

### **Introductory Notes by Lewis M. Branscomb**

This case illustrates that radical technology innovations, to support new markets, are no easier to develop in a large, deep-pockets firm than they are in startups. The case involves the development of amorphous semiconductors by GE and their application to medical diagnostic imaging products. The obstacles facing this technology included not only the complexity of the technology and the vital importance of its manufacturability but also the fact that it is an infrastructural technology – a means to an end, but not an end product itself.

Thus, while the technical innovators believed with passion that the technology would enable a variety of business opportunities, from new displays to medical imaging, the long time required to perfect the technology had to find support from a market vision at every stage. Then technical champions of the technology had such market visions but in a company like GE the business units controlled the firm's business priorities and determined what technologies they believed they required to realize those priorities. In this case (as is often the case with radical technical change) the Medical Instruments business unit was not persuaded that amorphous semiconductors were worth the cost and the risk.

The second difficulty was the fact that GE was not alone in pursuing amorphous semiconductors, and other firms whose core businesses were outside GE's interests, might succeed ahead of GE unless GE could move fast.

Throughout this case the amorphous semiconductor program, which like all such projects was subject to periodic reviews, was repeatedly considered for cancellation. Its champions were in Corporate Research throughout most of the period of this case. Its skeptics were in the management of the medical instruments business. It was necessary to appeal to Jack Welch, the CEO, to adjudicate the dispute; his intervention kept the program alive at a crucial point. But many months of work remained ahead before the technology would be ready for production and product introduction. It would be unreasonable to expect Welch to intervene a second time if the program did not make its goals.

It was in this situation that GE looked to ATP for a project to ensure the technology's manufacturability. The award constituted an endorsement of the breadth of value of the technology, provided support for partnership between GE and a smaller firm, Perkin Elmer, which would be the initial manufacturer, and kept the project funded while leadership of the Medical Instruments business unit was changed to an executive who was positive about the importance of the technology to his business unit.

The fact that the more efficient manufacturing process for amorphous semiconductor devices, developed under the ATP grant, was not used in the initial Mammography product introduction was primarily due to the unexpected, but very welcome success of the product. The cost burden of the 12 mask process used was not sufficient to prevent the acceptance of the product. Much of the technical learning will find its way into the evolutionary extensions of the production technology.

Should ATP have funded this project at GE? It would appear that the technology was highly successful, and two substantial benefits to US society resulted: the early and successful introduction of more efficient and effective tools for protection human health and a new electronics technology that will probably find a wide range of applications in the future. But would GE have succeeded without the ATP program? Would GE have sustained its rate of investment in the mammography program and the supporting amorphous semiconductor technology absence ATP support?

These questions are all the more salient as policy issues because the political objection that is sometimes voiced that large firms need not – and should not -- receive funding from ATP, although their collaboration with smaller firms supported by ATP may be highly desirable.

In 1995, when GE applied for the ATP grant to develop a more reliable and lower cost production process, they could not know that the 12 mask process used in the research pilot line would support scale up for product introduction, nor that the Senographe product would be so successful, even without the new production process.

The GE people involved recall that the ATP program allowed the momentum of the development program to be sustained. In the case of the mammography product, as in most high tech innovations, getting to market quickly was essential. Thus the program would perhaps have continued without ATP, but the business risks would have been seen as higher, the program might have been somewhat delayed, and the success of Senographe might have been significantly diluted.

**A Clear View of Innovation:  
Mammography Goes Digital  
By Bob Kolasky**

On the morning of April 4, 2000, in Washington, D.C., General Electric (GE) unveiled “the world’s first digital mammography system,” offering an alternative to film-based breast screening.<sup>1</sup> At the Washington event, Jeffrey Immelt — then head of GE’s Medical Systems business (GEMS), and soon to be Jack Welch’s successor as CEO of the whole company — feted representatives of the Department of Defense, the Department of Health and Human Services, and the Department of Commerce, praising the role that the U.S. government had played. Development of GE’s “Senographe 2000D” digital mammography system was an “example of the power of public-private collaboration,” said GE’s Director of Government Relations, J. Keith Morgan.<sup>2</sup> Like most soundbites, however, Morgan’s comment barely begins to tell the entire story.

After working on amorphous-silicon (a-Si) technology for more than twenty years, GE had used it to create a digital breast-screening device, and, for its effort, the company would be rewarded: by 2001, the digital mammography business was a half a billion dollar one annually, and it is expected to grow.<sup>3</sup>

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1 General Electric Medical Systems press release, April 4, 2000.

2 Ibid.

3 Author interview with Lonnie Edelheit, August 28, 2001.

Digital mammography technology benefits women who undergo breast-cancer screenings. It allows faster and potentially more accurate screening, with less exposure to dangerous radiation than film-based mammography machines, and its images allow doctors to do more detailed examinations. Digital medical imaging technology also has the potential to improve many other health care techniques including cardiology, radiology and angioplasty.

The story of the advent of this particular medical imaging device is not just a healthcare story, however. It is also a story of how a technology that showed promise as far back as the 1970s finally came to fruition. It is a story of how one company was able to recognize that promise and keep pursuing the technology despite the fact that, for a long time, there were few tangible rewards. It is a story of how that company was able to manage the technical risk of innovation during those twenty years. And, it is a story of collaboration between the U.S. government and one of America's biggest and most venerable companies.

### **A flexible electricity option**

The core technology for GE's digital mammography system was based on methods developed by GE researchers to use amorphous silicon in thin-film transistors (TFTs) on flat-panel digital detectors for medical imaging. As x-rays hit the panels, they turn into digital signals and are fed into computers that capture the image almost instantaneously.<sup>4</sup>

Conceptualized as a substitute for crystalline silicon, amorphous silicon's appeal as a noncrystalline compound lies largely in its flexibility, a flexibility which allows it to be used in a variety of applications. It also enhances the performance of the photovoltaic cells in which it is placed; this theoretically permits faster electronic reactions and higher-resolution displays. It is thus "unmatched as a photoreceptor for ... the switching material in large area liquid crystal displays [LCDs], for large photovoltaic panels and any other application that needs a high quality semiconductor that can be processed on large, curved or flexible substrates."<sup>5</sup>

Research with amorphous silicon began in England around 1968. By the 1970s, university physicists were conducting research with the material, as were scientists at RCA, Xerox, and other corporations.<sup>6</sup> In 1977, an RCA scientist was granted a U.S. patent for the use of amorphous silicon semiconductor devices in solar cells.<sup>7</sup> "The attractive feature of [amorphous silicon] technology is that once you get this down, you can address a whole range of marketplaces," says Mark Myers of Xerox. "Solar cells, all kinds of printing mechanisms, scanning imaging, medical imaging and ... flat-panel displays."<sup>8</sup>

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4 Didier M.C. Thibaud, "Digital Technology Pulls X-Rays Into the 21st Century," *Advanced Imaging*, June 1, 2001, p. 8.

5 Hellmut Fritzsche, ed., *Amorphous Silicon and Related Materials*, Vol. 1 of *Advances in Disordered Semiconductors*, Vol. 1) 1989, p. 4.

6 Fritzsche, *Amorphous Silicon and Related Materials*, p. 8.

7 *New York Times Abstracts*, February 24, 1977, p. 29, Col. 1

8 Mark Myers at Conference: "Between Invention and Innovation: Mapping the Funding for Early Stage, Technology Based Innovation," January 25, 2001.

From the late 1970s on, a number of large industrial companies — including RCA, Xerox, Ovonic Imaging Systems, Inc. (OIS), Toshiba, and Phillips, as well as GE — sought to develop products that took advantage of the qualities of amorphous silicon. One of the earliest applications explored was solar cells, spurred by the energy crisis of the 1970s. It was for that reason, and others, that, in 1979, General Electric was conducting research around amorphous silicon — research that almost two decades later would pay off with its success in digital mammography.

### **Shifts in GE's R&D Strategy**

Founded in the late 19<sup>th</sup> century, GE quickly established a reputation as one of the most innovative companies in the United States; its technical prowess had contributed greatly to its size and strength. The 1970s, however, had not been a period of great growth for GE.<sup>9</sup> GE's slow growth during that period was, in company lore, blamed in part on an outdated strategy toward corporate research and development.<sup>10</sup>

When Jack Welch became CEO in 1981, his goal was for the company to become "more high-spirited, more adaptable and more agile." Welch later wrote that, at that time, "some employees proudly described the company as a 'super-tanker' — strong and steady in the water. I respected that but wanted the company to be more like a speedboat, fast and agile, able to turn on a dime."<sup>11</sup> Part of that transition involved the implementation of a new corporate research and development (R&D) strategy.

At the beginning of the 1970s, "GE's lab was doing applied research that wasn't connected very closely to the business," says Lonnie Edelheit, who today serves as GE's Senior Vice President for Corporate R&D and Chief Technical Officer. A spokesman for GE's Corporate Research and Development Center (CRD) says that 75 percent of the company's R&D funding in that period came directly from General Electric's headquarters, and it was mainly up to the people at CRD to decide how to spend it. As a result, says the spokesman, "there was a lot of blue-sky R&D going on," only tenuously related to potential products and markets.

If GE's research lab were to be more responsive to the market opportunities that technological innovation presented, the best way was to create a system in which most R&D decisions were driven by the needs of the various businesses within the company. Welch removed control of most R&D funding from CRD, placing it in the hands of GE's operating units. The operating units — plastics, industrial systems, medical systems, avionics, and the like — were accountable to ever-changing markets. "We wanted to make R&D work more closely tied to the operations plan," says a GE spokesman.

The motivation behind the shift in mentality was that GE's research lab needed to be more responsive to the market opportunities that technological innovation presented and the best way to guarantee such responsiveness was to create a system where most R&D decisions were driven by the needs of the various businesses within the company. In practical terms, this shifted the emphasis from blue-sky research to short-term technical projects. Technology development at GE became more evolutionary than revolutionary.

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9 John P. Kotter and James L. Haskett, *Corporate Culture and Performance* (New York: The Free Press, 1992), p. 84.

10 Author interview, September 17, 2001, Schenectady, NY.

11 Jack Welch with John A. Byrne, *Jack: Straight From the Gut* (Warner Business Books, 2001), p. 127.

This change in research culture paid immediate dividends for GE. The company's rapid growth during the early part of Welch's tenure was due, at least in part, to the ability of GE's business units to move more quickly than their competitors. But it also reduced GE's capacity for radical, science-based product innovation. To get significant funding for research into an early-stage "enabling technology," there needed to be justification from an identified potential application, and progress had to be measured against the realization of that prospective application. This would hinder development of early-stage technologies like amorphous silicon.

It was amidst that shift of R&D culture that GE began to first do extensive research in amorphous silicon. With solar energy becoming less prominent to the company's future, the he initial prominent area of concentration was flat-screen displays. "In 1982, we started working on amorphous silicon thin film transistors with the objective, the specific objective, of active matrix displays,"<sup>12</sup> says Bruce Griffing, who served for more than a decade as Manager of Technical Development at CRD. Through its CRD labs in Schenectady, New York, GE placed substantial resources into developing and perfecting Liquid Crystalline Displays (LCDs) for use in display panels. GE had its eye on two markets: flat-screen televisions and airplane cockpit displays. Both were seen as potentially great opportunities for the company. Ultimately, however, neither would pan out for GE.

### **GE's Attempts to Enter the LCD Market**

GE had many competitors in the display market. Flat-screen displays using LCD technology were considered a significant improvement over other display processes, especially those using cathode-ray tubes. Advantages included a better range of colors, more contrast, larger screens, more compact forms, and expanded viewing angles. Practical production of usable flat panel displays was a prerequisite for realization of laptop computers. Amorphous silicon was considered key to such displays because it was more flexible and faster than other materials, without necessarily consuming more power.

During the 1980s, in addition to flat-screen televisions and laptop computer screens, there were several other applications for which amorphous silicon technology offered potential performance improvement, including scanners, airplane cockpit displays, and medical imaging devices. GE primarily focused its amorphous silicon research on flat-screen television and airplane cockpit displays and on medical imaging devices.

These three applications required different research into amorphous silicon. Flat-screen displays and airplane cockpit displays required the building of amorphous-silicon-based display screens, while medical imaging devices required amorphous-silicon-based detectors. So, while the corporate lab was working on the same technology for both markets, the actual development of the technology was differentiated based on application. For display technologies, the main challenge was to create a liquid crystal display with an amorphous silicon thin-film transistor in every pixel of the display. The ability to control each pixel separately allows for better viewing angles, more distinct colors, and faster refresh rates. A large part of the challenge was that

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<sup>12</sup> Bruce Griffing at Conference: "Between Invention and Innovation: Mapping the Funding for Early Stage, Technology Based Innovation," January 25, 2001.

production standards must be extremely high; a defect in even a few of the hundreds of thousands pixels can ruin the picture. Developing amorphous-silicon based detectors offers some of the same challenges, but the scientists also faced problems related to integrating photodiode technology into the detection panels.

GE's first substantial research on flat-panel displays using amorphous silicon technology was done in conjunction with its avionics unit. Since 1979, the company had had a contract with Boeing to develop LCD-based cockpit instruments for use in jets in place of electromechanical instruments.<sup>13</sup> The theoretical advantages of LCDs included more powerful graphic capabilities, easier maintenance, lower energy demands, and lighter weight.

GE also began investigating amorphous silicon technology for use in flat-panel televisions. In late 1985, GE purchased RCA Corporation, one of the world's largest producers of consumer electronic goods. RCA scientists had already been working with LCDs. The purchase of RCA coincided with GE's decision to shut down most of its own consumer electronics division. Thus, most of GE's flat-screen television efforts were concentrated in RCA's consumer electronics division. (At the same time, GE's work on LCDs for airplanes continued.) RCA faced intense competition from other consumer electronics companies, particularly Asian companies such as Toshiba and Samsung, for the flat-panel television market — a battle RCA was destined to lose. GE, however, did not hang onto RCA's consumer electronics business long enough to find out. In July 1987, GE sold its entire consumer electronics operation to the French electronics company, Thomson S.A. Soon after this July 1987 sale, GE was out of the consumer electronics business entirely. Griffing says:

GE's view about consumer electronics was that it was a commodity business. It would not be a high margin business going forward and that's why we didn't pursue it, and that's one of the reasons we didn't pull amorphous silicon along that particular direction.<sup>14</sup>

While GE was selling RCA's consumer electronics business and getting out of the market, Japanese electronics companies ended up dominating the early flat-screen display market for consumer goods. Meanwhile, GE was also in the process of making a decision to abandon the avionics market. By the early 1990s, the company had cut back on almost its entire avionics operations. "There was too much capacity chasing too little business," writes Welch.<sup>15</sup> Thus most of GE's research in two applications of amorphous silicon technology — flat-panel televisions and cockpit displays — came to an end.

### **CRD Focuses on Medical Imaging**

By the early 1990s, therefore, most of GE's research on amorphous silicon focused on medical imaging devices and thus on amorphous silicon detectors rather than amorphous silicon displays. This focus was a benefit, according to the scientists working in the lab. "The display business fortuitously die[d] at the right time," says George Possin, who had been a member of the research

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13 Kenneth J. Stein, "General Electric Developing LCD Matrix Displays with Thin Film Switches," *Aviation Week*, February 18, 1985, p. 149.

14 Griffing, Conference, January 25, 2001.

15 Welch, *Jack*, p. 145.

team working primarily on amorphous silicon technology, and who would later be the technical head of the amorphous silicon component of CRD's medical imaging project. "We probably couldn't afford to have done both display and medical imaging."<sup>16</sup>

Digital detectors (or imagers) are different than displays in that they combined the display technology of amorphous-silicon TFTs with an amorphous-silicon photodiode array, which controls how an image is gathered. A photodiode array is a linear series of discrete photodiodes on an integrated circuit chip. Photodiode arrays can detect optical signals and convert them into electrical signals. (In a way, it can be thought of as an electronic version of photographic film.) The integration of those two devices was a complicated process for GE engineers and it would take years of work in the labs to get the technology to a feasible level.

That period was an exciting time for the scientists working on the technology in GE's corporate lab in Schenectady. The abandonment of the LCD display market allowed for single-minded focus in research on medical imaging devices. Great strides were being made in integrating an amorphous silicon TFT panel with photodiode technology to provide faster, higher-quality images. Perhaps as a sign of the potential of the project, the CRD dubbed it the Apollo Project. Brian Giammbatista, who joined CRD as a physicist in 1989 working primarily on the Apollo Project, recalls that:

The process started at GE in 1986 or 1987. It was a very small project. 1989 was really when the project was growing. We were adding people. We were scaling up from a relatively small four-inch round glass to an eight-inch square glass.... [We were saying] now let's go up to something that is close to what an actual product would be and see if we can scale up and get good yield and maintain a good performance.<sup>17</sup>

The question of yield would remain an issue for the scientists for most of the next decade. It was crucial that GE's scientists be able to increase the yield of the amorphous silicon panels. (In this context, yield refers to the percentage of amorphous-silicon based panels with sufficiently low defect rates that the company's production line is able to produce. The higher the yield, the more efficient a manufacturing process is.) Given the complexity of the technology, a tiny speck of dirt has the potential to adversely effect yields as it might make the number of defected pixels to be large enough so as to render the image quality of the panel insufficient.

Eliminating the fuzziness of the digital images taken by amorphous silicon devices — the "noise" — was another one of the key challenges to the eventual use of the technology in medical imaging. In employing the technology for imaging devices, it was critical that GE's engineers be able to reach an adequate signal-to noise ratio — that is the ratio of useful image information to erratic information. Noise is inherent in digital imaging chains, and can have a dramatic impact on image quality. Around that time, Possin recalls being convinced that CRD was on to something with its amorphous silicon work in medical imaging. "We understood the sources of noise," he says.<sup>18</sup> Thus, although it would still be about five years until GE would create prototype amorphous-silicon-based medical imaging devices to test in the market, both Giammbattista and Possin, two

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<sup>16</sup> Author interview with George Possin, September 17, 2001.

<sup>17</sup> Author interview with Brian Giammbatista, October 4, 2001. All subsequent Giammbatista quotes are from same conversation.

<sup>18</sup> Author interview with George Possin, September 17, 2001.

of the key scientists on the project, were confident that the technology would ultimately prove its worth.

Griffing was convinced, as well. "I thought it was important and that it really had the potential to change the game" of medical imaging, explained Griffing.<sup>19</sup>

Despite the optimism of the scientists in the lab, GE's amorphous silicon work was not particularly popular with the medical systems business. As Possin and Giammbatista's boss), Griffing's strong support would prove essential. At one point he even considered leaving the company in protest over GEMS lack of support for the program. Fortunately for him, he had an ally in Lonnie Edelheit.

"People disagreed on whether it could be done and how well it would work," says Edelheit, who returned to GE as the head of the CRD (and Griffing's boss) in 1991, after having left the company for most of the 1980s. "[With respect to] medical imaging, they disagreed with how much of a technological advancement it was, as well as whether it could be done cost-effectively." Given GE's now decade-old R&D philosophy, such an opinion was likely to sound the death knell for the amorphous silicon work being done in Schenectady. It would be "very unusual" for the corporate research lab to win a battle with a business about advancing a technology that the business didn't want, says Edelheit.<sup>20</sup> And the executives at Medical Systems clearly didn't think it was worth investing in amorphous silicon — so if the Apollo Project was going to continue to receive significant funds from GE, CRD would have to get support from outside of GEMS.

### **Welch Makes a Decision**

The book, *Radical Innovation: How Mature Companies Can Outsmart Upstarts*, memorialized the conflict within GE between the research team and the Medical Systems business.<sup>21</sup>

The GEMS division manager [was not] a supporter of the project. The manager was keen on the numbers and was highly regarded for achieving his financial performance targets in the current line of business. He was alarmed by the project's technical uncertainties and by the potential negative impact that further development would have on the short-term financial performance of the division.

Giammbattista recalls the researchers' perspective:

The people at the lab were very confident that here was something that would work with adequate resources applied, so that we would get the process developed and so we would get the yield up. We were more involved in the technical issues and we felt those technical issues certainly could be solved. I suspect maybe some of the people out of the technical area probably had some concerns about the cost.... There was probably some justification for that, because it certainly was draining a

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<sup>19</sup> Richard Leifer, et al., *Radical Innovation: How Mature Companies Can Outsmart Upstarts* (Harvard Business School Press, 2000), p. 35.

<sup>20</sup> Author interview with Lonnie Edelheit, August 28, 2001.

<sup>21</sup> Richard Leifer, et al., *Radical Innovation: How Mature Companies Can Outsmart Upstarts* (Harvard Business School Press, 2000), p. 138.

lot of money and taking a lot of resources at CRD and ... it was a new technology being developed. It wasn't going to happen overnight.

With the research lab and the business unit unable to agree on whether it was worth pursuing amorphous silicon research for medical imaging, somebody else would have to make the decision. Given GE's corporate structure, that somebody else was Welch himself. By this time widely recognized as one of the nation's foremost CEOs, Welch had a reputation for making decisions that were in the stockholders' interests. In this case, he had to decide between the short-term financial pressures of the Medical Systems business and the long-term potential recognized by CRD.

Edelheit played the role of the technology's champion with Welch. He himself had gotten "the hard sell from [the CRD scientists] when he came back [to GE in 1991]," says Possin. "He believed the story [of the potential of the technology] and staked part of his career on that."<sup>22</sup>

Welch had to decide between the arguments in favor of the research that were presented by Edelheit and Griffing and the counter-arguments of GEMS head John Trani. Eventually, he decided that the company should continue to fund the Apollo Project through GEMS' research budget, along with additional funding from GE's general research money, the so-called "Chairman's fund."<sup>23</sup>

Edelheit considers this perhaps the crucial moment in GE's research into amorphous silicon. Without Welch's support, the project "would probably have limped along with corporate funds [the Chairman's Fund] and a little money from Medical Systems," says Edelheit.

This would have happened because we had scientists who thought this was an attractive plan, but it would have been a low-level project. There is no way that we would have been a market leader. We would have waited until someone else developed the technology and then tried to play catch-up.<sup>24</sup>

The Apollo Project was still subject to regular assessments from corporate headquarters, as frequently as twice a year; at each point, CRD had to demonstrate that it was making progress toward the ultimate goal of finding a place for the technology in the market. It was not until 1996, says Edelheit, and Trani's exit from the company, that the Apollo Project got GEMS' full support.<sup>25</sup>

### **Knocking on the Government's Door**

By 1993, GEMS and CRD were concentrating GE's amorphous silicon research primarily on developing a cardiac x-ray unit that the company hoped would improve the quality and speed of cardiac examinations. Such a device would use an amorphous-silicon arrayed panel to take cardiac images. Patients would be subjected to less radiation, because the image sensors are more sensitive than film; the images would take less time to develop and less space to store than with analog or

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<sup>22</sup> Author interview with George Possin, September 17, 2001.

<sup>23</sup> Author interview with Edelheit, Nov. 14, 2001.

<sup>24</sup> Ibid.

<sup>25</sup> Ibid.

film-based systems; and the quality of cardiac pictures would, it was hoped, be higher than film. Cardiac imagery was considered the best market to try the technology, because it was a high-end market with strong demand for better imaging devices. At the same time, however, the company also recognized other potential uses for amorphous-silicon based medical imaging devices, among them mammography and chest x-rays.

Even though Welch had made the decision for GEMS to continue funding the Apollo Project (with a little help from corporate funds), CRD still did not have all of the funding that it needed to be able to develop the amorphous silicon technology sufficiently to support all the research that it wanted in order to develop medical imaging devices. Therefore the executives at CRD did what they often did when they had a technology they believed in, but not necessarily the financial wherewithal to prove it: They applied for additional funding from the federal government.

In applying for government money, CRD was thus following an oft-charted course. The company's research lab has a history of seeking external funding to complement internal funds to help new product innovation. And the number one source of such funds is the federal government. According to GE, almost 10% of CRD's annual research budget for both basic and applied research (\$327 million in 2001) comes from the federal government. (GE's overall 2001 R&D budget is about \$3 billion.) GE has gotten government funding from the Department of Defense, the Department of Energy, the Department of Commerce, and the National Institutes of Health, among others. The continued government funding of GE is a long part of the company's history and it is a symbiotic relationship that both sides claim is beneficial.

The government gives GE money because it has different priorities than the company has. Edelheit explains:

Industry can ... understand the forces in the market, establish a product plan to meet those demands, and develop or find the technology needed to execute those product plans. In general, we focus on technologies that we believe have the greatest probability of being successfully introduced into the market as GE products. The big questions for us are: Can we get the technology to market? How high are the risks? What are the rewards?<sup>26</sup>

The government cares less about market share and more about the creation of products with the potential to benefit the American people.

National needs are a little different than individual business needs, and if the government does not use money to influence those businesses, then many of its priorities might not be met.<sup>27</sup>

GE's amorphous silicon research for medical imaging devices appeared to government funders to be a technological innovation that would be in the public interest. There were thought to be considerable public health advantages if digital imaging could prove to be a workable technology, and GE was one of the leaders in the technology. In particular, three agencies of the federal government would offer the company money to continue its research on the technology: the

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<sup>26</sup> Edelheit, testifying to Congress, January 28, 1998.

<sup>27</sup> Ibid.

Defense Advanced Research Projects Agency (DARPA) of the Department of Defense; the National Cancer Institute (NCI) of the National Institutes of Health (NIH), part of the Department of Health and Human Services (DHHS); and the Advanced Technology Program (ATP) of the National Institute of Standards and Technology (NIST), part of the Department of Commerce.

DARPA gave GE its first significant government money for the Apollo Project, to do research on direct digital x-ray systems. DARPA's mandate was to invest in technical innovation and the organization claims that it is ready to entertain any new ideas that show potential for military use.

A digital x-ray system was just such an idea. For the defense industry, digital x-rays held a great deal of potential to treat combat injuries. Around 1993, DARPA was "interested in advanced applications for tele-medicine in the field," says Mike Dejule, the lead in managing GE's relationship with DARPA on this technology. "It was a time that the military was going digital."<sup>28</sup> Such x-rays would allow for quicker diagnoses of combat injuries: military doctors would be able to develop images a lot faster at field hospitals, and those images could be sent instantly to doctors, even thousands of miles away from combat, for expert assistance at making diagnoses. From 1994 to 1996, DARPA pledged more than \$3 million to GE for work in medical imaging. "It really had a big impact," says Giammbatista, "it kept the momentum going." By 2001, DARPA had contributed more than \$10 million to the project.

Dejule estimates that the DARPA money sped up GE's innovation process in digital medical imaging by one or two years. In exchange for the money, the burden on the company was relatively light; it was required to file in-depth annual reports and shorter monthly reports with the agency. "[DARPA] did not bog us down into ... a military [procurement] contract," says Dejule. "They let us have more flexibility. The goal of the project was to do a demonstration." In March of 1995, GE did just that, giving a live demonstration of amorphous-silicon-based digital x-ray imaging at the first national Military Tele-Medicine Forum.

### **A Shift toward Mammography**

DARPA was not the only federal agency that contributed money to GE's Apollo Project, however. The National Cancer Institute (NCI) was also an early supporter. In 1994, GE got a pledge of almost \$1 million from NCI to develop a prototype digital mammography machine. Dr. Dwight Kaufman, deputy director of NCI's cancer-treatment division, explained NCI's motivation for such grants. "Corporate decisions are sometimes made that a specific area wouldn't be highly profitable, ... with the urging and assistance of NCI, a corporation will get into that area anyway."<sup>29</sup>

In GE's case, NCI's strategy appeared to be highly effective. Its pledge coincided with GE's strategic decision to shift the focus of its medical imaging research. Instead of concentrating almost all of its attention on developing a cardiac unit, GE Medical Systems and CRD were able to focus on mammography as well. "We started out thinking cardiac; let's go for the big-cost, big-

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28 Author interview with Mike Dejule, September 17, 2001. All subsequent Dejule quotes are from same conversation.

29 Dr. Dwight Kaufman, quoted in Andrea Rock, "Cause vs. Cure," *Working Woman*, October 1, 1994.

profit technology," says Cynthia Landberg, a CRD physicist who worked on the Senographe devices. "But the NIH grant got us pointed toward digital mammography."<sup>30</sup>

GE had been working simultaneously on both mammography and cardiac technology as far back as the early 1990s as part of the Apollo Project. But, according to Edelheit, without NCI funding the company would not be able to continue its dual focus on both medical imaging innovations. What the NCI money did was allow for GE to continue working on both potential applications of its research. In other words, GE was able to hold off making a decision about which digital imaging device to take to market first. "I was into cardiac and the government was into breast cancer," explains Edelheit. "Without the government money we might not have been able to do both."<sup>31</sup>

In 1997, executives at GE decided that the company should concentrate on mammography as the first digital device that GE would bring to market. GE's digital mammography machines were similar to the cardiac machines and the related benefits were also fairly similar: less radiation, easier storage, potentially better quality. The machines combined the use of amorphous silicon panels with computer technology to greatly speed up the mammography process.

Giammatista describes the technical challenges in the shift of focus:

The pixel pitch is smaller for mammography — 100 microns versus 200 microns — so everything is a little smaller, so you are a little more sensitive to defects. Also the performance requirements are slightly different. There's some moderate fine-tuning of both the process and the design, but it's really the same technology.

Landberg attributes the shift in focus in direction in part to the politics of breast cancer. The NCI grant was symbolic of the fact that breast cancer was becoming a more prominent political issue nationally, with an increased demand for more effective ways of obtaining mammograms. If successful, GE's digital technology would have a ready market.

From the early 1990s on in the United States the importance of mammograms for women had been increasing significantly. Breast cancer was a disease that was receiving increased exposure and increased funding to combat it. More than ever, women were being urged to take preemptive steps to combat breast cancer and to be vigilant in checking for the disease when symptoms — usually a lump on a woman's breast — arose. The mechanism for doing both is mammograms and the number of screenings being advised and prescribed by doctors was rising rapidly. Mammograms are x-rays of the breast, and like other forms of x-ray, mainly use film technology. Screeners used film to take an x-ray image of the breast, waited for the image to develop, and then examined it for signs of cancer. The whole process generally took about 30 minutes, more if additional examination was required.

The process is not wholly efficient. For one thing, studies showed that film-based mammograms were not always as accurate as women would like – sometimes even falling below 90% accuracy

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<sup>30</sup> Author interview with Cynthia Landberg, September 17, 2001. All subsequent Landberg quotes are from same conversation.

<sup>31</sup> Author interview with Edelheit, Nov. 14, 2001.

levels.<sup>32</sup> Mammograms also expose the subjects to potentially unhealthy radiation. The amount of time it took to complete the process, inaccuracies, and related uncertainty might deter some women from getting screened.

In theory, digital technology offered an improvement on all of those factors. And it also had the benefit of not sharing the practical disadvantages of film. Unlike film, digital images do not take up space, are not easy to lose and can be transferred a great distance almost instantaneously. Add that to the fact that such technology might very well be more accurate, expose women to less radiation and work faster, and it is easy to see the potential of digital mammography.

"Mammography provokes anxiety that increases if the patient has to be recalled for extra views. She begins to wonder if she has cancer," said Dr. Carl J. D'Orsi, vice chairman of radiology at the University of Massachusetts in 1997. "Digital technology has the potential to reduce these callbacks. You can magnify the image, change the contrast, and do a lot of things that you can't do with film."<sup>33</sup>

### **GE gets ATP Funding**

The final major government grant that GE received for the Apollo Project during the mid-1990s was from NIST's Advanced Technology Program (ATP). In 1995, the scientists at GE had proven that they could build a prototype of an amorphous-silicon-based digital medical imaging device but they were still worried about whether they could produce the necessary detection panels at such a level as to allow for its widespread use on the medical market. One major area of concern was the cost and performance of the 12-mask baseline process from which GE was able to produce the amorphous-silicon panel, which would take and transfer the medical image. GE worried that the process would be too costly to scale up and that it would not allow for a sufficient yield.

GE sought ATP funding to develop a 6-mask process for low-cost amorphous silicon technology. The company's proposal to ATP elaborated on the need:

This technology has already found application to the active matrix liquid crystal display market and the next major application will likely be in the area of medical imaging. The technical goal of the program is to reduce the number of mask steps required to have a low-cost high-yield process that does not compromise performance. If successful, the result of this program will be a decision to commercialize this technology in the U.S. and market it worldwide for medical imaging.<sup>34</sup>

The scientists at GE were concerned that, without ATP funding, the company would not be able to take advantage of the technology quickly enough to popularize it on the medical imaging market. The proposal made that case. "Without NIST funding, the program will be stretched out, resulting in higher-price systems that reduce the market potential and technology penetration. In

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32 U.S. Preventive Services Task Force. *Guide to Clinical Preventive Services*, 2nd Edition. Washington, D.C.: U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion, 1996.

33 Dr. Carl J. D'Orsi, quoted in Greg Freiherr, "Digital X-ray: Big promises, Big problems," *Diagnostic Imaging Magazine*, November 1, 1997.

34 GE Proposal to ATP, available at ATP offices in Gaithersburg, Md. 1995.

addition, higher cost systems will enhance the ability of foreign competitors to capture market share by introducing lower cost systems."<sup>35</sup>

The Advanced Technology Program was a logical source for funding for GE that would be earmarked to this part of the project because the ATP specialized in high-risk research with broad potential social benefits. ATP's primary goal was investing not in applications, as DARPA and NCI did, but rather in specific technologies. "ATP has a different set of goals," says Edelheit. "They want to create jobs, support technology. In this case, they wanted us to develop a good semiconductor process — and to keep that process in the U.S."

Part of ATP's charter was to promote technical innovations that would benefit American society as a whole, including three areas of particular importance: first, technologies that would improve quality of life for Americans; second, technologies that would help U.S. companies stay ahead of foreign competitors; and third, technologies that would have spillover effects for American science through diffusion of knowledge. GE made the case that the low-cost amorphous silicon project qualified on all three counts.

GE argued that the technology would allow for cheaper medical imaging devices that would lower the cost of health care and speed up the screening process, a public benefit. The technology would allow GE to stay ahead of foreign competitors. GE also argued that the work with amorphous silicon could be transferred to other applications — such as large-area sensors — on which other American companies were working.

Gerald Caesar was the project's champion within ATP. He had spent twenty years working on amorphous silicon technology in one way or the other. "I was very sensitive to the issues that were being raised by GE, which was the whole question of yields and of the cost of these imagers," says Caesar. "This was an opportunity where ATP funding could play a big role in a technology's success."<sup>36</sup>

The ATP judges, who made the final decision on funding, were convinced. "The broad-based benefits will ... eventually diffuse to other industries, in particular, to the flat-panel display sector," wrote one. "It offers the potential of broad-based U.S. economic benefits" wrote another. "This team has it all."<sup>37</sup> At the end of 1995, ATP decided to grant GE -- and its manufacturing partner, EG&G Reticon Co. -- \$3.2 million for a 36-month project (later stretched out to five years) to try to develop a cheaper amorphous silicon production process.

### **A Manufacturing Partner**

Another thing that made the project so appealing to ATP was that, by 1995, GE had launched into a partnership agreement with the Wellesley, Mass.-based EG&G Reticon Company. ATP encourages collaboration between big companies like GE and smaller ones; because such collaborations strengthen technological innovation through diffusion of knowledge. ATP gave

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<sup>35</sup> Ibid.

<sup>36</sup> Author interview with Gerald Ceasar, August 1, 2001.

<sup>37</sup> Comments on GE proposal from ATP judges, quoted in documents on file at the Advanced Technology Program, 1995.

EG&G and GE each roughly \$1.6 million to work on low-cost production of amorphous silicon technology.

Of course, for GE and EG&G, the partnership was about a lot more than receiving government money. GE's corporate lab in Schenectady and its Medical Systems business in Milwaukee were set up to do science and design, but executives at neither were particularly eager to do large-scale production of the medical imaging device panels. For that, the company wanted to farm out some of the production. EG&G Reticon, a high-tech industrial producer, had an instrument-producing unit in Santa Clara, California that offered GE that opportunity. For EG&G, the partnership with GE was a significant move. "Amorphous silicon technology ... is the single largest R&D project in EG&G's history," said EG&G chairman and CEO John Kucharski. "The technology offers clear advantages for medical imaging as well as for industrial applications such as non-destructive testing."<sup>38</sup>

"EG&G had some experience in amorphous silicon," says Giammbatista. GE Medical Systems did not really want to manufacture whole new technology, he says, so the theory was: "Let's find someone who had some experience in this technology and also someone who has another market for the technology."

GE agreed with EG&G that the smaller firm would manufacture some of the panels for the medical imaging devices that GE wanted built at its production facility in Santa Clara, which is capable of producing more than 10,000 panels a year.<sup>39</sup> In return, EG&G would also be able to use the technology to pursue other applications, such as amorphous silicon-based panels for use in the pipe welding market, industrial and cargo inspection, and dental imaging. (As part of a corporate overhaul, five years after EG&G signed the agreement with GE and received funding from ATP, the company changed its name to PerkinElmer.)<sup>40</sup>

As it turned out, as of early 2002, GE was still doing all of the production of its digital mammography imagers at its R&D lab in Schenectady. However, as the company expanded into the cardiac imaging business, Perkin Elmer was increasingly taking a more active role in the production of cardiac devices. Both companies, however, were employing the same amorphous silicon technology -- originally developed at GE and improved upon via collaborations between GE and PerkinElmer engineers -- to build the digital imaging devices. The companies "run the same process and some panels go to medical and some panels go to the other applications," says Giammbatista.

### **Proof of Concept**

By 1998 everything seemed to be in place for the advancement of amorphous silicon medical imaging devices at GE. The corporate scientists were convinced that they could use amorphous silicon technology to build effective digital medical imaging devices. They had demonstrated the technology via prototypes that relied on a single piece amorphous silicon flat panel with cesium iodide scintillator that sat on a glass substrate. The company had a manufacturing partner to help

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38 "GE and EG&G Sign Pact to Produce Digital X-Ray Detectors," *Biotech Equipment Update*, October 1, 1997.

39 Ibid.

<sup>40</sup> PerkinElmer Press Release, "EG&G Changes Name to PerkinElmer; Continues Transformation to a Focused HighTechnology Company." October 26, 1999.

build those panels for the devices. It had government funding to offset some of the costs. It had the support of both the head of the corporation, Welch, who was willing to listen to his scientists and prioritize digital imaging for GE's Medical Systems business, and the new head of GEMS, Immelt, who shared CRD's faith in the technology. The next step was to get permission to start selling digital mammography devices and to prove that the company could build enough devices to create a demand for them — and to prove that such a demand existed.

To begin that process, GE applied for a Premarket Approval (PMA) from the Food and Drug Administration to request clearance to market a digital mammography machine. PMA is the most stringent type of device marketing application required by FDA. PMA approval is to be based on a determination by FDA that the PMA contains sufficient valid scientific evidence that provides reasonable assurance that the device is safe and effective for its intended use or uses. Among the requirements to get a PMA to sell the company's digital mammography machines was proof that digital offered image quality equivalent to film, and that it did not pose any greater risk to its subjects. By 1999, the company was able to present such proof. At the time, "we didn't truly expect to [do] better than film," says Landberg. "We needed to prove equivalence range." The company was successful and by January, 2000 it had government clearance to sell the technology.<sup>41</sup>

## **Breakthrough**

GE would find a ready market. Hospitals and doctors were eager for a substitute for film-based mammography. There was little competition from other manufacturers. None of the potential foreign competitors could use amorphous silicon technology for medical imaging, and domestic competitors who were experimenting with other technologies (mainly Selenium-based) had not yet made it to market with a device that was as good as GE's machines. Thus GE had only to convince medical practitioners to spend the money to buy their Senographe device.

GE made a number of claims for the Senographe 2000D:

- digital machines were faster: a full digital mammogram could be completed in four minutes, as opposed to 20–30 minutes for film systems;
- the technology offered better images of dense breast tissue, which is particularly helpful for mammograms of younger women;
- digital could offer the same quality of image as film with only half as much exposure to radiation, or higher quality images with similar radiation levels;
- digital technology offered advanced imaging, allowing screeners to "zoom and roam" as well as magnify the images;
- digital images required less storage space, and could be linked with other new digital technology in hospitals;
- digital was easy for doctors and x-ray technicians to learn to use ("the learning curve ... has more to do with computer use than the technology," says Landberg).

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<sup>41</sup> U.S. Food & Drug Administration, Center for Devices and Radiological Health Web site, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?ID=5467>.

The Senographe machines entered the market selling for around \$200,000–300,000. By 2001, proceeds of the digital mammography business were about half a billion dollars for GE. Edelheit estimates that the company has already been able to recoup the \$150 million or so that it spent in developing the technology over the 1980s and 1990s. The technology has been praised by health officials for improving mammography.

### **A Need to Move Quickly**

Ironically, one of the victims of GE's success in the market was further technological innovation using amorphous silicon. CRD's scientists discovered that the 12-mask process for incorporating the material in display panels could be done at a cost that the market could support. Thus GE abandoned the alternative low-cost process that ATP had given GE \$1.6 million to research. By the time GE's scientists had developed a six-mask process — which they dubbed the "NIST process" — the market demand for the Senographe devices was so intense that both GE and its production partner, PerkinElmer, were already producing and selling all they could build. Thus, GE's scientists decided to stick with the already proven 12-mask process for the time being. As Possin said in 2001:

We don't have the resources to develop a new process because the business can sell everything we make right now.... A drop in manufacturing allows for process improvement, but we can't have that drop unless there would be significant long-run advantages.

Possin maintains that even if GE had the financial incentive to implement the six-mask process, to do so would not be a wise decision. "The bottom line is that the process was too aggressive. It was hard to maintain everything that needed to be included in the process," he says. "It was high-risk and didn't work consistently and we are not pursuing it right now." In addition, the six-mask process did not have the yield benefits that GE's researchers had anticipated. Giammbatista explains:

The initial argument is, okay, we're taking some layers out of the process and every layer has defects so the yield would obviously improve. As we got our hands dirty in the process, the conclusion we came to was that, in general the layers that we took out weren't the ones with the most defects. In fact, they tended to be ones that didn't have a lot of defects. And in many cases what we were doing was taking out was an extra protection ... layer. And so in some respects the NIST process is a little closer to the edge of the cliff, if you will. Rather than playing it safe, we're going to take some risks here and take out some of these protecting layers. Sure it works, but maybe you actually get a few extra defects.

The yield for digital mammography display imagers created using the 12-mask process is between 25 and 50 percent, which Possin considers acceptable. (This means that 25 to 50 percent of the imagers constructed are suitable for use in medical devices.) The so-called "NIST process" was unable to replicate that level of yield.

Possin and his colleagues maintain that there was, nevertheless, benefit in the work that CRD did on the NIST process. They were able to discover that one masking step could be taken out with

few quality concerns, and they were able to get a good deal of experience in exploring better ways to produce the amorphous silicon panels which allowed CRD. "We discovered some things we would use in the future, some of which we are using right now," says Possin.<sup>42</sup>

Among those lessons were discoveries about how to alter the slope of the diode sidewall, findings on how to simplify the common electrode structure and a method to develop a single-step process for strapped data line and metal common electrode.

The primary combined effect of this knowledge was that GE and PerkinElmer were able to reduce the amount of noise in the digital images that its machines produced. By cutting back on diode leakage and exposure the companies were able to build imagers that produced more robust mammography images. The benefits of noise reduction include: 1) The ability to take a wider dynamic range of breast images; 2) Mammographies that have lower doses of radiation; 3) Tests that make it easier to view structure in highly dense areas of the breast, and; 4) Progress toward advanced applications for the devices such as the ability to take multiple images of the breast.

According to Possin, the work done in developing the NIST process was essential in enabling GE to continue to improve the quality of its digital imaging devices. The benefit of the ATP money, he says, was that it allowed us to "focus on technology in a very fundamental way and not get hung up on deliverables. We were able to spend the money to really understand the technology and to fail at the technology. There is a tremendous benefit in this."<sup>43</sup>

"With the ATP money, we were able to say [to GE executives] that these guys [ATP] want us to understand the technology and optimize the process. And that is what we were able to do."

### **The Next Steps**

In 2002, GE remains the leader in the digital medical imaging market, but the story of the company's development of amorphous silicon technology is far from over. While the production of digital medical imagers for mammographies was running near full capacity in 2001, the company is just beginning to fully enter the cardiac market for digital x-ray devices with the Innova 2000. In addition to cardiology and mammography, the scientists at GE who have worked on the Apollo Project are now concentrating on other products using the technology in the medical imaging field. The company is now working on chest x-ray devices, machines to conduct angioplasties, and tomography machines that would provide even more detailed mammograms than the Senographe does. In addition, GE is still working — with the help of DARPA funding — on improving telemedical imaging devices for use near areas of combat. Meanwhile, PerkinElmer has made progress in other applications of GE's amorphous silicon technology, including devices for checking pipe welds.

In addition, both companies continue to try to improve on the production process by eliminating some steps in the masking process. GE executives have authorized between one and two million

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<sup>42</sup> Author interview with George Possin, September 17, 2001

<sup>43</sup> Author interview with George Possin, January 3, 2002.

dollars for the engineers at CRD to try to develop a new production process for the display panels – employing lessons learned during the development of the NIST process. The new process, which Possin characterizes as jointly developed by GE and PerkinElmer,<sup>44</sup> could potentially allow for a reduction in three of the masking steps, saving considerable time and money for both companies. GE's engineers will not know until 2003, however, whether they can perfect the new masking process and until then will continue to produce the digital medical imaging device using the baseline process that they first developed in the early 1990s.

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<sup>44</sup> Ibid.