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TO MANAGEMENT SCIENCE

Gerrit Reepmeyer

Risk-sharing in the Pharmaceutical Industry

The Case of Out-licensing

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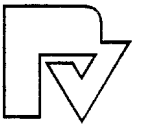
Risk-sharing in the Pharmaceutical Industry



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The Case of Out-licensing

Foreword by Oliver Gassmann,
University of St. Gallen, Switzerland

With 70 Figures
and 10 Tables

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Foreword

The productivity in pharmaceutical research and development faces intense pressure. R&D expenditures of the major US and European companies have topped US$ 33 billion in 2003 compared to around US$ 13 billion just a decade ago. At the same time, the number of new drug approvals has dropped from 53 in 1996 to only 35 in 2003. Moreover, the protraction of clinical trials has significantly reduced the effective time of patent protection. The consequences are devastating. Monopoly profits have started to decline and the average costs per new drug have reached a record level of close to US$ 1 billion today. As a result, any failure of a new substance in the R&D process can lead to considerable losses, and the risks of introducing a new drug to the market have grown tremendously. Particularly if a company is highly dependent on just a handful of mega-selling blockbuster drugs, the risks can be even greater. For example, Pfizer generated about 90% of its worldwide revenues in 2002 with just 8 products. Any shortfall of a promising late-stage drug candidate would have left Pfizer with a gaping hole in its product portfolio. In order to deal with these risks, many pharmaceutical companies have started to organize their R&D in partnership. In fact, more than 600 alliances in pharmaceutical R&D are signed every year. Several empirical studies confirm the rising importance of collaborations in the pharmaceutical industry, and they highlight that risk-sharing has emerged as one of the major challenges of today's collaboration management.

Mr. Reepmeyer tackles this issue by analyzing how pharmaceutical companies can share R&D risks by collaborating with external partners. He focuses on the young empirical phenomenon of out-licensing which has barely been subject to prior research. While other types of collaboration in the pharmaceutical industry, such as research alliances, co-development and in-licensing, are widely applied by practitioners and studied in great detail by scholars for several years, out-licensing has not received a similar level of attention. During the course of his investigation, Mr. Reepmeyer adopts the perspective of the pharmaceutical company that is about to sell the license to its partner company. He provides answers to the following questions: What importance does out-licensing at established pharmaceutical companies have today, and what are the main characteristics of these collaborative arrangements? How can these collaborations be managed in order to effectively and efficiently reduce R&D risks?

Mr. Reepmeyer uses a case study based research method which is well suited for the nature of this young practical phenomenon as well as the character of existing re-

search. The insights gained are based upon comprehensive and in-depth empirical evidence. The large number of interviews (86) corresponds to the high quality of the case studies. The selected case studies all follow a clear concept and comprise profound empirical findings. Mr. Reepmeyer's work covers three major case studies of Novartis, Schering and Roche as well as several small case studies which accentuate and highlight the issue of out-licensing throughout the entire book. In order to derive managerial recommendations, Mr. Reepmeyer uses the microeconomic theory of Adverse Selection – which has only recently been awarded the Nobel Prize. The application of this theory to the case of out-licensing is not only innovative in its nature, but also allows deducing concrete and tangible recommendations for pharmaceutical R&D managers. The results of Mr. Reepmeyer's research not only provide several novel insights about risk-sharing in pharmaceutical R&D collaborations, they also include a clear framework for the manageability of out-licensing collaborations.

Prof. Dr. Oliver Gassmann
Director, Institute of Technology Management
University of St. Gallen

Preface

This book originates from my dissertation at the Institute of Technology Management at the University of St. Gallen in Switzerland, titled 'Risk-sharing in Pharmaceutical R&D Collaborations – The Case of Out-licensing'. Out-licensing represents a fairly new strategy of established pharmaceutical companies to share R&D risks via collaborations. This book as well as my thesis exemplify this young empirical phenomenon by illustrating a couple of related case studies.

For supervising my thesis and for giving me the opportunity to exploit my academic aspirations, I would like to express my deep gratitude to Professor Oliver Gassmann. His support during the entire research process was always encouraging and cordially pleasant at the same time. I would also like to thank Professor Fritz Fahrni for co-supervising my thesis. As I was allowed to conduct some part of my research at the Columbia Business School in New York, I am indebted to both Professor Atul Nerkar for being my faculty sponsor as well as to Professor Pierre Azoulay for giving insightful directions to my research work. During my time at Columbia, I gratefully acknowledged financial support by the Swiss National Science Foundation.

This book as well as my thesis would not have been possible without the input of various research interviewees in miscellaneous companies. I would like to thank them for taking the time to discuss my research questions. For contributing valuable input to this work, I am thankful to several colleagues and students at the Institute of Technology Management, especially Michael Kickuth, Christoph Kausch, Jonathan Lüthi and Stefan Keidel. Last but not least, I would like to thank Dr. Werner Müller and Barbara Feß of Springer for managing the overall publication process. Writing this book has been a great learning experience for me. I hope that the results are inspiring and helpful for pharmaceutical managers as well as students and scholars of the pharmaceutical industry respectively.

Gerrit Reepmeyer

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1 Introduction

1.1 Motivation and Goal

1.1.1 Relevance of research subject

Management of research and development (R&D) at large pharmaceutical companies is facing severe conditions. The foremost concern with top management is the deteriorating R&D productivity.[1] R&D spending has arrived at a record level today, while the number of new drugs introduced to the market has been declining for several years or has remained constant at best.

In 2003, pharmaceutical companies invested more than US$ 33 billion in R&D worldwide compared to about US$ 13 billion just a decade ago. However, the number of new chemical entities (NCEs) which have been approved for market entry by the Food and Drug Administration (FDA) in the US has declined from 53 in 1996 to only 35 in 2003 (PhRMA 2004). As a response to this gap, the average R&D costs per new drug are constantly increasing. In 1976, it cost US$ 54 million to develop a new drug, US$ 231 million in 1987, and about US$ 280 million in 1991 (DiMasi 2001). This number has grown to close to US$ 1 billion by now (see Fig. 1). A recent Reuters study (2003a) supports this negative trend by concluding that the R&D performance of major pharmaceutical companies is sub-optimal. The long average development time in pharmaceutical R&D cannot be used as an excuse for the gap in R&D spending and new drug approvals, firstly because the greatest R&D expenses are in the final phases of drug development (within just a few years of market introduction), and secondly, because the observed trends in the 1990s were already present in the decades before.

Due to the escalating average R&D costs per new drug approval, the risks in pharmaceutical R&D have become paramount because any failure of a newly developed substance during the R&D process can cause significant losses. In accordance with the rising R&D input and declining output as well as the subsequently increasing R&D risks, many R&D projects are terminated at fairly early stages and long before they reach market introduction.[2] Hence, most pharmaceutical companies have built up large portfolios of patents and other forms of intellectual property, but they often

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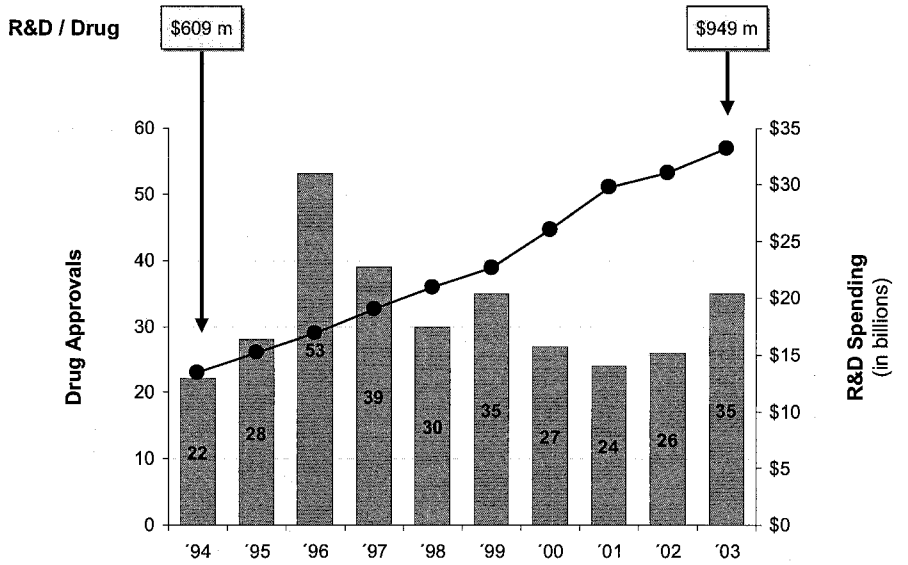
1 By definition, the R&D productivity describes the ratio of input in R&D versus its output.

2 Interview with McKinsey.



Source: PhRMA (2004)

Fig. 1. Declining productivity in pharmaceutical R&D.

use only a small portion of these intangible assets (see Festel 2004). The R&D results that have been achieved but not marketed cover valuable intellectual property, unpatented technology or interesting R&D projects across all stages of the R&D process which effectively decay in the companies' archives because their further development is oftentimes considered to be too risky. Although much idle intellectual property has little value, others could provide significant economic benefits (Festel 2004).[3]

Besides of the rise in R&D-related risks and the associated build-up of large inventories of intellectual property, most pharmaceutical companies have conceded that fundamental breakthroughs in technology or science are increasingly likely to occur outside their organizations. It has become clear today that not even the largest multinational company can hope to do all its research and development activities in-

[3] In this context, Joseph Zakrzewski, Vice President of Business Development at Eli Lilly, argues that "intellectual property that is sitting on my shelf is providing no value to shareholders or to patients" (see Longman 2004).