The contrasting roles of government in the development of biotechnology industry in the US and Germany

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Abstract

During the last 30 years, biotechnology development has charted different paths in the US and in Germany. Even though in Germany federal support programs started very early to target biotechnology, the innovative performance of this sector has been lagging behind that of the US, where the federal support was less direct. This article compares the two national science and technology (S&T) policies and analyzes the political, economic and social factors that determined the different paths. The paper concludes that an indirect S&T policy that tries to spread the factors, thereby enabling a preferable “economic ecology” for biotech development, is more successful than an interventionist policy. Political action, however, is limited and can only enhance science and technology development if the policies mesh with the social and economic dispositions. © 2000 Elsevier Science B.V. All rights reserved.

Keywords: Triple helix; Science and technology policy; Path dependence; Lock-ins; Catch-up strategies

1. Introduction: the triple helix and the new production of knowledge

The role of government is changing as industry relies more and more on academic research for generating marketable innovation and economic growth. This is especially true for science-based technologies such as artificial intelligence or biotechnology (Etzkowitz, 1993). Knowledge has become a capitalized good, an intangible, valuable asset for many companies. The more the line between basic and applied research disappears, the more publicly funded research institutes and universities become the source of commercially exploitable knowledge. As the quality of knowledge has changed, its mode of production has changed as well. As Gibbons et al. (1994) have pointed out, the “new production of knowledge” comprises the interaction of many disciplines and actors within a network of mutual reactions and feedback rather than a linear model 1 (for further discussion see also Powell and Owen-Smith, 1997). This new mode of knowledge production enhances and changes the trilateral network of relationships between academic institutions, government and industry. Challenging the notion that innovation is the result of successive units linked to a chain of development, the triple helix model suggests that innovation is a spiral movement that captures multiple reciprocal relationships among institutional sectors (public, private and academic) at different stages in
the capitalization of knowledge and thereby changes knowledge producing institutions (Etzkowitz and Leydesdorff, 1997). Just as the location of research has changed, the location of innovation has changed as well: Both research and innovation are not just the realm of the firm any more but take place in the interrelationship between the actors of the triple helix: academia, state and industry. This paper will show that biotechnology as a science-based technology is especially dependent on the cooperation and interaction of these actors because academic knowledge needs to be transferred to the industry at an early stage. State institutions and government policies play a crucial role providing these transfer mechanisms.

This paper sets out to discuss the contrasting roles of national governments in the development of high-tech industry and innovation within the triple helix network relations. This is a comparative study of US and German biotechnology policy. The attempt to shed light on the role of government in the context of high-tech innovation and development raises the following questions: First, do national paths differ due to different government politices and politics? Where are the institutional limits in generating innovation in the high-tech sector? Or, to put it differently: Does government have any impact on the innovative performance of high-tech industries? Secondly, if government policies and politics do matter, is there a best practice model or a style that is more efficient than another? And are the catch-up economies able to learn from the first mover?

The next sections of this paper will review US and German biotech history focusing in particular on the role of government policies and state institutions. In order to demonstrate the different performances of US and German biotech industry, some empirical evidence will be presented. The main argument stressed here is a structural one: The success of science and technology (S&T) policy is related to the institutional arrangements that enable knowledge transfer and innovation in a process oriented mode. The second argument is that all government influence is limited and that innovation, technological development and economic performance are not determined by government policies alone. Rather, to be effective government policies have to take into account the specific technological path of biotech development. Further, government policies need to address already existing social and market institutions that respond to the new incentives. Since institutions tend to have a logic of their own, direct policies that want to change the institutional setup are sometimes less effective than policies that address the institutional environment.

2. Biotech development in the US and Germany: history and performance

The government support for biotechnology development in Germany began in the late 1960s, when an OECD report identified this technology — among others — as one that was expected to play a key role in future economic development (OECD, 1966; Buchholz, 1979). Thus, biotechnology became one of the technologies to be supported by public funds. Historically, the government promoted future technologies because Germany was prosperous after the war, and it believed that the federal government was able to implement decisions for the achievement of intended outcomes that could continue this prosperity.

The big recession, starting in the early 1970s, however, put economic growth on hold. Political reaction to this crisis was an intensification of interventionist strategy. An active, direct and interventionist science and technology policy was regarded as a tool for developing a prosperous national economy (Hohn and Schimank, 1990). For this purpose, a federal Ministry of Science and Technology was founded in 1972, taking over and expanding the tasks that up to this date had been the responsibility of the Ministry of Economy and the Ministry for Scientific Research (BMBW, 1972). Various research priorities were identified for biotechnology, believing that biotechnology had future scientific and economic potential. With the inclusion of biotechnology into its funding programs for new technologies, the federal government — mostly through its Ministry of Science and Technology — has initiated several working groups, advisory boards, and funding program for the advancement of biotech research. Government funding for biotechnology has risen enormously over the last 30 years. From 1974 to 1995 federal R&D expenditures for biomedical
Table 1: Biotech industries compared (Ernst & Young, 1998)

<table>
<thead>
<tr>
<th></th>
<th>Germany 1997</th>
<th>Europe (including Germany) 1997</th>
<th>USA 1997</th>
<th>Percent change to prior year</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Financial data (in million DM)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revenues</td>
<td>577</td>
<td>5,369</td>
<td>31,498</td>
<td>19</td>
</tr>
<tr>
<td>R&amp;D expense</td>
<td>282</td>
<td>3,764</td>
<td>16,292</td>
<td>14</td>
</tr>
<tr>
<td>Net loss</td>
<td>69</td>
<td>3,980</td>
<td>7,423</td>
<td>-9</td>
</tr>
<tr>
<td><strong>Industry data</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of companies</td>
<td>173</td>
<td>1,036</td>
<td>1,274</td>
<td>-1</td>
</tr>
<tr>
<td>Employees</td>
<td>4,013</td>
<td>39,045</td>
<td>140,000</td>
<td>19</td>
</tr>
</tbody>
</table>

and biotechnology research in Germany increased from DM48 million to over DM430 million (BMFT, several years; BMBF, 1996b).

Even though the German federal government was the first to directly support biotech R&D and several funding programs were put into place to fund biotech research in academic and industrial research labs, the outcome has been quite different from the intention of making biotechnology a competitive industry. Despite the solid basic research that has been established over the years at the various universities and publicly funded research institutes, major innovations that can be transformed into marketable products have not emerged on the German pharmaceutical market (Streck, 1994; Dolata, 1995). As in other cases of high-technology (e.g., for IT see Gebhardt, 1997), Germany has fallen behind some of its major international competitors (Legler et al., 1997; Mackiewicz and Partner, 1998).

Taking the figures of 1997 into account, Table 1 shows that the United States outperforms all other countries in the biotech sector in terms of its number of companies and employees as well as in terms of sales and R&D expenditures. Table 2 shows that American biotech companies are dominating the world market for products sold. In 1993 and 1995, all top 10 products were developed in the US, and most of them sold by US companies. Foreign companies could not compete unless they bought licenses of products developed by US biotech companies. The enormous growth rate of European figures indicates a catch-up strategy, wherein European countries are striving to make biotechnology a recognizable industry in their own countries as it is in the US. 3 The US columns, on the other hand, show a consolidation of the national biotechnology industry. Net loss decreased and so did the number of companies. For the first time since the ups and downs the industry faced in 1993 and 1994, when a lot of new companies tried to enter the market and many established ones faced losses of capital and trust caused by negative testing results, the US biotech industry appears to be stable once again. The fact that no comparative German figures for the prior year exist can be taken as an indicator of how little biotechnology is recognized as an industry in Germany and abroad. 4

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2 One indicator of the excellent basic research in German biotechnology is the Nobel prize won by Christiane Nüsslein-Volhard, Max-Planck-Institute at Tübingen, in 1994.

3 The consultant company Ernst & Young has been reporting on the “European biotech industry” annually since 1994.

4 Biotechnology here is broadly defined to “include any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop microorganisms for specific use. The development of materials that mimic molecular structures or functions of living systems is included. These data are limited to research directed toward biotechnology, and further to ‘new biotechnology’, i.e., involving recombinant DNA, DNA transfer techniques, macromolecular structure, cell fusion, bioprocessing, etc.” (NIH, 1994). Biotech industry comprises entrepreneurial life science companies using “modern biological techniques to develop products or services to serve the needs of human healthcare or animal health, agriculture productivity, food processing, renewable resources or environmental affairs. The term entrepreneurial refers to the differentiation between multinational chemical, agrochemical or pharmaceutical companies and small and medium-sized life science companies” (Ernst & Young, 1997).
### Table 2

<table>
<thead>
<tr>
<th>Product</th>
<th>Developed by</th>
<th>Produced by</th>
<th>Net revenues in million US$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neupogen</td>
<td>Amgen (USA)</td>
<td>Amgen (USA)</td>
<td>719</td>
</tr>
<tr>
<td>EpoGen</td>
<td>Amgen (USA)</td>
<td>Amgen (USA)</td>
<td>587</td>
</tr>
<tr>
<td>Intron A</td>
<td>Boigen (USA)</td>
<td>Schering-Plough (USA)</td>
<td>572</td>
</tr>
<tr>
<td>Humulin</td>
<td>Genentech (USA)</td>
<td>Eli Lilly (USA)</td>
<td>560</td>
</tr>
<tr>
<td>Procrin</td>
<td>Amgen (USA)</td>
<td>Ortho Biotech / J&amp; J (USA)</td>
<td>500</td>
</tr>
<tr>
<td>Engerix</td>
<td>Genentech (USA)</td>
<td>SmithKline Beecham (USA/GB)</td>
<td>480</td>
</tr>
<tr>
<td>RecombiNAK HB</td>
<td>Chiron (USA)</td>
<td>Merck (USA)</td>
<td>245</td>
</tr>
<tr>
<td>Activase</td>
<td>Genentech (USA)</td>
<td>Genentech (USA)</td>
<td>236</td>
</tr>
<tr>
<td>Protopin</td>
<td>Genentech (USA)</td>
<td>Genentech (USA)</td>
<td>219</td>
</tr>
<tr>
<td>Roferon</td>
<td>Genentech (USA)</td>
<td>Hoffmann-LaRoche (CH)</td>
<td>172</td>
</tr>
<tr>
<td>Humatrope</td>
<td>Eli Lilly (USA)/Genentech (USA)/Novo Nordisk (DEN)/BioTechnology (USA)</td>
<td>Genentech (USA)</td>
<td>226</td>
</tr>
<tr>
<td>Cerezyme</td>
<td>Genzyme (USA)</td>
<td>Genzyme (USA)</td>
<td>215</td>
</tr>
</tbody>
</table>

Biotech innovation in big pharmaceutical corporations has been poor as well. Except for one medium-sized company, Boehringer Mannheim, which received approval for its genetically produced r-tpa factor Reteplase in 1996, the German pharmaceutical industry has no in-house biotech innovation on the market, neither in therapeutics, vaccines, or antibodies. Of the 31 genetically produced drugs admitted on the German pharmaceutical market in 1998, only nine were distributed, six produced, and one developed by German pharmaceutical companies; 14 were developed entirely by or in cooperation with US companies, mostly start-ups. The rest were developed by different European companies. In contrast, US companies are dominating their own domestic market: Of the 41 genetically produced drugs admitted in the US, 33 were developed, produced and distributed by US companies, only one by a German company (BIO, 1998; DECHHEMA, 1998; Giesecke, 1998).

Another indicator reveals the unintended outcome of federal biotech policy: Even though German companies were dominant on the world pharmaceutical market during the post war period, they have lost their share on the market during the last 20 years due to the lack of innovation, e.g., in the biotech sector. While German pharmaceutical companies made 17% of their turnover on the world pharmaceutical market in 1973, this share decreased to 8% in 1993 (BVK, 1997). The German chemical and pharmaceutical company Hoechst, ranking on the very top of the international scale in 1976, declined to number 10 in 1994. Hoechst could reclaim its position among the top three but only as a result of its merger with Marion Merrel Dow and Rhone Poulenc Rorer in 1996 (Sharp and Patel, 1996; Handelsblatt, 1997).

The decline of the German pharmaceutical industry was due not only to the cut back of R&D expenditures (Germany’s share of 13% of the total OECD budget for pharmaceutical R&D in 1973 declined to 7.7% in 1990, Sharp and Patel, 1996) but also to the absence of investment in biotech R&D, especially in modern biotechnology, until the 1980s. Thus, the dominance of the US companies’ share on the world pharmaceutical market, in
part, be explained by the innovative biotech industry in the US. The US share of biotechnically produced drugs on the world market in 1995 was 70%; whereas, the German share was 4% (BMWi, n.a.). Even though they are no more innovative than German pharmaceutical companies, US corporations in this sector have been able to use their regional advantage of shorter physical distance and common cultural background to outperform German and other foreign competitors. In addition, the US pharmaceutical market is not only the biggest national market but also the fastest growing one.

During the start-up phase of biotech industry development, US biotech companies were more interested in forming strategic alliances with domestic pharmaceutical companies, because they wanted to conquer the US market and needed strong partners with established distribution networks to do that (Forrest and Martin, 1992). Foreign companies became more of interest to US start-ups during the expansion phase. Thus, some foreign companies such as Hoffmann-LaRoche of Switzerland or Kadi of Sweden were able to maintain their competitive position by licensing biotechnology innovations. Both companies bought exclusive licensing rights for the European Market for Genentech’s first two innovations: human insulin and human growth hormone (Swanson, 1996). Genentech was the first economically successful biotech start-up with major innovations on the therapeutic market and served as a role model to other start-ups for nearly 20 years.

Why is the German biotech industry performing so poorly now compared to other nations? Considering the extraordinary engagement of the German federal government in biotech research, the lack of innovation is even more striking. In contrast, the US biotech industry is the strongest but has not relied on direct government support. The question arises as to what are the variables that support biotech innovation and how government’s policies can influence them.

3. Determinants of a national system of innovation

The approach of “National Innovation Systems” is used in order to define those variables. This comprises a set of factors in a nation which generates, selects and diffuses innovation (Freeman, 1987; Lundvall, 1992; Nelson, 1993; Edquist, 1997). Depending on the nation and technology analyzed this set of variables can be constituted by the various government actors and institutions involved in shaping and enacting technology or economic policy: academic research institutes, such as universities, the industry structure, the legal system of academic education, and institutions that promote technology transfer from academic research to the market. The variables enabling a supportive institutional arrangement for biotech industry development have to meet specific demands of the inherent path of technological development. This can be learnt from the American example. Here, biotechnology was embedded in an institutional arrangement that is characterized by more flexible organizational forms serving short-term, high-risk market-based economies.

Among those demands are short distances for the communication of tacit knowledge (Saxenian, 1994; Howells, 1996). In addition, further specific features include the length and especially the uncertainty of races to find new compounds. This search involves extensive time horizons that are due to strict safety regulations and thereby cause high capital intensity. At the same time, biotechnology is a high-risk technology, economically as well as technically. Thus, an enabling institutional arrangement has to provide for the maximum containment of those economic, technical and safety risks. These specific features — time intensity, uncertainty, capital intensity and risks — are inherent to the path of biotechnical develop-

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6 Only in 1997 have Merck and a few other pharmaceutical companies been able to bring in-house biotech innovation on the market. Merck has come up with Crixivan, a protease inhibitor fighting the expansion of HIV. Hoffmann-LaRoche has developed a similar product (Ernst & Young, 1996).

7 In 1995 and 1996 the average growth rate of the world pharmaceutical market ranged between 7% and 8%. At this time, the growth rate of the domestic US market was 11%, its volume US$54.7 million (Sharp and Patel, 1996; Handelsblatt, 1997, 1998).

8 For literature on contrasting styles of modern capitalist economies see Streeck (1991), Hollingsworth and Boyer (1997).
The innovation process is embedded in systems that vary among nations. These systems are determined by several institutions and variables. Some of them are subject to government’s S&T policies, but these policies can only be successful when they mesh with the rest of the existing system. The rest comprises variables and institutions such as academic researchers, small start-up companies, pharmaceutical corporations and financial markets funding high-tech R&D. In the case of biotechnology, government policies, economic and social institutions work best if they generate and diffuse knowledge. Reconsidering the crucial role of knowledge and knowledge transfer, we will now take a closer look at the determinants of success of the US model.

3.1. Academic researchers as entrepreneurs

As Tables 1 and 2 demonstrated, start-up firms play a crucial role in the advancement of biotech industry. They serve as a technology transfer mechanism to bring research results from the academic lab to the market. The start-up nurtures the new technology until big pharmaceutical corporations become interested in forming a strategic alliance and undertaking all subsequent steps of the product development process. To uncover the secret of the US biotech industry’s success means to understand first why start-ups are the motor of innovation and not big pharmaceutical companies with in-house research labs; and second, to find out what belongs to the "economic ecology" that makes start-ups develop and grow.

Biotech companies in the US are usually founded by faculty members of academic institutions and/or venture capitalists (Kenney, 1986). Entrepreneurs with an academic background command tacit knowledge (Polanyi, 1967) and sometimes own patents that grant them access to new scientific findings, that no one else is able to exploit. Transferring this knowledge to a company is the prevailing mechanism for its commercialization and finally its medical application. Usually, academic entrepreneurs either keep their position as a scientist and researcher or find other ways to stay in close contact with basic research and the latest developments in their fields. In this way, they are able to maintain a constant flow of information that otherwise would not be codified but might become an intangible good for the company after further development (Howells, 1996).

Academic institutions may profit from this close relationship as well. Apart from licensing revenues, they get information on industry needs as well as on breakthroughs of commercial research and possibly extramural grants for research projects (Powell and Owen-Smith, 1997). As these examples show, knowledge and information are the crucial assets in the biotech business. The communication of knowledge occurs not only between companies and academic institutions but also within companies. Thus, entrepreneurs attempt to keep information channels as short and direct as possible, avoiding hierarchies and division of labor that keeps research separate from management. 9

Even though there are functional differences and specializations within each company, the flow of communication among the key figures and functions can be maintained, and bureaucratic inefficiency avoided. Since biotech companies start with very limited personnel, it is much easier for them to overlook the operational effectiveness. Further, all biotech companies are specialized on a single or a few market niches. This strategy is not only necessary for the economic survival on a highly competitive market, but it also allows for the concentration of all company resources on a limited but specialized scope. In fact, biotech companies are more likely to found a new spin-off if they want to pursue a different line of technology than to integrate a new line into the established company (Acs et al., 1992; Audretsch and Stephan, 1994).

In contrast, in Germany the pharmaceutical sector is dominated by big corporations. German biotech start-ups are so marginal in size and turnover that they are neither serious competitors to the pharmaceutical industry nor interesting partners for strategic alliances. The scarce number of biotech start-ups founded in Germany is hardly worth mentioning even though the increasing number of newly founded

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9 There are exceptions, of course. Take, for example, the Belgian company Jansen Pharmaceutics, which is famous for its horizontal organization.
companies may indicate a catch-up strategy oriented toward the American model. The young entrepreneurs have yet to prove that their companies are competitive on the market. In 1997, the turnover of the entire start-up biotech industry in Germany was less than that of a medium-sized machine-tool company (Ernst & Young, 1998).

Table 3 shows the different phases of biotech development, indicating the time lag of the German development compared to the US lead and consequences of latecoming for future innovation and market development. In Germany, biotechnology is just about to form an industry, although there are no product innovations on the drug market yet. German companies are usually very small in size and have less equity than their American counterparts. Most of them do not target the integration of an entire innovation and product development chain. Rather, they specialize on services and platform technologies. The majority of the 173 biotech companies in Germany (figures of 1997) have less than 100 employees and average turnover of only a few million deutsche marks; 90% of them have a turnover of only a few DM100,000 with a research crew of three to 15. In comparison, US companies have an average of 90 employees and the most successful among them have a turnover of several US$100 million (Dolata, 1994; Clarke, 1998).

It has become clear that for a knowledge-based technology like biotechnology short distances and direct communication as well as permanent monitoring are important for bringing innovation to the market. Due to the different setups of the national innovation systems, there is a time lag of biotech development in Germany compared to the US. The German biotech innovation system is hampered by the lack of innovative start-ups and the dominance of big pharmaceutical companies with little innovative potential in modern biotechnology. The national performances of biotech innovation in the pharmaceutical sector vary according to national specific institutional arrangements that enable trajectories from the academic research lab to commercial application. In the US, these trajectories were created by the incubator situation for academic personnel at several universities to create high-tech start-ups (Kenney, 1986). This prevalent mechanism will be discussed in the next paragraphs.

3.2. Technology transfer from lab to industry

One missing link in Germany was the biotech companies — or an alternative trajectory in the start-up phase of biotech-industry development — due to the setup of the German innovation system. Several disincentives that are characteristic of the German system of innovation account for this missing trajectory thereby blocking technology transfer and the reciprocal interactions of the triple helix.

Academic researchers in Germany, for example, never had any significant incentives to file patents. According to German law, employees of public universities fully own their intellectual property. They do not have to share it with their employing institutions. This rule has turned out to be an obstacle to the overall innovative performance of German universities. Academics have to bear the cost of filing and sustaining patents all by themselves, and this can be very costly. In contrast, in the US the university’s technology transfer offices pay for the fees and in return get a share of the royalties. Technology transfer offices at German universities and at most public research institutes, however, are not run as for-profit enterprises.

Another disincentive for filing patents is the German and European patent law. Unlike the US rule “first to invent”, in Germany and at the European Patent Office the rule is “first to file”. An invention that has already been published, e.g., in a journal, cannot be patented afterwards in Europe. For academics, it is more important to publish than to patent. Subsequently, the possibility to file a patent is missed (Abramson et al., 1997).

Further, as civil servants, university researchers in Germany are not allowed to found their own enterprise or take an additional appointment as a professional member of a company’s scientific advisory board. Another obstacle is that technology-transfer offices are not run as businesses. Even though industry takes increasing interest in sponsoring academic research at German universities and academic research institutes, they become more dependent on corporate funding as public resources dry up; the cooperation between industry and academic research in Germany is far less common as in the US. Only very slowly do public research institutes realize that they can serve as incubators to advance technology
Table 3
Phases of biotech development on the pharmaceutical sector in the US and Germany (Giesecke, 1998)

<table>
<thead>
<tr>
<th>Phase</th>
<th>US companies</th>
<th>German companies</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st generation</td>
<td>Start up: First start-ups emerge after Cohen-Boyer gene splicing breakthrough; first innovations developed by academic researchers, substitutes for conventionally produced therapeutics; venture capital companies start getting interested in new industry; regional innovation clusters emerge; role model Genentech; long-term goal: become integrated pharmaceutical company.</td>
<td>1976–1984 Start biotech companies specialize on tools for compound development and on the service sector for pharmaceutical companies; goal is not to develop an end product but to license innovation; demand for investment capital could not be covered by the few resources existing; pharma companies take only little interest in German biotech companies;</td>
</tr>
<tr>
<td></td>
<td>Expansion: Spin-off of 1st generation and new foundings; new regional clusters emerge; acquisition of venture capital becomes easier after a few products of 1st generation companies are successfully marketed; boom of new biotech companies and increased need for capital.</td>
<td>1985–1993 Expansion: Biotechnology becomes less exotic for investors; more venture capital can be raised; more capital is needed for expansion; foreign investors take increased interest; successful US companies become the role models for R&amp;D finance, indications, business organization and alliance forming; long term goals are going public and production of drugs based on in-house innovations.</td>
</tr>
</tbody>
</table>
Consolidation

Negative results of clinical testing caused lack of confidence of investors; stagnation of development; first time number of biotech companies decreased; more strategic alliances with big pharma companies were formed to compensate lack of capital; companies which survived consolidated, some expanding overseas; targeting less ambitious indications; specialization on niche segments

New biotech companies find niches if they become innovation providers for big pharma companies; pharma companies set up biotech research units that imitate structure and operation of start-ups

Since 1995

Consolidation took place: New generation of biotech companies find niches after big pharma companies formed strategic alliances; more VC available; crisis of US biotech industry has almost been the exception; apart form tools biotech innovations that perform successfully on the market are still missing

New generation of biotech companies furthered by government initiatives, more VC and further differentiation and division of labor and technological tools; specialization on platform technologies, providers of biotech tools for pharma companies

Standardization of basic research methods gives access to new generation and new type of companies
transfer and thereby nurture a new high-tech industry (BMBF, 1996c; Abramson et al., 1997). The publicly funded German “Society for Biotechnology Research” (Gesellschaft für Biotechnologische Forschung) and the Gene center at Martinsried near Munich have recently started to provide for the technical infrastructure of labs, instruments, etc. in order to give entrepreneurs a chance for developing ideas into marketable innovations until that time at which the researcher is able to lead an independent enterprise (Clarke, 1998; Giesecke, 1998; König, 1998).

Contrasting these obstacles of technology transfer are the initiatives that were undertaken by the US government to integrate academic and industry research. New laws on technology transfer were enacted in the US during the 1980s to promote technology transfer and to remodel a structure that could not adjust to new economic developments that were dependent on high-technology changes. The Bayh-Dole-Act of 1980 and its revisions reacted to the fact that a lot of promising ideas and inventions born in academic research labs were not economically exploited. These laws enabled universities to derive a commercial benefit from the research undertaken in their institutes. Technology transfer offices were set up to market and license innovations and to found young enterprises within the university’s region (Abramson et al., 1997). Originally designed to speed up the conversion process after the end of the cold war, these policies helped to give birth to the US biotech industry.

3.3. Polity and politics of biotech innovation

The German government has pursued direct interventionist technology policy on the biotech sector through its Ministry of Science and Technology. This technology policy, however, was less effective than the American approach of a pluralist, heterogeneous and contextual technology policy. Even though there is no central agency coordinating science and technology policy in the US, the American approach was more effective because it supported an institutional arrangement that was favorable to the specific needs of biotech development. The structure and policies on the national government level that influence this institutional arrangement will be identified at this time.

The major government agency in charge of science and technology policy in the pharmaceutical biotech sector in Germany is, as mentioned before, the Ministry of Science and Technology. This agency designs and implements policies in almost all fields of science and technology (Stucke, 1993) whereas the US does not have a central agency for this field of public policy. All attempts to create a national agency with central competence and funding authority in post World War II America failed due to political disagreement on the power of such an agency. Instead of a central national agency, the Department of Health and Human Services (DHHS) and its research agency, the National Institutes of Health (NIH), are responsible for science and technology policy on the sector of pharmaceutical biotechnology. After World War II, since the US government made cancer research a national priority, NIH was able to expand its capacities and competence and to establish a research empire dedicated to the health sector (Swain, 1962; Fredrickson, 1981). A specific program to support biotechnology development as it was passed in Germany, however, was never enacted in the US. Instead, biotechnology was never seen as an end in itself but as a tool to expand the scientific frontier in medical research.

Other than the DHHS, the German Ministry of Science and Technology did not have much in-house competence on the field of biotechnology. Accordingly, the agency relied on industry and science expertise to design support programs for biotech development. Both industry and science experts, however, did not consider genetic engineering as a major source of product or process innovation in the early 1970s. Instead, they opted to continue research

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10 For discussion on the National Science Foundation that was designed to become the central agency for science and technology issues see Smith (1990) and Kleiman (1995).

11 Among the achievements of NIH biotech research are therapies and vaccines for child immune deficiency (ADA), AIDS, haemophilia, aenemia, hepatitis B, diabetes mellitus, haemophilus influenzae, kidney transplantation and others (FCCSET, 1993). Of the US$11 billion total NIH budget in 1994, US$3.4 billion were spent on biotech research (NIH, 1994).
on traditional fields of biotechnology (Buchholz, 1979; Jasanoff, 1985; Marschall, 1997; BMFT, several years). The science and economic experts upon which the government relied, were usually affiliated with those academic institutions and industrial companies that got extramural funds from the Ministry of Science and Technology. In this way, new incentives from outside the “inner circle” of government R&D funding were excluded. Instead, this structure perpetuated the same research directions that had been established over the years, resulting in lock-ins (Gebhardt and Giesecke, 1997; Marschall, 1997; Meyer-Krahmer and Schmoch, 1998).

One of the differences between the US and German political structure lies in the capacity and competence of the agency that assigns the research projects: In the German case, the instrument of governance is limited to monetary instruments whereas, in the US, scientific knowledge on in-house research and extramural funds put NIH in a strong position to compete at the state of the art. NIH emphasizes compatibility and benefits to in-house research projects (Schwartz and Friedman, 1992; NIH, 1993). This policy assures continuation of strategic research goals and, at the same time, opens up the possibility for integrating new incentives from outside to in-house research directions, thereby avoiding lock-ins.

In order to catch up, the German Ministry of Science and Technology in the 1980s and 1990s initiated several programs as part of the project funding measure to support more applied research with the intention to yield products competitive on national and international markets 12 (BMFT, several years). Even though in several projects, industry cooperated with universities and public research institutes, major technological breakthroughs and innovations with immediate industrial application could not be achieved.

This lack of innovation has structural reasons: The German landscape of scientific research institutions is very different from the US academic structure and does not necessarily connect new scientific knowledge to industrial demand. Besides industry and university research activities, publicly funded scientific institutions, such as the well-known Max-Planck-Society, federal laboratories, and others, have an important position in research and have expanded in post-war Germany. There is a division of labor between publicly funded research institutes and universities with their main focus on basic research on one hand and industry R&D with its main focus on application and commercialization on the other. Most of the researchers in publicly supported laboratories and at the universities viewed themselves as dedicated to basic research and resisted all efforts of the Ministry of Science and Technology to turn to applied, industry-related research. German federal and state laboratories and research institutes tended to stick to basic research whereas corporate researchers cooperated with companies, universities and federal labs in the US to get access to the latest technological and scientific developments. 13

Universities and federally funded research institutes contain a high degree of resistance against attempts of intervention whether on the part of the government or industry. The earmarked funding supplies universities and research institutes with autonomy on issues of research topics, money and personnel. With the rise of modern biotechnology and the blurring of the line that used to separate basic from applied research, the orientation toward basic research is not the main reason for failing communication between government, industry, and academic actors. Rather, it is the missing experience of close cooperation, the lack of established communication channels between these actors that inhibits a functioning system of innovation. 14 This traditional division of labor is maintained by an institutional inertia and hampers the dynamic process of the triple helix, where close contacts of academia, industry and gov-

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12 For example, the set up of centers of excellence (Genzentren) in Cologne, Berlin, Heidelberg and Munich with public and private funding; special funding program “Biotechnology 2000”; “BioRegio-contest” of 1996.

13 The German chemical and pharmaceutical corporation Hoechst, for example, invested US$70,000 million in 1981 over a 10-year period for a collaboration on basic biotech research with Massachusetts General Hospital (Culliton, 1982).

14 For sector-related problems of technology transfer and university—industry interaction, see Meyer-Krahmer and Schmoch (1998).
government could be established in order to further the triadic cooperation, and thereby, react to the specific challenges of new hybrid technologies and the new production of knowledge as in biotechnology.

Thus, the conclusion can be drawn that the German national innovation system does not have the structural set up that would enable the government to pursue a science and technology policy that furthers technology transfer and innovations on the biotech sector. Direct targeting by a government agency is, by definition, remote from the organization of research and development and cannot anticipate the innovative dynamic a specific technology — following its inherent logic of development — might take. Thus, the agency cannot generate an institutional arrangement that connects policy objectives and innovative potentials of one specific technology. It appears that public policy capacities and objectives alone are not sufficient to enable innovative activity. They have to meet an already existing institutional arrangement to constitute a functioning system of innovation.

3.4. The role of financial markets funding biotech R&D

A different government approach, technology transfer acts and a specific company type however, were only some of the variables constituting a more favorable opportunity structure for biotech innovative development in the US. Incentives to promote biotech innovation were distributed on various levels. For example, policies for promoting small and medium-sized high-tech enterprises and a venture capital industry were already enacted by the Small Business Administration in 1958, in order to provide for the financing of such enterprises in the US. The Small Business Investment Act supported venture capital (VC) companies, especially those that invested in high-tech companies. These venture capital companies became the prevailing model for an alternative equity and investment market that supported the rise of many successful high-tech enterprises, e.g., on the sector of information technology, biotechnology, telecommunication and many others. In addition, private venture capital companies were formed after World War II to meet the financial and managerial needs for small private enterprises within the regional networks of universities and other academic institutions (Etzkowitz, 1993; Murray and Marriott, 1998). While the first private US venture capital company was created in 1946 (American Research and Development, ARD), these kinds of businesses are only starting to develop now in Germany. Yet, they are very reluctant to invest in high risk industries, such as biotechnology. As Table 4 shows, the overall volume of venture capital in Germany is still small compared to the US figures; the VC invested in biotechnology in the US was DM1287 million in 1996, seven times the venture capital invested in German biotechnology. Even though only one out of 100 entrepreneurs that apply receive venture capital and many small companies are purchased by bigger ones during an early stage, the VC industry — at least for the last 35 years — has created a platform for many high-tech innovations that would otherwise have taken longer to develop or that would not have been developed at all (Lerner, 1994).

There are further differences concerning investment in both countries. The percentage of stockholders in Germany is 6.5% compared to that of 21.1%.

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For the German discussion on governance (Steuerung) see for example Scharpf (1988; 1989), Luhmann (1984; 1989).

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16 Since biotechnology research is a costly enterprise (an average of US$345 million until a new compound is found that is worth further development) and young start-up companies have no financial resources, this industry relies heavily on venture capital, following the example of information technology companies in the 1960s and 1970s (BIO, 1998).
in the US (Ernst & Young, 1998). Investment capital in the US rose from US$2.4 billion in 1969 to US$37 billion in 1995. One-third of venture capital invested in the US was spent on high technologies such as computer, software, telecommunication and biotechnology. German investors are more hesitant: Only 7% of the VC invested are spent on new technologies. The biggest share is invested in traditional technologies and services. There is also a noticeable difference of investors in both countries. While federal and state funded institutions are backing a high percentage of venture capital investment in Germany, in the US we find business angels, pension funds and insurance companies bearing the largest share. In Germany, pension funds and insurance companies are by law restricted to invest in venture capital. Furthermore, German investors are more hesitant to finance risky seed and start-up phases of companies. Only three, respectively 7% of VC are invested in seed and start-up phases, 60% go to established companies; US investors spend one-third on early phase (seed start-up and first phase) ventures (BVK, 1997; Handelsblatt, 1998; Mackewicz and Partner, 1998).

When the first private venture capital companies were founded in the late 1940s and the first public–private ones in the 1950s, there was no intention to support a biotech industry. However, these policy measures helped to promote other high-tech industries, such as computer and software industry. Biotechnology happened to have similar needs as these earlier technologies and, thus, found a favorable, promoting environment for its development into an industry of its own. Policy incentives alone, however, were not sufficient to initiate a VC industry and high-tech clusters in certain regions of the US. The attempt to settle small business investment corporations in metropolitan areas with little innovative dynamic and a weak economy during the 1970s and 1980s, in order to create a ‘third coast’ comparable to the high-tech centers on the East and West coasts and thereby enable high-tech ventures as university spin-offs, could not be realized. Disadvantages rooted in regional structures could not be compensated for by federal aid because several other determinants of the system of innovation were missing (Kenney and Florida, 1988; Green, 1991). This example demonstrates the long-term effect policy and politics can have, as well as the unintended consequences that may arise.

Complementary to the many supporting functions of venture capital industry in the US is the stock market for high-tech enterprises that show promising research results but do not yet yield profitable products. Until 1993, the US Nasdaq was the only stock exchange admitting such companies and thus providing exit opportunities for early stage investors. Nasdaq has had this international monopoly for more than 20 years and was able to establish not only a reliable investment market for high-risk technology ventures but has also helped many start-ups to grow from garage enterprises into mature companies. Since 1993, when the London stock exchange began to admit biotech companies, several alternative stock exchanges were established in Europe to serve the need for exit options of high-tech investors and enterprises (Arthur Anderson et al., 1994).

In 1997, the New Market (Neue Markt) was established in Frankfurt to attract more venture capital funding in young German high-technology companies. Even though the statistical data show satisfying market capitalization and volatility for its first year of operation, it is still too early to comment on the success of the New Market and its potential to become a German Nasdaq. The US original lists some 317 biotech companies out of some 5500 companies listed and is, therefore, without almost any competition as far as market capitalization and experience for high-tech ventures is concerned. At the German New Market, out of 86 companies listed until April 1999 only three were biotech companies (Qiagen, Morphosys and Rhein Biotech).

Even though these bids were quite successful, they may not disguise the fact that the few academic researchers who intend to start a biotech company in Germany still find raising equity their major problem. This does not so much concern the early stage then the secondary and expansion phases (Mackewicz and Partner, 1998). Incentives and policy measures to set up a venture capital industry that would become independent in the future and might

finance entire high-tech industries were never initiated by the German government until recently. Of course, federal and state funding measures, generally provided by publicly financed organizations to help fund high-tech enterprises, exist (Murray and Marriott, 1998). However, these funds were provided by public institutions for direct investment in young high-tech companies or to finance low interest loans. These measures have not enabled a sustainable venture capital industry that would be willing to invest in secondary and expansion phases. Thus, the supporting measures for setting up new biotech companies in Germany are unlikely to meet the specific demands of that industry.

The supporting conditions of a venture capital industry that existed in the US met at least three specific features inherent to the path of biotechnology development: First, it enabled the setup of small specialized research units in high-technology clusters, where distances were short enough to communicate tacit knowledge, which was crucial especially during the first phase of biotech industry development (see Table 3 and Zucker et al., 1994). Due to its specific mode of generating knowledge and innovation, biotechnology as an industry could best advance in small R&D units rooted in entrepreneurial companies. Second, it provided for the equity needed to finance biotech research until a patent or product became marketable and, thus, closed the equity and realization gap for early stage investors who wanted a profitable return before the start-up is listed at the Nasdaq or another stock market. Finally, venture capital companies provided for the managerial and business know-how needed to set up a high-tech company. Academic researchers founding their own business are usually confronted with financing and managing issues for the first time and, thus, need the skill and help of experienced professionals (Mackewicz and Partner, 1998; Zider, 1998).

3.5. German catch-up strategies to overcome blockages of the national innovation system

The German innovation system favors traditional basic research institutes and big pharmaceutical companies rather than small biotechnology start-up firms. Looking at the US model, however, it becomes questionable whether the German strategy is appropriate for the demands of biotechnology’s development into an industry. Besides, government itself cannot create all elements of a favorable “economic ecology” for biotech development.

In this respect, the conditions for biotechnology to become an independent industry in Germany were not very favorable. The lack of entrepreneurial culture among academics, for example, is a disadvantage that can hardly be compensated by policy measures. Further, there is no tradition in founding high-risk companies in Germany as was established in the US, starting with electronics and information technology in the 1950s and 1960s. There is no role model of a unique German biotech company as was Genentech and later Amgen for the US industry. Further, it is questionable whether all these companies that were founded in the last 3 to 5 years, in part through federal subsidies for equity, will raise sufficient venture capital for the secondary and expansion rounds.

One of the latest attempts of the federal support for biotechnology was the BioRegio-contest of 1995/1996. Until then, only a few dozens firms existed in Germany. Today, all of them are trying very hard to find and defend their technological niches. Characteristic of German biotech start-ups today is their specialization in one of the so-called platform technologies, which are defined as instru-

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18 Among those publicly financed organizations that provide credits and VC for start-up ventures in high tech and other sectors are the German Kreditanstalt für Wiederaufbau and the Deutsche Ausgleichsbank with its affiliated Technologie-Beteiligungs-gesellschaft, which has a special program for small high-tech enterprises (Beteiligungsprogramm für Technologieunternehmen) (Mackewicz and Partner, 1998).

19 Under the Biotechnologie 2000 program, all financial resources of extramural funding for biotechnology were orchestrated and new research directions defined in order to push academic and industry research toward more marketable products. An additional program was the BioRegio-contest. It awarded the top three of 17 applicant regions with federal money of DM50 million each over 5 years. The winners were Munich, Heidelberg and the wider Cologne-Rhineland area.
ments that have become crucial for further development of biotechnology. In Germany, this specialization is more prevalent than in any other European country or in the US. According to Ernst & Young statistics of 1998, almost one-third of German biotech companies concentrate on this segment and only 15% on therapeutics. In contrast, therapeutics is the dominant sector for all other European countries, comprising some 40% of biotech companies; whereas, platform technologies comprise roughly 20% (Ernst & Young, 1998).

Platform technologies comprise combinatorial chemistry and combinatorial biology as well as genomics and others. The specialization in one of the new platform technologies is the result of two specific features of biotechnology that only became visible along its path of development: First, the difficulties of the first generation of biotech companies in the US to develop new drugs, and the capital, time, and knowledge needed for innovative products caused a severe crises in the US biotech industry in 1993 and 1994 (see Table 3), which made clear that most companies were not capable of becoming a diversified or integrated pharmaceutical company comprising the total process of developing a new drug. The need for capital, for know-how concerning clinical testing and upscaling, for distribution networks, etc., led to a disintegration of the development process. Instead, many companies started to specialize on certain technological or service units as part of the whole innovation and production process. Second, the diversity of biotechnology, the manifold possibilities of its integration with other technologies into new hybrid technologies, and the standardization of some of the underlying processes (polymerase chain reaction, high throughput screening) for biotech research offered new market niches and, thus, possibilities for new specializations (Powell and Owen-Smith, 1997). The companies have learned from these developments. For German companies, a possibility to surmount the blockages in the national system of innovation and to contain technological and financial risks is by becoming a supplier of a technology or service component at the upstream or downstream end of the innovation and production process.

Despite the blockages, some biotech companies in Germany have managed to conquer niches that seem to be profitable for some time. Success cannot always be measured in terms of market innovations or sales. Rather, some German biotech companies have come up with promising business partners that invest in start-up developments and new ideas. Some of them were able to attract big German and international pharmaceutical companies. As these corporations are experiencing a large amount of restructuring in order to be more competitive and innovative, small start-ups are becoming outsourcing partners, thus, filling in niches that may give them a chance to survive in the long run.

Even though some of the blockages of the German innovation system may be overcome by concerted efforts of political, economic and academic actors to imitate the American success model, incentives for technology transfer remain a problem until this date.

In spite of the rigidities of the German innovation system that hinder the triple helix’s move from the level of basic research to the market place, by dissolving traditional boundaries of the division of labor, biotechnology in Germany has the chance to become a more solid industry in the future than it was in the past. While the US system of biotech innovation in the pharmaceutical industry enables the institutional arrangements to create new technologies and innovation, the German system — at least for some time — provides more stability for those companies that were able to overcome the blockages of the German innovation system. The staggered phases of German development compared to those of the US gave German biotech companies the chance to learn about the technological and economic risks in this sector. However, it is questionable if German companies are able to find developmental paths to avoid mistakes made by US and UK companies. Since the German economic environment does not favor risk technologies, only very few start-ups are listed at the stock market so far and, therefore, have not yet faced economic breakdowns as many US

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20 For example, a second generation biotech start-up at Munich, Morphosys, was able to form a strategic alliance with the Swedish-American pharma company Pharmacia and Upjohn, worth US$50 million in combinatorial biology, a platform technology (Wall Street Journal of Europe, 1997).
companies experienced in 1993 and British companies in 1997 (Casper, 1998).

4. Is there a future for German biotech development?

As these findings indicate, innovative performance is dependent on the setup of the specific national innovation system. This can only in part be shaped by government policy. A system of variables that constitutes a national system of innovation is very complex and cannot be anticipated by government actors in advance. These determinants develop over a long period of time. They are often rooted in cultural idiosyncrasies or in policy decisions that had entirely different intentions and date back to a time when the technology was not even thought of.

As the American example shows, it is not necessarily direct interventionist science and technology policy that accounts for successful innovations on a specific sector. Even though it seems to be paradoxical at first sight, direct government intervention aimed at promoting science-based high-technology industries is more likely to fail its goals than indirect, contextual measures that enhance or activate an already existing “economic ecology”. Incentives to nurture innovation of a certain technology might be more effective if they are spread out to create a preferable environment that connects academic innovation with market opportunities and, thus, meets the specific demands of a certain technology. Among those structural arrangements that meet the demands of biotechnology development are the incubator environments that academic research institutions can provide, the availability of venture capital and professional business advice, exit opportunities for early investors, the possibilities for diffusion of knowledge and last but not least, the competence of political actors to distribute research money where innovations are most probable.

The latter implies that the government has the capacities to accumulate and evaluate knowledge on the scientific edge. This, of course, is a very indirect means to foster high-tech innovation because, as the example of the NIH showed, political decision making must be transferred from the administrative level to the science and research level. Government capability to directly influence further innovation is thus rather limited. At most, government is capable of empowering a segment of the institutional arrangements that might condition high technology innovation on a sector, such as biotechnology.

The triadic relationship between the state, academic research, and industry existed in Germany as well as in the US. Yet, the interaction in Germany was only limited and did not capture reciprocal relationships in such a way that the spiral movement characteristic of the triple helix could be triggered. In the US, the major actors involved — federal government, academic researchers, start-up companies, pharmaceutical corporations and venture capital companies — were more intertwined and, thus, formed an “economic ecology” for biotech development on the pharmaceutical sector which was suitable for the specific properties of biotechnology. Resulting from these interactions and reciprocal relationships were the generation and communication of tacit knowledge as well as the diffusion of knowledge in general, the creation of incubators for entrepreneurs, the forming regional networks and strategic alliances, the development hybrid and platform technologies, the building competence on federal government institutions, the acquisition of sufficient money for R&D, the diffusion of business experience and expertise, the functioning of technology transfer, and the capabilities to contain technological and financial risks.

The US system of innovation provided a more favorable opportunity structure for biotech development because the triad relation of government, academia and industry had a disposition flexibly adjusted to the specific needs of biotech development. Most of the determinants furthering biotech development and innovation had already existed. The US had a comparatively long experience with other high-tech developments whereas, in Germany, many of those determinants are only now to be set up accordingly. Since the tools of the German government were limited to financial aid for research and development — besides a few incentives to further new ventures — many other crucial variables were and still are beyond the government’s reach, e.g., stronger incentives for academic researchers to become entrepreneurs, the creation of a self-sustaining
venture capital industry, the market size and growth rate of the pharmaceutical industry.

Only recently have government, academic and industry actors in Germany taken up steps to form a catch-up strategy that tries to overcome innovation blockages of the German system. While the German federal government tries to initiate the formation of regional networks by means of the BioRegio-Contest, the Program for Founding New Ventures (Existenzgründerprogramm) in cooperation with the German Science Foundation (Deutsche Forschungsgemeinschaft), and is taking steps to facilitate the transfer of intellectual property, actors in academia and industry are concentrating on the formation of further strategic alliances with US partners (BMBF, 1996a,c).

Academic researchers trying to imitate the American model and become biotech entrepreneurs have to consider three prevalent facts: First, learning from the US experience, would-be entrepreneurs have to take into account the economic risk involved in starting a company in this sector, with high expenses for R&D and no income for the first few years, especially when aiming at the therapeutic segment or considering to set up an integrated pharmaceutical industry. Second, since the international market for biotech products is already consolidated, and the entry barrier is much higher today than in the infant stage of that industry, newcomers have to conquer their niches strategically. Third, specializing on platform technologies can only be an interim solution. There are already too many platform companies on the market, and the competition has increased. In the long run, only a few companies will be able to survive in this segment. The others will have to develop therapeutics or look for alternatives. However, at the moment, the equity market in Germany might be willing to finance start up phase of biotech businesses, but it is unlikely that it will be capable of financing expansion phases which are sometimes riskier and require more money. Thus, even though learning from the US experience is possible to some degree, the German biotech industry will not escape from the same experiences of a painful consolidation process like those which their US role models had to survive.

It is apparent that efforts of direct interventionism were not able to overcome blockages that exist in the German system of biotech innovation. On the contrary, those government strategies even enhanced to a large extend the structural inertia that made the German system inappropriate for biotech development needs. To overcome these blockages, further tools beyond monetary ones have to be developed and, in fact, are on their way. However, only a more process-oriented approach, like the interaction and reciprocal relationships suggested by the triple helix model, will result in a self-sustainable biotech industry that is at least capable of becoming a supplier of platform technologies and that will bring a few internationally competitive therapeutics companies to the market.

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