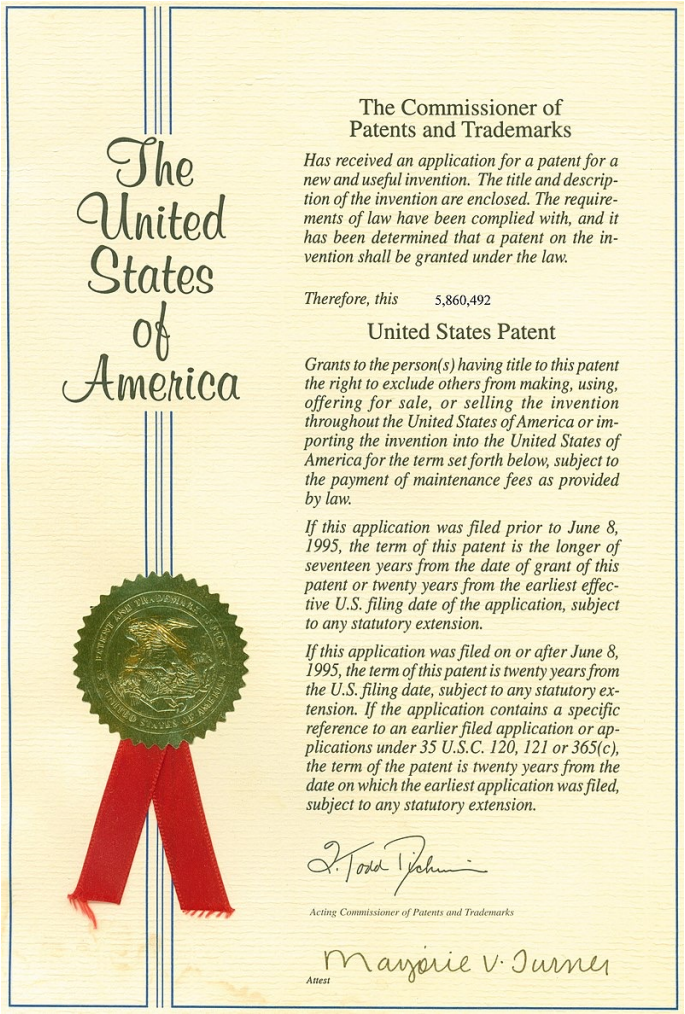
What are patents?

What is a patent?

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

Why is a patent **valuable**?

- Intellectual property *rights*
  - Start a new company
  - License out 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.

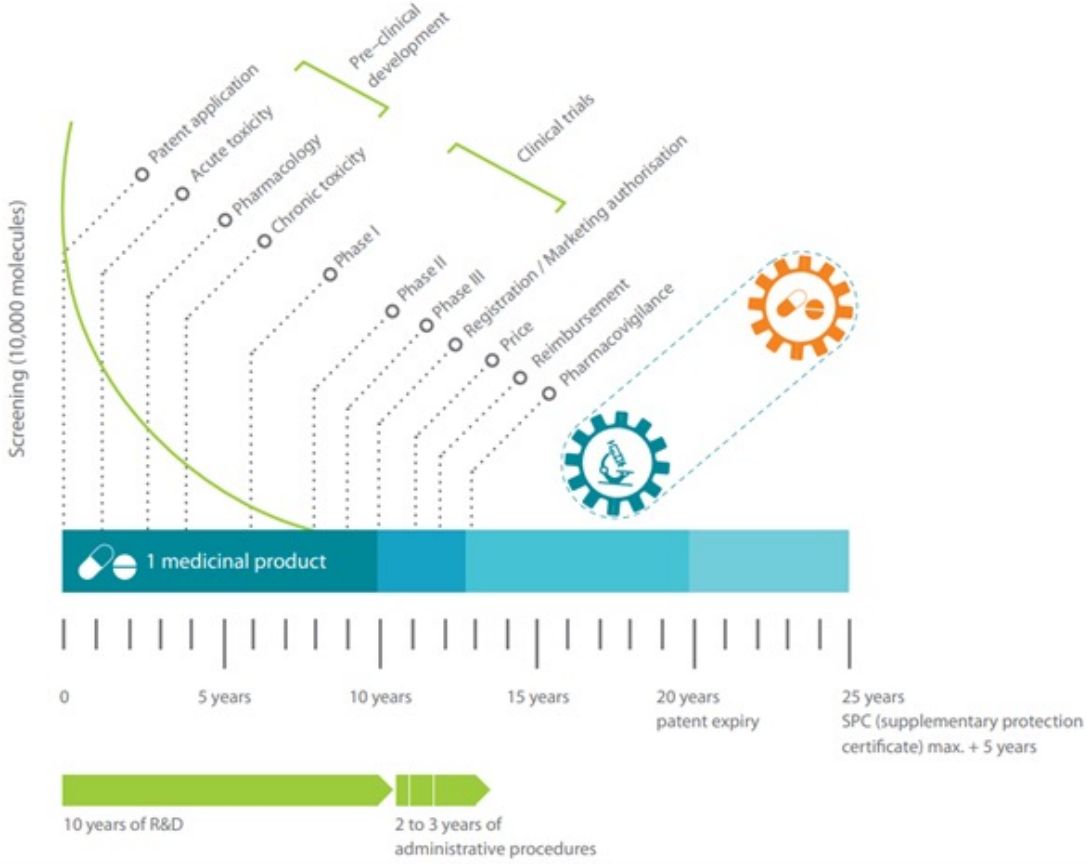
If this application was filed prior to June 8, 1995, the term of this patent is the longer of seventeen years from the date of grant of this patent or twenty years from the earliest effective U.S. filing date of the application, subject to any statutory extension.

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



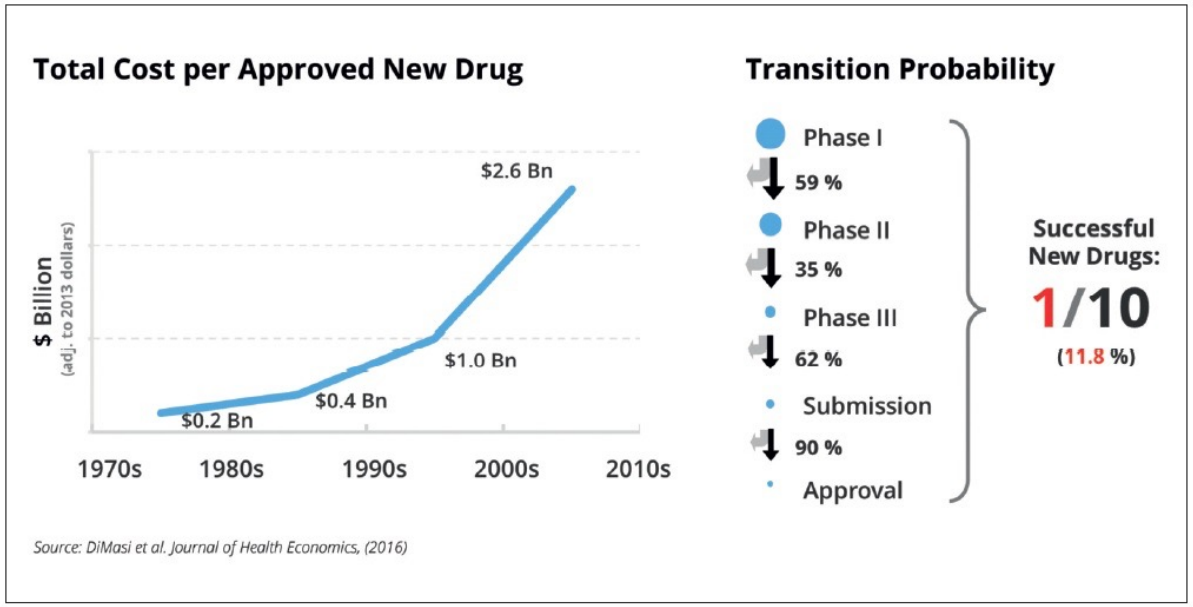
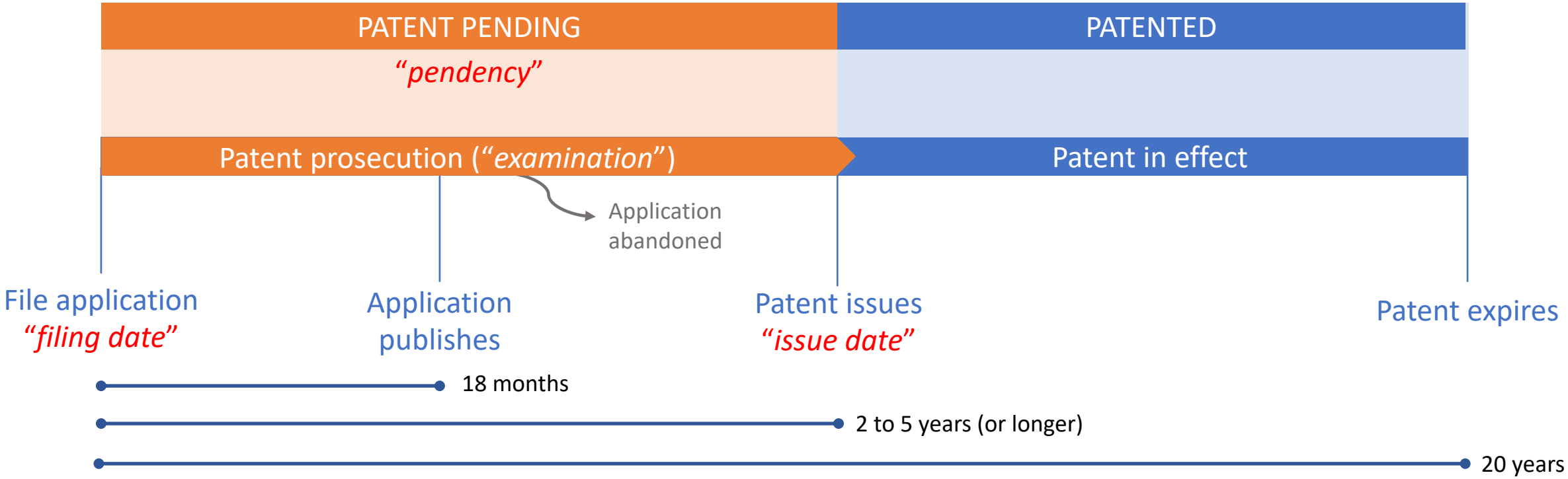


Figure 1 Costs of drug development have risen while overall probability of regulatory approval has reduced[1]. *Image taken from DiMasi JA et al. J Health Econ. 2016;47:20-33*

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

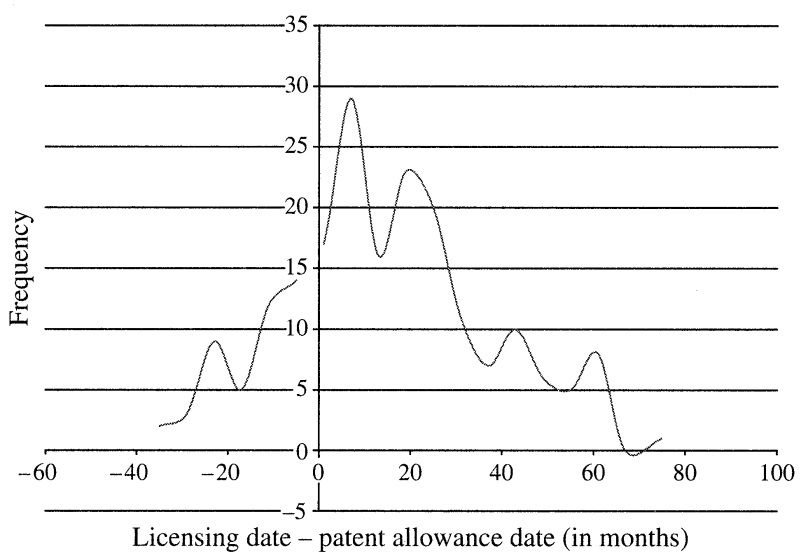
Overview of the patent application filing process (simplified)



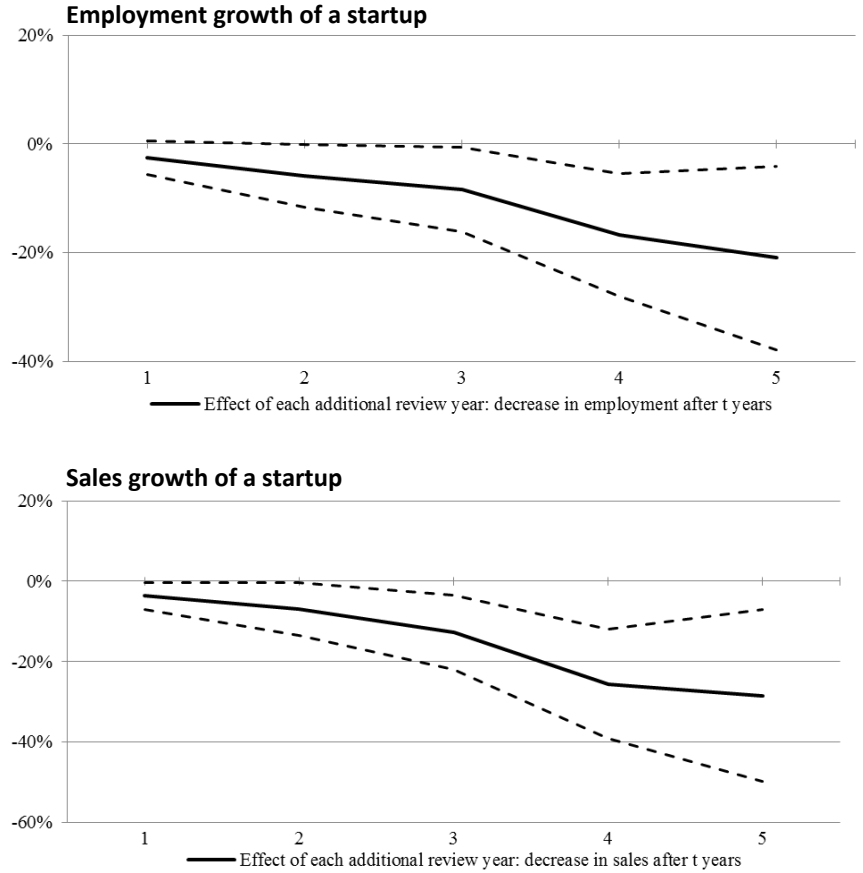
Note: Timeline not drawn to scale

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)

➢ In short: yes!

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

Datasets

Patent data from the USPTO:

- **Cancer Moonshot Patent Data** ("*Moonshot*")
  - ~270,000 observations (patent applications) filed from 1976 to 2016
  - Contains application bibliographic information (*filing date, grant date, technology category, etc.*)
- **Patent Examination Research Dataset (PatEx)** – 2022 release ("*PatEx*")
  - 3 main datasets (out of 16 total):
    - Application bibliographic info (*filing date, issue date, examiner, etc.*)
    - Inventor information (*inventor name, city of residence*)
    - Correspondence addresses (*name of law firm or legal department attached to the filing*)
  - ~190,000 observations each, after filtering for common observations with Moonshot

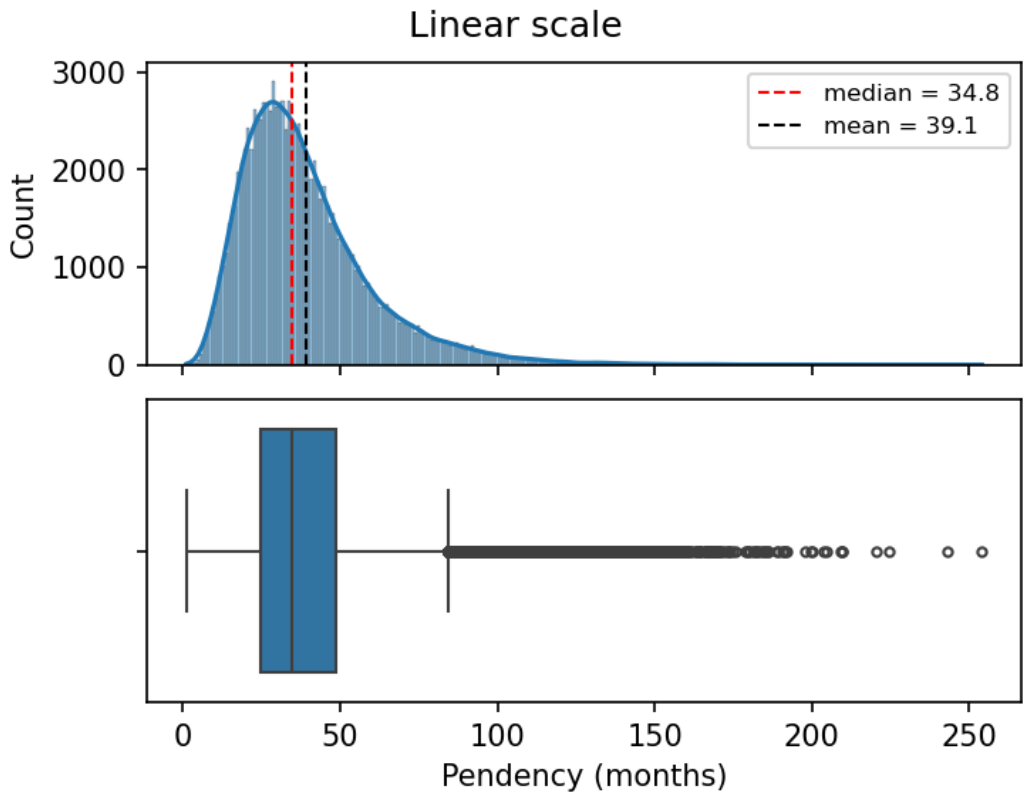
Geospatial data:

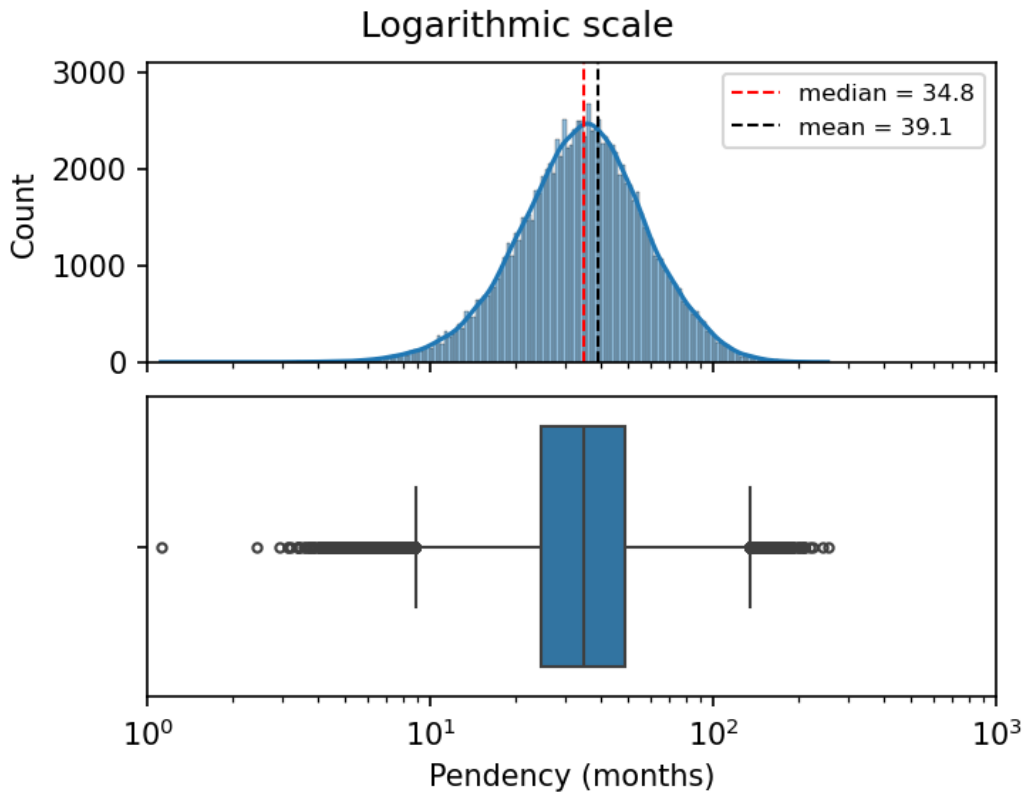
- Cities and Towns of the US (2014): ~38,000 observations

Additional data:

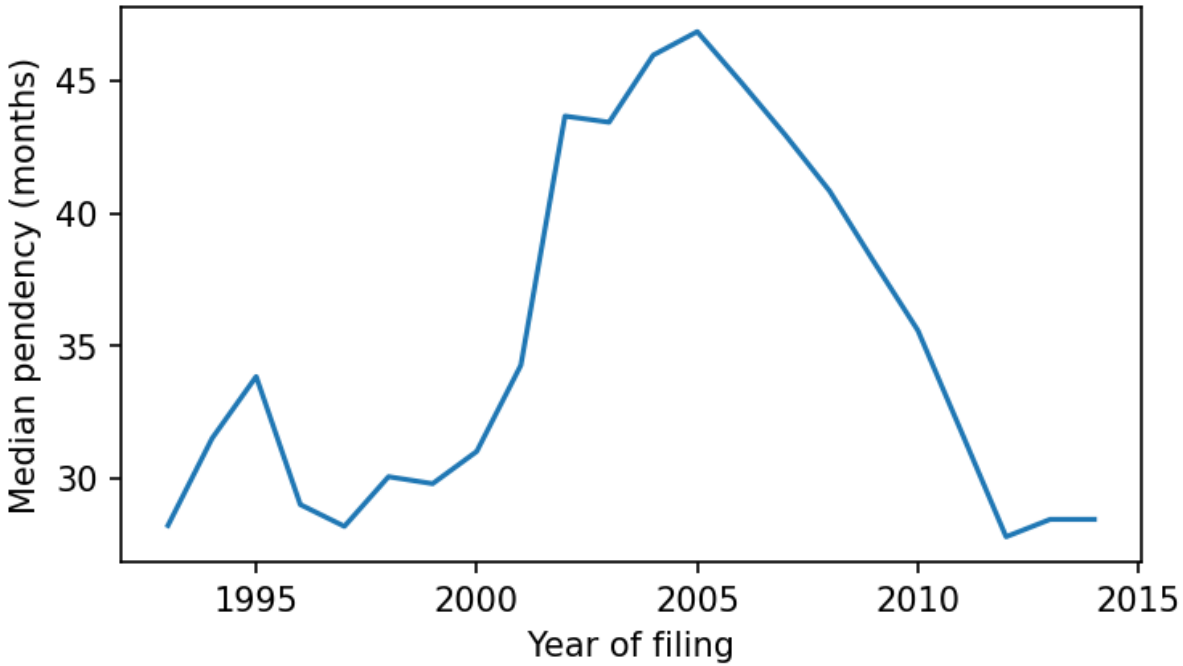
- Largest biotech companies
- Best law firms for life sciences IP (US)

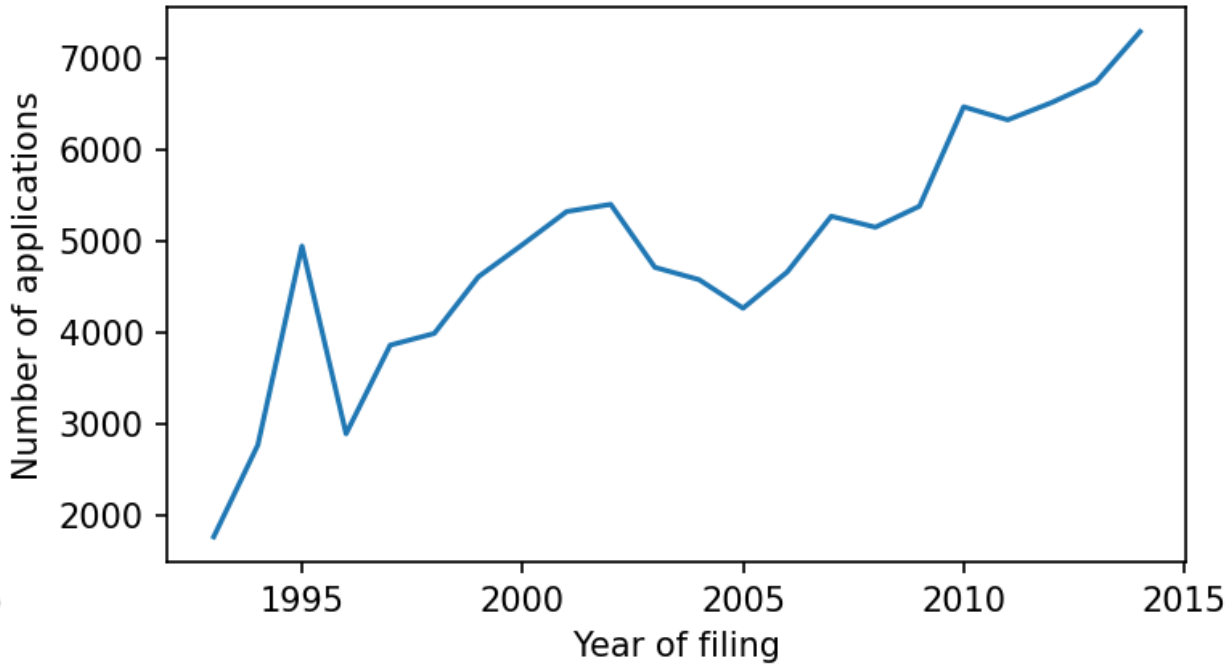
Distribution of pendency





Pendency has decreased over the years while number of filings has steadily increased





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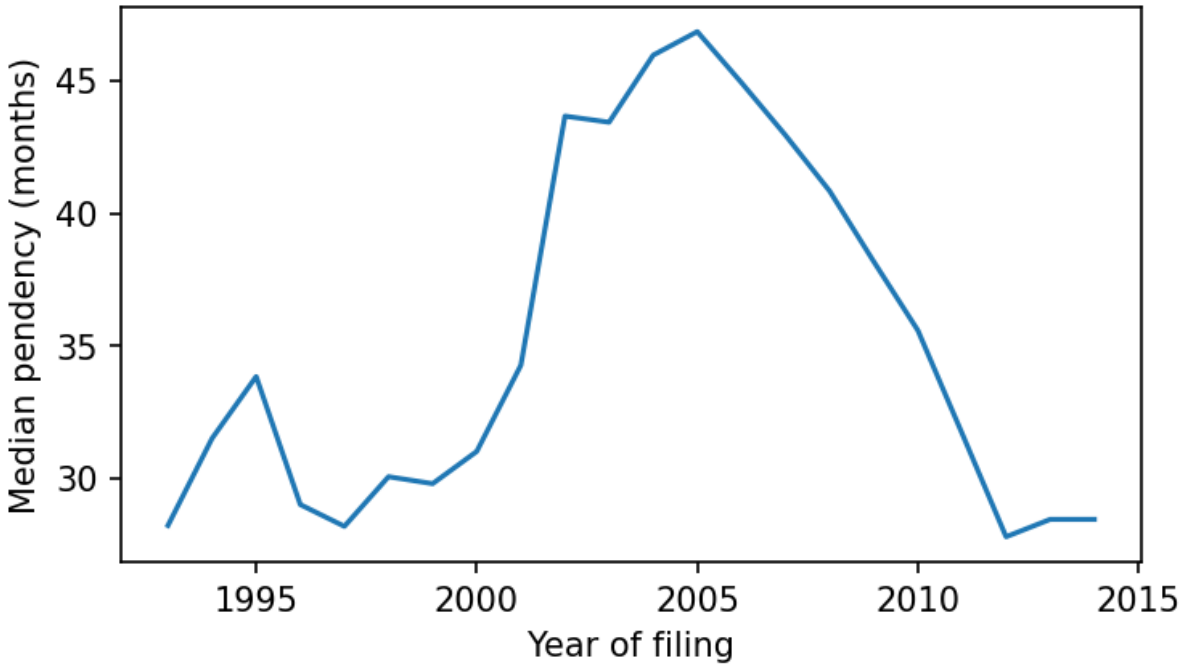
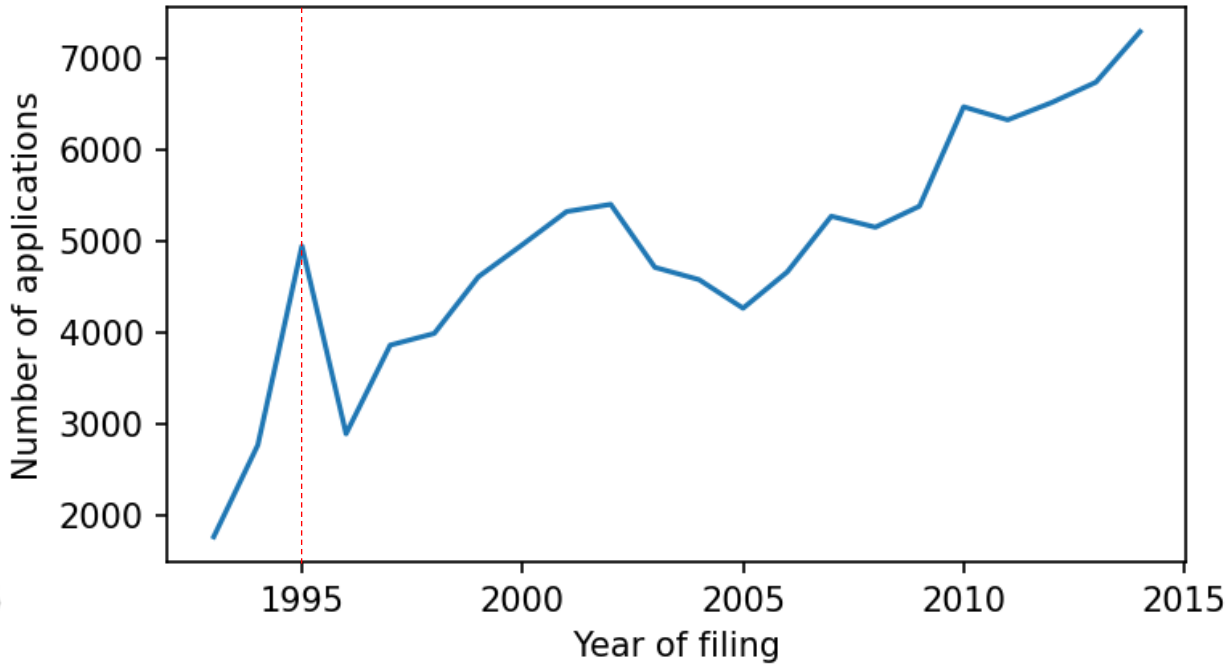
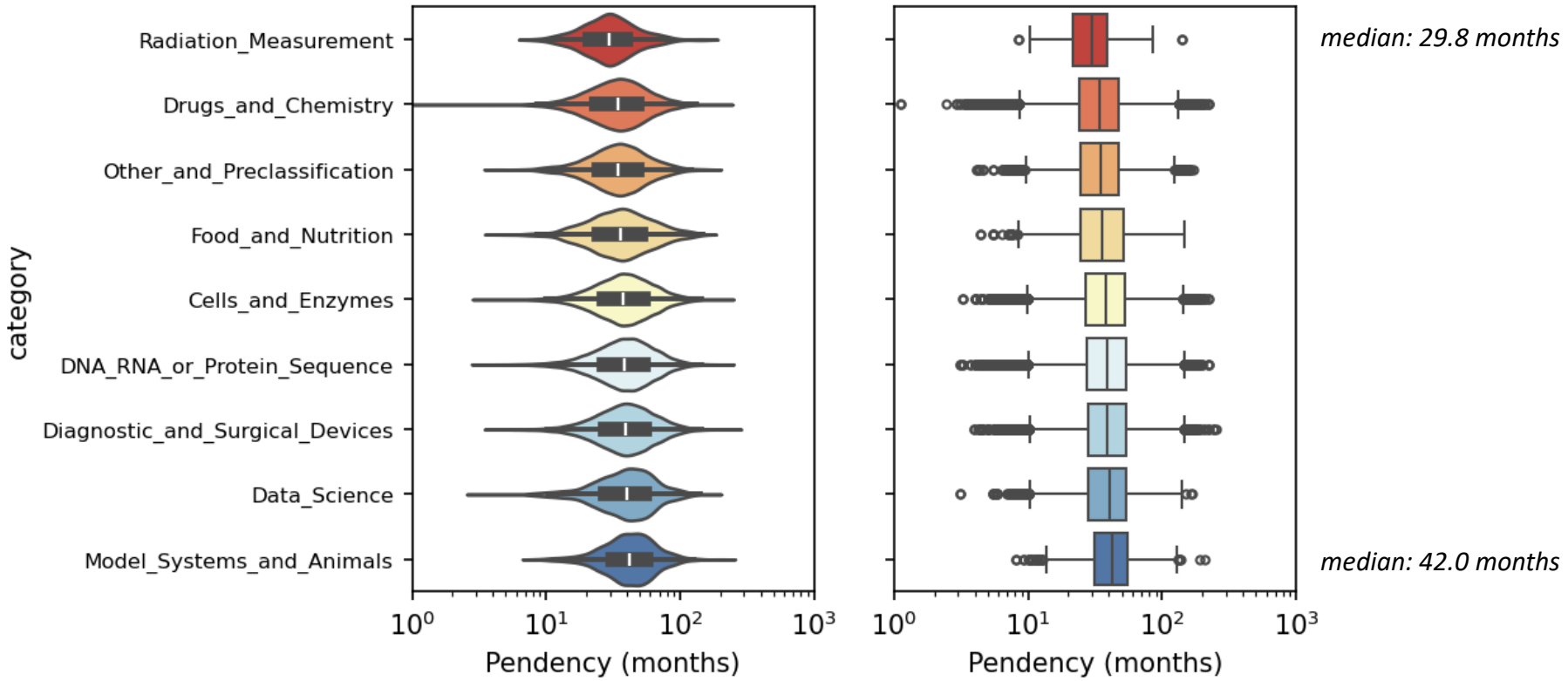




What happened in 1995?

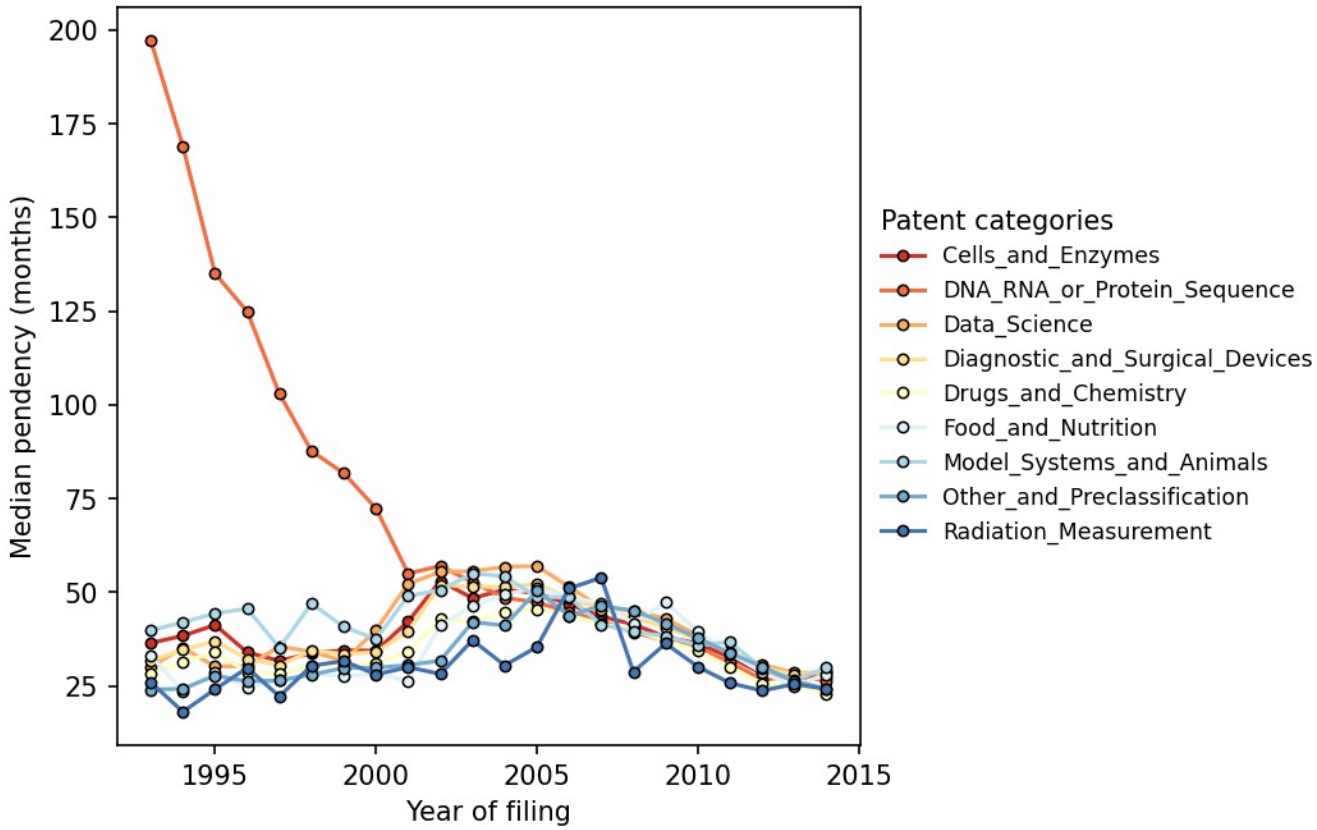
- US patent law changed (June 1995): Patent term now extends 20 years from the *application* date instead of 17 years from *grant* date (effectively shortening your patent term if your application takes longer than 3 years to grant!)
- Hence we see this ”surge” in the number of applications filed in 1995, as applicants try to file before the law takes effect

Certain categories are quicker to grant than others



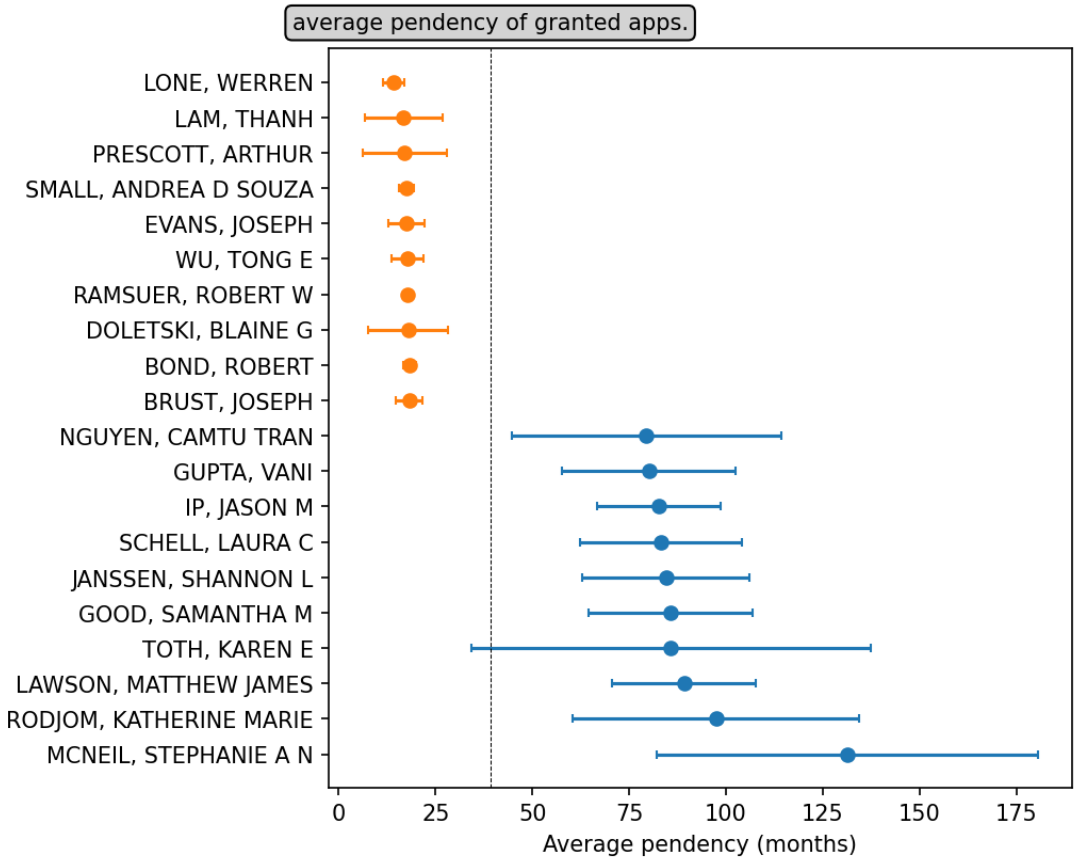
- Radiation-related patents seem to have the shortest pendency, while model systems and animals-related patents have the longest pendency

Pendency of genomics-based patents has decreased over the years



- New examination guidelines implemented in 2001 may have led to a decrease in pendency of genomics-based applications by giving applicants and examiners clearer guidelines to work with
- Genomics-based patent applications are particularly interesting, and we'll come back to them later

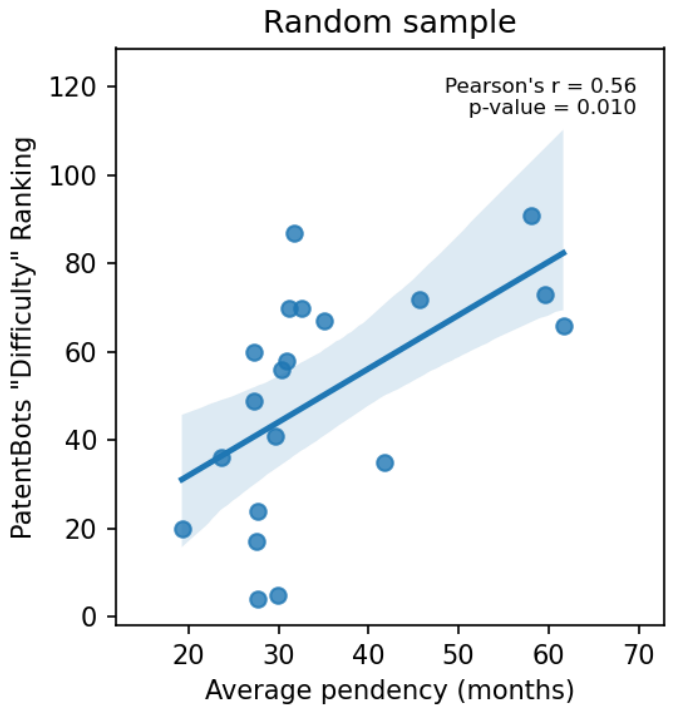
Different examiners vary widely in their average pendency



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

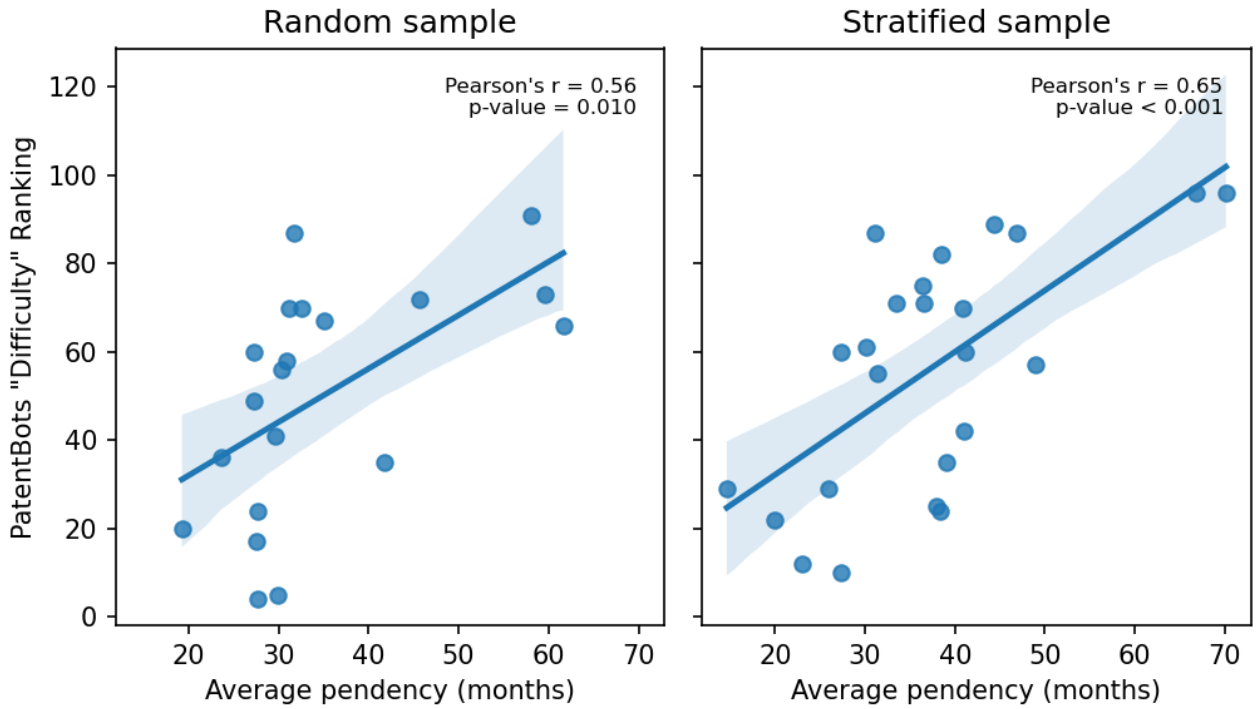
Is an examiner's average pendency time related to their "difficulty"?

- PatentBots maintains a database of USPTO examiners with their associated statistics
- PatentBots assigns a "Difficulty Ranking" to each examiner based on the percentage of applications granted in a 3-year timeframe (after the first office action)
- What's the relationship between an examiner's average pendency and their Difficulty Ranking on PatentBots?

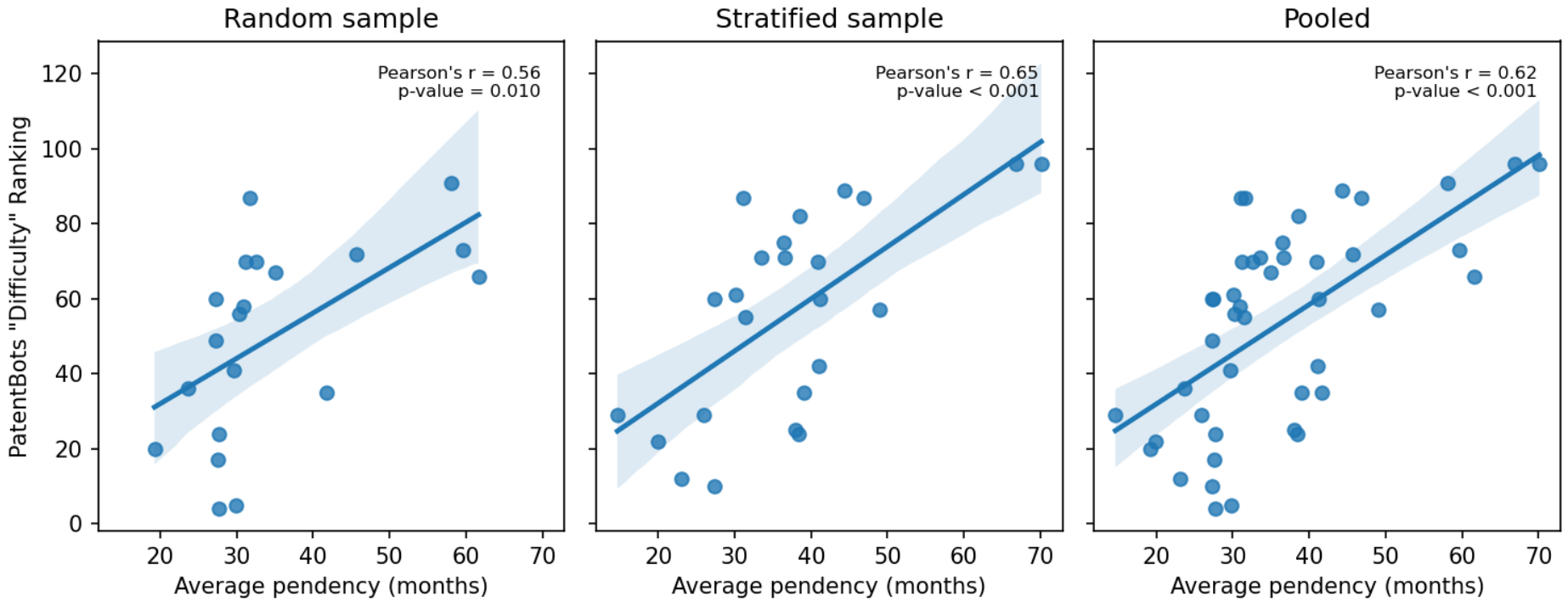


Is an examiner's pendency related to their "difficulty"?

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



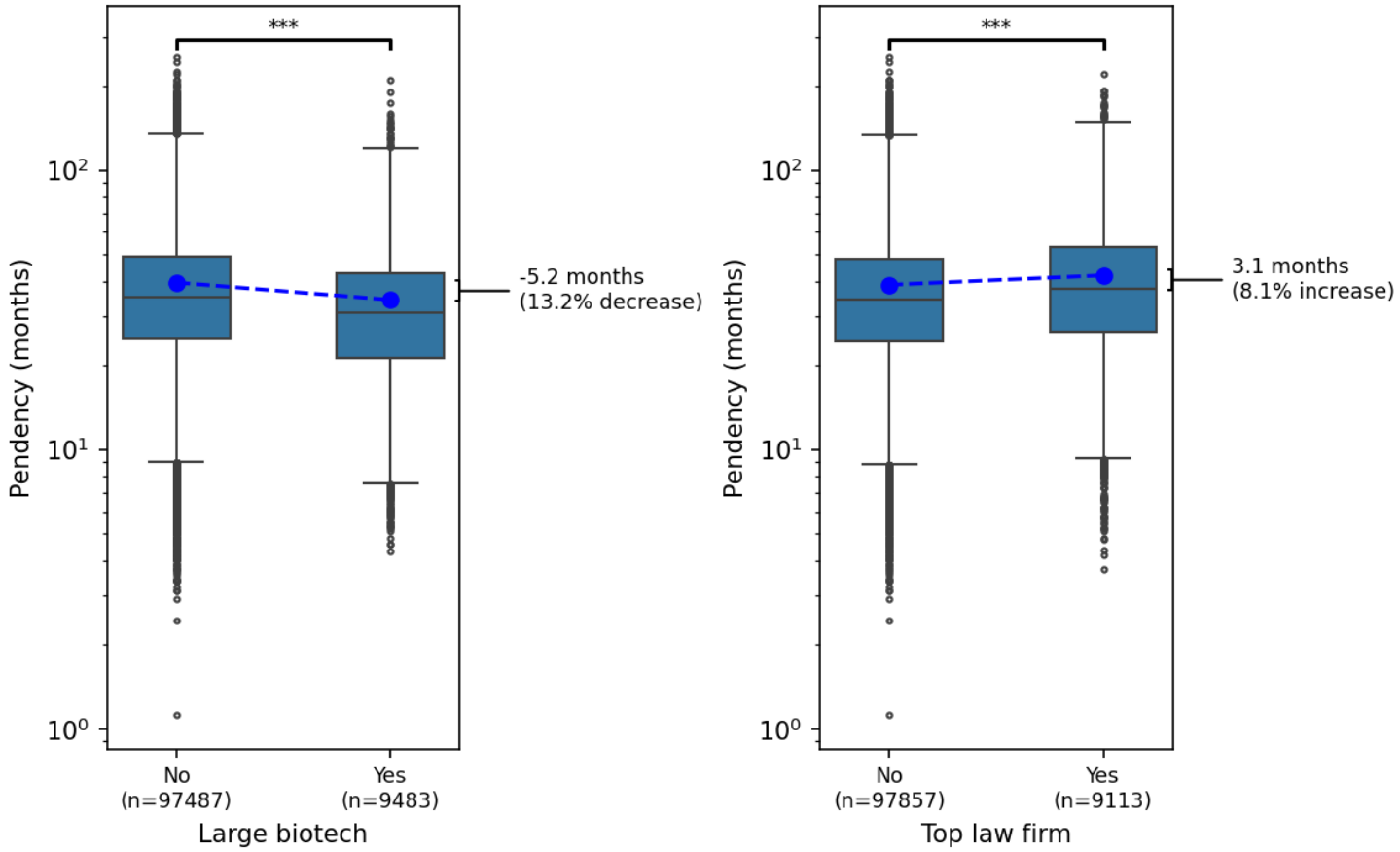
An examiner’s average pendency and “Difficulty Ranking” are correlated



- There appears to be a moderate-to-strong positive correlation between an examiner’s average pendency and their PatentBots difficulty rank

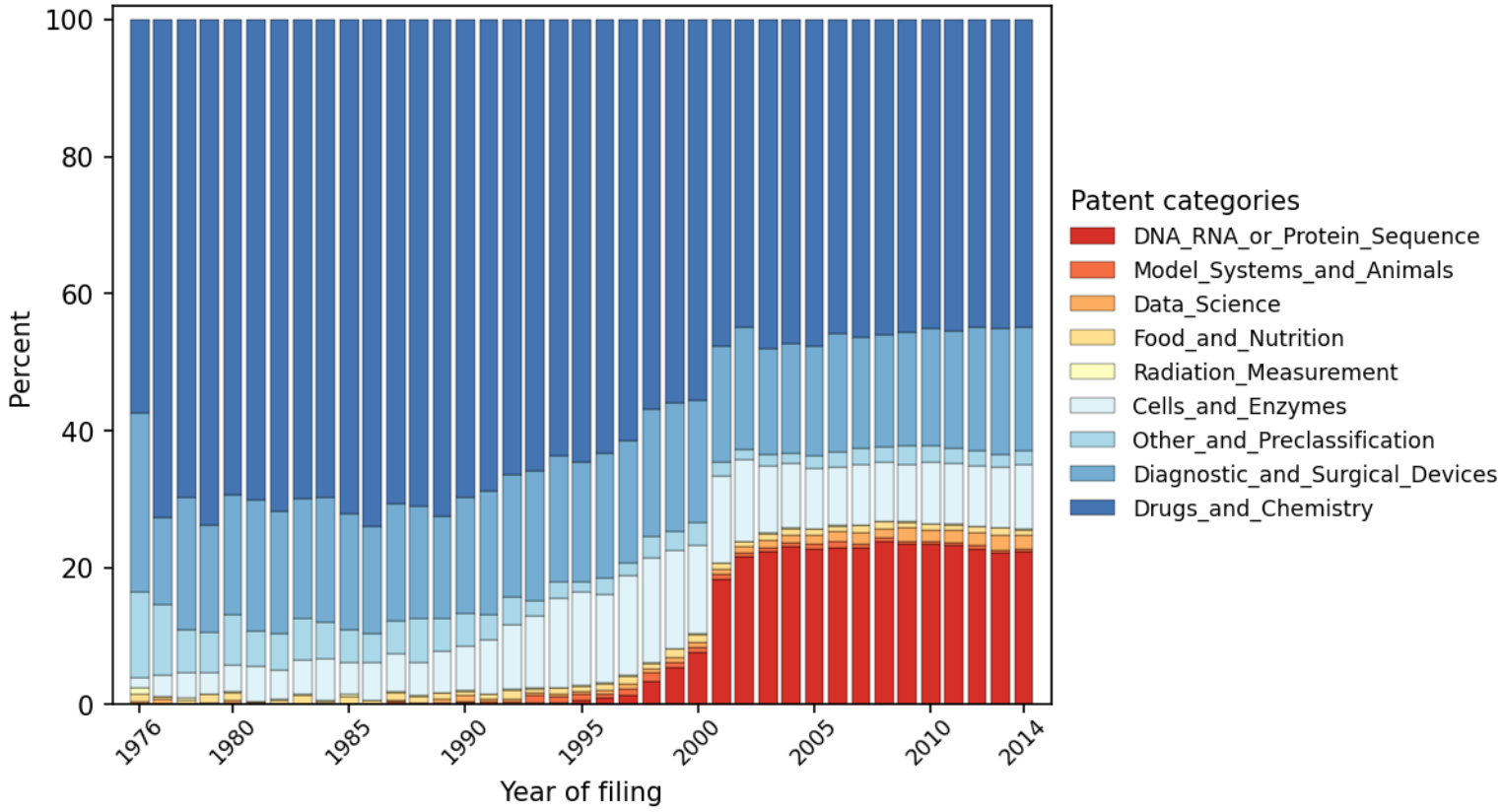
Are patents filed by large biotech companies / top law firms quicker to grant?

Large biotech = top 20 by market cap as of October 2023
Top law firm = top 32 US law firms for life sciences IP in 2023



- Patents filed by the largest biotech companies appear to have shorter pendency times on average
- Patents filed by top law firms appear to have slightly longer pendency times on average

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



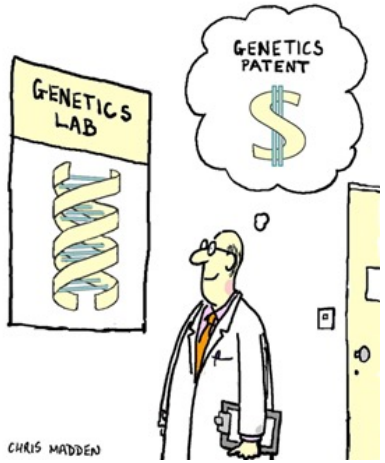
As the genomics era dawned, patent filings surged

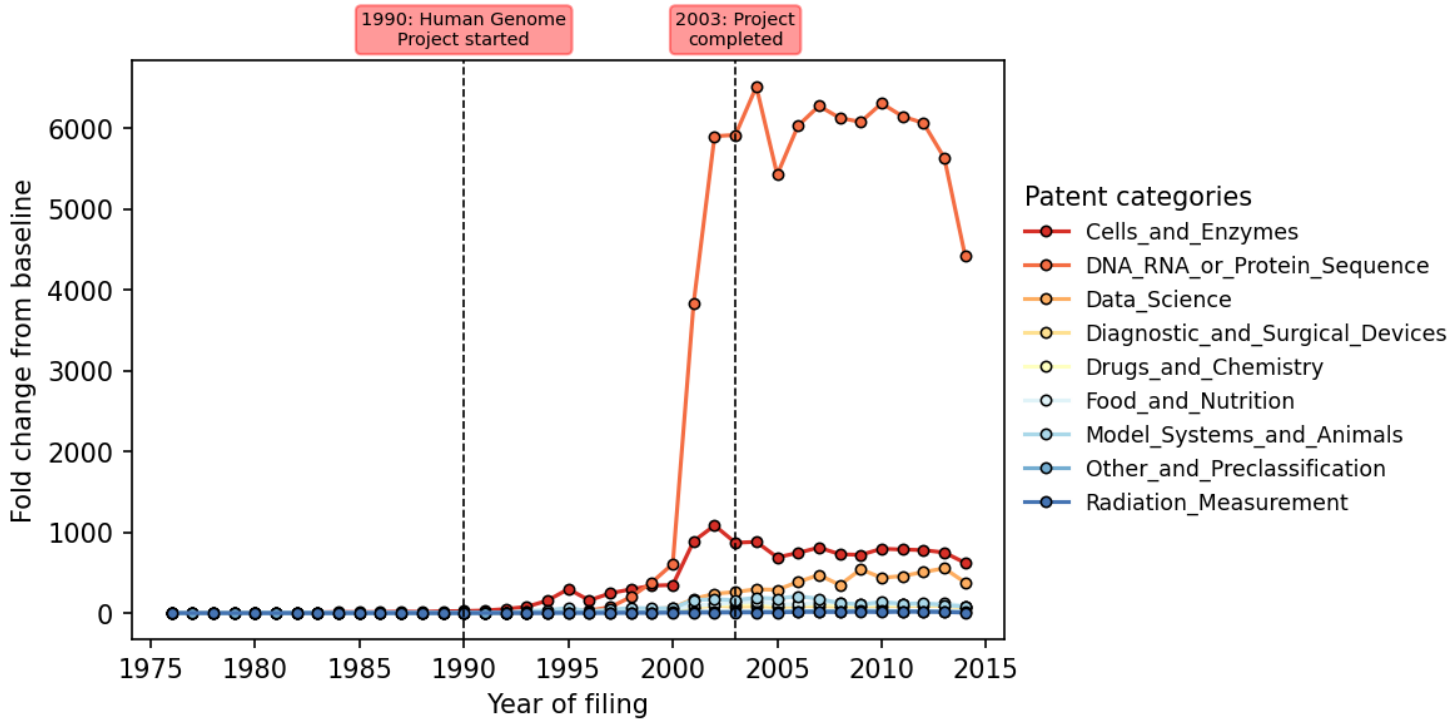
The Great Gene Grab

Will the frenzy of gene patenting drive innovation-or stifle medical advances?

By Antonio Regalado — September 1, 2000

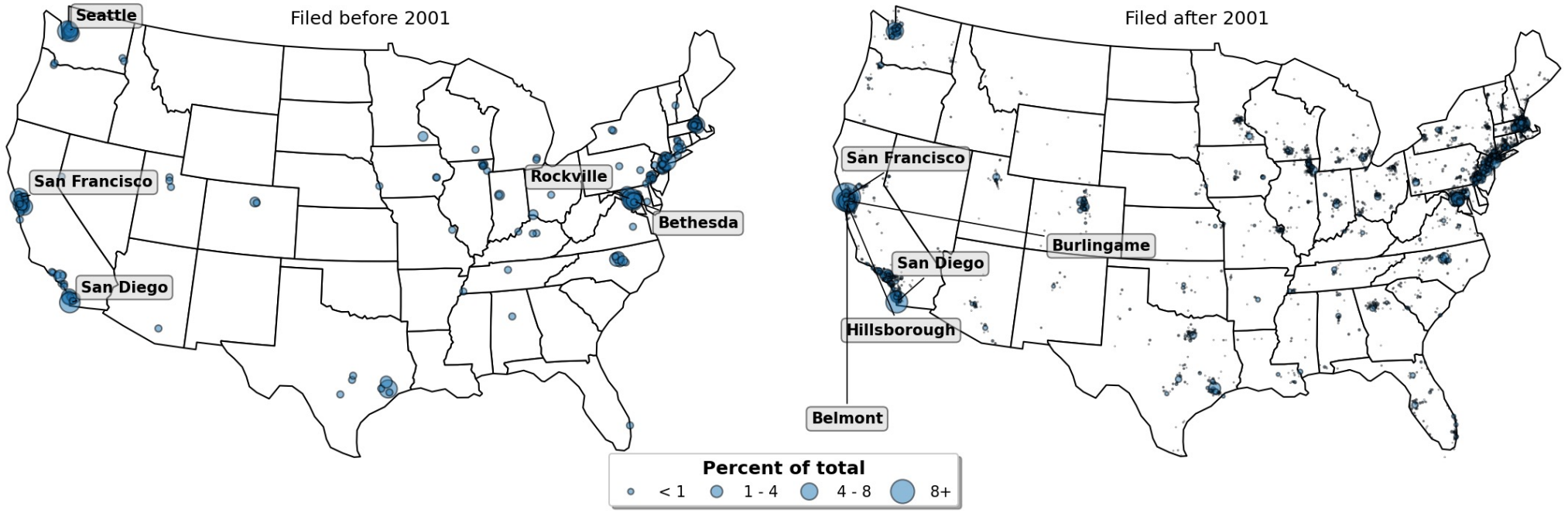
MIT Technology Review





Inventors on the earliest genomics-based applications came from biomedical hubs at the forefront of human genome sequencing

"Human Genome Sciences of Rockville, Md., which has been aggressively filing its claims since 1994 […]; it has patents pending on another 7,500 genes. Incyte Genomics of Palo Alto, Calif., tops the list with some 400 patented genes […]. Universities and government agencies are also involved: The University of California and the National Institutes of Health are among the most active gene patenters…"



- The location of inventors on genomics-based applications filed before 2001 reflect the dominance of a handful of cities at the forefront of the gene patent surge

Conclusions