Big pharma and monopoly capitalism: a long-term view

Giovanni Dosi[a] Luigi Marengo[b a] **Jacopo Staccioli**[c a] M. Enrica Virgillito[a c]

[a] *Institute of Economics, Scuola Superiore Sant'Anna, Pisa*

[b] *LUISS Guido Carli, Rome*

[c] *Department of Economic Policy, Università Cattolica del Sacro Cuore, Milan*

Università Cattolica del Sacro Cuore

Milan, 13th October, 2021

UNIVERSITÀ CATTOLICA del Sacro Cuore

Outline

1 Context and motivation

2 Data and methodology

3 Results

4 Conclusions

Context

- the pharmaceutical sector has been recognised as one of the most dependent on IPRs
- the reliance of pharma on patents descends from the very nature of its production activity
  - very low reproduction (i.e. *marginal*) costs
  - entry barriers almost exclusively related to knowledge generation
- patents ensure a temporary exclusive use of such knowledge which otherwise would be easily acquired by competitors
- knowledge embedded into pharmaceutical artefacts is often "discrete" and suitable to be summarised into patent *claims*

Relevant trends

1. low innovativeness of new therapeutical treatments since 1980s
   - evidence for new drugs approved in the US (Angell, 2005), EU (Motola et al., 2006; Van Luijn et al., 2010), Canada (Morgan et al., 2005)
2. low expenditure by "Big-Pharma" in R&D, especially regarding "basic research" (Light and Lexchin, 2005)
3. establishment of company business models favouring commercialisation and marketing to ensure sales, and acquisition of small innovative biotech companies to ensure research (Angell, 2005)
4. crucial role of public financing for *true* discoveries

   Cleary et al. (2018): NIH funding contributed to published research associated with 210 NMEs approved by the FDA between 2010 and 2016

   Moran et al. (2009): public financing responsible for 69% of research in neglected diseases

Motivation

- two distinctive roles of intellectual property rights (IPRs) in the economic literature

  incentive view: IPRs as incentives to undertake innovative activities
  - necessary evil to drive the "unbound Prometheus" of innovation in capitalist societies

  opportunity view: IPRs as forms of appropriation (i.e. obstacles to innovation diffusion)
  - mechanism of generation of (possibly) unproductive rents
- both streams of literature recognise patents as creators of intellectual monopolies

A word of caution

- IPRs are not a guarantee of innovative activities

  Light and Lexchin (2012): *"Innovation crisis in pharma"*

In a nutshell

Research question

- are IPR institutions meant to foster innovative activity in the pharmaceutical sector, or conversely to secure appropriation and profitability?

- technological- and firm-level analysis of the pharma sector under a long-term perspective
- identify patterns in patenting activities
  - patenting trends in pharma and underlying technological classification
  - distinguish between *process* and *product* innovations (i.e. FDA approved)
  - characterise patent *quality* by means of a number of indicators
  - identify patents whose innovative content is financed by government agencies
  - measure the extent of appropriability by studying *extended families*
- firm-level analysis of corporate performance for top patenting firms

Outline

1 Context and motivation

2 Data and methodology

3 Results

4 Conclusions

Definitions and data sources

Orange Book: drug products approved on the basis of safety and effectiveness by the FDA and related patent and exclusivity information

WIPO field: classification of patents into 35 broad technical fields (16 = `Pharmaceuticals`)

PATSTAT: bibliographical and legal event patent data from leading industrialised and developing countries

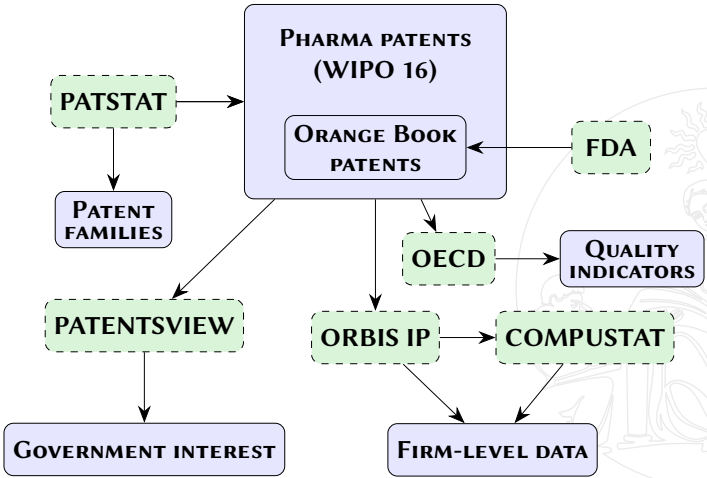
PatentsView: additional data on government interest statements on USPTO patents

OECD: patent quality indicators

ORBIS IP: matched firm-patent data (10-year rolling window of firm balance-sheet data)

Compustat: firms' fundamentals (balance-sheet data) since 1960

Flowchart


Pharma patents (WIPO 16)
PATSTAT
Orange Book patents
FDA
Patent families
OECD
Quality indicators
PATENTSVIEW
ORBIS IP
COMPUSTAT
Government interest
Firm-level data

Outline

1 Context and motivation

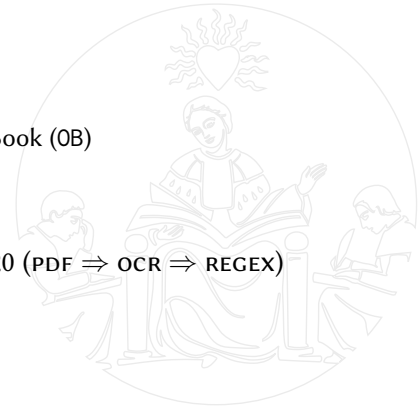
2 Data and methodology

3 **Results**

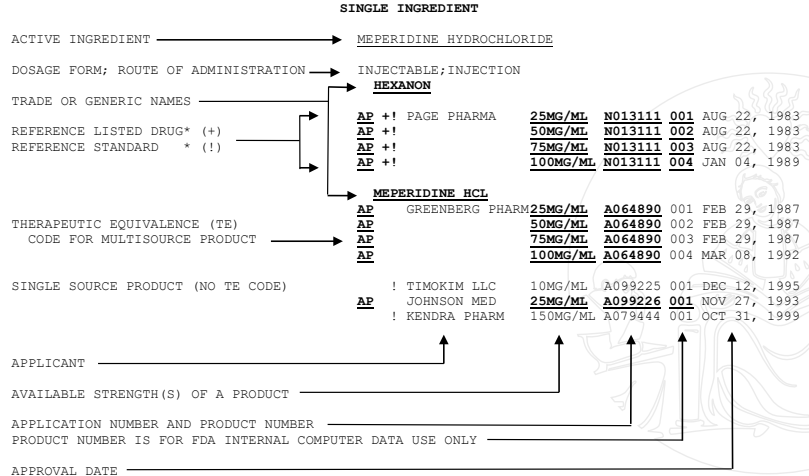
4 Conclusions

Summary statistics

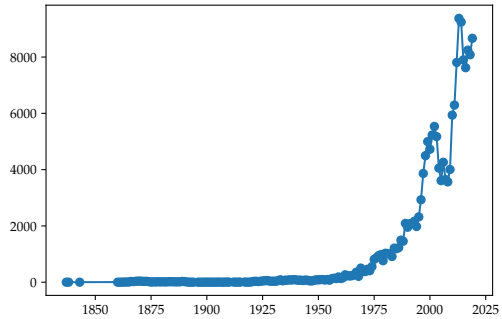
- there exist
  - 177,040 pharma patents (W16) since 1837
  - of which 171,743 ($\approx$ 97%) since 1968
  - of which 5,655 ($\approx$ 3.3%) are mentioned in the Orange Book (OB)
- years refer to the publication date of first grant
- OB takes into account all editions between 1985 and 2020 (PDF $\Rightarrow$ OCR $\Rightarrow$ REGEX)



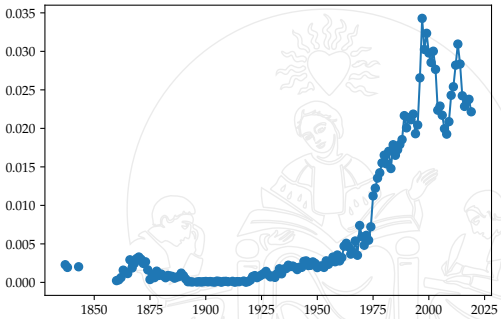
Orange Book excerpt



Long-run patenting activities in pharma (1837–2019)

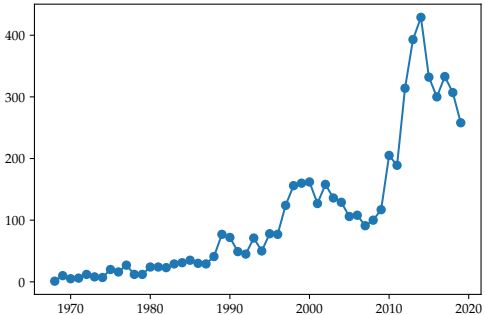


Absolute number of W16 patents

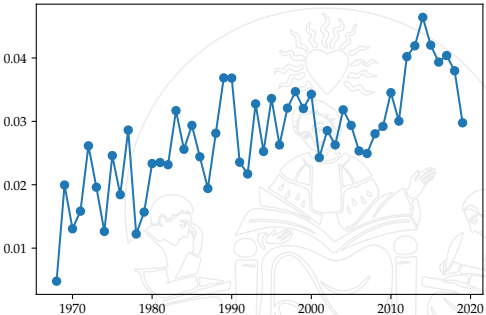


Fraction of W16 over all patents

Patents of drugs approved by the FDA (1968–2019)



Absolute number of OB patents



Fraction of OB patents over W16 patents

Technological classification of W16 and OB patents

CPC breakdown of W16 patents

code	count	definition
A61K	598,309	Preparations for medical…
C07D	126,946	Heterocyclic compounds
C07K	80,802	Peptides
C12N	55,074	Microorganisms or enzymes
Y10S	38,854	Former USPC classes
C07C	23,419	Acyclic/Carbocyclic compounds
G01N	18,659	Investigating/analysing materials…
A61L	17,036	Methods/apparatus for sterilising…
Y02A	15,033	Adaptation to climate change
A23L	9,346	Food, foodstuffs or beverages

CPC breakdown of OB patents

code	count	definition
A61K	34,041	Preparations for medical…
C07D	2,831	Heterocyclic compounds
Y10S	1,655	Former USPC classes
A61P	663	Specific therapeutic activity…
C07C	591	Acyclic/Carbocyclic compounds
A61M	509	Devices for introducing media…
C07K	408	Peptides
G01N	398	Investigating/analysing materials…
Y02A	370	Adaptation to climate change
A61J	239	Containers for medical…

NB: a patent can be assigned multiple CPC codes at once

Patent quality indicators

backward citations: help estimate the degree of novelty

- many backward citations may signal an *incremental* innovation

NPL citations: measure of the contribution of basic science to industrial technology

- same considerations as for backward citations

number of claims: determines the boundaries of patent protection (breadth)

- the more claims, the larger the protected scope

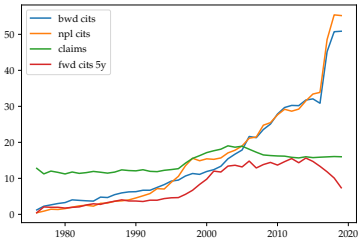
forward citations: signal technological importance of the patent for the development of subsequent technologies

- suffer from truncation effect

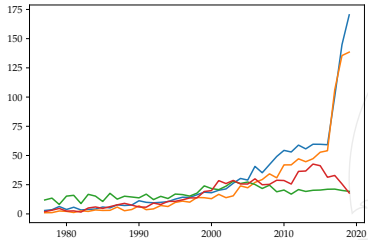
breakthrough: top 1% of most (forwardly) cited patents

- suffer from truncation effect

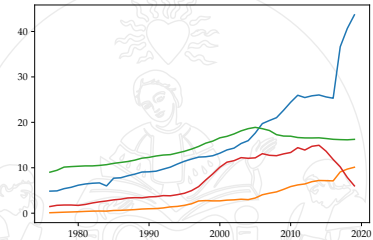
Patent quality indicators (cont'd)



W16 averages

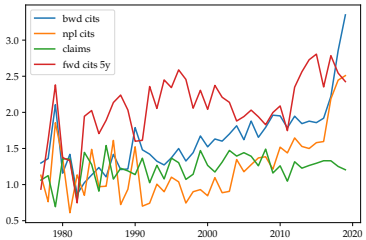


OB averages

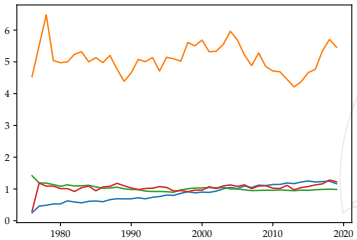


All patents averages

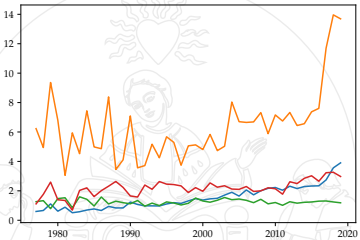
Patent quality indicators (cont'd)



Ratio OB/W16

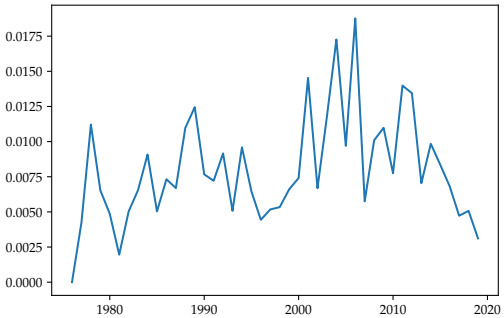


Ratio W16/all patents

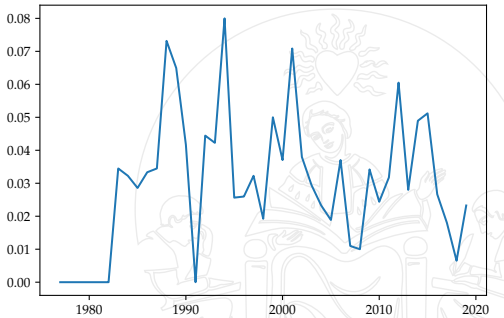


Ratio OB/all patents

Breakthrough patents



Share of W16 breakthrough patents



Share of OB breakthrough patents

Government interest

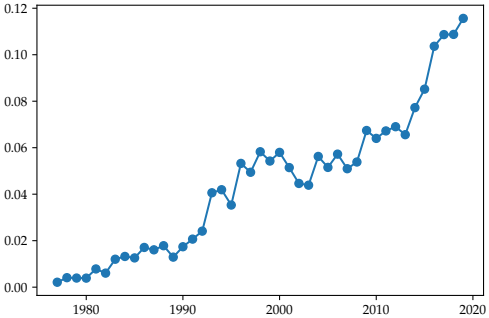
W16 patents by government agency interest

agency	count
Nat. Inst. of Health	10,661
Nat. Cancer Inst.	823
US Government	713
Dep. of Health and Human Services	652
Nat. Science Foundation	537
Dep. of Defense	380
Army	369
N. I. of Allergy and Infectious Diseases	335
Public Health Service	308
Dep. of Energy	276

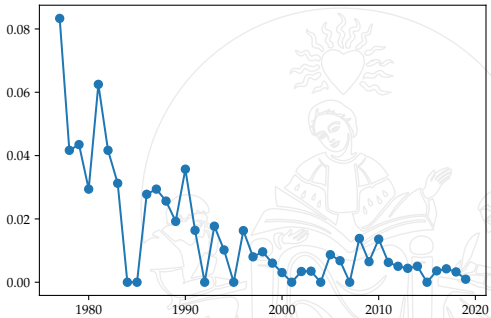
OB patents by government agency interest

agency	count
Nat. Inst. of Health	47
Dep. of Health and Human Services	16
National Cancer Inst.	10
US Government	4
Public Health Service	4
Dep. of Veterans Affairs	3
Army	3
Nat. Inst. on Aging	2
Nat. Inst. of Mental Health	2
Nat. Inst. of General Medical Sciences	2

Government interest (cont'd)



Share of W16 patents with government interest



Share of OB patents with government interest

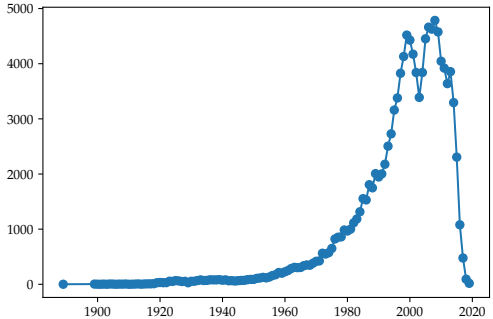
Extended patent families

INPADOC families

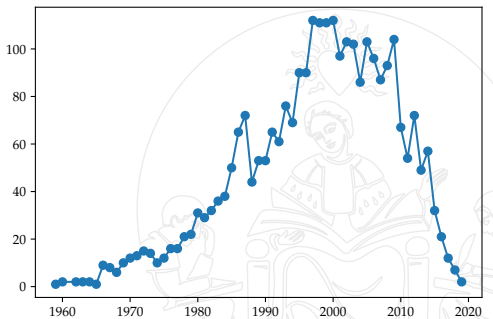
An extended patent family is a collection of patent documents covering a technology. The technical content covered by the applications is similar, but not necessarily the same. Members of an extended patent family will have at least one priority in common with at least one other member – either directly or indirectly. [EPO definition]

- extended families consolidate both direct and indirect priority links between patents
- it is possible to find two patent documents with no priority in common, but which are indirectly related because they both share at least one priority with a third application
- extended patent families provide useful information to understand applicant strategies to extend patent protection, cumulativeness of inventions and patent thickets (Martinez, 2011)

Extended patent families (cont'd)

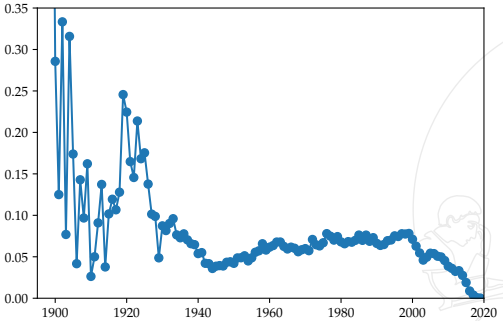


W16 newborn extended families by year



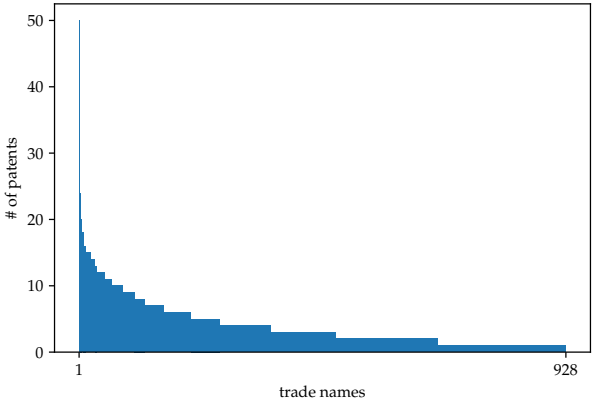
OB newborn extended families by year

Extended patent families (cont'd)



Ratio over stock of newborn W16 extended families

OB patents concentration (2021)



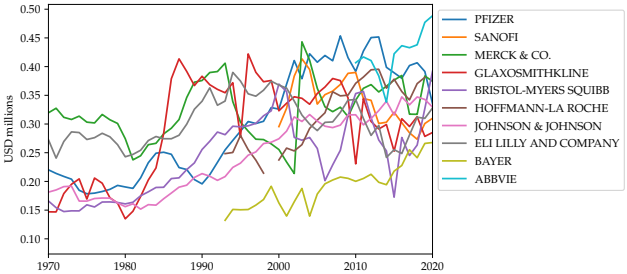
Distribution of OB patents by trade name

Trade name	# patents
VASCEPA	50
IMBRUVICA	31
HYSINGLA ER	24
ESBRIET	21
GATTEX KIT	20
XIFAXAN	19
VIEKIRA XR	18
SYMDEKO	18
VYVANSE	18
ORKAMBI	16
OSMOLEX ER	16
TRIKAFTA	16
ENVARSUS XR	16
XTAMPZA ER	15
DSUVIA	15

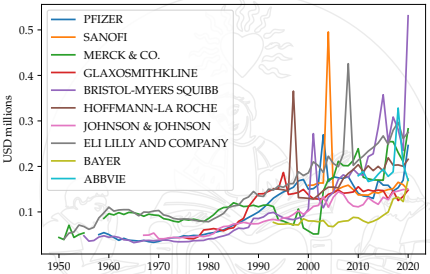
Firm level analysis – top firms and stock of patents

W16			OB		
Company	# patents	# patents / last sales (m$)	Company	# patents	# patents / last sales (m$)
Pfizer	4,228	0.1	Pfizer	206	0.0049
Sanofi	2,407	0.053	Ionis	205	0.2811
Merck	2,276	0.047	AbbVie	197	0.0043
GlaxoSmithKline	2,250	0.049	Johnson & Johnson	175	0.0021
Bristol-Myers Squibb	2,152	0.051	Merck	131	0.0027
Roche	2,116	0.032	GlaxoSmithKline	130	0.0028
Johnson & Johnson	1,858	0.022	Novartis	128	0.0026
Eli Lilly	1,832	0.075	Eli Lilly	122	0.0050
Bayer	1,699	0.034	Bristol-Myers Squibb	120	0.0028
AbbVie	1,411	0.031	AstraZeneca	119	0.0044

Firm level analysis – profitability and R&D expenditure

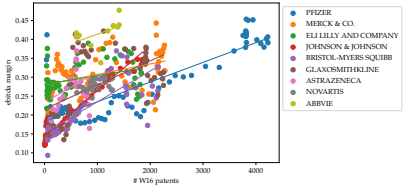


EBITDA margin of top 10 firms

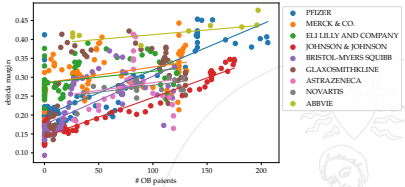


R&D margin of top 10 firms

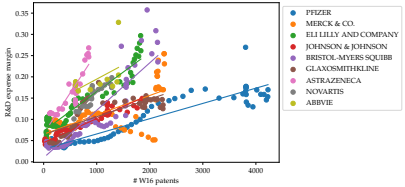
Firm level analysis – profitability and R&D expenditure (cont'd)



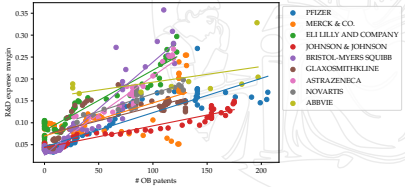
EBITDA margin and #W16 patents



EBITDA margin and #OB patents

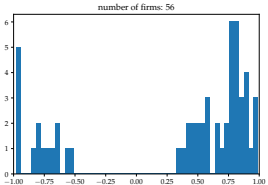


R&D margin and #W16 patents

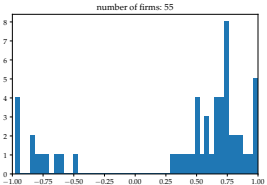


R&D margin and #OB patents

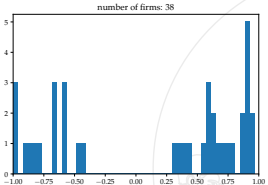
Firm level analysis – profitability and R&D expenditure (cont'd)



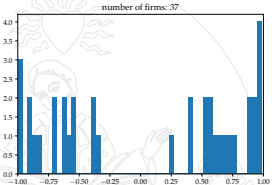
EBITDA margin and #W16 patents ρ distribution



EBITDA margin and #OB patents ρ distribution



R&D margin and #W16 patents ρ distribution



R&D margin and #OB patents ρ distribution

Outline

1 Context and motivation

2 Data and methodology

3 Results

4 **Conclusions**

Wrap-up

Findings

- increasing reliance on prior art and scientific knowledge
- low and decreasing amount of breakthrough innovations
- concentration of patenting into a few trade names
- decreasing government support, concentrated in few innovations
- fewer families with increasing size
- converging firm profit margins but diverging R&D margins

Discussion

- the explosion in patenting activity does *not* map into a corresponding explosion in innovative activity
- pharma patents have increasingly constituted legal barriers to protect intellectual monopolies rather than an incentive and a reward to innovative efforts

Thank you very much!

jacopo.staccioli@unicatt.it

this presentation is available at www.staccioli.org

Jacopo Staccioli gratefully acknowledges support by the PRIN project 201799ZJSN: *"Technological change, industry evolution, and employment dynamics"*