

# TENSIONS IN BIOMEDICINE

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## PUBLIC SCIENCE STRATEGIES TOWARD THE PATENTABILITY OF GENOMIC RESEARCH TOOLS

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### INTRODUCTION

**Aim:** contribute to the understanding of the institutional realignment in the innovation systems brought about by changes in the intellectual property (IP) regime that enabled the expansion of patent protection to new areas (e.g. living organisms) and new actors (e.g. universities)

These changes led to a proliferation of patents on inventions that could be defined as “research tools”

⇒ tangible or informational inputs whose primary usefulness is as tools for research rather than as products themselves

Research tools have been the flashpoint of IP tensions that took place over the last three decades

### THEORETICAL AND EMPIRICAL PUZZLES

**Two interrelated theoretical concerns:**

⇒ Innovation will be hampered due to high transaction costs on the circulation of knowledge (e.g. David and Foray, 1994; Heller and Eisenberg, 1998);

⇒ Market incentives will erode the norms of “open science”, thus threatening the very prerequisite of effective knowledge production (Dasgupta and David, 1994).

**Theoretical models claiming the opposite:**

⇒ Patents on downstream research results stimulate innovation and technology transfer (e.g. Kitch, 2003; Epstein, 2003)

⇒ “Open science” norms can co-exist in a state of “creative tension” with market institutions (e.g. Etzkowitz et al. 2000)

Thus, there is substantial theoretical disagreement on whether the hybridization of “open science” and market incentives will increase or decrease the efficiency of the innovation system

**Empirical studies** of the effects of patents have also produced contrasting results:

⇒ Little evidence to support the argument that university patents facilitate knowledge transfer from the public to the private sector (Mowery et al., 2001; Geuna and Nesta, 2006)

⇒ Surveys and bibliometrical studies provided some, although modest, evidence of the negative effect of patents on the propensity of scientists to disclose and share research results (e.g. Blumenthal et al., 1997 and 2005; Murray and Stern, 2005; Walsh et al., 2005 and 2007)

It is outside of the scope of this study to evaluate the actual impact of different IP regimes on the dissemination of research tools and on the innovation process. The aim is to contribute with new qualitative insights that

can shed more light on the reasons behind the choice of different IP strategies and the problems to which these choices point

### METHODS

**Case-study approach**, with a nested form of research design

**Biomedicine** was selected because the phenomenon of convergence of science and technology has been very strong there and problems related to patents on research tools particularly accentuated

Three biomedical subfields (human genome sequencing, stem cell research and synthetic biology) where IP tensions have been pronounced but that also present differences with respect to their innovative contexts

**Data sources:** interviews, written histories of major biotechnological developments, various documents and patenting and citation data

### RESULTS

(1) IP responses of the public biomedical research community have been heterogeneous. Depending on how close they are to “open science” or to market institutions, they can be grouped in 4 categories:

(i) **ROLL-BACK STRATEGIES**

- categorical opposition
- challenging patents
- pre-emptive publication

(ii) **“BUSINESS AS USUAL”**

- ignoring patents
- ignoring IP incentives

(iii) **HYBRID STRATEGIES**

- open source biotechnology
- publicly minded patenting and licensing

(iv) **MARKET ACCEPTANCE**

- broad patenting of upstream inventions
- enforcing patents against academics and firms
- licensing exclusively enabling research tools
- broadly relinquishing IP rights in exchange of private funding

(2) The incentives in favor of patenting are strong and they generally do not clash with the primary academic incentive to publish

(3) However, patenting also entails costs and the individuals and organizations that profit from patents are a minority

(4) Complacency towards the patent system is reinforced by: (i) necessity to complement public research funds with other sources such as licensing income (ii) large scope for unnoticed infringement of patents at research stage (iii) synergy of academia and biotech firms whose business models are highly reliant on patents

(iv) unpredictability of the patent regime, making it difficult to estimate whether the freedom to operate in certain research fields can be effectively defended by means other than patents

(5) Technology transfer officers and patent attorneys play a big role in shaping IP decisions

(6) Some IP responses point at two types of problems in the patent system: (i) problems related to patents *per se*, e.g. hampered access to research tools due to aggressively enforced patents (ii) problems related to the lack of integration and learning because of secrecy and fragmentation of research efforts

(7) When patent-related problems appear rank-and-file public researchers are usually passive in reacting to them. Action mainly comes from institutional actors, like the NIH, or even from actors outside of the public research system

(8) Research tools are a broad category. Research tools that cause most tensions are basic biological information whose utility lies in databases and techniques or model organisms that are enabling for multiple research agendas

(9) Although often presented as a publicly-minded practice, patenting of research tools for the purpose of non-exclusive licensing cannot be justified in terms of technology transfer

(10) The problem of academic patenting can hardly be analyzed in separation to the issue of industrial funding of academic research (“contamination” problem)

### CONCLUSION

Public biomedical scientists operate in a hybrid institutional setting. This is exemplified by the co-existence of different and sometimes conflicting IP strategies with respect to research tools

Currently it seems that academics are by and large able to get the best of the two worlds: ignore patents and rely on open science institutions when they act as users of patented inventions, while play according to the rules of the market when producing commercially interesting research results

However, some of the analyzed IP responses point at dysfunctions in the patent regime

One should also bear in mind that the lack of statistical evidence of major patent-related problems is not evidence of the lack of problems

Since there are few ways to quantitatively assess whether research tools are being optimally distributed in the biomedical innovation system, it is important to scrutinize the reactions of the research community to the developments in the patent system and infer some policy lessons from it