

Forecasting of Biosensor Technologies for Emerging Point of Care and Medical IoT Applications Using Bibliometrics and Patent Analysis

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Abstract—Healthcare is beginning to embrace point of care (POC) diagnostics and medical applications that are based on the internet of things (IoT) and the ubiquitous smart phone. Advanced medical diagnostics will utilize biosensors for biological data acquisition. This paper introduces the forecasting of biosensors that have the potential to be used in POC and IoT applications. For this research three types of biosensors were selected. These are biosensors for testing of blood, saliva, and breath. Bibliometrics and patent analysis of these biosensors are used to develop technology maturity rates based on the Fisher-Pry model. The Science Citation Index (SCI) is used for bibliometrics and patent analysis is derived from global patent databases. The Fisher-Pry projections or S-curves enable insights into the maturity levels of the emerging biosensor technologies under consideration and forecasting their growth. Patent analysis based on cumulative annual patent count indicated that blood biosensors reached their technology maturity midpoint in 2009 with the midpoints of saliva and breath biosensors lagging by 8 and 14 years respectively. Bibliometrics with annual publication count did not appear to provide much value in forecasting the maturity growth of the three biosensors.

I. INTRODUCTION AND BACKGROUND

The digital economy is firmly entrenched in healthcare. One emerging aspect is connected health which supports portable or wearable networked devices for personal and physician care [1], [2]. Besides the ubiquitous smart phone, there are three major technology trends that are converging to support this new healthcare environment of advanced medical diagnostics: (1) biological data acquisition by biosensors; (2) point of care (POC) diagnostics; and (3) medical applications based on the internet of things (IoT).

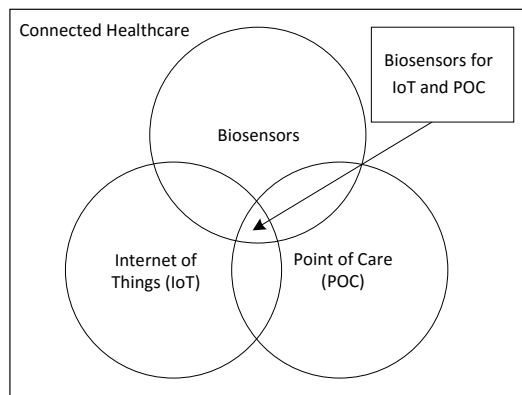


Figure 1: Biosensors for Point of Care (POC) and Internet of Things (IoT)

Biosensor technologies play a pivotal role in driving these trends. This paper attempts to identify the trends for the three types of biosensors that are considered important for POC and IoT based on the human sample types: blood, saliva, and breath [3] (Figure 1). A technology forecasting approach is applied based on bibliometric data. Technology forecasting, biosensors, POC, and IoT are explained further in the next sections. It should be noted that POC and IoT are medium to long term trends.

A. Technology Forecasting and Bibliometrics

Managers and executives involved in the technology fields are constantly seeking ways and means to make better strategic decisions with respect to research and development (R&D) management, new product development, new process technologies, production capabilities, commercialization, marketing, and investing in new technologies [4]. Innovation forecasting should help management with some aspects of these decisions. Innovation forecasting finds information on: (1) technology life cycle status by determining development advancement, growth rate, and status of dependent technologies; (2) innovation context receptivity due to economic and other influences; (3) product value chain and market prospects issues related to payoffs and fulfillment requirements [4]. Technology forecasting mainly relates to the technology life cycle and provide insights into technological change by predicting and profiling future characteristics of useful technologies or techniques. Innovation and technology forecasting use multiple methods to achieve their objectives [5]. One popular method is bibliometrics which is the statistical analysis of text, data, and information usually in the form of publications such as scholarly journals, books, articles, conference proceedings, and patent filings [6], [7]. When analyzing technologies the publication sources are generally scientific journals and patents.

Bibliometrics and data mining of patent data are gaining in importance due to the digital economy and increased access to global research and commercial data. Bibliometric methods are already well established in the field of library and information science especially for academic literature [8]. Citation and content analyses are the most common bibliometric methods.

Patents, representing intellectual property (IP) rights, also provide valuable insights into technology trends. Patent analysis uses patent data for technology forecasting and can be used in conjunction with other forecasting techniques to

provide guidance on the state of emerging technologies and their respective industries [9].

However, different types of sources used in bibliometric studies are limited to what they can indicate. Watts and Porter have separated out the indicators (by source type) to represent different stages of the technology life cycle [4]. The cycle starts with scientific publications followed by engineering publications and patent applications and then by newspapers and other popular publications. This is depicted in Table 1.

TABLE I: TECHNOLOGY LIFE CYCLE INDICATORS [4]

Factor	Indicator
R&D Profile	
Fundamental Research	No. of items in databases such as Science Citation Index
Applied Research	No. of items in databases such as Engineering Index
Development	No. of items in databases such as U.S. Patents
Application	No. of items in databases such as Newspapers Abstracts Daily
Societal Impacts	Issues raised in the Business and Popular Press abstracts
Growth Rate	Trends over time in number of items
Technological Issues	Technological needs noted
Maturation	Types of topics receiving attention
Offshoots	Spin-off technologies linked

The activity level of the indicators implies that the technology is at a specific stage of the life cycle [4], [10].

In this paper, the technology life cycle indicators are examined with two additional considerations:

- Bibliometrics now only refer to publications and bibliometrics for patents are referred to as “patent analysis” to emphasize the importance of patents for commercialization [11].
- Only the first three stages of the life cycle, namely fundamental research, applied research, and development, are considered with the assumption that, in general, biosensors for POC and IoT are still emerging technologies.

Traditionally, interest has been around emerging technologies and their early stages which have been measured by scientific publications and patents. Other approaches using expert opinions or judgments have been tried but the results have not been clear since emerging technologies are explained by expectations and visions and not facts [12]. A study revealed that some technologies indicated by experts to be critical turned out not to be so [13]. This study relied on the growth of scientific publications and patents as indicators of technology activity.

There are some concerns that using the number of patents to measure innovation may be misleading or insufficient [14]. For example, some patents are never commercialized or some companies use patenting to prevent others from entering their technology area. Also, patent laws and practices vary throughout the world and military inventions may not be made public. However, in general, growth of the number of

patents correlates well with technology development activities and the method does have the advantage of simplicity [15].

In his review paper, Martino explains the use of causal models for technology forecasting [10]. Causal models are characterized by variables whose relationships can be described by mathematical equations. The use of causal models is limited to forecasting the diffusion of emerging technologies where certain parameters such as substitution or imitation rates can be measured. Although causal models have been used for multiple decades, this is still an area of research. Some of the main research objectives are to determine the factors that influence the substitution and imitation coefficients and their values. One method is to use bibliometrics and patent analysis or, in general, bibliometric data.

The models describing technology diffusion or adoption typically follow a sigmoid curve shape (also called an S-curve). The S-curve is due to the changes in performance over the life of the technology. When the technology is first introduced its performance improves slowly due to a learning curve in developing the new technology. Once the initial hurdles are overcome the technology attracts significantly more technical talent and financial resources. At this point performance improves rapidly. Eventually, the technology reaches its useful limits, alternate technologies become more viable, and the improvement rate declines [16]–[18].

Technological forecasting with growth curves have been used in multiple fields over the last five decades [5], [19]. This quantitative approach uses trend extrapolation with the proposition that historical data on a technology can provide guidance to its trajectory [20]. The life cycle of a technology consists of four stages: introduction, growth, maturity, and decline [21]. Forecasting based on growth curves involves parameter estimation of the technology life cycle and hence the estimation of each stage of the life cycle. The term commonly used in the literature for the market adoption of a new technology is also referred to as “diffusion of innovations” [22], [23]. Innovation diffusion theory is now well established using many diffusion or growth models [10], [24].

The S-curves are also referred to as “growth curves”, “maturity curves”, “diffusion models”, or “adoption models”. The well-known models include: Fisher-Pry [25], Gompertz [26], [27], and Bass [28] named after their originators. In recent time more generalized models have been proposed that can be reduced to the above, however these still remain popular in the research community [10], [29], [30]. The Fisher-Pry model is generally appropriate for technology diffusion and life cycle forecasting. Hence, the authors have elected to implement this model first for the trend analysis of biosensor technologies applied to POC and medical IoT applications. The authors were unable to discover any prior study focused on biosensor growth curves with respect to POC and IoT. One recent patent analysis was on IoT but it was a general assessment to determine the main area of

patenting activity of IoT technologies and the top patent filers [31]. The major activity was in wireless networking with the top filers, LG, Ericsson, and Qualcomm, holding only about 5% of the total patents.

B. Medical Biosensor Technologies

A biosensor utilizes the specificity of a biological molecule to convert a biological signal into an optoelectronic, electrochemical, or piezoelectric signal. Specifically, a biosensor is used to analyze particular biological analytes, which can be liquid, gas, or solid [32]. Furthermore, biosensors are capable of enhancing the testing and measurement of various analytes. An analyte is a substance whose chemical or biological constituents are being identified, analyzed, and measured. Common analytes include glucose, lactate, urea, creatinine, cholesterol, uric acid, and DNA. Blood glucose is among the most commonly measured by biosensors. Accordingly, finger-prick glucose meters appear to be the most successful biosensor-based devices [33]. Already, a new generation of noninvasive blood monitoring biosensor techniques are being developed to avoid a finger prick [34].

In the medical arena biosensors are described in terms of the analytes that they analyze. For example, a glucose sensor measures the glucose analyte. The goal may also be to measure multiple analytes with one device. In this case a multisensor would be employed in place of a typical single biosensor. An increased ability to measure analytes has allowed modern biosensors to handle more sophisticated tasks. For instance, biosensors are now capable of performing a variety of specific tasks, such as detecting deoxyribonucleic acid (DNA) sequences on silicon chips or allowing for a lab-on-a-chip (also known as micro total analytical system, μ TAS) analysis [35].

Biosensors can also be described with respect to the sample solution to be tested; solutions for this purpose include mainly blood, breath, and saliva [3]. In this paper the biosensors have been described only in terms of the three solution types since the objective is to gain an understanding of the overall trends based on samples for POC testing. Blood is a bodily fluid that can reveal significant information about the human condition. For example, there are a large number of analytes (more than a hundred) contained in blood such as glucose, triglycerides, low-density lipoprotein (LDL) cholesterol, creatine kinase, oxygen, and sodium [36]. All these can be tested using an appropriate specific type of "blood sensor."

Biosensor technology is starting to respond to high market demands by making more accessible sensors. Two major trends of biosensor technology have been established to create more portable, cost-effective, and operational sensors. The first trend is the movement towards implementing label-free mechanisms in order to simplify operation. Label-free detection is defined as a biological sensing mechanism in which no staining, marking, or any other sort of label attachment is required for operation. The second is the

integration of the biosensor readout component so that the technology can become more compact [3]. Both efforts are complemented by an increasing reliance on microscale and nanoscale technology, allowing for biosensors to realistically accommodate a large global population with POC and IoT.

C. Point of Care Diagnostics

In vitro diagnostics (IVDs) based on POC applications are gaining in acceptance because medical or laboratory staff and facilities are not essential to providing results [37]. IVD is a preferred method for diagnosis because it is non-invasive and the testing can be performed outside the body in a "test-tube". Typically, samples of blood, saliva, urine, and other bodily fluids are taken as part of a health or disease management program. The samples do not require pre-preparation (or may require only a minimum amount of pre-preparation). In many cases, the tests produce results in a matter of seconds. This is in contrast to a hospital, clinic, or a physician's office where the turnaround time of test results is in hours and days. The tests are simple to administer and interpretation of the results are easy.

In today's environment the POC devices are starting to migrate from single-use test materials to view a stripe or color on paper to portable or handheld electronic instruments that provide more comprehensive results.

POC devices are increasingly based on emerging techniques such as molecular diagnostics for health and prevention, identification of a disease or a condition, and then for a treatment [38]. One common fluid sample for medical diagnostics is blood. Traditionally, molecular diagnostics using blood were limited to laboratories requiring preparation of the sample and sophisticated instrumentation. They also needed specialized technicians and were labor intensive. The new POC technologies using a drop of blood obtained from a tiny finger prick are in the process of replacing the traditional methods. The traditional lab-based technologies for molecular diagnostics such as enzyme-linked immunosorbent assay (ELISA), polymerase chain reaction (PCR), and mass spectrometry (MS) are being miniaturized and could be an integral part of portable or wearable POC devices in the foreseeable future using a lab-on-a-chip architecture [39], [40]. Biosensors are the first-in-line component of any POC application. Blood testing is very common together with testing of saliva, urine, and stool. However, if a consumer-friendly environment is important than saliva and breath are easier to work with. Such may be the case for the internet of things (IoT) in a health and wellness application.

D. Internet of things

The "internet of things" is of growing interest to the global community [41]. The IoT concept has the long-term potential to impact every aspect of our lives. This point is elaborated in the next section on market trends.

The expression "Internet of Things" (IoT), is accredited to Kevin Ashton, cofounder of the Auto-ID Center at the Massachusetts Institute of Technology, who originally coined

it in 1999 [42]. It is a mainstream term now. The International Telecommunication Union (ITU) is the international standards body responsible for IoT definitions and recommendations. It defines the Internet of Things (IoT) as “A global infrastructure for the information society, enabling advanced services by interconnecting (physical and virtual) things based on existing and evolving interoperable information and communication technologies. Note 1- Through the exploitation of identification, data capture, processing and communication capabilities, the IoT makes full use of things to offer services to all kinds of applications, whilst ensuring that security and privacy requirements are fulfilled. Note 2 - From a broader perspective, the IoT can be perceived as a vision with technological and societal implications” [43].

In the context of this research, IoT refers to wearable or portable devices such as smart watches, cardiac monitors, and glucose monitors embedded with electronics, software, sensors (including biosensors), and network connectivity that enable the acquisition and exchange of data. This is machine-to-machine (M2M) communications.

II. MARKET TRENDS FOR BIOSENSORS, POINT OF CARE, AND INTERNET OF THINGS

A. Biosensors and Point of Care Diagnostics

Biosensor technologies have grown dramatically over the past couple of decades, making them valuable for technology forecasting [32]. The global market was \$12 billion in 2013 and is expected to be about \$23 billion by 2020 with an estimated CAGR of 10% from 2014 to 2020 [33] (Figure 2). This high demand increases as technology improves, allowing for biosensors to improve in accuracy and versatility.

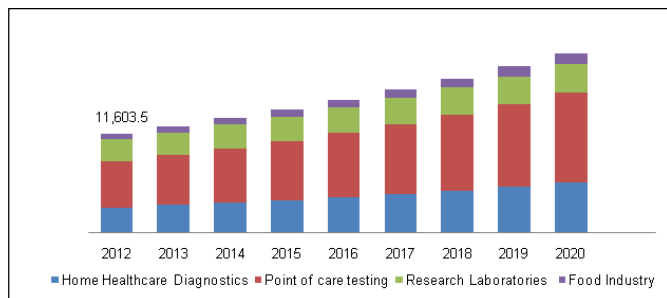


Figure 2: Global Biosensors Market by End-Use (USD Million) [33]

Six major vertical markets exist for biosensors: point of care (POC), home diagnostics, environmental, research laboratories, process industries, and biodefense [44]. POC and home diagnostics represent the two largest groups of biosensors. The POC market is the largest and represents about 45% of the total biosensor market for 2016 (Figure 3).

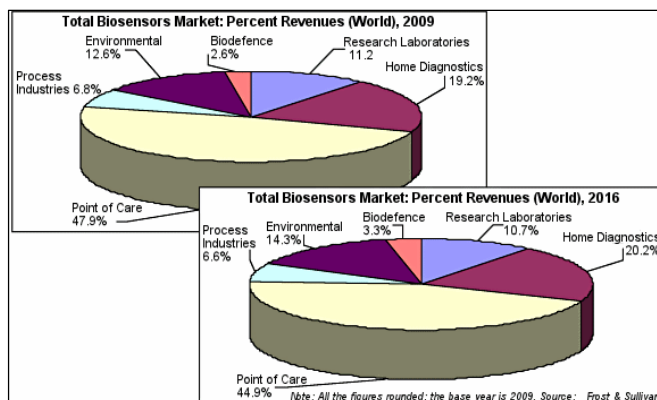


Figure 3: Global Biosensors Market: Percent of Revenues by Vertical Markets for 2009 and 2016 [44]

Biosensors are used in over 50 diverse end-user applications (Figure 4) and the number of applications is increasing significantly each year. Glucose monitoring is the dominant application because of the POC and home diagnostics markets. However, biosensor use in sectors such as process industries, environmental monitoring, security, and biodefense is growing rapidly. The biosensors associated with blood samples are also being developed for many specific types of analytes beyond glucose.

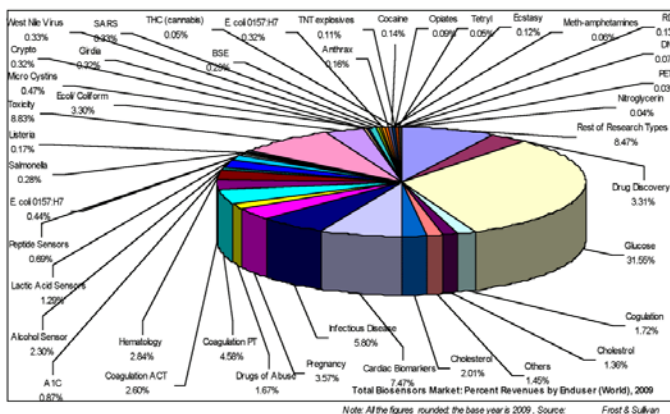


Figure 4: Global Biosensors Market: Percent Revenues By End-User Applications (2009) [28]

Commercial development of biosensors for health care has taken on a greater priority as the biosensor market becomes larger. Specifically, patient biochemical profiles must often be monitored before treatment, which can be most efficiently accomplished through biosensors. As a result, the physician can focus on the treatment instead of the measurement of the particular analytes related to their disease. Because of their increasing technical accuracy and convenience, biosensors can be aptly used for self-testing and care at home. Therefore, the forecasting of biosensor allows for assessing the fastest growing technologies that can be used clinically. Furthermore, there may be a convergence of POC and home care devices. With miniaturization, some of these may form part of IoT in the long term. This research

explores the evolution of medical biosensors that analyze blood, saliva, and breath individually and as a group.

B. Internet of things

According to Gartner’s research report on emerging technologies the new phenomena of IoT will have a transformational societal and business impact [45]. Adoption is expected to reach the mainstream in 5 to 10 years.

IoT will potentially impact healthcare with offerings of consumer wearable devices, home monitoring systems, and clinical instruments for physicians [46]. IoT based on biosensors can add a diverse portfolio of tools to address chronic disease management and population health and wellness. Through IoT, the cost of monitored care may also be reduced. The remote monitoring healthcare market segment is expected to grow from about \$400 million in 2014 to \$980 million by 2020 [46]. Geriatric and young patients are seeking technology-based treatments and options that can help them with the management of their chronic diseases. Such diseases are vast and diverse and include: diabetes, chronic obstructive pulmonary disease (COPD), cardiovascular disease (heart attacks and stroke), arthritis, cancer, obesity, oral health problems, and epilepsy.

Gartner claims that IoT is one of the top strategic technology trends and Cisco forecasts that 50 billion smart devices will be connected by 2020 [2] (Figure 5). Cisco names this as the “internet of everything”. Cisco defines the Internet of Everything (IoE) “as bringing together people, process, data, and things to make networked connections more relevant and valuable than ever before — turning information into actions that create new capabilities, richer experiences, and unprecedented economic opportunity for businesses, individuals, and countries.” The networking of these devices will enable a “mega-market” due to a convergence of large markets such as healthcare, home and building automation, automotive, and information and communications technologies (ICT). This market is projected to be in excess of \$14 trillion. Also, major technology companies such as Siemens, Ericsson, and Bosch will be supplemented by many other diverse companies ranging from media and logistics to pharmaceuticals as they converge on IoT platforms.

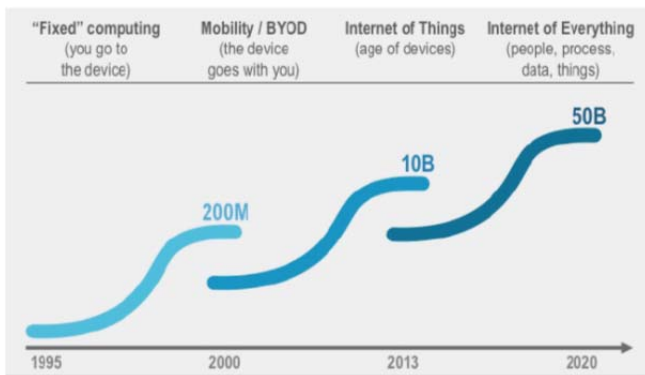


Figure 5: Growth Trends of the Things Connected to the Internet [2]

Cisco states that the connected healthcare and patient monitoring market for IoE is projected to be \$106 billion by 2020. IoE will provide better data-driven patient management and this in-turn will result in more efficient and effective healthcare. A summary of the current state of healthcare and improvements due to IoE is shown in Table 2.

TABLE 2: CURRENT HEALTHCARE STATE AND POTENTIAL HEALTHCARE STATE WITH IINTERNET OF EVERYTHING (IoE) [2]

2013 Current State (without IoE)	2022 Potential with IoE
Long hospital stays to ensure patients can thrive at home after discharge.	Reduced costs and improved quality of life from shorter hospital stays with home monitoring systems that ensure health.
Limited number of health conditions with home monitoring capabilities.	Wider number of health conditions with home monitoring capabilities.
Uncoordinated and manual collection of patient test records.	Improved decision making from single electronic collection of patient records.
Ad-hoc interpretation of medical test results and conditions.	Improved patient care from standardized treatments that conform to best practices.
Multiple doctors offer care in an uncoordinated manner.	Improved patient care and health outcomes from consolidated, patient-centric views of all treatment aspects.

III. TECHNOLOGY FORECASTING WITH FISHER-PRY MODEL

One type of life cycle growth curves are based on technology substitution. Such curves assume the substitution of an older technology by a newer one. This applies to biosensors. A prominent example of the substitution curve is the Fisher-Pry Model [25]. It is also known as the Fisher-Pry Analysis and the Fisher-Pry Diffusion Model. Fisher-Pry forecasting is similar to the growth of biological systems. This method projects the diffusion rate of new and technically superior technologies. Conversely, it can also project the replacement of old and inferior technologies. In this paper, diffusion indicates the progression along the technology life cycle. This mathematical technique follows the Logistic (or Logit) curve pattern. It is sigmoid shaped and symmetrical around the midpoint, that is, the midpoint is also the point of inflection. The inflection point is the point where technology curve reaches its maximum growth rate. It is also a point of reference to compare different S-curves.

One form, known as the Pearl curve form, is represented by the equation below (Equation 1, Figure 6) [15], [47].

$$\frac{Y_{FP}}{L - Y_{FP}} = 10^{A - Bt}$$

- Y_{FP}: Fisher-Pry curve
- L: Normalized upper growth limit (100)
- t: Time in years
- A: Time at which diffusion begins
- B: Rate at which diffusion will occur

Equation 1: Fisher-Pry Forecasting Model [47]

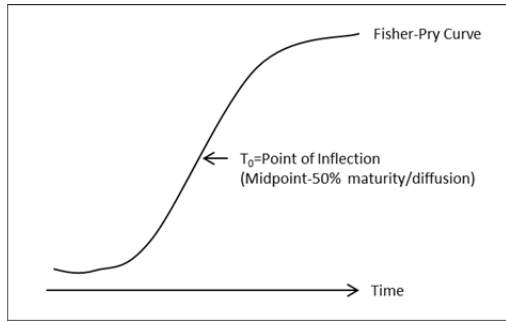


Figure 6: General Form of the Fisher-Pry Curve

The Fisher-Pry substitution shape (Y_{FP}) is determined by two parameters (A and B). One parameter (A) determines the starting point of the diffusion or substitution and the second parameter (B) determines the rate of diffusion. The two parameters are determined from early diffusion data. This data can be derived from data mining of patents, journal articles, and conference proceedings.

The Fisher-Pry equation can be converted to linear form as (Equation 2):

$$\text{Log} \left(\frac{Y_{FP}}{L - Y_{FP}} \right) = A - Bt$$

Equation 2: Log Form of Fisher-Pry Forecasting Model

Then linear regression is applied on the cumulative annual data to determine A and B as the intercept and slope of a straight line.

The resulting pattern can be used to extrapolate or project the time that diffusion will reach a given stage from introduction to decline. This forecasting technique has been used in multiple fields such as communications and consumer electronics to show how the installed base of equipment will change over time [47], [48].

IV. RESEARCH QUESTIONS

This goal of this research is to gain an understanding of the level of technology maturity for the initial three types of biosensors namely, blood, saliva, and breath that could drive medical POC and IoT applications. The authors have elected to use bibliometric and patent data with the Fisher-Pry model in this research. The approach is shown in Figure 7.

The specific research questions relate to these three biosensor types and include:

1. Which one of the three biosensor technologies—blood, saliva, and breath—is the most technologically mature?
2. What is the maturity progression of the other two biosensor technologies?
3. Can we make predictions from the results about the technology maturity and life cycle of the three biosensor technologies?

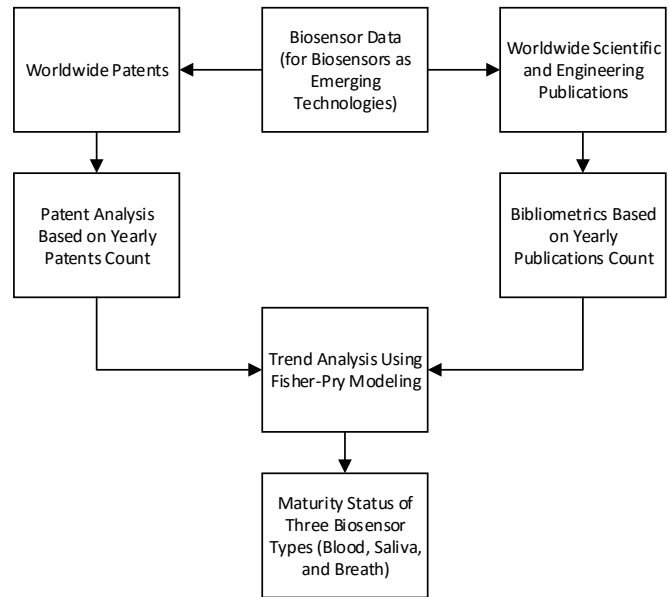


Figure 7: Point of Care (POC) and Internet of Things (IoT) Biosensors Forecasting Model

V. BIBLIOMETRIC AND PATENT DATA SOURCES

For this research, the sources of bibliometrics were well-established academic databases and data for the patent analysis was globally sourced from multiple national and international patent databases. The following table summarizes the sources (Table 3).

TABLE 3: DATA MINING SOURCES FOR BIBLIOMETRICS AND PATENT ANALYSIS

Research Task	Data Source	Database	Publisher
Bibliometrics	Science Citation Index (SCI)	Web of Science	Thomson Reuters
Bibliometrics	Engineering Index	Compendex (Engineering Village)	Elsevier
Patent Analysis	United States Patent and Trademark Office	USPTO	United States
Patent Analysis	International Patent Cooperation Treaty (PCT)	PATENTSCOPE	World Intellectual Property Organization (WIPO)
Patent Analysis	European Patent Office	EPO	European Union
Patent Analysis	Japan Patent Office	JPO	Japan
Patent Analysis	Korean Intellectual Property Office	KIPO	Republic of Korea
Patent Analysis	China Patent and Trademark Office	CPTO	China

The global patent analysis for annual patent count was carried out using AcclaimIP, a software package that accesses the major patent databases worldwide [49].

For this initial forecasting study the following keywords were used for obtaining data in both bibliometrics and patent analysis:

- Biosensors
- Biosensors and blood
- Biosensors and saliva
- Biosensors and breath

Since this is the first known study of such trend extrapolation for blood, saliva, and breath biosensors only basic keywords were used. The authors anticipate that future research will include more specific keywords and terms to address very specific types of biosensors.

VI. RESULTS

The research revealed that the number of patents for all types of biosensors was significantly more than the number of publications. This implied that basic and applied research was much less than commercial development. The number of patents totaled about 55,500 since their inception in 1982 whereas the number of scholarly publications totaled only about 26,000. (Also refer to the Appendix for annual counts of patents filed and publications for biosensors.) Furthermore, the research publications for saliva and breath biosensors totaled only about 100 over the same period. Hence, the results from the patent analysis are discussed first, followed by bibliometrics.

A. Patent Analysis

The worldwide patent databases were searched for biosensors to determine the total number of patents per year. The growth until around 2008 and then the decline are indicated in Figure 8.

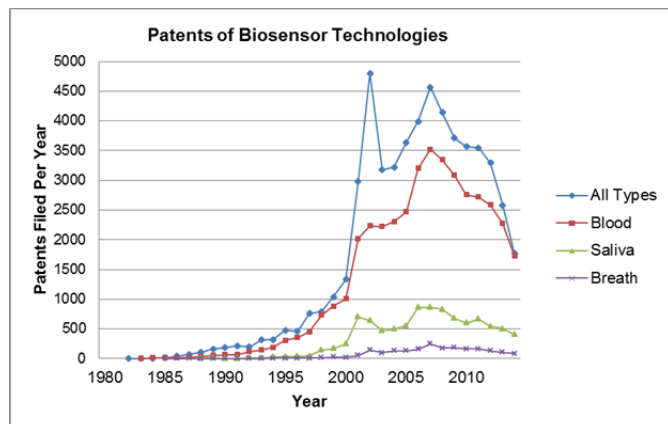


Figure 8: Patents Filed for Biosensors: All Types, Blood, Saliva, and Breath

The Fisher-Pry patent curve for all types of biosensors is calculated first by determining the two parameters A and B.

This is depicted in Figure 9. In this case A is -304.33 and B is 0.15. Then the patent data are extrapolated to beyond 2024 with the Fisher-Pry curve (Figure 10). The actual historical patent data are represented as “percent biosensor patents penetration.” In this paper, “penetration” refers to the cumulative patent or publication count that has been achieved with respect to the upper growth limit, L.

The upper growth limit, L, was estimated by first taking the cumulative patent number for all biosensors from 1982 to 2015 and then increasing that by 10%. The result was 61,041. Then this number was rounded to 62,000 to represent 100% penetration or full maturity. The authors understand that this is only a first level estimation but since L is unknown, this value was used as a basis for this study. The curve fitting of “percent biosensor patents penetration” to the Fisher-Pry curve in Figure 10 indicates that this may be a reasonable initial estimate. This value of L to represent 100% penetration is maintained for Figure 11, Figure 12, and Figure 13.

For the sake of avoiding repetition the figures depicting linear regression for parameters A and B are not shown for the other Fisher-Pry curves discussed later.

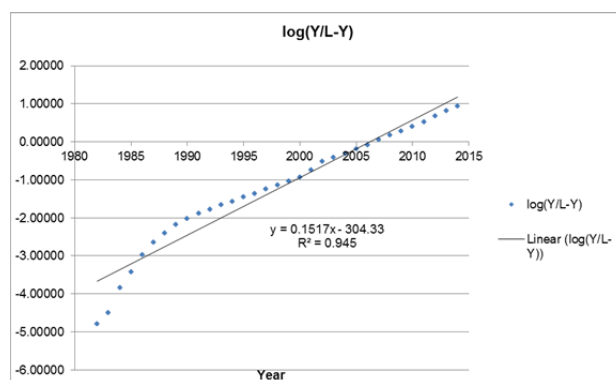


Figure 9: Using Linear Regression to Determine Parameters A and B for Biosensor Patents Fisher-Pry Curve (All Biosensor Types)

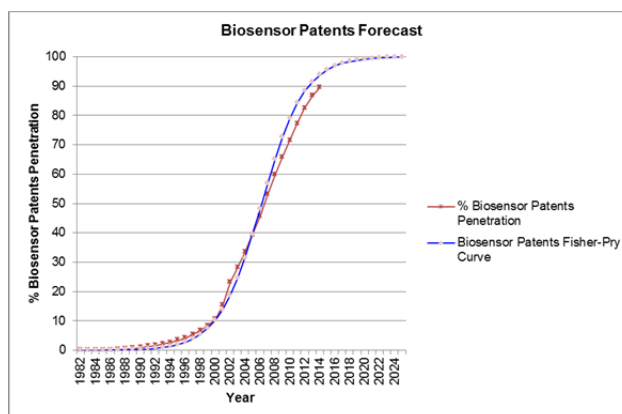


Figure 10: Biosensor Patents Fisher-Pry Curve (All Biosensor Types)

The following three figures depict the patent Fisher-Pry curves for blood, saliva, and breath biosensors respectively (Figure 11, Figure 12, and Figure 13).

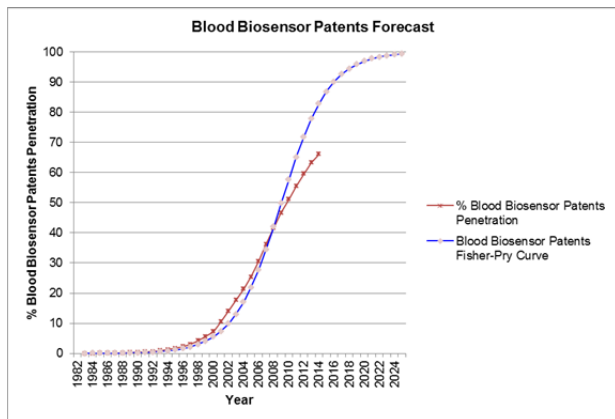


Figure 11: Fisher-Pry Curve: Patents Filed for Blood Biosensors

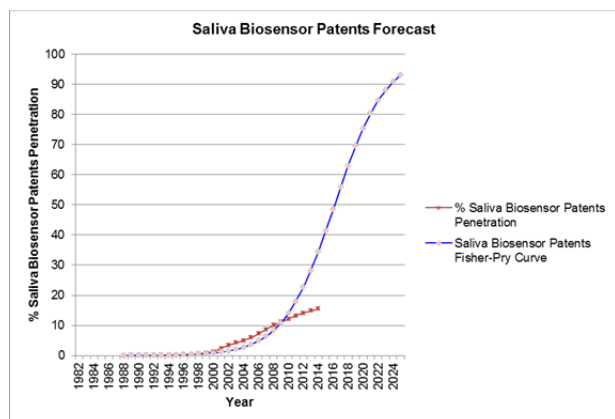


Figure 12: Fisher-Pry Curve: Patents Filed for Saliva Biosensors

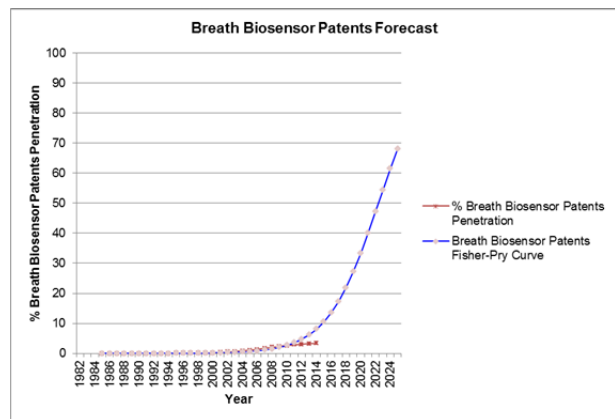


Figure 13: Fisher-Pry Curve: Patents Filed for Breath Biosensors

By overlaying all the patent biosensor Fisher-Pry curves and considering the technology maturity midpoint, the relative maturity levels of the different types of biosensors can be determined (Figure 14). The midpoint occurred in 2006 for all types of biosensors. The blood biosensors had the midpoint in 2009, a 3 year lag and will not reach their upper bound (L) before 2025. This implies continued, yet decreasing, growth in technology diffusion and innovation for

the next decade. The midpoints will be in 2017 and 2023 for saliva and breath respectively representing lags of 8 and 6 years with respect to the preceding blood biosensor technologies.

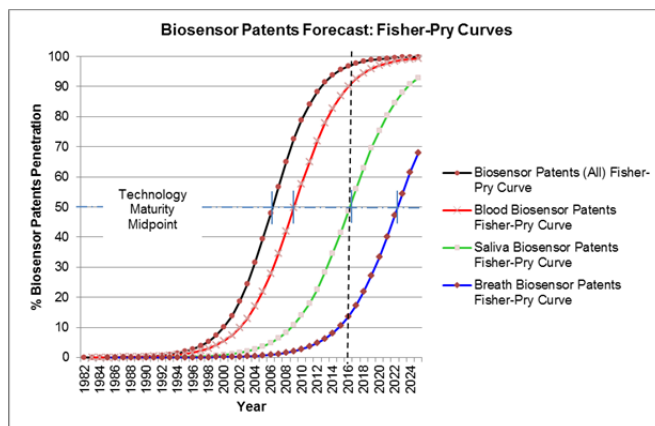


Figure 14: Comparison of Patent Biosensor Fisher-Pry Curves

Cumulative patent application numbers represented in the Fisher-Pry curves serve as indicators for technological diffusion trends, development, and life cycle stage [50], [51]. Patent growth in a particular technology tends to follow an s-shaped curve. When a new technology is introduced the number of patents is limited. This is followed by a growth period with increasing patent filings and grants. Eventually, a plateau is reached [52].

However, it is not clear if this applies across all industries. A study by Yoon and Lee discovered that one of the industries that is favorably represented by patent analysis for forecasting is biotechnology [53]. Hence, these indicators may prove useful for biosensors.

B. Bibliometrics

The biosensor publications count per year is based on the Web of Science database and is shown in Figure 15. The Web of Science citation database, with over 1 billion entries covering 53,000 major journals and books uses the Science Citation Index and other sources. Although the total number of publications for biosensors is increasing at a reasonable rate the blood, saliva, and breath biosensor related publications are flat and nominal.

The value of the upper growth limit, L, is estimated to be 30,000 based on the same approach as discussed earlier under the patents section.

Similar to the patent analysis based calculations, the Biosensor Publications are shown in Figure 16.

The following three figures depict the publications Fisher-Pry curves for blood, saliva, and breath biosensors respectively (Figure 17, Figure 18, and Figure 19).

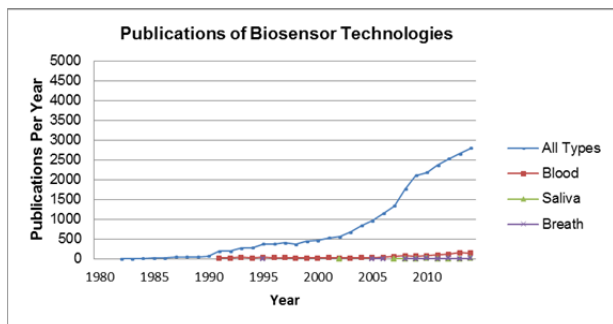


Figure 15: Biosensor Publications: All Types, Blood, Saliva, and Breath

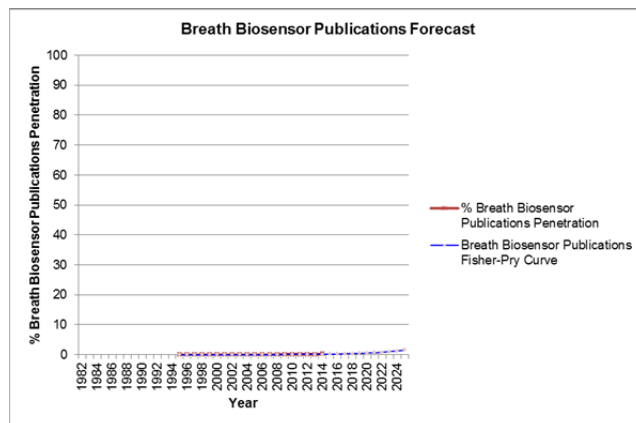


Figure 19: Fisher-Pry Curve: Breath Biosensor Publications

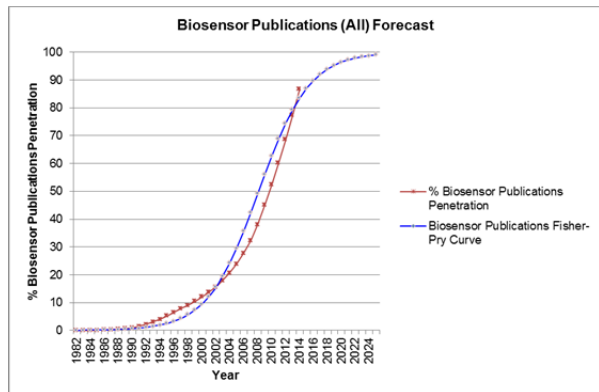


Figure 16: Biosensor Publications Fisher-Pry Curve (All Biosensor Types)

The combined Biosensor Publications Fisher-Pry curves are shown in Figure 20. The technology diffusion midpoint is considered to compare the relative maturity levels of the different types of biosensors. The midpoint occurred in 2008 for all types of biosensors combined. According to these curves the midpoint will occur beyond 2025 for the blood, saliva, and breath biosensors. It is not clear if the bibliometrics results are useful. This is discussed in the conclusion.

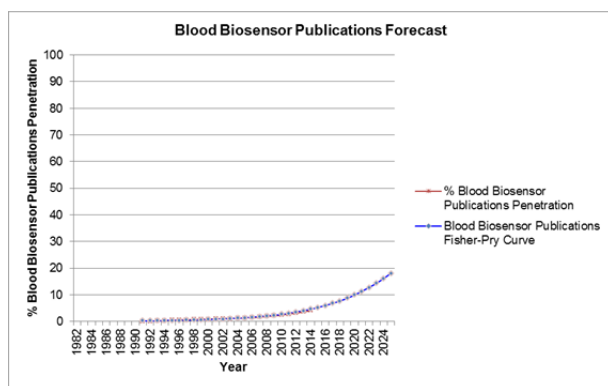


Figure 17: Fisher-Pry Curve: Blood Biosensor Publications

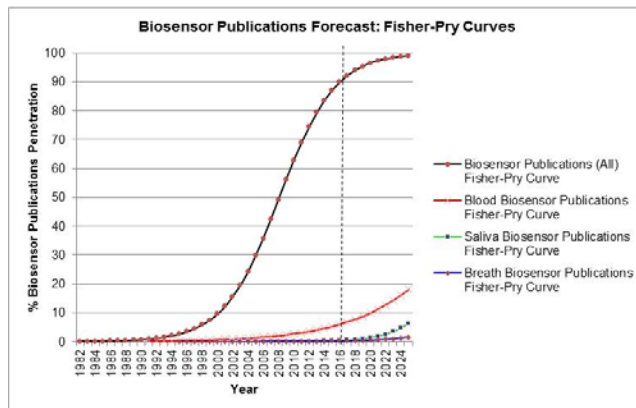


Figure 20: Comparison of Biosensor Publications Fisher-Pry Curves

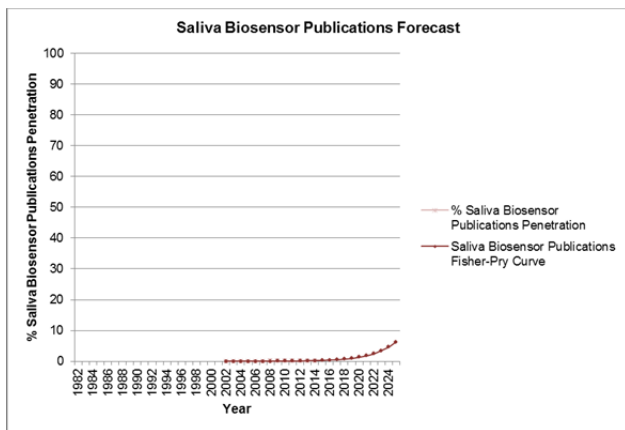


Figure 18: Fisher-Pry Curve: Saliva Biosensor Publications

VII. TEST COMPARISON OF FISHER-PRY CURVE RESULTS WITH GOMPERTZ CURVE

To test if the Fisher-Pry curves are better for growth curve modeling of biosensor technologies, the Gompertz curve was calculated for one test case using the global patent data for all types of biosensors.

The Gompertz model was initially designed for use in demographic studies and human mortality [26] and has been applied to technology forecasting [16], [54]. In the emerging technology context the law implies that the maturation and exit of older technologies make way for new technologies to drive the evolution process [55].

The Gompertz curve is similar to the Fisher-Pry curve but it is not symmetrical about the inflection point and reaches it

early in the growth trend (Equation 3). (The inflection point of Fisher-Pry curve is at the midpoint or 50% maturity whereas it is at 36.8% for Gompertz. This is characteristic of the curves.)

$$Y_G = L10^{-A10^{-Bt}}$$

- Y_G : Gompertz curve
- L: Normalized upper growth limit (100)
- t: Time in years
- A: Time at which diffusion begins
- B: Rate at which diffusion will occur

Equation 3: Gompertz Forecasting Model [54]

Similar to the calculations for the Fisher-Pry curve, the Gompertz curve (Y_G) is determined by two parameters (A and B). One parameter (A) determines the starting point of the diffusion and the second parameter (B) determines the rate of diffusion. The Gompertz equation can also be converted to linear form as (Equation 4):

$$\text{Log} \left(\text{Log} \left(\frac{L}{Y_G} \right) \right) = \text{Log} A - Bt$$

Equation 4: Log Linear Form of Gompertz Forecasting Model

Then linear regression can be applied on the cumulative annual data to determine Log A (and hence, A as $10^{\text{Log} A}$) and B as the intercept and slope of a straight line (Figure 21). The resulting Gompertz Curve is shown in comparison to the Fisher-Pry curve for this case in Figure 22. The Fisher-Pry is a better fit especially up till the technology maturity midpoint. (The “% biosensor patents penetration” is the actual maturity curve based on annual patent count.) Then it tends to overestimate the growth and maturation, that is, the technology matures later than predicted. The Gompertz curve overestimates the maturity curve until it reaches about 57% growth and then tends to underestimate.

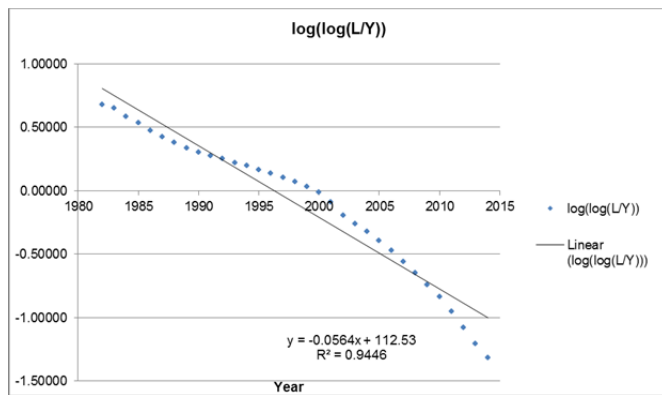


Figure 21: Using Linear Regression to Determine Parameters A and B for Biosensor Patents Gompertz Curve (All Biosensor Types)

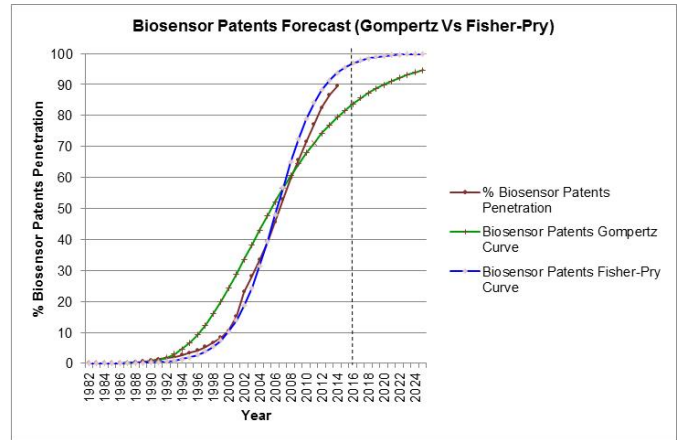


Figure 22: Comparison of Gompertz and Fisher-Pry Curves for Biosensor Patents (All Biosensor Types)

VIII. CONCLUSION

The Fisher-Pry projections or S-curves enable insights into the relative technology maturity levels of the emerging biosensor technologies under consideration and forecasting their growth. It also appears that the Fisher-Pry model is a better fit than the Gompertz model. Patent analysis indicated that blood biosensors reached the maturity midpoint in 2009 with saliva and breath biosensors lagging by 8 and 14 years respectively. From a life cycle perspective and based on this information, it may be assumed that blood biosensors are in late growth or early maturity, saliva biosensors are in the growth stage, and breath biosensors are in their infancy. Bibliometrics implied that the midpoint would occur beyond 2025. Patent analysis forecasted significantly earlier technology diffusion than bibliometrics. This is mainly due to the fact that the annual patent numbers (data points) and increments are significantly more than the annual publication numbers. The cumulative patent growth may indicate that the industry has accepted biosensor technologies and considers them to be viable. Hence, it is likely that biosensors will continue to be used in a variety of devices. Biosensor devices using blood samples appear to be heading towards maturity and saliva biosensors will follow beyond 2024. Breath biosensors are still in the introduction stage. It is the intention of the authors to develop further blood biosensor S-curves for specific analyte types such as glucose, cholesterol, cardiac biomarkers, and diverse infectious diseases. In these cases the upper limit, L will be reduced and determined by the total number of patents for blood glucose biosensors.

In this research bibliometrics based on annual publication count implied that saliva and breath biosensors were still in the very early stages of development with very few publications. This was based on the Web of Science database. A check was then performed using the Compendex database and similar results were obtained. A second check was done with the LexisNexis database and it also resulted in few publications for these biosensors. (LexisNexis contains

records of global newspapers, magazines, trade journals, and web publications.) At this point it may be concluded that bibliometrics does not bring much forecasting value for this research.

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APPENDIX

TABLE 4: PATENTS FILED FOR BIOSENSORS WORLDWIDE: ALL TYPES, BLOOD, SALIVA, AND BREATH

Year	Biosensor Patents Filed Per Year			
	All Types	Blood	Saliva	Breath
1982	1			
1983	1	1		
1984	7*	12		
1985	14	12		1
1986	44	14		1
1987	73	29		1
1988	108	42	6	0
1989	164	57	15	0
1990	183	70	4	0
1991	220	65	1	3
1992	196	118	12	0
1993	315	147	18	2
1994	320	192	29	6
1995	476	309	35	9
1996	459	353	39	8
1997	762	450	49	6
1998	795*	735	149	15
1999	1039*	882	173	29
2000	1332	1007	248	23
2001	2977	2017	707	52
2002	4802	2236	643	144
2003	3176	2219	475	101
2004	3220	2309	498	132
2005	3642	2471	555	131
2006	3989*	3199	866	161
2007	4567*	3521	864	249
2008	4140*	3347	831	178
2009	3713*	3082	680	187
2010	3570	2756	601	167
2011	3550*	2718	670	164
2012	3291	2586	543	130
2013	2579*	2273	506	105
2014	1767*	1723	409	87
Totals	55,492	40,952	9,626	2,092

*In some cases data mining using AcclaimIP resulted in the number of annual patents for all biosensors types being less than the sum of the number of the blood, saliva, and breath biosensors. The reason for this is still unclear. This may be due to the AcclaimIP search methodology or how data mining is performed within the diverse patent databases covered. The resolution remains under investigation.

TABLE 5: PUBLICATIONS FOR BIOSENSORS WORLDWIDE: ALL TYPES, BLOOD, SALIVA, AND BREATH

Year	Biosensor Publications Per Year			
	All Types	Blood	Saliva	Breath
1982	5			
1983	2			
1984	10			
1985	23			
1986	21			
1987	48			
1988	48			
1989	47			
1990	68			
1991	196	21		
1992	190	21		
1993	268	36		
1994	283	19		
1995	376	41		2
1996	377	28		
1997	405	29		
1998	363	19		
1999	441	20		
2000	459	20		
2001	531	29		
2002	558	26	2	
2003	671	25		
2004	839	30		
2005	962	32		6
2006	1141	41		2
2007	1341	64	5	
2008	1757	75	5	6
2009	2105	71	5	3
2010	2182	76	8	8
2011	2361	100	3	5
2012	2525	114	4	10
2013	2648	154	3	5
2014	2798	144	12	11
Totals	26,049	1,235	47	58