4.
The NMR Imaging Device Industry

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INTRODUCTION

NMR imaging is fast emerging as the "growth" technology in the diagnostic imaging field. The possibility of unrivaled image quality, coupled with the perceived demand for a less risky alternative to X-ray computed tomography (CT) and radionuclide scanning, has led numerous firms to invest heavily in NMR imaging research and development. Since *1976,* at least *23* companies worldwide have entered the NMR imaging marketplace. The industry is both dynamic and intensely competitive, Sales of NMR imaging devices over the next 5 years have been estimated by one source at **$6.4** billion **(60),** an estimate that some manufacturers contend is conservative. The future of the industry, however, will depend not only on the internal composition and behavior of the industry, but also on external economic and regulatory forces, including Federal and State policies toward technology development and diffusion, and third-party decisions regarding payment. This chapter will focus on the NMR imaging industry, while succeeding chapters will address external economic and regulatory forces affecting that industry.

To understand the forces driving the NMR imaging device industry, it is necessary first to focus on three elements that have become standard in the analysis of American industry: structure, conduct, and performance (31). Structure refers to the composition and boundaries of an industry, i.e., the number and size distribution of its firms and their ability to enter the marketplace. Conduct pertains to the behavior of such firms once they gain entry to the marketplace, e.g., their policies toward setting prices, differentiating their products, and engaging in competition with one another. Performance relates to the results of firms' behavior, i.e., how well the industry is able to achieve recognized economic goals of efficiency and profitability. Industry structure often influences the nature of market conduct, which, in turn, may affect the quality of industry performance.

INDUSTRY STRUCTURE

The NMR imaging device industry may be examined through several important structural features, including seller and buyer concentrations, barriers to entry, diversification of firms, and acquisition and merger activity. The findings presented here reflect our own interpretations of data from multiple sources and do not represent the official views of the firms concerned. (A description of the methods employed in our survey of manufacturers appears as app. B; detailed descriptions of manufacturers, products, and clinical placements of NMR imaging units appear in app. C.)

Seller Concentration

The NMR imaging device industry may be divided into three groups of manufacturers, based on their stage of research and development (R&D) as of October 1983 (see table 5). Of the 20 firms for which we have information, seven had reached an *advanced* stage in which they had conducted extensive preproduction technical testing and had placed numerous units in clinical sites outside their factories. Each of these advanced stage firms had also developed a commercial prototype system[1] that was available for placement. Two companies, Diasonics and Technicare, obtained FDA premarket approval for the sale of their devices in March 1984, and a third, Picker International, in May 1984.

[1]See subsequent discussion of industry development for definition of a commercial prototype system. By August 1984 Elscint had also reached the advanced stage. See app. C.

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Table 5.—The NMR Imaging Device Industry, October 1983

Companies in advanced stage of development
Engineering model(s) complete; mu/tip/e clinical placements outside factory; ongoing clinical studies since 1982 or earlier; commercial prototype system(s) available for placement:

- Bruker Instruments
- Diasonics Inc.[a]
- Fonar Corp.
- Philips Medical Systems
- Picker International[a]
- Siemens Medical Systems
- Technicare Corp.[a]
- Elscint Ltd.[b]

Companies in intermediate stage of development
Engineering model(s) complete; ***limited*** clinical placements outside factory; generally limited clinical study thus far; commercial prototype system(s) generally not yet available for placement:

- General Electric Co.
- M&D Technology Ltd.[c]
- Toshiba Corp.

Companies in early stage of development: [d]
Engineering model(s) under development; ***no*** clinical placements outside factory; commercial prototype system(s) still to be defined:

- ADAC Laboratories
- CGR Medical Corp.[e]
- Fischer Imaging Corp.[f]
- Hitachi Ltd.
- JEOL USA
- Nalorac Cryogenics[g]
- OMR Technology[h]
- Sanyo Electric
- Shimadzu Corp.

[a]FDA granted premarket approval in spring 1984
[b]In the advanced stage by August 1984 (see app. C).
[c]Had extensive clinical experience prior to formation of company.
[d]Two other firms that have announced plans to develop NMR imaging systems are Ansoldo SPA and Instrumentarium Oy
[e]engineering model complete, but clinical placement is not expected until 1984.
[f]Had been developing its own NMR imaging systems until acquired by Diasonics Inc in May 1983.
[g]As Indicated in app. C, Nalorac Cryogenics had two clinical placements by August 1964 However, these are small bore, high field strength systems that are currently being used for research purposes only.
[h]Acquired by Xonics Inc. in late 1983.

SOURCES Interviews with manufacturers; American Hospital Association, 1963 (6); Boteler, 1963 (20); and "Imaging Equipment Sales Close In On $4 Billion Mark, " *Diag Imag* 5(11)"55431, November 1963

By October 1983 four firms had progressed to an *intermediate* stage of R&D in which engineering and experimental models had been completed, but commercial prototype systems had either not yet been developed or not yet been installed in clinical sites. The extent of clinical study also varied widely among these manufacturers. M&D Technology Ltd. had the benefit of clinical experience acquired by its founders at the University of Aberdeen (Scotland) prior to its incorporation, but it had yet to reach the advanced production prototype stage.

Nine other manufacturers could be characterized as engaged in early R&D work in October 1983. Of these, only one (CGR Medical Corp.) had completed an experimental prototype on which clinical testing was expected to begin in 1984, One firm, Fischer Imaging Corp., had been acquired (May 1983) by a manufacturer in the advanced R&D group, Diasonics Inc. Complete details on the future organizational structure of the two companies and their respective NMR imaging programs are not available at this time.

Industry Profile. The multinational character of the NMR imaging device industry is reflected in the 19 firms listed in table 6.[2] In October 1983, U.S. companies accounted for 37 percent of the total, while Japanese corporations comprised another 26 percent. Five other nations had entries in the world market: West Germany and Great Britain with two companies each; and France, Israel, and the Netherlands with one apiece.[3]

Thirteen of the manufacturers (68 percent) are public corporations, some of which are giants in other fields (General Electric, Hitachi, Philips, Sanyo Electric, Siemens, Toshiba). Of the six privately held firms, two are owned by small groups of investors (Nalorac Cryogenics, OMR Technology[4]), while three others are subsidiaries of major corporations (Picker International, Bruker Instruments, CGR Medical Corp.). M&D Technology Ltd. is a unique entity financed by a combination of private individuals and public trusts in Aberdeen, Scotland.

In terms of organizational structure, 11 NMR imaging device manufacturers *(58* percent) are independent firms, seven (37 percent) are wholly owned subsidiaries, and one is the Medical Systems Division of a major public corporation (General Electric). Fifteen NMR manufacturers **(79** percent) have multiple product lines. Some of these

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[2]Because Fischer has been acquired by Diasonics, we have excluded it from table 6.

[3]Two other firms that have announced plans to develop NMR imaging systems are Ansoldo SPA of Genoa, Italy, and Instrumentarium Oy of Helsinki, Finland.

[4]OMR Technology has recently been acquired by Xonics Inc. , a publicly owned multiproduct firm in the United States.

Table 6.—The NMR Imaging Device Industry: Company Profile”

Company[b]	Ownership	Product lines (single or multi)	Organizational structure	Country
ADAC Laboratories	Public	Multi	Independent	United States
Bruker Instruments ., ...	Private	Multi	Subsidiary of Bruker Physik R.A.G	West Germany
CGR Medical Corp.	Private	Multi	Subsidiary of Thompson-Brandt	France
Diasonics Inc.	Public	Multi	Independent	United States
Elscint Ltd.	Public	Multi	Independent	Israel
Fonar Corp.	Public	Single	Independent	United States
General Electric Co.	Public	Multi	Independent[c]	United States
Hitachi Ltd.	Public	Multi	Independent	Japan
JEOL USA	Public	Multi	Subsidiary of JEOL	Japan
M&D Technology Ltd.	Private	Single	Independent	United Kingdom
Nalorac Cryogenics	Private	Single	Independent	United States
OMR Technology[d]	Private	Single	Independent	United States
Philips Medical Systems	Public	Multi	Subsidiary of North American Philips[e]	Netherlands
Picker International	Private	Multi	Subsidiary of GEC	United Kingdom
Sanyo Electric	Public	Multi	Independent	Japan
Shimadzu Corp.	Public	Multi	Independent	Japan
Siemens Medical Systems	Public	Multi	Subsidiary of Siemens A.G.	West Germany
Technicare Corp.	Public	Multi	Subsidiary of Johnson & Johnson	United States
Toshiba Corp.	Public	Multi	Independent	Japan

[a]As of October 1983 Two other firms that have announced plans to develop NMR imaging systems are Ansoldo SPA of Genoa, Italy, and Instrumentarium Oy of Helsinki, Finland
[b]In alphabetical order
[c]Medical Systems Division is responsible for NMR imaging R&D
[d]Acquired by Xonics Inc in late 1983 Information on the merger not available
[e]North American Philips is a trust associated with N V Philips of the Netherlands

SOURCES Interviews with manufacturers, Dun & Bradstreet, *Million Dollar Directory, 1983,* Parsipanny, NJ, 1983, Moody's Investors Service, *Moody's Industrial Manual 1982,* and *Moody's International Manual, 7982, New* York, 1982, and "Imaging Equipment Sales Close In On $4 Billion Mark, ' *Diag Imag* 5(11) 55-61, November 1983

have parent firms with products that extend beyond the boundaries of health care (see later discussion of diversification among firms). Of the three firms pursuing NMR imaging solely, all are independent, only one is publicly owned (Fonar Corp.), and all but one (M&D Technology Ltd.) are based in the United States (see table 6).

The number of employees engaged by each firm in NMR imaging-related work varies across the industry. Of the 12 companies for which such information could be obtained in August 1984, 4 had fewer than 50 full-time NMR employees, with 2 of these reporting NMR programs utilizing 10 or fewer full-time employees. At the other extreme, 8 firms reported program staffs (R&D plus administrative / marketing personnel) of 100 or more individuals, with one company (General Electric) employing over 500 persons.[5] Individuals with doctorates in physics, physical chemistry, and engineering comprise a substantial proportion of all full-time employees, ranging from at least 75 percent in the smallest firms to at least 12 percent in the NMR work forces of the largest companies.

Market *Share.* The traditional measure of seller concentration in an industry is the four-firm or eight-firm "concentration ratio, " i.e., the combined market share of the top four or eight firms as reflected in their annual sales (31). Because NMR imaging units have been considered investigational devices by the FDA and, thus, could not be sold at a profit in the United States, information on U.S. sales is not readily available. However, using the number of clinical placements as a proxy for sales, the industry appears to be concentrated among four firms that account for *79* percent of worldwide placements and *83* percent of placements in the United States (see table 7). As of August 1984, Technicare Corp. had placed more operational units in clinical settings (44) than any other manufacturer, garnering *30* percent of the 145 worldwide placements and 39

'See app. C for information on specific manufacturers,

Table 7.—The NMR Imaging Device Industry: Market Share as Reflected in Clinical Placements[a]

	Current placements (as of August 1984)		Current market share[c]	
Company[b]	Worldwide	U.S. only	Worldwide	U.S. only
Technicare Corp.	44	36	30 "/0	39 "/0
Picker International	28	12	19	13
Diasonics Inc.	23	19	16	20
Siemens Medical Systems	19	10	13	11
Fonar Corp.	9	6	6	6
Philips Medical Systems.	5	1	3	1
Bruker Instruments	4	2	3	2
Elscint Ltd.	4	2	3	2
General Electric Co.	4	3	3	3
M&D Technology Ltd.[d]	2	0	1	0
Nalorac Cryogenics	2	2	1	2
Toshiba Corp.[d]	1	0	1	0
Totals	145	93	100 %	100%

aNMR imaging systems placed in clinical sites outside factory; human Systems only (whole body and head).
bIn descending order of worldwide market share, as Of August 1984
cExpressed as percentage of total current placements Detail may not sum to 100 Percent because of rounding
dAs of October 1983.

SOURCES Interviews with manufacturers, Boteler, 1983 (20), American Hospital Association, 1983 (6); and "Imaging Equipment Sales Close In On $4 Billion Mark, " *Diag. Imag.* 5(1 1):55-61, November 1983

percent of those in the United States (36 of 93). Picker International was second, with 28 units worldwide (19 percent) and 12 in the United States (13 percent). Diasonics Inc. had placed 23 units worldwide (16 percent), with 19 of those in the United States (20 percent of the U.S. market). Siemens Medical Systems had slightly fewer placements, with 19 worldwide (13 percent) and 10 in the United States (11 percent).

NMR Imaging Systems. An important determinant of industry growth and seller concentration will be the product features offered in the NMR imaging systems. Manufacturers are investing great energy in product differentiation strategies designed to segment the market for NMR imaging devices (see discussion of nonprice competition policies of firms in the industry conduct section of this chapter). Considerable controversy exists over the optimal design and configuration of NMR imaging units (20). Much of the debate centers on magnet design (6), with various manufacturers pursuing different strategies.

At present, M&D Technology Ltd. is the only company that appears committed to resistive magnet design operating at relatively low field strengths (see table 8). At least five firms (Diasonics, Philips, Siemens, General Electric, and Nalorac Cryogenics) are strongly committed to superconducting magnet technology only. Philips and Siemens now offer both 5 and 15 kilogauss systems, whereas General Electric plans to market a 15 kilogauss model in 1984. Nalorac Cryogenics is developing three superconducting systems intended largely for research applications, with magnet strengths ranging from 10 to 40 kilogauss (see app. C).

Superconducting magnet systems are now offered by at least four other manufacturers, but three of them also offer resistive systems (Picker International, Technicare Corp., and Bruker Instruments) and one is experimenting actively with permanent magnets (Elscint Ltd.). Fonar Corp. is the only manufacturer that now bases its system design on permanent magnet technology, including a 3 kilogauss mobile, whole body unit. ADAC Laboratories is also developing a permanent magnet NMR imager and expects to have a production model ready in late 1985.

Buyer Concentration

Unlike the high seller concentration in the NMR imaging device industry, the number and diversity of potential buyers in the market is extraordinarily large, covering research laboratories and

Table 8.—Status of NMR Imaging Systems[a]

Company[b]	NMR imaging system: Magnet type	Field strength (kilogauss)	Bore size	Year first available	Clinical patients studied to date[c]
Bruker Instruments	R	1 .3[d]	B	1979	100
	s	47	A	1979	
	s	19d	A or H	1982	
	R	2.4	B	1984	
CGR Medical Corp.	R	1.5	B	1982	0
	s	3.5	B	1983	
	s	5	B	1983	
Diasonics Inc.	s	5[d,e]	‘B	1981	NA
Elscint Ltd.	s	5	B	1982	NA
Fonar Corp.	P	0.4	B	1980	2,200
	P	3[d]	B	1983	
	P	3[d]	BM	1983	
General Electric Co.	R	1 .2[f]	B	1982	600
	R	1.5[f]	B	1983	
	s	15d	B	1984	
M&D Technology Ltd.	R	0.4	B	197?	1,200
	R	0.8	B	1982	
Philips Medical Systems	R	1.5	B	1982	300
	s	30	A	1982	
	s	15d	B	1983	
	s	5[d]	B	1983	
Picker International	R	1 .5[d]	B	1978	
	s	3	B	1981	NA
	s	5[d]	B	1983	
Siemens Medical Systems	R	1,2	B	1980	
	R	2	B	1981	800
	s	5[d]	B	1983	
	s	15[d]	B	1983	
Technicare Corp.	s	15d	A	1980	4,750
	R	1 .5[d]	H	1981	
	s	3[f]	B	1982	
	s	5[d]	B	1983	
	s	6	B	1983	
	s	15	B	1983	
Toshiba Corp.	R	1.5	B	NA	NA

NA = Not available
KEY Magnet type P = Permanent
R = Resistive
S = Superconducting
Bore size A = Animal
B = Whole body
BM = Whole body (mobile)
H = Head

[a]As of August 1984
[b]In alphabetical order
[c]As of October 1983
[d]Probable commercial prototype System(S)
[e]System operating at 35 kilogauss
[f]No longer available

SOURCES Interviews with manufacturers, Boteler, 1983 (20); and American Hospital Association, 1983 (6)

various types of clinical facilities. Likely buyers in the clinical segment of the market include hospitals, private radiology groups, and health maintenance organizations (HMOs). Many manufacturers are optimistic that more than half of the 5,900 non-Federal, short-term general hospitals in the United States (5) will purchase NMR imagers by 1990. The prime buyers will be the leading teaching hospitals and medical centers, followed by large urban and moderate-sized community hospitals with bed capacities of at least 200. In the United States alone there are over

1,700 hospitals meeting this description (5) and a large number in Canada and Western Europe. NMR imaging manufacturers also expect to make in-roads into other segments of the U.S. hospital industry, including the smaller independent community hospitals (100 to 199 beds); Federal Government hospitals in the Veterans Administration, Department of Defense, and Public Health Service systems (numbering around 350 facilities); and long-term and specialty hospitals (roughly 1,000). Hospital chains, particularly investor-owned corporations, are expected to be prime purchasers of NMR imagers (see the discussion of hospital strategies in ch. .5).

Several hundred NMR imaging units are expected to be sold worldwide to private radiology groups and to physicians' offices outside hospitals. The approximately *236* HMOs and prepaid health plans in the United States *(193)* are another potential source of buyers, with some likely to purchase multiple units for outpatient as well as inpatient settings.

Finally, the medical research community is viewed as an important market segment. At least two manufacturers (Nalorac Cryogenics and JEOL) are firmly committed to developing NMR imaging systems specifically intended for research applications. Both firms are investing in superconducting magnet systems that will operate at relatively high field strengths and be capable of performing phosphorus spectroscopy as well as proton NMR imaging.

Barriers to Entry

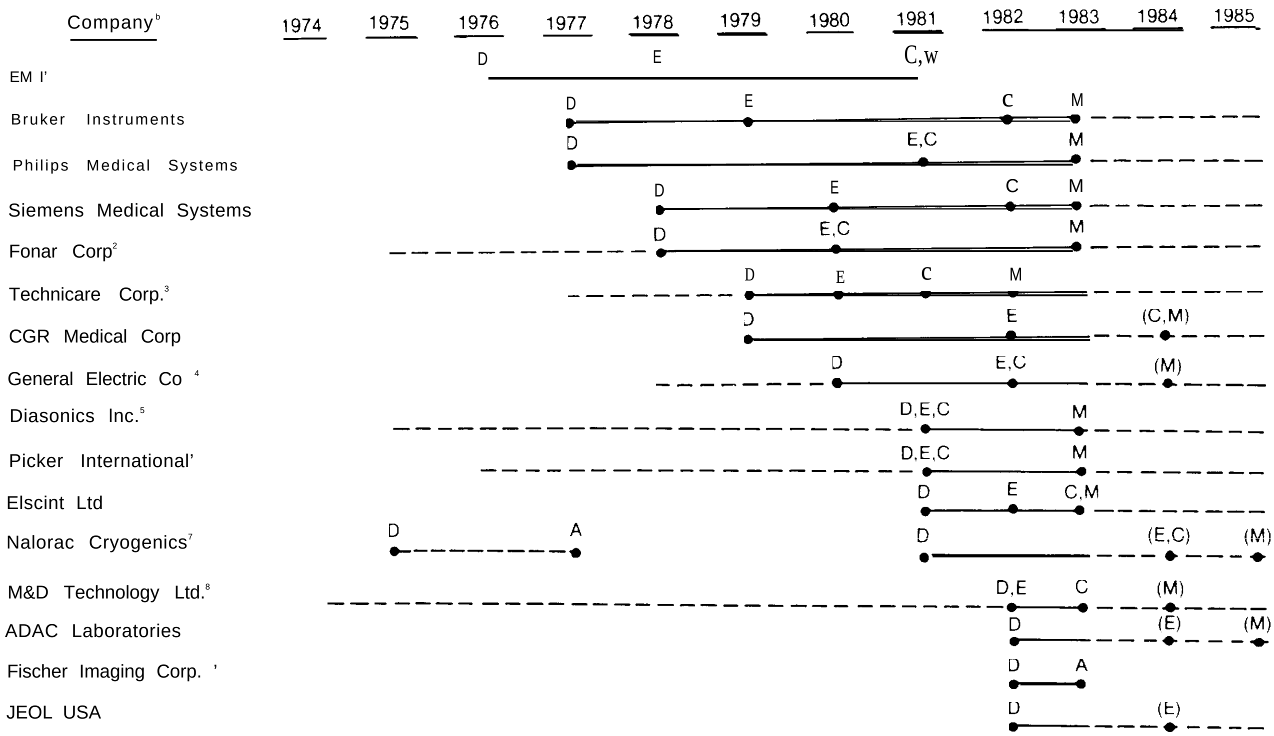
The ability of relatively small firms to enter the NMR imaging device industry depends on several key factors: their ability to attract adequate capitalization and technical/scientific talent for R&D, the development of strong university ties for collaborative research, and the ability to market products once they have been developed. At present, three small, single-product firms comprise 16 percent of the total number of firms in the industry (3 of 19 firms). Among them, one (Fonar Corp.) has attained advanced R&D status, and a second (M&D Technology Ltd.) stands on the threshold of commercial production. In order to understand the importance of these achievements, it is necessary first to examine the chronological development of the NMR imaging device industry.

Industry Development. The birth of the NMR imaging device industry can be traced to 1976 when EMI began work on building an NMR imaging machine. In 1977, two other companies (Bruker Instruments and Philips Medical Systems) embarked on parallel courses of NMR imaging R&D (see fig. 10). Between 1978 and 1980, five additional firms entered the industry. Fonar, drawing on several years of research by Raymond Damadian, was the first American company (and the only small single-product firm) to make a firm financial commitment to NMR imaging R&D during this period. Since 1980, the industry has experienced rapid growth, with four new entries in 1981 and another four in 1982. Data for the Japanese NMR imaging device industry are incomplete, but it is believed that several Japanese companies also entered the market during this time.

The pattern of NMR imaging development, i.e., the sequence of steps through which a manufacturer must pass in order to reach full production capability, generally consists of four major steps (see fig. 10):

1. *Corporate decision*— the manufacturer makes a corporate decision to invest in R&D activities and marshals its resources (capital, staff, facilities, materials) to assemble a program development effort whose first objective is to produce an experimental prototype or engineering model.
2. *Experimental prototype—upon* attaining this goal, the manufacturer can begin in-house testing that proceeds through several stages using "phantom" (inanimate) objects at first, and then laboratory animals and humans as imaging subjects. The knowledge and experience gained in the process facilitate the refinement of both system hardware and imaging techniques.
3. *Clinical placement outside the company* plant—manufacturers differ somewhat in their approach to clinical testing. Some prefer initial testing with humans on experimental in-house systems before seeking outside clinical placements of investigational units. Others choose to perform all clinical

Figure 10.–Chronological Development of the NMR Imaging Device Industry[a]



[a]Information on chronology of events not available for Ansoldo SPA Hitachi Ltd Instrumentarium Oy, OMR Technology (now Xonics) Sanyo Electric, Shimadzu Corp and Toshiba Corp
[b]In order of market entry based on corporate decision to invest in NMR imaging

KEY D = Corporate decision to invest in R&D efforts for NMR Imaging
E – First experimental prototype/engineering model available
C = First clinical placement of an NMR Imaging unit outside the company's plant
M = First commercial/marketing prototype system available for placement
A - Acquisition of company by other firm
W = Withdrawal of company from the industry
Letter symbols in parentheses ( ) Indicate projected events in the future
Dotted lines to the left of decision (D) points reflect R&D work that preceded formal company involvement or formation

[1]Began NMR R&D in 1976 produced first engineering model in 1978 sold its NMR imaging technology to Picker International in October 1981
[2]Founded in 1978 as RAAN EX Corp became Fonar Corp in 1980
[3]Parent company Johnson & Johnson, made initial commitment as early as 1977, but major R&D effort did not begin until the acquisition of Technicare in 1979
[4]Early R&D work in phosphorus spectroscopy began in 1978, but firm corporate commitment to NMR imaging was not made until 1980
[5]Initial R & D bagan as a University of California, San Francisco (UCSF) project with outside funding. In 1976, the Pfizer Corp began funding the work In 1981, Diasonics Inc purchased the rights to all patentable NMR technology developed under the UCSF-Pfizer agreement
[6]Formed in April 1981 after GEC of England acquired the Picker Corp and merged it with GEC Medical and Cambridge Medical Instruments GEC of England had begun NMR imaging R&D in 1977 In October 1981, Picker International purchased all NMR imaging technology that had been developed Independently by EMI of England since 1976
[7]Began early R&D on superconducting NMR systems in 1976 In 1977, the company was acquired by Nicolet Instruments Corp In 1981, the original founder of Nalorac Cryogenics purchased the company back from Nicolet and reaffirmed its commitment to developing NMR imaging systems
[8]Formed in 1982 to commercially develop the NMR imaging system that had evolved from the work of Professor Mallard at Aberdeen, Scotland since 1974

SOURCE Interviews with manufacturers

testing in outside clinical facilities with whom they have established close collaborative relationships. Regardless of the strategy employed, clinical placement of investigational systems outside the company's plant is a major step toward obtaining critical data for further refinement of the product and for defining the optimal configuration of the commercial system to be produced.

4. *Commercial* prototype—this is the last step of advanced R&D prior to full commercial production. The design and development of this prototype or commercial model often occurs concurrently with intensive clinical testing. Some manufacturers have cautiously delayed commercial prototype development until *after* thorough clinical testing in order to specify the best commercial design possible.

In the case of NMR imaging R&D, the time span required for completion of all four steps appears to have decreased over the years (see fig. 10). The early firms entering the market (e.g., EMI, Bruker Instruments, Philips Medical Systems, Siemens Medical Systems, and Fonar Corp.) each took 2 to 4 years to produce their first experimental systems. By contrast, firms entering the market in the last 2 to 3 years either have attained, or plan to attain, this goal in significantly less time. Overall, the actual or projected time frames of these late participants in NMR imaging are very much compressed, owing to the strong pressures of competition and to the knowledge about NMR imaging design conferred upon them by the pioneering efforts of their predecessors.

The pathways for entry[6] into the market have varied by manufacturer (see fig. 10). Essentially, four different routes have been followed, some simultaneously:

- *Government-supported* R&D—EMI entered the NMR market in 1976 with grant support from the Department of Health and Social Security (DHSS) in Great Britain. British Government support of university-based R&D at Nottingham and Aberdeen during the 1970s also later benefited Picker International and M&D Technology Ltd., respectively, when they decided to enter the NMR imaging market. Three firms (Bruker, Philips, and Siemens) have received grants from the West German Government, but only after each had initiated NMR program development with company resources.
- *University-based* R&D—all four small, single-product firms emerged as a direct result of university-based R&D at the following institutions: State University of New York (Fonar Corp.); University of Aberdeen (M&D Technology Ltd.); University of Nottingham (Nalorac Cryogenics); and University of California, Los Angeles (OMR Technology). In the case of Nalorac Cryogenics, the company's founder, James Carolan, had worked at Nottingham and later at Bruker before establishing his own firm.
- *Acquired* technology—two firms have successfully employed this strategy to accelerate their market entry and their progress toward advanced R&D. Picker International in 1981 purchased all NMR imaging technology that had been developed by EMI of England since 1976. That same year, Diasonics Inc. purchased the rights to all patentable NMR technology developed by Pfizer under an agreement with the University of California, San Francisco. A third firm, Fischer Imaging Corp., also sought to purchase NMR imaging technology from other manufacturers, but eventually was acquired by Diasonics Inc. in May 1983.
- *Internally based* R&D—the remaining firms in the industry have generally relied on internal R&D operations to develop their own NMR imaging technology. General Electric, Philips, Siemens and Technicare are examples of large companies marshaling their considerable R&D resources for directed NMR program development. Elscint and ADAC Laboratories have also committed themselves to internal R&D without benefit of government funding or of "off-the-shelf" technology. At least three firms (Bruker, Philips, and JEOL) have been able to draw directly on their corporate experience in manufacturing research laboratory NMR spectrometers.

The major elements affecting a company's ability to enter the marketplace generally have included the availability of capital, staff expertise, corporate experience, and collaborative links with major university research groups.

Capital Requirements for Market Entry. Interviews with manufacturers suggest that capital requirements for R&D have not been unduly excessive for those who have entered the field. Industry sources estimate that a new firm, or a firm lacking prior experience in NMR spectroscopy, requires between $4 million and $15 million for *initial* capitalization of R&D. This estimate does not include the capital required for expanding production capacity or for vertical integration of NMR imaging-related products, e.g., the capacity to build one's own magnets.

[6]The paths for entry do not necessarily reflect subsequent R&D strategy and are not mutually exclusive.

Table 9 shows the R&D expenditures incurred up to October 1983 by 12 companies involved in NMR program development. Expenditure levels are reflections, in part, of a company's stage of R&D effort. For instance, the four firms reporting expenditures of $1 million to $5 million have only recently entered the market and are engaged in early R&D. By contrast, the six companies reporting expenditures in excess of $10 million are involved in inter-mediate (two firms) or *advanced* (four) stages of R&D. There are exceptions to this pattern: the two firms with expenditures in the *$6* million to $10 million range have both attained *advanced* R&D status.

Staff Requirements for Market Entry. The importance of staff expertise to R&D activities in NMR imaging cannot be overstated. As mentioned earlier, Fonar Corp. and M&D Technology Ltd. were formed around innovative scientists and their specific techniques or methodologies. The technical complexity of NMR imaging dictates that manufacturers assemble R&D teams with expertise in such fields as physics, chemistry, engineering, and computer science. Specific knowledge of NMR spectroscopy is valuable. Several firms, including Technicare, Picker International, and General Electric, have aggressively recruited individuals who conducted some of the earliest NMR research in England in order to augment their in-house R&D staff talent.

For small firms, staff recruitment and development may be a constraint. A "critical mass" of at least five to six scientists appears to be necessary before a company can actively initiate R&D. Continued staff growth, as R&D activities mature, is vital to company survival. In the face of tight resource constraints, some firms have had to augment in-house expertise with outside consultants. Equally important for sustained program development is the need to establish a top-notch marketing and sales force. The larger, well-established firms with existing sales networks hold a critical competitive edge over smaller companies that lack such organization and expertise. Marketing and sales acumen may prove to be a decisive factor in the competitive marketplace that is rapidly developing.

Table 9.—Research and Development Expenditures Among Firms in the NMR Imaging Device Industry

R&D expenditures to date[a]	Number of firms reporting	Percentage
<$5 million	4	33%
$6-10 million	2	17
$11-20 million	1	8
>$20 million	5	42
Total	12	100%0

[a]As of October 1963
SOURCE Interviews with manufacturers

Collaborative Research With Universities and Major *Medical Centers.* University or major medical center research ties are considered essential in the industry, Every manufacturer engaged in either intermediate or advanced stage R&D in October 1983 had a close collaborative relationship with one or more universities or major medical centers (see table 10). The lack of university research links early in R&D is not necessarily a barrier to market entry for small firms, but future company survival—particularly in the clinical phases of product testing—may depend on the nature and quality of such agreements. Large firms also recognize the importance of collaborative research. Technicare, for example, has a stated policy of not placing units in clinical sites unless close working arrangements with the institutions can be established. Acquisition of clinical data is extremely important to the manufacturer in preparing for FDA premarket approval and for coverage decisions by third-party payers in the health care system.

Patents. Among the Federal policies that have been developed to promote innovative research and product development are those related to the protection of discoveries by patents. Although a thorough discussion of patent law and its commercial and societal ramifications is beyond the scope of this report (and the expertise of its authors), a few comments can be made regarding the NMR-related patents and their impacts.

A number of components of NMR imaging and spectroscopy systems would seem patentable. Among these are designs of: 1) the magnet used to produce the static magnetic field; 2) the radiofrequency coils used to emit and receive radiofrequency waves; 3) the gradient coils used to permit spatial encoding; and 4) the software techniques

Table 10.—Manufacturers' Collaborative Arrangements With Universities/Medical Centers[a]

Company:[b] university/medical center
ADAC Laboratories:
Negotiated, yet to be announced.
Bruker Instruments:
Baylor College of Medicine, Houston, TX
Yale University, New Haven, CT
CGR Medical Corp.:
None in USA (number in Europe not available)
Diasonics Inc.:
University of California, San Francisco (UCSF)
University of Texas, Dallas
University of Michigan, Ann Arbor
Elscint Ltd.:
Hebrew University, Jerusalem, Israel
Weitzman Institute, Rehovoth, Israel
Fonar Corp.:
University of California, Los Angeles (UCLA)
General Electric Co.:
Medical College of Wisconsin, Milwaukee
University of Pennsylvania, Philadelphia
Yale University, New Haven, CT
Duke University, Durham, NC
JEOL USA:
None at present
M&D Technology Ltd.:
University of Aberdeen, Scotland, U.K.
Nalorac Cryogenics:
None at present
Philips Medical Systems:
Neurological Institute, Columbia-Presbyterian Hospital, New York
University of Leiden, The Netherlands
Picker International:
University of Nottingham, Nottingham, U.K.
Royal Postgraduate Medical School and Hammersmith Hospital, London, U.K.
Mount Sinai Hospital, Cleveland, OH
Mayo Clinic, Rochester, MN
Bowman Gray Medical School, Winston-Salem, NC
University of British Columbia, Vancouver, Canada
City of Faith Medical and Research Center, Tulsa, OK
National Institutes of Health, Bethesda MD
University of Iowa, Iowa City
Queens Square Hospital, London, U.K.
Siemens Medical Systems:
Washington University, St. Louis, MO
University of Hanover Medical Center, Hanover, West Germany
Radiological Institute, Frankfurt, West Germany
Radiological Institute, Munich, West Germany
Mount Sinai Medical Center, Miami, FL
Allegheny General Hospital, Pittsburgh, PA
Technicare Corp.:
Massachusetts General Hospital, Boston, MA
University Hospital, Cleveland, OH
Cleveland Clinic Foundation, Cleveland, OH
University of Kentucky, Lexington
Indiana University, Indianapolis
Hershey Medical Center, Hershey, PA
Millard Fillmore Hospital, Buffalo, NY
St. Joseph's Hospital, London, Ontario, Canada
Johns Hopkins University, Baltimore, MD
Ontario Cancer Institute, Toronto, Canada
Charlotte Memorial Hospital, Charlotte, NC
New York Hospital, New York
Vanderbilt University, Nashville, TN
Defalque Clinic, Charleroi, Belgium
University of Florida, Gainesville
Baylor University Medical Center, Dallas, TX
Rush Presbyterian-St. Luke's Medical Center, Chicago
Toshiba Corp.:
Toshiba General Hospital, University of Tokyo, Japan

[a]As of August 1984, except M&D Technology Ltd. and Toshiba Corp. are as of October 1983 Information not available for Hitachi Ltd , OMR Technology (now Xonics Inc.), Sanyo Electric, and Shimadzu Corp
[b]In alphabetical order

SOURCES Interviews with manufacturers and American Hospital Association, 1983 (6)

used for spatial encoding, data gathering and image reconstruction.

Neither Lauterbur nor SUNY-Stony Brook patented Lauterbur's original NMR imaging technique or the apparatus (115).[7] On March 17, 1972, however, Raymond Damadian filed a patent application for an "Apparatus and Method for Detecting Cancer in Tissue" and received a patent in February 1974. Damadian has apparently filed an additional patent application in the United States, as well as patent applications in foreign countries (65). A number of NMR-related patents are apparently also held in a patent portfolio by the British Technology Group, formerly the National Research Development Corp. (120). Information regarding the types of license agreements, if any, related to such patents is not available. No attempt has been made to gather comprehensive information for this report regarding the number and types of patents held by NMR manufacturers.

A primary concern regarding patents is that they might create undesirable barriers to the entry of potential NMR manufacturing competitors into the marketplace. However, the existence of

[7]Apparently, the SUNY-Stony Brook was advised by an outside consultant not to proceed with a patent application.

at least 19 manufacturers of NMR imaging systems suggests that patents have not created such a barrier; the manufacturers we interviewed concurred with this view. Whether patentable discoveries will emerge, prohibitively expensive cross-licensing agreements will be devised, or pending lawsuits' will be settled in such a way as to change this situation is difficult to predict.

A second policy concern regarding patents is that manufacturers might: 1) stifle the prompt dissemination of scientific discoveries made by those university-based researchers whom they support in order to provide time for filing patents or 2) redirect the focus of university-based research away from "basic science" and toward the development of patentable devices and techniques. The existence of a large number of industry-university collaborative NMR research relationships (see table 10) suggests that universities have not found such research agreements prohibitively restrictive.[9]

This empirical inference was confirmed by discussions with a number of investigators whose NMR research is being supported in part by industry (1,184). Others, however, voiced concern that the scope of their research was more constrained when sponsored by industry than by NIH. Such a concern would seem to be more an argument for Federal research funds than an indictment of patents.

Finally, it is difficult to determine how beneficial the protection afforded by patents has been to the commercial development of NMR in this country. It is possible, for example, that many manufacturers have relied more on maintaining discoveries as "trade-secrets," rather than revealing confidential information in patent applications. Of interest in this regard, however, is the belief voiced by Lauterbur that acquisition of a patent by either SUNY-Stony Brook or himself would have accelerated commercial development of NMR imaging devices in the United States by virtue of providing a means of protecting a manufacturer's competitive advantage **(116).**

Regulatory Policies. We surveyed NMR manufacturers about their perceptions of the impact of various regulatory policies on the placement of their products in clinical sites.[10]

Of the various Federal and State policies affecting technological development and diffusion, none was perceived by manufacturers to be a serious constraint on NMR *development.* The FDA premarket approval (PMA) process is generally regarded as a time-consuming "hurdle" that is not overly obstructive. None of the firms interviewed felt that the PMA process had influenced either the pace of R&D activities or the placement of investigational units at clinical sites. (For a more complete discussion of issues pertaining to the FDA and its PMA process, see ch. **7.)**

By contrast, third-party payment policies, and to a lesser degree, State certificate-of-need programs, appear to cause major concern among manufacturers as potential barriers to NMR dif*fusion.* Coverage policy decisions of the Federal Medicare program, State Medicaid agencies, local Blue Cross/Blue Shield plans, and commercial insurance companies are considered critical to the future marketing of NMR imaging devices. Unfavorable coverage decisions—or even moderate delays in decision making—by the Health Care Financing Administration (HCFA) and other third-party payers could pose serious financial problems for those manufacturers in advanced stages of R&D. Coverage denials for NMR imaging could conceivably destroy the hospital segment of the market and militate strongly against entry of new firms into the industry. State prospective

[8] On Sept. 20, 1982, Fonar Corp. and Dr. Raymond Damadian filed suit in the U.S. District Court in Massachusetts against Johnson & Johnson and its subsidiary, Technicare Corp. **(65).** The suit charges Johnson & Johnson and Technicare with willfully infringing on Damadian's patent for using Nuclear Magnetic Resonance in detecting and diagnosing human disease and with unfair competition and interference in Fonar's ability to successfully market the apparatus covered by the patent. The defendants have denied the allegations and requested a judgment declaring the patent invalid. The matter is in the discovery stage **(65).**

[9] Many research agreements between industry and academia enable universities to benefit financially from the discoveries made by their faculty. Diasonics Inc., for example, holds the exclusive right to obtain an exclusive license to all patentable NMR technology discovered pursuant to the research project it supports at the University of California Under the terms of the license, the university is entitled to a royalty of **0.56** percent of the selling price of any NMR system sold by Diasonics that includes technology patented by the university (51).

[10] The views expressed by the manufacturers should not be considered to represent the views of either the authors or OTA.

payment programs are viewed by manufacturers with considerably less trepidation since, under many such programs (e.g., Maryland, New York, Massachusetts), hospitals have retained wide discretion in their capital-equipment purchases.

State certificate-of-need (CON) programs, on the other hand, are perceived as potentially troublesome constraints that might delay—or even limit —the placement of NMR imaging devices in specified geographic areas. Some manufacturers feel that CON policies could prove unusually restrictive in some areas of the country despite favorable coverage decisions by third-party payers. Should this occur, NMR diffusion could slow noticeably in the United States, sending discouraging signals to firms contemplating market entry.

Diversification of Firms

The firms that constitute the NMR imaging device industry display considerable diversity in their product lines and operations. Twelve companies *(63* percent) manufacture nonhealth care related products either directly or through a parent firm (see table 11). These products range from assorted electrical equipment and household appliances to electron microscopes and instruments for testing. In many instances, sales of these products far exceed those of health care related equipment and products.

Of the 15 firms identified in table 11 as multiproduct entities, all but two (Bruker Instruments and JEOL) produce diagnostic imaging equipment other than NMR imaging. Of these, six (CGR, Elscint, General Electric, Philips,[11] Picker, and Siemens) offer full diagnostic imaging productlines, including CT, ultrasound, nuclear medicine, digital radiography, and conventional X-ray and fluoroscope. An additional four firms (ADAC Laboratories, Hitachi, Technicare, and Toshiba) manufacture products in three or more diagnostic imaging modalities.

The diverse nature of industry firms serves to benefit their R&D efforts in NMR imaging by:

offering technical expertise gained in the development and marketing of other diagnostic imaging modalities, such as CT and nuclear medicine;

accelerating product development based on corporate experience with related technologies in nonhealth care fields, such as NMR spectroscopy; and

increasing the R&D resource base available to NMR imaging development through the sales of various other products in both health care and nonhealth care fields.

Diversification in the industry is likely to increase in the future, as some small firms expand operations into new product lines and as some large companies augment their already diverse portfolios.

Acquisition and Merger Activity

Since its inception in the mid-1970s, the NMR imaging device industry has witnessed a considerable number of acquisitions, mergers, and important trade agreements among its member firms. Acquisition and merger activity may be classified into four major groups (9,31,139):

- Product extension—in which a company gains entry into a related market by acquiring a firm that sells products not presently produced by the parent.
- Market extension—in which a company consolidates or increases its market share by acquiring a firm in the same product line.
- Conglomerate merger—in which a parent company acquires another company that is unrelated in either product or market.
- *Vertical* integration-in which a company acquires another firm whose activity is important to the processing, manufacturing, sale, or distribution of the parent company's product.

Most acquisitions and mergers in the industry have been oriented toward product extension involving various diagnostic imaging modalities (see table 12). Among these have been two cases involving NMR imaging. In one instance, Diasonics Inc., acquired the rights to NMR imaging technology developed under an agreement between Pfizer, Inc. and the University of California, San Francisco (UCSF) Radiological Imaging Labora-

[11] Philips manufactures nuclear cameras, sold in the United States through ADAC Laboratories.

Table 11.—Diversification Among Firms in the NMR Imaging Device Industry[a]

Company	Health-care-related products: Diagnostic imaging[b] CT	US	NM	DR	XR	Other medical products	Non-health-care-related products
ADAC Laboratories			✓	✓	✓	Radiation therapy planning; special procedures room; clinical information systems; medical linear accelerators	Instruments for non-destructive testing
Bruker Medical Instruments			NMR only			ECG monitors[c]; mobile defibrillators[c]; patient monitoring systems[c]	NMR spectrometers
CGR Medical Corp	✓	✓	✓	✓	✓	None	Assorted electrical appliances and equipment[c]
Diasonics Inc[d]		✓				None	None
Elscint Ltd.	✓	✓	✓	✓	✓	None	None
Fonar Corp			NMR only			None	None
General Electric Co	✓	✓	✓	✓	✓	Assorted electromedical equipment	Assorted electrical appliances and equipment
Hitachi Ltd.	✓	✓		NA	✓	NA	Assorted electrical appliances and equipment
JEOL USA			NMR only			Radioimmunoassay equipment; blood gas analyzers; fluid analyzers	NMR spectrometers, electron microscopes[c]
M&D-Technology Ltd.			NMR only			None	None
Nalorac Cryogenics			NMR only			None	Superconducting high-resolution analytical NMR magnets, gradient coils, power supplies, dewars, NMR probeheads
OMR Technology			NMR only			None	None
Philips Medical Systems[e]	✓	✓	✓	✓	✓	Surgical supplies;[c] dental equipment;[c] assorted electromedical equipment	NMR spectrometers; assorted electrical appliances and equipment[c]
Picker International	✓	✓	✓	✓	✓	ECG equipment; other electromedical equipment	N-one
Shimadzu Corp		✓		NA	✓	Assorted electromedical equipment	Assorted products and equipment
Siemens Medical Systems	✓	✓	✓	✓	✓	Assorted electromedical equipment	Assorted electrical appliances and equipment
Technicare Corp	✓	✓	✓	✓		Surgical instruments and supplies;[c] dental equipment	None
Toshiba Corp	✓	✓		✓	✓	NA	Assorted electrical appliances and equipment

NA = Information is either unavailable or unknown

[a] Firms listed in alphabetical order. No data for Sanyo Electric, which is recognized for its assorted non health-care related products. Information is as of August 1984 except for Hitachi Ltd., M&D Technology Ltd., OMR Technology, Shimadzu Corp and Toshiba Corp, all of which are as of October 1983

[b] Diagnostic imaging modalities other than NMR imaging

[c] Products made by parent firm only (see table 6 for information on parent companies)

[d] Diasonics also manufactures surgical C-arm imaging equipment

[e] Philips designs and manufactures nuclear cameras, sold in the United States through ADAC Laboratories

Key for diagnostic imaging CT = computed tomography, US = ultrasonography, NM = nuclear medicine; DR = digital radiography, XR conventional X-ray and fluoroscope

SOURCE Interviews with manufacturers, Arthur Young & Co, 1981 (9), Boteler, 1983 (20), and Emmitt & Lasersohn 1983 (60)

tory. In the other, Fischer Imaging Corp. entered into an agreement (not a merger) with M&D Technology Ltd. to become the exclusive marketing agent for M&D's NMR imager. This agreement was soon terminated, however, when Fischer was acquired by Diasonics in a product extension merger whose prime target was Fischer's line of X-ray equipment.

Market extension mergers have occurred less frequently in the young industry, but one case involving NMR imaging stands out: Picker International's acquisition of the technology developed by EMI of England. In this instance, Picker sought to reinforce and complement the NMR imaging technology previously developed independently by its parent firm, GEC of England. As with

Table 12.—Acquisitions, Mergers, and Key Trade Agreements in the NMR Imaging Device Industry Since 1971

Year and nature of acquisition/merger/trade agreement activity	Comment
ADAC Laboratories:	
1981: Agreement with Picker International for manufacturing digital angiography systems	—
1982: Agreement with Fischer Imaging Corp. for manufacturing digital angiography systems	Agreement terminated same year
Bruker Instruments:	
1982: 25% of company ownership acquired by IBM	IBM provides grant support to MIT and Harvard for NMR imaging research at Brigham & Women's Hospital (Boston) using Bruker equipment
1983: Acquired Oxford Research Systems from Oxford Instruments	—
CGR Medical Corp:	
1971: Created by the acquisition of Westinghouse Medical X-Ray Division by CGR of France	Market extension: X-ray equipment
1979: CGR of France merged with Thompson-CSF to form Thompson-Brandt	Conglomerate merger
Diasonics ***Inc.:***	
1981: Acquired rights to NMR technology developed under agreement between Pfizer and the UCSF Radiological Imaging Laboratory	Product extension: NMR imaging
1981: Acquired rights to cardiology ultrasound technology developed by Varian Associates	Product/market extension: phased array ultrasound
1982: Acquired Sonotron Holding A.G.	Vertical integration: Western European distributorship
1983: Acquired Sonics Imaging, Inc.	Vertical integration: Southeastern U.S. distributorship
1983: Acquired Fischer Imaging Corp.	Product extension: X-ray equipment
Fischer imaging Corp.:	
1980: Acquired the Medical Ultrasound Division of EMI	Product extension: ultrasound
1982: Agreement with ADAC Laboratories (see above)	(See ADAC Laboratories above)
1983: Agreement with M&D Technology Ltd. to become exclusive marketing agent for M&D NMR imager	Product extension: NMR imaging[b]; agreement terminated same year following acquisition by Diasonics (NMR) Ltd.
1983: Acquired by Diasonics Inc.	(See Diasonics Inc. above)
General Electric:	
1980: Acquired Thorn (CT Scanning Division of EMI)	Market extension: CT scanning
JEOL USA:	
1973: Parent firm, JEOL of Japan, acquired by Mitsubishi	Conglomerate merger: NMR spectroscopi[c]
1982: Agreement with Smith, Kline & French Laboratories for joint research into NMR spectroscopy	—
M&D Technology Ltd.:	
1982: Formed and financed by a combination of private and public investors	—
1983: Agreement with Fischer Imaging Corp. (see above)	(See Fischer Imaging Corp. above)
Nalorac Cryogenics:	
1977: Acquired by Nicolet Instruments	Product extension: superconducting magnets
1982: Divested by Nicolet Instruments and reestablished as independent firm	
Picker international:	
1981: Created by the acquisition of the Picker Corp. by GEC of England, and its subsequent merger with GEC Medical and Cambridge Medical Instruments	Product extension: X-ray equipment, CT scanning
1981: Acquired rights to NMR technology developed by EMI	Market extension: NMR imaging
1981: Agreement with ADAC Laboratories (see above)	(See ADAC Laboratories above)
Technicare Corp.:	
1979 Acquired by Johnson & Johnson, Inc., from Ohio Nuclear	Product extension: CT scanning
1982: Acquired Magnet Corp. of America	Vertical integration: superconducting magnets

[a]Diasonics' prime purpose i, acquiring Fischer Imaging Corp. was to obtain radiographic and fluoroscopic equipment to which it could add its comPuter software. Fischer Imaging Corp had, by May 1983, already made a commitment to NMR imaging, but had not yet begun extensive R&D.

[b]Fischer's May 1983 marketing agreement with M&D Technology Ltd. was an attempt to extend its product line into NMR imaging without having to conduct extensive R&D efforts, Two weeks after signing the agreement, Fischer was acquired by Diasonics.

[c]JEOL of Japan had been manufacturing NMR spectrometers since 1960 Following its acquisition by Mitsubishi, R&D efforts continued but It was not until 1982 that the company formally entered the NMR imaging field.

[d]Johnson & Johnson had developed interest in NMR imaging as early as 1977, but it was not until after the acquisition of Technicare (and its CT technology) that serious R&D efforts into NMR imaging were undertaken

SOURCES Interviews with manufacturers, Arthur Young & Co., 1981 (9), and Emmitt & Lasersohn, 1983 (60)

Diasonics' acquisition of the Pfizer-UCSF technology, Picker used its new technology to accelerate its market entry and to catapult to the industry forefront.

At least three mergers in the industry have involved vertical integration. In one case, integration has been "backward": Technicare's purchase of Magnet Corp. of America for the purpose of building its own superconducting magnet systems (see subsequent discussion in this chapter of the magnet manufacturing industry). The other two mergers represent "forward" integration whereby Diasonics acquired companies to expand its sales and distributorship network to specific geographic areas (see table 12 and later discussion in this chapter of vertical integration under "industry conduct").

Trade agreements involving marketing and distribution rights are fairly common in the industry, and those listed in table 12 are probably but a subset of all transactions that have taken place. Joint research ventures among firms, on the other hand, are rare, if not nonexistent. Manufacturers tend to be secretive about their NMR imaging designs and place units in clinical settings only if the hospitals agree not to accept a companion unit from a competitor for comparative study purposes.

As the NMR imaging device industry matures, one may expect further market extension and product extension mergers as some smaller firms are acquired by larger competitors or by firms seeking to enter the industry.[12] A high degree of vertical integration is also likely, as many firms will seek to expand internal capacity for marketing and distribution of products and for production of NMR component parts (e.g., magnets, cryogenic systems, and computer consoles and software). Magnet production capabilities are particularly important to manufacturers who wish to minimize both production costs and delays in receiving supplies in order to stay competitive with other companies. In addition to Technicare, which owns a magnet company, at least five other firms (Bruker, Diasonics, Elscint, Fonar, and Nalorac Cyogenics) possess in-house magnet manufacturing capabilities, while another seven plan to vertically integrate this function over the next 2 to 5 years.

The Magnet Manufacturing Industry. The magnet manufacturing industry is considerably more concentrated than the NMR imaging system manufacturing industry, Only a small number of firms make superconducting magnets, and little is known about manufacturers of resistive magnets.

According to a report from Hambrecht & Quist, as of September 1982 the majority of superconducting magnets used in NMR imaging systems worldwide had been supplied by a single manufacturer, Oxford Instruments, Ltd., a company based in the United Kingdom *(80)*. For the year ended March *1983*, Oxford Instruments had sales of *30* million English pounds, with profits of over 2.5 million pounds, an increase from 17.7 million pounds in sales and approximately 2 million pounds in profits in 1981-82 (1 19). In 1983, Oxford Instruments produced about six magnets per month and had secured long-term contracts to supply magnets to several NMR imaging manufacturers, including General Electric and Siemens (119). These orders would require an increase in Oxford's production capacity to about 12 magnets per month (119). To fulfill this increased demand, Oxford planned to hold a public stock offering in *1983* to secure funds to expand its production capability (119), and opened a manufacturing facility in the United States in a joint venture with Airco, Inc. (51). (Airco, a subsidiary of the British Oxygen Co. International, Ltd., has the capability of producing superconducting materials required in the manufacture of superconducting magnets.)

According to a 1982 prospectus issued by an American magnet manufacturer, Intermagnetics General Corp. (IGC), there are at least six American manufacturers selling superconducting magnets to NMR imaging manufacturers. To date, however, compared to Oxford Instruments, Ltd., these magnet manufacturers have not supplied significant numbers of superconducting magnets to NMR imaging manufacturers.[13]

[12] The acquisition of OMR Technology' by Xonics in late 1983 is a further example of product extension.

[13] IGC for example has been involved for over 10 years in the manufacture of the materials from which super-conducting magnets are constructed. Recently, it has begun applying its expertise in superconducting technology to the development of superconducting

Two principal superconducting materials are commercially available for the construction of superconducting magnets: niobium - titanium (Nb-Ti) wire and niobium - tin (Nb_3Sn) tape. According to the 1982 IGC prospectus, there are several foreign manufacturers of Nb-Ti and Nb_3Sn. and IGC is the leading domestic producer of both materials (150). Airco, Inc.; Magnet Corp. of America (now a subsidiary of Technicare); and Supercon, Inc., are the other domestic suppliers of Nb-Ti and Nb_3Sn.

magnets for use in NMR imaging systems. IGC increased its R&D expenditures from $264,000 in fiscal year 1981 to $1.5 million in fiscal year 1982 to help develop its magnet manufacturing capacity (104). It is currently manufacturing 0.5 tesla (T) and 1.5 T magnets. IGC supplied its first 1.5 T magnet (to Columbia-Presbyterian Medical Center) in March 1983 and planned to produce one to three magnets per month for the remainder of 1983. IGC has also begun construction of a new factory, which should be operational by 1984 and which will double its magnet production capacity. As of the end of August 1982, IGC had a backlog of $2.2 million in orders for superconducting magnets from NMR imaging manufacturers **(105).**

Oxford Instruments is the major supplier worldwide of resistive magnets for NMR imaging systems (80). Technicare and Bruker manufacture their own resistive magnets, and Fonar and OMR make their own permanent magnets.

With magnets accounting for an estimated 30 to 50 percent of the cost of NMR imaging systems,[14] it is not surprising that NMR imaging manufacturers are seeking to develop their own capacity to produce magnets. As stated previously, our survey of manufacturers found that six firms now produce at least some of their own magnets and seven others plan to develop their own capacity to manufacture magnets. According to IGC, however, it is unlikely that NMR imaging manufacturers will be able to meet their magnet supply needs themselves, and they are likely to want to have more than one source of magnets (154).

[14] According to M. J, Ross of IGC, 0.5 T magnets cost $300,000 to $350,000 and 1.5 T magnets cost over $500,000 (154).

INDUSTRY CONDUCT

The structural characteristics of the NMR imaging device industry (i.e., its high seller concentration, relatively easy market entry, considerable diversification, high degree of acquisition and merger activity, and low buyer concentration) have conflicting implications for competition among manufacturers. The behavior, or conduct, of the market is likely to be influenced not only by the policies and actions of individual firms, but also by their *reactions* to the policies of their rivals, Two important aspects of industry and market conduct are product pricing policies and nonprice competition strategies.

Product Pricing Policies

Based on interviews with manufacturers in 1983, the estimated sales price of a resistive magnet system is likely to range from $800,000 to $1.2 million. Superconducting magnet systems, depending on size and field strength, are expected to command prices between $1 million and $3 million, with the median expectation closer to $2 million. Since the FDA has only recently granted premarket approval for NMR imaging devices, there has been little experience with product pricing and sales.

Most of the manufacturers queried about sales price felt that it would not be a significant factor in determining future company market share. They instead stressed the importance of nonprice factors in differentiating their products from those of competitors (see discussion of product differentiation in this chapter). Only four firms viewed sales price as key to the coming competition for market share. Two companies expressly plan to segment the market on the basis of price, with lower magnet strength, less expensive NMR systems being offered to community hospitals and private radiology groups that may lack the requisite financial resources for purchasing the higher magnet strength, more costly models. One firm intends to develop medium-sized superconducting magnet systems that would sell for as low as $500,000 to $700,000. All four believe, though, that industrywide prices will decrease in the long-term (3 to 7 years from now) if for no other reason than that: 1) new magnet designs may lead to some efficiencies, 2) increased vertical integration in many companies should reduce production costs and create economies of scale, and 3) further experience with NMR imaging in clinical applications may point to an optimal system configuration that is less expensive to produce. It should be noted, however, that increased vertical integration could actually result in higher prices if such activity serves to diminish competition in the industry.

At least two manufacturers also believe that price cutting will not evolve simply as a consequence of the factors cited above, but rather become a conscious policy of the larger firms intent upon weakening and acquiring, or possibly driving out, smaller competitors. Such "predatory pricing" policies are employed in other industries (31). Their application here would, in the long run, make the NMR imaging device industry more concentrated than the current trend suggests (see earlier discussion of seller concentration and market share in this chapter). On the other hand, if one draws inferences from the experience with X-ray CT scanning, price competition may play little or no role in the coming industry "shakeout." Rather, as the next section suggests, nonprice factors may prove more important to company strategies.

Nonprice Competition

Product differentiation and vertical integration are both expected to figure prominently in the nonprice competition strategies of NMR imaging device firms, Given the diversity of potential buyers, the ability to differentiate one's product favorably from that of a rival may prove important to future company sales and market share. Vertical integration, in addition to its obvious economic benefits, may offer further advantage by raising barriers to entry for potential rivals (31),

Product *Differentiation.* Interviews with manufacturers have led to the identification and relative ranking, by tier, of nine *nonprice* factors considered important to NMR product differentiation in *future* sales efforts. In descending order of relative importance, [15] these elements are:

First Tier (4 factors):

1. Image quality—high-resolution images of various soft tissues in the head and body are considered essential to product sales. Almost without exception, this factor ranked first or among the top tier of elements.
2. *Product features and* capabilities—product features refer to the magnet type and field strength, bore size, radiofrequency coil design, computer system console and software, cryogenic systems for superconducting magnets, magnetic shields, etc. Product capabilities refer to measurement of T_1 and T_2 relaxation times, imaging capabilities, and spectral analysis capabilities in addition to proton NMR imaging. The relative importance of each feature or capability to a prospective buyer will depend on the buyer's fundamental imaging needs (e.g., clinical v. research) and level of sophistication. Innovative product capabilities, such as multislice imaging, are important means of product differentiation.
3. *Product* reliability—reliability is essential to the continuous operation of an imager and, therefore, is valued highly by prospective buyers. Lack of product reliability, such as the tendency for a magnet to "quench" (i. e., lose its magnetic properties), can have serious adverse effect on imager sales.
4. *Product* service—timely and responsive maintenance and repair service is important both for ensuring client satisfaction and for preserving company image. Distributor and service networks covering broad geographic areas are an important asset to marketing the product.

Second Tier (3 factors):

5. *Delivery time—at* present, delivery time can be very important to some buyers. Over time, however, as the industry matures and

[15] The reader should bear in mind that these views are those expressed by NMR manufacturers, which may or may not coincide with the percept ions of potential buyers and users of the technology.

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the production of NMR imaging units is streamlined in many firms, delivery time should become less important to buyers.

6 *Long-term viability* of *the manufacturer*—the larger, more well-established firms believe that size and tradition are important assets, and that buyers respond positively to companies whom they perceive to be viable for years to come. The smaller, newer firms concede this point, but argue that *product* characteristics (e.g., features and capabilities, image quality, reliability) will take precedence over company characteristics in determining future NMR imaging sales.

7. *Guarantee against technological obsolescence*—when purchasing expensive, new technologies, buyers frequently want assurance that the model they purchase today will not become obsolete in a short period of time. With a technology that is evolving and changing as rapidly as NMR imaging, such guarantees are difficult to make. Several manufacturers, therefore, have either: 1) delayed introduction of a commercial prototype until optimal system design can be satisfactorily determined, or 2) designed NMR systems that can be "upgraded" to accommodate new imaging needs or new advances in technology as they arise. However, when compared with other factors listed in the first tier, guarantees against product obsolescence were secondary in importance.

Third Tier (2 factors):

8. *Collaborative research—at* present, in the premarket stage of NMR imaging R&D, collaborative research with clinical centers holds great importance for manufacturers and hospitals alike. In the future, however, many firms expect that collaborative research will hold no more than tertiary importance (relative to the preceding factors) in influencing buyers' purchase decisions.

9. *Training and education—a* few firms believe that providing training services to buyers may become a distinguishing feature of some manufacturers' marketing and sales strategies. The relative importance of this factor to future sales, though, is not expected to be high.

Overall, product differentiation is emerging as an important part of each NMR manufacturer's nonprice competition strategy. Fonar Corp., for example, is placing great emphasis on its permanent magnet design. ADAC Laboratories, an acknowledged leader in "add-on" computer systems for diagnostic imaging modalities (185), intends to emphasize the company's strengths in image processing, data communication, and radiofrequency coil design as part of its marketing strategy, in addition to pursuing proprietary permanent magnet designs. General Electric has adopted a different tack, developing a 15 kilogauss superconducting magnet prototype, which the company believes will appeal to hospitals concerned about buying "adequate" magnet strength. Nalorac Cryogenics expects to differentiate its product by offering superconducting magnet systems that can operate within 10 to *20* kilogauss, but which can also be upgraded to 40 kilogauss for high-resolution animal studies and NMR spectroscopy. Regardless of the specific strategy employed, it seems clear that product differentiation will be important to each manufacturer's success and, in some cases, corporate survival.

Vertical Integration. In the earlier discussion of industry structure and corporate acquisition and merger activity, vertical integration in the NMR imaging device industry appeared to have important implications for production costs and, hence, for product pricing policies. Vertical integration can also be used by manufacturers to coerce rivals and influence market entry. For instance, in the NMR imaging device industry, the forward integration of distributorship networks could impede other firms from selling their products in some areas. Similarly, backward integration of magnet manufacturers could conceivably bar entry to potential competitors who are not capable of producing their own magnets and, therefore, must depend on outside suppliers.

Although at least one case of backward integration involving magnets has taken place in recent years (see Technicare in table 12), it is not likely that NMR manufacturers will gain control of either of the two major worldwide magnet suppliers (Oxford Instruments and Intermagnetics General Corp.). Instead, the net effect of many NMR manufacturers' plans to develop in-house magnet manufacturing capabilities will likely be to achieve greater independence from the magnet suppliers. An individual NMR imaging firm that chooses this strategy could gain a competitive edge only if its rivals did not vertically integrate in similar fashion, or, assuming that its rivals did follow suit, if its magnet operations were more efficient or produced higher quality magnets than those of its competitors. Vertical integration in the NMR imaging device industry, therefore, is more likely over the long run to influence industry conduct (i. e., product pricing and product differentiation) than industry structure (i.e., market entry by newcomers).

INDUSTRY PERFORMANCE

Industry performance is most frequently evaluated in terms of the efficiency and profitability of its firms (31). Common measures of *efficiency* include costs-to-sales ratios and percent of advertising or promotional costs-to-sales ratios *(9)*. Data on advertising and sales in the NMR imaging device industry are nonexistent because the FDA prohibits promotion and profitmaking sales during the premarket approval stage of development. Thus, the relative efficiency with which various firms allocate their resources to build NMR imagers cannot be determined at this time. It is expected that, following FDA approval, promotional activities will abound in the industry, largely for product differentiation purposes.

Profitability has been measured as the rate of return on investment (or assets) or the price-cost margin (i. e., the gap between price and marginal cost). As with the previous case of measuring efficiency, FDA prohibition on making a profit from the placement of an investigational device has precluded the quantitative assessment of NMR industry profitability. Available data on the X-ray and electromedical industry show returns on assets ranging from 5.6 percent for the larger firms to 11.4 percent for companies with smaller assets (9). It is expected that NMR imaging sales will likely become an important source of company revenues for many manufacturers over the next few years (60).

THE FUTURE OF NMR IMAGING IN RELATION TO OTHER DIAGNOSTIC IMAGING MODALITIES

Given the uncertainties regarding the nature and impact of future health care regulations, as well as the extent to which the clinical potential of NMR imaging will be realized, it is difficult to make estimates of future sales of NMR imagers with any degree of certainty.

Table 13 provides data on estimated sales of various diagnostic imaging modalities projected by F. Eberstadt & Co., Inc. *(60)*. As can be seen from the table, in mid-1983, worldwide sales of the diagnostic imaging industry were estimated at $4 billion per year, and this worldwide market is currently projected to continue expansion at a rate of 15 percent per year (60). Sales of ultrasound, digital X-ray equipment, and NMR imagers are expected to grow more rapidly than other segments of the diagnostic imaging market, primarily due to the reduction in or elimination of ionizing radiation associated with their use.

The table also shows that, despite a projected 21-percent increase in aggregate sales of X-ray modalities over the next 5 years, the percentage of all diagnostic imaging industry sales that can be attributed to X-ray modalities is expected to decrease by 41 percent (from a 72 percent to a 43 percent share) between 1983 and 1988. X-ray CT unit sales are projected to decrease during that time from $1 billion per year to $0.5 billion per year, a 76-percent decrease (from 25 percent down to 6 percent).

Table 13.—Diagnostic Imaging industry Sales Growth Projections

	1983(E)		1988(E)		1983 to 1988		
Modality	Market size ($ millions)	Percentage of industry sales (%)	Market size ($ millions)	Percentage of industry sales (%)	Overall percentage change in market size (%)	Annual percentage change in market size (%)	Overall change in fraction of industry sales (%)
All X-ray modalities	$2,900	72.5%	$3,500	43%	+21%	+4%	–41%
Conventional X-ray	(1,300)	(32.5)	(500)	(6)	(-61)	(–17)	(-82)
Digital X-ray[a]	(600)	(15,0)	(2,500)	(30)	(+317)	(+33)	(+100)
CT	(1,000)	(25,0)	(500)	(6)	(-50)	(-13)	(-76)
Ultrasound	750	19,0	1,900	23	+153	+20	+21
Nuclear medicine	250	6.0	300	4	+20	+5	–33
NMR	100	2,5	2,500	30	+2,500	+90	+1,100
Total	4,000	100,0	8,200	100	+105	± 15.0	—

[a]Includes both digital acid-on and full. systems with a digital capability

SOURCE R B Emmitt and J W Lasersohn, "Company Report on Diasonics," F. Eberstadt & Co , Inc , New York, May 26, 1983

NMR sales, in contrast, are expected to increase from $100 million per year in 1983 to $2.5 billion per year in 1988 (see tables 13 and 14 and fig. 11), an annual rate of growth in market size of 90 percent. According to this estimate, the percentage of industry sales attributable to sales of NMR imaging systems will increase from 2.5 percent in 1983 to 30 percent by 1988. The estimated rate of growth in worldwide NMR sales displayed in table 14 can be compared to a worldwide growth of X-ray CT unit sales of approximately *600* units per year over the first *5* years of X-ray CT availability (59). Most manufacturers with whom we spoke believed that the **50-50** percent split between U.S. and non-U. S. sales currently existing for X-ray CT systems will be observed for NMR sales as well.

It is useful to consider the assumptions on which the estimates are based. First, the estimates assume that, given the expected change to prospective systems of hospital payment, the hospital industry will be unable to bear a major increment in capital expenditures over the next several years. It is assumed, however, that although the rate of increase of *hospital* expenditures on imaging equipment may slow over the next several years, the slowing will be offset by increases in purchases by *private* radiology groups and that the recent growth in sales of diagnostic imaging equipment of **15** percent annually will remain constant over the next 5 years.

The second major assumption is that, at least in the near future, sales of NMR imaging systems will compete primarily with sales of X-ray CT systems. This situation is thought to be the case because both systems provide cross-sectional tomographic images with what is expected to be similar spatial resolution in the near future. The estimates therefore assume that many hospitals will be making decisions about purchasing either NMR imagers or X-ray CT scanners.[16]

[16]This will also be the case for hospitals that have one or more X-ray CT scanners and are contemplating buying additional ones, In 1980, more than 100 U.S. hospitals had more than one X-ray CT

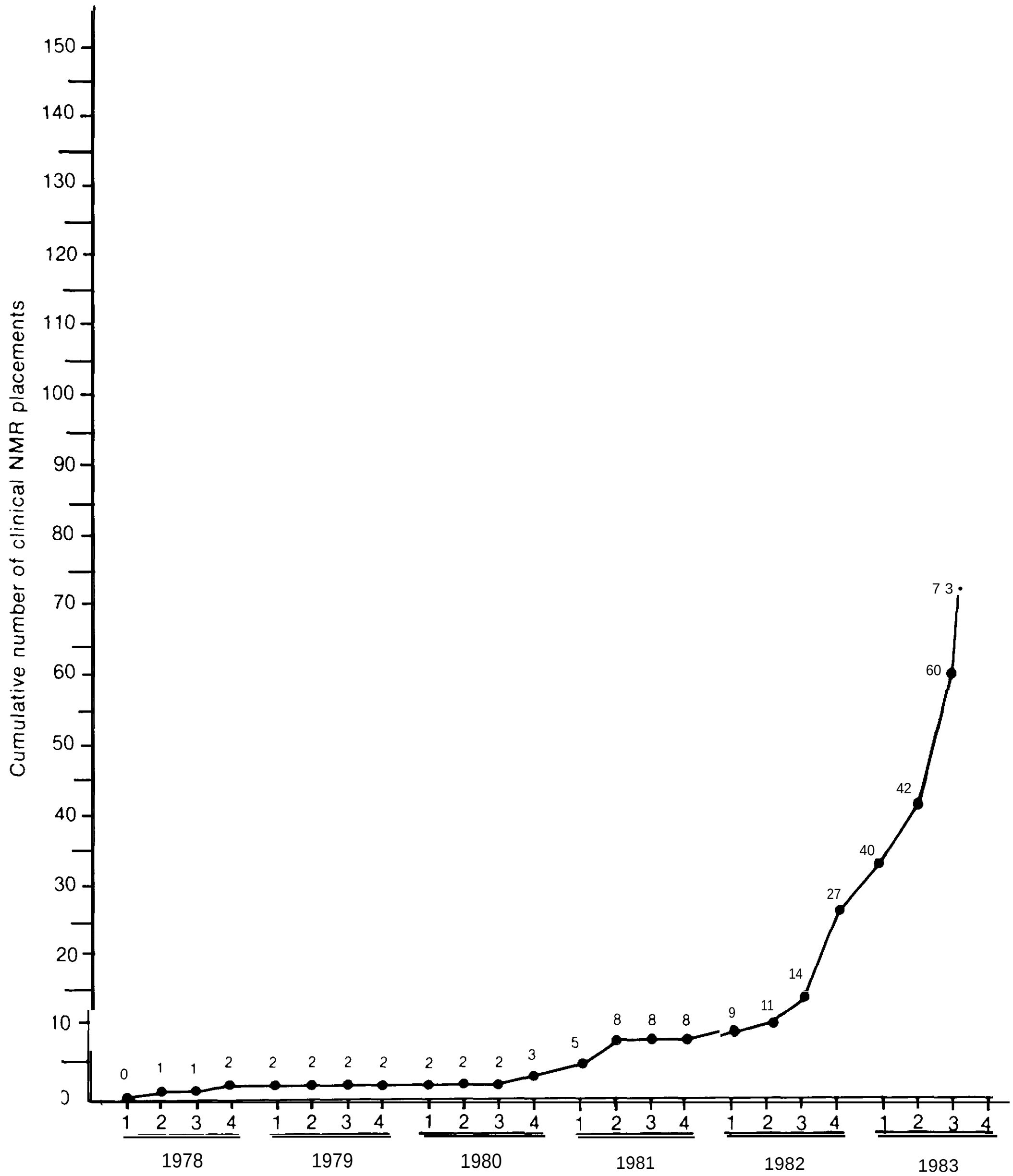
Table 14.— Estimated Worldwide NMR Market

Year[a]	Annual unit deliveries	Cumulative unit deliveries	Average sales price	Annual sales ($ million)
1982	15	15	$1,300,000	$ 20
1983E	75	90	1,300,000	100
1984E	200	290	1,500,000	300
1985E	400	690	1,600,000	650
1986E	650	1,340	1,700,000	1,100
1987E	905	2,290	1,850,000	1,750
1988E	1,250	3,540	2,000,000	2,500

[a]E = Estimated

SOURCE R B Emmitt and J W Lasersohn, "Company Report on Diasonics," F Eberstadt & Co , Inc , New York, May 26, 1983

Figure 11.—Cumulative Number of Worldwide Clinical NMR Placements Over Time



SOURCE: Interviews with NMR manufacturers

The third major assumption is that, if NMR imaging did not exist, the growth in X-ray CT-guided procedures would increase the sales of X-ray CT systems by **10 to 15** percent per year. Given current, annual sales of 1,000 X-ray CT units worldwide, this assumption implies that, without NMR, there would be the potential for sales of *2,000* X-ray CT units per year in *1988*.

The fourth assumption is that, in the NMR versus X-ray CT competition for this *2,000* unit-per-year market in 1988, NMR will capture 1,500 of the projected 2,000 unit sales. It should be

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scanner and approximately 450 additional hospitals, all with more than 300 beds, had at least one X-ray CT scanner (59). Sixty percent of X-ray CT systems sold in the United States in 1982, in fact, were the second third or fourth systems acquired by a hospital (61).

noted, though, that while the model assumes that sales of NMR imagers will exceed sales of X-ray CT imagers in 1988, it does not assume that use of NMR will replace use of X-ray CT clinically in the near future. 17

Finally, the estimates assume an annual inflation rate of 5 percent.

In addition to it being difficult to predict the magnitude and nature of future diagnostic imaging equipment sales, it seems equally hazardous at this time to project what the character of the NMR imager manufacturing industry will be 5 years hence. Although no predictions can be made regarding how many or which of the current NMR imaging manufacturers will be involved in the field in 1988, two general comments can be made. First, to the extent that "turf battles" between radiologists, nuclear medicine specialists, pathologists, neurologists, and cardiologists develop over control of NMR imaging and spectroscopy, the market shares of large X-ray manufacturing companies that are currently based on radiology franchises may decrease (60). Second, although the emergence of new imaging modalities was thought to be the primary challenge to major X-ray manufacturers in the 1970s, it is anticipated that the rapidly expanding role of data and image processing across all imaging modalities will become the major challenge to X-ray equipment manufacturers in the 1980s (60). To the extent that this does, in fact, become the case, future concentration or fragmentation in the diagnostic imaging market may, in large part, be determined by the responsiveness of large diagnostic imaging conglomerates to this anticipated trend (60).

[17]It seems very likely that NMR will not replace X-ray CT in the near future. There may always be a role, for example, for X-ray CT in patients with metallic implants who will not be considered candidates for NMR, and for guiding biopsy or surgical procedures that employ metallic instruments. Furthermore, it is difficult to predict the extent to which X-ray CT scanning techniques will improve in the future. In the 10 years since X-ray CT scanners were introduced, their scanning speed has increased 300 times, their spatial resolution has increased 8 times, their density resolution has increased 3 times, and their radiation dosage to the patient has decreased markedly (15). In addition, new X-ray CT scanners are being developed that are capable of completing a scan in about 30 milliseconds, permitting performance of real-time cardiac X-ray CT imaging (15).