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The characteristics and impacts of scientific publications in biotechnology research referenced in standards

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ABSTRACT

The integration of research papers in standards has not yet been addressed using quantitative approaches. This paper investigates the characteristics of research articles on biotechnology related to standards. The analysis is based on a study of standards produced by the standardization consortia *BioSharing*. Research, i.e. scientific articles, included in standards is more likely to lead to follow-up research and diffusion over a longer period of time than comparable scientific publications measured by the number of citations relative to most-related articles. In addition, research relying on scientific publications referenced in standards is more valuable for the research progress.

1. Introduction

The fundamental purpose of standards is to enable interoperability and coordination. Standards can arguably limit creativity in the research and innovation process, but recent studies have established that the potential drawbacks of standards are outweighed by the benefits (Allen and Sriram, 2000; Baldwin and Clark, 2000; Blind, 2004; Tassey, 2000; Temple et al., 2005). Standards reduce the costs of research and innovation by narrowing the set of research and technology opportunities while promoting interdependent research and innovation tasks (Baldwin and Clark, 2000). With regard to the research and innovation process as a whole, standardization is regarded as a catalyst which facilitates technology transfers (Bozeman, 2000), i.e. standards promote the diffusion of technology, as part of the innovation system (Besen and Farrell, 1994; Tassey, 2000). This matter fosters and creates value for the research and development (R&D) process, as well as other investments in knowledge creation (Temple et al., 2005). Overall, standards are a source of relevant information to actors within an innovation system. This implies that the research, as well as the standards community, constantly monitors, alerts and matches standardization efforts. On the one hand, the research community pulls information for research and pushes information on standardization. On the other hand, the standards community pulls information for standardization processes and provides input for research. In order to understand these interdependencies, we need to define the properties of standards in research, as well as the relation between research and standardization.

To date, literature has differentiated between three categories of standards: formal standards, consortia standards and de-facto standards. Formal standards are established by standard-setting organizations (SSOs), such as the International Organization for Standardization (ISO) or the European Committee for Standardization (CEN) (e.g. Büthe and Mattli, 2011), and follow a strict procedure, which is transparent to stakeholders and guarantees a high level of consensus, but can also be tedious and costly. Consortia standards[1] are those that evolve from an exclusive group or arrangement (e.g. Blind and Gauch, 2008; Leiponen, 2008; Delcamp and Leiponen, 2014). Consequently, the interests of all stakeholders are not necessarily considered, resulting in lower overall levels of consensus within a given industry or society as a whole. However, consortia standards have faster development cycles and greater general flexibility. Finally, coordination can be achieved through competition, leading to de-facto standards (e.g. Gallagher, 2007; Schilling, 2002; Shapiro and Varian, 1999; Shurmer and Swann, 1995; Suarez, 2004).

Interoperability and the coordination of research activities are of particular importance to industries, such as biotechnology, which rely on varying disciplines, technologies and skills (Gillis, 2003). Especially due to the vast increases in data, the research community has

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[1] See Hawkins (1999) for a first definition of standardization consortia.

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recognized the need for efficient standards for several years (Wang et al., 2005; Almeida et al., 2006; Quackenbush, 2006). In addition, research labs typically have document systems with SOPs (standard operating procedures), which can be understood as "best practices", ex. the use of the anatomy of the fruit fly as a semantic standard. However, there are currently no existing international standards published by SSOs, such as ISO, on biotechnology. At the European level, some standards have been published by CEN, but are limited to large-scale production, performance indicators and criteria for reaction vessels.

However, industry experts have indicated that more informal standards may be better suited to the needs of biotechnology, due to the dynamic and cooperative nature of the industry and that traditional patterns of standardization do not work (Rai, 2010). in addition, the development of more informal standards will be essential, as regulatory requirements evolve, for example in response to the imposition of increased requirements for the market entry of new products by authorities, such as the *US Food and Drug Administration* (FDA) and the *European Medicines Agency* (EMA). The success of less formal standards can already be observed in medical biotechnology, where several de-facto standards have evolved. The *World Health Organization* (WHO) affects standardization in medical biotechnology by publishing the *WHO Technical Report Series* (TRS), as well as by providing reference preparations, which serve as measurement standards. Furthermore, some consortia have evolved in medical biotechnology supporting the process of drug developments, e.g. the *CMC-Biotech Working Group* (CMC-BWG) and the *Predictive Safety Testing Consortium* (PSTC). CMC-BWG publishes practitioner guidelines, which support the standardization of quality requirements and PSTC assists the standardization of biomarkers. Noticeable across the whole biotechnology industry is the establishment of certain technological platforms, which can also be seen as de-facto standards, e.g. host organisms such as *Escherichia coli* and *Chinese Hamster Ovary Cells*. Concepts of the regulatory authorities, such as *Good Manufacturing Practices* (GMP) and *Quality by Design* (QbD), also diffuse into the whole industry, even outside of the regulatory framework.

As standardization at the beginning of the innovation process, particularly in basic research, has received little attention, this paper investigates the integration of research results into standards. The aim of the study is to gain a better understanding of the role of standardization along the research process. We will show that the scientific publications referenced in standards applied in biotechnology receive both significantly more follow-up citations and for a longer period of time, compared to similar publications grouped in a comparison sample. In addition, the next generation of articles referencing the scientific publications integrated into standards is of higher quality than a second comparison sample of articles. The results of our study can be transferred to other technologies and eventually reveal an enduring and effective instrument to foster innovation at early research stages via standardization activities.

In the past, research in standardization has often focused on compatibility of new products from a market perspective (Farrell and Saloner, 1985). Most attention has been paid to formal standards by SSO, as well as information and communications technology markets (Simcoe et al., 2009; Simcoe, 2012). However, few studies have investigated the interdependencies between standardization and research (Blind and Gauch, 2009; Zi and Blind, 2015). Therefore, we investigate the interplay of research and standards – as a specific and rather new form of science-technology relationship in biotechnology (see Subramanian and Soh, 2010 for more traditional links) – using the particular example of *BioSharing*, a standardization consortia active in biotechnology. Our paper contributes to this literature by investigating the implications of including research results into standards by referencing scientific publications for the first time. In contrast to standards in information and communication technologies, which reference so called standard-essential patents, this phenomenon is rather unusual – despite the high relevance of patents (e.g. Messeni Petruzzelli et al., 2015) – especially for biotechnology and many other technologies (ECSIP, 2014). On the one hand, we expand the empirical analyses of referencing patents into standards initiated by the seminal contribution by Rysman and Simcoe (2008), followed by a number of further studies referencing scientific publications in standards. On the other hand, we are not replicating their approach, rather we identify articles related to standards independent from a particular point in time. Moreover, we go one step further by looking at the impact of using scientific publications referenced in standards on follow-up research. The results of our analysis enhance our understanding of the role of standardization in the research phase. Furthermore, our study derives implications not only for SSOs and policy makers, but also and perhaps more importantly, the research community.

The remainder of the paper is organized as follows: Section 2 derives our hypotheses on the characteristics of scientific publications integrated in standards. In Section 3, we present our data, i.e. standards in biotechnology research and our methodology. The results of our empirical investigation, including the derivation of the implications of our results, the limitations of our research and proposals for future research, are then presented and discussed in Section 4. Section 5 summarizes and concludes this piece and provides suggestions for future activities.

2. Hypotheses

As previously noted, standardization increases interoperability and decreases coordination costs. However, standardization potentially limits variety and requires costly efforts to set up an efficient standardization process. The question arises as to how the tradeoff between the benefits and the costs of standards shift depending on the differentiation between basic research and more applied activities. For the purpose of our research, basic research is defined as "experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena and observable facts" and applied research as work that is "undertaken in order to acquire new knowledge directed primarily towards a specific practical aim or objective" (OECD, 2002).

Existing research on standards suggests that formal standards play an increasing role as a source of information when R&D activities are market-oriented (Blind and Gauch, 2009). In line with these findings, Zi and Blind (2015) have shown that researchers involved in formal standardization publish less or in lower ranked journals, whereas scientists focusing on applied research, i.e. publishing less due to confidential collaborations with industry or in more applied journals, are not impacted by this tradeoff.

In spite of the aforementioned arguments, there is also a line of argument in favor of standardization in early research phases. In a related research field, it is established that patenting researchers are more successful in publishing (Agrawal and Henderson, 2002; Van Looy et al., 2006; Czarnitzki et al., 2007, 2009; Stephan et al., 2007). Analogous to the field of patents, standardization activities arguably circulate relevant knowledge and are beneficial for those who seek knowledge relevant to current research challenges. However, in contrast to the positive relationship between publishing and patenting, the incentives for an involvement in standardization might be reduced by the threat of free-riders (Cabral and Salant, 2014).

Therefore, the role of standardization in research is an open empirical question, which we try to answer on the basis of the data available via *BioSharing*. To our knowledge, the only existing qualitative empirical evidence for the important role of different types of standards both for applied and basic researchers in nanotechnology is provided by Blind and Gauch (2009).

The general positive impacts of standards are valid for the production of knowledge, i.e. research, not only in process innovation in the sense of productivity (Acemoglu et al., 2012; Blind and Jungmittag, 2008), but also on product innovation (e.g. Lim and Prakash, 2014). From the general definition of terms, i.e. semantic standards, we can derive that standards mitigate misconceptions in the communication