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Millipore New Product Commercialization: A Tale of Two New Products

In 1993, Millipore was poised to launch several innovative product lines. Company executives had particularly high hopes for the LC/MS product line in the Waters Chromatography Division and Viresolve in the Process Division. Much of the potential success of these products rested on commercialization decisions made in the past three years by their respective protagonists: Dave Strand, V.P. for new business development at Waters, and Paul Sekhri, product manager for Viresolve at the Process Division.

In early 1990, Dave Strand was given the task of commercializing Millipore's innovative liquid chromatography/mass spectrometry (LC/MS) product line. Strand had come to Waters a few years earlier, when the software firm he helped found was purchased by Waters. A rising star in the Waters Chromatography Division, he hoped that successful introduction of these products would reestablish Waters' claim to technological leadership in the liquid chromatography (LC) marketplace. That title had been challenged for the first time in 1983 when Hewlett-Packard—until then a small player in the LC market—had beaten Waters to market with the photodiode array (PDA) detector for liquid chromatography systems. Waters still dominated the LC market that it gave birth to in 1958 with 40%-45% of the global LC market (to HP's 22%-23%). With the introduction of new technologies like LC/MS, Waters sought to place a lock on the LC market that would make it unprofitable for any firm to challenge its position. As Dave Strand put it, "We want to make the view not worth the climb."

In October 1990, Paul Sekhri, a young marketing manager with several years of experience working for start-ups in the biotech industry, was hired to commercialize a newly developed membrane system capable of removing viruses from protein drugs developed using biotechnology. Over the last few years Millipore had been struggling to better serve the rapidly growing biotechnology industry, and the virus removal product was one of the most promising biotechnology products that Millipore had yet developed. While "market characterization" and beta tests had been a central part of the development process, when Sekhri arrived he was met with many remaining commercialization issues:

> When I started, my boss, Tim Leahy, said, "Your job is to commercialize this product." So I asked, "What's the name of it?" He said, "That's up to you." I asked, "What are you charging for it?" He said, "That's up to you." I asked, "How are you distributing it?" He said "That's up to you." There was just a big, clean slate.

Research Associate Kevin Bartus prepared this case under the supervision of Professor V. Kasturi Rangan as the basis for class discussion rather than to illustrate either effective or ineffective handling of an administrative situation.

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Millipore's leading competitor in virus removal was Asahi, a small Japanese company. Asahi's membrane products, except for the virus removal membrane, were distributed in the United States by Pall. Worldwide, Pall was Millipore's leading competitor with 13% share. Millipore (with $174 million in sales) had 22%.

Millipore Corporate Background

With worldwide sales of $750 million in 1991, Millipore was the market leader in the $3.4 billion separations industry. Millipore's products were primarily based on two separations technologies: membrane technology and chromatography.

Membrane technology separated the components of a substance primarily according to the size of those components. A substance, such as water, air, or chemicals, was filtered through thin screens called membranes, which were made of various materials and had small holes of different sizes. The pores allowed components (molecules, ions or particles) of certain sizes to pass through, while others were trapped on the surface of the membrane. Millipore offered a wide range of membrane types, sizes, and configurations.

In a typical chromatographic separation, the substance or sample to be separated was injected into a fluid such as water. This solution was then pumped through a tube called a column which was packed with chemical materials. As the sample traveled through the column, the chemical packing separated the sample into its individual chemical molecules or components. As each component left the column, it was sensed by a detector, which transmitted a signal to a recording device. Information about each component was then depicted on a chart called a chromatogram. The total system consisted of an injector, a pump, a column, a detector, and a recorder. Millipore participated in a wide range of liquid chromatography applications.

The membrane separation and chromatography technologies were used in two types of customer applications: analysis and purification. Products for analytical applications were used to gain knowledge about a sample by detecting, identifying, and/or quantifying its chemical, physical, or biological components. Products for purification applications were used to help manufacture or process a customer's product by removing contaminants or by isolating and purifying specific components from complex mixtures.

Exhibit 1 provides an overview of the corporation's sales by customer application, customer segment, and geography. As can be seen from **Exhibit 1**, while chromatography technology was used predominantly in analytical applications, membrane technology was used for both analytical and purification applications. Millipore grouped its customers into eight major markets: pharmaceutical (e.g., Pfizer), biotechnology (e.g., Genentech), life-sciences (e.g., Massachusetts Institute of Technology), food-and-beverage (e.g., Coca-Cola), microelectronics (e.g., IBM), chemical (e.g., Dow), environmental (e.g., U.S. Environmental Protection Agency), and patient-care (e.g., Massachusetts General Hospital.) Its customers included corporations of all types and sizes, government agencies, hospitals, universities and research institutions.

Profit-and-loss responsibility at Millipore Corporation was organized by three major product divisions:

1. Chromatography Division (also called Waters chromatography, after Jim Waters, its founder.) The LC/MS project was being developed under this division.

2. Process Systems Group (purification applications of membrane technology.) The Virus Removal project was being developed under this division.

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3. Analytical Systems Division (analytical applications of membrane technology.)

A separate division called Intertech handled operations in Latin America, Eastern Europe, Africa, and Asia (except Japan, which was handled by Nihon Millipore.)

Table A shows an approximation of sales by each product division as constructed from **Exhibit 1**.

Table A Five-Year Sales History by Product Division ($ millions)

	1991	1990	1989	1988	1987
Waters	291	287	267	260	228
Process	267	238	194	177	142
Analytical	188	178	154	142	118
Intertech	67	68	62	59	46

Each of the first three divisions had profit-and-loss responsibility with independent marketing, sales, R&D, and manufacturing operations. Because of common membrane technology, Analytical and Process Systems shared manufacturing facilities. The company as a whole operated in 70 countries worldwide, with its world headquarters for Process Systems and Analytical Systems at Bedford, Massachusetts, and its Waters Chromatography division at Milford, Massachusetts. (See **Exhibit 2** for a corporate organization chart.)

As can be seen from **Exhibit 2**, core R&D, under Jack Johansen, was a key corporate function. Core R&D supplied divisions with short-term and long-term research support for product development as well as conducting some research of its own on core technologies with potential long-term payoffs. Approximately 80% of the corporation's $66 million R&D budget was spent on divisional product development projects and the rest on core R&D. The divisional R&D budgets were allocated more or less in proportion to their sales revenues. According to Millipore's technology V.P., roughly 50% of the R&D budget was spent on incremental new products and the other half on "change the name of the game" kind of innovations.

Sales and marketing functions at Millipore were organized under each division (see **Exhibit 3**). In each country, one of the divisional sales managers also acted as country manager, a position which included responsibility for administrative functions such as order-entry, shipment, and invoicing. For example, Art Caputo acted both as the North American sales manager for Waters and as the country manager for North America. The three major Millipore divisions shared common distribution warehouses and logistics facilities worldwide. The North American sales operation was headquartered at Marlborough, Massachusetts.

New Product Development

Core R&D supplied divisions with short-term and long-term research for product development in addition to conducting some research of its own on core technologies with potential long-term payoffs.

The initiative for division product development came up from the division. Each of the three divisions had its own unique new product development system. The Analytical and Process Groups were decentralized into market-focused Business Units. Project ideas were submitted by marketing, sales, and R&D people, and allocation of resources was made by the general managers of the Business Units and divisional presidents. Resources for new membrane development to support divisional projects were allocated by the Core Membrane V.P. for R&D who was also responsible for allocating resources to core research projects. The process was iterative, often involving ranking of projects based on their market potential and strategic importance with the final cut being made by budgetary

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constraints. (See **Exhibit 4** for the evaluation framework used at the Analytical Group.) At the Process Systems group, the procedure was more informal, but addressed similar issues. At Waters, the procedure was somewhat different. Top managers from each functional area constituted a New Product Committee. Marketing, Sales, R&D, Manufacturing, and overseas country heads were all part of this committee. They each brought in ideas supplied to them by their constituencies, and the committee as a whole then decided on how to allocate its resources.

John Gilmartin, the CEO of Millipore Corporation, had set a goal of 15% growth in sales accompanied by a 10% return on sales and assets. This had be achieved in an environment where the industry was growing at only about 8%. The corporation, therefore, was focused on exploiting niche marketing opportunities with new products. John Gilmartin had set a target of achieving 40% of annual sales from products introduced in the recent three years. Figures compiled by the corporate planning department indicated that such a target had not been achieved in the last five years.

Table B provides a brief description of the 11 key new product introductions in 1991.

Table B New Product Introduction in 1991

Waters Chromatography Division

1. *717 Auto Sampler*: Upgrade of existing Waters auto sampler line, redesigned and repositioned to address recurring reliability problems.
2. *996 Photo Diode Array (PDA) Detector*: An in-house redesign of a product originally sourced from a Japanese vendor.
3. *Millennium Software*: First chromatography software to integrate essentially all data collection and analysis functions required by liquid chromatographers. First Waters product to run on Windows. Required for use on 996 PDA. Useful only with other Waters products.

Analytical Division

4. *Analyzer Feed System (AFS)*: Water purifier for laboratory systems. Redesign of a previously failed product launch. 1992 revenues of $700,000.
5. *Base Station—Automated DNA Sequencer*: Developed by a now defunct division as part of a broad effort to exploit the growing biotech market. Effort undermined by early field problems and a dominant competitor.
6. *ConSep/1*: A liquid chromatography system developed at Analytical to allow customers to take advantage of Memsep—a technology recently purchased by Millipore, which incorporates a membrane (versus the more typical gel or treated beads) in a chromatographic column. Memsep's recent sales had been flagging, presumably because existing chromatography systems were not capable of utilizing the new technology to its full potential. Consep/1 was developed to address this need.
7. *Expedite*: An automated DNA synthesizing station. Developed in part to promote sales of specialty chemicals used to manufacture DNA, which are manufactured by a wholly owned subsidiary.

Process Division

8. *Viresolve*: Novel virus removal system developed for the biopharmaceutical market.
9. *Opti-Seal*: Replacement for existing product.
10. *Opti-Cap*: Replacement for existing product.
11. *IntegriTest*: Novel method for testing the integrity of membranes. Launch challenged by design problems and demanding training requirements.

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The LC/MS Project at the Waters Division

The LC/MS project at Waters had a checkered history. In 1990, Dave Strand inherited a program in tatters. No working mass spectrometer prototypes had been developed. Little systematic marketing research had been done, and there were no agreements with component vendors. (See **Exhibit 5** for a brief history of the previous product development effort.)

As can be seen from **Exhibit 5**, the LC/MS effort first originated with a desire to build an interface to feed into the mass spectrometer. A liquid chromatography system could separate different chemicals from a compound solution, and the typical chromatography detector could tell the analyst how much of each chemical was present. But identification of each chemical could be done only on the basis of comparison to a standard; if it was known that caffeine took 30 minutes to travel through a chromatography column made of silica gel, then the analyst had reason to believe that an unknown chemical taking 30 minutes to pass through silica gel was in fact caffeine. Mass spectrometry took identification a significant step further. A chemical like caffeine was broken into ionic components and flung against a screen (an electromagnetic field was used, thus differentiating between components on the basis of mass and charge). The pattern on the screen formed a unique "fingerprint" for each chemical, identifying the chemical with certainty. While conventional LC detectors were adequate for identifying a spectrum of 25 compounds or less, mass-specific detectors were enormously cost efficient over a larger range, exceeding 75 compounds.

In order for the output of an LC system to be fed directly into a mass spec, an "interface" had to drastically reduce the amount of liquid flow and turn the remaining liquid molecules into gaseous ions. Interfaces such as thermospray and particle beam had been developed for use with "small" molecules such as caffeine, but these interfaces often destroyed the "big" molecules, such as proteins, typically analyzed by the biotechnology industry. At the close of the 1980s, the electrospray interface became commercially available for the biotechnology market. By 1993, the most common LC/MS interfaces for "small" molecules were particle beam and thermospray, and electrospray for "large" molecules.[1]

There were approximately 10,000 mass spectrometrists in the United States, most of whom had a PhD. There were 100,000 chromatographers in the United States, most of whom did not have a PhD.

The two types of scientists usually worked for the same companies and often worked on the same development project. A large pharmaceutical company trying to discover a new drug, for example, might have a chromatography lab work on the more "routine" analysis and have the mass spectrometrists work on the more difficult problems. The mass spectrometrists might use their own chromatography equipment, but "to them it's just another input to their MS." Should the chromatographers require mass spectrometry, they would take a tray of samples up a floor or across the hall to the mass spectrometrists, who might charge a few hundred dollars per sample.

An integrated LC/MS system offered advantages to both mass spectrometrists and chromatographers. Mass spectrometrists, generally considered the more "elite" of the two groups due to more rigorous education and training requirements, already used liquid chromatography to separate compounds into pure samples prior to analysis by mass spectrometry. To them, an integrated system offered greater efficiency. Chromatographers often asked mass spectrometrists to positively identify chemicals for them on a mass spectrometer. To them, an integrated system,

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1. Molecules were characterized by their molecular weight as small or big. Amino acids, drug conjugates, neurotransmitters, carbohydrates, surfactants, peptides, proteins, and DNA represent a range of molecules from small to big.

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especially one that was easy enough for a chromatographer to run, offered the advantages of mass spectrometry without having to bother mass spectrometrists.

Customer Perceptions

One of the first tasks that Dave Strand concentrated on when he took over the job in 1990 was better understanding customer interest in LC/MS systems. Two focus sessions were conducted.

The first focus session, held in February of 1991, involved a group of chromatographers from the pharmaceutical, industrial chemical, and consumer products industries. These potential LC/MS customers were asked what they wanted in an LC/MS and how purchasing decisions might be made. Attributes of an ideal system included something "easy, straightforward, and rugged," and several chromatographers expressed a desire for a "table-top model." There was general agreement that the lower the price was, the more input the chromatographer would have on the purchasing decision, and the more widely used the unit would be. "On a benchtop for $50,000," said one chromatographer, "we'd have one for each of our development chemists." Others cited $100,000 as the price point that would allow chromatographers, not mass spectrometrists, to make the ultimate decision.

The second session, held in December of 1991, was conducted individually with scientists (predominantly PhD's) in the pharmaceutical and biotechnology industries. Participants were questioned on their desire for alternative LC and MS technologies, on their perception of Waters, and on their perceptions of potential LC/MS vendors. Several scientists voiced a desire for a smaller-scale LC system. "It fills a niche for biomolecules, small samples for research," said one participant (later market research indicated that in fact about 9% of the LC market was interested in smaller-scale LC). When asked to give their perceptions of Waters, reactions were mixed. "They're people who know HPLC," said one scientist. "Waters has a good reputation with us," said another.

Situation at the Start of 1993

With these concerns of focus-session participants in mind, and given the difficulty Waters continued to have in making arrangements for sourcing mass spec components, in 1992 Waters purchased Extrel, a $12 million manufacturer of laboratory analysis equipment. Extrel had built a credible reputation in mass spectrometry, with sales of about 30 research-grade, full-function mass spectrometers per year. As 1993 began, Waters and Extrel engineers were working hard to develop the lower-tier, mass-specific detector that Waters managers had sought for so many years. Meanwhile, sales of tailored LCs continued.

Commercialization of LC/MS

Market Definition: Chromatographers versus Mass Spectrometrists

By offering a "mass spec adapted for LC utilization," Waters planned to take advantage of its dominance in the LC marketplace. Although the centerpiece of Strand's launch, a scaled- down mass spectrometer, was aimed at chromatographers and not the mass spectrometrists, there was an important relationship of influence between the two customers. Mass spectrometrists were in a sense the "prima donnas" of the analytical laboratory, generally more highly educated and more highly paid than the chromatographers. Because of this status and because of their knowledge of the science of mass spectrometry, the purchase of a scaled-down mass spectrometer was likely to require their blessing, if not their official approval.

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Although Strand's "detector-level" mass spectrometer (so called because of its intended similarity to the other detectors used by chromatographers) was clearly aimed at lowering the dependence of chromatographers on mass spectrometrists, the latter were expected to feel no threat. Strand recalled the reaction of mass spectrometrists to the introduction of detector-level mass spectrometers for gas chromatography in the mid-'80s. Mass spectrometrists "looked at them as helpful, because they filtered out the mundane problems and allowed them to work on the more interesting problems." Far from feeling threatened, Strand expected mass spectrometrists to help chromatographers choose a good detector-level mass spectrometer. "There's a feeling," suggested Strand, "that you have to have their tacit blessing, that this is a good product." It may not be as powerful as my million-dollar machine, but for $100,000, this is a good beginner's tool and an acceptable adjunct to an LC system."

Strand felt that he had a good sense of what customers expected and desired. "I've attended probably every scientific conference there is and talked to a lot of people. We've done three rounds of focus sessions which have been very helpful in understanding what the product issues were. We think we know based on focus-session work what it would take to get customers to buy from us, and what price range and technology tradeoffs they would be willing to accept."

Although the detector-level mass spectrometer (called MSD or mass specific detector) had not yet been tested at any customer site, in late 1992 Waters conducted a focus session with mock-ups of the product to get feedback on size, serviceability, accessibility, and integration. The feedback was quite positive.

Segmentation

In 1991, the market for MSD integrated with LC systems was estimated to be $50 million. Although no one firm currently sold "detector-level" mass spectrometers for liquid chromatography, the market for these products was expected to be $110 million by 1996. The research-grade, full-function mass spectrometer integrated with gas or liquid chromtography sold for about $250,000 to $500,000. Competitors like Finnigan, VG, Sciex, and Hewlett-Packard occupied this $300 million market. HP and Varian also made a MSD integrated with gas chromatography. This, however, was a smaller $150 million market.

Dave Strand divided the potential market for LC/MS in two ways, both largely derived from Waters' experience with liquid chromatography. One approach segmented users into four groups, each comprising about a quarter of the existing LC/MS market: Pharmaceutical, Industrial Chemical, Biopharmaceutical, and Environmental. This segmentation was not based so much on SIC-type classifications as it was on the application that the LC was used for; for example, many traditional pharmaceutical companies had begun to use biotechnology to develop biopharmaceutical drugs.

Waters was already strong in both the pharmaceutical and the industrial chemical segments of the chromatography market. In 1989, the size of pharmaceutical segment of the chromatography market was $319 million, of which Waters held 27%. The industrial chemical segment was $438 million, of which Waters held 19%. Strand felt that LC/MS products would do particularly well in industrial chemicals, because "industrial is sort of mundane; often those sales for us are unopposed. But if you go into the pharmaceutical or any of the biopharmaceutical companies, there's brisk competition to get in there."

Strand also divided the market according to how research-oriented the chromatographer was. Sixty percent of all chromatographers were involved in quality control or quality assurance (QC/QA), involving tasks such as ensuring that each production batch had a desired level of a certain chemical. More research oriented were the methods developers (30%), who designed procedures for QC/QA. Most research oriented were the researchers (10%), who were involved in developing new chemicals or drugs. Many Waters managers saw a rough progression of influence from the

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researchers down to the methods developers and then to QA/QC, but no vendor had actively exploited that progression. Eighty-eight percent of current LC/MS sales were to researchers and methods developers, but Strand hoped that eventually his detector-level mass spectrometer would appeal to the much larger but much more conservative QC/QA market.

Comparable Introductions in the Past

Waters' managers expected sales for the detector-level mass spectrometer market to grow from $0 to $110 million in four years. This estimate was based on two similar introductions in the past: GC-MSD and PDA detectors. HP had introduced GC-MSD, a detector-level mass spectrometer (MSD, or "mass-specific detector") for gas chromatography in 1983, and later introduced PDA detectors. As illustrated in **Exhibit 6**, the GC-MSD market grew from zero to over 1,200 units in five years, an annualized growth of over 400%. Recalling these historic market growth rates played a large role in helping Strand estimate sales of the detector-level mass spectrometer. The estimate was also based on the expectation that 10%-12% of all LC systems would include a mass spec detector within four years, since in 1992 10%-12% of all LC systems had PDAs.

Launch

Strand had received several suggestions for the LC/MS introduction, though specific launch dates and details were yet to be finalized. One suggestion was to stage the launch. That is, the company would first tailor the Extrel mass spectrometer (named Benchmark) to capillary-scale liquid chromatography. This would be particularly appealing to biopharmaceutical researchers who worked with small sample sizes. Building on this experience, Waters could then launch the conventional scale LC tailored to the mass-specific detector (code-named "Mercury"). This would appeal to the industrial chemicals segment. This detector was expected to measure only 20" x 20" x 15" and weigh 150 lbs., compared with Benchmark at 3' x 2' x 2' and 350 lbs. It was considered ambitious, but not impossible, to introduce Benchmark at the 1993 Pittcon trade show for chromatographers, followed by the Mercury launch about six to nine months later at the American Society of Mass Spectrometrists.

Art Caputo, the Waters sales manager, was involved in virtually all of the major decisions on LC/MS development. His plan was to initially rely on Extrel salespeople and a handful of specialists, but slowly train his entire sales team of nearly 200 salespeople. "That is the only way we can ramp up Mercury sales from 50 units in 1991 to nearly 300 units by 1996," concluded Caputo.

Remaining Commercialization Issues

Waters managers believed that where chromatographers had the authority to purchase their own equipment, it was generally only for instruments costing $100,000 or less. While Benchmark was priced at $180,000 to $200,000, Mercury had to be priced below the $100,000 point. HP typically sold their GC/MSD for under $75,000, and although a detector-level mass spectrometer for LC systems was likely to sell for more, Waters took the GC/MSD as a starting point for calculating target cost. "We took the pieces apart on an HP GC/MSD and estimated that it could be built for about $20,000. We have set for ourselves a manufacturing target somewhat more than that, and achieving that would be very important for our success in this marketplace," reasoned Dave Strand. "It is an interesting industry," he added. "Competition is based on value-added and technology and participants usually respect each other's market position. There's been little disruption throughout the last decade. That's why we are keen to have that technological lead in Mercury," he concluded.

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Virus Removal Commercialization at the Process Group

When Paul Sekhri inherited the virus removal project in 1990, several working beta sites were already installed, and the original developers of the product idea were still involved in assisting him in the launch phase. (See **Exhibit 7** for a brief history of the virus removal product development.)

In 1985, Tony DiLeo, an R&D manager, knew that Millipore had only begun to exploit the tangential flow membrane technology that his team had developed. In tangential flow filtration, fluid circulated across the membrane surface and was slowly pulled through the membrane by suction. Because of their more sophisticated designs, tangential flow systems were not as simple for users to operate as conventional "dead-end" filters, such as coffee filters. Tangential flow did, however, offer less clogging and thus better performance when used to discriminate between particles of similar size.

At DiLeo's request, Ray Gabler, a top marketing manager, spoke with many of Millipore's key biotech and pharmaceutical customers to identify a list of 11 promising applications for this technology. Running preliminary experiments and investigating each application's complexity and probable length of development time, DiLeo and his group narrowed the list to three promising applications. One of these applications was virus removal.

Virus removal had always been a problem in the development of biotechnology drugs. Some drugs were derived directly from mammalian blood plasma or cells. When these substances were extracted from the body, viruses often came along for the ride. In 1985, for example, human growth hormone extracted from the pituitary glands of cadavers contained undetected Creutzfeldt-Jakob viruses, which infected and killed several treated patients. Another class of biotech drugs, such as Genetech's tPA for heart attacks, were developed using recombinant DNA, in which gene fragments from a mammalian cell were spliced into rapidly reproducing organisms. Monoclonal antibodies like Centacor's Centoxin for septic shock were also developed using mammalian cells, but instead of using only a gene fragment, the entire cell was used. In the development of both recombinant DNA drugs and monoclonal antibodies, viruses were often unintentionally removed from the mammal along with the original source cells. In addition, viruses sometimes inhabited the media used to grow cell cultures. Finally, viral contamination was a potential result of careless laboratory procedure.

When DiLeo and Gabler spoke with customers about this problem, it became apparent that these "biopharmaceutical" customers were highly dissatisfied with current methods of virus removal, and were very interested in more effective solutions to this problem. Indeed, two key customers were instrumental in convincing top management at Millipore to put resources into developing a membrane system capable of removing viruses in a consistent and validatable fashion. Validation, or proof of virus removal, was expected to become an increasingly important part of the FDA approval process.

The virus removal project was established with division funds in 1987. Day-to-day project management was handled by DiLeo, with Gabler handling customer contacts and negotiation of a total of six test sites. A detailed Program Plan that DiLeo developed in 1989 played a critical part in ensuring that development went smoothly. The plan included PERT charts developed by the scientist in charge of each facet of development, as well as estimates of performance parameters that enabled each of the sub-project teams to work in parallel. Although the original completion target was missed by about six months, the relative smoothness of the development project could be attributed to an accurate early product definition, continual contact with the market, and access to development resources.

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Industry

At least half of all of Millipore's business was directly or indirectly tied to the pharmaceutical market. Viresolve was one of several new products specifically designed to tap into a fast-growing segment of that market: "biopharmaceuticals." Biopharmaceuticals were therapeutics produced through genetic engineering, and both traditional pharmaceutical companies and recently founded biotech companies were taking part in the research. In 1992, the biopharmaceutical market was about $3 billion, expected to grow to $30 billion by the year 2000.

Competition

Inactivation of Viruses

The most prevalent ways of dealing with harmful viruses involved inactivating them instead of actually removing them. Viruses exhibited many of the characteristics of living organisms, and so inactivating a virus was tantamount to rendering it lifeless, and hence harmless. Methods of inactivation included physical techniques such as heat and ultraviolet radiation, but these methods could also harm or destroy the proteins that drug manufacturers wanted to process.

Chemical inactivation techniques were much more prevalent. The "solvent detergent" method, developed by the New York Blood Center, broke down the lipid (fat) coat that enveloped many viruses (in a manner very similar to soap breaking down oils). "I'd say every blood product company, and most pharmaceutical companies, use the solvent detergent method." said Paul Sekhri. "They have a very nice track record. In the three million units of product that have used solvent detergent, they have never had one incident of infection. But there's a drawback to that. You have to know the virus you're removing. Many viruses had no lipid coats, for example, and were thus unaffected by solvent detergent."

Millipore emphasized that any virus unaffected by inactivation methods such as solvent detergent represented an accident waiting to happen. "My approach to marketing Viresolve is that we can remove even unknown viruses," said Paul Sekhri. "That sounds really strange. But it's been interesting to see how the market is slowly embracing that thought. Every single major virological accident in the past ten years has been because of a virus that the manufacturer didn't know was there. We can address that with this system. With an inactivation method you can't."

Physical Removal of Viruses

Membranes were generally considered the most effective manner of physically removing viruses. Size exclusion membranes, like Viresolve, worked by allowing smaller molecules, like proteins, to pass. Larger particles, like viruses, were retained. (**Exhibit 8** shows the virus removal properties of Viresolve/70.) The size of a virus is characterized by its diameter in nanometers (one billionth of a meter). Viresolve's effectiveness is measured in terms of Log Reduction Value (i.e., 7 log removal meant that the membrane would miss one virus particle out of every 10 to the seventh power, or 10 million virus particles). Providing validation of virus removal was the competitive advantage that Millipore had chosen to emphasize in Viresolve over other membranes. There were two important types of validation. One involved providing published proof that a specific virus had been removed to a specific degree using the membrane product in the manufacturer's test facilities. This type of validation was instrumental in helping Millipore compete against conventional multi-use membranes. A second type of validation involved providing a method for the customer to test each

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purchased membrane to assure that it would remove viruses as advertised. Millipore had developed a "correlating integrity test" to meet this latter need, which appeared to be a substantial asset.

Some manufacturers of conventional filtration membranes, had recently repositioned their existing membrane lines to take advantage of the growing interest in virus removal. While their advertising emphasized the familiarity of their approach to virus removal, their technical documentation conceded less-effective performance than the newer Viresolve technology. For example, their 1990 literature claimed to remove the Murine (Mouse) Leukemia Virus to about 4 logs, while the Viresolve/70's 1992 literature claimed removal of the same virus to about 7 logs. This was far more virus particles than most drug raw materials contained. Moreover, the Pall membrane admittedly was not effective against the smallest known virus, polio, which Viresolve/70 could remove to 3.5 logs. **Exhibit 9** illustrates the performance of Viresolve against competitors, including Pall's Nylon 66 membrane. The exhibit plots virus size against removal rate by Viresolve. For example, Viresolve removed the Sindbis virus, a particle about 54.1 nanometers (billionths of a meter) in size, to 6 logs, while Pall's membrane was effective to only 3 logs.

Millipore managers were much more concerned about the new product developed by Asahi. Laboratory tests appeared to indicate that Asahi's "Planova" was effective in virus removal. Moreover, their membrane used the more familiar "dead-end" filtration technology, which worked in a manner similar to a coffee filter. In Viresolve's "tangential flow" technology, liquid flowed perpendicular to the surface and was drawn through the filter using suction. Because tangential flow systems were still relatively unfamiliar and because there were more process variables involved, they were generally more challenging for the customer to properly install.

A key advantage that tangential flow provided, however, was that it allowed Millipore to use membranes which held viruses back on the surface of the membrane. Asahi used a "hollow fiber" approach, which captured viruses within the membrane's depth. Taking advantage of their simpler membrane design, Millipore scientists developed a "correlating integrity test" to verify (or "validate") that a given Viresolve membrane would actually work as promised. The test was "nondestructive," and so the tested membrane could later be put to use with absolute confidence in its performance.

Asahi also had an integrity test that customers could use, but the test was "destructive" and so the membrane could be tested only after it had been used. Hence the customer could never be certain of the membrane's performance until after it had been used. "We won a major battle for a contract with a major British pharmaceutical company about three months ago," recalled Sekhri. "We went head to head with Asahi. They liked a lot of things about Asahi, but it came down to the integrity test. They didn't feel comfortable without absolutely knowing what their log values were. They thought of our test as being something really new, really special in the marketplace, and they went with Viresolve."

Commercialization Issues

Market Segmentation and the Viresolve Product Line

The pores in the Viresolve membrane were small enough to prevent viruses from passing but large enough to allow most proteins through. The smaller the protein, the more likely that a size exclusion approach would work for removing viruses. One type of market segmentation, therefore, was based on the size of the protein. There were three broad segments of the protein purification market.

First were the makers of proteins using recombinant DNA technology, in which genes were "spliced" into a host cell to enable that cell to manufacture the desired protein. These proteins tended

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to be small, generally under 70,000 daltons (unit of molecular weight). The Viresolve/70 was targeted at these customers—makers of interferons, growth factors, clotting stimulating factors, interleukins, and hormones.

A second segment was the makers of proteins using monoclonal antibodies, in which a cell which produced a desirable protein was fused with a cancerous ("immortal") cell to produce a hybrid cell capable of producing the desired protein and multiplying spontaneously to produce many more identical hybrid cells. These proteins were of moderate size, typically under 180,000 daltons. The Viresolve/180 was targeted at these customers—makers of Monoclonal antibodies and Ig fragments.

The third segment was blood processors, and Millipore had not yet developed a Viresolve-type product to meet this need. "It's probably the bigger part of the market," Sekhri conceded. "I get at least one call every week from a major blood company." The problem was that the principle of size exclusion, the method by which the Viresolve membrane operated, could not be readily applied to blood processing. Blood contains proteins that are as large, or larger, than the largest commonly found viruses. Techniques other than size exclusion had certainly been used in virus removal, but not as reliably. "We are working on that. It's kind of the next phase, maybe *Viresolve 3*."

Naming the Product

Soon after arriving at Millipore, Sekhri distributed a companywide memo requesting a name for a "new technology capable of removing viruses from proteins." Names like Virex, Viratain, and Virecut were submitted. Some, like Virex, were already used; Virex was a software program to remove computer viruses. At the conclusion of a meeting with about 20 Millipore people, Sekhri made the final choice to go with Viresolve.

Understanding Customer Needs—Installing "Specials"

Sekhri personally handled the first few sales. During 1991 and 1992, Sekhri and three applications engineers, trained to ensure that Viresolve performed optimally, helped the first 50 or 60 customers worldwide install pre-launch versions of Viresolve. These early versions of the product were known internally as "specials." Sekhri sought to ensure that the first industry impressions of Viresolve would be positive ones.

> It's a brand new technology in a very conservative market. We could not afford to have any failures in the marketplace. If a customer just got one of these things and ran it and then said, "It doesn't work," it could very well be because the customer didn't know what he or she was doing. If that customer started telling the very small, close-knit biotech market that Viresolve doesn't work, that would be the death blow to us.

The novel tangential-flow technology that Viresolve employed was a bit trickier to run than the traditional dead-end flow technology used by competitors. Explained Sekhri:

> You don't just press a button. There's optimization involved. So we thought that we would actually go out to every customer in the field ourselves, and do the trials, and write them up a full report, and then say, "Great, now you know how to do it and you're on your own."

This approach seemed to be succeeding in building appreciation for Viresolve, and for tangential-flow technology. Sekhri added, "If there is an existing perception on the part of customers, it may be that dead-end filtration is easiest, but our educated customers know that tangential-flow filtration makes a lot of sense for this application."

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The list of customers targeted for "specials" was developed by Sekhri with help from Nick Lambo, the Process Division sales manager. "We identified customers that had the highest potential for Viresolve products," Lambo recalled. But the actual sales calls were done by Paul Sekhri, with three applications engineers (one each in the United States, Europe, and Japan) handling installation. "We didn't really want to get our salespeople turned on to a product that was in alpha stages."

Costs and Pricing

Sekhri calculated a price for Viresolve by looking at what Millipore charged for its ultrafiltration membranes and calculating a premium based on what advantages Viresolve offered over ultrafiltration and the other membranes that competitors used to remove viruses. These filters often had relatively inconsistent pore sizes and had typically been designed nearly a decade earlier for other applications. Stated Sekhri:

> I knew that we had a three-part package. We had a membrane that was dedicated to the removal of viruses from proteins, and could do that reproducibly and predictably. We had validation data, which I have found to be almost as valuable as the membrane itself. Our competitors are running into problems with that right now. Their customers are saying, "It's great, we're using your membrane, so give us all of the validation data." But they don't have the data. And the third part was that we could verify the membrane's use through what's called a "correlating integrity test." So in thinking of what we charge for standard ultrafiltration membranes, I figured we could charge a premium.

Another pricing consideration was whether or not to sell the membrane modules as disposable. Sekhri asked a number of customers, "Would you rather spend more money for a single-use disposable, or spend less money for a reusable," although reusing a membrane meant having to prove that all of the previously retrieved viruses had been cleaned off. Acceptable tests for this were not reliable enough for some customers. According to Sekhri, customers said, "We'd rather have a single- use disposable, even if we have to pay a little bit more money for it." Viresolve modules were sold as single-use plastic devices and membranes, although the metal housing was permanent. One exception to this indifference to prices was the 10-square-foot module, which was considered by some customers to be too expensive for such frequent disposal. Added Sekhri: "So we compromised by validating five-time reuse."

The prices for Viresolve were as follows: $^1/_3$-square-foot module: $500; 1-square-foot module: $1,200; 10-square-foot module: $2,000. For the 1-square-foot module, the comparable price for an ultrafiltration membrane (the technology that Viresolve replaced for this application) was $500-$600. For the 10-square-foot module, it was $1,000-$1,200. Ultrafiltration membranes could be reused 10 to 20 times. The 1-square-foot module processed 20 to 30 liters, and the 10-square-foot module about 100 liters, with times varying by process. Prices on both of the smaller units had been raised once since initial introduction.

For many customers, the price of a Viresolve unit was a trivial part of their production costs. Interferon, for example, was worth $1.5 million a liter by the time it reached the Viresolve membrane in the process. Millipore recommended that Viresolve be installed in the downstream processing of biopharmaceuticals after steps like filtration, chromatography, centrifugation, extraction, flocculation, and electrokinetic separation had been completed.

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Launch

"We define a launch as: product is on the shelf, with a full complement of training and literature in place," said Nick Lambo. To Paul Sekhri, this translated into two chief tasks: "preparing the customer to buy, and preparing applications specialists [the salesforce] to sell."

Preparing Customers to Buy

Preparing customers to buy was done largely through word-of-mouth advertising and promotion. Sekhri had seeded the word-of-mouth process by ensuring that the first customers had favorable experiences. Promotion was done through the scientific press, conferences, and the trade press. Several of the product's developers wrote technical papers for prestigious scientific journals. Sekhri traveled extensively to attend trade conferences and make presentations, and he also hired a public relations firm. "We hired a PR firm because this is what I would consider really exciting news, a really good story. They helped us conduct a number of press conferences, and because of the press conferences we had a number of articles written into some pretty reputable journals. From reading these articles, people have called me up directly."

Viresolve Module Size

Millipore planned to introduce three different sizes of Viresolve: 1/3 square foot, 1 square foot, and 10 square foot. The smallest size was primarily for research work, the largest primarily for production work. Although tests at customer sites had taken place exclusively in R&D labs with small Viresolve modules, sales to production facilities were traditionally the Process Division's strength. The forthcoming 10-square-foot module would also allow Millipore salespeople to address the full life cycle of customer needs—from development of a new therapeutic to production of it.

Preparing the Sales Force to Sell

Training the sales force ("applications specialists") to sell Viresolve consisted chiefly of preparing training materials, conducting a two-day training seminar, and responding to follow-up questions from the field. During 1992, Sekhri prepared a "Launch Manual" and "Reference Materials" for each salesperson involved. The material included a description of the product line, prices, detailed answers to commonly asked questions, copies of Viresolve and competitive advertisements, published validation studies for Viresolve versus its competitors, and a step-by-step guide through the sales cycle. "I've launched the product in Europe and Japan, and they're kind of running by themselves," said Paul Sekhri. "I get maybe three to five FAXes a day" from salespeople around the world with questions.

The U.S. launch was originally scheduled for the fourth quarter of 1992, but was delayed until spring of 1993. In October of 1992, a "scaled back" version was conducted. One representative from each of four to six regions was brought in and given specialized training in Viresolve. These representatives had "the best and most concentrated opportunities for the product initially," according to Nick Lambo, who had a total of around 20 sales representatives dedicated to pharmaceuticals.

"The next step is to train the full U.S. sales force, and that's going to happen in April 1993. We're going to do this whole dog-and-pony show that we did in Europe for two days again." The training included presentations and teaching sessions, as well as "wet work" with actual Viresolve modules.

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A crucial part of the sales cycle was the conducting of a feasibility study using actual customer samples. The launch package described how the salesperson was to go about arranging these studies. Once the initial contact was made, customers filled out a form explaining their virus removal needs. The salesperson faxed the form to Millipore application engineers, who let the salesperson know within 48 hours whether or not the application appeared to make sense. Once a mutually convenient date was set, the application engineer, customer, and salesperson all met to conduct the feasibility study at the customer site, using a sample of the material to be purified. Within two weeks, application engineers completed a report and Federal Expressed it to the customer, who then made the decision whether or not to purchase Viresolve. From this point on, the salesperson kept in touch with the application engineers for any further technical assistance.

Launch Strategy

Two elements of the launch strategy were considered particularly crucial. First, Lambo and Sekhri wanted biopharmaceutical firms to use Viresolve in the R&D process, so that there was a natural progression to using it in production. This would happen both because of familiarity with the product and because of the product's inclusion in the FDA approval process. "What you want to do ideally is work with the customer as they develop the processes for drugs, to educate and inform them of our technology, to prove it on small scale so that it carries through into the process step," said Nick Lambo. "If you miss that opportunity to get it inserted early, there's a lot more work to be done."

The historic strength of Lambo's sales force made this particularly challenging. "My organization tends to focus on the production scale end," which was where the 10-square-foot version might be used. "But products like Viresolve have to be inserted in the R&D stages, early on. By the time production has begun, getting them retroactively inserted is difficult." To improve his organization's ability to handle this challenge, Lambo had hired an R&D engineer in California to concentrate strictly on "R&D insertion" of Millipore products, including Viresolve. "If that's successful, and we think it will be, then I'll rapidly apply for another headcount in other parts of the world."

The other crucial element of the launch strategy was to push the Viresolve/70 hardest in the initial stages of the launch. Because the disparity between protein and virus sizes was greatest for the applications that Viresolve/70 was targeted at, Sekhri felt that the chances for dramatic success were best with this product. Such dramatic success, it was felt, could help set the stage for the commercial success of later products in the Viresolve line.

Forecasting Sales

Sekhri had forecast sales of $200,000 in 1992. Viresolve had achieved $300,000 in sales by the middle of the fourth quarter.

Many managers at Millipore couldn't help but contrast Viresolve with launches of product line extensions, many of which began with sales in the millions of dollars. Nick Lambo expressed these sentiments: "Viresolve is an exciting product because it is a major leap of faith. It's something no one else has on the market. The frustrating part is, you're not going to see a rapid sales ramp."

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Remaining Commercialization Issues

Repeating Viresolve's European Successes in the United States

To date, interest in Europe had been particularly strong. Explained Sekhri:

> In Europe, the government has already published guidelines for virus removal. The United States has not yet published guidelines. That's why some U.S. customers say, "We'll use it when we're told we need to use it." Well, in Europe they're being told to use it. All of the early adopters came out of Europe.

The absence of U.S. regulations made the U.S. launch of Viresolve all the more challenging.

Millipore was working on the development of the 10-square-foot module which could be sold to manufacturing facilities. The smaller Viresolve modules were more suited to R&D facilities. "We've got to have the 10-square-foot module," insisted Nick Lambo. "This is not an R&D tool, and unless you can show a clear path to production scale, the product will have short-term interest." The 10-square-foot Viresolve module was one of the top development priorities of the R&D manager in the Pharmaceutical group of the Process Division.

Millipore was already looking into several promising extensions of the Viresolve product line. A similar system might be designed to remove nucleic acids or pyrogens. "Any time you have a product stream that could be contaminated by a biological agent you need a membrane to filter it out," explained Sekhri. Millipore was also very interested in designing a system to provide virus removal to blood processing companies, using a technology different from size exclusion.

While Viresolve would undoubtedly meet with a measure of success, some managers at Millipore were concerned that the product might have a limited window of opportunity. "There are some people in my organization who think that this product may have a short life cycle," noted Nick Lambo. "You're talking about mammalian cell technology and the viruses present in that. As technology moves away from that, as more products are being built through other kinds of technology, it may not be an issue." As genetic engineers gained the ability to chemically synthesize more proteins instead of modifying mammalian cells to produce them, these managers felt that there would be correspondingly less risk of viral infection. Other managers, however, argued that research on new biotechnology drugs would probably always involve the use of mammalian cells, and thus the need for virus removal products would continue.

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Exhibit 1 Five-Year Revenue Review by Technology/Market/Geography ($ in thousands)

	1991	1990	1989	1988	1987	5-Year Growth Rate
Sales by Product Line and Technology						
Analytical						
Membranes	$145,909	$139,358	$124,612	$123,241	$110,773	9%
Chromatography	265,412	259,693	242,574	230,741	207,944	8%
Other	42,429	38,638	29,698	18,824	6,392	96%
Sub-total	453,750	437,689	396,884	372,806	325,109	11%
Purification						
Membranes	257,476	226,156	186,981	170,307	130,084	19%
Chromatography	26,454	26,669	24,739	29,059	20,884	10%
Other	10,299	12,648	7,726	6,751	12,405	–
Sub-total	294,229	265,473	219,446	206,117	163,373	17%
Total	**$747, 979**	**$703,162**	**$616,330**	**$578,923**	**$488,482**	**13%**
Sales by Market						
Industrial[a]	$512,219	$476,104	$427,617	$399,406	$329,015	14%
University/Government	178,016	172,504	139,568	133,195	110,810	15%
Patient Care/Medical Research	57,744	54,554	49,145	46,322	48,657	3%
Total	**$747,979**	**$703,162**	**$616,330**	**$578,923**	**$488,482**	**13%**
Sales by Geographic Area						
United States	$274,718	$267,627	$250,218	$230,010	$203,827	9%
Western Europe	234,201	230,391	183,824	176,077	152,085	14%
Japan	171,279	136,205	120,123	112,838	86,206	18%
Other[b]	67,781	68,939	62,165	59,998	46,364	11%
Total	**$747,979**	**703,162**	**$616,330**	**$578,923**	**$488,482**	**13%**

[a]Under Industrial was included industries such as pharmaceutical, biotechnology, chemical, and microelectronics.
[b]This included sales to Latin America, Africa, Eastern Europe, and other countries in Asia except Japan.

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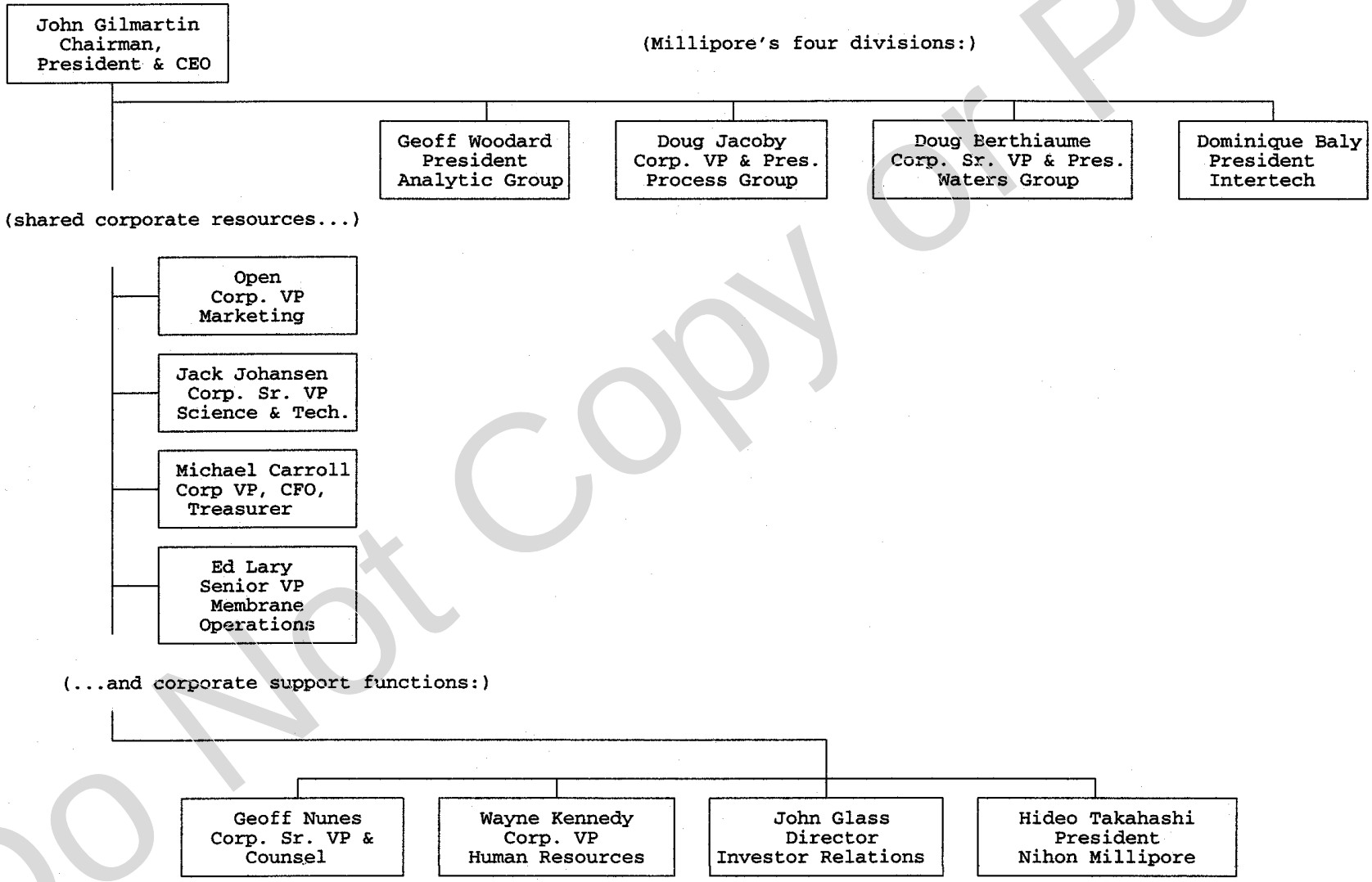
Exhibit 2 Millipore Organization Chart, March 1992



Source: Casewriter's depiction of organization from company data.

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Exhibit 3 Organization of Sales and Marketing Functions at Millipore

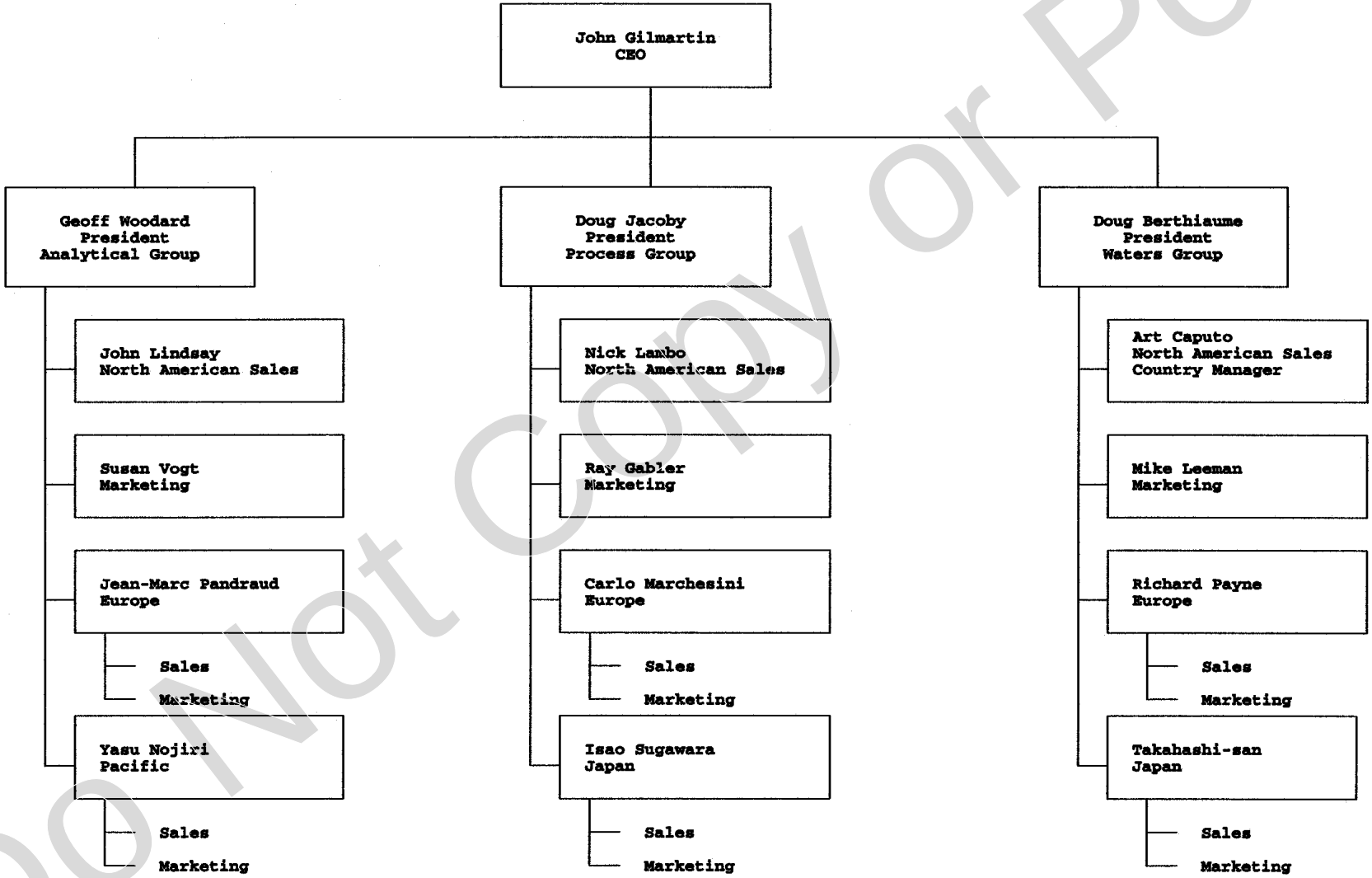

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Exhibit 4 New Product Evaluation Criteria at Analytical Group

	RETURN ANALYSIS	Weights	0	1	2
S	Market Size (potential market-current year)	7	<$5M	$5M-$20M	$20M>
S	Market Growth (5 years out)	9	<15%	15%-30%	30%>
S	Market Share (3rd year after K.O.)	5	<15%	15%-40%	40%>
S	Strategic Importance to Base Business	15	Base <$5M	Base=$5M-$20M	Base $20M>
S	Potential for new market segment	10	All business pertains to base	Some potential for new cust. base	Totally new customer base
F	3rd year sales (net of cannibalization)	9	<$1M	$1M-$4M	$4M>
F	Total 5 years sales (net of cannibalization)	12	<$4M	$4M-$15M	$15M>
F	Net Present Value	14	<$0M	$0M-$1.5M	$1.5M>
M	Potential Geographies for Sales	4	One geography	Two Geographies	Worldwide
M	Potential for Product Differentiation	9	Comp has similar and superior	Similar, but ours superior	We are only one in market
M	Potential Patent Protection	6	No patent position	Weak patent position	Strong patent position
		100			
	RISK ANALYSIS				
C	Total R&D Cost (5 Years-only MAG)	6	<$.75M	$.75M-$3M	>$3M
C	Total Capital Cost (5 years-only MAG)	3	<$.5M	$.5M-$2.5M	>$2.5M
C	Market Development Cost (5yrs Mktg & Prom)	4	<$.25M	$.25M-$1.5M	>$1.5M
R	Technology Risk	9	We already own technology	Technology exists	Technology requires invention
R	Strength of Technology Skills	7	Have skills and necessary quantity	Have skills, not nec. quantity	Do not have nec. skills or quantity
R	Product/Engineering Development Risk	4	We do it everyday	Others do it, we have to acquire	No one has done it
R	Strength of Development Skills	4	Have skills and necessary quantity	Have skills, not nec. quantity	Do not have nec. skills or quantity
R	Manufacturing Technology Risk	4	We do it everyday	Others do it, we have to acquire	Requires Mfg. invention
R	Strength of Manufacturing Skills	4	Have skills and necessary quantity	Have skills, not nec. quantity	Do not have nec. skills or quantity
R	Sales and Service Skills	4	Sales force well trained	Significant training & redirection	Add specialists
R	Regulatory impact	3	Not regulated	Regulated, we're in	Regulated, we're not in
Cmp	Presence of dominant competitor	3	Competitor has <15% share	Competitor has 15%-40% share	Competitor has >40% share
Cmp	Number of competitors	2	<3	3-5	>5
Cmp	Risk of Existing Competitive Technology	4	No existing competitive technology	Exists, but not fully developed	Comp. tech already commercialized
Cmp	Risk of Alternative New Technology	4	No existing alternative new tech.	Exists, but not fully developed	Alternative new tech. commercialized
		65			

Weighing Breakdown

Return

Strategic (S) _____46% Risk - Cost (C) _____20%

Financial (F) _____35% Risk (R) _____60%

Miscellaneous (M) - 19% Competition (Cmp) - 20%

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Exhibit 5 History of the LC/MS Project

1985: A marketing manager and a scientist at Waters collaborated to develop liquid chromatography systems tailored specifically for use with the mass spectrometers and interfaces offered by mass spectrometry firms.

1986: Sales of "tailored LCs" begin.

1987: Sales of "tailored LCs" hit $500,000. Funding officially assigned to development program. Waters begins a series of meetings with component vendors with the aim of eventually building mass spectrometers in-house using purchased components. A favorite idea involves developing a smaller version of the full-scale mass spectrometer offered by other firms. Scientists at Waters also begin to develop proprietary LC/MS interfaces.

1988: Newly hired project manager from outside builds a team of scientists capable of developing a full-scale mass spectrometer in-house. Interface development scaled back. New strategy is to aim for the high end of the analytic market with a full-scale machine, eventually offering a smaller mass spectrometer in addition. Vendor agreements are pursued, some as a temporary measure until component manufacture can be brought in-house.

1989: Project manager is dismissed amidst financial and strategic concerns. Much of the scientific team he assembled disperses.

1990: Dave Strand inherits the LC/MS program.

1992: Extrel acquired.

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Exhibit 6 Growth Rates of Two Similar Products: GC-MSD and LC-PDA

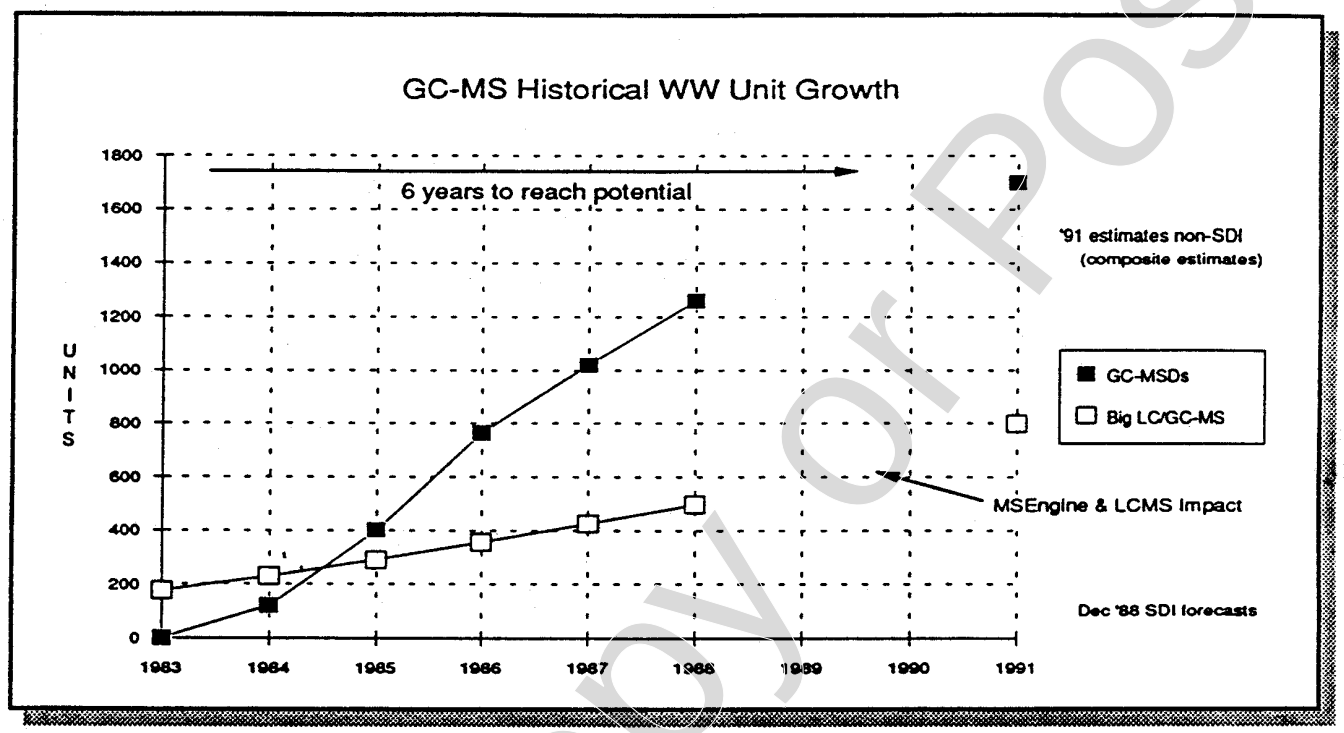

Exhibit 7 History of the Viresolve Project

1985: Tangential flow expert at Millipore searches for additional applications of tangential flow technology. A top marketing manager generates a short list of potential applications. Technical team tests feasibility of potential applications.

1986: Promising virus removal trials are presented to top management. Proponents of virus removal gather further customer information, and a major Millipore customer makes a presentation to top management requesting development of a virus removal product.

1987: Project is officially funded, and development work begins. Membrane manufacturing process is altered to enable production of membranes with fewer defects in pore size.

1988: Development work continues. Decision made to focus on membrane development before firming designs for a device to deploy the membrane.

1989: Formal project plan constructed by project leader, allowing different sections of project team to more effectively work in parallel.

1990: Working membrane developed. In all, six tests at customer sites are conducted between 1987 and 1990. Paul Sekhri hired to commercialize product.

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Exhibit 8 Virus Removal Properties of Viresolve/70

VIRESOLVE/70 QUALIFICATION

PREDICTED MINIMUM SYSTEM PERFORMANCE

- **Virus removal in PBS**

	Virus Diameter (nm)	1-Stage (log removal)	2-Stage (log removal)
Parvovirus	22	1.5-1.8	2.7-3.0
Hepatitis C	40	3.3-3.4	6.5-6.7
BVD	40	3.3-3.4	6.5-6.7
HBV	42	3.5-3.8	6.8-7.1
Adenovirus	70	6.0-6.3	
HIV	100	7.4-7.7	
Herpesvirus	100	7.4-7.7	

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Exhibit 9 Viresolve's Performance Against Competitors

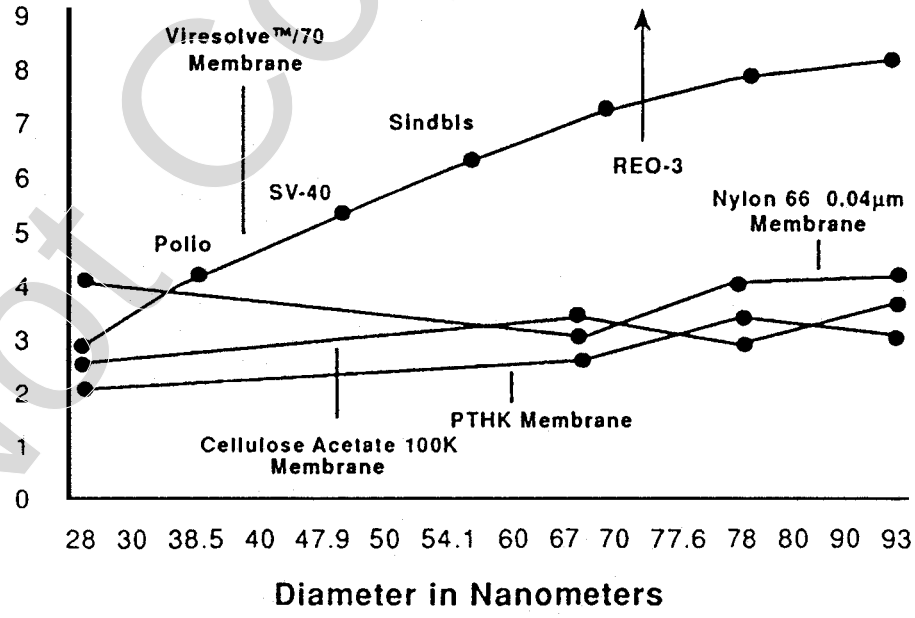
NEW MEMBRANE PROVIDES VALIDATABLE PERFORMANCE

Millipore, the world leader in membrane technology, has developed the Viresolve virus removal module, the first technology to deliver validatable viral clearance.

Viresolve modules consist of unique nanoselective membranes that can remove 4-6 logs of 40 nm sized viruses and 8+ logs of retroviruses, while recovering greater than 90% of proteins the size of human albumin and smaller. In fact, log reduction values can be almost doubled by running Viresolve modules in series.

MAMMALIAN VIRUS RETENTION BY VIRESOLVE IS PREDICTABLE

Particle LRV As A Function Of Particle Diameter
(Includes Mammalian Viruses)



Minimum virus removal using Viresolve/70 system.

Note: "LRV" = Log Reduction Value = $\frac{\text{C feed}}{\text{C filtrate}}$

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