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THE DIVISION OF LABOR, COORDINATION, AND INTEGRATION:

CASE STUDIES IN THE ORGANIZATION OF PRODUCT DESIGN

MEDICAL INSTRUMENTS

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Introduction

This is the third of a series of case studies conducted by the Industrial Performance Center at MIT as part of a larger project on the organization of product design and development. It focuses on six firms producing medical devices. The larger project is a response to the changes in the organizational concerns and structures of industrial companies over the last fifteen years. In that period, there has been a radical shift in the kinds of organizations which managerial practitioners, and those who study and advise them in universities, consulting firms, and the like, think most effective and have sought to create within their own institutions. Prior to this shift, certainly in the earlier postwar decades, but in another sense from the beginning of the industrial revolution, the organizational ideal was hierarchical, built around a highly articulated division of labor. The boundaries between the various parts of the organization and between the business firm and its suppliers and customers were sharply defined. There were clear lines of authority running from the base of a management hierarchy to its peak where decision-making authority was ultimately vested. In recent years, companies have in contrast sought organizational structures that decentralize authority, increase horizontal communication, blur boundaries and emphasize integration between organizational units and occupational divisions. This project, of which the medical devices case study is one part, is designed to explore these new organizational forms, to define more clearly exactly what is involved in the kind of integration they achieve, and to reconcile these new concerns with the older emphasis on the division of labor. The focus on product design and development activities was chosen because it is an area where it has always been difficult to achieve the sharp division of labor that was central to the old organizational prescriptions. If the product is not yet known, it is difficult to define the pieces into which the attempt to create it will be divided. Even before the current organizational revolution, it would appear product design and development required a great degree of integration across the boundaries of the industrial and occupational landscape.

Part I — The Medical Instruments Industry Study

Medical Devices as an Industry

The medical products industry was selected for one of the cases because it is characterized by particularly sharp occupational divisions: research and product development require the cooperation of people with skills acquired through, and defined by, advanced professional degrees. These include medical doctors, typically with specialties in particular areas of medicine. They also include Ph.D.'s in physics, biology, chemistry, and a number of engineering specialties. The professional identities associated with these occupational pedigrees would thus appear to pose especially strong barriers to the kind of integration sought by the new organizational prescriptions.

This might have turned out to be the case had we focused narrowly on pharmaceuticals. But we were led instead, in part by accidents of the contacts required for access, in part because of our technological focus, to study that segment of the industry generally termed medical instruments or medical devices. However, as we came to realize, medical instruments presented another problem for our study of integration, namely, that it is very weakly defined as an industry. The firms, occupational specialties, and academic fields which one might associate with the industry do not really identify with each other. The problem is in some measure associated with the very notion of an "industry", in point of fact a rather vague analytical concept. In economics, the term is used to identify a "competitive field" or at least a field of potential competition. Attempts to go beyond that and identify the factors that determine the boundaries of such a field generally emphasize a group of firms that share a common technology, a common customer base, and a common set of specialized inputs. Where this is the case, the firms are likely to encounter each other as competitors, actual or potential, in several different markets.

In common parlance, especially among laymen, but even among economists and management scholars, an industry frequently means a set of firms who perceive themselves as sharing a common identity. Discussions among a group of researchers in a large Sloan Foundation program organized around industries has suggested that important moments in the evolution of an

industry are defined by when that identity, and the ability to articulate its implications for business strategy, crystallize or dissolve. Charlie Chaplin's films were apparently such a defining moment in the early motion picture industry and the Sloan researchers have begun to talk about whether an industry has its "Chaplin" or has lost its "Chaplin". (The Model-T Ford was clearly such a defining moment in the automobile industry.) The modern banking industry in the United States has, according to those studying it for the Sloan project, "lost its Chaplin." Managers and corporate strategists are adrift; similar firms are pursuing completely opposing strategies —one seeking to expand branch banking, the other closing out all of its branches, for example— and, within a single company, the dominant strategy is opposed by important managerial factions. Two factors seem to be responsible for this sense of chaos and anarchy in the structure of decision-making within the industry. The first is deregulation, which has brought branches of the industry that were previously separated from each other by strong institutional boundaries into direct competition. The second factor is technological change, which by speeding up communication and enhancing the capacity for information processing has had something of the same effect.

It is not clear that the medical instruments industry ever had a "Chaplin". To the extent that firms in the industry have a common identity, that identity is provided by the Food and Drug Administration (FDA), which must approve all products on the market. FDA processes and procedures structure product development activities in all pharmaceutical and medical devices firms. Regulatory procedures in other countries differ somewhat but the United States is such a large market, and the FDA such an important regulatory model for foreign agencies, that U.S. procedures are a major influence on the structure of firms throughout the world. The procedures are by no means static; they evolve and change significantly over time. But recent changes have not altered the demands they make on the organizational structure of companies under their jurisdiction.

The firms that one might associate with a medical devices industry do, however, draw heavily on what is popularly known as "high technology" and, almost by definition, this is subject to

extremely rapid and discontinuous change. Part of the industry is really an extension of the pharmaceutical industry and draws on the advances in biology and chemistry that have revolutionized the search for new drug therapies. Other new medical devices are built around information technology; and indeed almost every innovation, even those basically dependent on biology and chemistry, draw on information technology to some extent. And other advanced technologies such as lasers and nuclear radiation are a potential source of important new devices for medical imaging, diagnosis, and treatment. In the universities, where the identities of the professions associated with the new technologies are anchored, scholars working on these different technologies have only the vaguest sense of their relationship to each other. Thus, for diagnostic imaging, laser technologies, ultrasound, nuclear engineering, the measurement and analysis of electrical and magnetic signals associated with electrical engineering, as well as chemistry and biology, are all potential sources of diagnostic innovation for the same medical conditions, but each of these technologies are the province of academic specialties that typically have little intercourse with each other.[1] Even more surprising, firms do not seem to see the relationship among these very different technologies; they certainly were never mentioned in our interviews. Thus the kinds of problems associated with crossing professional boundaries which motivated our choice of this case, do not seem to arise or, alternatively, are so profound and deeply embedded in the way product development is thought about and organized that they are never addressed at all.

The company interviews did, however, reveal a very different set of boundary problems associated with the new technologies. Those problems involve a tension between the newer approach associated with the scholarly communities which are the progenitors of the advanced technologies being adopted in the industry, and that associated with the old pharmaceutical industry and, even more importantly, with the clinical practice of medicine, where these new technologies must win acceptance to be commercially viable. That there is such a tension is widely accepted. How exactly to characterize it is a little more difficult. One way is to

[1] There are attempts to collect these activities under the broad heading of Medical Imaging.

distinguish between a theoretically based and a more ad-hoc, empirical approach. A more complex typology, developed by Donald Stokes, suggests that we should think of research and development in terms of two, orthogonal dimensions. The distinction between theoretically and empirically driven approaches is one of these. But a second is the distinction between curiosity and problem-driven innovations. On this second dimension, the newer approach shares the same location with the older pharmaceutical industry and with clinical practice. All are problem-driven, in contrast to other parts of the academic community that are often driven by curiosity.

The case study is composed of five companies, Aspect, Chiron, Daiichi Pure Chemicals, Shimadzu, and Oticon. Aspect Medical Systems, Inc., based in Massachusetts, is a ten-year-old, privately held company that produces an electronic monitor for tracking the effect of anesthesia on the brain. Chiron Corporation, headquartered in Emeryville, California, is one of the largest biotechnology companies in the world. Daiichi Pure Chemicals Co., Ltd. is one of the companies of the Daiichi Group of Tokyo, Japan; in addition to manufacturing various chemicals used in the production of pharmaceuticals, it produces and markets a range of diagnostics products to test for a number of diseases. The medical systems division of Shimadzu Corporation, headquartered in Kyoto, Japan, produces systems for all areas of medical imaging, from ultrasounds to MRI to CT scanners. Finally, Oticon is a Denmark-based innovator in the field of electronic hearing aids.

Aspect

The firm that most clearly illustrates the nature of the problem identified above is Aspect. Aspect is a single product company and this simplifies its organizational and strategic problems. But what makes Aspect such a good vehicle to study the relationship between research and clinical practice is the very long chain from the basic research idea that launched the company to the final product upon which the company's viability as a commercial entity has come to rest.

The basic research idea behind the company's product was developed by the company's founder when he worked as a visiting fellow at Harvard University. It is a signal-processing technique for extracting information from the signals emitted by various organs of the human body. The technique uses bispectral analysis combined with statistical algorithms to reduce these complex

signals to a single numerical index, the Bispectral Index™ or BIS. This approach holds the promise of an easier way to monitor the change in the performance of the organs over time, compared to the direct interpretation of the complex signal itself. The firm was founded on the notion that that monitoring technique would be useful in the diagnosis and treatment of various medical conditions and, on this basis, attracted enough venture capital to launch the enterprise, but it was not initially clear what organ the firm should target and what conditions it should seek to detect.

The initial plan was to develop a device for monitoring the heart, but the company quickly concluded that heart monitoring was a small and already crowded field. In addition, heart events are rare, making the task of validating the real-world performance of a heart monitoring system a drawn-out task. They eventually turned to the brain instead. Once focused on the brain, they began to develop the technology as a means of studying the impact of anesthesia with the idea that it would then be possible to more accurately control dosage. Anesthesiologists currently determine the dosage of anesthetic based on the accepted standard dosages for a typical middle-aged male, and on the basis of various clinical indicators of patient condition, such as heart rate and blood pressure. In the absence of direct data on the patient's depth of anesthesia, the standard dosages have tended to be generous, in order to avoid any possibility of the patient regaining partial consciousness during the operation. The company set to work to create a demand for its technology even as it was developing the technology itself. The device which it ultimately brought to market looked very much like a regular electroencephalogram (EEG) monitor, a relatively small computer instrument that picks up signals from a series of disposable sensor pads attached to the patient's head. In addition to displaying the standard EEG charts, the instrument processed the data from the sensors using a refined version of the founder's original algorithm, and displayed the resulting BIS index, a number ranging from 0 for total lack of brain activity to 100 for a fully awake person. The anesthesiologist could then use the index to determine the condition of the patient and vary the amount of anesthetic being administered to avoid a set of conditions about which the company, through an elaborate public relations campaign, sought to teach the anesthesiology profession to be concerned. In addition to the

electronic instrument itself, the company developed a special disposable sensor pad that eliminated the need for the careful prepping previously required to obtain the high quality signal required by the device. Ultimately, the company came to see these disposable pads which it developed to connect the instrument to the forehead of the patient as a significant source of revenue, beyond the BIS technology itself or the instrument which embodied it. The pads would not be sold, of course, unless the technology won acceptance and the instrument was purchased as a way of monitoring the patient. But the instrument was a one-shot purchase, whereas the pads would generate a continuous stream of revenue.

The development process from the time that the company began to focus on anesthesia divides into a series of distinct steps. The first of these was to develop an instrument which would collect brain signals, measure, analyze, and convert them into an index associated with the levels of consciousness which the anesthetic controlled. The second step was then to introduce that instrument into operating rooms and persuade anesthesiologists to play around with it in their routine practice, in order to understand the relationship between the index and the conventional clinical indicators used to gauge the patient's condition, and to make judgments about the anesthesia which they were administering. Finally, on the basis of the experience of the pioneer users, they had to persuade the larger professional community that the device was a useful adjunct to its modus operandi. They had to do all of this, moreover, in a way that was acceptable to the FDA, whose standards controlled what product they could release, how and to whom they could release it, and what claims could be made on its behalf.

The initial product design was dominated by the need to fit the product into the operating room, already crowded with instruments and personnel, and to make it attractive to the anesthesiologist and easy to use. Designers spent a lot of time in the operating room watching what was going on and how other instruments fit into it, and testing alternative designs with focus groups of doctors, nurses, and other operating room technicians. Attention focused on such issues as the size and color of the instrument, whether it should be stationary or portable, mounted on a movable rod or hand held, above the anesthesiologist or at eye level, etc. A separate debate

surrounded the nature of the display and how much data to offer the user. Should the device display the final index only, or would it be better to show the EEG graph itself and the various components of the index? Although the latter would ultimately be superfluous, it was felt that they would be necessary for the more curious early adopters, and that they might give the uninitiated more confidence in the BIS index. They could also possibly be found at some later time to be correlated with an important clinical detail or some condition not yet salient in the profession.

To appreciate this last point, it is important to recognize that, initially, there was absolutely no demand, not only no demand for the product but no demand for the service which the product was designed to provide. There was no demand for the service first because the relationship between the BIS index and the condition that the device was designed to indicate had not yet been worked out. Second, there was no demand because the professional community was not generally concerned about the condition, as explained earlier. The company thus had essentially two different tasks, both of which involved inducing various practitioners to begin using the technology, recording the results, and then disseminating them. The first task involved, in a sense, completing the technological development by working out empirically the association between the measurement and the medical condition it was supposed to measure. The second task involved creating an interest in that condition.

The typical anesthetic, a cocktail of various compounds, has three distinct effects upon a patient. First, it reduces the patient's involuntary movement by acting as a neuromuscular blocker. Second, it provides an analgesic effect by reducing the pain actually experienced by the patient. The third effect is hypnosis, which affects the patient's ability to recall the operation. After initial research and testing, the company decided to focus on the last of these three effects, as it showed very good correlation with the BIS index.

For the task of working out the relationship between the index and patient recall, it was enough to develop trials with experienced doctors in whose results one would have confidence. This could in principle be done through systematic clinical trials paid for by the company. The second

task, however, was more complicated. It involved a three-pronged approach: first, the company sought to persuade “lead users”, respected doctors in highly visible institutions such as teaching hospitals, to use and endorse the device. Second, it involved persuading researchers to experiment with the technology and publish the results in articles in influential scientific journals and papers at important professional meetings. The company then sought to disseminate these papers through its salesmen, its booths at professional meetings, mass mailings, etc. Finally, the company hired a specialized public relations firm to promote articles, reports and programs in the mass media that highlighted the condition that the instrument sought to measure. Having decided to focus on patient recall, for example, they managed to place several magazine articles including patient testimonials about the effects of recalling certain details of the actual operation on their psychological well being. These articles, which appeared to originate independently of the company, were then disseminated in a manner similar to the way in which scientific material was disseminated. The pace of this “campaign” to develop a market for the product was controlled by a separate, parallel campaign to obtain FDA approval.

An important consideration in FDA strategy was the protection, or lack thereof, that one or another approach would offer against the encroachment of competitors. The technology itself was of course protected by patents. But there were potentially a number of different technologies for monitoring the effects of anesthesia, even for monitoring the brain waves that reflected these effects. And, it will be recalled, the company was investing heavily to create a demand for such measures, demand that was in no sense linked to its own monitoring device. Thus, even if one particular path to FDA approval might be more complicated and prolonged than another, it might nonetheless be attractive to the company if it created a barrier that a competitor would have to surmount. On the other hand, some of what the company was being asked to prove was a relationship between physical measures and clinical conditions that other technologies might be able to use as evidence in behalf of their own claims. In this case, the more prolonged FDA approval might in fact actually constitute an investment in a public good.

Because the company was initially a start-up, the development of the business structure and organization was closely linked to the process of product development in the extended sense of the term that we have been describing. The manufacturing organization, the sales organization, and even the product development organization in the narrow sense of the term were all tied to the pace of the campaign to create product demand. Thus, in the case of product development, the plan from the very beginning was to create a second-generation product, drawing on the experience with the first generation, which would be smaller, cheaper and easier to use. Planning for the second generation began even before the first generation was launched and on the market. But the development process was continually postponed because of the slow pace of demand development and FDA approval, and in order to collect more information about the context in which the product would be used. Eventually, the product development organization was reduced in size, almost to the point of elimination, so that it had to be rebuilt when the company finally decided to proceed. A significant factor in this, and in several other decisions about how to build the company internally, was the possibility that the company's technology would be bought by, or licensed to, one of several companies that supply clinical information management systems. The BIS would then be disseminated as part of such a system and would not necessarily appear as a separate instrument in the operating room. This might have eliminated the need for a second-generation product, although a licensing agreement would not necessarily have precluded the company from also marketing a stand-alone instrument itself.

A similar set of decisions were made with respect to the company's sales force and sales strategy. The key decision was whether and when to develop its own sales force. This was partly linked to the question of whether the technology would be licensed to a maker of clinical information management systems, a move that might obviate the need for a separate sales force. Alternatively, the instrument could be sold through a medical instruments distributor with its own sales organization rather than marketed directly to hospitals. And the decision about a sales organization was also linked to the question of how to develop product demand. Early sales were closely linked to the strategy of placing the technology with key users who were visible in the professional community and/or would use the instrument for clinical trials and write papers

disseminating the results. Pricing was determined more by the interest in having the device put in use than by the desire to generate revenue. For example, one of our respondents believed that when the instrument was provided freely, it was simply ignored; but if the doctor or his hospital had to make a decision to buy it, or at least pay a fee to use it, they would be more likely to use it. These were not judgments which conventional sales people were accustomed to making and early sales were handled directly by company officers, several of whom were also professional researchers with advanced degrees. Later, however, as the expansion of demand came to depend, or was viewed as depending, on more conventional variables, and the pressures to generate revenue increased, the company did begin to create its own sales force and to move sales efforts away from people without experience in that area. Demand generation remained an important factor in the company's decisions. The decision to create an internal sales force and not to license the technology or use a wholesale company was based on the conviction that another company would not be sufficiently committed to developing a market for the product.

In terms of the problem of bridging the considerable distance between the basic research underlying high tech innovations in medical devices, and the clinical context in which those innovations find a market (if they find a market), Aspect appears to be typical. But Aspect may be less typical in terms of its relatively direct and unrestrained approach to solving the problem. One company that better illustrates the organizational tensions and strategic choices that this problem poses is Chiron. The comparison between Chiron and Aspect is not simply one of contrasts however; there are important similarities as well.

Chiron

Chiron, like Aspect, is still growing and filling out its organizational structure. But it has defined for itself a much broader mission than Aspect's: it is trying to do regularly, for a continuous stream of new products, what Aspect is seeking to do with its index for monitoring the effects of anesthesia. Hence, one dimension of Chiron's organizational structure is designed to launch particular new technologies. This side of the organization is directly comparable to Aspect. A second dimension of Chiron's organizational structure is designed to identify promising

technologies; it thus seeks to resolve a problem that Aspect has not addressed directly. Finally, in 1992, Chiron entered into a partnership with Ciba-Geigy, a much larger Swiss pharmaceutical firm. (Ciba-Geigy has since merged with Sandoz to form Novartis.) As part of that process, Ciba-Geigy acquired 49.9% of Chiron, and Chiron's diagnostics division, the subject of our study, absorbed Ciba-Geigy's diagnostic division, which had been known as Ciba-Corning Diagnostics. Decisions which at Aspect revolved around the development of sales and manufacturing organizations were at Chiron centered around the process of integrating the new division into the culture and structure of the Chiron organization. It is here that the tension between the research thrust in new product development and the clinical practice in which those products must find a market emerges most clearly.

In seeking to understand the first dimension of the organizational structure at Chiron, we focused on one particular technology within Chiron Diagnostics, specifically, its family of nucleic acid based diagnostic tests. These tests use branched DNA (bDNA) probes to measure directly the presence of viral DNA or RNA in blood or plasma. This technique allows the quantification of viral load in the blood, in contrast to the more common diagnostic tests that give a binary, positive or negative, response. The technology was obtained by an acquisition and thus did not actually grow out of Chiron's own research, but there is a significant internal research component to the attempt to bring the technology to market. That research component is driven by the fact that Chiron has a direct competitor in the monitoring of viral load. The competitor's technology, polymerase chain reaction or PCR, has certain advantages relative to Chiron's (although it has certain disadvantages as well). In brief, Chiron's technology yields a measure of viral load that is more repeatable from test to test than its competitor's but is also less sensitive. Internal research is directed at overcoming the disadvantages of this technology by increasing its sensitivity. There was no comparable basic laboratory research dimension in Aspect's development process.

In other respects, Chiron and Aspect faced similar problems. The monitoring of viral load is a supply-driven technology in very much the way that BIS as a monitor of depth of anesthesia is supply driven. It is a technology for which there was initially no demand. Hence, the major

thrust of product development has been to create a market. Chiron's approach to this is very similar to Aspect's. It seeks to induce the medical and scientific communities to introduce the technology into their practice and to experiment with it, both to familiarize themselves with its potential and to discover new uses. For this purpose, Chiron thinks of the targets in terms of a social community with a pyramidal structure. At the top of the pyramid are prestigious research institutions and teaching hospitals. In the middle are large urban medical centers. The mass of general practitioners and smaller clinics form the base of the pyramid. New practices are introduced at the top of the pyramid. Lower levels tend to imitate the level above them, after a time lag. They do this for reasons related to the structure of the profession, which are both social and technical. Personnel tend, for example, to move down the pyramid in the course of their careers. Students for example absorb standard practice in teaching hospitals and then, when they graduate, move to lower level institutions, carrying those practices with them. One of the functions of higher level institutions is to develop new knowledge, and lower levels within the pyramid thus look to them to keep up with the frontier. The higher levels are also more prestigious and are imitated for that reason so that practice is disseminated like any fashion in a social hierarchy. In principle, one could separate out the purely social effects of the hierarchy from the technical effects, i.e., the way in which the advancement of knowledge takes place and is disseminated. But in practice, since much of the knowledge is clinical, reflected in judgment and intuition, and not scientifically verified, the distinction is hard to make. We return to this point in the context of a discussion of tacit knowledge in the next section of the paper, when we consider the theoretical implications of the case findings.

At any rate, Chiron's strategy, like Aspect's, is to introduce the new technology at the top of the pyramid and get professionals there to play with it, verifying the relationship between measures of viral load and the medical conditions they are seeking to treat, discovering new ways in which the measure might relate to clinical practice, and incorporating the technology into their clinical routine.

An important difference between Aspect and Chiron, however, is that Aspect is a single product company and the company is defined by that product. Chiron defines itself in terms of its ability to generate a stream of new products over time. The company was in fact founded by the chairman of the biology department of the University of California at San Francisco in an attempt to compete with other universities that were able to offer faculty a richer set of commercial ventures to affiliate with. He developed a vision of the company in which the UCSF faculty served as the center of a network of biotech researchers that gathered information about evolving technologies and their potential commercial applications. His goal, as others in the company articulated it to us in the interviews, was to make Chiron the best-informed commercial enterprise of its kind in the country. And a major concern in guiding the evolution of Chiron's structure was to make it the central node in the biomedical research community. His strategy for doing so was to draw scientists from all parts of the biotech community into a continuing interchange, either through the UCSF faculty or directly with company personnel. A senior technical manager at the company discussed a number of aspects of this strategy in the interviews. One of these was the need to give information freely to outsiders in the expectation that they would in this way be drawn into a continuing conversation in which they in turn would deliver information to the company. The company sought to protect itself from the loss of commercially valuable information assets through a complex system of patent protection, but its strategy compelled it to accept some risks in this regard. Another dimension of the strategy was to make its test equipment and chemical assays freely available to leading research labs so that they would almost automatically report back results to company scientists. Our respondent was particularly concerned that the company be in close touch with biomedical researchers throughout the country — indeed throughout the world. He saw one of the main advantages of the merger with Ciba-Corning Diagnostics, located in Massachusetts, as facilitating an expansion of Chiron's scientific network on the East Coast where connections had been weak.

The Ciba-Corning merger, however, posed a problem for Chiron, a problem that underscores in a very sharp way the tension between research as a source of new products and the clinical practice into which they must be introduced and absorbed if they are to be successfully

commercialized. Chiron is, as the founder stressed, and every other respondent mentioned at some point in our interviews, a research-driven organization. Ciba-Corning Diagnostics is basically a marketing company, whose research and development is driven by ideas that its salesmen collect from the market where the company's existing products are strong. The merger was not really Chiron's idea; as mentioned earlier, Chiron had acquired the company somewhat inadvertently as part of its deal with Ciba-Geigy. But once the merger had occurred, Chiron decided to integrate Ciba-Corning Diagnostics with its own marketing organization. Chiron saw the basic problem in the merger as a clash between two organizational cultures, its own research-oriented culture and Ciba-Corning's (and indeed Ciba-Geigy's) market-oriented culture. It sought to resolve this conflict by imposing its culture on its newly acquired division. As our respondent explained, if you are getting ideas for innovation from the market, you are always following, never leading. His intonation suggested that the real profit went to the leaders. (This is a view which, as we shall see, marketing organizations do not necessarily accept.) The problem here is that there is a real difference, as we have seen, between the marketing efforts of organizations generating radically new products like those of Chiron and Aspect, and the marketing of a product for which there is already a perceived need. Of course, marketing organizations are already integrated into the professional community in which they sell their products. And one could thus argue that a good marketing organization that specializes in a given disease or medical specialty should be better at integrating even a radical innovation into clinical practice than an organization like Chiron or Aspect that is basically starting from scratch. The problem is that research-driven organizations will not necessarily come up with new products that are all narrowly targeted toward a given professional community. Since it is the evolution of research that drives the innovative process, not the perceived needs of the market, there is no particular reason to expect that the marketing organization which works for one innovation will necessarily be well adopted to commercializing the next.

The problem is incipient in Aspect's strategy as well as Chiron's. Aspect's technology might well move next to monitor the heart or the kidney but the marketing organization it is creating is dedicated to penetrating the anesthesiology profession and will be of limited use if the company

moves in these new directions. The problem is, however, somewhat abstract in the case of Aspect, since it has taken it five years to commercialize its product. At Chiron, which is generating a stream of new products, each one hard on the heels of the other, the problem is more acute. The wisdom of the merger between Chiron and Ciba-Corning diagnostics is thus open to question. In fairness to Chiron, as already noted, that merger was not Chiron's idea.

What a third alternative to the strategy that Chiron appears to be pursuing might look like is suggested by one of the Japanese companies that we visited, Daiichi Pure Chemicals. We actually gained entree into this company through Chiron, which had entered into several cooperative ventures to develop and market its products for Japan, although those ventures are not the major interest in contrasting the two approaches. The original reason for including the Japanese companies in the study was to pick up possible national variations. (As noted earlier, the second company was Shimadzu.) Although it has proved difficult to separate national patterns from other sources of variation in structure and strategy, the insights into alternative strategies for combining research and marketing, which are highlighted by Daiichi especially, do need to be placed in the context of the broader comparison between the U.S. and Japanese companies.

Daiichi Pure Chemicals and Shimadzu

The Japanese companies are difficult to compare directly to either Chiron or Aspect. They are much older, with a base of mature technologies, and their medical divisions are parts of larger, diversified parent companies. The parent of Daiichi Pure Chemicals makes therapeutic drugs, but Shimadzu produces aircraft equipment, industrial machinery, and other scientific and process instruments, in addition to its medical systems and equipment. In general, however, these two companies appear, relative to the two American companies with which we spent the most time, to be much more driven by the market than by research and development. They seem to be less tightly integrated in terms of communication across, and cooperation among, the different divisions of the larger corporate entity. The latter is somewhat surprising in light of the conventional wisdom about Japanese business. It could simply reflect the younger age and research/venture orientation of the American companies we are using as a point of comparison,

but there are certain parallels here to our findings from a separate study involving Matsushita Electrical Co.[2] We return to discuss these findings below.

The marketing orientation of the Japanese companies emerged directly in the interviews. In both companies, when asked where ideas for new products came from, the immediate and emphatic response was, "The market". Daiichi reported that it tended to develop new products for diseases on which it was already working, such as diseases of the liver, because its existing products gave it such good contacts with the market. And this is consistent with the way in which the company's relationship with Chiron has played out. Initially, Daiichi agreed to adapt for Japan, and to market there, bDNA diagnostic kits for both Hepatitis C and HIV, but only the former survived. At Shimadzu, we focused on a new device the company was developing to image the brain, a major technological breakthrough involving development efforts over twice the average size, with a four-year time to market. Here too, the respondents insisted that the device was driven by the market, not the research community. It emerged, however, that in this particular case, the development costs were being subsidized by a government agency and that an important market was the university research community interested in mapping the cognitive functions of the brain. This research community was, however, sharply distinguished from the medical research community. Both Shimadzu and Daiichi emphasized that there was no medical research community in Japan comparable to that in the United States, and that research never constituted a backdoor for clinical trials there as it had for DNA testing at Chiron and, to a lesser extent, with Aspect's BIS index. From one perspective, this looks like a difference between the regulatory regimes in the two countries, but our respondents attributed it to the fact that there was simply no funding in Japan for the kind of clinical research conducted in the United States and hence no comparable research establishment.

At Daiichi, an important second source of new products were those they licensed from abroad. They maintained that these arrangements generally originated with foreign developers looking for

[2] Some of the findings from that study have been reported in Piore, Lester, and Malek, "Case Studies in the Organization of Product Development: The Cellular Telephone Equipment Industry," MIT Industrial Performance Center Working Paper 95-008WP, July 1995.

a way of marketing their product in Japan, who would contact them through their parent company, Daiichi Pharmaceuticals. These licensing agreements were also market driven in the sense that the foreigners were attracted to Daiichi Pharmaceuticals by that company's reputation for strength in Japan in the drug markets at which the particular foreign diagnostic technique was targeted. When Daiichi Pure Chemicals had a similar strength in that market, the parent referred the inquiry to its subsidiary. The company did not seem to monitor foreign markets systematically for possible devices, or even to pay particularly close attention to developments abroad, although we probed this extensively in our questioning. We specifically asked, how many of the professionals in the organization were tied into scientific networks in such a way that they automatically followed developments abroad and attended international scientific meetings. Our respondents reported that of the 50 researchers dedicated to diagnostics in the company, 10 currently fell into this category; but it was clear from the way that they answered the question that this was not an explicit criterion in decisions about staff recruitment.

At first, it was difficult to believe that a company so dependent on foreign licensing for its new product development, in an industry where new products were such an important source of revenue, did not attempt to engage more systematically with the biotech research community. And we still suspect that we may have missed important aspects of the company's strategy. But in the light of the conflict between marketing and research-based strategies that became apparent at Chiron, Daiichi's strategy begins to appear more plausible. It is after all a company with a strong organization for selling drugs [diagnostic kits?] in certain markets within Japan. One might think of the international research community as very large and difficult to penetrate, spawning any number of small, venture companies working on new technologies of all sorts, driven by research, with no obvious, a priori mapping onto the market structure. On the other hand, the organizations with marketing capabilities —Daiichi among them— are fairly large and visible. It is thus reasonable to think that when the venture company has moved a new technology to a point where it can be targeted at a particular market, it will search for a marketing firm; and that the alternative strategy, in which the marketing company searches for the innovations or the

innovators attempt, as Chiron is doing, to create a marketing company, is not going to be the most efficient one.

This conjecture is reinforced by what are along other dimensions very strong similarities between the approaches of the companies in the two countries. For market development, for example, both of the Japanese companies, like their American counterparts, thought of the medical community in terms of a pyramidal hierarchy and sought to introduce their products through lead users at the top. Demand would then spread downward and outward through imitation. The institutional structure of this pyramid as they described it was also very similar to the structure described by the American companies: Teaching hospitals and large, urban medical centers stood at the top; a mass of clinics and doctors in private practice at the base. Daiichi actually produced test kits that it sold primarily to large, commercial laboratories, but the laboratories were in effect working for doctors who requested particular tests by name, and the company marketed directly to these doctors. It sought to develop interest in new products and disseminate information through professional organs, scientific meetings, journal articles, special seminars and the like. And like its American counterparts, it considered lead users drawn from teaching hospitals and large medical centers key in this process. An important difference between Japan and the United States emphasized by Daiichi was the role of company sales representatives: Daiichi claimed that they had such a close relationship to the network of practitioners in those areas in which the company specialized that they in effect gave private tutorials on new products. The company's strategy was to pick a single product each year upon which its sales reps would concentrate. This was possible, our respondents asserted, because of the geographic and social compactness of Japan. The role of the sales representative, however, also led Japanese companies to concentrate in the development of new products on areas where they already had established connections, and it was another factor making product development market, as opposed to research, driven. A second factor distinguishing the structure of the Japanese medical community from that of the United States was, as already mentioned, the paucity of clinical research. Although sharply distinguished from "research", new drugs and devices were tested through networks of practitioners. Shimadzu described a network of relationships with lead users in

university hospitals that it used for clinical trials of its new equipment, which was very similar to that of Daiichi or for that matter to those used by companies in the United States.

The Food and Drug Administration

Finally, in reviewing the material gathered at the various companies visited for this study, the role of the FDA requires special mention. To naive outsiders coming to the industry as we did for the first time, the way in which the presence of the FDA pervades the thinking of our informants was striking; it is impossible to imagine how the industry would operate without such regulation. One interpretation of the FDA's role is that it relieves managers in the industry of any ethical or moral responsibility for their actions. In reality, the relationship is almost certainly more nuanced, but it is noteworthy that ethical and moral implications were never once mentioned in any of our interviews. On the other hand, the reaction of the FDA was a continual preoccupation in virtually every deliberate action, and the FDA, it was clear, was understood as a social watchdog.

The literature on industrial regulation and government bureaucracy offers two very different perspectives. In one perspective, regulation tends to rigidify practice. It imposes rules upon the operations that it governs; the industry then tends to work to rule; the rules tend to substitute for the judgment of the people whose behavior they govern and, in cases like ours, regulation tends to relieve the players of the responsibility of thinking through the implications of the behavior that the rules govern. There were some suggestions in our interviews that the FDA has this effect, especially in production. Our respondents at Chiron particularly were concerned that the ISO 9000 standards that the FDA had recently imposed made it very difficult to generate variability in the assays that the company produced, in a way that foreclosed clinical variations that might prove important for research.

But the general tenor of the discussion of the FDA was actually much more consistent with a very different perspective developed in the literature on "street level bureaucracies." These are organizations that, of necessity, root a great deal of discretion in personnel at the base of the hierarchy, such as the patrolman on the beat in police departments or the classroom teacher in the

schools. The mission of such organizations is so complex that it cannot be reduced to a simple set of rules or laws. Attempts to do so quickly lead to a complex and cumbersome body of regulation that cannot possibly be interpreted literally or enforced in its entirety. An attempt to monitor and enforce every rule would paralyze the system. As a result, considerable discretion is lodged in the officers at the base of the bureaucratic hierarchy — the patrolman on the beat in the case of the police, the classroom teacher in the case of the school, the officer who reviews the company's application at the FDA. The discretion is exercised in accord with a broad and general conception of the mission of the agency. The police, for example, are charged with maintaining social order; the schools with training citizens. When a rulebook does exist, the street level bureaucrat exercises this discretion by deciding which rules to enforce and how to enforce them. But he or she does so, not by reference to the rules, but by balancing the complex aims of the organization directly and then looking for the particular rules whose application will enable him or her to effect this balance. The behavior of the agency is thus better understood by looking directly at what these aims are, how they are perceived within the agency, how the weights placed upon competing goals are determined and vary over time. Again, in classic fashion, the variation at the FDA responded —or, at least, our respondents, whose fate depended on the FDA's decisions, thought that it responded— to the political environment. Lower level officials looked toward the pronouncements of its top officials for shifts in the balance which the lower level administrators would attempt to strike. Thus, at Aspect, there was considerable interest in recent pronouncements that placed increased weight on cost cutting and required submission of data on the cost impact of new technologies. For Aspect, this was likely to be favorable in the long run, since the company expected that more precise measurement of the effects of anesthesia would enable reduced dosages and lead to shorter time spent in the operating room, in the recovery room, and ultimately in the hospital. But in the short run, it increased the documentation that was required to gain approval. At Chiron, the pressure from the organized gay community to increase access to AIDS treatments was thought to be leading the FDA to overlook the fact that viral load kits being distributed for experimental purposes were often being used for clinical practice. This led the company to believe that it could count on that as a strategy for creating a

market even before it was actually able to present evidence on the clinical effectiveness of viral load testing. More generally, the company faced a problem of predicting FDA response as it mapped out its development strategy. The strategic problem for the company was complicated because, while it wanted to get its own product into the market as quickly as possible, it also wanted the Agency to impose the greatest possible hurdles for its competitors. It was not always clear whether data collected by one company in clinical trials could be used by its competitors to support a claim for a rival product.

In order to predict the FDA response, the company used special consultants who were retired FDA employees. The role of these consultants was essentially that of a boundary spanner. It is thus another example of the general problem with which our study is concerned. The consultant can be looked on as a classic linguistic interpreter, a point to which we return in the final section of the paper.

Another classic problem in street level bureaucracy, which emerged in the interviews, is the conflict between vague and general versus narrow and specific rules. The rules most consistent with the discretion of the street level bureaucrat are vague and general. Thus the police like stop-and-frisk laws because these can be applied by the officer to stop any behavior that threatens local standards of social order. But such vague laws are precisely for that reason inconsistent with the protection of the civil liberties of the citizen. In the case of the FDA, the conflict emerged around the issue of the tight ISO 9000 standards that the agency had adopted and imposed on the industry for the production and testing of products. At Chiron, some of our informants felt that these standards precluded the kind of spontaneous variation in the product which might lead to the discovery of new clinical applications of a test.

Part II — Implications for Theory

We came to this case with a set of relatively well-formed theoretical ideas gathered earlier in the project. These ideas were first developed through a review of the literature and interviews with colleagues at MIT active in the area of product design and development. They were then

expanded and revised in the light of our field interviews in pilot studies and the case studies of the cellular telephones and blue jeans industries. How useful are these ideas in understanding design and development of medical devices? In what ways does the medical device case suggest that these ideas might be extended and/or altered?

At the core of the theory that emerged earlier in this research is the distinction between two approaches to the organization of the design and development process, namely, the analytical and the interpretive. These can also be thought of as alternative ways of understanding behavior and managing human endeavors more broadly. In the analytical approach, human action is viewed as the product of a deliberate decision-making process, the solution to a "problem". The actors formulate that problem in terms of a sharp distinction between ends on the one hand, and means and/or constraints on the other; they understand the relationship between the means and ends in terms of a well-defined causal model. They then organize the available means subject to the constraints imposed by the environment so as to maximize the ends. The approach is used both prescriptively and descriptively. As a prescription, it dominates thinking in managerial science and engineering and lies at the heart of the theories of design and product development that emerged in most of the discussions with our colleagues. As a characterization of how people actually behave, it is the fulcrum around which orthodox economic theory is built and has been extended to a general theory of human behavior, now prominent in other social sciences, where it is generally termed rational choice. It is a reasonable approach where alternatives can be readily identified and clearly specified, and where they are known, if not with certainty, at least probabilistically. But where the alternatives are ambiguous, where means and ends are difficult to distinguish, and where there is radical uncertainty —a kind of ignorance where it is impossible to specify what the alternatives actually are as is frequently the case in product design, especially at the early stages— the analytical approach is difficult to apply.

The interpretative approach is, by contrast, a way of thinking about human endeavors where means and ends are ambiguous, hard or impossible to separate, and difficult to specify. It also captures a world which is so complex and uncertain that even its possible states are unknown in

advance, a world of what is variously termed ignorance, radical uncertainty, or knightenian uncertainty where we do not know what to attach probabilities to. In this approach, human activity is viewed as a process that is ongoing in time, a process which need not be self-conscious nor specifically motivated, but one which generally has a direction which can be managed. A useful example, we have found, is the conversation at a cocktail or dinner party. The guests, once brought together, begin to talk to each other in what is often termed idle conversation. But the hostess can manage the party, breaking up conversation groups and creating new ones, introducing topics of conversation, changing the subject when discussion lags or becomes too intense. What the hostess cannot do is determine, or even predict, where the conversation will ultimately lead or what kinds of relationships might emerge among the guests in that process.

While the analytical and the interpretative approaches to design are distinctly different and present a sharp contrast, the one to the other, managers need not necessarily choose between them. Each yields different insights into the same situation. Most endeavors can be best understood by looking at them first through the lens of one approach and then that of the other. In this sense, the relationship between analysis and interpretation is analogous to the wave and the particle theories of light. Nonetheless, some business situations seem better characterized by one approach than the other.

Our initial research convinced us that the kind of integration which is sought in the new managerial techniques and organizational structures, and which is critical to the collaboration across occupational specialties and domains of practice in design and product development, has to be thought of interpretatively. But management thinking tends to be dominated by the analytical alternative. The interpretative approach is relatively underdeveloped and poorly understood, even by those who draw upon it, often intuitively, in their normal operations. We have thus come to see the major theoretical task of the project as working out the interpretative approach as an alternative and specifying more precisely when it is likely to be more appropriate and why.

Attempting to do this, we have found it useful to think of the different domains that must be linked for design and development —and in the process of organizational integration more generally— as linguistic communities. The integration processes can then be understood literally as one of interpretation as that term is understood in relation to the process of translation from one language to another. Alternatively, integration might involve the kind of linguistic merger that seems to occur when people from different linguistic communities come into contact with each other repeatedly over a prolonged period of time. Contemporary research suggests that language leaves such a wide space for ambiguity and misunderstanding that the processes at stake when people from different linguistic communities come into contact are also operative in contacts between people who speak the same language. The process through which we deal with, and overcome, ambiguity in ordinary conversation generates novel ideas and understandings. Part of what we mean by creativity in the design of new products can be thought of as the generation of new expressions and understandings that grow out of this process.

Linguistic Metaphors in Medical Devices

Much of the material gathered in the medical devices case fits well within this scheme. One can think of the two metaphors drawn out of the linguistic analogy as two alternative organizational forms for dealing with the problem of integration. One organizational form preserves the different organizational entities but attempts to create bridges between them. The bridging function can be performed either by individuals or by organization components. In both cases, they function as translators or interpreters between linguistic communities. We saw that this is a powerful way to understand the role of the consultant in helping companies like Aspect or Chiron think about the FDA. It is by extension a way to understand the role of the lawyer in helping the organization negotiate the legal environment. The lawyer, when playing this role, is not being asked to predict the outcome of court cases or to negotiate a solution but rather to help the company frame its business strategy so that it will be perceived favorably in a legal or judicial environment. Indeed, we often talk about lawyers and judges as “interpreting” the law. In market driven firms, the role of the sales division is a good illustration of an organizational structure that performs this

interpretative function. In a sense, one could think of these firms as offering “interpretation” to the technology driven firms whose products they represent through licensing agreements or strategic alliances.

From the point of view of the sales organization itself, however, their modus operandi is probably best understood in terms of the cocktail party metaphor, a metaphor that suggests less a “bridge” between two linguistic communities than their fusion. The firm’s customer representatives regularly visit the doctors and laboratories in their territories even when they are not particularly concerned with making a sale. In this way they are continually engaged in the kind of idle conversation that one associates with a cocktail party. But from the analytical perspective, the goal of the sales organization is to make a profitable sale. Its performance can be judged against that measure and the salesmen regarded in these terms through commission-based compensation. Often it is also asked not just to enter into “idle” conversation but to collect specific information about the customer or to “educate” the customer about new products that the company is launching. These activities have very specific goals and hence can also best be understood in analytical terms.

In companies like Aspect or Chiron [or Oticon] which developed their own sales forces, the sales organization is much more an extension of the process of product design and development. Here, the cocktail party metaphor, and the image of a fusion of two linguistic communities which it implies is critical to understanding what the company is trying to achieve. At Aspect, in fact, one can think of the emphasis as shifting over time from the role of sales as fusion to that of bridging, from the cocktail party to the translator. At Aspect, when the product was in the stages of initial development and an understanding of the world of the customer was most important, sales were actually handled by top management itself; the understanding was too “precious” to pass through several organizational layers. Indeed, the interviews at Aspect suggested that at this early stage, the interpretative dimension of the sales function was so central that the goal-driven orientation of making profitable sales was suppressed. One of the reasons for creating a separate sales organization at the later stages of the developmental process was to make the profitability of

individual sales more central to the sales process. Even at this stage, however, it is notable that in selecting personnel for the new sales organization, the company tended to choose anesthesiology nurses, who knew the world into which they were introducing the product, and train them in sales, rather than the other way around.

The sales function in these medical device firms is usefully contrasted to that at a fast food restaurant like McDonald's or to a checker in a supermarket, particularly as these jobs have become increasingly automated in order to collect and analyze point of sale information. Such information is useful in analytic decision making. The "information" being gathered by the sales people in medical devices is clearly of a different kind and cannot be reduced to the numbers gathered by the scanner in the supermarket or generated by the register at McDonald's.

It is also instructive to compare the sales function in the medical device firms in our case study to the prescription, which has grown out of the vogue in cross functional integration, for top management to be assigned customers for which they actually take sales responsibility. One can imagine that this would facilitate top management's ability to listen to and understand the regular sales force as it plays its interpretative role, mediating between the two worlds. But it is difficult to believe that an on-going business with an established line of products wants or needs the kind of integration into the customers world which, for example, Aspect needed in the early stages of product development when its sales were handled by the company's top executives.

Networking and its limits

The conversational metaphor and its extension, the cocktail party, are also useful in understanding the network of researchers that Chiron is trying to create and maintain. Referring back to our earlier study of denim jeans, there are obvious parallels here with the network among the different laundries which one of our respondents, Claude Blankiet, was trying to create for Levi's. There are also parallels to the position that the manager of Martelli, an Italian jeans

laundry we visited, was trying to occupy in the Italian jeans industry by working for as many different clients as he possibly could.[3]

On the other hand, there is a particular problem that emerged quite starkly in the interviews in medical devices that appeared only at the edges of the blue jeans case. That is the prospect that critical information will leak to competitors in the process of the "idle conversation" which is involved in creating and then maintaining the kind of network at whose center Chiron is seeking to stand. This prospect has several effects. One is that it will inhibit outsiders from talking to you. Chiron sought to overcome this problem by giving information in order to later receive, a kind of gift exchange. Another solution is to surround the company's intellectual assets with as much patent protection as possible and then to limit what is revealed to information which is protected in that way. Even with extensive patent protection, this obviously constitutes a substantial inhibition of the conversation.

A solution to this problem is integration of the company through mergers and acquisitions, in order to create an *internal network.* This is essentially the strategy that Levi's has pursued in blue jeans, and it is apparently the strategy that the Swiss pharmaceutical companies are pursuing in the drug industry.

Indeed, the more basic question is why external networks work at all. Our interviews are full of examples of alliances among firms, which were aborted when one party or another went off to undertake the project on its own or with another partner, to the point where one is left to wonder how any conversation among firms that are potential competitors is at all possible.

One answer is that the value of particular scientific breakthroughs may not be as great as it initially appears. This is in part because of the distance between the science and the commercial application, and the difficulty of actually creating a market for a new device. Particularly telling in this regard is Chiron's viral load measurement technology. At first blush, the ability to measure

[3] See Piore, Lester, and Malek, "The Division of Labor, Coordination, and Integration: Case Studies in the Organization of Product Design in the Blue Jeans Industry," MIT Industrial Performance Center Working Paper 97-005WP, March 1997.

viral load appears to be a major breakthrough in clinical practice, but in fact the value of that breakthrough very much depends upon the disease. Chiron initially sought to develop the technology for tuberculosis but, on closer inspection, the treatment for tuberculosis does not require a measure of this kind. The treatment is the same whatever the severity of the disease and hence is unaffected by any knowledge of viral load. Chiron has developed the technology for HIV, and it is now becoming standard in clinical practice. But the current centrality of the measure seems to be an accident of the way HIV treatment has evolved in the last two years through the development of combinations ("cocktails") of different drugs which need to be specially tailored to the individual patient and then adjusted over time. These new therapies came as a surprise to the research community. Had a drug therapy which cured or even controlled the virus emerged, as occurred in the case of tuberculosis — indeed, should it emerge even now — there would be no market for Chiron's technology. The other factor in reducing the value of specific scientific breakthroughs is that the most important piece of information is the very existence of a market for a given type of technology. The existence of such a market cannot be maintained as a secret. And patent protection may not be very effective in protecting that market once it has emerged (or as we have seen is often the case, been created). In recent years, companies that have pioneered the development of oral therapies, for example, have been displaced rapidly by injection therapies that were developed once the market had been targeted.

Still another reason why internal networks may be less prevalent than the logic of the problem suggests is that the relevant technologies are the province of a single professional community that could be covered by a network of the kind that Chiron is seeking to create. In medical imaging, as we have already noted, magnetic, electric, ultrasonic, and nuclear technologies, provinces of very different academic specialties, are all potentially in play. In contrast, the areas in which Chiron is working may be less professionally heterogeneous. Or Chiron's strategy may be misguided. We have already suggested that the relatively specialized nature of sales organizations in the industry relative to the range of possible markets into which a particular technology may lead makes vertical integration a questionable strategy.

The Hermeneutic Process

One of the most striking features of the medical devices case is the way in which the companies seek to create a market for new products by penetrating the ethos of the clinical practice and fitting their device into the on-going activity of the clinician. The most detailed description of this strategy emerged in our interviews at Aspect, but essentially the same strategy was adopted by Chiron and by Shimadzu in Japan. From one perspective, this approach to the design process is not well captured by the cocktail party metaphor. The companies might be described as entering into conversations with the professional community, but the conversations are anything but "idle". They are oriented toward a specific goal, and a specific list of means or instruments are used to achieve that goal. In Aspect's case, for example, the goal is to win acceptance for their device in the operating room. The means are direct observation and focus groups, and subsequently a public relations campaign centered on lead users, key institutions, papers delivered at professional conferences and published in scientific journals, strategic sales and trials. Highly directed approaches of this kind are well captured by the analytic model.

The underlying process that the companies are using to achieve their goal, however, is actually "interpretative". The company is essentially trying to "translate" its technology into a form that fits into the on-going clinical practice of its potential customers. For these purposes, it is useful to think of the customers' behavior in interpretive terms. And indeed the process that the companies are using for this purpose fits nicely into the framework suggested by the German philosopher Heidegger who is in many ways the father of the interpretative approach.

The analytical approach would have us think of the customer as motivated by a explicit benefit-cost calculus and would lead the firm to present its product to the customer in terms of its effect upon the benefits and costs of his or her practice. Economists tend to think of these costs and benefits in monetary terms, but alternative theories which see the clinician as motivated by the health or comfort of his or her patients are essentially variants of the same approach. Heidegger argues that we should not think of human behavior as motivated at all. Rather he urges us to conceive of behavior as a process on-going in time that continues unselfconsciously unless

interrupted. That behavior may be directed toward some end, but under normal circumstances, the end is ill-defined and only vaguely perceived. Thus, Heidegger argues, a carpenter hammering a nail into a board on a house is not conscious of the hammer as an instrument or the penetration of the nail into the board, the attachment of the board to the house, or even the house itself as goals of his action. It is only when the activity is interrupted and cannot for some reason continue, when, for example, the head flies off the hammer, that he is forced to think about what he is doing and recast the problem in analytical terms. Ultimately, he might be forced to evaluate the instruments as means to an end, and consider alternatives — fixing the hammer, looking for a different hammer, gluing the wood onto the frame, perhaps even abandoning the project of building the house. At this point, it is meaningful to understand his behavior as analytic. But between the uninterrupted activity and the full-fledged analysis, there is a good deal of space. The carpenter's first instinct is not analysis at all, but to reach for alternatives which are "ready at hand", simply putting the head back on the hammer or picking up another from the tool box, and falling back unselfconsciously into the rhythm of activity.

Understood in these terms, Aspect's goal is to introduce its technology, the BIS index, into the on-going process of the operating room so that it becomes a part of the continuing routine of the anesthesiologist. It is seeking to make the BIS like the carpenter's hammer, ready at hand so that the anesthesiologist reaches for it unselfconsciously in the routine of his or her practice. Thus, the company has sought to design the equipment so that it looks and feels like a part of the operating room. It has then sought to get lead-users to play with the equipment in a way that would lead them first to see it as an extension of their clinical observation of the patient, but with the ultimate goal being for that piece of equipment to take the place of that observation. This process fits the cocktail party metaphor in the sense that what Aspect is looking for are users who are adept at idle play in their practice —doctors who like gadgets— in the same way that party goers are adept at idle conversation. The company's public relations campaign tries to enter the on-going process in a different way, by creating enough of a breakdown in the normal routines of the operating room so that the practitioners begin to think self-consciously about problems of patient awareness which the BIS is designed to overcome. It does not want,

however, to maintain this level of self-consciousness indefinitely. If it were to do so, the practitioners would be looking for other instruments which might be better for the task. Ultimately, the idea is that the company's instrument should fall into the background: continually present but unremarkable. The instrument should become like the elements of a language that we have so successfully mastered that we use them without conscious effort. Thus, language in use enables us to think about the substance of communication without thinking at all about how to construct the sentences that we use to convey our thoughts. In that same sense, the ideal medical device is one that we can use to think about the patient's condition without focusing on the device at all.