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**Title**

# Patenting and the organisation of research activities: An empirical study of innovation in the Australian biotechnology industry

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## Introduction

In the course of its relatively short life, the biotechnology field has moved outside the laboratory and beyond the context of academic communities. The expansion of new technological opportunities in biotechnology has led an increasing array of producers and users to launch biotech-enabled products onto the market. The transition of these scientific efforts into marketable products has however lagged substantially behind expectations. This lag is being underscored in the current circumstances as biopharmaceutical companies reduce R&D budgets in light of an approaching 'patent cliff' on earlier development efforts and in light of the relatively limited number of new products that are emerging from current innovation efforts. This is leading to an increasingly intensive exploration of ways to transform the distributed innovation activities in this field into marketable products.

In this light, this paper addresses the need to better understand the way these activities are being organized and the role that patenting plays in the commercialization modes of the industry. It studies the commercialization efforts of Australian biotechnology organizations in terms of patenting, licensing, and product development efforts. The empirical analysis of patenting and commercialization modes of biotechnology organizations follows on the work of Kasch & Dowlin (2008), Wakeman (2011) and a growing body of empirical work that combines information about industrial actors, their patenting-activity and licensing activities (public disclosures), and the emergence of products (clinical trial data) in order to better understand commercialization efforts in this field.

We study the relationship between patenting and licensing in light of drugs/substances that have been introduced for clinical trials. We pursue the hypothesis that there is a strong but temporally-conditioned relationship between patenting and licensing which depends on the technology, characteristics of the firm, and characteristics of their patented knowledge stocks. We expect that licensing and the origination of products are complementary activities that build on internal knowledge stocks (patents) but that the division of labor between patenting firms and commercializing firms are interrelated but distinct. The paper compiles a comprehensive set of data on organizations, patents, and clinical trials and for a 25 year period to better understand the division of labor of the biotech industry and its commercialization modes.

## Organization and Innovation

The biotechnology industry evolves by applying emerging scientific knowledge to specific therapeutic problems. New techniques are making the avenues for potentially useful products more plentiful. The prospect of high-payoffs has been driving the search and development processes down these avenues. The development and verification processes are however highly uncertain and protracted, with only a relatively small proportion making it through the clinical trials and onto the market as fully fledged new products.

These protracted and uncertain research and innovation processes involve an increasing number and range of organizations. The industry is closely allied with research activities at universities and research institutes. It is notably associated with large incumbent pharmaceutical firms. However, small, research-intensive firms (often spin-offs) are also recognized to play a key role in managing the selection of scientific ideas to produce valuable technical innovations (Gittelman and Kogut, 2003). Much of the research activities are not defined as 'biotech' but are carried out in specialized business and research services (OECD, 2006)[1]. In between the university and industry, Mirowski &

[1] "The sector Property and Business Services (ANZSIC Division L) reported the largest share of biotechnology-active firms (61%) and the highest share of biotechnology R&D expenditures (69%)." (OECD, 2006: 60).

Van Horn (2005) posit a "modern paradigm of privatized science" involving the ascendant role of Contract Research Organization (CROs). In addition to the changing participants in the division of labour, the distributed landscape of biotechnology organizations landscape is furthermore characterized by the role of inter-organizational networks, including collaboration, alliances, but also 'virtual' forms of organization.

The way firms are organized reflects prevailing uncertainty of the industry and the type of innovation in question. Firms adopt flexible organizational structures in the face of persistent uncertainty (Harrigan, 1985): this can be seen in the new modes that are emerging to organize research, development and innovation in the biotech field. One peculiar factor here is the regulatory uncertainty connected to clinical trials (Kasch & Dowling, 2008). The guidelines for 'matching organization to innovation' (Chesbrough and Teece, 1996) do not necessarily follow 'autonomous' versus 'systemic' divisions. Firms tend to be co-opetive, alternating and integrating competitive and cooperative strategies (Brandenburger & Nalebuff, 1996). The relationship depends on the relationship between internal and external competencies, with biotech firms tending to be more likely to exploit technologies internally if they belong to their core competencies and they can achieve synergy (Kasch & Dowlin, 2008). The relationship may also have a temporal dimension in the biotech industry, given the protracted development horizons of biotech enabled products.

A strategy based on cooperation as opposed to an in-house strategy may depend on different factors, including the grant of key patents (Wakeman 2011). The importance of patenting is another recognized feature of the biotech industry. The prospect of monopoly protection is instrumental in a landscape which involves a constant trade-off between 'cooperation' and 'control' during the long development horizons. Literature on the role of patents in technology-based collaboration will provide the backdrop. This work includes the literature focusing on the cumulative and collaborative modes of knowledge production, including patent studies that focus on the 'cumulative systems technologies' (Merges & Nelson, 1990; Gallini & Scotchmer, 2004) or 'sequential innovations'. (e.g. Scotchmer 1991; Gilbert and Shapiro; Klemperer,1990; Bessen & Maskin, 2007; Encaoua et. al, 2005). See also the network of learning perspective (Powell et al, 1996; Rhoten & Powell, 2007) as well as the related work on markets for technology/for patents (Arora and Gambardella, 1994; Gambardella, 1995; Bresnahan and Gambardella (1998); Gambardella, Guiri, Luzzi (2007).

**Data and approach**

The paper studies the role that patenting plays in the commercialization strategies of biotech organizations (in Australia). Following Wakeman (2012), the paper distinguishes between commercialization strategies substantially based on licensing, on co-development, or on going it alone. The analysis addresses questions associated with the strategic management of R&D and with the organization of 'markets for technology'. In order to understand the role of the patenting in the road towards commercialization, the paper applies a distinction (from the open innovation literature) between i) The outside-in processes or 'inbound activities' in which the company attempts to enrich its own knowledge base by integrating external knowledge sources. (Laursen and Salter, 2006; Lettl et al., 2006; Piller and Walcher, 2006); ii) The inside-out process or 'outbound activities', in which the firm shifts exploitation outside itself by licensing IP and/or multiplying technology, for example by corporate venturing activities (Vanhaverbecke et al., 2008), and new ventures and spin-offs (Chesbrough, 2007); or iii) The coupled process refers to co-creation with (mainly) complementary partners.

To this end, the paper compiles empirical information about how the biotech industry in Australia currently uses patents and licensing based strategies. This paper combines the following sets of

information:

i. Organizational data for 1500 'entities' which predominantly sort under a set of 90 named groups. Information includes type, region, ownership, and R&D and collaboration (from public disclosures).
ii. Product, license (license in and license out) and clinical trial data for Australian biotechnology firms (1985-2011): Entities who have 'originated' a pharmaceutical product for clinical trials. Australian Originators: 110 Australian company names and 650 pharmaceutical products. Source: Informa Healthcare Pharmaprojects database 2011.
iii. Patenting data covering national and international applications and/or grants (1985-2009). 1.08 million patent records. Source: IP Australia.

The paper links patent stocks to organizations that are involved in licensing and other forms for collaboration. It will provide insight into the degree and direction of patenting and licensing activities of different Australian organizations active in the biotechnology field. Analysis is currently underway…