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Institutions

- Congress (sporadic player)
- Past and current: courts (mostly CAFC and Supreme Court)
- Current and future: greater role for PTO and other executive branch actors
    - In part a function of Supreme Court interest

The PTO and the Solicitor General

- Duffy (2010): Federal Circuit in "shadow of SG"
- USG is amicus in 17/19 Supreme Court cases decided on merits from1996-June 2011
  - 19 Supreme Court cases vs. 23 CAFC cases *en banc*
- Influential: SG won 9/10 cases where it disagreed with CAFC
- *But* SG is largely "convenor" of underlying exec branch agencies
- PTO most important agency (on brief in all cases except *Stanford v. Roche*)

Problems with SG/S. Ct. as policymaker

- *Ex post* decision making → delay, uncertainty
- Retroactivity
- SG positions worked out under time pressure, so not always fully thought through (e.g. *Prometheus*)
  - Supreme Court doesn't have full "foundation"
- The *ex ante* guideline alternative . . .

Ex Ante approaches: DNA patenting and PTO Guidelines

- Utility guidelines (1999-2001)
- Written description guidelines (1999-2001)
- Enhanced notice, forestalled genomics patent thicket (Walsh et al. 2003)
- PTO "nudged" by NIH (NIH as "early warning system")
    - Well regarded by biopharma community
- Affirmed in *In re Fisher* (2005)

- NIH limited to life sciences
- DOJ Antitrust, FTC, NIST
  - FTC particularly active (including recent Section 112 guidelines)

- "Notice externalities" (Meurer & Menell 2012)
- Section 112 guidelines (Feb. 2011)
- What if some version had been developed (and tested, refined) in 1990s?
- *Cf. In re Alappat* (Fed. Cir. 1994)
  - Could be seen as PTO attempt to improve notice, place limits on scope

AIA increases prominence of PTO

- *Chevron* deference if guidelines implemented via trial-type procedures of post-grant review?
  - section 324(b): "petition raises novel or unsettled legal question important to other patents or patent applications"

- Life sciences (reasonably) successful in avoiding notice problems, thickets
  - Contrast with ICT
- *Ex ante* bet by PTO/NIH paid off
- More prospective/*ex ante* work across exec branch
- Judicial review, *ex post* adaptation still very important
  - Foundation for future judicial development