

Are We All Global Now?
Local versus Foreign Sources of
Corporate Competence: The Case of the
Japanese Pharmaceutical Industry

December 2003

Forthcoming, *Strategic Management Journal*
special issue on *Global Acquisition, Protection,
and Leveraging of Technological Competencies*

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Abstract: This study links the highly distinctive national contexts of the pharmaceutical industry to the evolution of innovative capabilities for Japanese drug firms from 1975 to 1995. During these two decades, the Japanese domestic environment for pharmaceuticals changed radically, encouraging a “bubble” of trivial innovations. Experience by Japanese firms in their domestic market predominantly determined their innovative capabilities, pushing these firms towards trivial innovation. Corporate experience in the socially “proximate” markets of Southern Europe served as a strategic complement for significant innovation by Japanese drug firms, and thus as a partial counterweight to the home market. Unfortunately, corporate diversification was a strategic substitute for significant innovation, and many Japanese drug firms are significantly diversified. The resulting degradation of innovative capability for Japanese drug firms has locked most of them into an increasingly unattractive home market.

A great paradox of contemporary economies is that as markets steadily globalize, many firms retain their distinct national identities. Indeed, the bulk of empirical evidence is that most multinational firms remain “national firms with international operations” (Doremus, et al., 1999; Dunning, 1996; Hu, 1992; Porter, 1990a, 1990b, 1998). Despite this historical evidence, another prominent group of scholars has contended that strong national identities are becoming a competitive liability in globalizing markets. These scholars argue that successful multinational firms will increasingly tap the advantages of multiple national locations, and integrate those advantages into truly global capabilities (Bartlett & Ghoshal, 1989; Bryan, et al., 1999; Galbraith, 2000; Doz, et al., 2001).

At the heart of differences between these two scholarly views is the role of national context in determining corporate capabilities. Most large firms in the global economy sell products in and draw resources from multiple nations. Thus, large firms are simultaneously active in multiple and competing national contexts, which often differ quite radically. For Porter and others, experiences in the “home” national context predominate. These local experiences deterministically shape corporate capabilities. In contrast, for the globalists, well-organized multinational firms can opportunistically pick and choose how to assemble their corporate

competence out of a wide range of possible national contexts. The strategic intent of managers as they assemble the capability of their firm can transcend experience in the firm's home base.

This study examines the importance of experiences in domestic versus foreign contexts among 50 Japanese pharmaceutical firms, 1975 to 1995. We find that the domestic Japanese context predominantly determines both the capabilities of these firms at one point in time and the evolution of these capabilities over time. We also find that "proximate" foreign contexts in Southern Europe play an important, though secondary role in determining capabilities for Japanese drug firms. More "distant" foreign contexts have no impact on the capabilities of these firms at all. Finally, we find that diversification by Japanese firms out of ethical pharmaceuticals into chemicals and OTC products significantly reduces the beneficial impact of proximate foreign contexts.

These findings somewhat moderate the purity of the "home base" arguments: proximate national contexts indeed matter after all, and other industry contexts matter for diversified firms. Yet even these moderating findings reinforce the powerful role of historical experience in shaping corporate capabilities and cast doubt that managerial "intent" can easily transcend historical experience.

The Japanese pharmaceutical industry offers a natural experiment for testing the role of historical experience and managerial "intent" in the evolution of corporate capability. This industry changed significantly after 1981, becoming markedly different from important overseas markets in the USA and Europe. As such, in the early 1980s, it might seem to an outside observer that established Japanese drug firms faced a central strategic choice: they could deepen ties to their domestic market, or they could turn their back on it and concentrate on the increasingly different global markets. The fundamental strategic choice for any pharmaceutical

firm is between focusing limited resources for innovation on commercially important, “blockbuster” drugs or fragmenting resources into proliferation of many minor, imitative or ineffective products (Thomas, 1994). Over the 21 years of this study, most Japanese drug firms shifted emphasis toward numerous trivial products, swamping their domestic industry with a “bubble” of trivial innovations sold nowhere else in the world outside Japan. This business strategy ultimately proved to be dysfunctional, trapping Japanese firms in their home market. And that home market became ever less attractive, as desperate government officials tightened price controls for drugs to contain public expenditure on the innovation bubble. Yet, of the more than 60 Japanese pharmaceutical firms examined in this study, not one broke ranks to alter its innovation strategy to focus on blockbusters.

Problem and Hypotheses

This study examines how local contexts shape the capabilities of firms and the evolution of those capabilities over time. The literature defines resources as the stocks of strategic assets (valuable, rare, inimitable, and non-substitutable) that are owned or controlled by the firm, and capabilities as the capacity of the firm to deploy these resources for competitive advantage (Amit and Schoemaker, 1993; Nelson and Winter, 1982). Some scholars have theorized that existing capabilities are determined by historical experience, but that the future evolution of capabilities is a matter of choice and intent by managers (Dosi, et al., 2000). Yet, the empirical evidence suggests that the historical experience of a firm profoundly determines the future trajectory of its capabilities every bit as much as it determines current capabilities (Helfat and Lieberman, 2002).

Local contexts provide multinational firms with resources. Everyone recognizes that these resources are heavily imprinted by the nature of their local context. Where the debate is joined is the extent to which national contexts also determine capabilities, as firms assemble

diverse resources from diverse nations into their firm-specific competitive advantage. Those who see multinational firms as retaining their national identities hypothesize that the local context of the “home base” powerfully determines capability, while foreign contexts have much less impact.

A prominent series of case studies of industrial districts provides extensive empirical evidence for the first part of this hypothesis—that local context indeed determines capabilities (Piore and Sabel, 1984; Porter, 1990a; Saxenian, 1994; McKendrick, Doner, and Haggard, 2000; Bresnahan, Gambardella, and Saxenian 2001). Local context in these case studies is defined as the institutional and competitive environment. Context is thus a complex, multidimensional construct, incorporating aspects of consumer demand, worker supply, technology systems, competitive rivalries, and corporate governance.

A broad theoretical literature addresses the second part of this hypothesis—that foreign contexts have less impact on corporate capabilities. The five most important theories from this literature relate to: 1) physical distance and frequency of social interactions, 2) cultural distance and the content of social interactions, 3) complementarities in activity systems, 4) organizational inertia, and 5) organizational politics. We review each of these theories below, and then formulate hypotheses for this study.

The first theory as to why domestic context matters more than foreign context relates to geography, or physical distance and resulting the frequency of interactions. Physical closeness facilitates frequent contact among executives of different local firms and mobility of workers across local firms. Interfirm contact and managerial mobility are reduced if not eliminated as the geographic distance among firms increases. Hence, the access costs to resources and information in a national market are not uniform across firms, but rather are lower for firms

based in that market. Porter (1998) argues that localized increasing returns in supply of key inputs provide lower access costs to local inputs, such as skilled labor, componentry, or venture capital. Foreign firms face higher costs to employ these inputs. Krugman (1991) examines “agglomeration economies” that provide benefits of scale to local firms, but not foreign ones. Jaffe et al (1993) document knowledge spillovers that occur rapidly for local firms but diffuse much more slowly for geographically distant firms. Kono, et al. (1998), Sorenson and Audia (2000), and Sorenson and Stuart (2001) demonstrate that the density of social contacts is higher locally than with geographically distant regions, enabling business practices to diffuse more rapidly locally.

The second theory as to why local context matters more than foreign relates to social structure, or social distance and the content of interactions. Powell and Smith-Doerr (1994) well criticize the fixation of economists with a literal geographic interpretation of proximity, arguing that it is really “shared social practices” that determine asymmetries in access costs between local and foreign firms. It is thus not the frequency, but rather the quality of relationships that matter. Powell and Smith-Doerr argue that the core driver of access costs to local inputs and technology is really trust, and trust is facilitated by cultural norms. Bresnahan, Gambardella, and Saxenian (2001) provide supporting evidence for this claim, finding that Israel and Taiwan are more “proximate” to California’s Silicon Valley cluster of information technology companies than the Boston region of the USA. They find that employee mobility and supply connections to global networks matter far more than geographic distance to facilitate interactions. They further find that institutional isomorphism for entrepreneurship, university science, labor relations, and other social practices makes the quality of interactions higher. This isomorphism enables trust and understanding that make possible transmission and absorption of knowledge. Proximity is

therefore really cognitive/cultural similarity that enables and sustains trust. Acs, Audretsch, and Feldman (1994) find that large firms are better at capturing knowledge spillovers from other large firms, while small firms are better at capturing spillovers from universities—small firms are culturally more isomorphic to universities than large firms.

A third theory as to why domestic context matters more than foreign lies in organizational inertia, or history and the timing of interactions. The founding of the firm creates routines and cognition that deeply affect the ongoing activities of a firm (Stinchcombe, 1965; Boeker, 1988). The very nature of these ongoing activities renders limited and local any search for new routines (Nelson and Winter, 1982; Teece, Pisano, and Schuen, 1997). In its operations, firms also accumulate a set of assets that are critical for ongoing operations, or put differently are complementary for its activities. These internal assets heavily influence the trajectory over time of adaptation, learning, and growth for the firm (Dosi, 1982; Mitchell, 1989; Helfat, 1997; Christensen, 1997; Klepper and Simmons, 2000). The firm is thus historically imprinted with its initial experiences. The weight of these initial experiences restricts adoption of new practice, and creates path dependence for corporate choices over time.

The fourth theory as to why local context matters more than foreign context is provided by the activity systems that underlie corporate capability and firm strategy (Porter, 1996). This third theory relates to technology rather than social ties. In their seminal work, Milgrom and Roberts (1990, 1995) model the firm as an activity system, or as a collection of discrete routines that are complementary to each other. Routines are complementary in the sense of Milgrom and Roberts if the benefit of one activity is increased as the scale of another activity increases. The firm is thus seen as an integrated package of well-chosen internally consistent routines that “fit” with each other. Adoption of a new activity by the firm may have no impact on the firm’s

overall operations if that new activity is not complementary to the existing activity set. Indeed, a new activity may even be a substitute for the existing routines, whereby the benefit of one routine is actually reduced as the scale of the new routine increases. Successful adoption of a new, non-complementary activity may therefore require widespread changes in the existing activity set of the firm in order to “fit” in the new activity.

The initial papers by Milgrom and Roberts have stimulated a vigorous body of both theoretical and empirical work. Porter and Siggelkow (2001) have theoretically modeled the effects of different contexts on activity systems. Ichniowski and Shaw (1997, 1999 with Prenzushi) have provided empirical evidence that American manufacturing firms imitating their Japanese counterparts by adopting isolated human resource practices experienced no effect on their productivity. In contrast, American firms that adopted at once an internally coherent set of several of these HRM activities experienced large, positive effects on productivity. These Japanese HRM practices thus represent a documented complementary activity set.

The literature defines resources as strategic assets under control of firms. Yet, “resources” exist in the surrounding local environment (Foss and Eriksen, 1995)—let us label them “local resources” or “local routines.” Local resources are “semi-private goods” (as Telser, 1987 calls them) in that they are available to firms active in the local environment, rather than proprietary to a single firm. Examples of local resources in the pharmaceutical industry are doctor behaviors for adopting new drugs, university clinical trials for testing effectiveness of new drugs, government pricing regulations for launch of new drugs. Local resources in the domestic context (by consumers, suppliers, other firms) are likely to be complementary to the proprietary resources and internal routines of domestic firms. The activity set for domestic firms is indeed presumably structured from preexisting routines in the domestic context, such as HRM practices,

science procedures, and marketing norms. Hence, local routines, because they are institutional proximate, are highly likely to be complementary to and to “fit” within the firms current activity set. Resources and routines in foreign contexts (by consumers, suppliers, competitors, regulators, and so on) are more likely to be institutional distant and not complementary. Indeed, foreign resources may even be substitutes for the existing activity system of domestic firms, in that adoption of isolated foreign routines reduces the benefits from the firms current operations.

A fifth and final reason why domestic context may matter more than foreign context lies in organizational politics of multidivisional firms, and the competing interests of managers. The resources of a firm are inherently limited, and targeting of corporate resources on foreign projects inevitably diverts these resources away from domestic projects. Corporate investment in a diversified firm offers political selection among projects based not only on financial returns for investors, but also the managerial “returns” for different divisions. Managers in these other divisions of a diversified firm would fight international expansion in any one division if it reduced their own investment funds and social status within the firm. The political weight that each division carries in the investment process is often proxied by the relative size or financial weight of the division within the firm (Pfeffer and Salancik, 1978; Pfeffer, 1981). Diversified firms would thus react very differently to opportunities for international expansion than firms operating only in one industry. The other divisions would appear from the outside to be strategic substitutes for the internationalizing division, because the presence of these other divisions reduces productivity and expansion for the internationalizing division. Yet the substitution process lies entirely in the realm of organizational politics, rather than “technology.”

The literature clearly contains a very diverse and conflicting set of explanations for the importance of local context, drawn from different disciplines. We propose to parse among these

different hypotheses using data from the Japanese pharmaceutical industry during 1975 to 1995. This industry offers several advantages for study. First, it is a large industry with many firms. Over 60 firms innovated new drugs during the 1980s industry bubble, with 38 of these firms established before 1981 and over 20 new entrants after that year. The 38 established firms are highly varied, in terms of size, in terms of foreign experience, and terms of diversification. In other nations, innovative pharmaceutical firms are far more homogenous. This inter-firm variation enables us to better disentangle the multiple possible drivers of impact for local context. Second, the Japanese drug industry underwent a fundamental change after 1981, with an explosion of trivial new products entering the market causing the average product life to be more than halved. This transformation was unique among the developed nations. This inter-temporal variation also enables us to better disentangle the drivers of impact for local context. Third, health care as an industry is highly nation-specific, driven by sharp differences in culture and institutions. It is thus possible to construct sensible measures of cultural distance and proximity for the drug markets of various nations. Fourth, new drugs are not homogenous. Most (in Japan at least) are completely trivial, either completely imitative of many other molecules already on the market or medically ineffective with no benefit whatsoever to consumers. Others are fundamental innovations with great medical benefit and huge sales all over the world. This diversity of innovative quality, hence the diversity of innovative capability further aids disentangling the drivers of impact of local context.

The most basic hypotheses of this study draws from all five perspectives above. We regard each firm as a collection of capabilities, which offer differential advantages relative to other firms in the industry. These differential advantages are costly to acquire, and hence are accumulated in a path-dependent manner through experience of each firm.

H1A: Experience for a firm in its local context determines the capabilities of the firm

H1B: Experience for a firm in foreign contexts has less impact on firm capabilities than the domestic context. Foreign contexts may have no impact at all on capabilities.

The “distance” between contexts drives the first two theories above as to why foreign contexts have less impact than the local one. While there is a large volume of evidence that physical distance matters, it is unlikely to play any role for the industry examined by this study. Japan is an island, geographically distant from all the historically important markets for pharmaceuticals. There is only quite limited practical difference in physical distance among these various markets from Japan. In contrast, there is great variation among the major markets in their degree of cultural isomorphism with Japan (as described in the next section of this paper). This variation allows testing in this study for our second hypothesis.

H2: Experience in a foreign country has more impact on the capabilities of a firm as the proximity between the home and foreign countries increases. Proximity between countries is measured as the degree of isomorphism between their contexts, or institutional environments.

The fundamental shift in the Japanese institutional environment after 1981 allows us to test the impact of organizational inertia.

H3A: The post-1981 domestic context in Japan has less impact on firm capabilities than the pre-1981 domestic context.

H3B: The age of the firm (hence the duration of its experience in the pre-1981 domestic context in Japan) impacts firm capabilities.

Finally, two of the five theories allow for the possibility that other resources (either foreign or diversified) may be strategic complements or strategic substitutes to domestic

resources. Both the activity system approach and the organizational politics approach recognize that corporate accumulation of certain resources may increase or decrease the current productivity of domestic resources, and hence increase or decrease the future accumulation of domestic resources. Such patterns of complementarity or substitution imply organizational mechanics that go far beyond the mere diffusion of information. The empirical presence of complementarity or substitution thus provides important information as to the underlying mechanisms driving corporate capabilities.

H4A: Experience for a firm in its foreign markets may be a strategic substitute for experience in domestic markets. Specifically, increases in foreign experience may reduce the productivity of domestic experience.

H4B: Experience for a firm in diversified markets may be a strategic substitute for experience in domestic markets. Specifically, increases in corporate operations outside the focal industry (ethical pharmaceuticals in this study) may reduce the productivity of domestic experience.

Institutional Context

This study examines our hypotheses in the context of the Japanese pharmaceutical industry. In the early 1980s, Japan seemed ready to add pharmaceuticals to its conquest of high technology industries. The Japanese government adopted a new patent law in 1975 that provided stronger protection for new product innovation, alongside existing protection for process technology (Howells and Neary, 1995). In 1981, the government promulgated new pricing regulations, described in detail immediately below. Both policy changes were adopted to reward newly launched pharmaceutical innovations relative to more established drug products. This policy shift occurred in an industry that already offered huge incentives for discovery of new drugs. Prices for pharmaceutical products in Japan were by far the highest in the world. Per capita drug consumption on a unit basis was also the highest in the world, making the Japanese

pharmaceutical market a surprising close second in terms of revenues after the United States (*Economist*, 1993). Japanese drug firms responded to these lucrative domestic incentives by pouring money into pharmaceutical research, steadily increasing the share of Japanese firms in world corporate R&D spending in this industry to 17 percent (JPMA, various years). By that time, traditionally strong competitors in the drug industry spent far less—British and German firms each collectively accounted for only 10 percent of world corporate R&D, while Swiss firms spent only 8 percent.

Pharmaceutical firms face a fundamental strategic tradeoff, between focusing their R&D efforts on a small number of significant and highly innovative new products or alternately, fragmenting their R&D into discovery of many minor or imitative products. A common proxy for the innovative significance of new drugs is the number of nations into which the drug diffuses. All the developed nations regulate new drugs, requiring testing and regulatory approval prior to launch. New drugs also require extensive marketing efforts to alter established medical practice and encourage adoption of new products. Both regulatory testing and marketing are fixed costs in each market that preceded widespread consumption. Historically, regulatory regimes have widely differed across nations. For example, Norway historically required firms to demonstrate medical “need” for their new products, in addition to proving safety and efficacy. The expenses of marketing launches are usually as costly as those of regulatory approval. Significant drugs offer benefits sufficient to offset the fixed costs of multiple launches. Trivial products will be launched into only one or two markets, filling local niches. This study will denote drugs launched into six or more developed nations as “global products.”

Figure 1 traces the strategic choices made by pharmaceutical firms on average in the most innovative nations. The vertical axis gives the percentage of discoveries that are global

products—significant drugs with widespread distribution. The horizontal axis gives the number of new molecules innovated per billion US dollars of R&D expense. The strategic tradeoff between significance and number for drug discoveries is very clear. Actually, it is somewhat odd to observe any dispersion at all in Figure 1. The greatest success, in terms of profits and growth, occur in the NW quadrant, with a focus on global drugs (Agarwal, et. al., 2001; Thomas, 1994; Yeoh and Roth, 1999). Yet, French, Japanese, and Italian drug firms persist in an inferior strategy of proliferation of minor products. Worse, since 1981, Japanese firms shifted even further towards fragmenting their innovative efforts towards discovery of trivial products that sell almost nowhere else in the world. This “bubble” of trivial innovation has swamped the domestic Japanese market, rendering it by the 1990s quite different from those of other commercially important nations (see Figure 2).

Three institutional arrangements underlie the Japanese drug bubble. First, as mentioned above, the Ministry of Health and Welfare (MHW) in 1981 fundamentally altered its regulation of Japanese drug prices (Howells and Neary, 1995; Masuyama and Campbell, 1996; Mitchell, Roehl, and Campbell, 1996; Thomas, 2001). Drug prices in Japan, as in most developed nations, are set by government regulation and paid by national health insurance from general tax revenues. MHW continued for several years after 1981 to set regulated launch prices very high. But in that year, the ministry year began to regularly lower prices of established products by an average of five percent a year. MHW’s new regime of time-dependent prices meant that, among comparable molecules, newer drugs would have higher prices than older drugs. In and of itself, this regulatory tactic was relatively innocuous. Yet the forced price declines interacted with two other elements of the domestic institutional environment of Japan to backfire on MHW and unleash the drug innovation bubble.

The second central component of the Japanese institutional environment for pharmaceuticals is doctor demand. Drawing from ancient Chinese traditions, Japanese doctors practice *bungyo*, the combination of prescription and dispensing so that doctors directly distribute drugs to patients (Yoshikawa, 1993). Pricing for doctor services is set by the Japanese government, and these regulated tariffs poorly compensate Japanese doctors for time spent with patients (Akira, 1993). The institutional norm for doctors has consequently evolved to severely minimize patient time, consequently minimizing information transmitted to their patients. Japanese doctors offset their low fees for meeting patients by over-prescribing and over-supplying pharmaceuticals. Doctors purchase drugs from wholesalers, who sell them at a discount off retail prices set through regulation by MHW. Yet MHW fully reimburses doctors at the official retail price for all drugs they prescribe and dispense. The resulting “doctor’s margin” is pure income for the prescribing physician. Doctors and hospitals have a strong incentive to prescribe/dispense the most expensive drugs among comparable therapeutic alternatives, and regularly do so (Ikegami, Ikeda, and Kawai, 1998). Japanese doctors have a powerful incentive to over-prescribe products, so much so that the Japanese spend more on drugs than anybody else in the world (*Economist*, 1993). This over-prescription rarely takes the form of excess consumption of a single product, but rather simultaneous dispensing of many different drugs with each doctor visit, a tradition the Japanese label *poly-pharmacy* (Ikegami, 1996).

The practice of *bungyo* is more than mere tradition. Since the 1950s, the MHW has regularly tried to curtail *bungyo*, both to improve patient treatment and to curtail medical costs. Each MHW effort at curtailment has been met with vigorous political protest by the Japanese Medical Association (JMA), the national trade association for physicians. And until quite recently, the JMA has regularly defeated MHW proposals (Masuyama and Campbell, 1996).

These defeats are not surprising given the enormous and sustained financial contributions by physicians to the Liberal Democratic Party (LDP). Doctors were reportedly the third most generous financial and political supporters of the LDP, after only rice farmers and construction firms, who comparably benefited from LDP largesse (Howells and Neary, 1995).

A third key feature of the Japanese pharmaceutical institutional environment is its clinical trial process. Like all developed nations, Japan requires premarket approval (registration) for all new drugs, including both animal (preclinical) and human (clinical) trials. However, the clinical trial system in Japan is completely distinctive from that of other nations (Berger and Fukunishi, 1996). One particular difference between the FDA and MHW systems for clinical trials is MHW's historic disregard for drug efficacy. The MHW system displays an acute concern for drug safety, arguably more so than the FDA, particularly in recent years. Yet, MHW has historically required only minimal tests for product effectiveness. Since the most expensive and difficult parts of FDA required testing is for efficacy, new drug approval costs in Japan are much smaller than in the United States. A brazen example of this difference in clinical trial standards is provided by Krestin, a mushroom derivative similar to the infamous Laetrile in the USA and sold as an anti-cancer product. Krestin is chemically inert, so that it has no effect on the body, yet for several years in the mid-1980s it was the best selling drug in Japan. Krestin succeeded because it carried a high price, and was completely safe. Krestin has not been approved for use in any other advanced market, and would clearly never be approved by the FDA for launch in the US. Total sales of Krestin and comparable ineffective anticancer products reached \$1 billion a year in Japan (Fukushima, 1989), making up over 10 percent of the total demand in Japan.

MHW pricing, doctor demand, and the clinical trial system interact all together to discourage introduction of significant new drugs in Japan, and to encourage the proliferation

there of trivial ones. Due to MHW regulations, prices for established products drop rapidly on average. Due to the nature of doctor incentives, doctors promptly discontinue dispensing older, cheaper drugs and adopt newer, more expensive products. Patients have little knowledge or understanding of such product shifts, and no real opportunity to question them in the very hierarchical medical culture in Japan. Thus, if a firm in Japan sticks with even moderately old products, it has a product portfolio with pervasive and severely declining sales. Product proliferation by Japanese drug firms is enabled by registration process in Japan. The very lenient standards for effectiveness make it vastly cheaper and easier to register many new products in Japan than in other major pharmaceutical markets. Were US or British firms to attempt comparable proliferation of minor products, they would face extraordinarily high research costs to prove their products before their own local regulators.

Notable evidence for these institutional interactions is provided by the beta-blocker segment of the pharmaceutical industry. Beta-blockers are cardiovascular products, among the most commercially important drug launches of the late 1970s. The top panel of Figure 3 presents the aggregate market share for the first four successful products introduced into the beta-blocker therapeutic category in the United States and in Japan. Examining this figure, we find very different product life cycles. The trend for the USA is shown at the top, and we should note in passing that the US trend is essentially the same as that in Britain, Germany, and France. The first few products to be introduced lock up the market. Thus there is a strong disincentive to imitation in the US, since late entrants have minimal demand. As the lower two panels of Figure 3 make clear, there is minimal successful late entry in the US, and as a consequence almost no exit. In contrast, in Japan the first four products succeed initially, but then rapidly lose market share. There are waves of imitative beta-blocker products that come and go. Over 30 distinct

products achieve a 1 percent market share of this segment at one time or another, though half of these products subsequently fail. Note that these products are distinct molecules that have the same biomedical function, each with its own patent, its own brand name, and its own marketing presence.

Japanese drug firms are thus incited to constantly restock their product portfolio with minor new products to sell. The response of Japanese firms during the 1980s was an explosion, or a bubble, of trivial innovation (see Figure 2 again, and Figure 4). The number of new drugs discovered and launched by Japanese firms rose from an average of 8 a year before 1981 to 13 a year by the late 1980s. The proportion of these new drugs so trivial that they sold only in Japan and nowhere else in the world rose from 45 percent before 1981 to over 75 percent by the later 1980s. The waves of imitative new products on the market acted to significantly shorten the average product lifetime. The mid-point of the product life cycle for all drugs launched into Japan (by both domestic and foreign firms) fell from 14 years in 1980, to 8 years in 1985 and 5 years in 1990 (Thomas, 2001). Comparable midpoints for drugs in the USA were 20 years in 1980, 18 years in 1985, and 15 years in 1990, while in Britain, comparable life-cycle midpoints were 21 years, 18 years, and 19 years (Thomas, 2001). Consumption of new drugs also significantly drove up public expenditure on health care in Japan, completely contrary to MHW intentions when it “reformed” drug pricing in 1981 and thereby inadvertently triggered the drug innovation bubble. Under great pressure from the Ministry of Finance in Japan, MHW began to cut initial launch prices relative to global norms, while continuing its regular price cuts of 5 percent per year.

Some of the degradation of the domestic market for pharmaceuticals was accomplished by changes in the population of domestic firms. The 1980s saw entry into the industry of a host

of unrelated diversifiers: Ajinomoto (food products); Asahi Chemical, Mitsubishi Chemical, Mitui Chemical (petrochemicals); Kanebo, Kowa, Teijin, Toray (synthetic textiles); Lion, Morishita (consumer products); and Kirin, Suntory (brewing). None of these new entrants innovated significant drugs, yet by the late 1980's they accounted for 10 percent of annual drug discoveries in Japan. Other than these large, diversified entrants mentioned above, no new domestic firms successfully entered the Japanese drug industry. This outcome is in stark contrast with the USA that saw creation of many important biotech firms that have achieved success and even prominence with discovery of significant new drugs. Finally, US and European firms began delaying launch of their own innovations in Japan, and even bypassing the Japanese market altogether. This partial foreign withdrawal from Japan created a “drug lag” whereby important new medicines became available overseas years earlier than in Japan (Thomas, 2001).

Data, Variables, and Estimation

The core competence of pharmaceutical firms in Japan is discovery of new drugs. The first item of data for this study therefore is every new molecule innovated by Japanese firms since 1960. For each of these distinct molecules, this study identified the innovator (usually the patent owner). Ownership of each innovation is determined by reference to Merck & Co. (2001), supplemented by James Capel (1995). The period for this study is 1975 to 1995, and 62 different Japanese firms innovated 270 molecules during that period. An additional 88 drugs were discovered by Japanese firms before 1975.

Financial data, including R&D expenditure and sales, were available for 52 Japanese firms that innovated new drugs, from 1975 onwards. Financial data were not available for several sample firms before 1975, and this data limitation determines the start date for the panel

data used for this study. These 52 firms account for almost every drug discovered in Japan between 1960 and 1995.

For our statistical analysis, we will limit attention to the 38 of the 52 Japanese drug firms that innovated a new drug on or before 1981. The age of each of these 38 firms is computed using the first year of discovery of any new drug as the birth year for the firm.

The study collected launch dates between 1960 to 2003 for all Japanese innovations in the 14 most important commercial markets in the world (Australia, Belgium, Canada, Denmark, France, Germany, Italy, Japan, Netherlands, Norway, Sweden, Switzerland, United Kingdom, and USA). Drug launches for each firm are tabulated from DeHaen (1988) for 1960 to 1969, from FDA (1985) for 1970 to 1982, and from data by IMS, Inc. for 1983 to 2003. Of the 270 drugs discovered by Japanese firms during 1975 to 1995, 162 were launched only in Japan, 51 were launched in two to five countries, and 34 were launched in six or more countries.

For purposes of this study, we label as “global drugs” those Japanese innovations that are subsequently launched in six or more foreign nations out of a possible 13 for this study. We end the study period in 1995 rather than 2003, our final year of data, to avoid censoring or truncation that might occur if launches new Japanese drugs in foreign nations might be later than the launch date in Japan. We label as “local drugs” those Japanese innovations that are never launched outside Japan. We regard global drugs as commercially significant innovations. This use of diffusion as a proxy for innovative significance has long been used by the FDA, where widely diffused molecules are labeled as “consensus drugs.” This approach has also been employed in Thomas (1994) and Yeoh and Roth (1999). The logic for this measurement tactic is that important innovations will provide sufficient commercial potential that firms pay the repeated fixed costs for premarket testing and launch marketing in multiple nations. Trivial

discoveries by Japanese firms will be sold only in Japan itself. An intermediate class of drugs will diffuse somewhat outside Japan, but not sufficiently to become global products.

Discovery of a new drug is the outcome of a complex organizational capability. Firms acquire this capability through experience in specific contexts. This study contrasts the effects of participation in local and foreign contexts for pharmaceutical innovation. Two previous studies provide prototypes for this analysis. Darr, Argote, and Eppel (1995) examined organizational experience among pizza restaurants, some of which were individually owned and others of which were members of chains. They contrasted the effects of historical production experience at local, chain, and industry levels on unit production costs. Their findings were that local and chain experience both lowered unit costs, but not industry experience. Ingram and Baum (1997) examined knowledge transfer and administrative constraint posed by chain membership for hotels located in Manhattan. They contrasted the effects of historical membership experience in local and non-local markets on unit mortality. They found that local experience significantly reduced mortality, while non-local experience actually increased mortality under some circumstances.

For purposes of this study, define experience in a given context for firm i in year t as the following sum over years j from start year T_0 to year $(t-1)$:

$$(1) \quad \textit{Experience in context}_{i,t} = \sum_{j=T_0}^{t-1} \textit{Local Launch}_{i,j}$$

where $\textit{Launch}_{i,j}$ gives the number of new drugs discovered by and launched in the given context by firm i in year j during each year from the start year T_0 to the year before the current one.

Our study will consider four distinct contexts: Old Japan (1960 to 1981), New Japan (1982-1995), Southern Europe, and Anglo-Nordic Nations. The domestic context in Japan changed fundamentally after 1981, as discussed in the previous section. Our sample period runs

from 1960 to 1995, and we split that sample in 1981 to distinguish the old and new contexts in Japan. Experience in “Old Japan” increments from 1960 to 1980, then ceases to increment thereafter. Experience in “New Japan” is zero until 1980, then increments for 1981 to 1995.

Experiences in overseas markets for Japanese firms differ fundamentally from that in their home market. Those markets will employ distinct routines for pricing, doctor demand, and clinical trials. For example, in the USA, pricing is unregulated by government except for laws promoting competition by generic imitators after patent expiry; doctor demand is driven by findings on efficacy and side effects from clinical trials; and clinical trials must meet stringent FDA requirements based on the high standards of US university science. Experience for Japanese firm i in year t in foreign market k is calculated as:

$$(2) \quad \textit{Experience Overseas}_{i,t} = \sum_{k=2}^{14} \sum_{j=1960}^{t-1} \textit{Foreign Launch}_{i,j,k}$$

where $\textit{Foreign Launch}_{i,j,k}$ gives the number of the discoveries of firm i launched in foreign country k in year j . Data for this sample cover launches in 13 foreign countries.

Our second hypothesis require us to segregate foreign countries into those that are culturally and socially “proximate” to Japan from those that are “distant.” Griffin (1986, 1987) suggests that Japan is likely to be most “proximate” in terms of pharmaceuticals to nations the of Southern Europe, especially France and Italy. Griffin contrasts several features of pharmaceutical demand and regulation. He finds that premarket regulation is less stringent in Southern Europe compared to Northern Europe; that that the percentage of GDP spent on drugs is higher in the South; that the number of distinct prescriptions per capita (or poly-pharmacy, as the Japanese call it) is greater in the South; and that per-capita reports of drug side-effect is much higher in the North. The last fact is especially striking, given that Southern European nations consume far more drugs and regulate them far less stringently than Northern nations. Griffin

demonstrates that these features of drug consumption are highly correlated with the percentage of the population that is Roman Catholic, excluding Japan. He quickly adds:

The explanation for these relationships is open to speculation. The most likely rationale is that in Catholic countries there is a greater acceptance of “authority.” The medical profession is seen in a more paternalistic role and this is accepted by the patient, consequently more medicines per capita are used. But in Protestant countries there is a greater reluctance to accept medicines prescribed by medical authority and due to the Protestant ethic of rejection of “authority” a greater tendency to find fault with them. Protestant countries thus have a higher rate of adverse drug reaction [side-effect] reporting. (Griffin, 1987)

In each of these consumption features, Japan matches the Catholic nations of Southern Europe: lenient regulation, high drug consumption, poly-pharmacy, and low patient activism. Japan differs only in that its price regulations set high prices, while Southern European nations are notorious for their low regulated prices. We will thus split the 13 sample nations foreign to Japan into an Anglo-Nordic or “Protestant” group (Australia, Canada, Denmark, Netherlands, Norway, Sweden, UK, and USA) and a Southern European or “Catholic” group (Belgium, France, Germany, Italy, and Switzerland). We argue that the Southern European nations are more “proximate” to Japan than the more stringently regulated Anglo-Nordic nations. Thus, the cumulative experience by Japanese firms in launching their discoveries in Southern Europe are more likely to be complementary to the ongoing activity system than experience in the Anglo-Nordic nations. Overseas experience in Equation 2 will be calculated separately for each firm for these two groups of countries.

Data on corporate sales and diversification were taken from the *JPMA Data Book* (JPMA, various years) for 1985-95 and from the *Japan Company Handbook* (Toyo Keizai Shinposha, various years) for earlier years. These sources were extensively supplemented by

Nomura (1983), James Capel (1995), and HSBC Securities (2000). All financial data are converted to constant-yen levels (1980 base) using the GDP deflator.

Finally, the literature on the pharmaceutical industry indicates an additional factor that must be considered as a control in our analysis. The scale of corporate expenditure on research and development is widely regarded as a basic determinant of innovative productivity, particularly in the economics literature (Henderson and Cockburn, 1994, 1996; Thomas, 1990).

Study hypotheses will be tested using two structurings of the data. First, we examine a single cross-section across the 38 sample firms in 1981. The historical experience of firms 1960 to 1981 will be used to predict the innovative capabilities of these firms, or their future innovations 1982 to 1995. Second, we examine a panel dataset of cross-section and time-series data for the 38 firms in each of the 21 years 1975 to 1995. The historical experience of each firm up to year $T-1$ ($1975 \leq T \leq 1995$) will be used to predict innovations by these firms in year T .

We expect the number of drugs discovered by Japanese firms to be highly non-normally distributed. The number of innovations discovered by a firm in any given year is a discrete random variable that is highly skewed, with most firms discovering no new drugs. Further, the variance of this variable is heteroskedastic, with means and variances positively related, since firms that discover few new drugs have low variance while firms that discover many new drugs do so with great volatility year to year.

We will adopt two estimation strategies to deal with the non-normal distribution of annual discoveries. First, we will aggregate the discoveries of each firm after the pivotal year 1981 that triggered the drug bubble in Japan. By the law of large numbers, we expect the cumulative discoveries of Japanese firms from 1982 to 1995 to be a single normally distributed random variable. We can thus use ordinary least squares to analyze a single year cross section of

firms in 1981. Denote the cumulative innovations of firm i in years 1982 to 1995 as $N_{82-95, i}$.

The equation to be estimated is then:

$$(3) \quad EV(N_{82-95, i}) = \beta_0 + \beta_1*(Japan\ Experience_{81, i}) + \beta_2*(S.\ Europe\ Experience_{81, i}) \\ + \beta_3*(Anglo/Nordic\ Experience_{81, i}) + \beta_4*Age_{81, i} \\ + \beta_5*(Share\ of\ Corporate\ Sales\ Outside\ Ethical\ Drugs_{81, i})$$

To allow for complementarity and substitutability among various national contexts and diversification, we will also enter dyadic interaction terms. Interaction terms using experience in the Anglo-Nordic nations are not expected to be important. In fact, when interaction terms with Anglo-Nordic experience were included in estimations, they were never statistically significant. Such interaction terms are thus dropped from the analysis. We will therefore use three interaction terms: a) between Japanese experience and Southern European experience, b) between Japanese experience and diversification, and c) between Southern European experience and diversification. Table 1 gives means, standard deviations, and bivariate correlations among variables for the cross-section dataset.

The second approach for estimation will employ a panel dataset of the 38 sample firms in each of the 21 sample years, 1975 to 1995. Denote the annual innovations of firm i in year t as $N_{t, i}$. The equation to be estimated is then:

$$(3) \quad EV(N_{t, i}) = \exp(\beta_0 + \beta_1*\log(Japan\ Experience_{t, i}) + \beta_2*\log(S.\ Europe\ Experience_{t, i}) \\ + \beta_3*\log(Anglo/Nordic\ Experience_{t, i}) + \beta_4*\log(Age_{t, i}) \\ + \beta_5*\log(Share\ of\ Corporate\ Sales\ Outside\ Ethical\ Drugs_{t, i}))$$

We will treat the dependent variable $N_{t, i}$ as Poisson-like in distribution, so that:

$$(4) \quad \text{Var}(N_{t, i}) = \Phi * EV(N_{t, i})$$

where Φ is a parameter to be estimated. If Φ is exactly unity, then the distribution of $N_{t,i}$ is precisely Poisson. We further specify that the distribution for $N_{t,i}$ be of the linear exponential family, a broad class of distributions that includes the normal, Poisson, gamma, multinomial, and others. If these two specifications are valid, then the maximum quasi-likelihood procedures produce consistent estimates (Gourieroux, Monfort, and Trognon, 1984a; Gourieroux, Monfort, and Trognon, 1984b; McCullagh and Nelder, 1983). For estimation with panel data, we will also include the three interaction terms among national contexts and diversification. We will also include binary variables for each firm, allowing for fixed effects among firms. Table 2 gives means, standard deviations, and bivariate correlations among variables for the cross-section dataset.

Findings

Findings for statistical estimation are reported below. To provide greater understanding of these statistical findings, some simple data and statistics are reported first for a single firm (Tanabe Seiyaku) and for decadal aggregates of firms. While the statistical findings are of course the most important for this study, the more casual and detailed data presented first provide useful insights into the underlying phenomena captured in the statistical analysis.

Tanabe Seiyaku

The oldest Japanese pharmaceutical firm is Tanabe Seiyaku, founded in 1678 as a wholesale pharmacy (Odagiri and Goto, 1996). It is also one of the largest, ranking sixth among all Japanese firms in terms of drug sales in 1981, at the start of the drug bubble. Tanabe's first patented new drug was launched in 1953, and all four of its discoveries before 1973 were diffused to two or three countries. In 1973, Tanabe launched diltiazem, a pioneering calcium

antagonist to treat hypertension and angina. Diltiazem helped define a new therapeutic category, and diffused to almost every nation in the world. In the US market, it was licensed to the leading American firm Pfizer and sold with great success by Pfizer under the trade name Cardizem. Diltiazem became an important blockbuster drug, so that by 1983, exports of the its raw material made up 18 percent of Tanabe’s total sales and over 40 percent of its corporate profits (Nomura Securities, 1983).

Unfortunately, the bright innovative and commercial promise suggested by diltiazem was never realized. As such, Tanabe provides a vivid illustration of the damaging effects of the drug bubble on the innovative capabilities of Japanese drug firms. Clearly, with diltiazem, Tanabe was capable of pharmaceutical research at the highest level. Yet after 1985, with the drug bubble well established in Japan, the complete roster of Tanabe’s innovations is as follows.

1987	aspoxicillin	Doyle	treatment of athlete’s foot
1988	denopamine	Kalgut	cardio-tonic
1993	ecabet	Gastrom	H-2 antagonist (anti-ulcer drug)
1993	imidapril	Tanatril	ace inhibitor (cardiovascular drug)
1994	docarpamine	Tanadopa	cardio-tonic

All of these products but Tanatril are completely local, sold only in Japan. The overseas failure of Tanabe’s innovations was completely expected, given the nature of these products. Cardio-tonics, like most tonics, are universally regarded in Western medicine as ineffective. Cardio-tonics supposedly give “nutrition” for the heart, and some version of them could be bought in the United States only in unregulated and unapproved form in a health food store. By undertaking research for Kalgut and Tanadopa, Tanabe deliberately and knowingly targeted Japan and only Japan for their launch. In contrast, the other three products are effective, but are all late to extremely late in their therapeutic category life-cycles. (Again, see Figure 6 for the effects of timing on product success in the US versus Japan). Regarding Doyle, there are many well-

established treatments for athlete's foot, often sold over the counter in Western pharmacies. Some of these products have been established for decades. Only in Japan, would there be a market for Doyle, a new high-priced prescription product to treat this condition. Gastrom is derived from the resin of pine trees, and used to treat stomach ulcers. This somewhat dubious product is also extremely late, 15 years after launch of SmithKline's blockbuster innovation Tagamet, the H-2 antagonist, and 11 years after Glaxo's similar blockbuster, Zantac. Only Tanatril, an ace inhibitor used to treat hypertension, offered the remote possibility of overseas commercial success. Yet Tanatril was also quite late to market, and highly unlikely to be commercially successful overseas. In Japan, Tanatril would find a strong place in the second or third waves of ace inhibitors (like the late entering beta-blockers in Figure 6). Licensed by two smaller German firms, Tanatril was launched in France and Germany in 1999 to fill small product niches. Data from IMS indicate that by 2001, overseas sales of Tanatril were trivial, amounting to less than 5 percent of unit sales in Japan and less than 2 percent of Japanese revenues.

The collapse in innovative significance for Tanabe during the drug bubble makes this firm somewhat distinctive among the large established firms in Japan, as the next subsection documents. Tanabe is also significantly more diversified than most of the large, established Japanese firms. Only about 65 percent of Tanabe's corporate sales are in ethical pharmaceuticals. OTC pharmaceuticals make up another 5 percent. A quite broad range of other products, most sold entirely in Japan, make up the remainder of sales, including nutritional products, food additives, bulk chemicals, diagnostic agents, and hospital supplies.

Once we recognize Tanabe as a significantly diversified firm, its innovative performance ceases to be distinctive. Among the 15 largest Japanese drug firms in terms of sales in 1981, six

were significantly diversified so that ethical pharmaceutical sales ranged from 35 to 65 percent of sales. Those firms were Chugai, Kyowa Hakko, Meiji, Nippon Kayaku, Takeda, and Tanabe. All of these firms except Taisho innovated a global drug before 1981. None of these firms except Takeda repeated this performance after 1981. Takeda is by far the largest of the Japanese drug firms, over twice the size of the next largest firm, and one with significant overseas distribution of its innovations.

Firm Averages by Decade and Age

Table 3 breaks out the innovations of Japanese drug firms by decade and by the age and of its innovations. At the top of Table 3, data is reported for those firms that launched five or more new drugs before 1975. These firms have the greatest experience in the pre-bubble Japanese home market. We expect these old and large firms to be least impacted by the degradation of the Japanese market. At the bottom of Table 3, data is reported for 12 firms that did not launch any drug innovations before 1980. The entire experience of these firms in Japan is during the drug bubble. We expect these younger firms to be most impacted by the drug bubble, and to innovate predominantly trivial products. Table 3 reports the share of aggregate innovations for all firms in each class that were sold only in Japan, and the share of innovations that diffused to Japan and just one overseas market.

Examination of Table 3 provides casual but provocative confirmation for our hypotheses. The five firms with the greatest experience in pre-1975 Japan suffered only minimal degradation of innovative capability. The share of all innovations by these firms that were local products rose from 52.6 percent before 1975 to only 54.1 percent after 1985—almost no change. The share of their innovations that were local products plus those that diffused to two countries (Japan and one overseas market) rose from 60.5 percent to 75.75 percent. In contrast, 100

percent of the products were trivial for Japanese firms that did not first innovate until after 1980. The deterioration of innovation quality rises almost monotonically with the youthfulness of corporate innovative activity.

Estimation Findings

Results of estimation for Equation 3 with the cross section data are presented in Table 4. The estimated models perform astonishingly. It is striking just how well the pre-1981 experience of firms predicts their cumulative innovations 1982 to 1995, particularly when we remember how volatile the innovation process is. The results of Table 4 provide strong support for the study hypotheses. Experience in the pre-1981 domestic Japanese industry contributes significantly to innovative capability. Experience in “proximate” major markets of Southern Europe, notably France, Germany, and Italy, also contributes to innovative capability, though only for mid-diffusion and global drugs. Experience in the “distant” Anglo-Nordic markets does not contribute at all, despite the fact that the USA is the by far the most important scientific and commercial market in the global pharmaceutical industry. To check this finding on the Anglo-Nordic context, estimations were repeated but with disaggregation of the Anglo/Nordic experience variable into several possible components: the US alone versus all other “Protestant” nations, the US and UK together versus the remainder, English-speaking nations versus the remainder. These results are not reported here, and yielded results identical to those reported in Table 4—experience by Japanese firms in these “distant” overseas markets has no statistically significant effect on innovative capacity.

Estimates with the cross section data in Table 4 do not provide support for H3 on organizational inertia. We cannot test H3A using the cross section data (estimates using the panel data reported below do in fact support H3A). H3B is not supported, almost certainly

because corporate experience better captures the path dependent determinants of innovative capabilities than the simple age variable.

Estimates with the cross section data in Table 4 support H4 on strategic complements and substitutes, at least for the disaggregation of drug innovations into different types. For innovation of trivial drugs sold only in Japan, corporate experience in Southern Europe is a strategic substitute and corporate experience outside ethical drugs (mainly in chemicals and OTC drugs, both predominantly domestic activities) is a strategic complement. The substitutability of Southern European experience occurs only above a threshold of 5.14 ($= 1.13/.22$) domestic launches in Japan. This threshold is slightly above the sample mean for historical domestic launches in the cross section data (see Table 1).

The reversed pattern of strategic linkages hold for the innovation of significant new drugs. Experience for a firm in Southern Europe is a complement to experience in the domestic Japanese market for significant innovation, while experience in diversified markets is a strategic substitute. The complementarity of Southern European experience occurs only above another threshold, this time of 2.25 ($= .09/.04$) domestic launches in Japan. Most firms in the cross section sample clear this threshold (remember that only established firms are included in the cross section data; hence historic domestic launches for all these firms are at least 1.0).

These findings are repeated in the panel data reported in Table 5. Here the thresholds are lower at which points corporate experience in Southern Europe becomes complementary or substitutable with domestic Japanese experiences. But we must remember that the independent variables in Table 5 are expressed in logarithms, so the variables means are lower as well (see Table 2).

Discussion

Japan in the 1980s and early 1990s experienced a “drug bubble.” Changes in patent law and price regulations inadvertently triggered innovation of a tsunami of trivial new molecules, and an associated explosion of domestic consumption. Before 1981, Japanese drug firms innovated a mix of trivial and significant new drugs. With the onset of the drug bubble, these firms shifted their innovative efforts pronouncedly towards trivial products that sold only in the domestic market. The drug bubble attracted entry of some 20 firms from related industries during the 1980s. All of these firms completely succumbed to the incentives of the drug bubble—every single innovation of the new entrants was a trivial product sold only in Japan. The response varied among the roughly 40 drug innovators already established by 1981. Firms with extensive distribution of their innovations in Southern Europe and minimal diversification outside ethical pharmaceuticals resisted the drug bubble and continued significant innovation. These firms, including Daiichi, Fujisawa, Sankyo, and Yamanouchi, have continued innovation of significant products, including Prevacid and Mevalotin, among the commercially most important drugs of the last 20 years. Firms with minimal distribution in Southern Europe and extensive diversification shut down innovation of significant products and overseas exports of new drugs. These firms, including Kyowa Hakko, Meiji, Nippon Kayaku, and Tanabe, all had innovated significant products during the 1960s and 1970s, including bleomycin (Kyowa) and diltiazem (Tanabe). Yet despite the booming sales, profits, and research expenditures of the 1980s and 1990s drug bubble, these firms ceased to innovate significant drugs. Finally, distribution in the scientifically and commercial important markets of the Anglo-American and Nordic countries had no relationship whatsoever to innovation by Japanese drug firms.

The immediate implications of these findings are very clear. Distribution in Southern Europe is a strategic complement to innovation of significant drugs for Japanese firms. Production of chemicals and OTC medicines (almost entirely for the Japanese market) are strategic substitutes for significant innovation. And distribution in the Anglo-Nordic countries is strategically independent of drug innovation for Japanese firms.

These implications, however, also expose the true complexity of the innovative process. The terms “complement” and “substitutes” are borrowed from economics, and retain the bloodless and mechanical aura of that discipline. Yet the actual processes that generate this complementarity and substitutability seem far more social and political than economic. The “proximity” of Southern Europe and Japan in pharmaceuticals and “distance” of Anglo-Nordic countries and Japan are entirely driven by social forces (such as the cultural ways that medicines are perceived and used) and politics (particularly the relative standing of university doctors versus commercial practitioners in each country). And it is highly unlikely that firms with separate chemical and pharmaceutical divisions actually commingle the value chains for these divisions, except at the senior management level. The “substitutability” of chemicals and drugs thus appears to represent an internal political tradeoff rather than a technological one. Yet this tradeoff is no less real for being based in the internal politics of firms, as the tradeoff has been documented for Japan in this study and for the United States in an earlier study (Davis and Thomas, 199x). This political tradeoff is also quite probably behind the commercial collapse of the German pharmaceutical industry, that was preeminent globally for most of the 20th century and comprised predominantly of chemical-drug combines.

The findings of this study also suggest that scholars in strategic management might well on occasions alter the phrase “capability” to “intent” (Dosi, et al., 2000; Helfat and Lieberman,

2002). The diversified firms Kyowa Hakko, Meiji, Nippon Kayaku, and Tanabe were all clearly capable of significant innovation. Their global drugs were innovated in the 1960s and 1970s when the sales and R&D expense of their firms were relatively small and the cross-national diffusion of science was much slower. For these firms to exit significant innovation during the great wealth of the Japanese drug bubble and the 1980s proliferation of biomedical science suggests a far more complex social and political process for innovation than is captured by the word “capability.”

Whichever terms are used to describe the existence and evolution of corporate capabilities, we must acknowledge the powerful role of historical experience in creating these capabilities. The domestic context of firms inevitably acts to powerfully shape this historical experience, hence to shape firm capabilities.

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**Table 1: Cross Section Data for 1981:
Means, Standard Deviations, and Correlations for Study Variables**

Number of observations is 38. Each observation is a Japanese drug firm in 1981.

	Mean	Standard Deviation	# of Discoveries	# of Local Discover	# Mid-diffusion Discoveries	# Global Discover	log (R&D)	% Non-Ethical Sales	Age of Firm	Jspsn Launches	S. Europe Launches	Anglo-Nordic Launches	Japan X S. Europe	Japan X Non-Ethical	S. Europe X Non-Ethical
Cumulative Discoveries, 1982-1995	4.6	3.3	*												
Cumulative Local Discoveries, 1982-1995	3.0	1.9	.77	*											
Cumulative Mid-diffusion Discoveries, 1982-1995	.9	1.3	.71	.22	*										
Cumulative Global Discoveries, 1982-1995	.7	1.1	.68	.26	.59	*									
log (Corporate R&D) in 1981	1.33	1.0	.70	.58	.46	.48	*								
% of Sales NOT in Ethical Drugs, 1981	.33	.3	-.21	-.15	.00	-.38	.19	*							
Age of Firm = (1981 – Year of First Discovery)	15.4	6.3	.48	.26	.42	.47	.36	-.23	*						
Cumulative Launches in Japan, 1958-1981	4.7	3.6	.92	.65	.77	.66	.66	-.15	.58	*					
Cumulative Launches in Southern Europe, 1958-1981	4.5	4.3	.68	.28	.74	.65	.49	-.02	.69	.72	*				
Cumulative Launches in Anglo-Nordic Countries, 1958-1981	3.1	3.7	.52	.29	.41	.55	.41	-.07	.53	.56	.65	*			
Interaction: Cumulative Launches in Japan times Cumulative Launches in S. Europe, 1958-1981	32.6	47.5	.80	.43	.87	.62	.52	-.02	.44	.82	.78	.52	*		
Interaction: Cumulative Launches in Japan, 1958-1981, times % of Sales NOT in Ethical Drugs, 1981	1.4	1.7	.57	.45	.64	.13	.53	.48	.30	.66	.57	.31	.73	*	
Interaction: Cumulative Launches in S. Europe, 1958-1981, times % of Sales NOT in Ethical Drugs, 1981	1.5	2.4	.33	.17	.50	.09	.35	.47	.43	.42	.70	.43	.58	.75	*

**Table 2: Panel Data for 1975-1995:
Means, Standard Deviations, and Correlations for Study Variables**

Number of observations is 835. Each observation is a sample firm during a single year, 1975 to 1995.

	Mean	Standard Deviation	# of Discoveries	# of Local Discoveries	# Mid-diffusion	# Global Discoveries	log (R&D)	& Non-Ethical Sales	Age of Firm	log (Old Japan)	log (New Japan)	log (S. Europe)	log (Anglo Nordic)	Japan X S. Europe	Japan X Non-Ethical	S. Europe X Non-Ethical
Total # of Discoveries	.26	.50	*													
# of Local Discoveries	.16	.39	.76	*												
# Mid-diffusion Discoveries	.06	.24	.48	-.03	*											
# of Global Discoveries	.04	.20	.43	.01	.07	*										
log (R&D)	1.5	1.15	.26	.21	.09	.15	*									
% of Sales Not in Ethical Drugs	.34	.30	-.07	-.03	-.01	-.09	.17	*								
Age of Firm	17.5	8.9	.19	.14	.06	.12	.58	-.20	*							
log (1+ Cumulative Launches in Japan up to 1981)	1.32	.62	.31	.20	.16	.14	.62	-.24	.65	*						
log (1+ Cumulative Launches in Japan after 1981)	.21	.25	.03	.06	-.04	-.09	.47	-.10	.57	.19	*					
log (1+ Cumulative Launches in Southern Europe)	1.28	.97	.27	.10	.17	.21	.56	-.12	.81	.67	.33	*				
log (1+ Cumulative Launches in Anglo-Nordic Countries)	.97	.99	.27	.11	.12	.12	.56	-.10	.65	.69	.31	.78	*			
Interaction: log (1+ Japan Launches) times log (S. Europe Launches)	2.17	2.07	.33	.20	.25	.26	.55	-.13	.70	.87	.28	.92	.82	*		
Interaction: log (1+ Japan Launches) times % Sales Not in Ethical Drugs	.41	.39	.11	.09	.08	.01	.34	.68	.25	.39	.01	.35	.29	.38	*	
Interaction: log (1+ S. Europe Launches) times % Sales Not in Ethical Drugs	.39	.57	.11	.10	.07	.01	.30	.51	.42	.37	.09	.56	.46	.48	.85	*

**Table 3: Trivial Discoveries as Share of All Discoveries,
by Firm Age/Scale and Decade, 1955 to 1995**

	1955-1974	1975-1985	1986-1995
<u>Old and Large</u> • 1 st discovery 1956-1964 • 5-14 discoveries by 1974 • RD>¥4.8B in 1975 • 5 firms in this class	<i>diffusion = 1</i> 52.6%	<i>diffusion = 1</i> 51.7%	<i>diffusion = 1</i> 54.1%
	<i>diffusion = 1 or 2</i> 60.5%	<i>diffusion = 1 or 2</i> 72.4%	<i>diffusion = 1 or 2</i> 75.75%
<u>Old and Medium Size</u> • 1 st discovery 1962-1966 • 3-6 discoveries by 1974 • ¥4.5B>RD>¥2.0B in 1975 • 8 firms in this class	<i>diffusion = 1</i> 35.3%	<i>diffusion = 1</i> 53.8%	<i>diffusion = 1</i> 52.6%
	<i>diffusion = 1 or 2</i> 52.9%	<i>diffusion = 1 or 2</i> 69.2%	<i>diffusion = 1 or 2</i> 75.8%
<u>Old and Small</u> • 1 st discovery 1955-1968 • 1-3 discoveries by 1974 • R&D<¥1.3B in 1975 • 13 firms in this class	<i>diffusion = 1</i> 37.0%	<i>diffusion = 1</i> 52.4%	<i>diffusion = 1</i> 77.1%
	<i>diffusion = 1 or 2</i> 51.9%	<i>diffusion = 1 or 2</i> 66.7%	<i>diffusion = 1 or 2</i> 82.9%
<u>1970s Entrants</u> • 1 st discovery 1970-1979 • 1-5 discoveries 1975-1985 • 10 firms in this class		<i>diffusion = 1</i> 53.8%	<i>diffusion = 1</i> 80.0%
		<i>diffusion = 1 or 2</i> 73.1%	<i>diffusion = 1 or 2</i> 90.0%
<u>1980s Entrants</u> • 1 st discovery 1980-1991 • 1-5 discoveries 1986-1995 • 12 firms in this class		<i>diffusion = 1</i> 91.0%	<i>diffusion = 1</i> 87.5%
		<i>diffusion = 1 or 2</i> 100.0%	<i>diffusion = 1 or 2</i> 100.0%

Old & Big: Eisai, Fujisawa, Sankyo, Shionogi, Takeda

Old & Medium: Chugai, Daiichi, Dainippon, Meiji, Sumitomo, Yamanouchi, Yoshitomi

Old & Small: Ajinomoto, Green Cross, Kaken, Kissei, Kyorin, Kyowa Hakko, Nippon Kayaku, Nippon Shinyaku, Santen, Taisho, Teikoku Hormone, Tokyo Tanabe, Toyama

1970s: Hisamitsu, Hokuriku, Mochida, Morishita, Nikken, Nippon Chemiphar, Ono, Otsuka, Taiho, Toyo Jozo

1980s: Ashahi, Kanebo, Kowa Shinyaku, Lion, Mitsubishi, Mitsui, Nippon Zoki, SS Pharma, Suntory, Torii, Wakamoto, Zeria

Table 4: Cross-Section Data for 1981, Cumulative Discoveries of Different Types of Drugs by Japanese Pharmaceutical Firms During 1982-1995

Standard errors in parentheses; * denotes significance at 5 percent level;
** denotes significance at 1 percent level; *** denotes significance at 0.1 percent level

Values for All Independent Variables Are as of 1981	Dependent Variable is Cumulative Number of New Molecules Discovered by Each Firm, 1982 to 1995							
	All Drugs		Local Drugs Only		Mid-Diffusion Drugs Only		Global Drugs Only	
Intercept	1.60 (.55)**	1.71 (.67)*	1.39 (.71)	.83 (.71)	-.14 (.38)	.83 (.71)	.33 (.38)	1.25 (.38)
log (R&D)	.68 (.26)*	.71 (.28)*	.57 (.35)	.67 (.27)*	-.11 (.18)	.71 (.27)*	.25 (.13)*	.13 (.13)
Cumulative Launches in Japan, 1958-1981	.71 (.10)***	.70 (.15)***	.44 (.11)***	1.13 (.10)***	.22 (.06)***	1.13 (.10)***	.05 (.07)	.09 (.14)
Cumulative Launches in Southern Europe, 1958-81	.05 (.06)	-.03 (.18)	-.23 (.08)**	.40 (.19)*	.17 (.05)***	.25 (.19)	.15 (.05)***	-.05 (.10)
Cumulative Launches in Anglo-Nordic Nations, 1958-1981	.01 (.07)	.01 (.07)	.03 (.09)	.07 (.07)	-.06 (.05)	.01 (.07)	.04 (.05)	.01 (.04)
Percentage of Sales NOT in Ethical Pharmaceuticals	-2.10 (.69)***	-2.28 (.84)*	1.17 (1.05)	-1.04 (1.39)	.19 (.48)	-.85 (.78)	-1.45 (.45)***	.62 (.67)
Age of Firm (1981 minus year of first discovery)	-.06 (.03)*	-.05 (.04)	-.05 (.05)	-.10 (.04)*	-.03 (.03)	-.02 (.02)	.05 (.03)	.07 (.03)*
Pre-1982 Japan Launches * S. Europe Launches		.005 (.012)		-.22 (.02)***		.06 (.02)***		.04 (.01)***
Pre-1982 Japan Launches * % Sales NOT Ethical Drugs		-.109 (.524)		.61 (.25)**		.41 (.35)		-.56 (.15)***
S. Europe Launches * % Sales NOT Ethical Drugs		.128 (.291)		.21 (.29)		-.12 (.16)		.01 (.14)
Adjusted R-Square Statistic	.89	.88	.49	.73	.66	.75	.54	.76
F Statistic	50.5	30.9	9.12	18.1	14.7	13.4	8.16	21.1

Local drugs are launched only in Japan. Mid-diffusion drugs are launched in 2 to 5 nations. Global drugs are launched in 6 to 14 nations. Number of observations is 38 firms. Firms entering industry after 1981 are excluded from this analysis

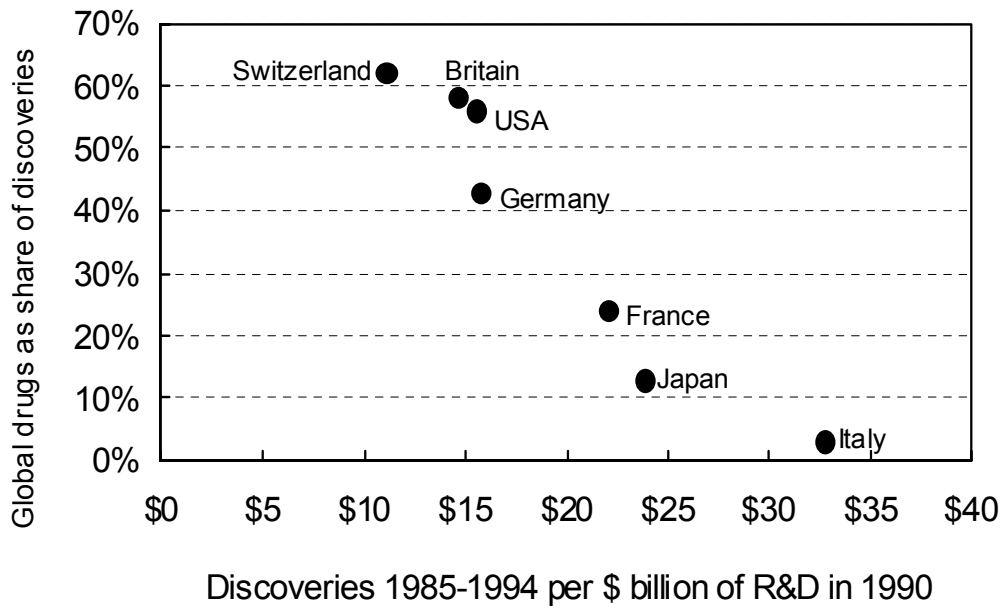
Table 5: Panel Data for 1975-1995, Annual Discoveries of Different Types of Drugs by Japanese Pharmaceutical Firms

Standard errors in parentheses; * denotes significance at 5 percent level;
** denotes significance at 1 percent level; *** denotes significance at 0.1 percent level

Values for All Independent Variables Are as of 1981	Dependent Variable is Number of New Molecules Discovered by a Firm During a Year from 1975 to 1995							
	All Drugs		Local Drugs Only		Mid-Diffusion Drugs Only		Global Drugs Only	
Intercept	-2.59 (.23)**	1.71 (.67)*	-2.98 (.29)***	-4.38 (.51)***	-4.36 (.48)***	-4.02 (.84)***	-5.10 (.58)***	-3.74 (.88)***
log (R&D)	.25 (.07)***	.41 (.38)	.57 (.35)	.71 (.27)*	-.11 (.18)	-.03 (.24)	.25 (.13)*	.41 (.37)
log (1+ Cumulative Launches in pre-1982 Japan)	.89 (.12)***	.89 (.23)***	.97 (.19)***	1.90 (.35)***	.87 (.33)***	.32 (.68)	1.09 (.29)***	.80 (.73)
log (1 + Cumulative Launches in post-1981 Japan)	.35 (.10)***	.70 (.15)***	.45 (.21)**	1.56 (.37)***	-1.88 (.63)***	-2.45 (.71)***	-.78 (.34)**	-4.12 (.85)***
log (1+ Cumulative Launches in Southern Europe)	.31 (.13)**	.44 (.24)*	-.18 (.07)**	1.62 (.22)***	.36 (.11)***	.25 (.19)	.66 (.25)***	-.37 (.47)
log(1+ Cumulative Launches in Anglo-Nordic Nations)	.12 (.16)	.13 (.15)	.21 (.16)	.19 (.14)	.37 (.24)	-.13 (.55)	-.20 (.25)	-.42 (.28)
Percentage of Sales NOT in Ethical Pharmaceuticals	-.35 (.33)	-.31 (.35)	.19 (.32)	-5.95 (1.52)***	.10 (.48)	.75 (.78)	-1.69 (.55)***	-1.35 (1.73)
Age of Firm (1981 minus year of first discovery)	-.01 (.01)	-.05 (.04)	.32 (.62)	.90 (.68)	-.01 (.03)	-.02 (.02)	.05 (.03)	.00 (.04)
Pre-1982 Japan Launches * S. Europe Launches		.10 (.09)		-.93 (.13)***		.32 (.12)***		.98 (.30)***
Pre-1982 Japan Launches * % Sales NOT Ethical Drugs		-.38 (.67)		2.45 (.90)**		-.07 (1.30)		.35 (.73)
S. Europe Launches * % Sales NOT Ethical Drugs		.01 (.36)		.61 (.58)		-.46 (.75)		-2.24 (.66)***
log (Quasi-Likelihood)	-459.2	-457.1	-364.0	-325.8	-167.8	-146.5	-129.7	-112.7
Chi-Square Statistic	108.0	110.3	44.9	56.9	38.7	47.4	37.3	55.5

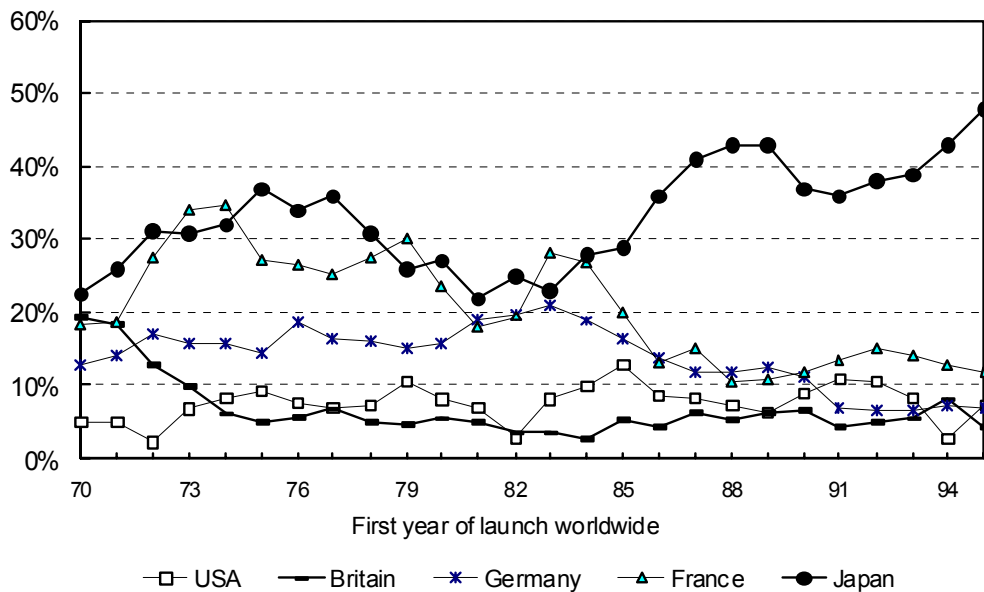
Number of observations is 835 firm-years. Firms entering industry after 1981 are excluded from this analysis. Fixed effects included for firms and are jointly significant. Estimates for fixed effects not reported in this table.

Figure 1: Tradeoffs in Drug Innovation



Source: Thomas, 2001

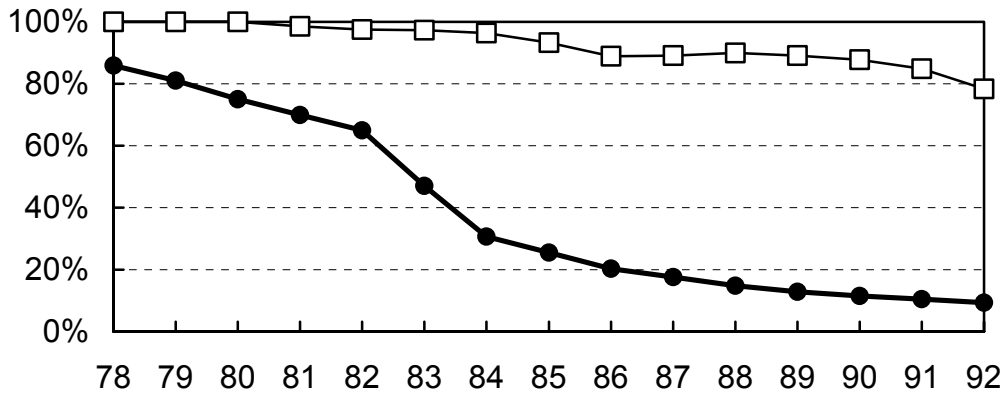
Figure 2: Local Drugs as Share of Launches



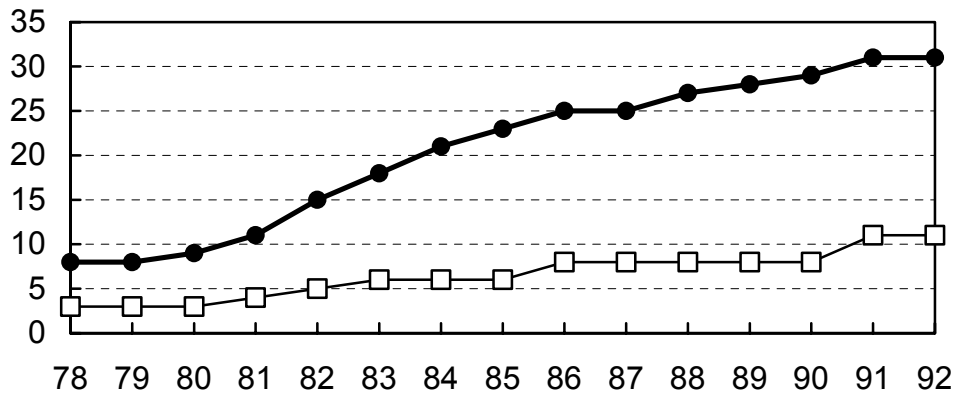
Source: OE CD, various years

Figure 3: Comparative Product Life Cycles: Beta Blocker Drugs: Japan & US

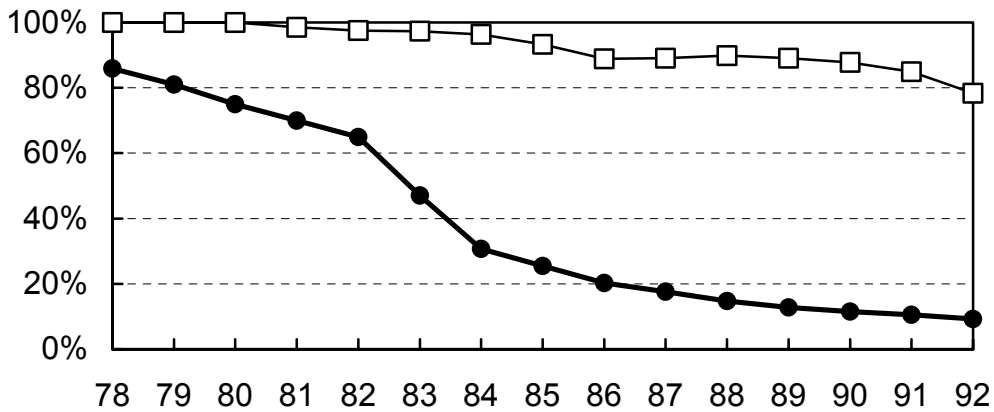
A: Aggregate Market Share: First 4 Products with 1% Share



B: Cumulative Introductions



C: Cumulative Exits



—□— Products in US —●— Products in Japan

Figure 4: Drug Discoveries by Japanese Firms: Number and Type

