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Market Size and Economics for Biosensors

13.1 INTRODUCTION

Biosensors are gradually being used in an increasing number of applications. Heffner (2006) very recently emphasizes that though medical applications still remain the major area of application, biosensors are gradually penetrating a wide variety of non-medical areas. This author indicates that the breadth and depth of biosensor applications has resulted in a 25% increase in the world biosensor market prediction made as early as August 2002 by Kalorama Information for the year 2005 of $2.3 billion to $2.9 billion. The revised estimate was made in the year 2006. Heffner (2006) further indicates that earlier predictions indicated that the medical application was around 90% of the total biosensor market, which includes clinical applications for diabetes, cholesterol, and coagulation monitoring. However, medical applications of biosensors are now down to around 60%. Heffner (2006) attributes these changes to the rapidly advancing technologies and to some serious business challenges.

Newman and Setford (2006) in their very recent review of enzymatic biosensors indicate that the biosensor field has expanded dramatically in the last 45 years or so since the first demonstration of a biosensor application in 1962. These authors emphasize that the self-diagnosis of blood glucose levels by diabetes sufferers, however, still remains the dominant area of biosensor application. In their recent review they provide a historical development of the biosensor field and also provide a commercial perspective.

Business Wire (2005a,b) mentions that Frost and Sullivan (http://www.sensors.frost.com) indicate that the revenue from the World Biosensors market was $2.34 billion in 2004. This is projected to increase by 87.1% to $4.38 billion by the year 2008. This report emphasizes that a couple of key issues that are restraining the biosensor market are a small number of research laboratories and a low level of commercialization of biosensors that are developed in research laboratories. The increased investment in new laboratories is essential to permit the application research required for determining the commercial applicability of biosensors.

Market Research.com (2005) has projected the medical biosensor applications and market to the year 2008. This 81-page report was published by Takeda Pacific, and provides (at least the authors claim this) critical business and competitive intelligence required for
strategic planning and market research in the biosensor area. The report claims to cover the United States, United Kingdom, Europe, Asia, and global markets.

The report estimates that global biosensor market for medical purposes to about $7.1 billion in the year 2004. For the years 2005, 2006, 2007, and 2008, the estimated biosensor market is in dollar billion, 7.79, 8.54, 9.37, and 10.28, respectively. This report analyzes medical biosensors and applications, diabetes and clinical applications, and medical biosensors for artificial organs. The report emphasizes the development of innovative medical biosensor devices that would work as a part of artificial organs such pancreas, liver, or kidney. The report also examines the activities at key biosensor companies, and selected academic centers. Finally, it also provides a future outlook for the development of biosensors.

Yurish et al. (2005) have recently analyzed the trends in world sensors and microelectromechanical systems (MEMS) markets. These authors emphasize that fixed and durable medical sensors are gradually being replaced by disposable biosensors that cost less and are more hygienic. They indicate that low cost and high volume sales are becoming the key components for remaining competitive in the medical biosensor market. In order to enhance biosensor market penetration into non-medical areas of application, increasing investment is recommended for biosensor R & D (Infoshop.com, 2005; Frost and Sullivan, 2005). Yurish et al. (2005) cite a Business Communication Company, Inc. (Norwalk, CT, USA) report (RG-116N Fiber Optic Sensors) that the global revenues for fiber optic sensors was projected to be $304.3 million for the year 2006. This was projected to increase by 4.1% to $371.8 million by the year 2010.

Fraser (1995) indicated that in 1995 the control of diabetes or the determination of blood glucose levels was the only high-volume market for biosensors. However, even at that time this author indicated that there were opportunities available in a variety of lower volume niches in the medical diagnostics, pharmaceuticals, and other areas. This author emphasized that the future expansion of biosensor technology would be dictated by a balance between market opportunities and technical and/or financial obstacles.

Menon (2004) in a short review on optical biosensors mentions two models of commercial case studies for biosensors. He indicates that the first biosensor was commercialized in 1991. The two models are the razor blade model and the OEM model.

In the razor blade model the technology platform for the biosensor is such that the revenue is generated by a consumable commodity rather than by an actual instrument. The razor/razor blade is a good example, wherein the revenue is generated from the sale of razor blades. This author emphasizes that photonics based biosensors, such as the glucose monitor is based on this principle. In the OEM model, the biosensors such as the SPR biosensor made by Biacore provides high throughput. These are expensive instruments, and costs of hundreds of thousands of dollars, and can only be purchased by industrial organizations and well-heeled university research laboratories.

An example or two of the razor/razor blade model as it applies to biosensors and diagnostics is perhaps useful here. The diabetic test strip market is very large and profitable. These strips cost a few cents to make, and sell for 60–75 cents each in boxes of 100 for $60–75 (DiabetesStore.com, 2007; Diabetic Test Strips, 2007). Small Times (2007) emphasizes that these strips are the profit center. It is estimated that there are 12 million diabetics who use these strips eight or more times a day. This means that over close to 100 million strips are used each day in the United States alone. Using the low value of 60 cents per strip
this leads to a revenue of $60 million from diabetic strips in the United States alone. The number of diabetics is estimated to climb to 14.5 million by the year 2008 (Diabetic Test Strips, 2007). The number of diabetics was estimated to be 12 million in the year 2003 (Smalltimes, 2003). One may anticipate errors in the estimate of the actual number of diabetics made by different authors, nevertheless, the numbers of diabetics is very large, and in all probability, this number is bound to increase due to increasing obesity and poor nutritional intake by quite a large fraction of the population, in general. Diabetic Test Strip (2007) indicated that the sales of diabetic strips was $1.6 billion in the year 2002. In the year 2008 this diabetes glucose monitoring market was estimated to be $3 billion, and is/was expected to climb by 7.2% annually in the year 2003–2008, period.

The glucose testing meters in accord with the razor/razor blade model are either available at no cost, or at a minimal cost and their price is decreasing. A very recent check on the prices for glucose meters on the internet (Test Medical Symptoms@Home, Inc., 2007) reveals that one can get a glucose meter plus 10 test strips for a price range of $15–66. As mentioned above, most companies will supply meters free of charge, and this is also evident from the recent TV advertisements, at least in the United States, especially if one is of age (65 and over, generally), and under Medicare. Testing strips and meters are also available for monitoring and determining cholesterol levels. Some strips like the Cardiochip PA Cholesterol Plus Glucose Test will check cholesterol and glucose in multi-panel test strips (Test Medical Symptoms@Home, Inc., 2007). One may also obtain meters to check for cholesterol, low-density lipoproteins (LDL) and high-density lipoproteins (HDL).

Axela Biosensors (2006) has recently indicated that it will incorporate Beckman Coulter’s Universal Linker Capture Technology in its dotLab™ biosensors. It further indicates that Beckman Coulter reported a 2005 annual sales of $2.44 billion. Out of this 71.5% of this revenue was generated by recurring revenue from supplies, test kits, services, and operating lease agreements. Once again, reinforcing the razor blade–razor model. Finally, one may also have noticed the razor–razor blade model in other non-biosensor business/marketing areas such as the printers and printer cartridges, where the major profit lies in the sale of the printer cartridges vis-à-vis the cost of the printer itself.

Radke and Evangelyn (2002) analyzed the biosensor market for the pathogen detection industry. These authors combined the military, food, medical, and the food industry together. In the year 2002, their estimate for the pathogen detection systems was $56 million, with an anticipated compounded annual growth rate of 4.5%. By the year 2005 these authors estimated this market to grow to $192 million with an estimate of 34 million tests. This works out to about $5.64 per test. Perhaps, under present day circumstances this number could be estimated to be $10 per test. These authors further state that as legislation creates new standards for microbial monitoring, especially after a pathogenic outbreak or two that seems to occur regularly after periodic intervals, there will be pressure to commercialize biosensors for food industry application that are increasingly sensitive to these pathogenic organisms.

Patel (2006) in a recent review of affinity biosensors for food analysis applications estimates the projected global affinity biosensor market to grow from $6.1 billion in 2004 to $8.2 billion in the year 2009 for the major industrial sectors such as Pharma, Medicare, and Food. This represents a 34.4% increase in about 5 years. Note that, and as expected, the projected estimates for the worldwide biosensor market are different by different authors. The projections are dependent upon who is making these projections, on what assumptions are
these projections based on, and the reliability of these assumptions and projections, and the
individual or organization making these projections.

Kalorama Information (2006) has recently published a report entitled “Medical and
Biological Sensors and Sensor Systems: Markets, Applications, and Competitors Worldwide,
2nd Edition.” In this 290 page, $3500 report the authors analyze the commercial challenges
for biosensors. They also discuss the advantages of different biosensors such as the surface
plasmon resonance (SPR) biosensor, the use of monolithic semiconductor processing, the
application of thin and thick films for sensor fabrication, the applications of polymer films
in sensors and fiber-optic biosensors. These authors delineate biosensor applications, and
also present their estimates of the biosensor markets by geographic locations such as North
America, Europe, Japan, Latin America, China and Japan, and the rest of the world. These
authors emphasize that the commercial medical biosensor market is dynamic in the sense
that reports that are a year or two old are out of date due to the rapid penetration of new tech-
nology. Finally, the report emphasizes the potential markets and emerging technologies in the
different biosensor areas of application.

These authors also attempt to analyze the different variables that may influence the size of
biosensor markets, or how the biosensor revenues may be affected. Some of these variables
include (a) the high costs of biosensor development, (b) there are manufacturing and product
problems, (c) technologies that are synergistic with biosensors are maturing and competing,
and (d) nanotechnology and miniaturization is bound to influence biosensor development
costs and economics in general. Interestingly enough, these authors also examine the role that
small companies with niche markets play vis-à-vis large companies with mass markets.

The Center for High-Rate Manufacturing (CHM) in Boston, Massachusetts is funded by
the National Science Foundation in Arlington, Virginia and includes Northeastern University
in Boston, the University of Massachusetts in Lowell, the University of New Hampshire in
Durham, and Michigan State University in East Lansing (Center of High-Rate Manufacturing,
2007). One of the thrusts of this center is nanotemplate-enabled high-rate manufacturing.
The intent here is to guide nanobuilding blocks to self-assemble over large areas in high-
rate, scaleable, commercially viable processes such as injection molding, and extrusion. The
authors emphasize that their template process will permit the fabrication of a single carbon
nanotube (CNT) electromechanical switch. The authors estimate that the market for these
switches at $100 billion. The center has combined with Nantero, a company that manufactures
CNT computer memory switches. These nanotemplates are also to be used in a biosensor for
the rapid (8–10 min detection time) analysis of antibodies. The authors emphasize that they
have developed technical cost models for each step of their nanoprocess to help analyze the
tradeoffs between economic and environmental tradeoffs. This is in-line with the current line
of thinking of the possible hazards in nanomanufacturing processes. Also, fiscal feasibility
and economics of scale-up of each nanoprocess is being carefully analyzed.

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13.2 COLLABORATION BETWEEN COMPANIES, UNIVERSITIES, AND
STATE AND GOVERNMENTAL AGENCIES: TRENDS IN COLLABORATION

Different trends and models for collaboration between different entities are being noticed
at the present time. Some of these trends are presented here. Incubators are springing up
wherein scholarly research at universities may be gradually turned into or groomed to
becoming successful business ventures. The University of Connecticut at Storrs is one such example (UConn Advance, 2005). Zangari, the executive program director of the Technology Incubator Program (TIP) indicates that the incubator nurtures startup high-tech companies. The intent is to bring the University of Connecticut’s new ideas to the market place. The incubator provides newly minted entrepreneurs laboratory and office space, and ready access to UConn’s facilities and equipment. TIP fits in with the broader perspective of UConn’s larger Office of Technology Commercialization. In essence, the TIP program provides entrepreneurs with assistance to get rolling for less than it would cost them to rent office space, etc. Zangari further underscores the importance of the TIP program in that (a) half of small businesses fail within 4 years, and (b) 87% of companies that used the incubator facilities stay within the community.

Kent State University’s (Kent, Ohio) Office of Technology and Economic Development also assists university faculty to startup new companies (Kent State University: Research and Graduate Studies News, 2006). The biosensor program at Kent State University is a good example of collaboration between a university and a company. Two startup companies, Origen and Pathogen Detection Systems have emerged from the co-licensing of liquid biosensor technology developed jointly by Kent State University and NEOUCOM. The liquid biosensor technology used by these startup companies can detect bioterrorism agents, pathogens in food and water, and it has potential for military, environmental, and medical applications. Kent State University’s Office of Technology and Economic Development also provides (a) leads to venture capital, (b) management talent, (c) office and laboratory space, and (d) leads to design, manufacturing, and new technologies. The primary intent is to facilitate regional economic growth for Northeast Ohio.

University of Oxford News (2004) indicated that Isis Innovation, Oxford’s technology company will collaborate with Mitsui to take the University’s Intellectual Property into Japanese markets. Mitsui is one of Japan’s biggest companies, and its Europe affiliate (Mitsui, Europe) had recently made an investment in Oxford BioSciences Ltd. (a company spun out of the University of Oxford in the year 2000). The intent, of course, is to eventually introduce advanced products into new markets.

Business Wire (2005) indicates that Advance Nanotech, Inc. in New York is a premier provider of financing and support services to help drive the commercialization of nanotechnology devices. This company has recently announced the financing of BiMAT. This is new technology that should assist in the early detection of Avian Influenza (Bird Flu) in humans and in animals. BiMAT is a partnership between Advance Nanotech, Inc. and The Center for Advanced Photonics and Electronics (CAPE) at the University of Cambridge, United Kingdom, Alps Electric Company, Dow Corning Corporation, and the Marconi Corporation. CAPE is an integrated research facility for electrical engineering. The BiMAT technology should assist first responders such as medics, emergency medical technicians (EMTs), and doctors to analyze microscopic biological material quickly for pathogenic diseases on site. This procedure will eliminate the need to send the testing material to laboratories offsite, and thereby eliminate the problems and errors associated with this type of transfer.

Business Wire (2005) indicates that the sensor BiMAT is developing is an integrated, low cost, and disposable biosensor and sensor arrays. They may be used for point-of-care (POC) diagnostics, clinical monitoring, and for biomolecular research. These biosensors will incorporate thin film polysilicon transistors deposited on lightweight, inexpensive
substrates. Advance Nanotech, Inc emphasizes that these low-cost thin film (TFT) devices will have a wide range of application for disposable biosensors that they plan to develop.

At this juncture it is perhaps appropriate to provide an example of collaboration between two companies. Axela Biosensors, Toronto, Ontario, Canada, has acquired the license to use the patented A²R universal linker capture technology from Beckman Coulter (Axela Biosensors, 2006). This technology will be incorporated into Axela’s dotLab™ Sensors, and provide researchers the unique ability to create user-defined multiplex biomarker panels. Axela Biosensors indicates that this will permit the researchers using this new launched dotLab system to create multiplex assays without the need for specialized pipetting or spotting techniques. Also, this technique will permit researchers to build combined assays with micromolar and picomolar sensitivity requirements.

Phylogica (2006), a drug discovery company in Subiaco, Western Australia has recently indicated that Axela Biosensors will be testing its novel screening technology on Phylogica’s large pool of small protein fragment (peptides). These peptides, Phylogica claims act as drugs by blocking a disease process at the protein level. Phylogica indicates that the initial step in the collaboration involves the validation of Axela’s diffractive optics technology (DOT) so that it can effectively analyze Phylomer® (small protein fragments) candidates. The diffracted light in the DOT technology will be used to analyze the interactions between proteins, antibodies, and other smaller molecules.

Tekes teknologiaporssi (2006) located in Finland recently indicates that a United Kingdom company is looking for assay development partners to help develop and manufacture its highly sensitive and low cost biosensor assay that greatly reduces sample preparation and incubation time. Their ligand-binding assay uses standard immunoassay techniques. Since their biosensors are robust, they are able to quantitatively detect analytes in complex aqueous-based systems with generally no sample preparation. This biosensor is apparently easy to use, reduces incubation time, and is also highly sensitive.

The patented technology uses a proprietary method of growing a polymer layer on a single-use electrode. This acts as the transducer in the biosensor system, and reduces sample time. The UK company indicates other advantages that include easy and quick sample preparation, can work with milk, plasma, and blood samples, only very small samples are required, and it is very sensitive (for example low femtomole detection of large proteins). Furthermore, the development platform has a low capital as well as a low consumable cost. Besides, the biosensor is able to detect a wide range of low, medium, and high molecular weight analytes. The quantitative results obtained during the detection process may be used for both monitoring and screening applications.

### 13.3 FACTORS THAT COULD HELP INCREASE/DECREASE BIOSENSOR MARKETS

Fraser (1995) as early as 1995 indicated that as far as biosensor markets are concerned, there are problems waiting for biosensor solutions. In effect, the future expansion of biosensor markets will depend on the balance between market opportunities and technical/or financial obstacles. A Kalorama Information (2006) report indicates the following four factors that
would help expand the biosensor market: greater quality of life expectation, innovative new technologies, research at Industrial/Governmental/Academic Laboratories, and the gradual acceptance of biosensor methods to help improve healthcare and other applications.

Business Wire (2005) indicates that a few technical problems are slowing down the commercialization of biosensors. These include selectivity, reproducibility, reliability, and the cost of manufacturing. These types of considerations not only delay new product launches but also prevent the large-scale production of a wide variety of newly developed biosensors. This author emphasizes that the manufacturing aspects need to be streamlined. Miniaturization and the application of nanotechnology and nanobiotechnology principles should assist the biosensor field to make inroads into hitherto untapped areas of application. These authors emphasize that the high costs of R&D for a new biosensor remains significantly high (around $40–50 million, and involves 8–10 years development time). This coupled with the lack of financial support for these types of endeavors limits the development of biosensor to larger companies, and excludes the smaller ones. Smaller companies (less than 50 personnel perhaps; an arbitrary number) can, however, develop biosensors in niche and specialized areas of application (Business Wire, 2005).

Heffner (2006) estimates that it can take about 5 years and $40 million to get a biosensor to the market. The author emphasize that poorly capitalized sensor companies can go out of business before reaching commercialization. This is particularly true if the companies are not careful and frugal especially in the development of medical sensors where regulatory approval is necessary. Fortunately, however, this author indicates that due to similarities in the detection of pathogens and human diseases, and for environmental applications, some of the technical know how and resources may be diverted from these types of areas where regulatory approval is not as strict as is for human application. It is important to point out that for medical purposes, at least, the newer products (biosensors) must go through developmental as well as regulatory steps (or process).

Further collaboration between University–Industry partners should assist in driving down the costs for biosensor development and assist in their commercialization. Non-biosensor technologies continue to pose a threat to biosensors, especially since they are inexpensive compared to the biosensors. However, end users of biosensors should be educated on the fact that although other methods of analysis are available, it is the ease of use of the biosensors that makes them the correct choice of technique of application for the detection of most analytes of interest.

Parce (2006) of Nanosys, Inc., located in Palo Alto, California delivered an interesting seminar at Columbia University, New York, NY entitled “Research in Academia and Start-up Companies: Different Goals, Different Focus,” emphasizes the difference in goals, funding, and external forces whilst doing research in the academia and in industry. This is in spite of the fact that methods and tools for research are the same. The author highlights these differences for products over the last 20 years, which followed the path from an R&D process to a start-up company. Examples of biosensor and microfluidic (lab-on-a-chip) systems were presented. The author emphasizes that the fundamental research discovery is just the tip of the iceberg with regard to the series of engineering efforts required to effectively bring product to the market. He predicts that similar processes will also apply to nanotechnology products as well.
The National Science Foundation, NSF 05-526 (2005) Program Solicitation document entitled, Sensors and Sensor Networks (Sensors) has also identified some of the problems that hinder the development and subsequent commercialization of biosensors. These include required advances in enhanced sensitivity, selectivity, speed, robustness, and fewer false alarms. Besides, these biosensors should be able to function unattended, and in unusual, extreme, and complex environments. The above-mentioned document emphasizes the need for improved methods for sensor fabrication and manufacture, advances in signal processing, and integration with electronics on a chip. Lower power consumption would also be of assistance. This document further emphasizes economic manufacture and the delivery of biosensors. The NSF document does, however, indicate that emerging technologies (nanotechnology quickly comes to mind) do exhibit the potential to provide biosensors of lower cost, greater robustness, and increased lifetime and reliability.

In a subsequent National Science Foundation Program Solicitation, 06-566 entitled Biophotonics with a proposal submission window: August 15, 2007 — September 15, 2007, the NSF requested for proposals that use innovative basic research in biomedical photonics which would then lay the foundation for new techniques and applications in medical diagnostics and therapies. The program solicitation indicated that molecular-specific sensing, imaging, and monitoring systems with high optical sensitivity and resolution would be of considerable assistance in biology and medicine. The program solicitation further states that low cost diagnostics will need the integration of photonics, microbiology, and material science.

13.4 EXAMPLES OF BIOSENSOR COMPANIES, THEIR PRODUCT, AND THEIR FINANCIAL BACKERS

Different examples of biosensor companies along with their product and what analyte it detects will be presented here. Information on their financial backers wherever available is also presented. Most, if not all, of the examples have been selected at random to provide an overall perspective of the biosensors that have been or are in the process of being commercialized.

Biophage Pharma, a Canadian biopharmaceutical company develops new therapeutic and diagnostic products based on phage technology against bacterial contamination (Biophage Pharma, Inc., 2007). This company has developed a portable PDSR biosensor, and provides service in immunogenicity and immunotoxicity. Furthermore, its MELISAR testing device may be used for the detection of sensitization to more than 20 different allergens and pollen from a single blood sample. The company specializes in immunogenicity and immunotoxicity, as mentioned above, and in the sensitization to metals.

The company has recently indicated that it has recently received orders from clinics in California and in Quebec for its MELISA® detection device (Biophage Pharma, Inc., 2006). The company indicates that the MELISA® test is the first scientifically validated metal allergy test, and this should help consolidate their product development activities, and focus on the commercialization of its new PDS portable biosensor. The MELISA® detection test is able to simultaneously screen for metals such as nickel, mercury, lead, silver, gold, zirconium, titanium, and manganese. This should assist in metal-sensitive patients suffering from
ailments such as Psoriasis, Eczema, systemic lupus erythematosus (SLE), Sjorgen’s disease, etc. The company recommends using the MELISA testing procedure prior to any invasive procedure such as pacemakers, silicone breast implants, insertion of screws, knee prosthesis, and cochlear implants, etc. This will assist in identifying alternate solutions, if necessary, to these invasive procedures.

Axela Biosensors (2006) referred to earlier in this chapter is located in Toronto, Ontario, Canada, commercializes products that assist in the validation of protein biomarkers from discovery into routine clinical practice. Its DOT permits the real time detection and making quantitative of protein binding events in complex media. The DOT is an efficient and low cost tool. The DOT sensor is an optical sensor that uses microfluidics and photonic technology. Axela Biosensors is a privately held company whose major investor is Ven Growth Private Equity Partners, which is one of Canada’s premier private equity managers.

Babcock (2007) in an interesting talk entitled “Adventures in Technology Development: How an SB Startup is Commercializing The Next Big Biosensor” mentions the different facets involved in setting up a start-up company for a MEMS-based biosensor. He indicates that this is the world’s most sensitive detector of mass in fluid systems. The biosensor is designed to monitor the progression of HIV in developing countries (a highly important and much needed topic and area of use). He also outlines the different types of resources available at the local business/university/technology interface. Needless, to say the path that he took from a University of California postdoctoral student in physics to a small business CEO is anticipated to be rather circuitous. Most such frequent lectures at meetings of interest where scientists convene to analyze and discuss technical topics would help encourage university faculty members, especially those who have never thought of such matters, to venture off on their own also.

IST results (2006) have recently indicated that a Cypriot startup company, SignalGeneriX founded in 2004 is using digital signal processing (DSP) to assist in the detection of prostate cancer and three-dimensional positioning. The company has obtained a broad portfolio of intellectual property rights for core DSP algorithms (for example, security biometrics, speech recognition, and image compression). The intent of the company is to specialize in solutions for the medical, telecommunications, environmental monitoring, security, and military applications.

The initial financing for SignalGeneriX was from personal funds, research grants, and from bank loans. Their project entitled TAMIRUT includes eight consortium partners. The company aims to develop a new ultrasound biosensor for the early detection of prostate cancer with the 4 million Euros (equivalent to $5.19 million: exchange rate €1 = $1.2976, January 25, 2007) that they have raised. The company emphasizes that prostate cancer is one of the highest cancer risks for men in Europe, and is apparently curable only at an early stage. Thus, the need for early detection. This will compete with the prostate specific antigen (PSA) test that is already being used to screen for prostate cancer.

The TAMIRUT approach is based on an approach already being used for ultrasonic imaging of fluid flow in the heart and in the liver. The CEO of SignalGeneriX, Professor Anthony Constantinides of Imperial College, London emphasizes that the microbubbles used in TAMIRUT are capable of binding to specific molecular structures found in prostate cancer. Lipid coating on the microbubbles reflects the ultrasound. The analysis of the local concentrations of the microbubbles reveals the existence and grading of prostate
cancer tumors. The company has developed along with Genoa University signal processing methods that distinguish microbubble echoes from tissue echoes. This technique is apparently consistent with the Program Guidelines on Biophotonics issued by the NSF in 2007 (National Science Foundation, PD 07-7236, Program Solicitation, Biophotonics, 2007) for proposals that are, and we quote, “very fundamental in science and engineering to lay the foundation for new technologies beyond those that are mature and ready for use in medical diagnostics and therapies.”

Ohmx is a privately held company in Evanston, Illinois (Ohmx, 2006). It was founded by Professor Thomas Meade of Northwestern University in Evanston, Illinois. Very recently, the Illinois Technology Enterprise Center (ITEC) has invested $25,000 in Ohmx Corporation. Meade indicates that ITEC has been a tremendous source for Ohmx in help identifying initial investors, and federal and state grant funding agencies. The company is developing portable, electrical detection devices for use in diagnostics, drug development, and biodefense, food, water and environmental applications. The company was founded in the year 2005, and has raised more than three million dollars since then on completing a Sales of Preferred Stock financing in February 2006.

The basis of the research on biosensors at Ohmx is a new, simple, and easy way to detect a wide variety of bacteria, viruses, and molds. The company plans to develop a low cost, simple to use, reusable biosensor reader that uses a disposable biosensor chip to detect a wide variety of harmful analytes in a fluid system. The size of the biosensor is to be like a personal digital assistant (PDA). The company’s research is at the interface of molecular engineering, analytical chemistry, and biology.

Applied Nanotech, Inc. a subsidiary of Nano-Proprietary, Inc. (Applied Nanotech, Inc., 2006) indicates that miniaturized enzymatic biosensors are in demand in the medical, environmental, and chemical analysis arena. They emphasize that the rapid commercialization of biosensors is hindered by cost, manufacturing complexity, and single use of a specific analyte. Besides, the sensitivity of the analyte to be detected is limited by the substrate that the enzyme is immobilized on. This company has developed a miniaturized biosensor array based on enzyme-coated nanotubes (ECNT). They indicate that their ECNT tongue can analyze quite a few analytes from a single drop of blood, urine, or saliva for metabolic analysis. They also emphasize that their sensor manufacturing process is scaleable to produce hundreds of sensors on a miniaturized chip.

Furthermore, their sensor uses low power, and can also be operated by a battery. The ECNT biosensor is able to detect glucose, phenol, formaldehyde, hydrogen peroxide, lactose, uric acid, alcohols, and ascorbic acid. Furthermore, the ECNT biosensor can also be used for toxic gas detection and for chemical warfare sensing.

Innovative Biosensors, Inc. (IBI) located in College Park, Maryland develops and manufactures rapid testing systems for the detection of pathogens (Innovative Biosensors, Inc., 2006). Some of the pathogens that its biosensor can detect/or will be able to detect includes (a) a rapid test for bovine spongiform encephalopathy (BSE). A grant has been awarded by the National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI), and Small Business Innovation Research (SBIR) program; (b) detection of E. coli 0157:H7 in foods. IBI has also entered into a cooperative R&D agreement with the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) for the development of a Severe Acute Respiratory Syndrome (SARS) test using the company’s CANARY™
technology. A highly sensitive, portable and rapid detection system is to be developed for SARS. The cellular analysis and notification of antigen risks and yields (CANARY™) was originally developed by Rider et al. (2003) in the Lincoln Laboratory at Massachusetts Institute of Technology (MIT) in Boston, Massachusetts. IBI has obtained an exclusive license for the CANARY technology. IBI (2006) indicates that in May 2005 the company had raised $3.5 million in Series A financing. In October 2006 the company, IBI announced that it had raised a total of $6.25 million in its A round of financing with the help of additional investors.

Professor Evangelyn Alocilja and her colleagues of the National Center for Food Protection and Defense (NCFCD) at Michigan State University, East Lansing are also developing biosensors for the rapid detection of microbial pathogens in foods and products (National Center for Food Protection Defense, 2006). These researchers are using polyclonal antibodies as biological sensing elements. Polyaniline is used as the molecular nanotransmitter and molecular bridge. The NCFPD plans to develop an electrochemical biosensor prototype disposable unit for the detection of Bacillus anthracis in food products in less than 15 min per sample. The sensitivity of the proposed biosensor will be in the 10 to 100 cfu/ml range. This NCFPD estimates should be applicable for the field-testing of real-time diagnosis of pathogenic contaminants.

West Virginia’s Lane Department of Computer Science and Electrical Engineering is developing a microchip sensor (the size of a postage stamp) that can detect bacteria in a water sample to improve its quality (Wilson, 2001). The biosensor may be used for both municipal and home-based water systems. Multi-Sense, a start-up company is collaborating with West Virginia University to provide part of the research support and prototyping the sensor, as well as leasing laboratory space on campus for its activities. For a start-up company all of this can be very expensive, and this way the university acts as an incubator, which is of value to the start-up company. This should assist Multi-Sense in its commercialization efforts.

Nanosensors, Inc. located in Santa Clara, is a nanotechnology company and its principal business is to develop and market sensors for the detection of explosives, chemicals, and biological agents (Sensors Speciality Markets, 2006). It uses its recently licensed silicon-based biosensor to detect E. coli. Their biosensor consists of two different parts: (a) a disposable housing unit on which the actual sensor is mounted, and (b) an external, but separate acquisition unit. The signal in the acquisition unit is converted to an appropriate format so that results can be displayed. The company plans to field test their initial units in early 2007. The company indicates that it hopes that feedback information from the field trials will help improve, and also help them to assess the commercial viability of their biosensor.

Oxford Biosensors is located in Oxfordshire, United Kingdom and was formed in the year 2000 from technology that emanated from the University of Oxford. Its primary intent is to make a new category of diagnostics for Primary Health Care (Oxford Biosensors, 2007). The company would like to make low complexity detection devices that are suitable for POC by health workers, with a minimal of training. Each of these strips will measure health-related variables that are associated with different diseases. This is to be made possible from a single finger prick blood sample. The company has its own pilot manufacturing facility, and does not need to outsource. This aspect has a major impact on biosensor cost, since companies often outsource.
Tormey (2007) in a guest editorial entitled, “New economics drive product development in biotech” indicates that specialization in design and manufacturing has changed the product design and development business. He indicates that specialized, smaller, and leaner design and manufacturing units provide companies with economies of scale that they cannot achieve by themselves. These smaller specialized manufacturing companies may provide a significant time-to-market advantage. This is important, since they indicate that for example, if your product has a 6-month delay, this could result in a 33% less life cycle profit.

Large pharmaceutical companies use biosensors to screen for drugs. Business Resource Software, Inc. (2007) indicates that Nepkar located in Oxford, United Kingdom plans to revolutionize drug screening. It will use yeast genetic engineering for the discovery of new drugs. Nepkar plans to engineer human cell targets in yeast such that the yeast can respond to molecules, both natural and unnatural, that match the target. Screens for new drugs are possible that either block the target function (antagonists) or mimic the action of the natural ligand (agonists).

Nepkar indicates that the initial sets of targets are G-protein-coupled receptors (GPCRs). They are a major focus of pharmaceutical drug discovery. Apparently, according to Business Resource Software, Inc. (2007) of the top 100 drugs, 18 are directed at GPCRs. Furthermore, apparently an estimated 60% of all commercial drugs act on GPCRs.

Nepkar requires £1.5 million (equivalent to US $2.939 million, exchange rate £1 = $1.9592, exchange rate January 29, 2007) to build a staff base and for operating expenses for 2 years (Business Resource Software, Inc., 2007). After 2 years the company expects to have a neutral cash flow based on its rapidly growing contract drug discovery operation, and a greatly expanded intellectual property portfolio. A seed capital £250,000 (US $489,800, exchange rate January 29, 2007) has been provided by British Biotech, and a further £250,000 will be provided by British Biotech to help develop a yeast-based GPCR screen. For its financial backing of Nepkar, British Biotech will retain a 15% stake in Nepkar.

Finally, it is perhaps appropriate to mention three companies that make the SPR biosensor. The biggest one is Biacore that has recently been bought by General Electric (GE) in the USA (Biacore, 2006). Biacore is now a part of GE healthcare. The intent of the acquisition is to create a center of excellence wherein a wide range of solutions to the life science community will be offered. GE emphasizes that products from both companies may be used from early research in academia all the way up to manufacturing and quality control in the pharmaceutical and biotechnology industries. GE emphasizes that together with Biacore they can provide unbeatable solutions to help elucidate disease mechanisms and also help provide novel therapeutics. The SPR systems provide protein interactions in real time. The software that comes along with it provides values of the binding and dissociation rate coefficient values, along with affinity values. However, the analysis does not take into consideration the influence of external diffusional limitations as well as the heterogeneities that exist on the biosensor surface. This is one of the major themes of this book to help rectify the errors made in the estimation of the binding and dissociation rate coefficients, and in the affinity values.

The error arises due to the fact that the commercially available programs that come along with the biosensor equipment from the different manufacturers do not take into account either the diffusional limitations that are present in these types of systems, and the heterogeneities that are inherently present on biosensor surfaces. The aim is that if the
biosensor is run properly these diffusional effects will not be present. In effect, if these diffusional effects are present, then one is really observing ‘diffusion-disguised’ kinetics, and not inherent kinetics, as is claimed. Furthermore, the effects of heterogeneities on the surface are completely ignored. As mentioned thorough out in different chapters in the book, the influence of heterogeneities on the biosensor surface can be quite severe on the values of the binding and dissociation rate coefficients, and affinity values estimated.

Biosensing Instruments (2006) located in Tempe, Arizona also provides high-performance SPR instruments for research and analysis. Both slow and fast kinetics of analyte–receptor interactions may be determined, as well as the size of the analytes involved in these interactions.

Genoptics (2006) located in Cedex, France uses surface plasmon resonance imaging (SPRi) to determine biomolecular interactions in the life science laboratory in a multiplex fashion. Multiplex implies the simultaneous measurement of all of the phenomena observed on a biochip surface for an entire reaction.

Sensortec was founded in 1996, and is in St. Helier, Jersey, United Kingdom (Sensortec, 2006). It has developed a robust and flexible platform for disposable biosensors. Immunoassay techniques are used for detection purposes. Low cost materials are used to produce the disposable cartridge. Blood samples may be manipulated by fluidics.

The company also has a new platform technology for food quality assurance and environmental applications at a competitive price. Their technology platform can be automated, multiplexed, and miniaturized. This makes it suitable for point-of-use applications. Pharmaceutical applications are also possible. The company indicates that due to the simple and novel potentiometric measurements involved, their UTSTM biosensor is more sensitive than current amperometric and optical biosensors. Furthermore, the company emphasizes that their UTSTM technology requires minimal sample preparation. Additional advantages include rapid detection times (less than 15 min), for single analyte detection, and a wide dynamic range (4 to 5 orders of magnitude). The design of the biosensor is such that it may be operated as a one time disposable diagnostic, as a panel for diagnostic tests, and even as a small sensor array.

The company is financially backed by Chordcapital (Chord Capital, Sensortec, 2006). Sensortec has licensed its technology to DxTech LLC, a private company located in Melbourne, Florida. DxTech will use the Sensortec technology for the development of a multi-analyte microfluidic cartridge for use in its diagnostic platform. DxTech (2006) hopes to initiate the transition between centralized to distributed diagnostics with its unique, fluid-based medical diagnostic platform. The company claims that real-time diagnostics may be obtained at POC that will be of assistance to clinicians. A drop of blood is only required for a credit card size disposable cartridge.

VTT Technical Research Center with its corporate headquarters in Espoo, Finland is the biggest contract research organization in Northern Europe (VTT, 2006). It provides high-end technology solutions and innovation services. The VTT organization was established in 1942, and last year its turnover was 225 million euros or 291.3 million US dollars (€1 = US $1.2948, exchange rate January 29, 2007). The company is using its strengths in biotechnology, information technology, and in electronics to develop and manufacture an inexpensive disposable biosensor using the results obtained from different research institutes. VTT promotes networking between companies and also helps create new businesses.
One of VTT’s area in biosensor research is the development of advanced systems for sensing phenomena at the molecular level. Tailored coatings with functional molecules are placed/immobilized/adsorbed on appropriate substrates to promote molecular recognition. This sensing is aided by case-specific transducers. The company’s immuno- and DNA-based sensors, as well as their chemical sensors find applications in the areas of biomedical engineering, clinical diagnostics, and in the monitoring of different types of processes.

It is of interest to note that even a university would, besides its many roles, also like to present itself with available technology (in this case biosensor) platforms, and is seeking potential collaborators in the biosensor and other areas. Biopartner (2006) indicates that the University of West England at Coldharbour Lane in Bristol, England has developed a portfolio of biosensors that may be used in the detection of volatile organic compounds (VOCs) based on heated ceramics and conducting polymers. These biosensors find applications in the indoor environment, agri-food, and in the biomedical areas. UWE indicates that its screen-printed carbon electrodes (SPCEs) may be used for the detection of environmental pollutants in air, water, and contaminated land. Also these SPCEs may be used for the detection of clinical metabolites, hormones, bacteria, and trace heavy metals in water. UWE is also actively pursuing collaborators (companies) in the clinical diagnostic and environmental areas requiring R&D to identify target marker compounds.

Phillips (2005) located in Eindhoven, The Netherlands has developed a biosensor that provides high analytical performance with simplicity in use and is also of low cost. One biosensor is based on magnetic particles (for magnetic biosensors), and the other is based on Raman spectroscopy (for optical biosensors). Phillips emphasizes that their biosensors should improve on the different biosensor performance parameters such as sensitivity, speed, and reliability for applications such as protein and pathogen monitoring, near patient testing in medical centers and at home-testing for variables such as blood, urine, and saliva tests. The company is also looking at developing a disposable biosensor that would be manufactured at low cost. This is for possible use in a hand-held reader.

Phillips emphasizes that the current trend is to be able to predict diseases before the symptoms actually manifest themselves. This is possible if one has very sensitive biosensors to be able to detect the relevant biomarkers for the different diseases. The company indicates that their biosensors are able to detect specific molecules (for example, these biomarkers for different diseases) at very low concentrations (for example, $10^{-13}$ moles per liter, and at lower concentrations).

The goal of the Nanoscale Science and Engineering Center (NSEC) at Ohio State University, Columbus, Ohio is to create devices that will make diagnostics, treating, and managing diseases easier, less expensive, and more effective. The NSEC center collaborates with the Center for Multifunctional Polymer Nanomaterials and Devices (CMPND), Center for Advanced Polymer and Composites Engineering (CAPCE), and Integrative Graduate Education and Research Training Program (IGERT). The CMPND center has an on-going program for the use of conjugates of biomolecules and nanoparticles or conductive polymers for biosensors and lab-on-a-chip devices. This center indicates that for the future of health care low-cost and highly sensitive biosensors and lab-on-a-chip devices are essential. This center further states that the present-day biosensors that rely on optical and radiation methods are either too expensive or are not sensitive enough for single-molecule detection and analysis. In order to facilitate single-molecule analysis, the CMPND center
plans to use nanoparticles and conductive polymers to form conjugates with biomolecules for advanced proteomic biosensing applications. The CMPND center is also exploring ligand–protein–nanofiber interactions with the eventual goal of developing high-performance electrical signal based biosensors for the early detection of chemical and biological agents.

13.5 CONCLUSIONS

This last chapter attempts to provide a perspective of what is required to setup a biosensor industry. At the outset it is appropriate to indicate that the author has spent his entire life in the academia with a few summers spent at private companies and at National Laboratories. Five years were also spent at the National Chemical Laboratory in India. Also, some consultancy with biosensor and other types of companies has also been undertaken in the US.

After providing an introduction to the market for biosensors in this chapter, the trends in collaboration between companies, universities, and state and governmental agencies are presented, followed by the factors that may help increase or decrease the biosensor markets. Examples of real life biosensor companies are given. The biosensors may be at different stages of development on getting the biosensor to the market. Some companies may already have their biosensor on the market. This is besides the ones used for measuring sugar levels for managing diabetes.

Besides the monitoring of sugar levels for diabetics, the biosensor can be a valuable tool for diagnostic purposes as well as for the detection of pathogens in the environment. Except for the monitoring of sugar levels in diabetic patients (which is a huge market, and it is increasing due to the rise in obesity levels in individuals worldwide coupled with poor food and exercise habits), biosensors are finding it difficult to make any major headway in other possible areas of application. This is in spite of the fact that they can be of tremendous use to diagnose early quite a few intractable and insidious autoimmune diseases, for example. Needless to say, quite a few of these diseases may be managed better if they were diagnosed during their early stages of incidence.

The information presented in this chapter is difficult to get from the classical open literature sources, such as journals. Thus, most of the information presented in this chapter is obtained from internet sources. There may be a reliability factor here. Needless to say, private companies will guard this type of economic information very carefully.

Biacore in Sweden, which manufactured and marketed the SPR biosensor was one of the more successful, if not the most successful biosensor company. It has recently merged with General Electric in their Life Sciences division. The reason for this is not clear; however, if this author is permitted to speculate, it could be that a biosensor company as strong as Biacore was unable to stay strong and independent for long. If this is true, and there may be quite a few reasons behind this, this does not bode well for the biosensor industry as such; though this may be just a single and isolated example.

Examples of biosensor companies seeking financial backers or collaborators are also presented in this chapter. Due to the relatively small biosensor markets, and the time and resources required to bring a biosensor to the market hinders venture capitalists as well as possible biosensor entrepreneurs to help develop biosensors for newer applications, where
reasonable amounts of profits or return on investment (ROI) may be obtained. Hopefully in the not to distant future with advances in biosensor technology, and in nanotechnology, especially the manufacturing aspects, and the lessons that the companies and the individuals have learned in bringing biosensors (successfully or even unsuccessfully) to the market will all come together in the future to let companies make reasonable amounts of profit by manufacturing and marketing biosensors for different areas of application. This may begin to attract more venture capitalists to support and develop biosensors for newer applications.

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