

Development of the hydrogel-based biosensors: An overview of patented technologies[†]

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Abstract: This overview concerns recent patents and patented technologies in relation to the development of hydrogel-based biosensors, published until 2022. As a result, 257 patent documents and 145 simple patent families have been searched through different specialized patent databases. Furthermore, the patent classification confirmed that the most claimed inventions concern chemical analysis of biological material and biospecific binding assay materials with an insoluble carrier for immobilizing immunochemicals. Overall, research, development, and innovation concerning hydrogel-based biosensors are based on improvements in the synthesis of hydrogels, biomolecule immobilization and detection, as well as microelectronic device integration and microfabrication techniques. A collection of recent patented technologies is proposed at the end. In this respect, it aimed to demonstrate potential trends and challenges in relation to the development of hydrogel-based biosensors.

Keywords: hydrogel; biochemical sensing, biosensors; patent analysis; innovation

1. Introduction

Hydrogel-based biosensors are sensors that immobilize and detect biological molecules such as enzymes or antibodies using a hydrogel matrix [1,2]. For several decades, researchers have been working on the creation of hydrogel-based biosensors [3]. Medical diagnostics [1,2], pharmaceutical drug delivery [4], food safety [5], and environmental monitoring [6] are among the applications for these devices.

Hydrogels are hydrophilic polymer-based materials [7]. They are similar to biological tissues in terms of their soft and hydrated nature and can thus be used as scaffolds for cell growth and tissue regeneration [8]. Further, thanks to their properties, they have applications in various fields, including biomedical engineering, drug delivery, and tissue engineering [9]. Hydrogels can be made from a variety of polymeric materials, including synthetic polymers and natural polymers such as cellulose [10], chitosan [11], and lignin [12].

In the field of biosensors, hydrogels can be used as sensitive components that respond to specific biological signals, such as changes in pH, temperature, or glucose levels [13,14]. The hydrated nature of hydrogels also allows for efficient transport of biomolecules, making them suitable for use in biosensors [1]. For the development of such devices, it is crucial to have affordable sensor manufacturing capabilities. However, due to the complexity of hydrogel-based sensing devices, new manufacturing techniques are required for their production at a high level of efficiency [15]. Using three-dimensional (3D) printing, various hydrogels can be printed into complex 3D structures that could be used as sensing platforms [16]. Likewise, hydrogel-based biosensors can be 3D printed using various techniques such as soft lithography, microcontact printing, microfluidics, droplet

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printing, stereolithography, etc. [9]. In this way, the choice of 3D printing technique depends on the desired size, complexity, and performance of the hydrogel-based biosensor.

Patented technologies in this area are increasing rapidly through different key developments, including the synthesis of hydrogels, the immobilization of biomolecules, the detection of biomolecules, their integration with microelectronic devices, and microfabrication techniques [16,17].

This overview concerns recent patented technologies in relation to the development of hydrogel-based biosensors and their applications. According to publication dates, patent families, patent classifications, and patent jurisdictions, a patent analysis is given. It is proposed on the basis of standards of patent analysis, which are considered tools for research planning [17-20]. This can help identify key players and trends, as well as assess the level of competition in a particular market. Moreover, this involves analyzing a company's patent portfolio to identify opportunities for growth or potential challenges [21]. Finally, a collection of recent patents and patented technologies in relation to the development of hydrogel-based biosensors is proposed to demonstrate potential trends and challenges.

2. Methods

The search for patent documents around the world was carried out using the three databases: "Patentscope", "Espacenet" and "The Lens". The first and second ones are free patent search services administered by the World Intellectual Property Organization (WIPO) (Geneva, Switzerland) and the European Patent Office (EPO) (Munich, Germany), respectively [22,23]. However, the third one is a commercial patent data set developed by the Cambia Institute (Canberra, Australia) [24].

Overall, different keywords and codes were used to retrieve patent documents in relation to the development of hydrogel-based biosensors. The search was then refined to include only two types of patent documents (i.e., patent applications and granted patents) published until December 31st, 2022. The results were analyzed according to publication dates, patent families, patent classifications, and patent jurisdictions. The two types of patent documents chosen for this study are defined as:

- **Patent application:** A patent application is a formal, prepared document, submitted to the appropriate patent office by the depositor (i.e., applicant), that includes a detailed description of the invention, including how it works and what makes it different from existing technologies. The application also includes a set of claims that define the scope of the patent protection being sought. The patent office then examines the application to determine if the invention meets the criteria for patentability, including novelty, non-obviousness, and usefulness. If the application is approved, a patent is granted [25].
- **Granted patent:** A granted patent is a form of legal protection that gives the patent holder (i.e., owner or assignee) the exclusive right to prevent others from making, using, selling, or importing an invention for a certain period of time [26].

3. Results and discussion

3.1. Publication dates

The publication date of a patent document refers to the date on which the patent application is made available to the public by the appropriate patent office responsible for granting patents. The publication date is an important milestone in the patent process, as it marks the point at which the information contained in the patent application becomes publicly available. It's important to note that a patent application's publication does not ensure that a patent will be granted [27].

Figure 1 displays the evolution of patent documents related to the development of hydrogel-based biosensors between 1991 and 2022. The results concern the filing, grant,

and publication dates of patent applications, granted patents, and patent documents, respectively.

Since the first patent application was filed in 1991, we can assume that the year 1991 is considered the start of patenting activities in this area. Thus, this first patent application was granted in 1996 [28]. Through the granted patent, Malmqvist *et al.* invented a sensor unit for use in a surface plasmon resonance-based biosensor system. The claimed biosensor system included a replaceable dielectric substrate coated with a metal film that has two or more sensing areas arranged so that a liquid stream can pass through them in series or parallel. Each of these sensing areas included a layer of hydrogel containing at least one functional group [28].

Analytically, between 1991 and 2022, 257 patent documents related to the development of hydrogel-based biosensors were published. These include the publication of 195 patent applications and 62 granted patents. Furthermore, 65% of patent documents were published during the last 10 years (i.e., 2002–2022). Furthermore, the most patent applications were filed in 2018 (17 patent applications), and the most patents were granted in 2014 (6 granted patents). However, the maximum number of published patent documents was 21 in 2021.

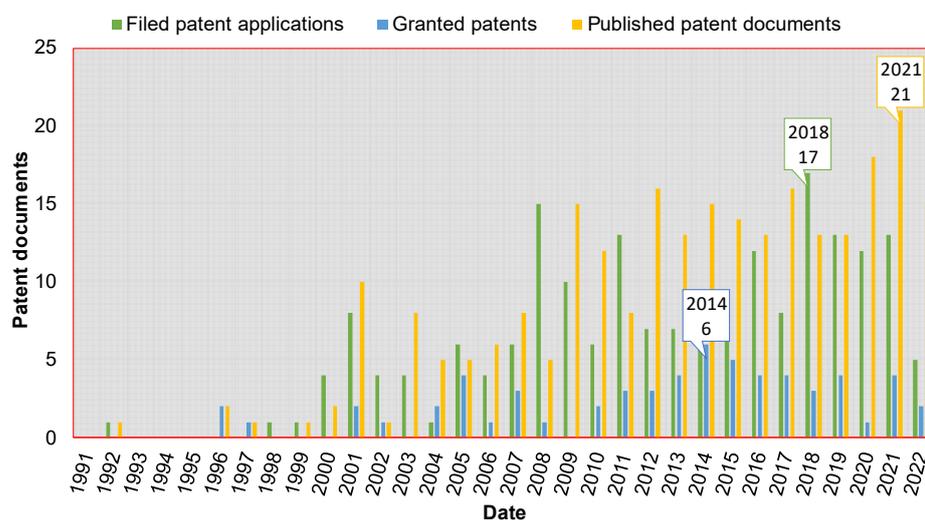


Figure 1. The evolution of patent documents (i.e., patent applications and granted patents) related to the development of hydrogel-based biosensors between 1991 and 2022.

3.2. Patent families

A patent family is a collection of patent documents that are related to each other by the same priority application and protect the same invention or a closely related group of inventions in different jurisdictions (i.e., countries or regions). It's worth noting that a patent family can include both granted patents and pending patent applications. Overall, "simple families" and "extended families" are terms used in the context of patent families to describe different levels of relatedness between patent documents [29].

In relation to the development of hydrogel-based biosensors between 1991 and 2022, we found 145 simple families and 138 extended families. These results indicate, on the one hand, that 145 simple families of patent documents refer to a collection of 145 related patent documents that share the same priority application or priority date. This means that 145 patent documents published between 1991 and 2022 cover the same invention and are based on the same original filing. On the other hand, 138 extended families of patent documents refer to a collection of 138 related patent documents that cover the same invention but may have different priority dates. This means that 138 patent documents were filed and/or granted for the same invention in different countries at different times between 1991 and 2022, out of a total of 257 published between 1991 and 2022.

3.3. Patent classifications

Patent classification is used to categorize patent documents according to their technical subject matter. The main patent classification system used is the International Patent Classification (IPC). It is a standardized system maintained by WIPO and is used by patent offices around the world. It is divided into eight main sections, which are further divided into smaller classes and subclasses. Each subclass is further subdivided into groups and subgroups, each with its own code [30].

Table 1 presents the top 10 IPC codes of patent documents related to the development of hydrogel-based biosensors between 1991 and 2022. The most common IPC code concerns investigating or analyzing biological materials (e.g., blood, urine, etc.) by chemical analysis such as immunoassay or biospecific binding assay with an insoluble carrier for immobilizing immunochemicals. The G01N33/543 subgroup recorded 45 patent documents with a contribution per total of 17.51%. This code's related group (i.e., G01N33/00) appears twice in the top ten, with 28 and 14 patent documents in G01N33/53 and G01N33/487, respectively. Another group of patent classifications, with its three subgroups (i.e., A61B5/145, A61B5/274, and A61B5/06), is also present among the top 10. In addition, the A61B5/00 code, which concerns measuring for diagnostic purposes, recorded 35 patent documents with a contribution rate of 13.62%. Another point is that five IPC codes (i.e., G01N33/543, A61B5/00, C12Q1/00, G01N27/327, and A61B5/145) have been presented as relevant in a previous study concerning cellulose-based biosensors [16]. However, the IPC code C08J3/075 has been presented as relevant for patent classifications of biopolymer-based hydrogels [31].

Table 1. IPC codes (Top 10) of all published patent documents related to the development of hydrogel-based biosensors between 1991 and 2022.

IPC code	Description	Patent documents	Contribution per total (%)
G01N33/543	Investigating or analyzing biological materials (e.g., blood, urine, etc.) by chemical analysis such as immunoassay or biospecific binding assay with an insoluble carrier for immobilizing immunochemicals	45	17.51
A61B5/00	Measuring for diagnostic purposes	35	13.62
G01N33/53	Investigating or analyzing biological materials (e.g., blood, urine, etc.) by chemical analysis such as immunoassay or biospecific binding assay	28	10.89
C12Q1/00	Measuring or testing processes involving enzymes, nucleic acids, or microorganisms	26	10.12
G01N27/327	Biochemical electrodes	17	6.61
A61B5/145	Measuring for diagnostic purposes, such as measuring the characteristics of blood in vivo (e.g., gas concentration, pH, etc.)	16	6.23
A61B5/274	Measuring or recording bioelectric or biomagnetic signals of the body, including bioelectric electrodes, using snap or button fasteners	14	5.45
G01N33/487	Physical analysis of liquid biological materials	14	5.45
A61B5/06	Measuring for diagnostic purposes, such as devices for detecting or locating foreign bodies	12	4.67
C08J3/075	Treatment or compounding of macromolecular substances, such as the formation of macromolecular gels in aqueous media	12	4.67
Others ¹	-	-	14.79

¹Minor other IPC codes are required to complete 100% of the total contribution.

3.4. Patent jurisdictions

Patent jurisdiction refers to the legal authority that governs the issuance, enforcement, and litigation of patents [32]. There are national patent jurisdictions, which are individual countries (e.g., the United States, China, Australia, etc.), and regional patent jurisdictions (e.g., Europe, Eurasia, Africa, etc.), which cover multiple countries [33]. For example, patents granted in the United States, through the United States Patent and Trademark Office (USPTO), have legal effect only within the United States and its territories. However, patents granted in China through the China National Intellectual Property Administration (CNIPA) are enforceable only in China. An example of regional patent jurisdictions concerns the EPO, which is responsible for granting patents in the member states of the European Union. While patents are granted by national or regional authorities, they are subject to international agreements and treaties. The Patent Cooperation Treaty (PCT), for example, is an international agreement that enables applicants to file a single patent application that can be used to seek protection in multiple countries. The PCT does not grant patents, but it simplifies the process of filing and coordinating patent applications in multiple countries. It's important to note that WIPO oversees this international system [34].

Table 2 presents the jurisdictions of patent documents related to the development of hydrogel-based biosensors between 1991 and 2022. At first sight, the “quadruple”, constituting the reputable jurisdictions, always emerges from several studies on patent analysis. This includes the United States, the PCT, Europe, and China. In fact, these jurisdictions have been presented as relevant in the case of inventions concerning cellulose-based biosensors as well as hydrogel-based coatings [16,21].

Besides, the United States leads the patent race in relation to the development of hydrogel-based biosensors. In the first place, the United States encompasses 121 patent documents with a total contribution of 47.08%. The WIPO-administered international agreement PCT then encapsulates 67 patent documents with a contribution rate of 26.07%. Next, the regional patent jurisdiction EPO, which is responsible for granting patents in the member states of the European Union, encompasses 28 patent documents with a contribution per document of 10.89%. Finally, in fourth place, China encapsulates 24 patent documents with a total contribution of 9.34% via the CNIPA.

Table 2. Jurisdictions for all published patent documents related to the development of hydrogel-based biosensors between 1991 and 2022.

Jurisdiction	Patent documents	Contribution per total (%)
United States	121	47.08
PCT (WIPO) ¹	67	26.07
Europe (EPO) ²	28	10.89
China	24	9.34
Republic of Korea	8	3.11
Australia	3	1.17
Canada	2	0.78
Russia	2	0.78
Germany	1	0.39
Japan	1	0.39

¹The WIPO manages the international Patent Cooperation Treaty (PCT) system.

²Member states of the European Union through the European Patent Office (EPO).

3.5. Recent patents and technologically relevant patents

Several criteria can be considered when selecting the most relevant patents and recent patent technologies. Criteria include technological relevance, the scope of protection (i.e., patent families), the filing date (i.e., newer patents), and patent quality (i.e., granted patents). Table 3 presents the recent patented technologies in relation to the development of hydrogel-based biosensors. This includes only four patent documents according to the

four reputable jurisdictions through their patent offices, namely the USPTO, WIPO, EPO, and CNIPA (c.f., 3.4. Patent jurisdictions). It's worth noting that this part will be more detailed in a future patent analysis-based study.

Table 3. Recent patents and patented technologies in the area of the development of hydrogel-based biosensors.

Patent	Jurisdiction	Summary	Publication	Families ¹
US10281419B2	United States	The invention relates to a hydrogel-based interdigitated microelectrode biosensor. The system includes a first interdigitated microelectrode that comprises several first protrusion electrodes arranged in a comb-like configuration and a second interdigitated microelectrode positioned opposite to the first one on the substrate. The second interdigitated microelectrode includes multiple second protrusion electrodes arranged in a comb-like pattern as well. The hydrogel is provided between the interdigitated microelectrodes such that the presence and concentration of a biological substance, such as a protein, are detected by measuring the impedance between the interdigitated microelectrodes.	May 7, 2019	4s. / 4ex.
WO2019/023712A1	PCT	The invention relates to a method for <i>in situ</i> sensing of water stress in a plant by contacting a plant with a biosensor. The biosensor comprises a hydrophilic polymer matrix capable of giving a detectable response to changes in local water potential in the plant and detecting the response, thereby sensing water stress in the plant. Further, the hydrophilic polymer matrix contains entangled and covalently bound polymers, such as hydrogel.	Jan 31, 2019	3s. / 3ex.
EP3103393B1	Europe	The invention relates to a biosensor that can be implanted in the body. The biosensor incorporates a hydrogel as a sensing material that responds to a particular analyte within a pressure measurement chamber. The chamber is connected to a pressure sensor, which can detect any changes in pressure. The sensor material in the pressure measurement chamber is linked to a compensation material that maintains a relationship between temperature and pressure volume. This relationship opposes any temperature-based changes in pressure or volume of the sensor material and partially neutralizes any cross-sensitivity-induced variations in volume of the sensor material.	Aug 30, 2017	5s. / 5ex.
CN104684475B	China	The invention relates to an implantable biocompatible biosensor. The biosensor comprises a chip layer that has numerous vertically aligned holes, a power source, and one or more sensors that are connected to the power source and situated on the chip layer. Additionally, the biosensor includes a hydrogel matrix that comes into contact with the chip layer and contains one or more angiogenesis-stimulating factors. These factors facilitate the growth of organic matter through the multiple holes in the chip layer once the biosensor is implanted in a living organism.	Mar 1, 2017	8s. / 8ex.

¹Patent families (s.: Simple / ex.: Extended).

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4. Conclusions

In summary, our analysis of the patent landscape for hydrogel-based biosensors revealed 257 patent documents, including 195 patent applications and 62 granted patents. Notably, the majority of the patents were published within the last decade, accounting for 65% of the total documents. Furthermore, the United States, the PCT, Europe, and China were the top jurisdictions with a combined contribution of 93.38%. Additionally, most of the patent documents were focused on the investigation and analysis of biological materials using chemical analysis techniques such as immunoassay or biospecific binding assay with an insoluble carrier for immobilizing immunochemicals. These findings provide important insights into the current state of the hydrogel-based biosensor patent landscape and could guide future research and development in this field.

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