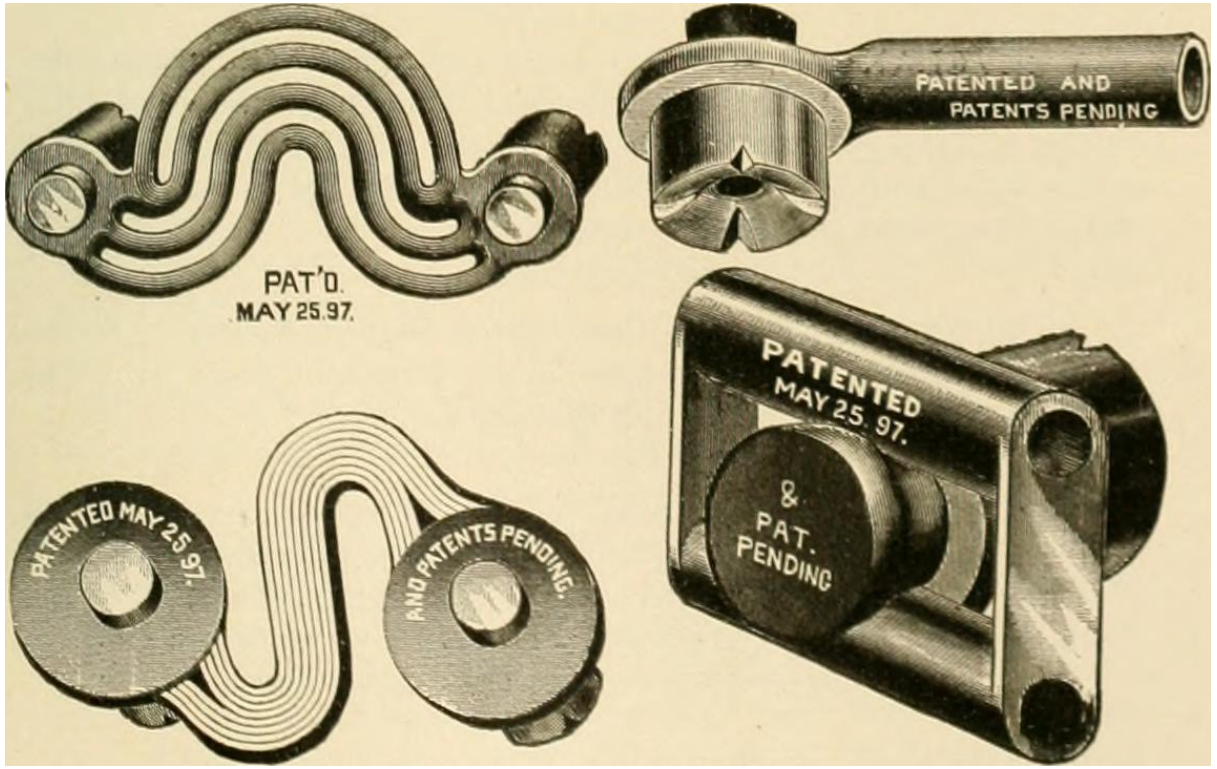


Patent Pending:

An exploratory analysis of the biotech patent landscape through USPTO patent data

October 2023

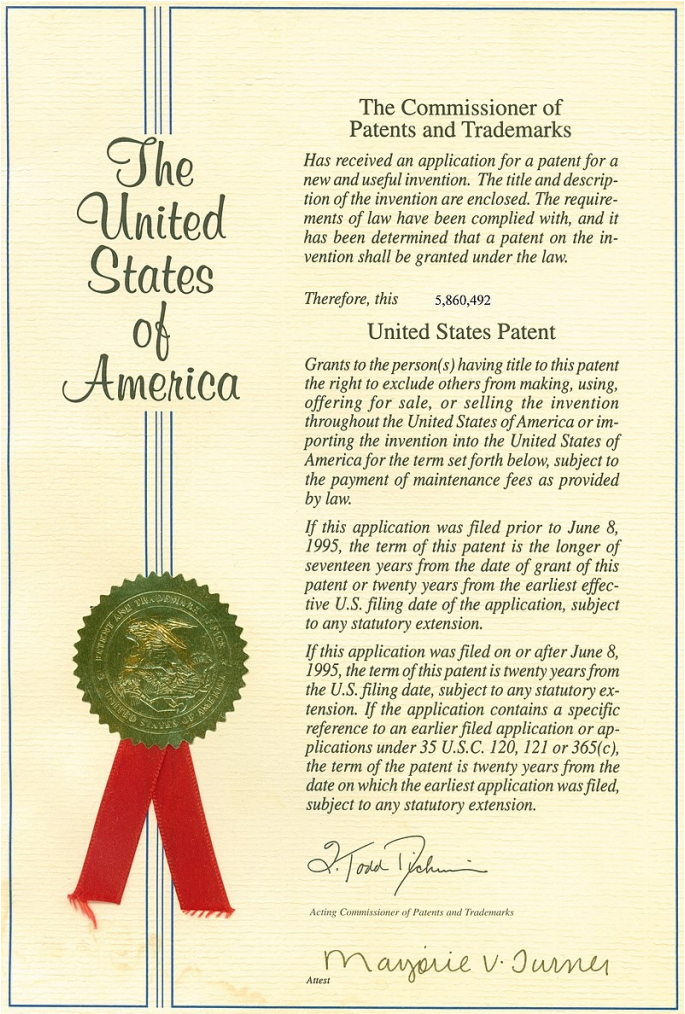
What are patents?

What is a (utility) patent?

- Publish how to **make and use** an invention/technology
- Others cannot **make, use, sell (or offer to sell), or import** in the U.S. for 20 years without either:
  - Your permission (e.g., a license), or
  - Invalidating your patent

Why are patents **valuable**?

- With intellectual property *rights*, you can:
  - Start a new company
  - License to other interested companies (exclusively or non-exclusively), for:
    - Further R&D;
    - Rights to make;
    - Rights to sell;
  - Sell your patent (M&A)


The United States of America

The Commissioner of Patents and Trademarks

Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this 5,860,492

United States Patent

Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America for the term set forth below, subject to the payment of maintenance fees as provided by law.

If this application was filed prior to June 8, 1995, the term of this patent is the longer of seventeen years from the date of grant of this patent or twenty years from the earliest effective U.S. filing date of the application, subject to any statutory extension.

If this application was filed on or after June 8, 1995, the term of this patent is twenty years from the U.S. filing date, subject to any statutory extension. If the application contains a specific reference to an earlier filed application or applications under 35 U.S.C. 120, 121 or 365(c), the term of the patent is twenty years from the date on which the earliest application was filed, subject to any statutory extension.

Acting Commissioner of Patents and Trademarks

Attest

The (important) role of patents in biotech / pharma

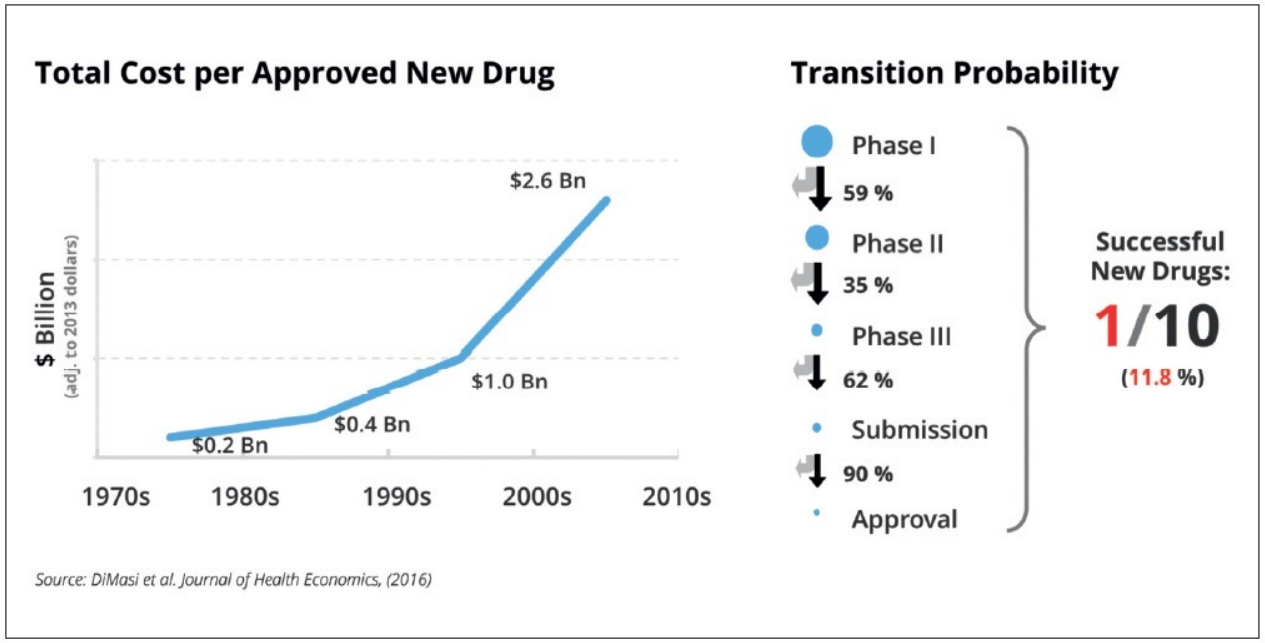
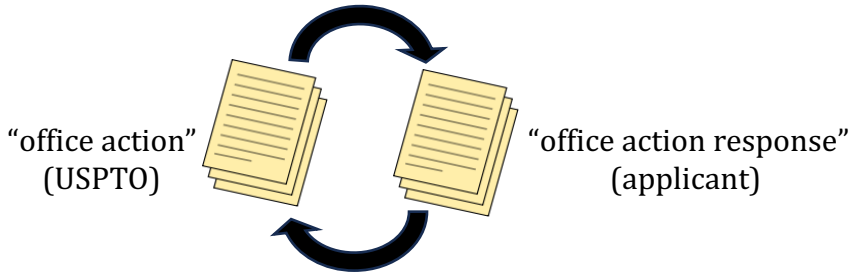


Figure 1 Costs of drug development have risen while overall probability of regulatory approval has reduced[1]. *Image taken from DiMasi JA et al. J Health Econ. 2016;47:20-33*

Source: https://qbdgroup.com/en/blog/the-key-role-of-regulatory-affairs-in-the-pharmaceutical-industry-from-drug-development-to-commercialization/

Simplified overview of the patent application filing process



PATENT PENDING

PATENTED

"pendency"

Patent prosecution ("*examination*")

Patent in effect

Application abandoned

File application
"filing date"

Application publishes

Patent issues
"issue date"

Patent expires

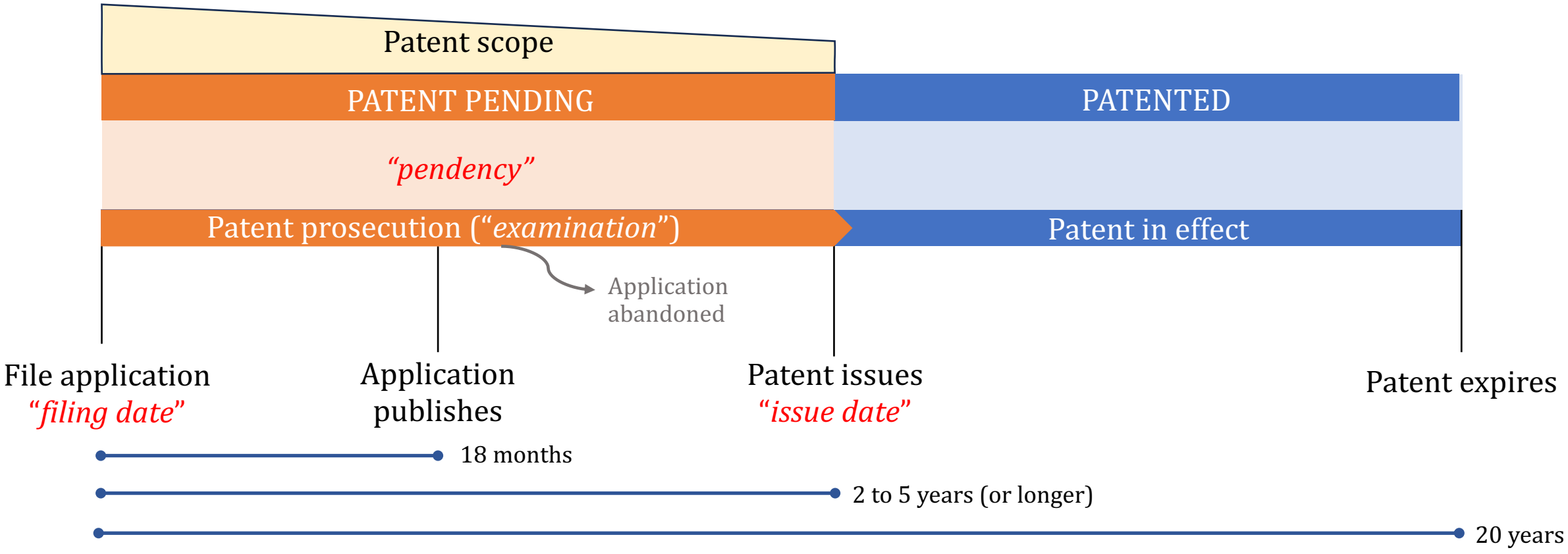
18 months

2 to 5 years (or longer)

20 years

Note: Timeline not drawn to scale

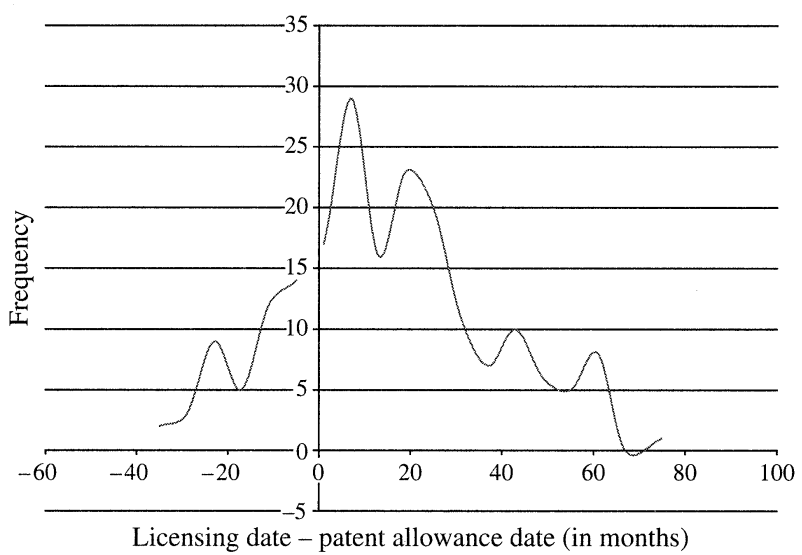
Simplified overview of the patent application filing process



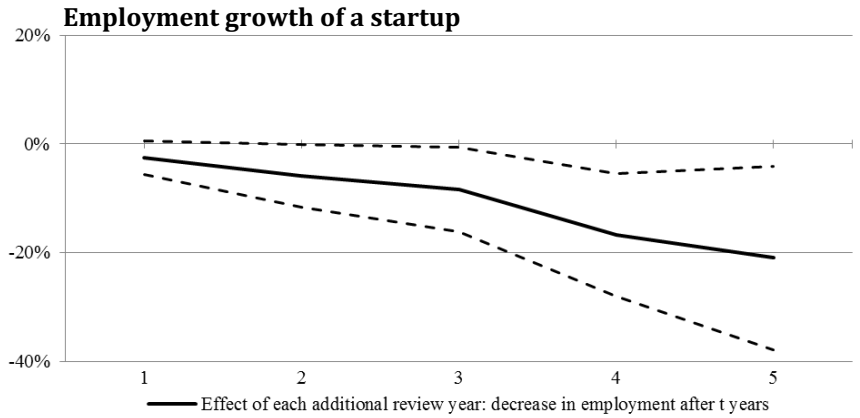
Note: Timeline not drawn to scale

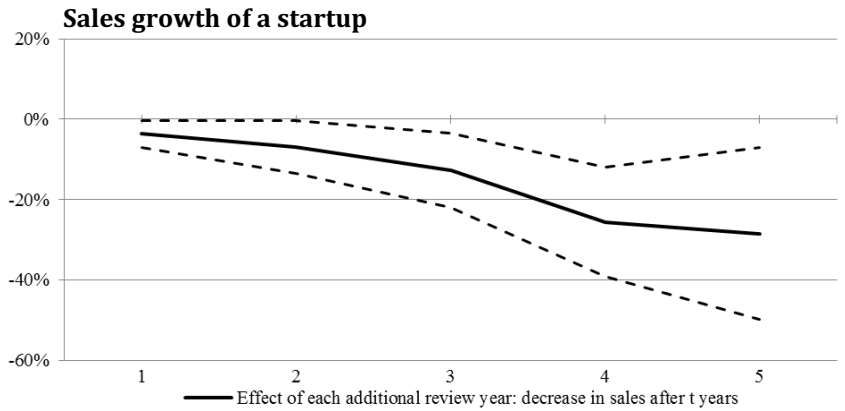
Patent pendency: Does timing really matter?

Figure 2 Distribution of Difference Between Patent Allowance and Licensing Dates



- Licensing timing and patent allowance are closely linked (Gans *et al.*, 2008)

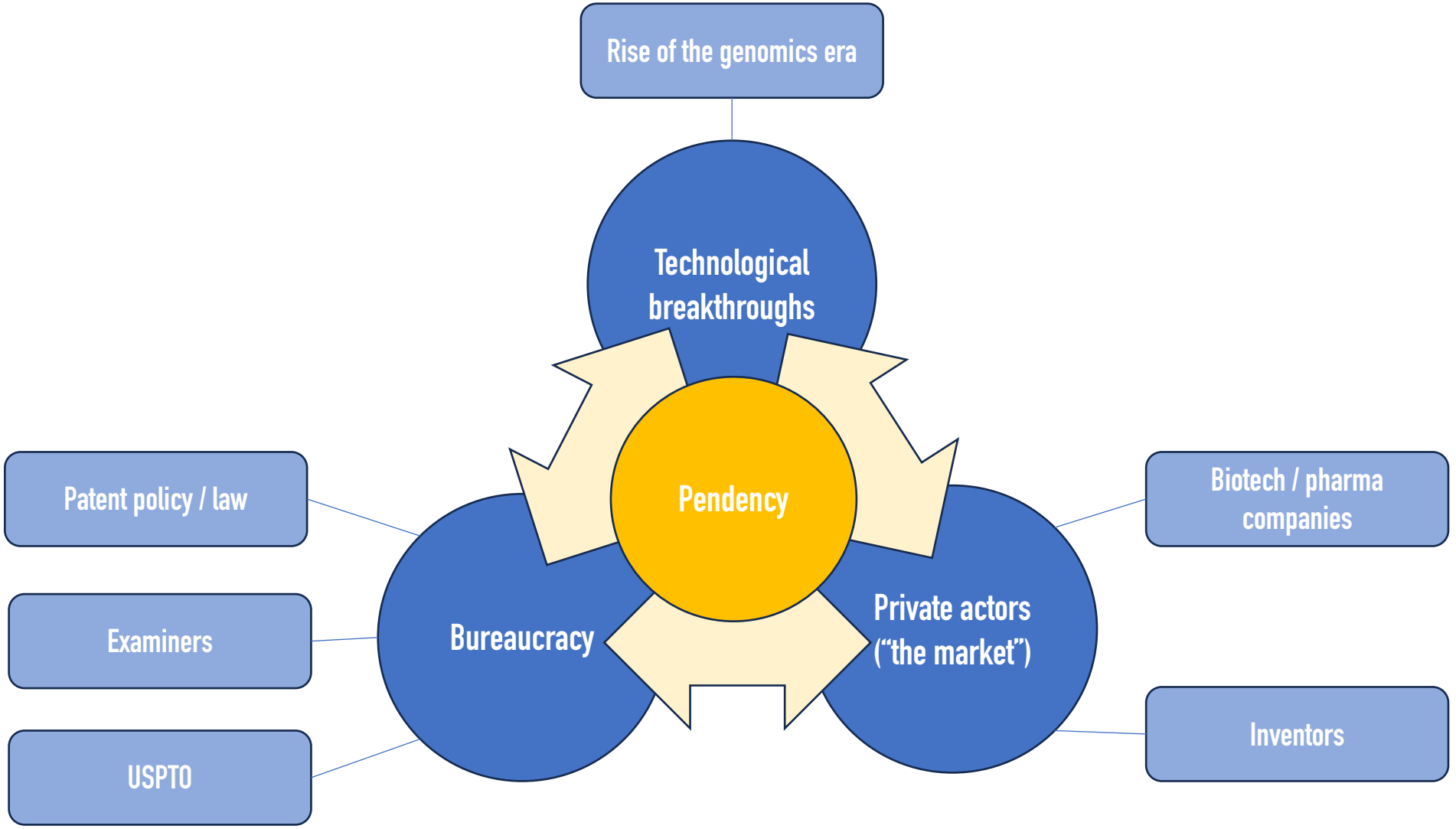




- Delays in patent examination hinders multiple aspects of startup growth (Farre-Mensa *et al.*, 2016)

Gans *et al.*, 2008
Farre-Mensa *et al.*, 2016

A multi-faceted analysis of patent data



Datasets

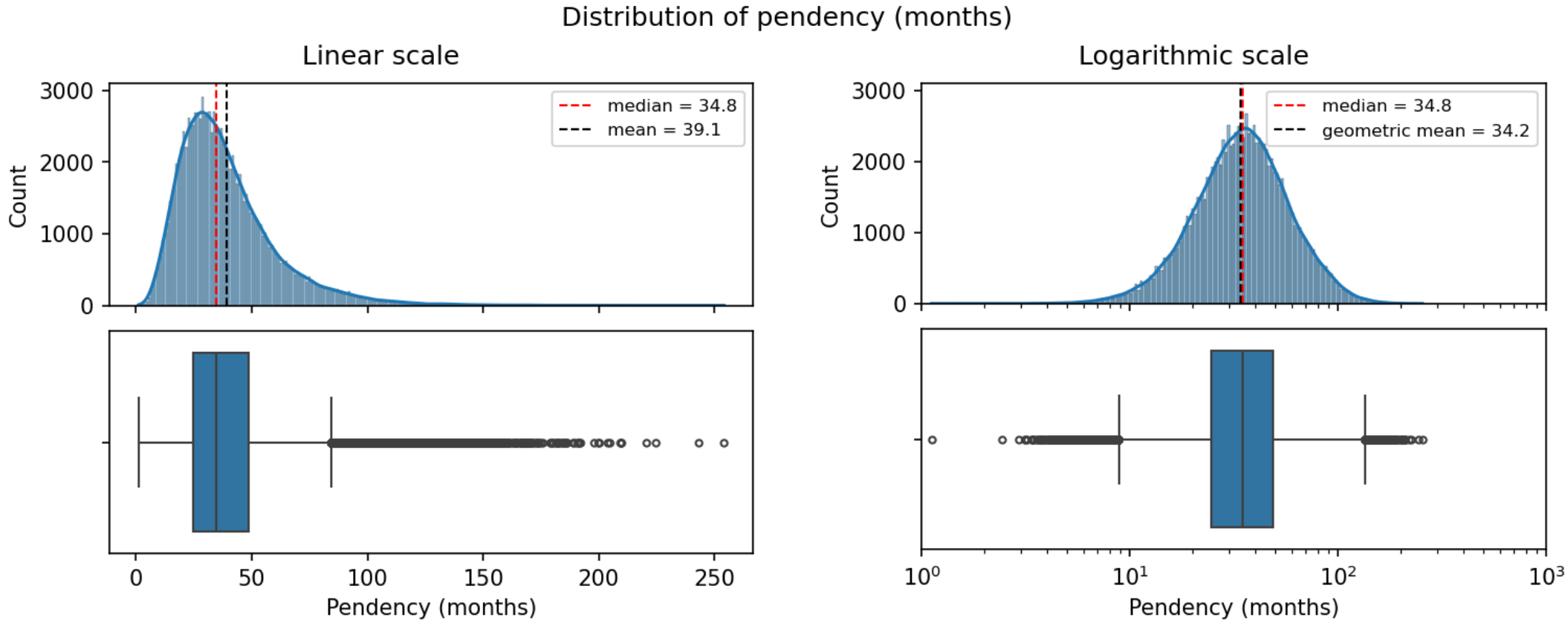
Patent data from the USPTO:

- Cancer Moonshot Patent Data ("*Moonshot*")
  - ~270,000 **cancer research-related** patent applications filed from 1976 to 2016
- Patent Examination Research Dataset 2022 release ("*PatEx*")
  - 3 attribute-rich datasets
  - ~190,000 observations per dataset, after filtering for common observations with Moonshot

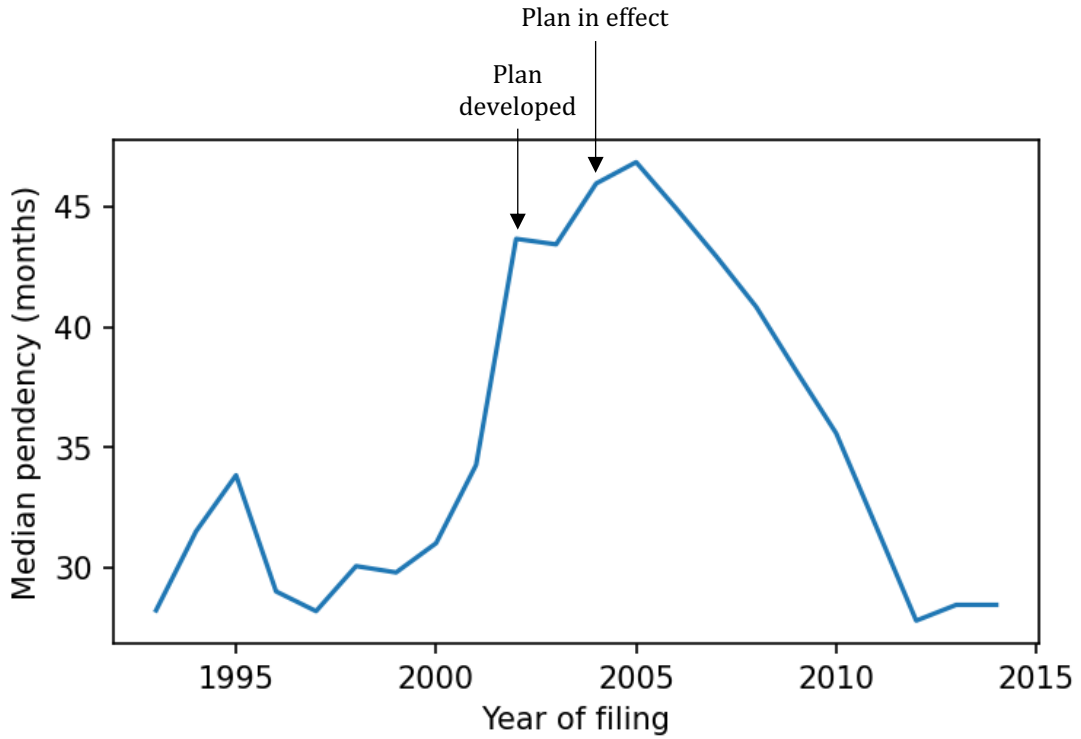
Additional data:

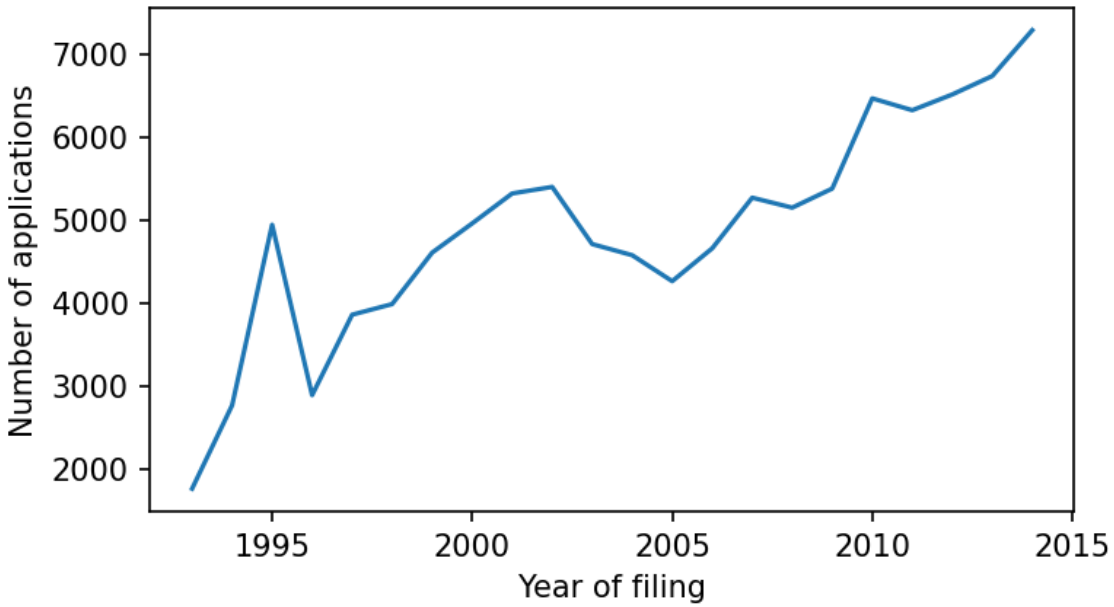
- Cities and Towns of the US (2014): ~38,000 observations
- Largest biotech companies (market data)

Distribution of pendency



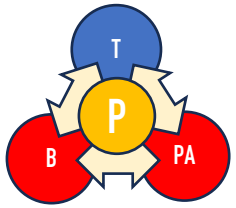
Policy is sensitive to the market…

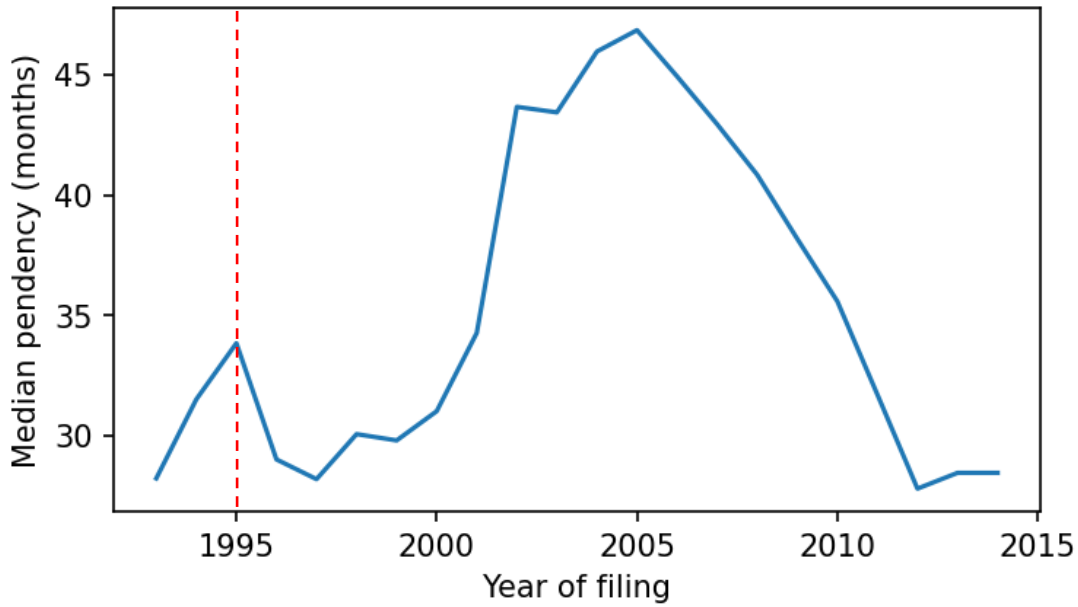


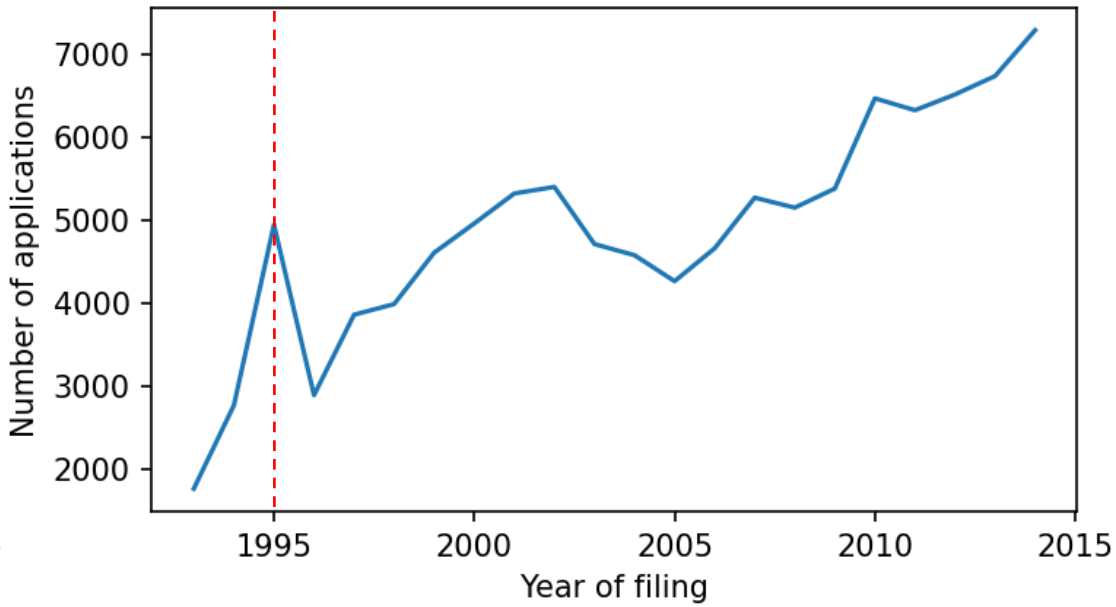


- In 2002, the USPTO developed the *21st Century Strategic Plan* in response to increasing application filings and increasing pendency times
  - One of the ***key*** strategic goals was to "*reduce patent and trademark pendency*" (source)
  - Plan went into effect in 2004 (source)

Policy is sensitive to the market… and the market is sensitive to policy



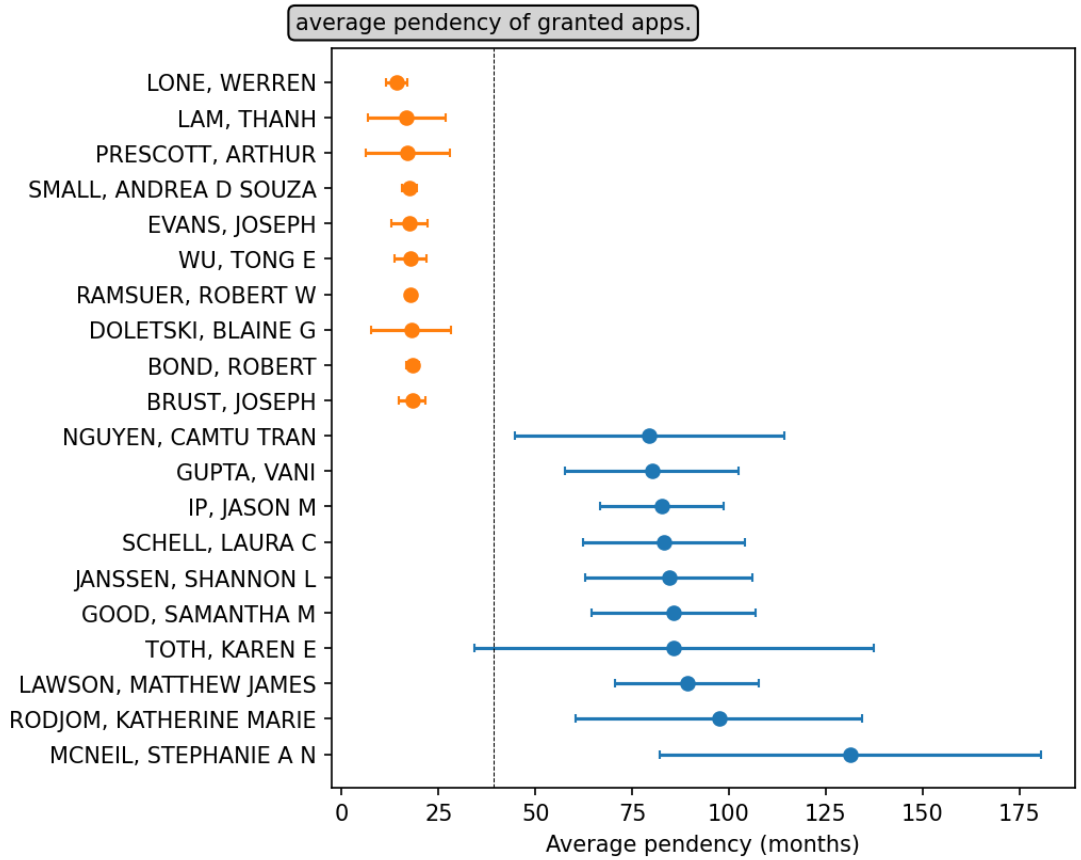




What happened in 1995?

- US patent law changed: Patent term now extends 20 years from the *filing* date instead of 17 years from *grant* date (effectively shortening your patent term if your application takes longer than 3 years to grant!)
  - Hence, we see a ”surge” in the number of applications filed – the market *responds*!

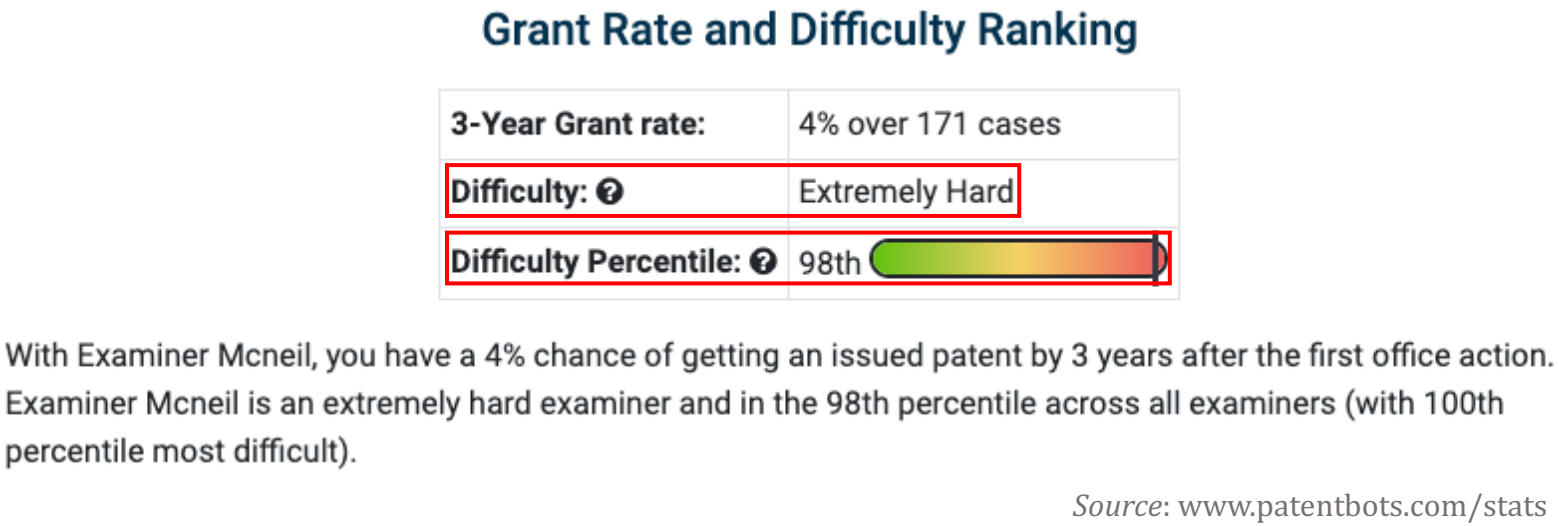
From the macro to the micro… the effect of individual examiners on pendency



- Can the average pendency of an examiner tell us anything about how “easy” or “difficult” a particular examiner is?

Is an examiner's average pendency time related to their "difficulty"?

- PatentBots maintains a database of USPTO examiners with associated statistics
- Each examiner is assigned a "Difficulty Ranking" based on the percentage of applications granted in a 3-year timeframe (after the first office action)



Grant Rate and Difficulty Ranking

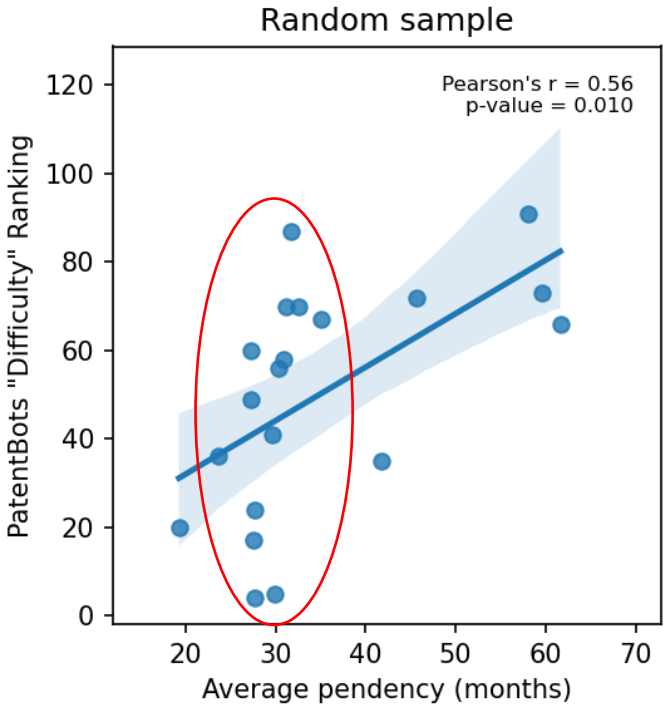
3-Year Grant rate:	4% over 171 cases
Difficulty:	Extremely Hard
Difficulty Percentile:	98th

With Examiner Mcneil, you have a 4% chance of getting an issued patent by 3 years after the first office action. Examiner Mcneil is an extremely hard examiner and in the 98th percentile across all examiners (with 100th percentile most difficult).

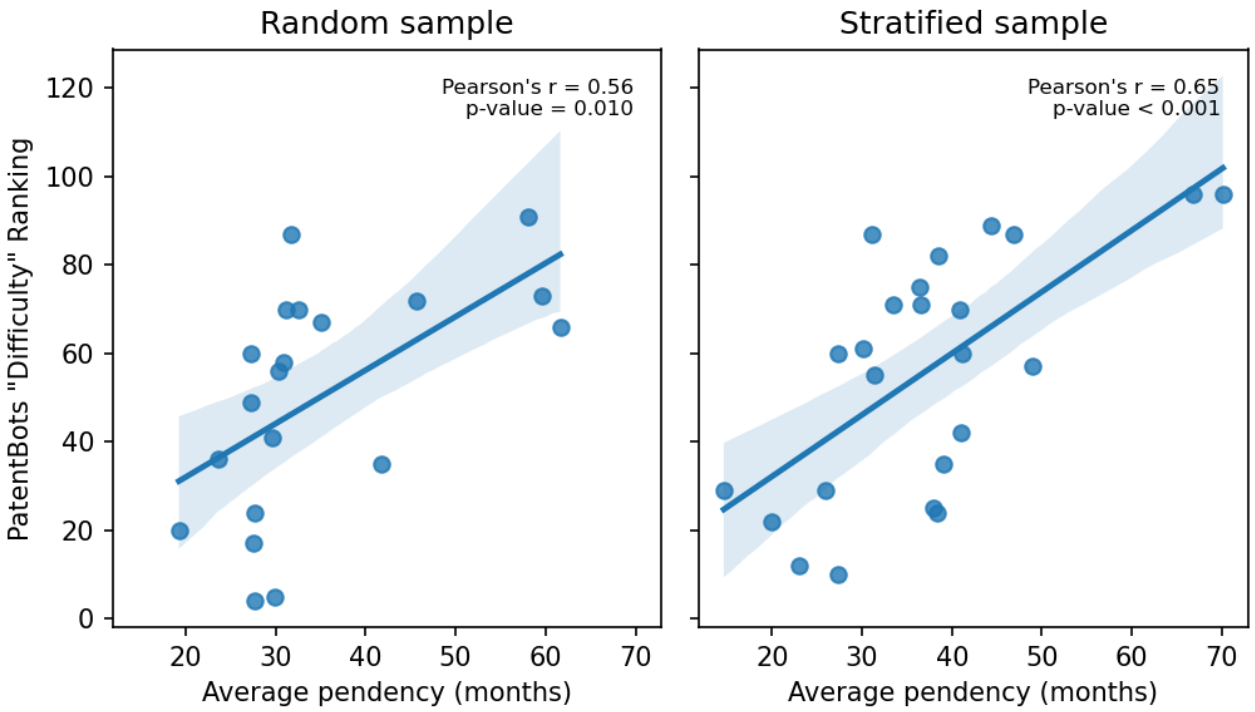
Source: www.patentbots.com/stats

➢ What's the relationship between an examiner's average pendency and their Difficulty Ranking on PatentBots?

Is an examiner’s average pendency time related to their “difficulty”?

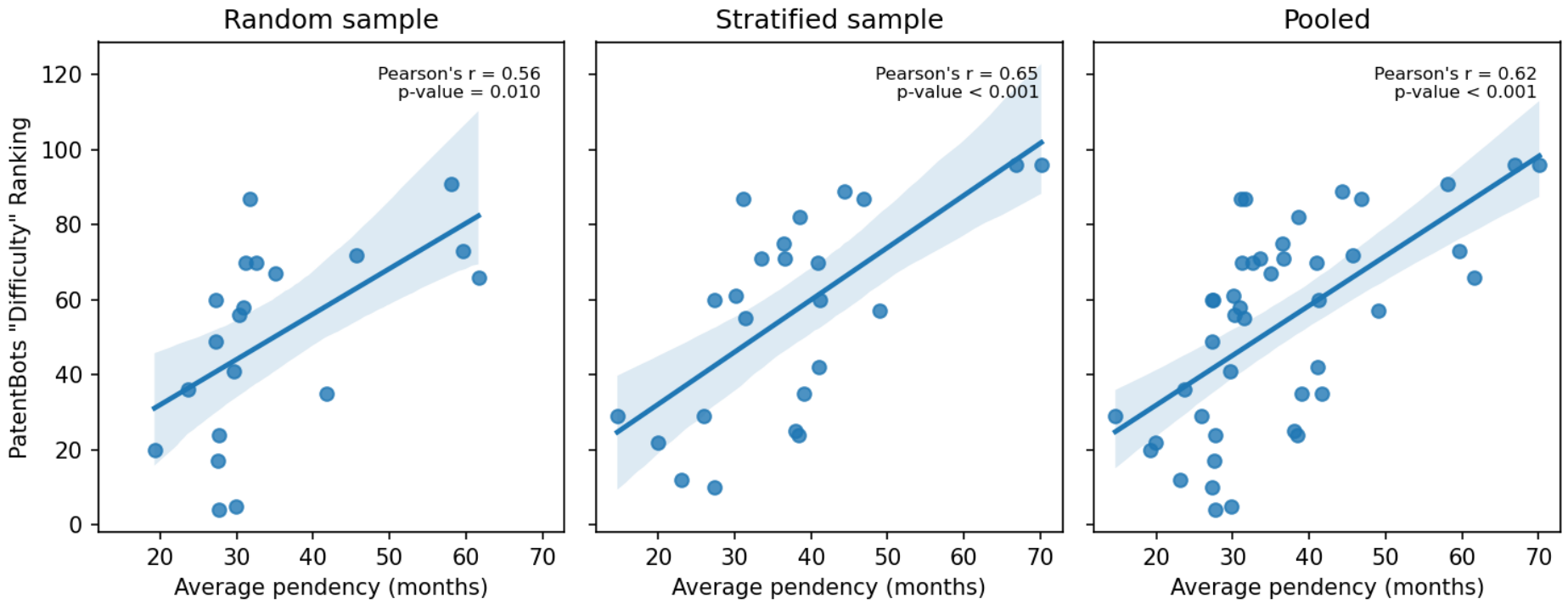


Is an examiner's pendency related to their "difficulty"?



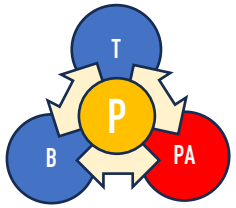
- Stratified sampling can help ensure a better representation across the range of average pendency values

An examiner's average pendency and "Difficulty Ranking" are correlated



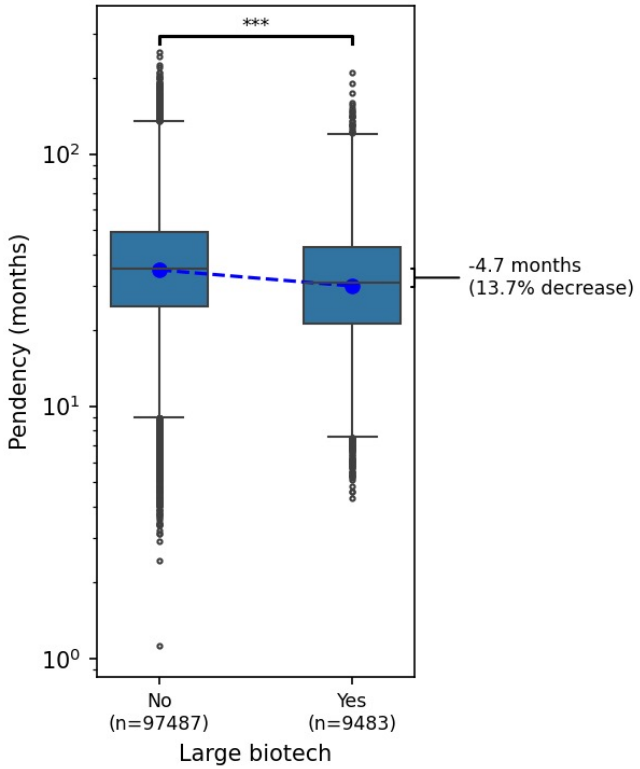
- There appears to be a moderate-to-strong positive correlation between an examiner's average pendency and their PatentBots difficulty ranking
- The PatentBots ranking only tells one part of the story… Average pendency gives more information!

Are patents filed by large biotech companies quicker to grant?



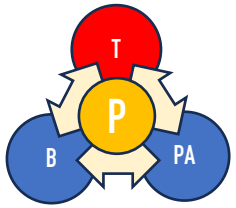
- Large biotech companies often conduct thorough patent due diligence throughout the R&D process before application filing

- *"Large biotech"* = top 20 biotech cos. by market cap (as of October 2023) (*source*)

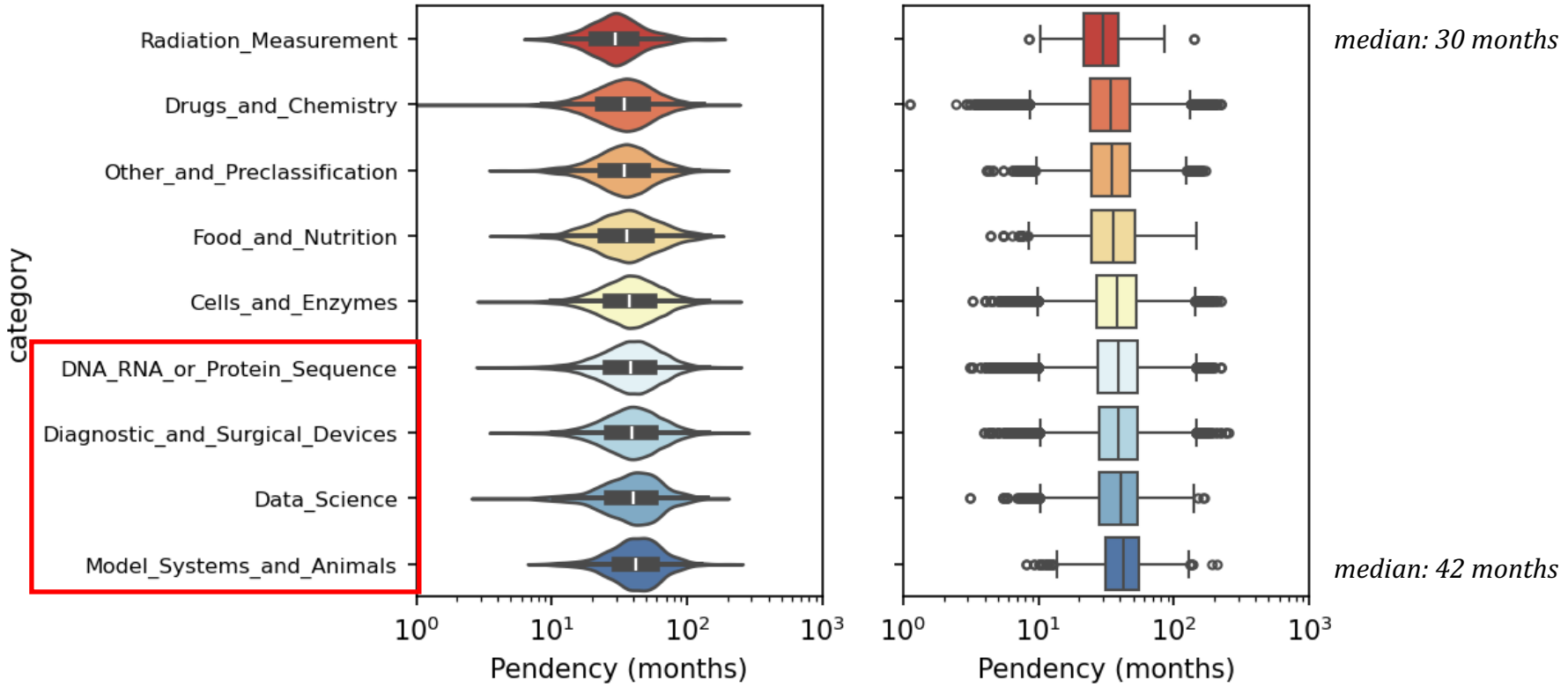


- Patents filed by the largest biotech companies appear to have shorter pendency times on average

Certain patent categories are quicker to grant than others



Subject matter patentability: Laws of nature, physical phenomena, and abstract ideas cannot be patented

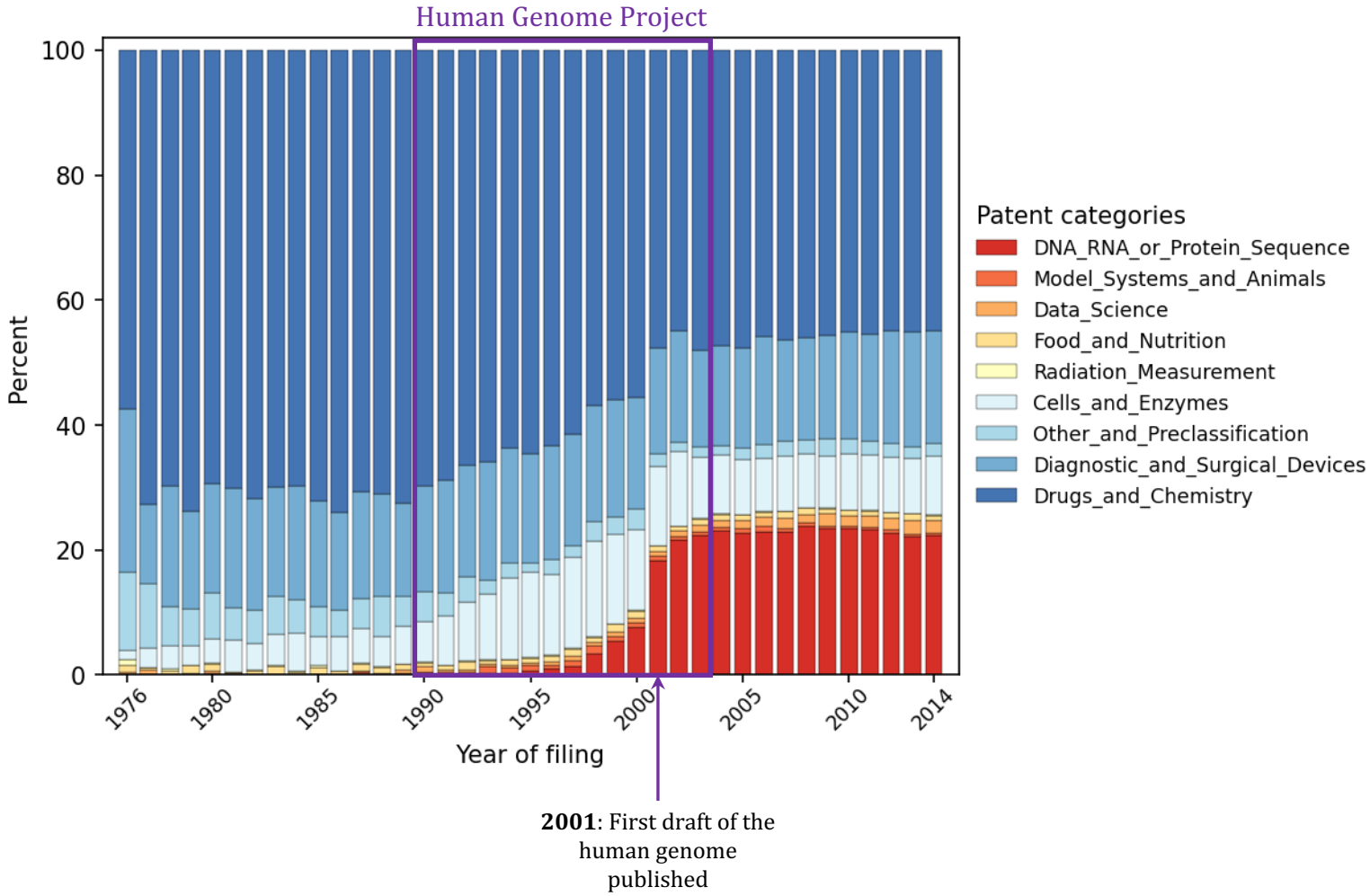


median: 30 months

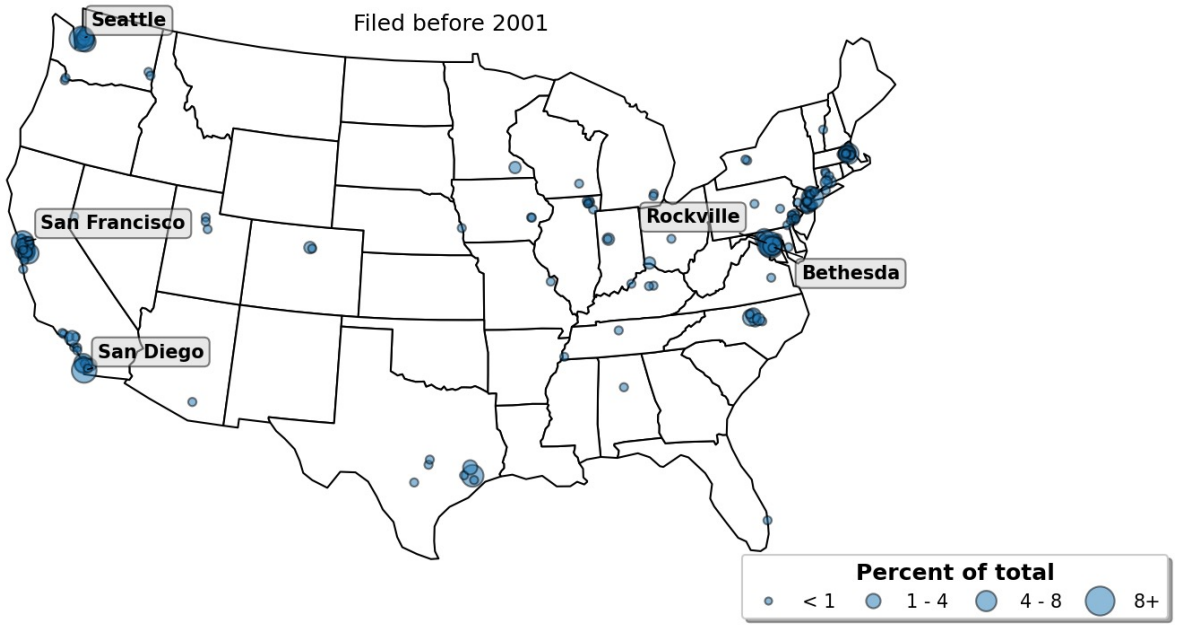
median: 42 months

- Radiation and pharmaceutical drug patents seem to have shorter median pendencies, while categories related to abstract ideas and physical phenomena (e.g., software, DNA, animals) have longer median pendencies

Patent category filing trends reflect the development and emergence of new technologies

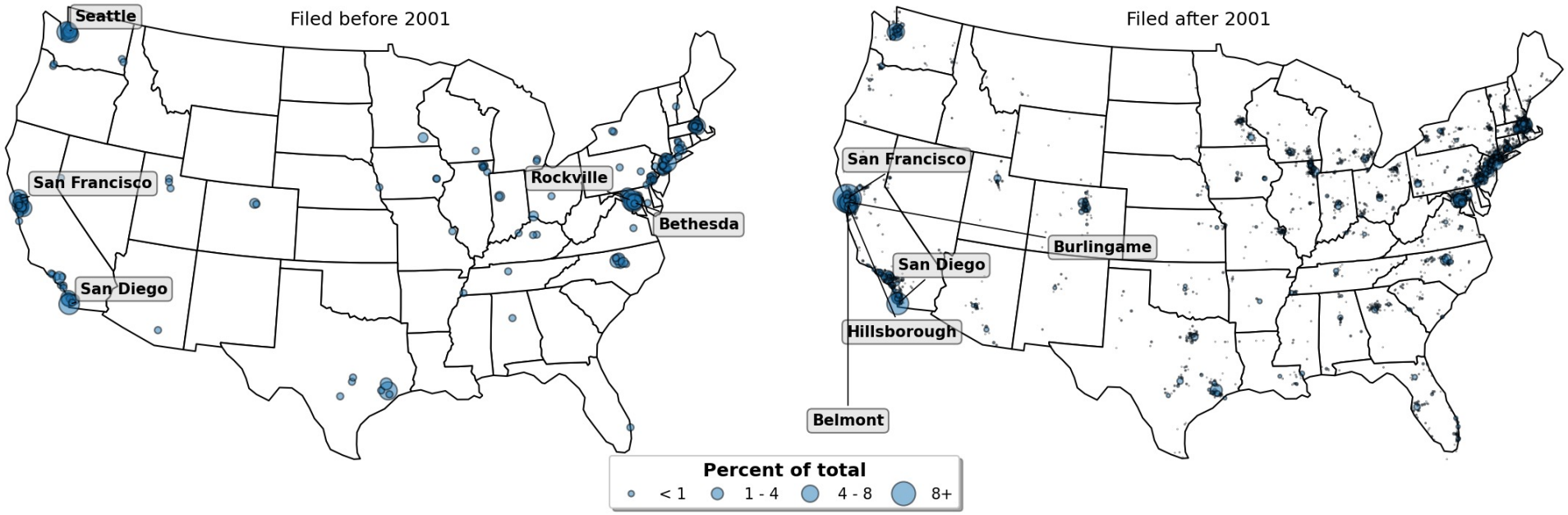


Where were the key players of the genomics era based?



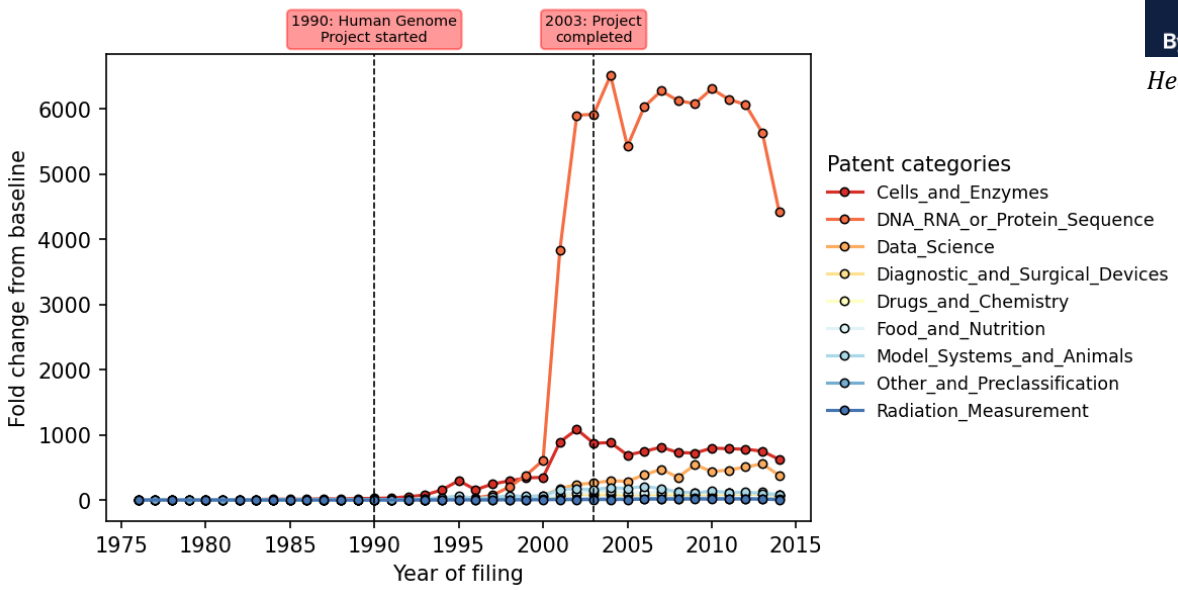
- The location of inventors on the earliest genomics patents align with the locations of known powerhouses of that time: the NIH (*Bethesda*), Human Genome Sciences (*Rockville*), Incyte Genomics (*Palo Alto*), and the University of California system (*source*)

Where were the key players of the genomics era based?

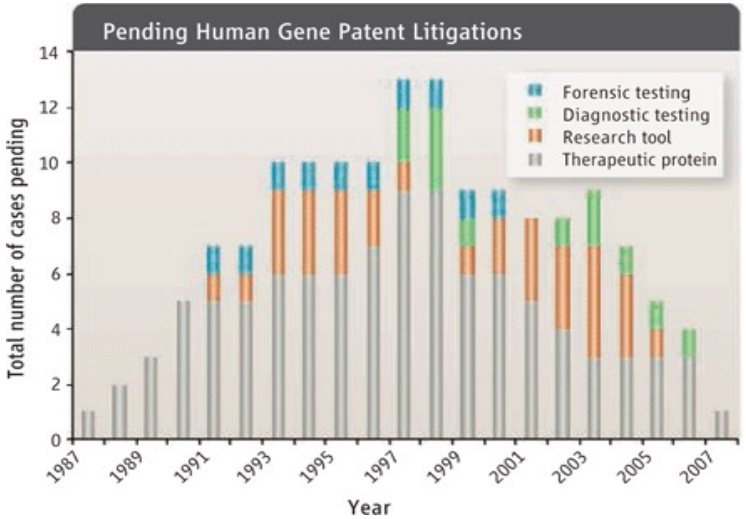


- The location of inventors on the earliest genomics patents align with the locations of known powerhouses of that time: the NIH (*Bethesda*), Human Genome Sciences (*Rockville*), Incyte Genomics (*Palo Alto*), and the University of California system (*source*)

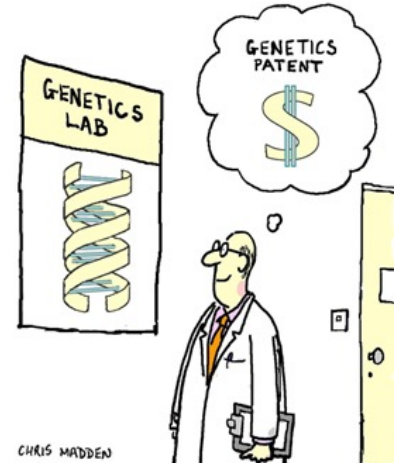
As the genomics era dawned, the increase in patent filings was highest for gene patents than for any other category



Headlines in popular press (2000) (from MIT Tech. Review)



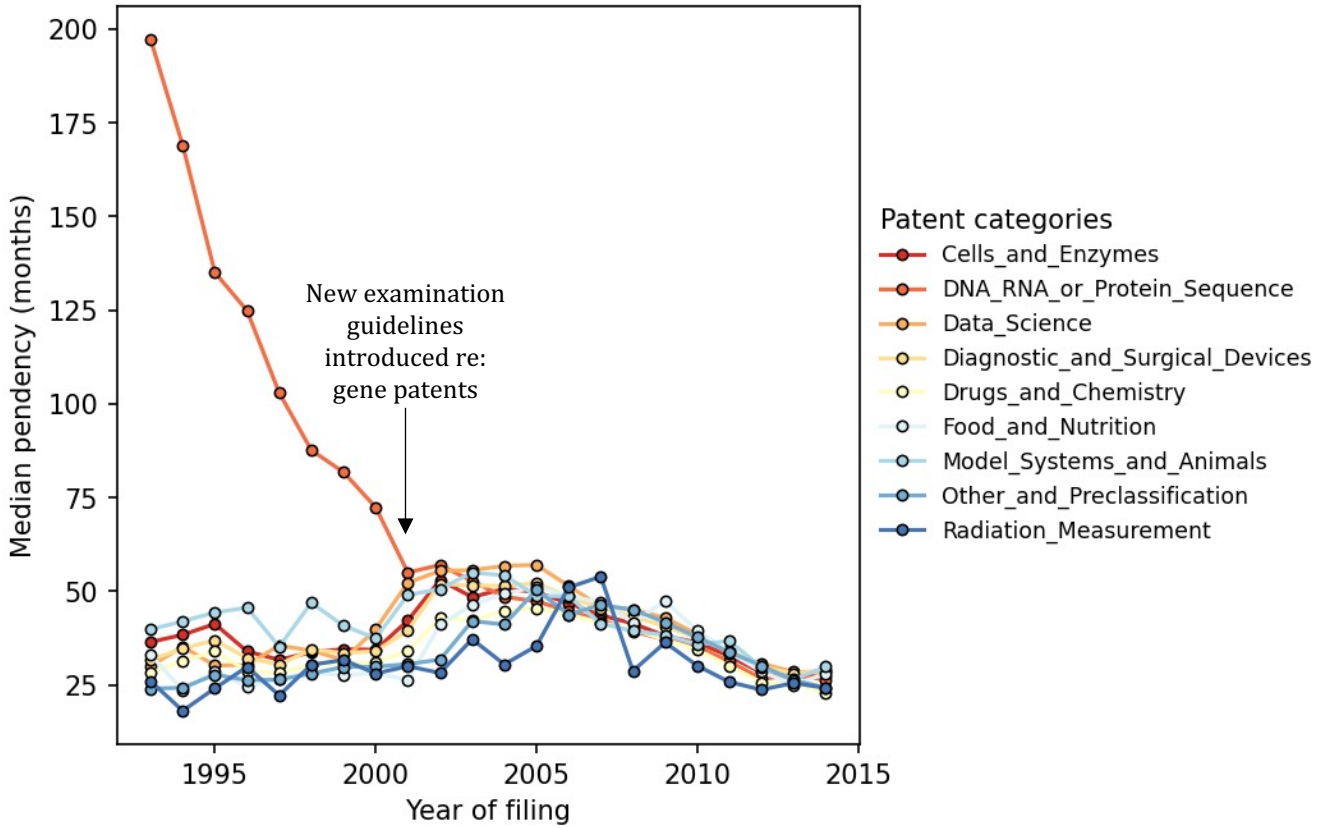
Legal conflicts over gene patents (highest peak in 1997-1999) (from Holman, Science, 2008)



Cartoon commentary (2005)

- The early years of gene patenting (1990 - 2000) were marked by high levels of social and legal controversy and conflict

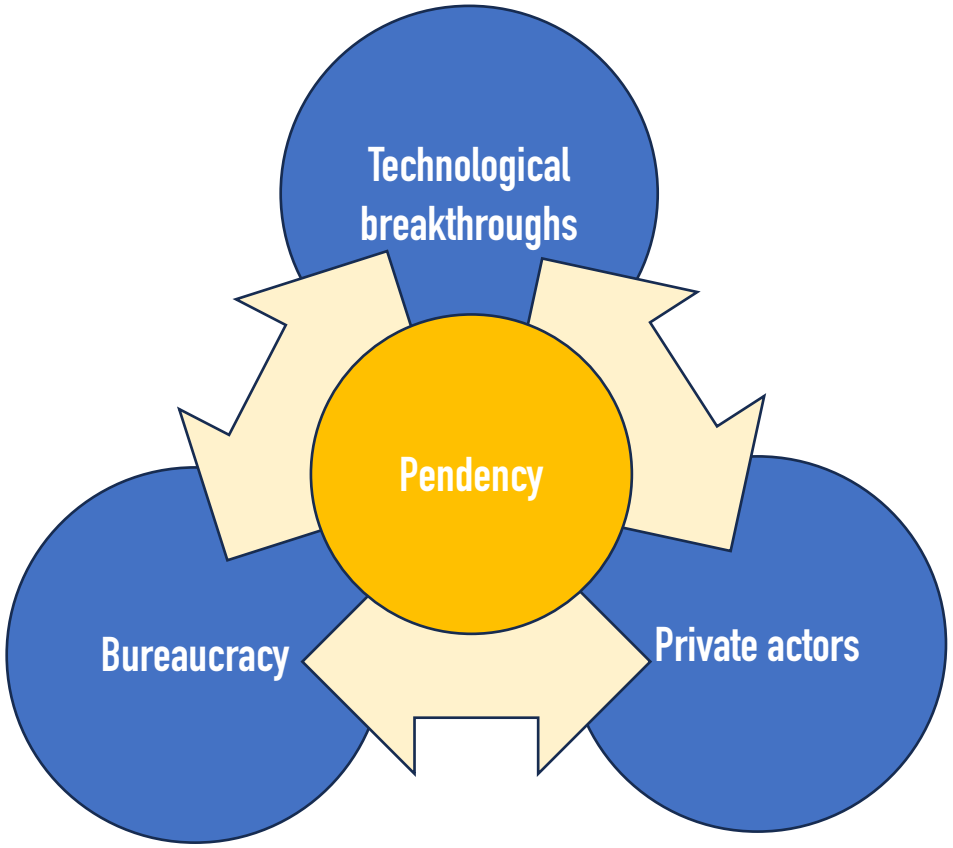
Policy is sensitive to technological developments



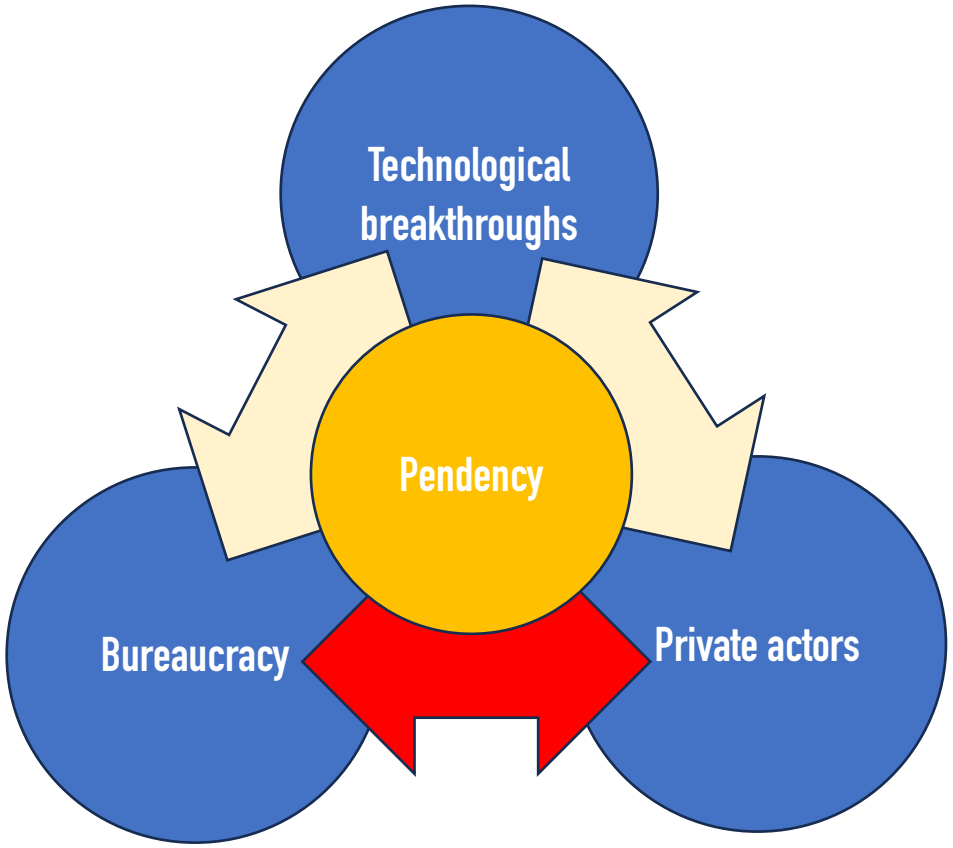
- The social and legal controversy surrounding gene patents may be linked to why gene patents had longer pendency times compared to other categories during this period
- In response, new examination guidelines were implemented in 2001 that set firm guidelines for examiners to "*reject patents that do not describe a 'specific, substantial and credible' use for DNA sequence*" (Morrison, 2001)

Morrison, J. Marshall Rev. Intell. Prop. L. 142

Conclusions and future work



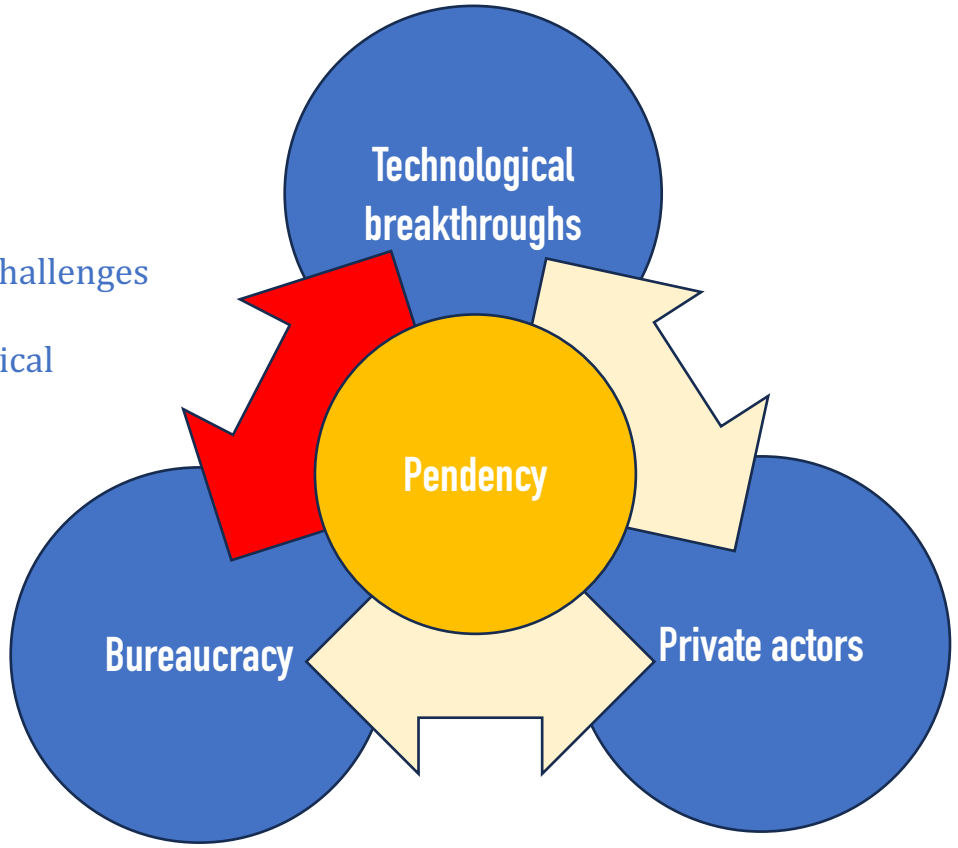
Conclusions and future work



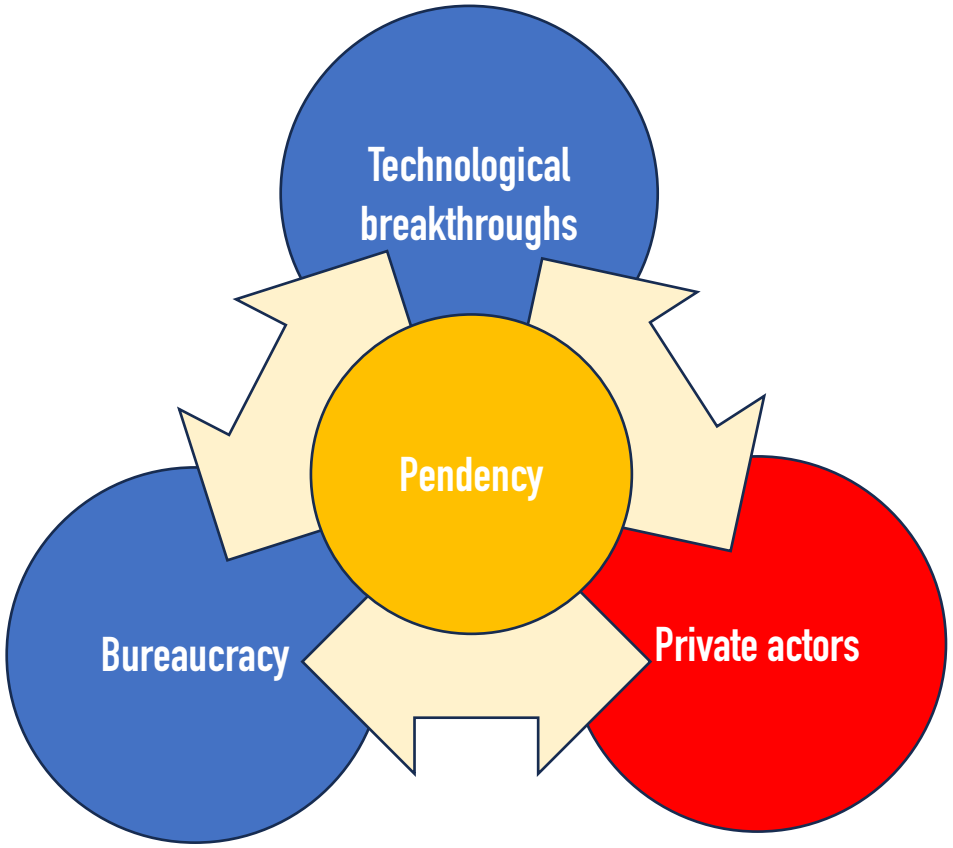
- Changes in the market affect patent policy and law (*decrease in pendency*)
- The market responds to changes in policy/law (*increase in pendency*)
- Comparative, cross-country examination of patent pendency

Conclusions and future work

- Development of disruptive technology challenges *status quo* policy (*increase in pendency*)
- Policy changes in response to technological development (*decrease in pendency*)



Conclusions and future work



- Patents filed by the largest companies have shorter pendency times on average

Conclusions and future work

- Individual examiners can have a significant impact on pendency – adapt your strategy accordingly
- What factors can help speed up pendency times even for “difficult” examiners?