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Genomics as a new research regime? Evidence from the Netherlands

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ABSTRACT

Social scientists commenting on developments in the life sciences have suggested that the rise of genomics in the field of human genetics does not only involve a shift in the research agenda from relatively rare monogenetic disorders to multifactorial, common diseases, but also involves a transformation on the institutional level of research regimes. In the (Dutch) genomics landscape, in which such research regimes are embedded, increasingly dominant values and objectives exert pressures on researchers to collaborate with industrial partners and to valorize knowledge results. To assess how these pressures are actually taken up and transforming research regimes, a multi-level approach is developed and applied in two case studies in which regimes are characterized in terms of the identities of actors, the knowledge and products exchanged and the principles that coordinate these exchanges. We describe the dominant regime in a typical genomics research field (Alzheimer's disease) as compared to the regime in a typical clinical genetics research field (Duchenne Muscular Dystrophy) and show whether and how these research regimes are transforming in response to landscape pressures. The analysis shows that the AD regime has not been transformed against the background of changing landscape expectations and that the DMD regime did change, but under the condition of maturation. Developments on the level of genomics research regimes follow a dynamics of their own more than reflecting a changing genomics landscape.

1. Introduction

Does genomics represent a new type of biomedical research system? This is the question that Martin (2001) raised to draw attention to changing arrangements in networks of actors involved in the production, use and commercial exploitation of human genetic data. Historically, biomedical knowledge production occurred in biochemistry-based networks of basic scientists, clinical researchers, pharmaceutical companies and patient groups. Since the 1980s, the development of biological drugs and gene-based technologies have brought molecular biologists, geneticists and newly formed biotechnology companies into the center of the biomedical knowledge production system. Until about 2000, however, these developments took place in strongly aligned networks of laboratories and clinics, with close cooperation between researchers and clinicians and a strong focus on the demands of patients and patients' families (Hopkins, 2004, 2006a; Rabeharisoa, 2003; Callon and Rabeharisoa, 2008). In the Netherlands, for example, regional clinical genetics centers played an important part as nodes linking genetic laboratory research and diagnosis with clinical patient care and counseling (Nelis, 1998; Stemerding, 1993; Boon, 2008). Characteristic for this early genetic research system were the absence of large firms as leading actors, informal self-regulation, ad-hoc funding, and bottom-up initiatives. Hence, this research system can be conceived as being governed by an 'internal regime' (Hopkins, 2009).

In contrast, Hopkins (2009) argues that in recent years, research in medical genomics is more and more governed by an 'external regime' including laws, regulations, social norms and involving wider groups, like biotechnology companies, policy makers and funding agencies. One of the most prominent organizational features of this new type of research system is the accommodation and intensification of university–industry linkages in several respects. Firstly, various technology transfer initiatives and the creation of a large number of academic spin-offs reflect the increased collaboration in terms of knowledge production and uptake. Secondly, companies specializing in research tool development and contract genotyping services exploit the commercial opportunities offered by the increased use of large datasets. Thirdly, while genetic databases are usually funded by the state and set up by academic researchers in collaboration with clinical actors, biotechnology firms and pharmaceutical companies involved in testing and drug development are eager to get access and may even be prepared to co-sponsor them (Coriat et al., 2003; Hopkins, 2006b; Martin, 2001; Martin and Kaye, 2000; Mayrhofer and Prainsack, 2009). The rise of medical genomics, thus, not only brings a new research agenda (from rare monogenic diseases to common multifactorial diseases)

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but also new methodological approaches (high-throughput technologies and large biobanks) accompanied by new social relations and institutional arrangements in the biomedical research system.

The pattern of development in medical genomics has also been described in the broader contexts of (i) the biotechnology industry, a growing science-based industry characterized by large multinational companies that conduct in-house research and dedicated biotechnology firms that are financially independent by virtue of their intellectual property, even without delivering commercial products (Coriat et al., 2003), and (ii) the knowledge society as a changing contract between science and society, fostering an increase of academic researchers' orientation toward the production of 'relevant' knowledge, i.e., the solution of societal problems and support for innovations and economic growth (Hessels and Van Lente, 2008; Hessels, 2010; Berman, 2008; Slaughter and Rhoades, 1996). These patterns are supported by powerful and continuous state interventions. New advisory committees and funding agencies are founded to stimulate, facilitate and co-ordinate university–industry collaborations. Science and technology policy instruments include research funding programmes, support for technology transfer, financial and technical support for start-up firms and regional clusters, R&D tax credits, and a focus on funding applicable research. Substantial public investments are reserved in order to gain advantages in this key area of the knowledge economy.

The emergence of genomics as a new type of research system takes place in the broader context of a knowledge economy that is itself changing. However, it is unclear what the relations between changes at different levels are. The central research question therefore reads: how do changes pertaining to genomics (as an emerging science field) relate to changes of the biotechnology sector and the knowledge society in general? Is the emergence of a new type of research system in medical genomics an autonomous, internally driven development or does it (also) reflect responses to broader developments? In terms of the foregoing distinction between 'internal' and 'external' regimes: is the new government by an external regime in medical genomics a result of increased landscape pressure or of a voluntary externalization and formalization of the internal regime.

By addressing this question we contribute to an ongoing debate in research policy studies about university–industry relations. Gibbons et al. (1994) and Nowotny et al. (2001) argue that modern science systems are shifting from academic, investigator-initiated and discipline-based (mode 1) knowledge production toward problem-focused, interdisciplinary, and societally relevant (mode 2) knowledge production. Intensified science–industry relations are an integral part of this macro-level process in which society is 'speaking back' to science (Gibbons, 1999, 2000). According to Etzkowitz et al. (2008) entrepreneurial universities play an increasingly central role where state interventions and university initiatives are converging. Others note, however, that supporting evidence for this development is soft (Gibb and Hannon, 2006; Hessels, 2010). Whether scientists indeed listen to society-speaking-back is often contingent upon the local work environment, for example whether or not others in their research group, preferably the chair, are active in technology transfer (Bercovitz and Feldman, 2008).

Bonaccorsi (2008) takes another position in the debate in his analysis of search regimes in new research systems. He has introduced the notion of technical complementarity to denote the dependence of researchers on specific equipment or infrastructure to perform their research. He argues that new sciences like genomics are increasingly dependent on the production of advanced technology to manipulate and observe phenomena at micro and nano level. Intensified science–industry relations are then a result of increased technical complementarity within sciences rather than a new problem orientation of the science system in general. This reference to research-internal drivers also brings to mind a third explanation from 'finalization theory' developed by the Starnberger group in the 1970s (Böhme et al., 1973, 1983). They argued that any science goes through three phases of theory maturation. After the second phase, when its theoretical program has come to organize the field, science starts to absorb external goals of research. Science–industry relations occur in this third phase.

The emergence of genomics as a new type of research regime is a multifaceted and complex process with diverse drivers. In this article we develop a *multi-level approach* to conceptualize this process. The approach distinguishes between transformation processes at different empirical levels: the 'landscape' and the 'regime' level. We use this approach as a starting point for an empirical investigation of developments at these different levels. From this perspective we have studied the rise of genomics in the Netherlands as an example of an innovation landscape in transition. In the Netherlands, a major initiative was the foundation of the Netherlands Genomics Initiative (NGI) in 2002, allocating 580 million Euros for genomics research and innovation between 2002 and 2012. Countries like the UK, Canada and Belgium (Flanders) have programs in place that are to some degree comparable to the Dutch NGI. NGI is interesting for its decentralized organization of valorization[1] activities. In this sense, NGI is most similar to Genome Canada: both programs strongly aim at integrating valorization in the whole research organization by requiring researchers to incorporate valorization activities into their research projects. For an international comparison, see Boekholt et al. (2007).

In this article we claim that developments on the level of the Dutch *genomics landscape* indeed represent a more general transformation involving a 'changing contract' between science and society and the promise of a science-based biotechnology industry. Developments on the level of *genomics research regimes*, however, mainly follow a dynamics of their own showing aspects of technical complementarity and maturation. Mature regimes are more likely to develop relations with industry. To support these claims, we compare two research regimes: one is a typical case of new genomics research and the other is rooted in the early clinical genetics regime.

2. A multi-level approach of innovation

Based on existing literature, we have developed a multi-level approach to conceptualize complex, multifaceted transformation processes in systems of innovation. Callon's concept of techno-economic networks (TEN) is used as a starting point (Callon, 1991; Callon et al., 1992). Our approach shows how TEN can be tailored to study multi-level processes.

A TEN is "a coordinated set of heterogeneous actors – laboratories, technical research centers, industrial companies, financial organizations, users, and public authorities – which participate collectively in the development and diffusion of innovations, and which via many interactions organize the relationships between scientific and technical research and the marketplace" (Callon et al., 1992, p. 220). Networks are organized around poles, which are characterized by the kinds of objects which actors in different network positions produce and exchange. We distinguish four different poles of the genomics innovation system (Fig. 1)[2]:

[1] Valorization is a Dutch science policy concept for what is elsewhere called science impact or the third mission of universities (see below).

[2] See De Laat (1996) for a similar modification of the original figure (Callon et al., 1992).