INNOVATION AND INDUSTRY DEVELOPMENT:
THE CASE OF COCHLEAR IMPLANTS

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ABSTRACT

In an earlier paper in this series, Van de Ven and Garud (1989) proposed a social system framework for understanding the emergence of new industries. This paper adopts this social system framework to empirically examine how an industrial infrastructure emerged to develop and commercialize a biomedical innovation (cochlear implants). This infrastructure includes institutional arrangements, resource endowments, and technical economic activities. It is found that this infrastructure for cochlear implants emerged through an accretion of numerous technical and institutional events involving many public and private sector actors over an extended period of time. Moreover, the very institutional arrangements and resource endowments that emerged to facilitate and provide momentum to the emergence of the cochlear implant industry became inertial forces that hindered subsequent technological developments by private firms. The findings emphasize that the management of innovation must be concerned not only with

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microdevelopments of a proprietary technical device or product but also with the creation of an industrial system that embodies the social, economic, and political infrastructure that any technological community needs to sustain its members.

INTRODUCTION

An understanding of how technological innovations emerge to create new industries or reconstruct existing ones is invaluable to industrial policy makers and entrepreneurs, particularly those who argue that the engine for corporate revitalization and economic reform is the development and commercialization of new technologies (Rosenbloom, 1986). It is also critical for advancing knowledge of the generative process by which novel technical and institutional forms arise. Based on an intensive longitudinal field study, this paper narrates the sequence of events that occurred over a 35-year period to develop and commercialize the cochlear implant, a new-to-the-world biomedical technology that provides hearing to profoundly deaf people.

This history of the origination and development of cochlear implants is based on the social system framework originally introduced by Van de Ven and Garud (1989). Since the process of innovation typically transcends the boundaries of existing firms, industries, and populations of organizations (Astley, 1985), the framework focuses on the issues and events in constructing an industrial infrastructure for innovation. This infrastructure includes not only the traditional definition of an industry, consisting of the set of firms developing similar or substitute products, but also all the other actors in the public and private sectors who play key roles in the development of an industrial system for innovation. This system includes (1) institutional arrangements to legitimate, regulate, and standardize a new technology, (2) public resource endowments of basic scientific knowledge, financing mechanisms, and a pool of competent labor, as well as (3) technical economic activities of applied R&D, manufacturing, marketing, and distribution by private firms to commercialize the innovation for profit.

Section I of this paper develops the propositions that were used to guide the research on how and why this industrial infrastructure emerges and stabilizes over time. We argue that the odds of successful innovation development for an individual firm are largely a function of the extent to which this infrastructure is developed at the industrial community level. While this industry-level infrastructure enables and constrains individual actors to innovate, it is the latter who construct and change the industrial infrastructure. This infrastructure does not emerge all at once through the actions of one or even a few individual actors. Instead, it emerges through an accretion of numerous events in building institutional arrangements, resource endowments,

and technical economic activities which involve many public and private sector actors over an extended period of time.

Section II operationalizes the framework by describing the methods used in a longitudinal study of the development of cochlear implants. Based on these methods, Section III presents the results by showing the time series of events in the development of institutional arrangements, resource endowments, and technical economic activities for cochlear implants. Qualitative richness to the event time series is provided by narrating the historical development of the the cochlear implant industry in terms of and when the social system emerged, the network of actors involved, and how these functions and actors interacted over time to facilitate and constrain the development of cochlear implants.

A concluding discussion in Section IV focuses on the interdependent roles played by public and private sector actors in developing and commercializing new technologies, such as the cochlear implant. These interdependent roles explain why the risk, time, and cost to an individual actor are significantly influenced by developments in the overall industrial system.

I. TECHNOLOGICAL DEVELOPMENT AS AN EMERGENT SOCIAL SYSTEM

The proposition that technological and institutional innovations reciprocally co-produce each other within the system under investigation is a relatively new development in economic and organization theory (Ruttan and Hayami, 1984, p. 203). This proposition was central to Marx's (1867; tr. 1906) analysis of the dialectical relations between the forces of production (i.e., technology, or the equipment and labor processes used in production) and the relations of production (i.e., institutions, especially property rights or ownership of production forces) within the superstructure of cultural and resource endowments of a society. However, perhaps because of ambiguities in Marx's own writings on the manner in which the development of the forces and relations of production occurs (Bottomore, 1983), organizational and economics scholars subsequently formulated one-sided theories of technical and institutional change.

Those advocating a technological imperative perspective treated technological innovation as something that happened to the firm but was not determined within it (Abernathy and Clark, 1985, p. 3). Technological innovation was viewed as an environmental shock to which organizations or an economic system were to adapt if they were to survive (see reviews by Ruttan, 1978; Freeman, 1986; and Tornatzky and Fleischer, 1990). However, the potency of this technological imperative view weakened as the definition of technology expanded from that of a physical concrete device or artifact to that

which included proprietary design knowledge that is embodied in the physical artifact (Layton, 1986). This knowledge is socially constructed (Pinch and Bijker, 1987), recognized and protected as a property right through the institutions of patents or royalties (Nelson, 1982), and imprinted with the economic and cultural endowments of a society at the time of its creation (Thirtle and Ruttan, 1986).

A second perspective maintained that institutional rather than technical change was the dynamic source of social and economic development. This "institutional determinism" perspective, as Ruttan (1978) labeled it, emphasized that changes in institutional arrangements precede and constrain technical change (North and Thomas, 1973; North, 1990). However, as Commons (1950) emphasized, institutional arrangements not only constrain action, they also liberate and expand the freedom of individuals to undertake a wide variety of actions, including due process provisions for creating and changing the institutional arrangements. Institutional arrangements are defined as administrative rules, norms, laws, and conventions that society uses to legitimate, regulate, and coordinate the actions and expectations of individuals, and thereby make them predictable (Ruttan, 1978; Powell and DiMaggio, 1991). Hurwicz (1993) importantly points out that institutional rules or laws are typically written by specifying (1) the roles (rights and duties) of various institutional actors and (2) the assignment of these roles to actors, be they individuals, firms, trade associations, or state agencies. Individuals and organizations become institutional actors by exercising the institutional roles that they either assume or are assigned. In this way, institutional arrangements have created roles for "artificial persons"—such as firms, unions, trade associations, state agencies, and even markets—that enable them to act as though they are individuals. Much of the current work on institutionalism in organization theory (Powell and DiMaggio, 1991) and political science (March and Olsen, 1989) is focusing on the processes by which these institutional arrangements and actors emerge, and how this larger exogenous institutionalized environment enables and constrains entrepreneurs and organizations to develop only certain types of technologies and practices.

A third, and older, tradition emphasized that resource endowments of a society create a supply and demand for both technical and institutional innovations (Ruttan, 1978). As exemplified in Rosenberg and Birdzell's (1986) historical examination of "How the West Grew Rich," this perspective maintains that technical and institutional changes occur as a result of advances in the supply of resource endowments, that is, knowledge about new social and economic possibilities, as well as the financial capital and human competencies that are available to develop and apply these possibilities. The demand for technical and institutional change, in turn, is brought about by changes in expectations generated by knowledge of new

possibilities as well as the pressure of population growth against relative factor prices or scarcity of land, labor, and capital (Schultz, 1968; Ruttan, 1978).

Arguments over the relative priority of technical, institutional, or resource endowments are generally unproductive. Technical and institutional changes are highly interdependent and therefore must be analyzed within a context of continuing interaction. So also, Ruttan (1978) argues that demand for and supply of technical and institutional change interact with shifts in resource endowments of new knowledge and relative scarcity of land, labor and capital. Ruttan and Hayami (1984) proposed an induced theory of innovation which provides a more balanced treatment of the reciprocal relationships between technical and institutional innovations and resource endowments. Although developed independently of Marx, their theory echoes Marx's analysis of the reciprocal relationships among changes in technology, institutions, and resource endowments in an economic sector. Ruttan and Hayami argued that in the study of long-term social and economic change the relationships among these variables must be treated as endogenous, and not as givens within a general equilibrium model. "Failure to analyze historical change in a general equilibrium context tends to result in a unidimensional perspective on the relationships bearing on technical and institutional change" (Ruttan and Haymi, 1984, p. 216).

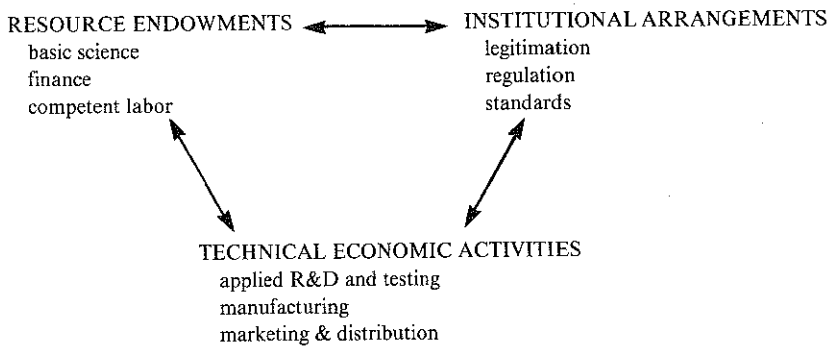
Ruttan's model emphasizes the role of history in understanding innovation development; that is, the temporal sequence of events and activities that occur to create and transform basic scientific knowledge into commercially viable products or services delivered to customers. Numerous case histories demonstrate that new technologies are seldom, if ever, developed by a single firm alone in the vacuum of an institutionalized environment (see, e.g., Usher, 1954; Jewkes, Sawers, and Stillerman, 1958; Constant, 1980; Nelson, 1982; and Chandler, 1990). Many complementary innovations in technical and organizational arrangements are usually required before a particular technology is suitable for commercial application (Binswanger and Ruttan, 1978; Hughes, 1983; Rosenberg, 1983). Research reviews by Mowery (1985), Thirtle and Ruttan (1986), Freeman (1986), and Dosi (1988) show that the commercial success or failure of a technological innovation is, in great measure, a reflection of the institutional arrangements and available resource endowments which embody the social, economic, and political infrastructure that any community needs to sustain its members.

The social system framework proposed by Van de Ven and Garud (1989) articulates the components of an industrial infrastructure for technological innovation. This framework, outlined in Table 1, adopts an augmented view of an industry and focuses on temporal relationships among key components of this industrial infrastructure. Components of the social system include (1) institutional arrangements that legitimate, regulate, and standardize a new

Table 1. A Social System Framework for Understanding Industry Emergence and Technological Development

- Institutional Arrangements
  - Legitimation (creation of trust)
  - Governance (norms, rules, regulations, laws)
  - Technology standards
- Resource Endowments
  - Basic scientific/technological knowledge
  - Financing and insurance arrangements
  - Human competence pool (training and accreditation)
- Technical Economic Activities
  - Firm technological development functions: R&D, testing, manufacturing, marketing
  - Firm network/resource channel activities: appropriation of common goods (science, financing, labor) vendor-supplier-distributor channels
  - Firm relations with co-venturers and rivals

Proposed reciprocal relationships among components of the social system.



Source: Adapted from Van de Ven and Garud, 1989.

technology, (2) resource endowments, such as basic scientific knowledge, financal arrangements, and competent labor, as well as (3) technical economic activities of applied R&D, manufacturing, marketing, and distribution by private entrepreneurial firms to commercialize the innovation for profit. As the bottom of Table 1 illustrates, we follow Ruttan and Hayami (1984) in proposing that these components of the social system are reciprocally interrelated. Only brief descriptions of these system components are provided below since they were discussed at length in Van de Ven and Garud (1989).

1. *Institutional Arrangements*

In the context of the emergence of a new biomedical innovation, the institutional arrangements examined here focus on legitimating, regulating,

and standardizing a new technology. The ultimate authorities that legitimate, regulate, and standardize a new technology are governmental organizations, professional trade associations, and scientific communities that society recognizes as its delegated agencies (Galaskiewicz, 1985; Scott, 1987). Firms may either adapt to institutional requirements or attempt to build their goals and procedures directly into society as institutional rules (Meyer and Rowan, 1977). Thus firms compete not only in the marketplace but also in this political institutional context. Rival firms often cooperate by collectively manipulating their institutional environment to legitimize and gain access to resources necessary for collective survival (Hirsch 1975; Meyer and Rowan, 1977; Pfeffer and Salancik, 1978).

2. *Resource Endowments*

Three kinds of resources are critical to the development of most every technological innovation: (a) advancements in basic scientific or technological knowledge, (b) financing and insurance mechanisms, and (c) a pool of competent human resources (Mowery and Rosenberg, 1979). While private entrepreneurs or firms do engage in the development of these resources, typically, public organizations—often viewed as external to an industry—play a major role in creating and providing these public goods.

3. *Technical Economic Activities*

The commercial component of the system focuses the traditional industrial economics definition of an industry (Porter, 1980), which consists of the set of firms developing product innovations that are related to or close substitutes for one another. The focus here is on the actions of individual entrepreneurs and firms who typically appropriate basic knowledge from the public domain and transform it into proprietary technical knowledge through applied R&D work in areas related to a technological innovation. If they persist in developing the technology, they subsequently develop a line of products and gain access to the complementary assets or functions (e.g., manufacturing, marketing, and distribution) necessary to establish an economically viable business.

The social system framework maps a conceptual territory of the essential components of an infrastructure for innovation at the interorganizational level of analysis. Perhaps more than anything else, it helps one get a handle on the key elements of an industrial infrastructure. Van de Ven and Garud (1989) reviewed an eclectic body of literature indicating that these functions are necessary (not sufficient) conditions that need to be put in place to foster the development and commercialization of technological innovations. While many of these functions have been studied in varying degrees by different disciplines, they have been treated as "externalities" (Porter, 1980) to the system under investigation. But by doing so, one is not likely to study how institutional

arrangements, resource endowments, and technical economic activities are interdependent and reciprocally influence one another over time.

A. Processes of Industry Emergence

Although common folklore often suggests that innovations emerge all at once by chance or by the actions of one or a few key entrepreneurs, detailed historical studies indicate quite the opposite. Usher (1954, p. 60) insisted that the history of mechanical inventions is not the history of single inventors or of random chance events. Gilfillan (1935, p. 5) observed "a perpetual accretion of little details... probably having neither beginning, completion nor definable limits" in the gradual evolution of shipbuilding. Constant (1980) found that advances in aircraft propulsion emerged not from flashes of disembodied inspiration but from many incremental changes and recombinations of existing technology and institutional arrangements, which added up to what might be called a technological revolution.

Moreover, there is a systemic nature to technological advances, as demonstrated in studies by Hughes (1983) of electrical power, Ruttan and Hayami (1984) of agricultural innovations, and by Kuhn (1982) and Hull (1988) of science in general. Developments in other complementary technologies, institutions, and resource endowments often explain bottlenecks and breakthroughs in the development of a given technology. Thus, as Rosenberg (1983, p. 49) states, "What is really involved is a process of cumulative accretion of useful knowledge, to which many people make essential contributions, even though the prizes and recognition are usually accorded to the one actor who happens to have been on the stage at a critical moment."

Discontinuities are inherent to the numerous events required to develop institutional arrangements, resource endowments, and technical economic activities, particularly since they require the involvement of many actors from public and private organizations over an extended period of time. Individual events are often not made known to others, and various acts of insights pertaining to technical, resource, and institutional capabilities are often required to overcome bottlenecks. These acts or events accumulate probabilistically; they do not proceed deterministically under the stress of necessity or progress (Rosenberg, 1983). They are possible for only a limited number of actors who, by virtue of their different roles, competencies, and available resources, become exposed to conditions that bring both awareness of problems and elements of solutions within their frame of reference. Thus, Usher (1954, p. 67) stated that "emergent novelty becomes truly significant only through accumulation" of many discontinuous events of technical and institutional change.

These historical studies lead to two basic propositions that we will explore in this research.

Proposition 1. Events pertaining to the creation of institutional arrangements, resource endowments, and technical economic activities are reciprocally related over time to develop and commercialize an innovation.

Proposition 2. Numerous actors from both the public and private sectors make significant contributions in creating each of the components of an industrial system.

The process can begin any number of ways and varies by the technology being developed. For example, it could begin with purposeful intentions and inventive ideas of entrepreneurs, who undertake a stream of activities to gain the resources, competence, and endorsements necessary to develop an economically viable enterprise. As they undertake these activities, the paths of independent entrepreneurs intersect. These intersections provide occasions for interaction and for recognizing areas for establishing cooperative and competitive relationships. Cooperative relationships emerge among the actors who can achieve complementary benefits by integrating their functional specializations. Competitive relationships emerge as alternative technological paths become evident and as different entrepreneurs or firms pursue alternative paths.

Private firms launch technical economic activities by entering into relationships with research institutes to gain access to and appropriate the basic knowledge and prototypes needed to begin applied R&D. Depending upon the specific alternative technical design chosen by an entrepreneurial firm, it becomes highly dependent upon different clusters of basic research institutions that have been producing and directing the accumulation of basic knowledge, techniques, and experience associated with that design. By engaging in cooperative relationships and licensing agreements, clusters of entrepreneurial actors in both the public and private sectors increasingly isolate themselves from traditional industries by virtue of their interdependencies, growing commitments to, and unique know-how of a new technology. Isolation frees the actors from the institutional constraints of existing technologies and industries (Astley, 1985). However, these actors cannot survive for long in a vacuum. Isolation enables and facilitates these actors to modify and construct distinctive resource endowments and institutional arrangements that are tailored to advancing their technology. As the number of actors gains a critical mass, a complex network of relationships begins to emerge that becomes recognized as a new industrial sector, and that takes the form of a hierarchical, loosely coupled system.[1] We view this emerging system as consisting of the key institutional actors who govern, integrate, and conduct all the activities required to transform a technological innovation into a commercially viable line of products or services delivered to customers. The structure of this system, when fully developed, consists of the institutional arrangements, resource endowments, and technical economic components illustrated in Table 1.

B. Processes of Industry Stabilization

Innovation uncertainty decreases over time as components of the industrial infrastructure emerge. This infrastructure defines key technical and institutional parameters for the innovation. Correspondingly, transitions from development to commercialization activities often entail shifts from radical to incremental and from divergent to convergent progressions in the development of system functions (Rosenkopf and Tushman, 1992). This developmental pattern often culminates in the selection of a dominant design for the technology from among competing alternatives (Utterback and Abernathy, 1975). This selection process is largely produced by a convergence in developments of institutional arrangements, resource endowments, and technical economic activities that emerged over time to embody preferences for the dominant design (Ruttan and Hayami, 1984; Anderson and Tushman, 1990). As this dominant design emerges, there is a leveling off in further developments of the industrial infrastructure. Once largely established, the system systematically channels and constrains further technological advances in the direction of the dominant design. This leads to our proposition on how the industrial infrastructure stabilizes over time.

Proposition 3. The very institutional arrangements and resource endowments that initially develop to facilitate technical economic activities become inertial forces that constrain subsequent development in the direction of a chosen dominant design.

We will now empirically explore the three propositions by describing the methods and findings from a longitudinal study of the development and commercialization of a biomedical innovation, cochlear implants.

II. METHODOLOGY

A. Longitudinal Field Research Setting

An intensive real-time longitudinal study was undertaken of the cochlear implant, which is a biomedical innovation that provides hearing to many profoundly deaf people. Real-time tracking of the development of cochlear implants occurred from 1983 to 1989. When the research began, baseline data were obtained through interviews and archival information, and a case history was prepared on developments in cochlear implants prior to 1983 (see Garud and Van de Ven, 1989, 1990). Real-time data were collected with multiple methods and from multiple sources in order to triangulate (Yin, 1982, p. 50) on the major events in the development of the innovation and industry over

time. These sources include direct field observations and attendance at trade conferences where numerous interviews were conducted with actors from different organizations involved in different functions of cochlear implant development, reviews of trade literature, monthly observations of day-long management meetings of one of the firms involved in this innovation, as well as the administration of standardized questionnaires and interviews every six to twelve months with key actors involved in the innovation.

The multiple data sources were content analyzed to develop a chronological list of events in the development of cochlear implants. Van de Ven and Poole (1990) describe these procedures. Events were defined as critical incidents when actions occurred to develop each of the institutional mechanisms, resource endowments, and proprietary functions of the social system framework in Table 1. A qualitative database computer program (Rbase) was used to record the date, the actor, the action, the outcome (if evident), and the data source of each event. Over the seven years of real-time tracking plus historical baseline data, 1,009 events were recorded in the database. Table 2 shows an example of a few events in the qualitative data file. These events are the data points for analyzing the development of cochlear implants.

Of course, these events do not represent the population of occurrences in the development of cochlear implants. Even with thousands of person-days of real-time field observations, it was not humanly possible to observe and record all possible incidents that happened over time. Thus, as is well established in classical test theory of item sampling (Lord and Novick, 1968), the events represent a sample of indicators describing what happened over time. However, it is important to recognize that the events do not represent a random sample. Although the researchers gained unprecedented, intimate, and on-going access to many of the key actors and firms engaged in the development of cochlear implants over the years, this degree of access was not uniform across all actors. Moreover, during intensive periods of activity it was impossible for the research team to directly observe simultaneous events going on in multiple sites in Austria, Australia, and the United States. We compensated for these limitations by conducting retrospective interviews with, and obtaining relevant documents from, the actors involved in the events we heard about as soon after they occurred as possible.

Two basic procedures were used to enhance the validity of the events entered into the qualitative data file. First, the entry of events from raw data sources into the data file was performed by two researchers (who were also engaged in real-time field observations). Consensus was required among these researchers on a consistent interpretation of the decision rules used to identify events. Second, the resulting list of events was reviewed by selected informants who were engaged in different functions of cochlear implant development. They were asked to indicate if any events that occurred in the innovation's development were missing or incorrectly described. Based on this feedback, event listings were revised if they conformed to the decision rules for defining each event.

Table 2. Example of Events in Development of Cochlear Implants

Incident Number: 4 Date: 01/01/57
Event: French researchers, Djourno and Eyries, implant electrode on auditory nerve of patient as part of their experiments on the use of electricity to stimulate the cochlea of the ear.
Data Source: AORL May-June 1976; also reported in ASHA May 1985
Keywords: Academicians, Basic research

Incident Number: 5 Date: 01/01/61
Event: William House and James Doyle of the Walt Disney Hearing Center in Los Angeles conduct the first cochlear implant in the United States by implanting a limited number of patients using a single elecrode.
Data Source: ASHA May 1985. Initial report of event was published in W. F. House and K. Berliner, "Cochlear Implants: Progress and Perspectives," *Annals of Otology, Rhinology and Larynology,* Supplement 91 (1982), pp. 1-124.
Keywords: House, Academicians, Basic research

Incident Number: 9 Date: 01/01/65
Event: Dr. Simmons at Stanford encounters resistance of otological community to his cochlear experiments. Support was provided by researchers at Bell Telephone Labs. Simmons stated, "I submitted a paper for the 1965 meeting of Am. Otol Soc. which was rejected because the topic was considered too controversial. None of the nationally known figures in audition whom I contacted were willing to invest even consultative time, let along participate in this experiment. The one exception was the research group at the Bell Telephone Labs. I am certain to this day that without that confirmation, the data would not have been believed and attributed by the East Coast Establishment as just another outrageous claim from 'those nuts in California.'"
Data Source: Simmons talk reported in Research Resources Reporter HHS, July 1984, p. 6.; also in AORL, May-June 1976;
Keywords: Academicians, Association, Simmons, Legitimation

Incident Number: 10 Date: 01/01/67
Event: University of Melbourne initiates work on CI under the direction of Dr. Graem Clark. (Melbourne did not develop its first CI device prototype until 1977.)
Data Source: Letter of July 1986
Keywords: University of Melbourne, Clark, Academicians, Basic research

In order to analyze temporal patterns in this chronological list of qualitative events, each event was coded in terms of the following dichotomous variables that are central to the research propositions.

A. *Institutional arrangements*: Any event pertaining to the legitimation, establishment of governance structures, regulations, or technical standards for the overall cochlear implant industry. Institutional events are a composite sum of the frequency of the following three functions.
   1. Legitimation—events involving activities undertaken to publicize, endorse, support or resist cochlear implants as a legitimate new medical technology or procedure.

2. Governance/regulation—events involving the establishment or application of rules, regulations, or laws pertaining to cochlear implant development or commercialization. This includes incidents when the U.S. Food and Drug Administration (FDA) develops uniform protocols to review and approve cochlear implants for commercial release.
3. Technical standards—events involving the setting of technical standards pertaining to cochlear implant components, processes, or evaluation criteria for all industry participants.

B. *Resource endowments*: All events relating to the development of basic research knowledge, pools of competence, and financial instruments that are publicly available to all cochlear implant industry participants. Resource endowment events are a composite sum of the frequency of the following three coded functions.
   1. Basic science—events pertaining to the creation of basic scientific or technological knowledge that is made available in the public domain and which, though not immediately applicable, forms building blocks on which products or services are developed by individual firms.
   2. Competence pool—incidents involving the development and dissemination of professional competence in cochlear implants through, for example, courses, degrees, seminars, conferences, journals, and communications directed at large numbers of people in the industry.
   3. Financing arrangements—events involving the procurement and allocation of financial resources to the development, commercialization, or adoption of cochlear implants.

C. *Technical economic activities*: All events involving the private appropriation, applied R&D, clinical trials and regulatory reviews, manufacturing, marketing, distribution, and service of cochlear implant products for profit. Technical economic events are a composite sum of the frequency of these events.

D. *Actors*: The organizations or individuals involved in each event were coded into the following categories:
   1. professional/industry trade association
   2. regulatory agency
   3. financing agency or investor
   4. academic, research, or educational institution
   5. clinics, customers, or users of cochlear implants
   6. private, for-profit organization

Two researchers independently coded each event, and they agreed on 93% of all codes. Differences were resolved through mutual consensus.

In addition to these coded event sequence data, longitudinal quantitative data were obtained on other important measures of cochlear implant technological and industry development over time, including dates the FDA granted its approval for carrying out clinical investigations and for commercial sale of the device; dates, dollar amounts, and recipients of all research grants and contracts by the National Institute of Health (NIH) to conduct research on areas related to cochlear implants; citations of technical publications on cochlear implants in refereed journals; dates and recipients of all patents awarded related to cochlear implants; training programs organized by firms in the industry; and the number of industry conferences held over time.

III. RESULTS ON THE EMERGENCE OF COCHLEAR IMPLANT INDUSTRY

Both statistical and historical data analyses methods will be presented to describe the process of cochlear implant's development and to empirically explore our propositions on the emergence and stabilization of the cochlear implant industry. First, time series graphs will be presented on the occurrences of events pertaining to the temporal order and sequence of creating institutional arrangements, resource endowments, and technical economic activities. Deeper meaning and insight to these statistical temporal patterns will be obtained from the historical narration of how cochlear implants were developed and commercialized.

A. Results on Event Time Series

Figure 1 plots the cumulative frequencies and temporal distributions of 1,009 events that were recorded in the development and commercialization of cochlear implants from 1955 to 1989. Figure 1A plots the composite number of events pertaining to the development of institutional arrangements (totaling 90, or about 10% of all events), resource endowments (187, or 20% of all events), and technical economic activities (706, or 70% of all events) of the social system framework. These data are presented in two ways: Figure 1A shows the cumulative number of events over time, while Figure 1B shows the number of events per quarter. While the latter plots the actual event data that are used in the statistical analysis presented, the former are clearly easier to visualize. Thus, the remaining graphs are presented as cumulative frequencies of coded events over time.

Both Figures 1A and 1B show that events in the development of resource endowments and institutional arrangements preceded the development of technical economic events by over 22 years, but that the latter occurred at a more rapid rate after 1980 and far exceeded the number of events pertaining

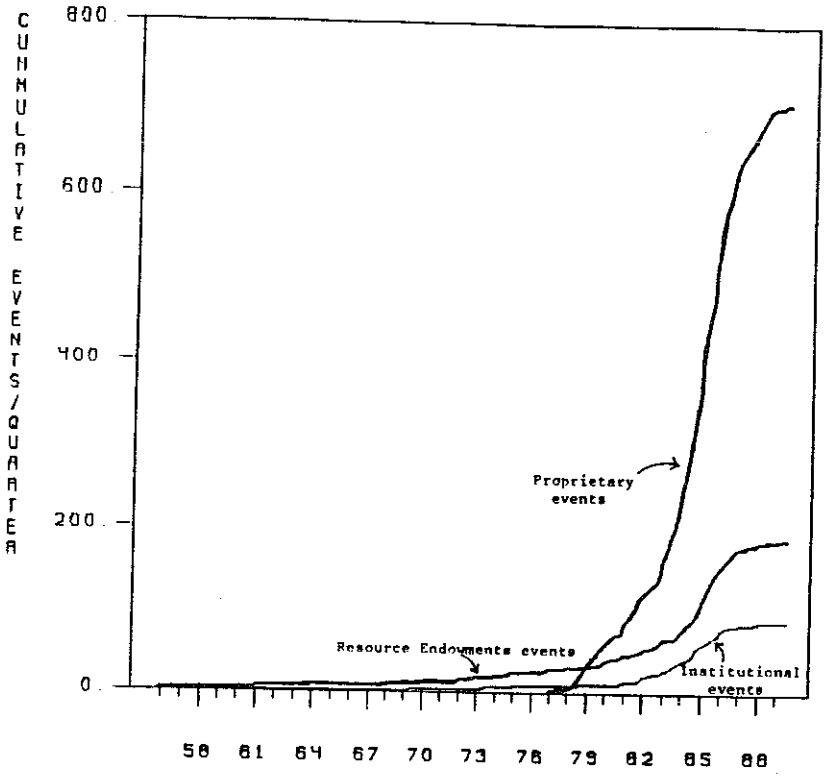


Figure 1A. Cumulative Number of Subsytem Events

to institutional arrangements and resource endowments. Moreover, there are positive interactions among these three event time series from 1980 to 1989. While the steepness of the s-shaped curves differs, the inflection points of the institutional arrangements, resource endowments, and technical economic activities time series in Figure 1A occur at approximately the same dates. In other words, when events were undertaken to develop technical economic activities, there were also dramatic increases in the number of events performed to further develop institutional arrangements and resource endowments for cochlear implants.

In order to examine the statistical associations among institutional arranagements, resource endowments, and technical economic events, we constructed a contingency table of how the occurrences of these events temporally preceded and followed one another (see Table 3). The chi-square test for the contingency table is highly significant (0.0000 level), indicating that there is an interrelated pattern to the occurrence of institutional arrangements,

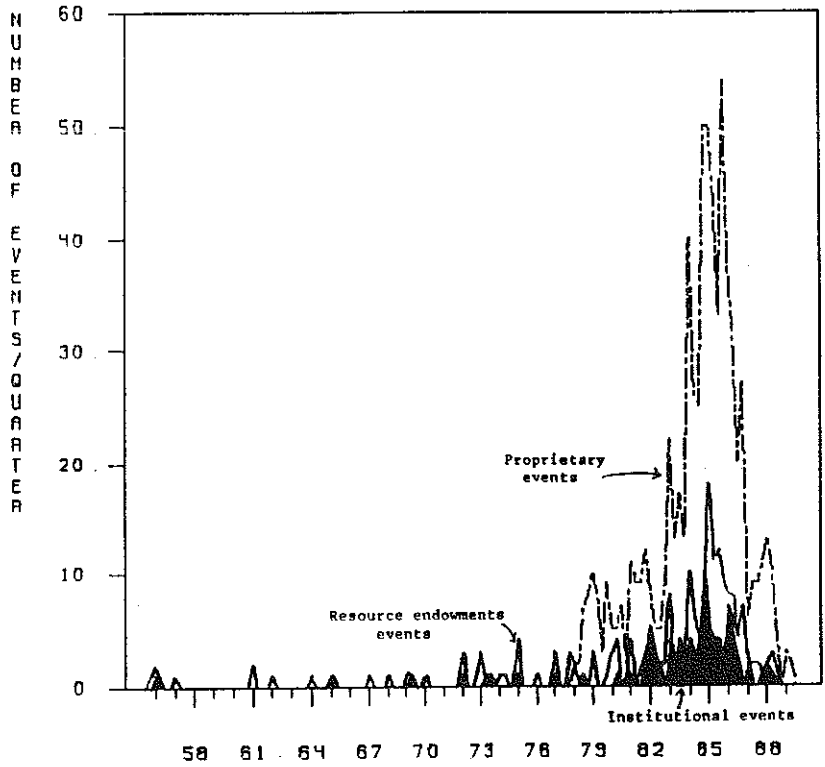


Figure 1B. Quarterly Number of Subsystem Events

resource endowments, and technical economic events. As was foretold by the time series plots in Figure 1, the contingency table shows that in the vast majority of cases, when an event occurred in the development of either an institutional arrangement or resource endowment, the next event that occurred was a technical economic activity. This suggests that the former were driving the latter.

Excluding technical economic events, the contingency table also shows that a greater percentage of institutional arrangement events were immediately followed by resource endowment events than they were by another institutional arrangement event. The reverse is true for the occurrence of resource endowments events. The findings that 29% of resource endowments events were followed by another similar event, while this was true for only 10% of institutional events, are indicative of a greater internal momentum, or path-dependent process, to the development of resource endowments than there is to the development of institutional arrangements.

Table 3. Contingency Table of Observed Frequencies in Which Institutional, Resource, and Technical Events Preceded and Followed Each Other

	Subsequent Event at t + 1						
	Institutional Arrangements Event		*Resource Endowments Event*		*Technical Economic Event*		
Receding event at t							
Institutional event	10	9%	26	25%	70	66%	106
Resource endowment event	26	12%	62	29%	128	59%	216
Technical economic event	67	10%	131	19%	489	71%	687
	103		219		687		1,009

Note: Chi square test = 88.50, 4 degrees of freedom, p-value = 0.0000

To further examine this pattern of relationships among events, we aggregated the frequencies of each type of event into quarterly (three month) counts and computed two sets of time series multiple regression analyses shown in Table 4. Each equation contains a constant term as well as the lagged dependent variable in order to reflect the accumulated base levels of the dependent variable from previous periods over and above the direct contributions of the independent variables in a given period. The degree of serially correlated error terms was examined by computing the Durbin-Watson statistic and, with one exception, was not found to be significant in any of the equations. For each equation, the results in Table 4 show the regression coefficient, its standard error, and its significance for each lagged independent variable, as well as the adjusted R^2 for the overall equation.

Results of the two regression equations in the top of Table 4 show how well institutional arrangements and resource endowments influence one another from 1955 to 1977, before any technical economic events had occurred in cochlear implant's development. The first equation shows that resource endowments events significantly explained the occurrence of institutional arrangements events, and the second equation shows the reciprocal that the latter explained significant variations in occurrences of resource endowments events. Importantly, in neither of the equations is the lagged dependent variable a significant predictor. Caution should be taken in concluding that these results support proposition 1 because the Durban-Watson statistic indicates that significant autocorrelation is present in the regression of resource endowments events.

The bottom of Table 4 shows the results of three time series regression equations undertaken to determine how well each type of event explained variations in the others from 1977 (when technical economic events began) to

Table 4A. Results on Two Time Series Regression Analyses on Institutional Arrangements and Resource Endowments Before Proprietary Events in Cochlear Implant Development from 1955 to 1977

	Dependent Variables			
	Institutional Arrangements Events at t		*Resource Endowments Events at t*	
Independent Variables	*Beta*	*Standard Error*	*Beta*	*Standard Error*
Institutional arrangements				
Events at $t-1$	0.14	0.10		
Events at t			0.94*	0.26
Resource endowments				
Events at $t-1$			−0.09	0.10
Events at t	0.14*	0.04		
Constant	0.04	0.03	0.23*	0.08
Durban-Watson statistic	1.93		2.11	
Significance of Durban-Watson	0.12		0.00	
Adjusted R^2	0.13		0.12	
N(number of quarters)	84		84	

Note: * $p < 0.01$.

Table 4B. Results of Three Time Series Regression Analyses on Institutional, Resource, and Technical Events during the Development of Cochlear Implants from 1977 to 1989

	Dependent Variables					
	Institutional Arrangements Events at t		*Resource Endowments Events at t*		*Technical Economic Events at t*	
Independent Variables	*Beta*	*Standard Error*	*Beta*	*Standard Error*	*Beta*	*Standard Error*
Institutional arrangements						
Events at $t-1$	0.08	0.14				
Events at t			0.03	0.20	1.69*	0.56
Resource endowments						
Events at $t-1$			0.07	0.10		
Events at t	−0.01	0.11			1.87*	0.36
Technical economic						
Events at $t-1$					0.25**	0.10
Events at t	0.10*	0.03	0.22*	0.04		
Constant	0.01	0.29	−0.28	0.40	1.96**	1.19
Durban-Watson statistic	2.11		2.29		2.47	
Significance of Durban-Watson	0.26		0.11		0.56	
Adjusted R^2	0.55		0.75		0.83	
N (number of quarters)	50		50		50	

Notes: * $p < 0.01$.
** $p < 0.05$.

1989. The regression results show that during this period, technical economic events significantly influenced increases in the number of institutional arrangements and resource endowments. Moreover, the latter significantly influenced the former. Interestingly, the significant reciprocal relationships observed between resource endowments and institutional arrangements from 1955 to 1977 vanished or were swallowed up by technical economic events from 1977 to 1989.

The bottom of Table 4 also shows that the three regression equations explain between 55 and 83% of the variance in the occurrence of institutional arrangements, resource endowments, and technical economic events during the period from 1977 to 1989. While these results clearly support proposition 1, they also indicate that the development of each component of the system is not completely determined. As should be expected when tracking a highly uncertain emergent process of innovation, the results show that substantial unexplained components of chance, noise, or error exist in the process.

B. Specific Activities within System Components

Figure 2 provides a breakdown of these events by specific functions in the three subsystems. The specific institutional arrangements graphed are events that occurred to legitimate, regulate, and standardize the emerging industry. Resource endowments include basic scientific research, financing, and education events. In terms of technical economic activities, events to undertake applied R&D, clinical trials and FDA review procedures, and marketing functions are plotted. To maximize visual clarity, the horizontal axis of the dates when these events occurred shifts from a yearly scale (for 1956-1979) to a quarterly scale (for 1980-1989), thereby stretching out in Figure 2 the steep incline portions of the s-shaped curves shown in Figure 1A.

Four qualitatively different periods in the historical development of cochlear implants are noted at the bottom of Figure 2. The first "endowments creation" period began about 1955 and consisted primarily of advances in basic scientific knowledge of cochlear implants by universities and basic research institutes, supported by a few events to legitimate and finance this research in the public domain. The second period focused on efforts by private firms beginning in 1977 to appropriate this basic research knowledge for undertaking technical economic activities by entering into relationships with basic research institutes and by initiating applied R&D, manufacturing, clinical trials, and marketing functions. Once these relationships were established, a third "expansion" period is shown in which a rapid growth occurred from 1983 to 1986 in the number of events to develop each component of the emergent industry system. This expansion period was followed by a period of "stabilization" in all functional areas, during which a dominant design for cochlear implants emerged. As the historical narrative of events in the next section will show, the very institutional structures created in prior periods for industry growth began to constrain subsequent development.

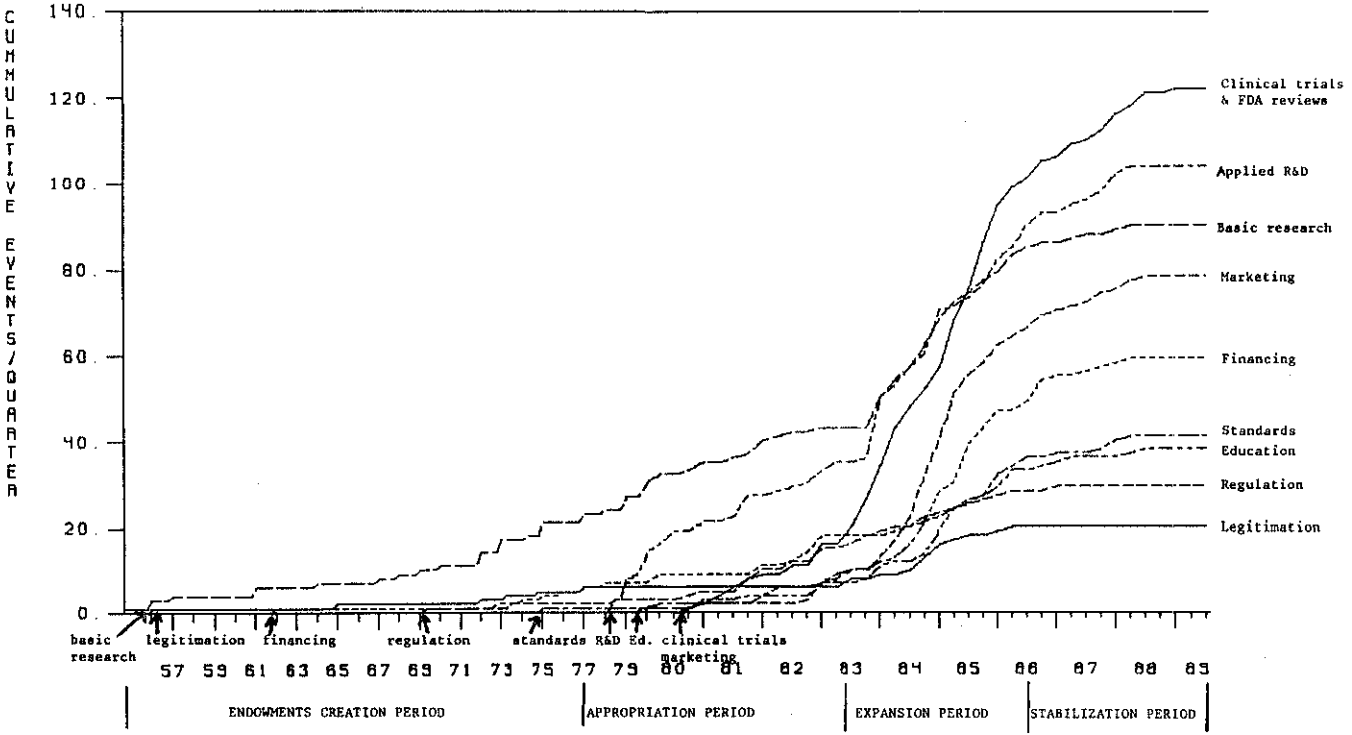


Figure 2. Cumulative Events in Development of Functions for Cochlear Implant Industry System

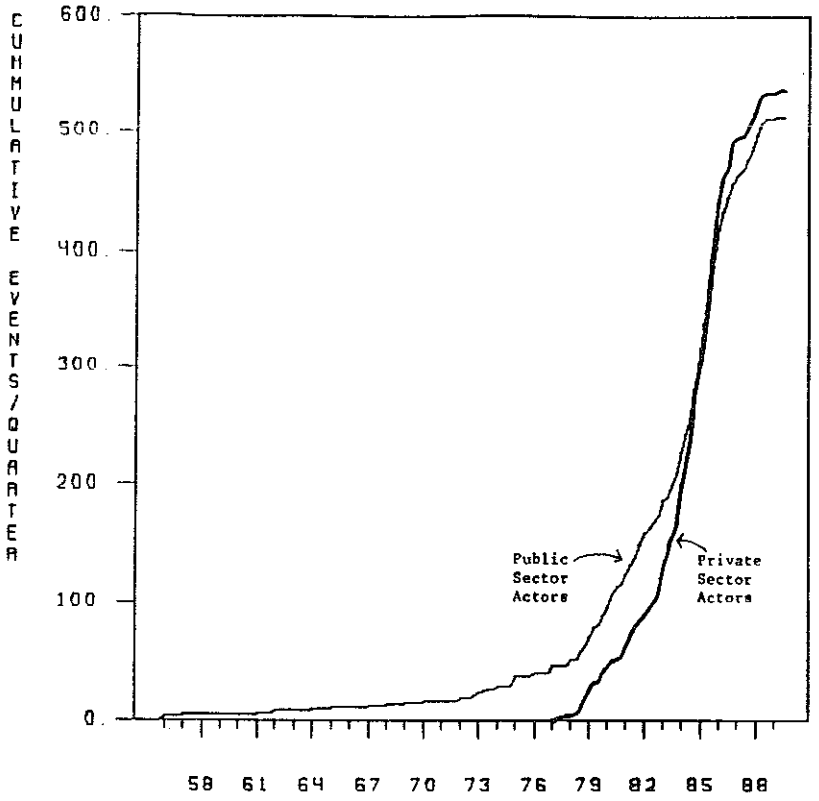


Figure 3. Cumulative Events in Which Public and Private Sector Actors Participated

C. Roles of Institutional Actors

Figures 3 and 4 plot the actors involved in the events to develop these system components over time. Figure 3 shows that the public sector played the major role during the initial periods of industry emergence, and that private-sector actors did not become involved in cochlear implant development until the late 1970s. However, when private firms became involved there was also a dramatic increase in the number of events performed by public sector actors, particularly from 1980 to 1986. A breakout of the public sector actors is provided in Figure 4. It shows that among the public sector actors, academic research units played the dominant lead role, followed by regulatory agencies (particularly the FDA),

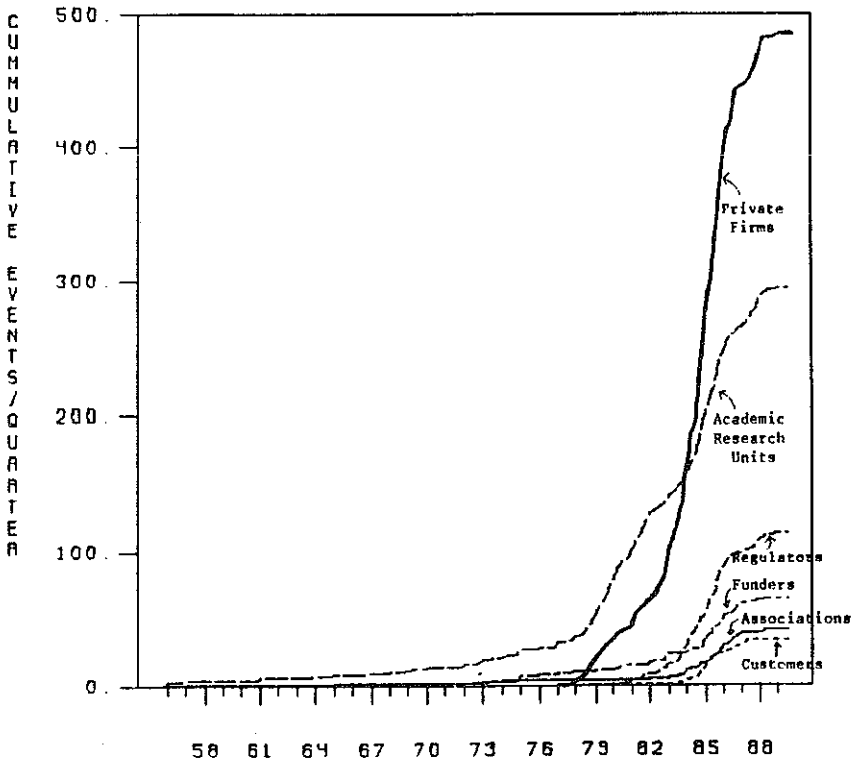


Figure 4. Cumulative Events in Which Different Types of Actors Participated

funding agencies (principally the National Institute of Health), and professional or industry associations. For comparative purposes, Figure 4 again plots the involvement of private firms (as in Fig. 3) as well as cochlear implant customers (patients and otological clinics), who were classified as neither public or private actors and, hence, not included in Figure 3.

In order to statistically determine the relative contributions of these actors in developing each function of the cochlear implant system, Table 5 shows the results of a series of multiple regression time series equations that were computed for each function (the dependent variables in the rows) on the six kinds of actors (the independent variables in the columns). For each equation the table shows the regression coefficient and its significance for each independent variable, as well as the adjusted R^2 for the overall equation. Caution should be taken in interpreting the relative contributions of different actors from Table 5 since unstandardized beta coefficients are reported.

Table 5. Results of Time Series Regression Analysis of the Contributions of Various Actors in Developing Cochlear Implant Industry Functions

	Independent Variables							
Dependent Variable	*Constant*	*Professional Associated*	*Regulator Agencies*	*Funding Agencies*	*Academic Research*	*Customers Clinics*	*Private Firms*	*Adjusted R^2*
Institutional arrangements								
Legitimation	0.00	0.12	−0.11*	−0.03	0.03	0.23*	0.03	0.48
Regulation/ governance	0.03	0.00	0.13*	0.05	0.04	−0.12**	0.00	0.34
Industry standards	−0.01	0.35*	0.08**	0.05**	0.04	−0.16	0.07*	0.61
Resource endowments								
Basic research	0.07	0.30	0.01	0.09	0.21*	0.37*	−0.03	0.61
Financing	−0.02	0.18**	0.12	0.81*	−0.03	0.05	0.02	0.81
Education and training	−0.02	0.02	−0.10	0.27*	0.04	0.36*	0.05**	0.58
Technical economic activities								
Applied R&D	0.16*	0.27	−0.24	0.22	0.22*	−0.01	0.13**	0.49
Clinical tests and reviews	0.08	0.16	0.83*	0.24*	−0.10*	0.03	0.05**	0.92
Manufacturing	−0.01	−0.20*	−0.04	0.05	0.01	0.09	0.36*	0.37
Marketing	−0.02	0.13	−0.2	0.00	−0.01	0.11*	0.84*	0.82

Notes: Regression coefficients are unstandardized betas.
* = Beta coefficient is at least 2 its standard error.
** = Beta coefficient is at least 1 ½ its standard error.

The table shows that statistically significant contributions were made by at least two or more different types of actors in the development of each system function of the cochlear implant industry. Most of the detailed results from the regression equations are as expected and will be discussed in the historical narrative below. Overall, they lend clear support for proposition 2 that numerous public and private actors played key roles in the development of each component of the cochlear implant industry.

D. Historical Development of Cochlear Implants

We will now provide historical meaning to these event time series by describing the temporal progression of events in each period of cochlear implant's development.

1. *Period 1: The Creation of Resource Endowments*

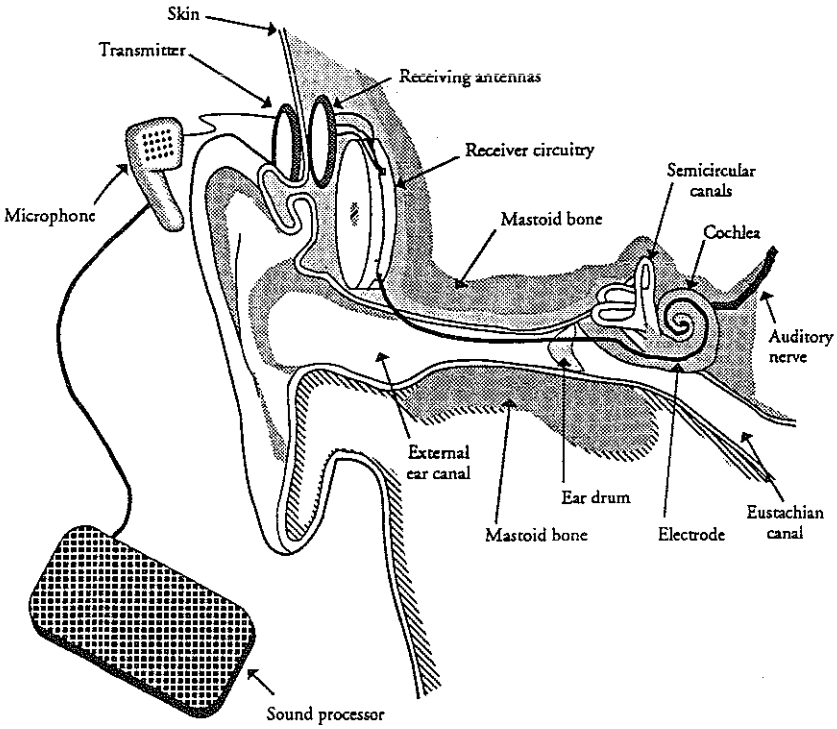
Figure 2 shows that basic research and technology advances in the public domain by academic research units predated by more than 22 years any other components of what came to be a cochlear implant industry. These advances were supported by research contracts and grants from public research

foundations and philanthropists, and a few key legitimation events by otological professional associations. Several earlier technical advances set the stage for this institutional support. The concept of using electricity to bring hearing to the deaf goes back almost 200 years, when an Italian scientist, Volta, first observed the effects of electrical stimulation of the ear (ASHA, 1985). More recently, experiments involving such stimulations were conducted by French researchers in 1957. The first cochlear implant in the United States was performed in 1961 by a clinical physician, William House, founder of the Walt Disney Hearing Center (now named the House Ear Institute) in Los Angeles. Based on many trials and disappointments with attempts to develop more sophisticated multiple channel devices, House and his colleague, Jack Urban, pursued a strategy of beginning with the simplest single-channel device for restoring hearing to the profoundly deaf and using an experimental trial-and-error approach to guide their research.

In contrast, other researchers at this time were pursuing more theoretical approaches, most of whom argued that the cochlea was a complex organ which could be replicated only by the insertion of a cochlear device that had multiple electrodes, each electrode allowing the transmission of different frequencies at different locations of the cochlea. For example, Blair Simmons and Robert White of Stanford University initiated cochlear implant-related work in the early 1960s while examining a related phenomenon under an NIH grant. Working in the laboratories of the University of California at San Francisco, Robert Michelson and his colleagues demonstrated that intra-cochlear electrodes could be maintained in animals, and concluded that single-channel devices were incapable of replicating the complex human cochlear structures. In addition, during the 1970s, cochlear implant research programs were under way by Graem Clark at the University of Melbourne, Australia, Ingeborg and Ervin Hochmiars at the University of Insbrook in Vienna, Austria, Donald Eddington at the University of Utah, and Robert Bilger and his associates at the University of Pittsburgh.

Each of these researchers began with different starting assumptions and pursued fundamentally different technological designs for cochlear implants. In addition to the single versus multiple channel designs (illustrated in Fig. 5), one group of scientists focused on maximizing safety with a short electrode insertion (House), or with an electrode that was placed outside the cochlea (Hochmiars). Others focused on maximizing the efficacy of speech discrimination with multiple electrodes that were inserted deep into different parts of the cochlea (Clark, Michelson, and Bilger), or with alternative transmission schemes (Eddington).

These and other researchers disseminated the results of their work in typical academic ways: through journal publications, professional conferences, student education, patent applications, and research proposals. In other words, resource endowment contributions of basic research knowledge were dis-



Comparison of Single- and Multi-channel Cochlear Implants

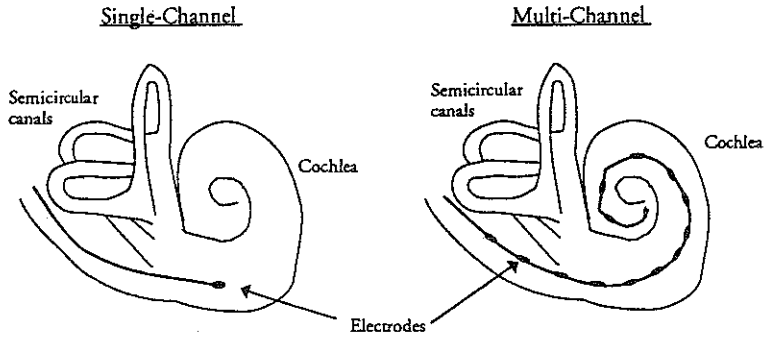


Figure 5. Cochlear Implant Device (Adapted from Loeb, 1985)

seminated through institutional mechanisms, which in turn contributed to building other resource endowments of human competence and financing to support further basic research.

As one should expect with a new technological paradigm (Dosi, 1982; Rappa, 1989), the institutional legitimacy of basic research in cochlear implants has historically been contested terrain. Several early events to establish institutional rules on technical developments were dismissed. One controversy occurred in the late 1950s when Dr. House developed a new surgical approach, known as the mastoid facial recess, which made access to the inner ear feasible. This approach was particularly upsetting to many neurosurgeons because the surgical procedure was reported to be an invasion of their domain if it was used to approach acoustic tumors. In spite of this peer-group pressure, House continued with his approach.

A second controversy again involved Dr. House, who in the mid-1970s was censured by colleagues in his professional association for continued development of a single-channel device. Many otologists believed that once a single-channel device was implanted, the ear would be unsuitable for a multiple channel system, which at the time was thought to be technically superior to a single-channel system. This delayed proprietary appropriation of cochlear implants by private firms because those developing multiple channel devices were purported to be on the verge of a major breakthrough which did not materialize until several years later.

The contested legitimacy of cochlear implants spilled over into institutional research funding decisions, which in turn were influenced both by chance events in an unrelated area and by technological preferences that channeled future basic research in particular directions. For example, in the early 1960s Dr. Simmons at Stanford University submitted a research proposal to NIH which included plans for human implantation of a cochlear implant device when developed. After a site visit by an NIH review panel, Simmons received a favorable scientific recommendation but was not awarded a research contract on moral grounds. NIH later reversed this decision. This change in attitude was triggered by some unrelated experiments by Brindley in England on human cortical stimulation in blind persons. Brindley's work was published in 1967 and generated much interest in the United States. It stimulated NIH to establish its own new neural control laboratory with the mission to underwrite contracts for research in electrical stimulation. The main targets for these contracts were vision and cerebral stimulation; hearing was "an afterthought" (Simmons, 1985).

From 1970 to 1987 the NIH provided various universities a total of $29 million in grants and contracts for cochlear implant research. However, much of this funding was directed to developing multiple channel designs. A resource allocation officer of NIH attended the first international conference related to cochlear implants in 1973, became impressed with the scientific rationale

for multichannel implants, and concluded that NIH should support basic research on multichannel designs as a way of encouraging alternatives to the controversial single-channel devices that House was implanting in increasing numbers of patients.

This 1973 international conference represented the first major institutional event to legitimate cochlear implant technology. Several other legitimating events occurred years later when the two most influential professional associations took action. The first was an official endorsement of cochlear implants by the American Medical Association in 1983. The second was the creation of a special ad hoc committee on cochlear implants by the American Speech Language and Hearing Association (ASHA) in 1984. In May 1985, ASHA published responses to a survey of firms in the cochlear implant industry which is reported as being read widely by the medical community. In 1985, the American Academy of Otolaryngology-Head and Neck Surgery endorsed the cochlear implant device to the OHTA. Based on this, the Office of Health Technology Assessment (OHTA) published a booklet in 1986 endorsing the safety/efficacy of cochlear implants, a step essential for receiving Medicare coverage for the implants (discussed in the next period).

By the late 1970s seven leading research units worldwide had developed prototype cochlear implant devices for human implantations. But human implantation required approval from the FDA in the United States and similar regulatory agencies in other countries. Obtaining such approval is a costly and extended process, which often exceeded the resource capabilities of the academic research units. This set the stage for establishing relationships between basic research units and private firms. Basic research units needed additional resources and competencies that private firms could provide to conduct clinical trials, manufacture, and market their prototype devices. Some private firms, in turn, were following basic research advances in otology, and awaited the development of concrete prototype devices, because abstract theories that were available in the public domain and published in technical journals were very difficult to appropriate for commercial applications.

2. *Period 2: Appropriation of Public Knowledge by Private Firms*

The period between 1979 and 1982 was marked by the initiation of technical economic activities by five private firms: 3M, Storz, Symbion, Nucleus, and Biostem. In order to acquire the basic scientific knowledge for proprietary use, these firms commonly negotiated and entered into interorganizational relationships with different universities and teaching clinics who were undertaking basic research during the first period. Figure 2 shows that during this period the dominant functional events were both basic and applied research as private firms and academic units engaged in joint research activities. As the resource dependence theory (Pfeffer and Salancik, 1978; Galaskiewicz, 1985)

suggests, when an organization does not possess all the capabilities necessary to develop an innovation by itself (which it seldom does), it creates new organizational forms (here entering into interorganizational relationships with others) to obtain the needed capabilities.

Less well understood are the high levels of required effort, uncertainty, and unintended consequences to parties who entered into these long-term relational contracts. In several instances, aborted efforts at establishing cooperative interorganizational relationships became competitive relationships in a few years between the firms involved. For example, in February 1977, 3M was approached by the University of Melbourne in Australia with a request to help commercialize its cochlear implant technology. This event precipitated fifteen months of information sharing, study, and negotiations of possible ways to structure a relationship. Considerations included a joint venture, underwriting of R&D expenses in exchange for exclusive rights to patents and devices developed, a marketing and distribution relationship, as well as an outright acquisition of the university's cochlear implant program and patents by 3M. However, reportedly for nationalistic reasons, the parties could not come to an agreement, and negotiations between the University of Melbourne and 3M were terminated in May 1980. In September 1980 the Australian Department of Productivity commissioned and granted startup funding to Nucleus Corporation to commercialize the University of Melbourne's cochlear implant program. Within a few years thereafter Nucleus grew to become 3M's major competitor, the industry leader in technical performance and product sales by January 1987, and acquired 3M's cochlear implant products, patents, and programs in August 1989, when 3M exited from the industry.

Between 1978 and 1982, 3M also worked with Dr. Robin Michelson of the University of California San Francisco (UCSF) to develop a multiple channel implant device. Through this 3M-UCSF relationship, a cochlear device was developed and implanted in two or three individuals during 1980 and 1981. This relationship was terminated, reportedly because of differing academic and commercial orientations of the public and private sector parties. Upon termination of this agreement in 1982, UCSF went on to license its technology with another new business startup, Storz in 1983, while 3M entered into licensing agreements with the House Ear Institute and with the Hochmiars in Vienna, Austria, in 1981. A subsidiary company of 3M had already established a vendor relationship by manufacturing components for House's cochlear implant devices in 1977. Two other private firms, Symbion and Biostem, entered into relationships with cochlear implant research programs under way at the University of Utah and at Stanford University, respectively, both in 1983.

These new interorganizational relationships largely determined the technological paths of private firms. They were highly risky undertakings in terms of technological and market uncertainties, idiosyncratic investments, and institutional compatibility. They "locked" private firms into specific

technological paths when it was highly uncertain which, if any, of the paths would eventually be successful in the market that, as yet, did not exist. Embedded in the choice by private firms of which public research units to coventure with was an eventual lock in to the particular technological design that the research unit was pursuing. Significant irreversible investments over an extended period of time were required of private firms to undertake the clinical trials, FDA regulatory review and approval procedures, and applied R&D, manufacturing, and marketing activities to determine the commercial viability of the specific cochlear implant prototype appropriated from a research unit. Furthermore, the decision to enter into a licensing agreement with one research unit often constrained possibilities of entering into agreements with other basic research units. Path-specific investments, knowledge, and interorganizational commitments foreclose shifting to others quickly. Finally, as the 3M-UCSF and 3M-University of Melbourne relationships exemplify, some relational contracts terminated not because of technological problems but because of incompatible or divergent institutional orientations or cultural practices.

3. *Period 3: Industry Expansion Period*

Figures 1 and 2 show that from about 1983 to 1986 a dramatic increase occurred in the number of events to develop each function of the cochlear implant industry. This rapid industry expansion period will be described in terms of the major developmental patterns that occurred in parallel and interacted over time across subsystems of the emerging industry system.

a. Technical economic activities. Efforts in applied R&D, manufacturing, clinical trials and regulatory affairs, and marketing began sequentially from 1979 to 1981, and all grew at rapid but differentiated rates during the expansion period (see Fig. 2). While applied R&D was the dominant technical economic activity at the beginning of this period, the number of institutionally prescribed events to conduct clinical trials and obtain regulatory approvals for devices surpassed all other technical economic activities at the end of this expansion period. As discussed below, institutional regulations of the FDA largely explain the sequential development of these economic functions.

However, instances of opportunistic leapfrogging of functions also occurred. For example, at the 1985 Otolaryngology conference, 3M promoted the introduction of its second-generation device, even though it had not yet completed clinical trials, obtained FDA regulatory approval, and scaled up manufacturing on this device. This action was taken based on superior early test results obtained in Europe with this experimental device. Shortly after the August 1985 conference, 3M sales persons reported that the promotion of this experimental device at the trade show was adversely affecting sales of its first

single-channel device. Audiologists were apparently awaiting the release of the second device. Unfortunately, release of the second device had to be delayed because the superior early test results of the device from Europe could not be corroborated by tests in the United States.

A second instance involved a firm submitting an informal application to the FDA for a premarket approval (PMA) for its cochlear implant device before the necessary preceding research and clinical trials were completed. It was reported that the application was submitted in order to identify FDA's standard of the number of clinical trials necessary to obtain regulatory approval. The FDA declined the informal application.

One explanation for this leapfrogging behavior relates to a major dilemma of internal corporate venturing, as discussed by Burgelman (1983) and Biggadike (1979). Building a new sustainable business requires not only rapid market entry of the first product but also the creation of a beachhead in the market for a new technology. Creating this beachhead often requires the strategic development of a related line of products for sequential market entry. A cochlear implant manager stated that it is unlikely that a business can be created and sustained with a single product in the marketplace. An ongoing business requires the creation of synergy across functions, which is obtained from undertaking R&D, testing, manufacturing, marketing, and service on a family of related products over time. But Burgelman (1983) notes that the implementation of this strategy may lead to strategic neglect in managing all the interdependencies entailed in developing a family of products.

b. Institutional regulation. All medical products, including cochlear devices, are subject to review and approval by the FDA in the United States. The essential steps in the approval process have been summarized by Yin and Segerson (1986). In order to conduct clinical tests on humans, an "investigational device exemption" (IDE) must be obtained from the FDA based on clinical tests of the device on animals. Next, each of the clinical sites is required to obtain an "institutional review board" clearance to certify its capability to conduct clinical tests on humans. After test results indicate a minimum level of safety and effectiveness has been achieved, the device must be submitted to the FDA panel for a premarket approval (PMA). If the FDA finds that the device is safe and effective, it grants its approval for commercial sale after having approved the prevalence of "good manufacturing practices." This entire institutional procedure of obtaining FDA approval from the initiation of clinical trials on animals can take anywhere from three to five years and costs millions of dollars (Grabowski and Vernon, 1982).

The application of this institutional regulatory structure to a new-to-the-world biomedical innovation, such as cochlear implants, required making innovations in the institutional structure itself. In 1981, when 3M applied to the FDA for an IDE status for its first cochlear implant device, it was reported

that FDA personnel and panel members did not possess the necessary knowledge to evaluate the application. As a result, 3M was requested to prepare additional documents and information in order to educate FDA personnel and scientific review panels about the nature of cochlear implants and the safety of electrical stimulation of the cochlea. In November 1984, the FDA awarded the 3M-House device its first PMA approval for the commercial release of a cochlear implant product in the United States. Noting the historic nature of this approval, the FDA announced, "This is the first time that one of the five human senses has been replaced by an electronic device." This coincided with a letter from U.S. President Reagan to the chairman of 3M congratulating 3M for its accomplishment and contribution to the well-being of society.

At the same time, the FDA undertook a contradictory institutional legitimating event by circulating a status report stating that the multichannel device is potentially superior to the single-channel technology it had just approved. Resonating with the FDA report and initiated by competing firms, other testimonials began appearing in the news media urging customers to wait for the superior multichannel implant. One such testimonial provided by Dr. Daniel Ling, dean of Applied Health Sciences at the University of Western Ontario (a consultant retained by Nucleus) appeared in the November 30, 1984, *Wall Street Journal.* It read:

> Single-channel implants are better than nothing. But that is all they are—better than nothing. Why implant a single-channel today when you know a 22-channel is right around the corner?

In response, researchers associated with the single-channel technology claimed that there was no evidence to suggest that multichannel devices were superior to single-channel devices. In reaction, physicians implanting multichannel devices argued that it was unethical to implant a single-channel device when a multichannel device would be available soon. The net effects of these claims and counterclaims were to limit 3M's window of market opportunity with the only commercially available device, and for Nucleus to achieve the institutional legitimation of an "FDA approved" status for its multichannel device even though formal approval was not granted until July 1985.

In the meantime, 3M asked the FDA to police claims of safety and efficacy being made by cochlear implant manufacturers before they had been able to substantiate their claims before an FDA panel. Competitors, restricted by FDA policies from widely promoting safety/efficacy aspects during the investigational device exemption (IDE) stage, responded by encouraging independent researchers to publish articles in refereed journals that extolled the virtues of the multichannel device. For example, Loeb of NIH supported the superiority of the multichannel device over the single-channel devices in an article that appeared in the February 1985 issue of the *Scientific American.*

Parallel with technical economic efforts to increase sales of the 3M/House device, 3M initiated institutional efforts to protect its window of opportunity by requesting the FDA to apply the same rigorous scrutiny to other firms' devices that it had been subject to. This appeal for an entry barrier was made in response to a request from the FDA to manufacturers seeking their inputs for crafting guidelines for PMA applications. 3M argued that tests involving a minimum of 100 patients be required before a device be approved by the FDA. To support these arguments, 3M researchers organized a technical seminar for FDA staff in January 1985 in Washington, D.C. Nucleus also provided its inputs on PMA guidelines to the FDA. Since Nucleus had data on only 43 patients at the time of its premarket approval application to the FDA, imposing a minimum of 100 patients to demonstrate clinical safety, as proposed by 3M, could significantly delay Nucleus's device approval by the FDA. Thus, audiologists from Nucleus argued that the sample size required in clinical trials should be a function of the claims made about each device, the statistical approach adopted to support such claims, and the actual performance of each device. After some deliberations, FDA agreed with Nucleus' arguments, and 3M's efforts to erect an institutional entry barrier failed. The FDA circulated its draft guidelines in June 1985 stating that it would not specify the number of patients required for a PMAA but, rather, would leave sample size requirements flexible.

In July 1985, the FDA granted its second PMA approval to Nucleus to commercially market its 22-channel device in the United States. Beyond the two commercially available devices (3M/House single-channel device and the Nucleus multichannel device), the FDA reported in September 1986 that six centers in the United States were carrying out R&D and clinical trials of ten different cochlear devices after having sought investigational device exemptions (IDEs) from them. For instance, 3M was developing three other devices: one an extension of the House device to be implanted in children; another an advanced single-channel device in collaboration with the Hochmiars of Austria; and third, an in-house effort to develop an advanced multichannel device. Similarly, Nucleus was in the process of developing an extension of its FDA approved 22-channel device approved for children, and a 4-channel device for adults. Correspondingly, the FDA was viewed by industry analysts at the time as becoming more knowledgeable about cochlear implants, and as exercising more of its authority and knowledge by prescribing what firms must do to obtain regulatory approval for their cochlear implants.

c. Financial reimbursement. While private firms were simultaneously following FDA regulations to develop their devices and competing to influence the construction of these institutional regulations to benefit their proprietary purposes, they also cooperated with one another, and with other public sector actors, to obtain financial reimbursement for patients from health insurance

carriers for cochlear implantations. This resource endowment was considered critical to market success because the cost for a cochlear implant and associated surgical expenses averages $20,000 per patient. Radcliffe (1984) reported that this cost would severely restrict adoption of commercially available cochlear implants.

3M and Symbion in 1983 were the first to initiate efforts to convince third-party insurance payers to extend coverage to cochlear implants. Other firms also sought coverage for their cochlear devices. In 1983, 3M was successful in getting coverage for its experimental single-channel House device. However, the health insurance coverage obtained was for a very small population of the deaf. In December 1985, a Cochlear Implant Industry Council, consisting of representatives from 3M, Nucleus, Storz, and Symbion, was formed under the auspices of the Hearing Industries Manufacturers' Association. The purpose of this council was to create a united proposal to the Prospective Payment Assessment Committee of the Public Health System to obtain broader Medicare coverage for cochlear implants. The council provided a new organizational form for cooperation to reconcile the previously competitive individual self-interest appeals of rival firms. In December 1986, the council was successful in obtaining wider coverage for cochlear implants from third-party payers as well as from Medicare. As noted earlier, the willingness of health care insurance carriers to include cochlear implants in their medical payment reimbursement systems was also influenced by cochlear implant endorsements of prestigious medical associations, as well as FDA regulatory approvals of several cochlear implant devices.

Having successfully completed negotiations for Medicare coverage, the council began to address other issues for joint action that would benefit the growth of the industry. For instance, the council developed and submitted its recommendations to the FDA to simplify clinical testing requirements in order to reduce the costs involved. The council also disseminated public service announcements about cochlear implants in order to increase public education and legitimacy. In addition, the American Association of Otolaryngology initiated a committee of representatives from industry, clinics, audiology, psychoacoustics, and other disciplines to study and recommend technical standards for this industry.

d. Industry standards. Throughout this industry expansion period technological and market uncertainties remained high, and the absence of common criteria for testing and comparing alternative cochlear implant devices made it difficult to evaluate the safety and efficacy of competing technologies (OHTA Report, 1986). Because each device embodied different features, testing and reporting standards during the initial part of the industry expansion period served more to legitimate particular paths than to act as selection mechanisms for the technologically superior paths. Firms developed and used standards

to signal to the scientific and clinical communities the legitimacy of their particular claims. But, at the same time, these testing and reporting standards reflected each firm's proprietary product attributes. As Constant (1987) observed with the jet aircraft engine, testing and reporting standards almost became tautological with the products they were supposed to test, with the two forming a self-reinforcing cycle. As a result, technical changes were reflected in multiple standards, each confirming the expectations of different researchers while not yet possessing the power to act as selection mechanisms.

Thus, unlike prior periods when few standards existed, the industry expansion period witnessed the proliferation of standards. Whereas earlier claims were perceived as noise and hyperbole, now they were ambiguous, possessing relevant cues only to those who understood or employed particular standards while being vague to others employing a different set of standards. There were frequent reports of exaggerated claims made by rival firms of the superiority of their devices (Windmill et al., 1987). But given the lack of commonly accepted testing and reporting standards, it was not clear which firm was exaggerating. However, as the OHTA report acknowledged, the ambiguities of testing procedures and standards for processing speech were not necessarily a disadvantage in early periods of technological development, because they afforded a measure of technical freedom to experiment, and clinical flexibility to select alternative cochlear devices for a particular patient.

Other independent researchers began forming, each with different frames of references and possessing the power to develop industry-wide testing comparison and reporting standards. For example, results of comparative tests conducted by the University of Iowa began appearing in clinical journals in 1985. The results suggested that multichannel devices were superior to single-channel devices. Over time, other articles continued referencing the University of Iowa results, thereby increasing its visibility. These technical reports and articles accumulated and began to shape the development of institutional standards. According to one informant, the multichannel technology earned greater legitimacy as a result of the theoretical rationale justifying its design, which the House single-channel design lacked to the same degree. The early results by independent testing units, which appeared to confirm the initial announcements by the NIH, the FDA, and some health insurance carriers of the potential superiority of the multichannel technology, also contributed to the favorable reputation of the multichannel technology.

As testing procedures and standards congruent with the multichannel technology became more widely accepted over time, the testimonials of various researchers and firms began losing their ambiguity. Key technology evaluators began employing standards associated with the multichannel device, which now possessed the power to select other trajectories. These standards became commonly accepted (and hence a potent institutional selection mechanism), which, in turn, triggered other selection mechanisms. For example, audiologists

interfacing with the ultimate customer began providing media testimonials that resulted in patients awaiting availability of more sophisticated products, even though the 3M/House single-channel device had received regulatory approvals and was commercially available. Thus, despite regulatory approvals, the 3M/House device became prematurely obsolete.

e. Competence pools. Both public and private actors played key roles in building a labor pool of competent cochlear implant practitioners. 3M and Nucleus, the two leading private firms, initiated and conducted 33 regional training programs throughout the country from 1982 to 1986 to educate otologists and clinicians in diagnostic and surgical skills for implanting cochlear devices. So also, academic research units and professional associations conducted 20 training programs for physicians between 1982 and 1986. Educational programs were initiated for new specialized disciplines and services. For example, a new specialty of psychoacoustics services emerged to provide patient therapy on sound discrimination after a surgical cochlear implant procedure—a service provided before by surgeons. These educational activities resulted in a wider appreciation of cochlear implant-related skills and knowledge in the medical community.

The creation of these resources for the industry represent "common goods" that can be freely drawn upon by industry participants. It has long been recognized that the creation of these public goods is problematic because of the "free rider" problem (Olson, 1965). It is rational for an individual firm not to make investments in creating these resource endowments when it can freely draw upon them. However, if all individual parties behaved in this self-interested way no industry infrastructure would develop.

The qualitative event sequence data indicate that both patterns of self-interest and collective-regarding behavior were displayed. Self-interested behavior and free riding by private firms clearly occurred in the appropriation of basic research and technology for proprietary gain, since no private firm was found to play any significant role. Collective behavior appeared when incentives were present for individual firms to join together and cooperate to achieve an outcome that they would find difficult to achieve individually; for example, gaining coverage from third-party payers to finance sales of their products to end-users. In addition, professional associations and industry councils (which were funded by and represented the interests of private firms) conducted training programs to disseminate a common stock of knowledge on cochlear implants. Finally, it appeared that the burden of creating other common goods fell on the first mover in the industry.

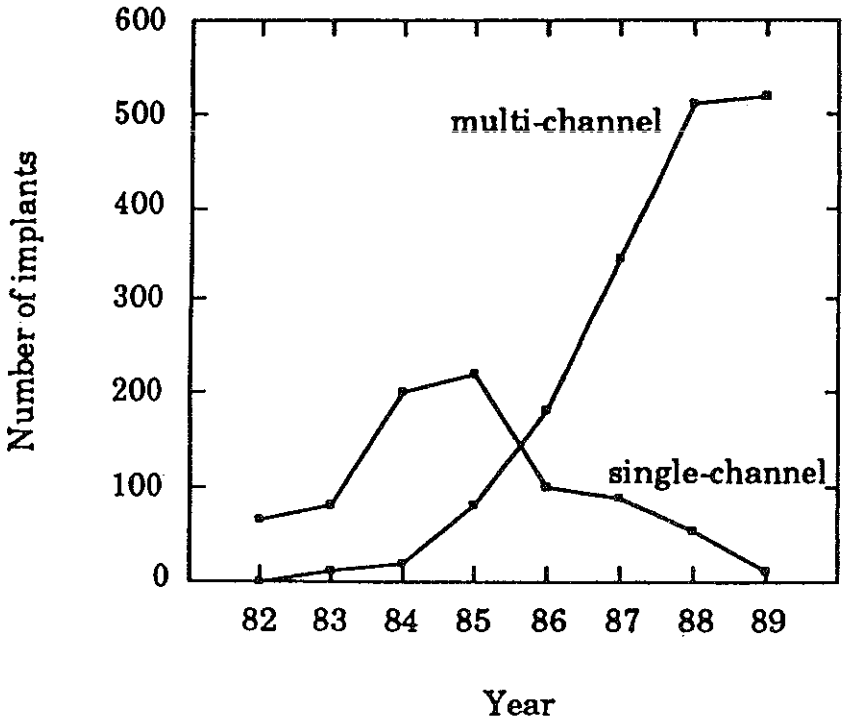
Indeed, the first mover, 3M, deployed considerably greater resources than any of its competitors in the industry. For example, it spent considerable efforts to educate the FDA about safety-related issues, which became taken for granted in subsequent reviews of applications for cochlear implant devices. As

noted above, the first two movers also initiated numerous training programs for physicians (costs which subsequent competitors did not need to incur). Finally, the first mover was the major force in persuading third-party payers to include cochlear implants in their payment reimbursement systems. Although much of the literature has emphasized first-mover advantages in an industry, it has largely ignored Veblen's (1917) analysis of first-mover burdens of creating common resource endowments that permit free-riding by other industry participants.

4. *Period 4: Industry Stabilization and Emergence of a Dominant Design*

Figures 1 and 2 show that by 1986 a leveling off occurred in the number of events in the development of each component of the cochlear implant industry system. The infrastructure for industry takeoff had become largely established. Another institution, the market, could finally begin operating to determine the economic viability of cochlear implants. Institutional arrangements developed in prior periods played out to select the multichannel technology, as embodied in the Nucleus 22-channel device, as the dominant design for the industry. Furthermore, the very institutional arrangements and resource endowments created to facilitate industry emergence became inertial forces that hindered subsequent technological development and adaptation by individual firms.

a. Market selection mechanism. By mid-1985 the FDA had approved two devices for large-scale commercial sale to customers. Prior to this time implantation of devices was only authorized to conduct clinical trials. However, as Figure 6 illustrates, diffusion and adoption among potential beneficiaries was slow and sales of cochlear implants from 1986 to the present are far lower than anticipated. Contrary to a strongly held assumption, many profoundly deaf patients were not buying cochlear implant devices even though several proven devices were commercially available. This assumption could not be seriously tested until cochlear implant devices were commercially available and used to create a new market. Prior to that time, firms reported no difficulties finding enough patients for clinical trials of experimental devices. As noted previously, 3M and Nucleus conducted extensive marketing studies and training programs from 1984 to 1986 with leading otological clinics throughout the United States. They received numerous public accolades and endorsements from otologists and patients alike applauding the arrival of cochlear implants. But clinical trials of experimental devices among carefully selected patients, as required by the FDA regulatory process, did not substitute for the "acid test" of attempting to penetrate and create a new market with commercially approved devices.



Source: Nucleus Corporation, 1990

Figure 6. Annual Number of Single- and Multichannel Cochlear Implants, 1982-1989

b. Institutional selection of a dominant design. The interactions of institutional and technological events of prior periods resulted in a changing set of criteria for evaluating alternative cochlear implant designs over time. Initially, FDA evaluators felt more comfortable in granting regulatory approvals to a single-channel device because its simplicity facilitated the FDA evaluation process. It also possessed the best potential device to demonstrate safety, particularly when the effects of electrical stimulation were unclear. However, the demonstration of device safety, while necessary to legitimate the new technology, was not sufficient to offer sustained legitimacy to the particular product. Efficacy (or the ability to provide speech discrimination) was required for a particular technological path to sustain legitimacy. Thus, those who pursued the single-channel route performed a yeomanly service for other more

complex designs that followed by establishing the safety of the new class of technologies.

The importance of establishing this safety for the entire industry was reflected in an incident when some of the FDA-approved House single-channel devices failed in the market in 1985, prompting a voluntary recall of the device by 3M. At 3M's initiative, representatives from all companies agreed not to engage in adverse publicity on this event, since this could irreparably tarnish the image of the entire new industry.

The recall also marked a key transition from what will be labeled as *normative control*, representing efforts by specific firms to shape emerging product testing standards, to *coercive control*, representing increasing assertiveness by the FDA to regulate the activities of firms (Meyer and Rowan, 1977). Coercive control manifested itself in growing regulatory guidelines for device approvals, a process that led eventually to an open meeting of cochlear implant participants in 1987. At this meeting firms and researchers combined successfully to convince the FDA not to institute further proposed stringent tests.

In 1987, comparative tests carried out by independent institutions surfaced results that were not congruent with the growing theory that single-channel devices were too simplistic and could not provide speech discrimination. These results were obtained from studies by the University of Iowa on the Hochmiar single-channel device, and by the Central Institute for the Deaf in St. Louis on the House single-channel device for children. The lead investigators of these studies, both previously strong critics of the single-channel technology, stated the need to reexamine assumptions as a consequence of the strong performance of the single-channel devices. These results led Berliner, an audiologist at the House Ear Institute, to make a plea to the scientific community to "be more open to possibilities and less tied to theory of the full potential of the single-channel device."

But these study results and Berliner's appeal came too late. In 1988, the NIH and the FDA jointly sponsored a "consensus development conference" for the purposes of establishing future institutional directions for NIH funding and FDA regulatory approvals. At the conference, House stated that the results documented in the University of Iowa and Central Institute for the Deaf clearly suggested the need to reexamine old theoretical biases. Instead, an institutional consensus statement emerged among the conference participants that multichannel devices were superior to the single-channel devices—at least in adults. In explaining the consensus conference statement, Berliner stated that otologists were "converging on the multi-channel device in order to reduce cognitive dissonance of the most appropriate device that they should implant."

c. Institutional "lock in" to technological paths. Ironically, the very institutional structures that emerged to facilitate and provide momentum to

the emergence of the cochlear implant industry became inertial forces that constrained the flexibility of private firms to adapt to the changing circumstances in the stabilization period. Indeed, the market and institutional selection pressures mentioned above prompted several firms with the nonwinning design to take efforts to redirect their product development efforts. But these efforts were thwarted by the very institutional structures they earlier worked hard to develop.

For example, in 1986, 3M decided to discontinue any further major investments in the development of the House single-channel device, and to shift development efforts to its second-generation Hochmiar device as well as a new multichannel device. This prompted the FDA to send a directive to 3M requiring that it maintain its field service and support activities for the 3M/House single-channel device—a directive that 3M management had already issued internally.

In the social-political process of setting FDA evaluation criteria, it was mentioned that 3M proposed a minimum sample size of 100 patients for clinical trials. The FDA rejected this argument, deciding instead to allow each firm flexibility to adopt the sample size that is required to statistically demonstrate claims made for a device. In 1986, when 3M submitted its next Hochmiar single-channel device for FDA product market approval, the FDA ruled that a minimum of 100 clinical trials was required, consistent with the number of patients 3M argued were required to evaluate the safety and efficacy of its prior 3M/House device.

In 1987, 3M and House were engaged in clinical trials implanting a children's single-channel device in a planned 100 patients (as required in prior devices). However, the FDA restricted 3M's clinical trials to using as few children as possible "because of concerns that the procedure may damage the cochlea, thereby eliminating the (child) patient from consideration for future cochlear implants with improved technologies" (FDA Status Report, 1986). This institutional requirement to reduce the number of clinical trials on the 3M/House children's device substantially reduced planned revenues to 3M and House, which in turn decreased the reinvested capital available to support future developmental work on the device.

In mid-1986, 3M undertook concerted in-house effort to develop a multichannel device with a new technological route that was believed to be superior to the Nucleus 22-channel device. After several years of R&D, 3M obtained approval from the FDA to commence clinical trials of the new device by human implantation. However, two related difficulties were encountered in obtaining a sufficient number of patients for clinical trials. First, health insurance carriers dropped coverage for experimental devices, choosing instead to reimburse patients for only those devices that had now been approved for commercial release by the FDA. Second, often on the advice of their otologists, patients preferred commercially approved cochlear implants that were proved

to be safe and efficacious over experimental devices. Recognizing its mounting developmental costs and the new institutional and market hurdles to be surmounted to create a credible challenge to the new supremacy of the Nucleus device, 3M discontinued further development of its experimental multichannel device in 1988.

The commercial viability of cochlear implants as a profitable industry had become unpredictable and was questioned by industry analysts. Market demand for cochlear implants was reported to be insufficient to profitably support more than two or three firms. Fears arose that cochlear implants may become an orphan industry. As a consequence, an industry shakeout began to occur. Several pioneering firms exited from the new industry, some by selling their cochlear implant products, patents, and rights to the new industry leader, Nucleus, thereby solidifying its dominant position. In late 1985, Nucleus acquired Biostem's single-channel technology. Storz and Symbion announced plans to reduce their financial commitments to their cochlear implant programs, reportedly because they did not perceive the cochlear implant market growing at a fast enough pace. In 1986, Storz approached 3M for a possible collaborative relationship. Before negotiations could be completed, Storz was acquired by American Cynamide. Storz was reported to perceive the market for cochlear implants growing at a much slower pace than earlier anticipated. Symbion sought other partners in June 1986 for similar reasons. In October 1986, 3M too decided to shift its focus from cochlear implants to the development of advanced hearing aids in the short term. In August 1989, following nine months of negotiations, 3M divested itself of cochlear implants by selling its cochlear implant patents, products, and services to Nucleus. Nine months of multilateral negotiations were required to overcome numerous hurdles for 3M to exit from the cochlear implant industry. The principal challenges involved concerns expressed by 3M's basic research coventurers, Hochmiars and House, that the transfer of joint rights to cochlear implant products and patents from 3M to Nucleus would not be in their interests. A consensus was achieved that was satisfactory to all parties involved.

V. CONCLUDING DISCUSSION

One might conclude that since this research was based on a single case, the findings cannot be generalized to other cases. Longitudinal studies of other innovations are sorely needed to generalize the findings and to identify the conditions in which they apply. However, this caveat and call for further research does not diminish what we believe are two significant contributions of this research.

First, this research demonstrates that a new-to-the-world innovation and its supporting industrial infrastructure did not emerge all at once by a discrete

event, by random chance, by individual genius, or by the necessity of a technological imperative or institutional determinism, as has often been suggested in the literature. Instead, we found that the cochlear implant system emerged through the accretion of numerous events involving many public and private sector actors over an extended period of time. This research found support for our overall proposition that institutional arrangements, resource endowments, and technical economic activities are highly interdependent and co-produce each other over time. Moreover, the qualitative analysis found that the very institutional arrangements and resource endowments created to facilitate industry emergence became inertial forces that hindered subsequent technological development and adaptation by proprietary firms. These major research findings demonstrate that the generative process by which a revolutionary innovation emerges has a dynamic history that itself is important to study systematically if one is to understand how novel forms of technologies, organizations, and institutions emerge.

Second, we believe that this research demonstrates the utility of the industry social system framework for examining key components of this generative process, and the roles of public and private sectors actors in creating an infrastructure that supports technological development. By taking an augmented view of an industry, the framework provides an understanding of how various institutional arrangements and resource endowments (often viewed as externalities) influence the creation of an industry, commonly viewed as the group of firms competing to produce similar or substitute products.

These findings have important practical implications for innovation managers and policy makers engaged in the national debate on corporate revitalization and international competitiveness. First, the cochlear implant case suggests that success at creating a monopoly by commercializing a new technology does not rest so much on a unique command of basic research, or on the control of all the competencies and resources relevant to innovation. Instead, it rests more on orchestrating a highly uncertain journey by linking with numerous organizations and actors and appropriating the competencies and resources relevant to developing and commercializing the innovation. This journey consists of an interactive search process involving large amounts of backing and forthing between developments in basic research, financing, and competence capabilities (the resource endowments subsystem), institutional legitimation, regulations, and standards, as well as technical economic activities.

Different search and linking patterns should be expected for innovations in different industrial sectors. As Nelson and Winter (1977, p. 51) discuss, in many sectors there are many R&D organizations—some profit oriented, some governmental, some academic—doing different things but interacting in a synergistic way. In particuler, in medicine, agriculture, and several other sectors, private for-profit organizations do the bulk of applied R&D that leads

to marketing products. However, academic institutions play a major role in creating the basic knowledge and data that are used in the more applied work.

Most people understand that the development and commercialization of an innovation make for a highly uncertain business. Less often understood is that the source of much of this uncertainty confronting individual entrepreneurs and investors resides at the system or industry level. The cochlear implant case highlights that if institutional and resource endowments functions have not yet emerged for an innovation, entrepreneurs are exposed to high uncertainties and risks in not knowing what kinds of institutional regulations, technical standards, financing arrangements, and specialized competencies will emerge for the innovation. Uncertainties are reduced as these institutional arrangements and resource endowments become established and embodied in a dominant technological design for the innovation. Therefore, the time and cost incurred in developing and commercializing innovations are largely dependent upon the rates in which institutional arrangements and resource endowments are developed.

Development time and cost should also vary with innovation novelty. The more novel the innovation, the greater the changes required in all system functions and, hence, the greater the time and chance of failure incurred in developing and commercializing an innovation. For new technologies within established industries, some of the functions, such as governance institutions, may be already established and may change in only subtle, nearly invisible ways. That, however, does not deny their importance. It largely explains why radical new-to-the-world innovations are far more difficult to develop and commercialize than incremental innovations within established industries.

This study also demonstrates that any given entrepreneurial firm is but one actor, able to perform only a limited set of roles and dependent upon many other actors to accomplish all the functions needed for an industry to emerge and survive. As a consequence, an individual firm must make strategic choices concerning the kinds of technical economic, resource endowments, and institutional activities in which it will engage, and what other actors it will link with to achieve self-interest and collective objectives. These choices and transactions evolve over time, not only as a result of individual firm behavior but just as importantly by the interdependencies that accumulate among firms across industry subsystems.

An important practical implication is that it is in the self interests of private competing entrepreneurs to cooperate in collectively building an industrial infrastructure that any technological community needs to sustain its members. Conventional wisdom is that entrepreneurs act independently and compete to be the first into the market with their new product or service. There are many technologies and industries in which this may lead to successful monopoly profits. However, this practice may lead to unsuccessful results when the innovation involves a new technology for a new industry. The leading firm

that chooses to go it alone must bear significant first-mover burdens which permit free riding by other industry participants. In return for these burdens, first movers are generally believed to have the greatest degrees of freedom to shape industry rules, technology standards, and product perceptions in the directions that benefit them the most (Porter, 1985).

However, these first-mover benefits do not appear to be empirically substantiated for technologies with weak appropriability regimes; that is, those that are easy to imitate, reverse engineer, or substitute (Teece, 1987). Anderson and Tushman (1990) found that the original breakthroughs in cement, glass, and minicomputers almost never became the dominant design except where strong patent protection existed. Thus, as in the case of 3M with its single-channel cochlear implant design, the technological design of the first mover often turns out not to become the dominant design that ultimately yields the greatest profits. This is because while striking out to be the first to introduce a new technology, the first mover will inevitably make mistakes. And the followers, who are observing the practice of the first mover, can make adjustments in their own technologies. As a result, after the first mover has introduced the product in the market, then the second, third, and fourth movers (who have been carefully following the leader) can often and rapidly introduce a more significant, advanced, and better product or service. In short, there are strong economic motives for entrepreneurial firms to find ways to cooperate and collectively share the costs and benefits of building an industrial infrastructure while they simultaneously compete to develop their proprietary products.

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NOTES

1. Of course, hierarchy in an industry system is a matter of degree, and some industry systems may be only minimally, if at all, hierarchical. Hierarchy is often a consequence of institutional constraints imposed by political and governmental regulatory bodies. Hierarchy also emerges in relationships with key linking-pin organizations that either become dominant industry leaders or control access to critical resources (money, competence, technology) needed by other firms in the industry.

Loose coupling promotes both flexibility and stability to the structure of an industry. Links between subsystems are only as rich or tight as is necessary to ensure the survival of the system (Aldrich and Whetten, 1981, p. 388). Based on Simon's (1962) architecture of complexity, Aldrich and Whetten discuss how a loosely joined system provides short-run independence of subsystems and long-run dependence only in an aggregate way. The overall social system can be fairly stable, due to the absence of strong ties or links between elements and subsystems, but individual subsystems can be free to adapt quickly to local environmental conditions. Thus, in a complex, heterogeneous, and changing environment, a loosely joined system is highly adaptive.

REFERENCES

Abernathy, W. J., and K. B. Clark. 1985. "Innovation: Mapping the Winds of Creative Destruction." *Research Policy*, 14, 3-22.

Aldrich, H. and D. Whetten. 1981. "Organization-sets, Action Sets, and Networks: Making the Most of Simplicity." In P. C. Nystrom and W. H. Starbuck (eds.), *Handbook of Organizational Design*, Oxford: Oxford University Press, pp. 385-407.

Anderson, P. and M. L. Tushman. 1990. "Technological Discontinuities and Dominant Designs: A Cyclical Model of Technological Change." *Administrative Science Quarterly*, 35, 604-633.

ASHA. 1985. "Cochlear Implants: Five Companies Respond to ASHA Survey." *American Speech and Hearing Association.*

Astley, W. G. 1985. "The Two Ecologies: Population and Community Perspectives on Organizational Evolution." *Administrative Sciences Quarterly*, 30, 224-241.

Biggadike, R. 1979. "The Risky Business of Diversification." *Harvard Business Review,* 56, 103-111.

Binswanger, H. P. and V. W. Ruttan. 1978. *Induced Innovation.* Baltimore: Johns Hopkins University Press.

Bottomore, T. (ed.) 1983. *A Dictionary of Marxist Thought.* Cambridge, MA: Harvard University Press.

Burgelman, R. A. 1983. "A Process Model of Internal Corporate Venturing in the Diversified Major Firm." *Administrative Science Quarterly*, 28, 223-244.

Chandler, Jr., A. D. 1990. *Scale and Scope: The Dynamics of Industrial Capitalism.* Cambridge, MA: Harvard University Press.

Commons, J. R. 1950. *The Economics of Collective Action.* New York: MacMillan.

Constant E. W. 1980. *The Origins of the Turbojet Revolution.* Baltimore: John Hopkins University Press.

Constant, E. W. 1987. "The Social Locus of Technological Practice: Community, System, or Organization?" In W. E. Bijker, T. P. Hughes, and T. J. Pinch (eds.), *The Social Construction of Technological Systems: New Directions in the Sociology and History of Technology.* Cambridge, MA: MIT Press.

Dosi, G. 1982. "Technological Paradigms and Technological Trajectories." *Research Policy*, 11, 147-162.

Dosi, G. 1988. "Sources, Procedures, and Microeconomic Effects of Innovation." *Journal of Economic Literature*, 26, 1120-1171.

Freeman, C. 1986. *The Economics of Industrial Innovation.* Cambridge, MA: MIT Press.

Galaskiewicz, J. 1985. "Interorganizational Relations." *Annual Review of Sociology* 11, 281-304.

Garud, R. and A. H. Van de Ven. 1989. "Innovation and the Emergence of Industries." In A. H. Van de Ven, H. Angle, and M. S. Poole (eds.), *Research on the Management of Innovation.* New York: Harper Collins, Ballinger Division.

Garud, R. and A. H. Van de Ven. 1990. "Development of the Cochlear Implant Program at 3M Corporation." Strategic Management Research Center, Carlson School of Management, University of Minnesota, Minneapolis, MN.

Gilfillan, S. G. 1935. *The Sociology of Invention.* Cambridge, MA: MIT Press.

Grabowski H. G. and J. M. Vernon. 1982. "The Pharmaceutical Industry." In R. Nelson (ed.), *Government and Technical Progress: A Cross-Industry Analysis.* New York: Pergamon Press, pp. 283-362.

Hirsch, P. M. 1975. "Organizational Effectiveness and the Institutional Environment." *Administrative Science Quarterly*, 20, 327-344.

Hughes, T. P. 1983. *Networks of Power: Electrification in Western Society, 1880-1930.* Baltimore: Johns Hopkins University Press.

Hull, D. L. 1988. *Science as a Process: An Evolutionary Account of the Social and Conceptual Development of Science.* Chicago, IL: University of Chicago Press.

Hurwicz, L. 1993. "Institutional Change: Endogenous Evolution vs. Design." *Journal of Comparative Economics*, 17.

Jewkes, J., D. Sawers, and R. Stillerman. 1958. *The Sources of Invention.* New York: Macmillan.

Kuhn, T. S. (1982). *The Structure of Scientific Revolutions.* Homewood, IL: Richard Irwin.

Layton, E. 1986. "Technology as Knowledge." *Technology & Culture*, 15, 31-41.

Lord, F. M. and M. R. Novick. 1968. *Statistical Theories of Mental Test Scores.* Reading, MA: Addison-Wesley.

March, J. G. and J. P. Olsen (1989). *Rediscovering Institutions: The Organizational Basis of Politics.* New York: Free Press.

Marx, K. 1906. *Capital*, Vol. I. New York: Modern Library, n.d. First published in 1867 by Otto Meissner, Hamburg, and published in English by Charles H. Kerr, Chicago.

Meyer, J. W. and B. Rowan. 1977. "Institutionalized Organizations: Formal Structure as Myth and Ceremony." *American Journal of Sociology*, 83(2), 340-363.

Mowery, D. C. 1985. "Market Structure and Innovation: A Critical Survey." Presented at conference on "New Technology as Organizational Innovation" at the Netherlands Institute for Advanced Studies in Humanities, Wassenaar.

Mowery, D. C. and N. Rosenberg. 1979. "The Influence of Market Demand upon Innovation: A Critical Review of Some Recent Empirical Studies." *Research Policy*, April.

Nelson, R. N. 1982. *Government and Technical Progress: A Cross-industry Analysis.* New York: Pergamon Press.

Nelson, R. N. and S. G. Winter. 1977. "In Search of a Useful Theory of Innovation." *Research Policy*, 6, 36-76.

North, D. C. (1990). *Institutions, Institutional Change and Economic Performance.* London: Cambridge University Press.

North, D. C. and R. P. Thomas. 1973. *The Rise of the Western World.* London: Cambridge University Press.

Olson, M. 1965. *The Logic of Collective Action: Public Goods and the Theory of Groups.* Cambridge: Harvard University Press.

Pfeffer, J. and G. Salancik. 1978. *The External Control of Organizations.* New York: Harper & Row.

Pinch, T. F. and W. E. Bijker. 1987. "The Social Construction of Facts and Artifacts: Or How the Sociology of Science and the Sociology of Technology Might Benefit Each Other." In W. E. Bijker, T. P. Hughes, and T. F. Pinch (eds.), *The Social Construction of Technological Systems: New Directions in the Sociology and History of Technology.* Cambridge, MA: MIT Press.

Porter, M. E. 1980. *Competitive Strategy: Techniques for Analyzing Industries and Competitors.* New York: Free Press.

Porter, M. E. 1985. *Competitive Advantage.* New York: Free Press

Powell, W. W. and P. DiMaggio. 1991 *The New Institutionalism in Organizational Analysis*. Chicago: University of Chicago Press.

Radcliffe, D. 1984. "The Cochlear Implant: Its Time Has Come." *Hearing Journal*, 37(11), 7-15.

Rappa, M. 1989. "The Dynamics of R&D Communities: Implications for Technology Strategy." Paper presented at the CORS/TIMS/ORSA Conference, May 1989, in Vancouver, Canada.

Rosenberg, N. 1983. *Inside the Black Box. Technology and Economics*. Cambridge: Cambridge University Press.

Rosenberg, N. and L. E. Birdzell, Jr. 1986. *How the West Grew Rich*. Berkeley: University of California Press.

Rosenbloom, R. S. 1986. "Product Innovation in a Scientific Age." *New Ideas for Successful Marketing*. Chicago: Proceedings of the 1966 World Congress, American Marketing Association, chap. 23.

Rosenkopf L. and M. L. Tushman. 1992. "On the Co-evolution of Organization and Technology." Paper presented at conference on organizational evolution, New York University.

Ruttan, V. W. 1978. "Induced Institutional Change." In H. P. Binswanger and V. W. Ruttan (eds.), *Induced Innovation*. Baltimore: Johns Hopkins University Press, pp. 327-357.

Ruttan, V.W. and Y. Hayami. 1984. "Toward A Theory of Induced Institutional Innovation." *Journal of Development Studies*, 20(4), 203-223.

Schultz, T. W. 1968. "Institutions and the Rising Economic Value of Man." *American Journal of Agricultural Economics*, 50, 1113-1122.

Scott, W. R. 1987. "The Adolescence of Institutional Theory." *Administrative Science Quarterly*, 32, 493-511.

Simon, H. A. 1962. "The Architecture of Complexity." *Proceedings of the American Philosophical Society*, 106, 467-482.

Simmons, F. B. 1985. "Some Medical, Social, and Psychological Considerations in Cochlear Implants." *Seminars in Hearing*, 6, 1-6.

Teece, D. 1987. "Profiting from Technological Innovation: Implications for Integration, Collaboration, Licensing, and Public Policy." In D. J. Teece (ed.), *The Competitive Challenge*. New York: Harper Collins, Ballinger Division.

Thirtle C. G. and V. W. Ruttan. 1986. *The Role of Demand and Supply in the Generation and Diffusion of Technical Change*, Bulletin No. 86-5. University of Minnesota Economic Development Center, Minneapolis, MN.

Tornatsky, L.G. and M. Fleischer. 1990. *The Processes of Technological Innovation*. Lexington, MA: D. C. Heath.

Usher, A. P. 1954. *A History of Mechanical Inventions*. Cambridge, MA: Harvard University Press.

Utterback, J. M. and W. J. Abernathy. 1975. "A Dynamic Model of Process and Product Innovations." *Omega*, 3, 639-656.

Van de Ven, A. H. and R. Garud. 1989. "A Framework for Understanding the Emergence of New Industries." *Research on Technological Innovation Management and Policy*, 4, 295-225.

Van de Ven, A. H. and M. S. Poole. 1990. "Methods for Studying Innovation Development in the Minnesota Innovation Research Program." *Organization Science*, 1(3) (August), 313-335.

Veblen, T. 1917. *The Imperial Germany and the Industrial Revolution*. London: MacMillan.

Windmill, I. M., S. Martinez, M. B. Nolph, and B. Eisenmenger. 1987. "The Downside of Cochlear Implants." *Hearing Journal*, January 18-21.

Yin, L. and P. E. Segerson. 1986. "Cochlear Implants: Overview of Safety and Effectiveness." *Otolaryngologic Clinics of North America*, 19(2), 423-433.

Yin, R. K. 1982. "Studying the Implementation of Public Programs." In W. Williams et al. (eds.), *Studying Implementation: Methodological and Administrative Issues*. Chatham, NJ: Chatham House.