Alexander Styhre

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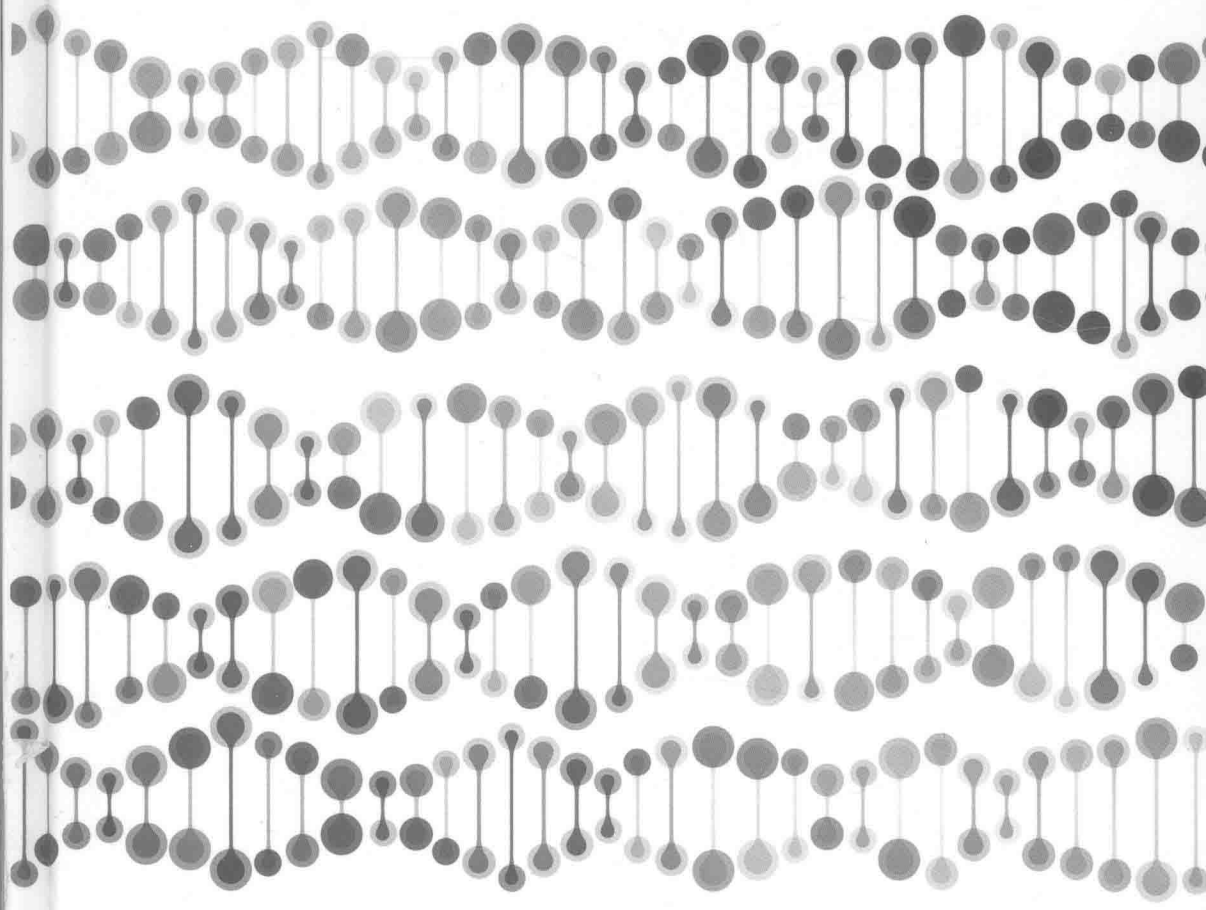
Bundling Technologies and Life



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Preface

This book is a spin-off from work that I am fortunate to have done over the last few years. I originally received a research grant from the Bank of Sweden's Tercentenary Fund to study the commercialization of life sciences, and I started to conduct research work in a major pharmaceutical company, in a number of smaller biotechnology firms, and in academic research settings. This study was reported in the monograph *Venturing into the Bioeconomy* (Palgrave Macmillan, 2011) that I co-authored with Mats Sundgren. The interest in life-science commercialization and the transfer from basic laboratory research to actual therapies used in the clinic led to a study of assisted fertilization clinics and the underlying field of reproductive medicine. This research work, which I conducted in collaboration with my colleague Rebecca Arman, was published in the volume *Reproductive Medicine and the Life Sciences in the Contemporary Economy* (Gower, 2013). When we were working in the assisted fertilization clinics study, I was writing a more theoretical volume eventually entitled *Organizations and the Bioeconomy* (Routledge, 2012) that aimed to integrate and discuss the recent literature on the increased role of the life sciences in the contemporary economy for an organization theory and management studies audience. In other words, I have been involved in studying and theorizing life-science commercialization activities for some time. When conducting research in the field of pharmaceuticals, I was informed that the field of life-science research operates under a different regulatory regime than the pharmaceutical industry; namely biomaterials and medical devices (a term used here to capture a quite diverse set of medical technologies and therapies) could possibly play a more central role in an era when big pharma often fail in their new drug development work and are unsuccessful in delivering new and innovative therapies. Since not much had been written about biomaterials and medical devices in comparison with pharmaceuticals, both in the social science literature more generally and in the organization theory literature more specifically, I was intrigued by this domain of expertise operating (primarily but not exclusively) on the tissue level of the human body. This research monograph reports empirical data from the field of the life sciences, historically receiving less attention than the

traditional small-molecule drug therapies, antibodies and biologics, that is, therapies operating on the molecular level making up big pharma. This volume not only reports empirical material but seeks (1) to provide an analytical framework to help theorize how biological organisms and engineered materials are capable of being co-aligned and integrated, and (2) to examine the wider socioeconomic and cultural setting in which biomaterials and medical device innovation occurs. Perhaps the aim to both provide analytical frameworks and to capture the practical, political and financial difficulties involved in life-science innovation and commercialization reveals gargantuan and not entirely flattering ambitions, but that is, I think, how this field needs to be understood and explained. This research monograph is therefore a form of hybrid text that contain elements of organization theory, philosophy of science, popular science and science policy. I am aware that this may confuse the reader, but I still think this is how biomaterials innovation needs to be understood, as that which emerges in the intersection of scientific and technological advancement and regulatory and market-based opportunities. A professional field and an emerging life-science industry cannot be understood unless someone takes on the task of imposing a theoretical framework that enables certain perspectives. After all, social systems and practices, just like biological systems and epistemic objects, never 'speak for themselves', but are always 'spoken for' and represented by scientists and scholars – and yet these fields cannot be reduced to such perspectives, as there are almost infinite possibilities for enacting social worlds. As a consequence, no analytical framework is worth its salt unless it is put to the test of being used in empirical studies. As Ian Hacking (1983) has persuasively argued, researchers both 'represent' (in other words, theorize) and 'intervene' (in natural, quasi-natural and social systems, in other words, conduct systematic inquiry) and therefore scientific work unfolds as a movement of critical self-correction back and forth between theoretical models and hypotheses, with the accumulation of data either supporting or modifying (occasionally even falsifying) the theoretical models. The price paid for this two-sided ambition is a certain messiness that may be annoying for some readers. Theorists enjoy and take great pleasure in elegant deductive reasoning in which theoretical propositions and statements are connected like the moving parts of a well-designed mechanical clock, and empiricists and experimentalists favour the reporting of data that are relatively devoid of interpretations and explanations that disturb or even distort the presentation of what is intended to appear as factual conditions. Representing a discipline (organization theory and business administration as an academic discipline) and an institution (the business school) that is constantly criticized for either producing research

that is practically irrelevant or theoretically unsophisticated, that is, of limited intellectual value, I am convinced that I have little to lose if I open up for a small amount of messiness. As Davis (1971) remarked in a much-cited paper more than four decades ago, it is the capacity to arouse a sense of curiosity and to attract attention that marks the skilled scholar. That is, the objective for business scholars should be to publish books and journal articles that are interesting, intellectually stimulating and that, as a consequence, as Karl Popper would have said, put daring hypotheses to the test. Whether this volume manages to accomplish these not-too-modest goals is not for me to say, but the text has been written with this ambition in mind. If nothing else, it may inspire more scholars in organization theory and management studies and in business schools to conduct research on life-science innovation and commercialization. It is actually quite curious that not more researchers are exploring the goldmine of opportunities for scholarly studies in this professional field.

Acknowledgements

I would like to thank all the company representatives, entrepreneurs and venture capitalist firm representatives who agreed to dedicate some of their precious time to this study. They have been given little in return, other than a thank you and the general reassurance that I would make the best use of their empirical data. For the sake of anonymity, enacted as a gold standard for the writing of this monograph, these persons will not be thanked by name, but they know who they are. In addition, I would like to thank colleagues at the School of Business, Economics, and Law, University of Gothenburg for contributing to an intellectual atmosphere where it has been possible to articulate and debate new ideas and thought. I would also like to thank the Bank of Sweden's Tercentenary Fund and the Swedish Research Council for providing me with the research grants out of which I have tried to squeeze as much empirical data as practically possible. Without such research funding, it is complicated to move in any direction these days. Finally, I am grateful to the Commissioning Editor Francine O'Sullivan and Assistant Commissioning Editor Emily Mew at Edward Elgar for giving me a contract for a book that, when the book proposal was written, could not really find any competing books, testifying to the marginal role of biomaterials and medical devices as an object of scholarly attention.

Contents

PART I

Theoretical framework

1. Life and materiality, nature and artifice: transgressing the divide

INTRODUCTION

This book addresses the innovation of biomaterials taking place in corporations and in academic research settings. Biomaterials is a complex term, bridging two different epistemological traditions in the Western episteme. First, it includes the concept of life, *bios*, the totality of material resources endowed with a vitalist force, the possibility of continually changing and modifying. Life is associated with restless creativity and change, the ceaseless becoming of nature. Second, the term includes materiality, matter that is treated as inert and immutable, always already in place and serving its purpose by being predictable and unchangeable. While everything pertaining to life is addressed within the life sciences – biology, medicine, biochemistry and so forth – inert matter belongs to the engineering sciences, the sciences committed to the handling of materiality on various levels, ranging from the nanoscale (for example, nanobots and microelectronics) to the macroscale (for example, technological systems and infrastructures). These two terms have been, by and large, examined along divergent paths and have only occasionally been combined. However, the advancement of biomaterials used in the life sciences, including a series of innovations such as pacemakers in cardiology, artificial joints in orthopaedic surgery and dental implants in dental surgery, shows that the epistemological line of demarcation between life and non-life, vital and inert matter, is no longer as decisive as previously assumed. Rather than being separated by insurmountable and definite ontological boundaries, various forms of materiality can jointly support one another, and biomaterials – fabricated and engineered materials capable of interacting with the human body – is increasingly becoming a key field of research for the future. Speaking of tissue engineering, Faulkner (2009: 640) mentions 'biomedical technologies' and points to some of the therapeutic areas:

> Innovative *biomedical* technologies traverse regulatory borders between more or less well-defined sectors … including medical devices, pharmaceuticals,

> cell therapy, pharmacogenetics, and blood products. Amongst these, tissue-engineered products stand out because of their hybrid material artifactual characteristics. The currently marketed products of TE are generally taken to include cultured cell implants, for traumatic knee cartilage injury ... bone substitutes, and 'living' skin tissues for burns or chronic ulcers. Further developments are expected to include vascular prostheses, organ-assist devices (liver and kidney), whole organs, structures (heart valves and joints), neurological tissues and stem cell therapies.

Biomaterials is by no means an entirely new area of research and development as, for example, types of prosthesis have been used since antiquity, but during the last few decades the general growth in life-science know-how derived from intense research work has led to a more pronounced interest in using biomaterials in various therapies. While research programmes such as embryonic stem cell research hold the promise of restoring the human body 'from the bottom up' by helping, for example, organs grow new cells, biomaterials operates the other way around by supporting existing organs and tissues, and functionality is accomplished by reinforcing previously impaired bodily functions, or by displacing entire body parts, as in the case of dental implants. Stem cell research has served as the paradigmatic research programme in the last few years, and much progress has been demonstrated, but the scenario in which entire organs are grown and transplanted into patients, or where organs are restored through stem cell therapies, is still a thing for the future. In the meantime, various forms of biomaterials may help human beings live longer, happier and more convenient lives.

The study of biomaterials innovation is, then, not strictly a matter of reporting empirical materials from the field, but also demands a detailed examination of the key terms, including *bios* and materiality. In many cases, organization and management studies only scratch the surface of innovation activities in that there is no proper analysis of the underlying claims of knowledge that serve as the basis for the innovation work. That is, simply providing informed stories from the field of biomaterials innovation is not enough to fully explain the challenges and concerns involved in biomaterials innovation; the entire conceptual framework involved in such innovation activities needs to be examined. As a consequence, this volume includes not only empirical materials collected in biomaterials companies, but also dedicates a relatively significant space to a review of literature relevant to the study of biomaterials firms and biomaterials innovation. Since the organization and management studies literature has been only marginally interested in various forms of materiality, much of the literature addressing life, materiality and biomaterials is collected from outside the field of organization and management

studies. Science and technology studies, sociology, gender studies, anthropology and political science are a few disciplines that have contributed to this study. In other words, this volume aims to combine organization theory and studies of life-science and biomaterials production.

The field of experimental medicine is of relatively recent origin, beginning in the last few years of the eighteenth century and becoming institutionalized in the medical schools developed outside the medieval university system in the nineteenth century, first in France and then elsewhere (Bynum, 1994). In Germany, the university system modernized during the same century as experimental scientific practices were developed and related to practical needs in industry and society more broadly (Lenoir, 1994). In this period, disciplines such as biology and chemistry were institutionalized and accommodated within the university system. Moreover, during the nineteenth century, the first polytechnic universities and engineering schools were developed, and the engineering sciences were gradually established. By the last few decades of the nineteenth century, engineers were commonly hailed, especially in the USA, as the bearers of modernist virtues, including rational thinking, and as proponents of systematic methods of inquiry (Shenhav, 1999). The substantial growth of university-based research, developed during the nineteenth century, led to R&D activities in industry in the twentieth century as increasingly larger corporations acquired the capital needed to hire their own scientific expertise. From the 1970s, much effort has been made to bring academic and industry-based research together, preferably in the form of joint ventures, research centres and technology transfer offices (TTOs). Today, American elite universities at the forefront of research work serve as role models for these kinds of university–industry collaborations, recognized and endorsed by policy-makers worldwide. Individual examples such as Stanford University and the Silicon Valley computer industry cluster, or MIT and high-tech companies in Massachusetts, are repeated time and again to further reinforce the need to make academic research work spill over into business ventures and patenting activities. In fewer than two centuries, academic research has moved from being a quite narrow professional domain of expertise, a form of safe haven where a few talented individuals could tinker with their theories and experimental apparatuses, to a veritable innovation machinery expected to produce new mind-boggling research findings and accompanying possibilities (see, for example, Berman, 2012a, 2012b). However, as this volume hopes to be able to demonstrate, innovation work is not a trivial matter and new therapies in, for example, medicine are produced at the intersection of a variety of institutional arrangements and under the

influence of various practical and political conditions. Not only is it costly to identify and develop new biomaterials, but there is a tight regulatory framework specifying in detail what clinical studies need to be reported to make the biomaterial in question subject to approval by the Food and Drug Aministration (FDA) and similar authorities, and just in case the biomaterial manages to pass this test, there is still the challenge of marketing new therapies in the health care industry. In other words, biomaterials innovation is never strictly a matter of 'smart people inventing clever materials in the lab'; it is just as much a matter of mobilizing various domains of expertise to establish the new product as a safe and credible therapy with high efficacy. Biomaterials innovation is thus both a matter of intervening in biological systems and exploring material structures and surfaces, and a matter of mobilizing social resources to get the approval from authorities. This volume is written with the ambition to cover the whole series of concerns in biomaterials innovation, ranging from more biophilosophical questions regarding the nature of life and organisms to issues pertaining to the financing of the innovation work. In this view, biomaterials innovation is not only a matter of the work of a diligent researcher in the laboratory, but is just as much about the entrepreneurial skills needed to bring new products to the market and to convince in many cases recalcitrant and conservative physicians to make use of new biomaterials and therapies. Biomaterials innovation – and any form of innovation in the life sciences for that matter – is thus the practice of aligning the molecular and cellular systems of the biological organisms explored with social activities and interests. As students of laboratory practices have demonstrated, the research laboratory may appear as a confined space in which slices of nature are created (or at best reproduced) to become subject to minute control in the experimental situation, but it is in fact fundamentally open to external influences such as social interests.

A MATERIAL VIEW OF ORGANIZING

The history of the social sciences, and more specifically organization theory, demonstrates that social theorists and philosophers have always been preoccupied with looking beyond or below what is immediately observable – what lends itself to immediate inspection. Underneath the familiar appearances of everyday life, it is postulated that there are principles, geometrical structures, ideologies, subtexts – virtually anything that is capable of providing an anchoring point for the wide variety of events, occurrences, species and so forth – making up the material