



Restructuring and innovation in pharmaceuticals and biotech: The impact of financialisation

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ABSTRACT

In this paper we explore whether a financialisation perspective can provide a more empirically satisfying account of recent developments in the pharmaceutical industry than the more commonly used resource-based or transaction cost approaches. Specifically, we note the evolution of the pharmaceutical industry structure from giant vertically integrated firms, selling patent protected blockbuster products at premium prices, to greater vertical disintegration. Big Pharma¹ now sources a significant volume of early stage R&D activity externally, through outright acquisitions or alliances, especially with biotechnology firms. Much of the reason for such vertical disintegration is to be found in the fundamental tension experienced between the high R&D spend necessitated by the cost of pharmaceutical innovation and declining returns on this expenditure in terms generating new product sales and FDA approval rates, which have remained broadly constant at an average of 20–35 approvals per year. The new R&D outsourcing strategy has not delivered an increase in marketable drug discoveries or new 'blockbuster' profits. Instead, shareholder returns have been maintained through Big Pharma's decision to distribute cash back to shareholders via share buybacks and dividends (as advocated by Jensen). Thus we conclude that such developments within Big Pharma worldwide are best explained through the lens of a financialisation, as opposed to a resource-based or transaction cost framework.

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1. Introduction

The Big Pharma industry has undergone major changes since the time when Froud et al. (2006, p. 153) argued it enjoyed a 'licence to print money'. Operating as giant vertically integrated firms, Big Pharma's high returns arose from a combination of enforceable patent rights, price-insensitive purchasers and a sympathetic regulatory environment. In this environment, blockbuster drugs defined as ethical pharmaceuticals generating annual sales of at least \$1bn, which were protected by patents, were sold into the healthcare market at premium prices.

However, this traditional blockbuster model now confronts a 'patent cliff' (Kaitin, 2010) as key patents in the major pharmaceutical firms' portfolios face imminent expiry with little or no replacement by newer products capable of generating blockbuster-sized revenues. The traditional business model of the Big Pharma industry was that of resource-based innovation, in which US Food and Drug Administration (FDA) approval facilitated long-lasting patents and strong cost recovery. Once blockbuster drugs go out of patent, generics invade Big Pharma's lucrative blockbuster markets, forcing considerable price

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¹ The term 'Big Pharma' refers to large usually multinational pharmaceutical firms such as Pfizer and GSK. By way of contrast, in using the term 'biotech', we are referring to small speciality pharmaceutical and diagnostics firms.

erosion. Generics can quickly reduce drug prices by over 80% (Garnier, 2008) and so a significant proportion of Big Pharma's current revenue is progressively exposed to generic competition as key patents in portfolios expire.

The response of Big Pharma has been firstly to continue with a significant commitment to R&D, allied with heavy investment in marketing and distribution to maximise revenues from successful innovation. But secondly, and significantly, Big Pharma companies have increasingly focused on restructuring activity which includes both mergers and acquisitions as well as accessing the products of innovative effort carried out by smaller biotechnology firms (biotechs) (Andersson et al., 2010; Haslam et al., 2011). This article assembles evidence that a traditional integrated model of the Big Pharma firm, whose high investment returns enabled it to focus on research-based drug discovery, has given way to a financialised model whose priority of defending returns to shareholders may no longer support the strategies most conducive to new 'blockbuster' discovery. We argue that financialisation occurs when the main objective of financial investors, to generate a higher and less risky return on equity and debt, gains in importance over – and moves out of line with – the concerns of employees, customers, suppliers and others directly involved in the flow of material and human (as distinct from capital) resources. Investor interests start to conflict with other stakeholders' once the relationship between investment, innovation and return on capital ceases to be clear. The conflict is exhibited in emergence of company strategies and an industry structure which preserve profitability without reversing the fall in R&D productivity and innovation.

During the period 1985–2000, Big Pharma delivered high shareholder returns, with an annual Return on Equity (ROE) of over 20% (Baber and Kang, 1996; *BusinessWeek*, 2004; Trombetta, 2005). In this period the industry also continued delivering new drugs, benefiting customers while generating returns derived from earlier investments in internal R&D activity. We argue that subsequent to this period, a key symptom of financialisation is that Big Pharma firms ROEs are maintained using financial strategies (such as raising debt and outsourcing R&D) that no longer benefit customers. Associated structural change, especially the outsourcing of early stage R&D activity used to generate future revenue, has not arrested the rapid rise in cost for each new discovery.

This paper therefore assesses whether such a 'financialisation' perspective, taking greater account of external pressures on resources and strategy especially from financial markets, can offer a more empirically satisfying explanation for pharmaceutical/biotechnology industry development than widely used transaction-cost and resource-based approaches. We argue that these widely adopted approaches do not easily explain the Pharma industry's move to greater outsourcing and geographically dispersion of R&D and production which have yet to yield new products comparable to the blockbusters delivered under the industry's previously vertically integrated structure. Nor are these theories consistent with the spread of strategic alliances between Big Pharma and biotech, as an alternative to full acquisition and vertical integration.

The paper adopts the following structure. Section 2 explores the tension between R&D for innovation and financial returns and FDA approval. Importantly, we argue that all R&D, both outsourced and in-house, represents a significant gamble given the low rate of approvals by the US FDA. Section 3 then discusses the current developing relationship between Big Pharma and the biotech industry which we argue is a direct response to the above changes. Section 4 focuses on the case of the Big Pharma firm, GSK, as it responds to the major problem faced by generics in a fashion that we argue is consistent with general industry trends. In Section 5, we return to the typology of section 2 to argue that the transition from an originally integrated to a more financialised firm is clearly visible in the Big Pharma industry, and GSK in particular, despite the complexity of restructuring to date.

2. The tension between R&D for innovation and financial returns and FDA approval

Until recently, Big Pharma profitability was derived from a small number of highly profitable 'blockbuster' drugs, developed from investing in a wide portfolio of research projects, each with a low probability of success. Large, vertically integrated firms carried out virtually all the stages of the drug discovery and commercialisation process, from the discovery of the New Molecular Entities (NMEs) that constitute the active ingredients in medicines to large scale clinical trials, production and marketing. Globally, Big Pharma's R&D expenditure continued to rise until 2010 (Hirschler, 2011). In the US, the dominant Pharma market, R&D expenditure as a percentage of sales is still above 16%, a level first reached in the early 1990s as Fig. 1 shows.

However, Big Pharma has experienced a significant decline in R&D productivity. Slower discovery of NMEs from the late 1990s (see Fig. 2), in spite of persistently high R&D investment as a proportion of sales (Hirschler, 2011), has led to a drying up of Pharma drug development pipelines. Simultaneously, sales income from existing blockbusters is threatened by the prospective entry of providers of low cost generic drugs as a result of the expiry of key patents protecting existing blockbusters.

The industry's traditionally high investment returns from past R&D are now under threat from shortening effective patent lives and rising generic competition, and its ability to retain a proprietary-technology advantage is challenged by lower and increasingly uncertain returns from its ongoing R&D spend. Fig. 3 shows how productivity of pharmaceutical sector R&D has continued to decline, resulting in a rising cost per approved NME (Scannell et al., 2012). This decline in R&D productivity may have been exaggerated if, as critics of the industry's data allege, it overstates its R&D spend (and understates its advertising spend) by misclassifying some promotional costs as research costs, especially in later-stage (Phase IV) trials (Gagnon and Lexchin, 2008). But even a more restrictive definition of R&D spend does not remove the productivity decline. This may even be worse than Fig. 3 suggests given that the therapeutic significance of NMEs has also declined, with NMEs now providing "only minor clinical advantages over existing treatments" (Light and Lexchin, 2012).

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