Cumulative Innovation in Software and Biopharmaceuticals

Arti K. Rai

Duke Law School and Institute for Genome Sciences & Policy

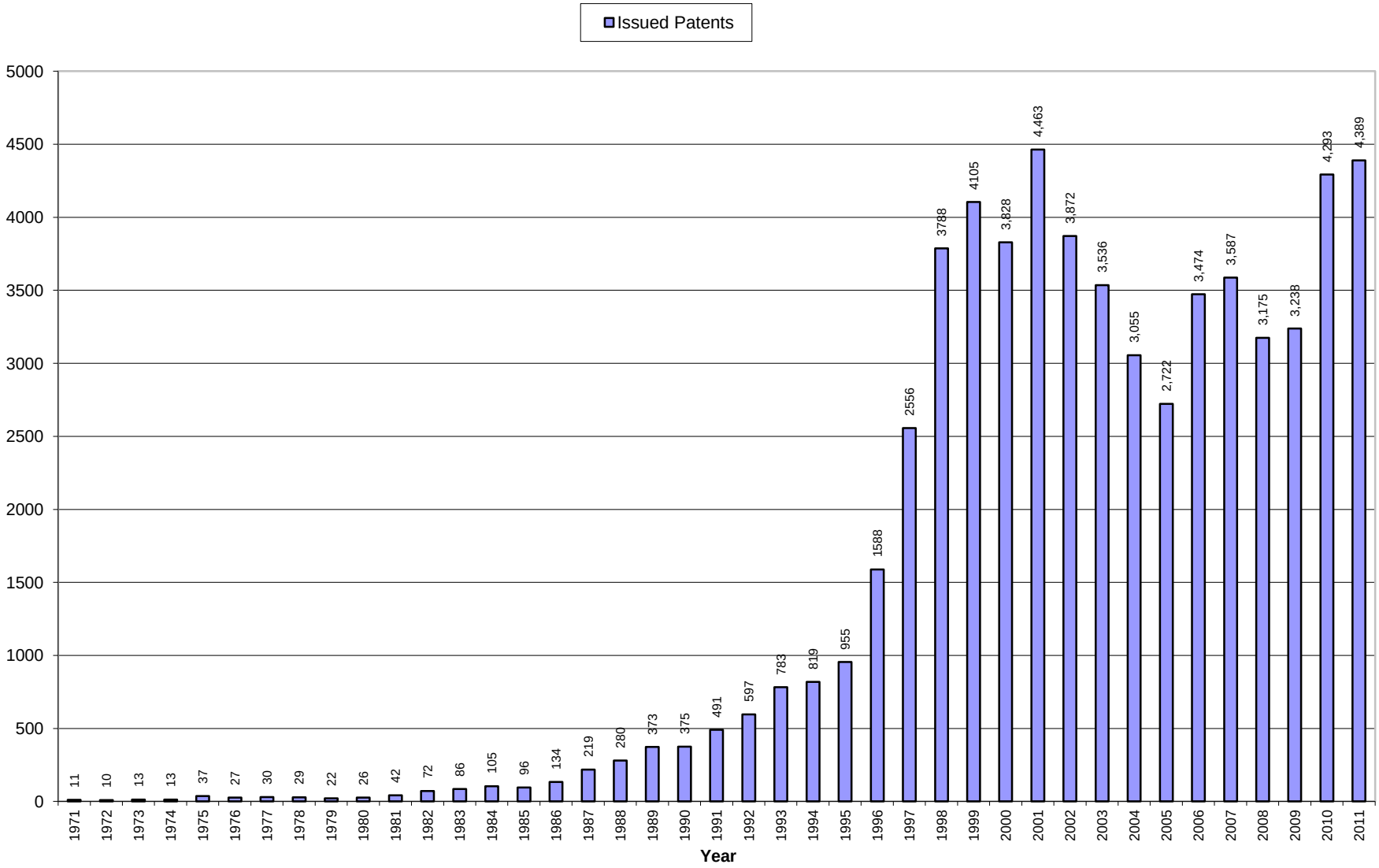
Cumulative Innovation in Software

- Large defensive patent portfolios (MAD)
  - Billions of dollars in acquisition costs
  - Failure of MAD in smartphones, other contexts
- Litigation by NPEs
  - 2/3 to 3/4 on software patents
  - Patents typically held invalid if case goes to judgment
  - $29 billion in annual direct costs for small and large firms; $500 billion in overall costs over last 20 years for publicly traded firms (Bessen & Meurer 2012, 2011)

Cumulative Innovation in Biopharma

- End-product patents on biologics, small molecule chemicals only *part* of patent puzzle
- Lots of "upstream" DNA patents, patents on Dx methods
  - Secret infringement in R&D for end products (large distance between patents, market)
  - *Can't* secretly infringe patents in "diagnostic marketplace" (inc. whole genome sequencing)

Number of items loaded into the DNA Patent Database by year as of 2012



Source: Mara Snyder and Bob Cook-Deegan, DNA Patent Database, 2 January 2012

Patent Obstacles in Biopharma Dx

- Jensen & Murray (2005): 20% of human genome patented
- HHS Secretary's Advisory Committee on Genomes, Health, Society (2010)
  - Gene patents unnecessary for commercializing Dx
  - WGS imperiled by gene patents
  - Report *very* influential in *ACLU v. Myriad*

PSM and Supreme Court: more guidance in biopharma

Biopharma

- *Prometheus v. Mayo* (2012)
  - Examined 1000s of Dx claims
  - 79% of diagnostic method claims rendered ineligible (Hannes and Canaves 2012)
- *Myriad* (2013)
  - Strict limits on DNA patents?
  - HHS/NIH extremely influential in debate (Rai 2012)

Software

- *Bilski*
  - no “abstract” patents
  - but otherwise little guidance

Excessive Scope, Vagueness

- “Section 112” tools: written description and definiteness
- WD, definiteness applied extensively in biopharma
  - Including bioinformatics software
  - Contrast with other software

Bioinformatics: Art Unit 1631

- Created in 1999
- HGP and related projects – PTO saw large influx of apps for data processing
- Concern that "claims [in these apps] are written very broadly, frequently to the point of incomprehensibility"
  - N.B. AU 1631 excludes medical imaging patents, which *have been* subject of NPE suits (Tucker 2011)

Data from Calendar Year 2003

AU 1631

- 290/378 apps (77%) had 112 rejections
- 30% of Section 112 rejections included WD
- 95% of Section 112 rejections included definiteness

AU 2123

- 111/197 (56%) had 112 rejections
- Fewer than 10% of Section 112 rejections included WD
- 50% of Section 112 rejections included definiteness

Conclusion

- Cumulative innovation in both areas
  - "Distance to market" short in diagnostics
- But patent institutions have worked very differently