Special Topic 1

Market for Patents

Market for ideas

→ Περίπου 1 στις 7 πατέντες πωλείται κατά την διάρκεια ζωής της.

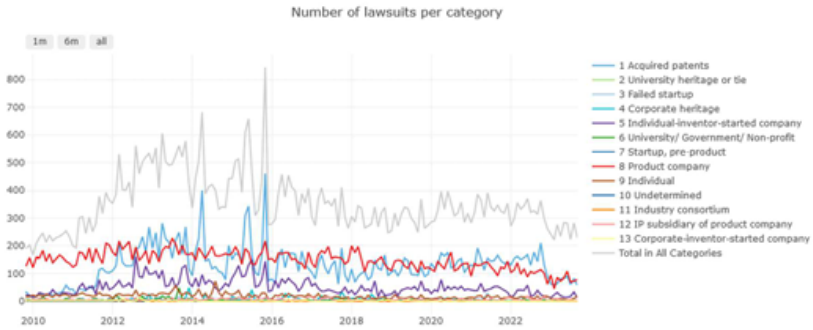
→ Μελέτες έχουν δείξει ότι η αγοραπωλησία πατεντών δίνει ώθηση στην οικονομική μεγέθυνση:

→ Αυτοί που τις πουλάνε έχουν χαρτοφυλάκια μακριά από τις συγκεκριμένες πατέντες

→ Αυτοί που τις αγοράζουν έχουν χαρτοφυλάκια σχετικά με τις συγκεκριμένες πατέντες

→ Αγοραστές με προηγούμενη τεχνολογική σύνδεση με τις εταιρείες-στόχους τους παράγουν περισσότερα διπλώματα ευρεσιτεχνίας στη συνέχεια.

Κίνδυνος: Non-Practicing Entities



https://npe.law.stanford.edu/

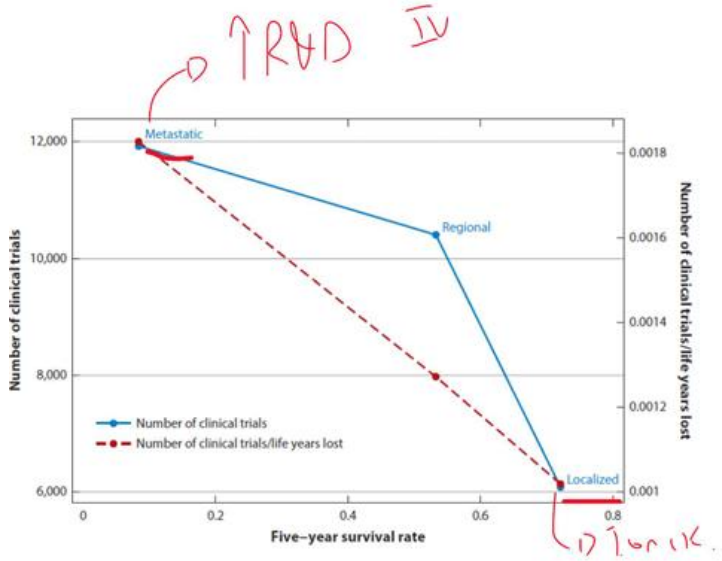
Μεγάλη βιβλιογραφία που εξετάζει αν οι NPEs είναι καλές ή όχι για την οικονομία και market-clearing.

- Downstream innovation drops in fields where patents have been acquired by NPEs.

Special Topic 2
Pharma (Mostly…) and Patent Length

- Before a drug can be sold to consumers, firms are required to document evidence from randomized clinical trials that their drug is safe and effective.
- However, private firms face strong economic and legal incentives to file for patent protection on candidate drug compounds very early in the drug discovery process, prior to starting clinical trials.

- The simple statistics of power calculations imply that clinical trials will need to be longer if the drug targets a patient population with a lower mortality rate.
- For example, it will take less time to document a statistically significant improvement in survival among late-stage breast cancer patients than it will among early-stage breast cancer patients.



- Metastatic cancer patients have a much lower 5-year survival rate (on the order of 10%) than regional (on the order of 50%) or localized (on the order of 70%) cancer patients, and metastatic patients are much more frequently targeted by clinical trials, being allowed to enroll in approximately 12,000 clinical trials, compared to approximately 10,000 for regional patients and approximately 6,000 for localized patients.

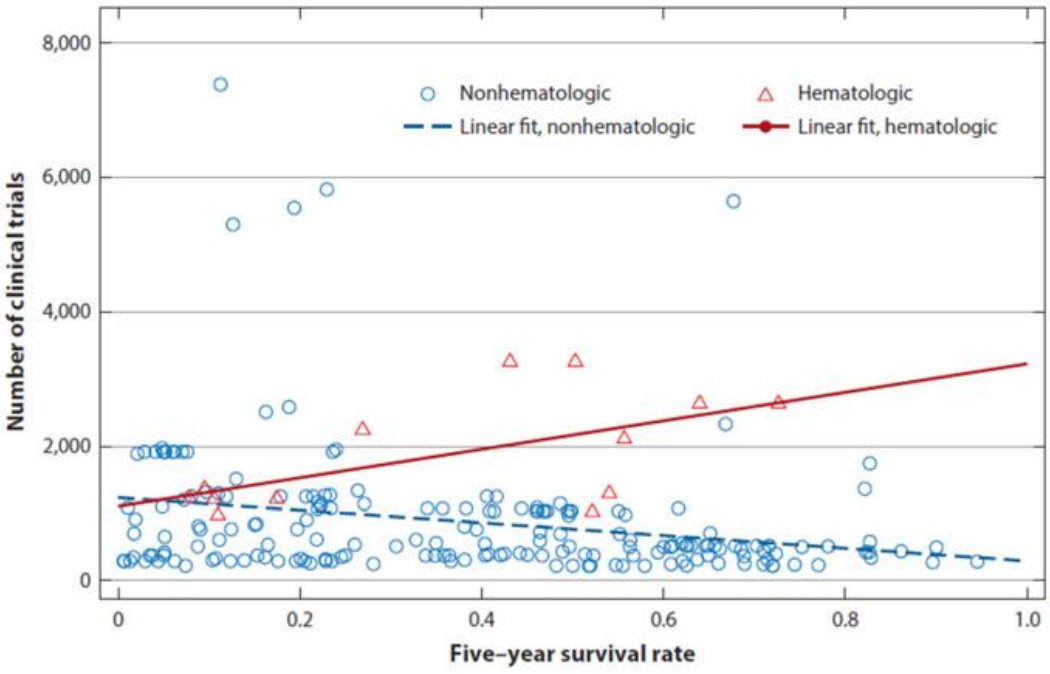
- To take advantage of the fact that, for some cancers, firms are not required to show that drug treatments improve survival but instead are allowed to show that drug treatments improve an intermediate or surrogate end point that is observed more quickly.

- As an example, clinical trial end points for leukemia treatments are generally based on blood cell counts and related bone marrow measures, rather than on observed survival outcomes.

- For cancers for which such surrogate end points are consistently and predictably allowed, we expect to see less of a negative relationship between commercialization lags and research investments.

- **Figure 4** contrasts hematologic cancers, which are essentially always approved on the basis of surrogate end points, with other cancers and documents that, among hematologic cancers, there is not a negative relationship between 5-year survival rates (our proxy for commercialization lags) and research investments.

- This fact is consistent with there being a causal relationship where, if firms are allowed to conduct shorter clinical trials for a given cancer, more trials will be conducted.



Data Exclusivity.

- Data exclusivity refers to the period during which clinical trial results, detailing the approved drug's toxicology and efficacy, cannot be used by generic entrants for subsequent marketing approval. As clinical trials are costly, data exclusivity creates entry barriers and hence is a source of market exclusivity independent of patent protection.

- Data exclusivity, in contrast, is granted for a fixed period upon the approval of a new drug for marketing. At market approval, a new drug enjoys concurrent protection from the remaining patent term and from the fixed period of data exclusivity.

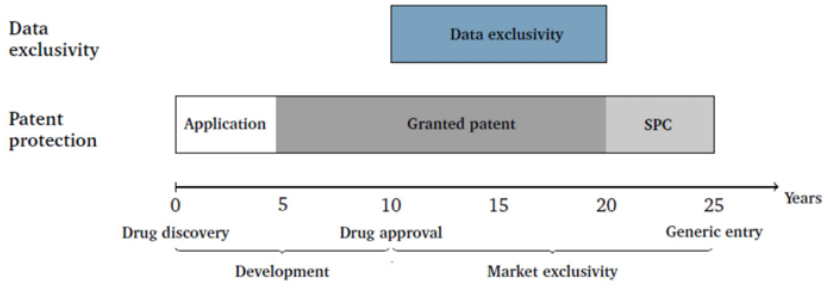
- Data exclusivity (or test data protection) prevents marketing authorization bodies from processing so-called abridged applications for marketing a generic drug before a certain number of years after the first marketing authorization for the originator product have elapsed.

- Only after a drug's protection via patents (and SPCs) has lapsed *and* in absence of data exclusivity, can generic companies file abridged applications.

- Abridged applications have the advantage that **they do not require the applicant to provide results of pre-clinical tests or clinical trials but only to demonstrate that a product is similar to the original drug**.

- If a drug still enjoys data exclusivity, however, generic entrants need to submit data from complete clinical trials. In light of the costs of conducting clinical trials, data exclusivity creates a significant barrier to entry for generic companies

Figure 1: Life cycle of pharmaceutical products



- For marketing authorization applications made from November 2005 onward, the period of data exclusivity in Europe was harmonized as eight years from the date of first authorization in Europe with an additional period of two years

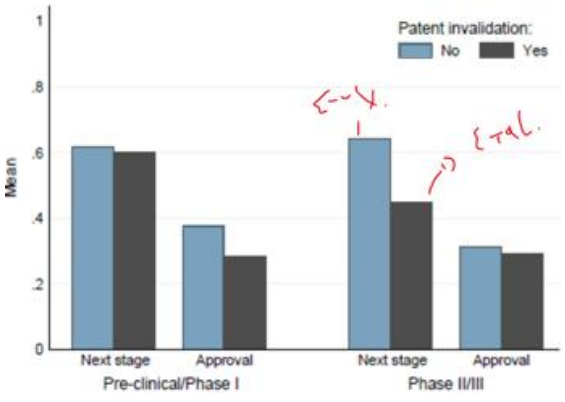
- Their study analyzed development histories of drugs for which underlying patents have been at risk of invalidation in opposition proceedings at the European Patent Office (EPO): when a patent is invalidated, data exclusivity becomes the sole source of market exclusivity.

- If the remaining patent term after drug approval exceeds the period of data exclusivity, patent invalidation will lead to a reduction in the overall duration of market exclusivity

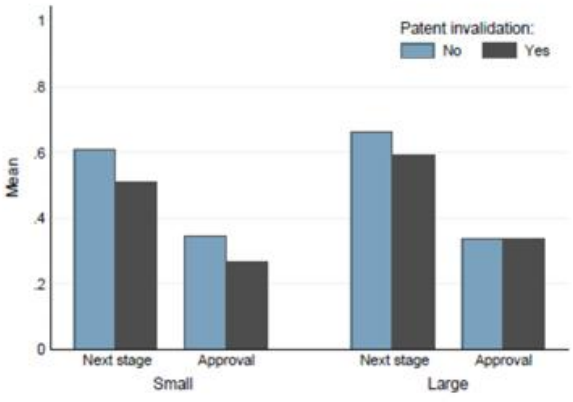
- **The loss of one year of market exclusivity lowers the likelihood of drug approval by about 3.5% relative to an unconditional approval rate of 30.5%.**

- This response to a loss in expected market exclusivity is **quite immediate: firms overwhelmingly abandon treated drug projects right after the patent is invalidated and do not pursue the next development phase**.

(a) By development stage



(b) By size of orginator



- At the same time, other observers have identified the **increasing acquisition of additional patents by brand-name drug makers, often of doubtful validity or applicability, in order to delay generic Competition**.

- This activity has been given the equally evocative label of "**evergreening**". Later issued, later expiring patents tend to be weaker, in the sense that a court is less likely to conclude that they are valid and infringed by a competing generic product.

- **They tend not to be patents that cover the active ingredient**—what we call "AI patents"—but patents pertaining to ancillary aspects of the drug. In the case of the blockbuster **antidepressant Paxil (paroxetine), for example, the branded drug maker secured 10 such patents.**

- The last expiring patent would, unless challenged, have blocked generic competition until 2019, compared to a successful challenge that secured generic approval and entry in 2003.

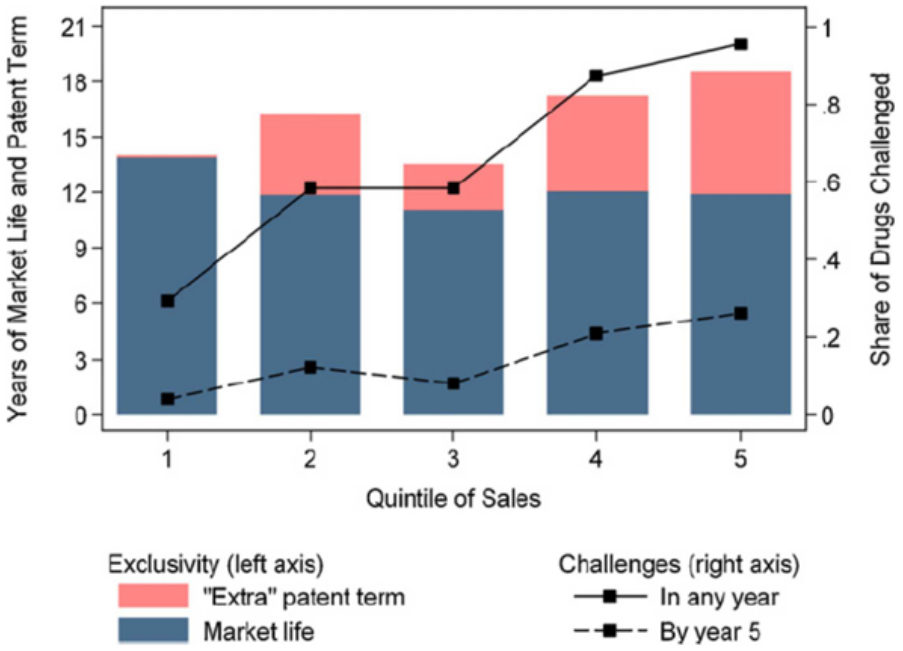
- Such patenting strategies are part of a larger set of tactics, which also include new formulations and other product line extensions, that can lengthen market exclusivity for therapies facing generic entry

- After a branded drug maker places a patented drug on the market**, a generic firm may seek to market a competing version of the same drug by filing an Abbreviated New Drug Application, or ANDA, with the FDA**.

- If the generic firm chooses not to challenge any branded drug patents, the FDA delays approval until all patents expire. A generic firm seeking pre-expiration entry files an ANDA asserting that one or more patents are invalid or not infringed by the proposed generic product.

- To encourage these challenges, **the Act provides a bounty to the first challenger, a period of 180 days of exclusivity** during which other generics cannot enter

- The likelihood that an ANDA includes a patent challenge increases sharply with drug sales. **While generic entrants challenge patents for just 29 percent of drugs in the bottom quintile of sales, they do so for 96 percent of drugs in the top quintile (p-value < .01).**



- Taken together, results show that challenges are playing a restorative role, ratcheting back the effective market life of drugs with large nominal patent terms to about 12 years.

- They are particularly likely for large sales drugs, as critics of these challenges warn. However, this appears to reflect that evergreening is also particularly likely for these drugs.

Special Topic 3: International Patent Options