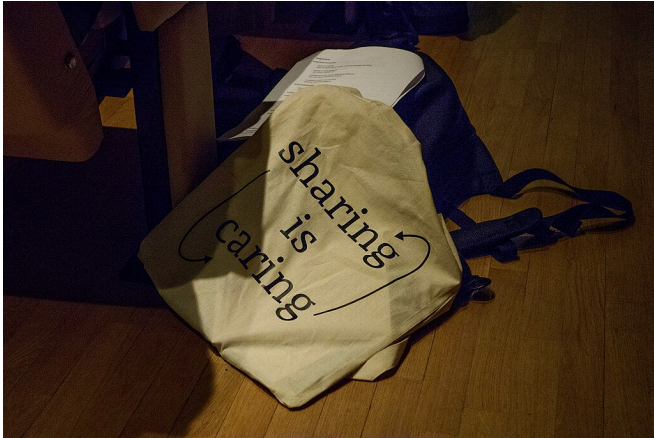
Benefits of LDT regulation:

- ▶ Individual test validation
- ▶ Patient confidence
- ▶ Lower health care costs

Benefits of low-patent market:

- ▶ Competition
- ▶ Rapid innovation
- ▶ Information sharing

A Possible Approach



Sam Donvil, https://commons.wikimedia.org/wiki/File:20170620_sharing_is_caring_032_s.jpg.