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# Patentability searching for biomaterial and related polymers

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A B S T R A C T

The understanding of the technical aspects of biomaterials as well as the understanding of the polymer structures and their characteristics are requirements for a searcher in the field of biomaterials and related polymers. Faced with an increasing number of sources of information, e.g. patents, non-patent literature, internet citations, internal databases, external databases, patent office examiners are challenged with the constant need to develop a search strategy in order to achieve the most efficient and complete search. Thoroughness and persistence are critical when it comes to search in this technical field. It is no exaggeration to say that a good searcher will have to use competitive intelligence tactics, checking new databases, new product announcements and technical literature for evidence or prior art. It is therefore crucial for patent office examiners to structure the way in which they develop their search strategy in the context of this broadening of available public information.



## 1. Introduction

### 1.1. *A short history of polymers in the field of biomaterials [3]*

The technical field of Biomaterials was revolutionized by the emergence of synthetic polymers which became available in the 1920s. It opened up a new area for innovation in the field of medical-device pioneers. Biomaterials, which were by definition considered as biologically inert or compatible materials placed inside a human body on a long term or even permanent basis, were mainly used in the practise of wound closure or dental repair. They were mainly made of materials derived from plants, ores or animal sources [4]. Since the beginning of the last century and especially the last 60 years, the technical field of medical devices in contact with living tissues has experienced tremendous technological advances. The main groups of materials used are metal, ceramics and polymers. It is this last group that is the subject of this article.

Polymers are classified in three main groups: thermoplastics, rubbers and thermosets [5]. It is the specific properties of these three groups which will influence their choice as material for medical devices.

- The thermoplastics, e.g. polyethylene, polyvinyl chloride, which were often referred to as “plastics” are linear or branched polymers that can be melted upon application of heat and can be moulded and remoulded. It is to be noted that plastics remain the most widely used polymers.
- The rubbers, e.g. latex, are materials that display elastomeric properties. It means that they can be stretched to high extensions and will spring back rapidly when the stress is released. The rubbers are also described as crosslinkable linear polymers.
- The thermosets, e.g. polyimides, urea-formaldehyde resins, are heavily crosslinked polymers that are rigid and intractable. They consist of a dense three dimensional molecular network and, like rubbers, degrade rather than melt upon heating.

From 1930 to the 1950s, polymethyl methacrylate (PMMA), was the most widely used polymer for biomaterials as its biocompatibility and versatility made it the material of choice when rigidity was required in a medical device. PMMA is still used nowadays for bone cement, intra-ocular lenses, etc.

In the 1940s, polyvinyl chloride (PVC) and polydimethylsiloxane (silicone) became available. The flexibility of silicone allowed the development of flexible-device components.

Still today, PVC is the most widely used polymer for blood bags and medical tubing. It is also to be noted that silicone was the first implantable elastomer since the hydrocephalus shunt first implanted in 1955 [6,7].

Between 1940 and 1960, namely during the Second World War and Cold War, tremendous advances took place in medical industry. That period saw the development of pacemakers, e.g. silicone-coated epoxy encased pulse generators with polytetrafluoroethylene-insulated stainless steel wire leads.

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Numerous medical devices were developed such as vascular prostheses (PMMA, polyethylene tubing), blood-pump devices (avothane polyurethane/polydimethylsiloxane copolymer), intraaortic balloon pump (latex rubber on polyethylene catheter), synthetic vascular prosthesis (Vinyon N – polyvinyl chloride polyacrylonitrile copolymer), bone-fixation implants (Polyester urethane rigid foam), heart-lung machines as well as tissue adhesives (cyanoacrylates and hydrocolloids), occlusive wound dressings (polyethylene), dental restoratives (glycidyl dimethacrylates, bisphenol dimethacrylates, polyurethanes) and hard contact lenses (PMMA) [8–10].

The 1960s until the 1980s saw the development of early polyurethane implants for orthopaedic-fixation devices for use on chronic ailments. The main problem that the first polyurethane implants faced was their biodegradability. Therefore, the focus was on biodurability for long-term applications of polyurethane based implants. Intensive advances in orthopaedic devices led to routine artificial hip and knee replacements. New tissue-fixation techniques produced durable prosthetic valves from animals as well as the introduction of bioabsorbable sutures and reconstructive surgery implants.

During the 1970s, the medical devices were even more complex and refined: mammary prostheses were coated with foam for better tissue attachment. Blood vessels were coated with endothelial cells. Balloon catheter was introduced, expanded polytetrafluoroethylene was introduced for medium-diameter vascular prostheses. The commercialization of the first transdermal drug delivery device as well as the first synthetic conductive-hydrogel skin adhesive for stimulation and sensing electrodes took place.

Finally, during the 1980s, one of the greatest achievements of biomaterials technology was the introduction of the polyurethane heart from the University of Utah in the USA.

The years between 1970 and 1980 have taught engineers and scientists that there is no such thing as an "inert" implant. They realised that all biomaterials were affected by the physiological responses of living tissues. It was no surprise that the latest developments focus on this new technology [11–13].

During the 1990s, researchers explored the development of "intelligent" biomaterials that could change their characteristics in response to environmental physical and chemical stimuli. The most famous example was the development of hydrogel polymers which respond to thermal, pH or electrical stimuli. They react by swelling, eroding or contracting. Medical devices were areas designed to intervene in cellular or biochemical processes. One of the promising areas concerned tissue engineering as well as coating with barrier films or bioactive molecules which could modulate biological responses [14].

The 2000s have seen the advance of biological processes and how they assist or complicate medical devices performance. Some conventional biomaterials have been further developed such as high-strength engineering thermoplastics and composites, ultrahigh molecular weight polyethylene, oxidation and hydrolysis resistant polyurethanes. Biostable or biodegradable scaffolds were developed which promote tissue in-growth.

The general idea was shifted from having a permanent implanted prosthesis to replace damaged tissue, to implanting a reconstructive or regenerative temporary scaffold that enables the body to heal itself [15–18].

What next? Although the years of development for biomaterials have shown tremendous achievements, one of the remaining limitations in polymer-based biomaterials is still their biocompatibility: some problems remain for instance in the autoimmune responses to implants, the calcification of cardiovascular devices, the biodegradation of permanent implants and the tissue resorption in the submicrometer wear particles.

The last ten years have seen the development of hybrid bioartificial organs consisting of biological and synthetic components, hybrid devices simulating liver, pancreas and kidney functions. But, before continuing down this path, industry and society must consider ethical and legal issues in the development of these new hybrid biomaterials.

Less promising, but still note-worthy is the trend for some scientists to try to develop the use of combinatorial and computer designed strategies to provide the next generation of biomaterials [16,19].

After a brief history of the development of polymers in the field of biomaterials, it is also important to emphasize that a similar trend has occurred in the development of patent search documentation from paper group search to the development of new computer tools.

### *1.2. From paper groups to online search [20,21]*

Since the 1990s, another revolution took place independently of the development of the technical field of biomaterials and related polymers: the search for prior art.

Before the 1990s, patent examiners used to search exclusively in classified documentation and operated what was called a "paper group search". Searchers flipped through classified collections of paper copies in the search rooms of the major patent offices, the classified collections being mainly based on patent documents. They were classified into groups defined by the major technical characteristics defining the invention. Since the 1990s, the development of electronic and computer tools has seen the shift from manual search to online search with the yearly growth in the number of documents scanned and available in online databases. Given the enormous volume and complexity of today's online databases, further complicated by the emergence of the internet as a tool for search for state of the art, it became difficult for searchers to run a search in biomaterial related polymers. One of the reasons is that it concerns two aspects of the same technical invention, namely the material involved and more precisely the polymers as well as the specific function as biomaterial material for which an enormous amount of information might be retrieved by using keywords.

## 2. Search techniques

### *2.1. The main types of searches related to patent search*

Search professionals generally recognize the following six search types [22]:

- Due diligence search (an evaluation or verification of all facts)
- Patentability search
- Infringement search
- Freedom to use search
- Document status search
- Product/process specification search
- A due diligence search is designed to capture all relevant documentation available to a diligent searcher at a defined date. It will usually require a team of searchers working independently. Historically, the concept of the diligent searcher emanates from patent cases such as General Tire versus Firestone and the Beecham Group Ltd amoxicillin. In these two cases, the validity of a patent was in dispute and a due diligence search was done in order to justify revocation.
- A patentability search is designed to uncover any barriers that will prevent a patent from being granted. Therefore, the searcher will seek to answer the following questions: is the invention new, inventive and susceptible of industrial applicability.

- The infringement search is usually conducted by a patent proprietor who needs to prove that an infringer has carried out a prohibited act, that is that the infringer has made, used, sold or imported a patented product, or has used a patented process, or has made, used or sold a product made directly from a patented process. As a remark, under the European Patent Convention, it is also possible to invoke rights based on the published application (Article 67(1) EPC), provided the patent is then granted (Article 68 EPC).
- A freedom to use search involves a narrow subject area and is limited to a few keywords as well as patent classes and inventors or applicants. The idea behind it is to determine whether a known technology is free to use, that means if a patent already covers that technology and if so, is this patent still valid and where.
- A document status search is a search requested by companies wishing to make, use, import or sell generic drugs or goods under a specific jurisdiction. Although similar to a freedom to use search, it is a more specific search, since the name of the product or drug is known and is country dependent.
- The product/process specification search is the narrowest of all the presented searching types and may be requested by a company wishing to find more information about a specific technology. The result of this type of search is often a licence or cross-licence between companies.

### *2.2. The type of search at the European Patent Office*

Among the different searches mentioned above, a patentability search is the closest to the type of search done at the European Patent Office. For instance, at the European Patent Office, the objective of a search is to discover the state of the art which is relevant for the purpose of determining whether the invention to which the application relates is new and involves inventive step. It is similar to the patentability search mentioned above. The examination procedure and the preparation for the search opinion depend on the search for the knowledge of the state of the art on which assessment of the patentability of the invention is based. The search must, therefore, be as complete and effective as possible.

Irrespective of the type of search, every searcher will have to answer basically three questions when it comes to search technique: what to search, where to search and how to search. Although this article concerns biomaterials and related polymers, the same three questions can be applied to any technical field as well as any searcher (examiners, patent attorneys or private persons) [23].

It is also important to take into account the strategic aspects that applicants may consider when it comes to drafting a patent application: from pure economic aspects such as costs, to possible infringement or licences, the reasons may be multiple and different from one applicant to the other. To emphasize this last economic aspect, it is important to be aware of the fact that about 40% of the applications filed at the European Patent Office are filed by less than 2% of applicants which shows a very high concentration of interests [24]. An interesting statistic is also that 18% of the European patents are used to form a new company which is often followed by licencing of the patent right [25,26]. It means that for applicants, the search results are a first answer to analyse the value of their attempt to obtain a patent right.

## 3. The search process: essential steps for a structured search

The crucial point for every searcher is to develop with time and experience a search strategy which will help her or him to gain time, efficiency, increase the search quality and finally tackle timeliness due to cost restrictions. As discussed above, the objective of the search is to discover the relevant state of the art for the purpose of assessing novelty and inventive step. The assessment of patentability at a search stage can have direct impact on the execution of the search itself.

The literature presents a great variety of approaches to systematic on-line search. The search process we present is derived from one of the basis approaches developed at the EPO for the training of new examiners [27]. The search strategy mainly covers the following steps:

1. The objects of the search (What?)
   - study of the application and interpretation of the claims
   - identification of the technical features as well as the effects of the claimed invention
   - identification of the search concepts
2. The search tools (Where?)
   - inventory of classes corresponding to each search concept
   - identification of the keywords that describe these concepts and formulation of related terms, synonyms or other variations of the keywords
   - search on bibliographic data: related applications, citations, existing search report, inventors, authors
3. The search strategy (How?)
   - formulation of search queries possibly with the help of a search table.
   - selection of the databases where the search queries will be run
   - evaluation of the search results
   - if needed, modification of the search queries in view of the result obtained to refocus the search for the remaining features

The search may require several days over several sessions, making it difficult to remember all the terms and strategies used. It is therefore important to keep a search log which is quite often expressed as a search table for patent examiners. The search table will gather all the search concepts and to each search concept will correspond one or more essential features of the invention. The elaboration of such a search table will be exemplified in section 4 of this paper.

### *3.1. Analysis of the invention*

This first step will help the searcher to identify the subject of the invention and is achieved by identifying throughout the description and claims the main area of technology covered by the invention. In the field of biomaterials, the subject of the invention may relate to a new polymer, a new process for manufacturing it or the specific and new area of application of a polymer already known from the prior art.

### *3.2. Interpretation of the claims*

One of the essential steps involved in the search process includes a critical analysis of the claims with the aim of identifying the search concepts. This should be made in the light of the description and drawings, if any. For instance, the study of the embodiments of the invention and examples may help to understand better the wording of the claim.

Attention should also be drawn to the context of the claims, description and drawings sufficiently to identify the problem underlying the invention, the inventive concept leading to its solution, the features essential to the solution as found in the claims and the results and effects obtained. It may occur that technical features essential for the solution of the stated problem are only indicated in the description. In such cases, although not mentioned in the claims, these features should be included in the search [28].

#### *3.2.1. Meaning of the words*

Since the extent of protection conferred by a European patent or application is determined by the claims, the wording of claims is crucial: article 84 EPC stipulates that the claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description.

Therefore, each claim should be read giving the words the meaning and the scope which they normally have in the relevant art by explicit definition. In particular cases wherein the description gives the words a special meaning, a step for the searcher would be to look at the description of the application in order to know exactly what is meant by such wording, which may appear clear for some skilled readers but which may be unclear for others [29].

*… in the light of the description*

Although the claims may appear clear to the skilled reader, it is important to analyse what the claims really cover, including the dependent claims and the examples in order to get a better picture as to what the invention really means [30].

In some cases, it is worth looking into the description to see if it is clear which technical feature is responsible for any effect the applicant is claiming. In other cases, it will be necessary to look into (comparative) examples to see where and why any effects arise.

Thus, a thorough analysis of the description allows the searcher to identify the technical field to which the invention relates, the problem existing in the prior art and the solution proposed in order to solve it and the particular advantages of the invention.

#### *3.2.2. Parameters in the claims*

Particular problems arise where parameters are recited in the claims. If the parameter relates to characteristics of a compound, again the examples will have to be consulted to see if it is—for instance—likely that prior art compounds will fall within a certain claim.

If on the other hand operational parameters are used (eg. a process is defined as being carried out so that a certain parameter is respected) then it is necessary to check the description to see which particular effect is associated with operating within the parameters. The technical features giving rise to the effect should then be searched [31]. It is to be noted that chemical and physical properties may also be directly searched in the patent full-text database PCTFULL, a full-text database of PCT applications developed by STN & FIZ and which contains more than 1.8 million record and more than 1.3 million images, covering the time period 1978 to the present [32].

Discussing the particular cases of biomaterials and related polymers, it is common that polymers are described and defined by technical features relating to their physical properties such as strength, elongation, modulus, toughness, crystal nucleation rate, radial stiffness, etc [33–35]. In section 4 of this paper, we will look at some cases where such physical properties are present in claims and discuss how the analysis of the description may help the searcher to decide whether such properties have to be taken into account for the search.

### *3.3. Identification of the search concepts*

Having analysed the claims, the next step consists of defining the search concepts as precisely as possible. A search concept corresponds to one or more essential features of the invention.

The starting point for deriving the search concepts may not only be the *independent* claims of the invention but may also be the dependant claims in order to cover all aspects and embodiments of the invention. The importance of the analysis of the dependant claims should not be overlooked in the process for defining the subject of search. Indeed, a *dependent* claim, rather than adding a further feature, may provide more detail of an element figuring already in the independent claim. Such a situation will be detailed below when analysing the subject of search of a specific case. The elaboration of such a search table will be exemplified in section 4 of this paper.

### *3.4. Collection of the search tools*

Three basis components exist which can be used in the search [36]:

Classification units of various schemes
Keywords and synonyms
Bibliographic links between cited and citing documents (reference hunting)

#### *3.4.1. Databases at the European Patent Office*

At the European Patent Office, the search is carried out in-house or external collections of documents or databases, the content of which are accessible by means of words, classification symbols or indexing codes. About 140 databases are accessible to perform a search at the EPO. These databases generally contain in their records title and abstract of published patents and give access to non-patent publications like scientific papers.

#### *3.4.2. Classes*

If for a given subject-matter a relevant classification exists, retrieving and analysing the documents to which this classification has been allotted is a very efficient way of searching.

Within the EPO, documents have classes using the following classification systems:

IPC – International Patent Classification
ECLA – European Classification (EPO subdivision of the EPC)
ICO – In Computer Only Codes
UCLA – US patent Classification
FI-Classes – Japanese Patent & Trademark Office sub-division

ICO codes and keywords (KWs) allow transversal classification and/or highlight specific aspects within an ECLA group. These codes provide in-depth retrieval possibilities.

#### *3.4.3. Keywords and synonyms*

The majority of European applications are Euro-PCT, that is to say International applications under the Patent Cooperation Treaty (PCT) entering the regional phase in Europe before the European Patent Office as elected or designated office. It is important to keep in mind that around 30–40% of International applications filed in the United States are filed from abroad, and many are filed by people who may not have English as a native language and who may not use the usual wording for the person skilled in the art in a specific technical field. There are many examples where different terms or equivalent terms are used in different countries for the same technical features. Problems of translations may also appear for instance in the situation where the applicant is from Asia such as Japanese or Korean translated applications.

Therefore the terms used in the claims are sometimes not adequate for keyword searching. For a complete search it is normally necessary to add synonyms to the terms found. In the field related to polymers, documents related to polyethylene for example, may be retrieved using various synonyms such as ethylene homopolymer, ethylene polymer, polythene or the abbreviation PE. Acronyms should also be considered when carrying out a search. For instance, possible acronyms or abbreviations of polyhydroxybutyrate are PHB, P3HB, P4HB but also PHA (polyhydroxyalkanoate).

Additionally, trade names and trade marks, when known by the searcher or sometimes mentioned in the description of the searched invention, may often constitute a successful entry for a search [37].

### 3.5. A possible search strategy [38–40]

The purpose of this section is to look at the different tools which are identified in the above sections and which can be currently used during the search. It will be focused on how they may be applied to deal with the extreme cases in order to keep the search burden reasonable yet as complete as possible. It will also be necessary to have a look at how some of the tools work in practise by looking at some problem cases and deciding which ones of the available options might be most appropriate in order to retrieve the most relevant prior art.

The search strategy should determine the sections of the documentation to be consulted covering all directly relevant technical fields and may then have to be extended to sections of the documentation covering analogous fields. The question which technical fields are to be regarded as analogous has to be considered in the light of what appears to be the essential technical contribution of the invention. Another principle in determining the extension of the search in analogous fields should be whether it is probable that a reasonable objection of lack of inventive step could be established on the basis of what is likely to be found by the search in these fields [41].

As detailed earlier in this section of this paper the search process is split into four stages: the initial analysis of the invention and the establishment of a search table recording all the search concepts, the actual search approach (search strategy), the evaluation of the documents found and if necessary the adaptation of the search approach [42].

A structured search approach will help to ensure that the search proceeds in a logical manner and to keep track of the coverage of the search and its completeness in terms of the previously established search elements such as key words, classes and databases. The following search approaches can be distinguished [43]:

a) a brief search/high precision search : searching for terms contained in the claim and text using relevant words.
b) a classification based search
c) studying a complete classification unit
d) keyword search: specific or unusual terms being applicable for the inventive concept
e) combination of classification based search and keyword search
f) citation hunting

None of these search approaches alone will find all the relevant documents. Each search approach is likely to find something the others missed and, consequently, a combination of approaches is needed in order to perform a thorough search.

It is clear that apart from the type of searches a searcher might conduct, a good knowledge of the technical field as well as the tools for carrying out the search are extremely important to achieve the best results, since understanding the invention (even though the wording of the claims might be not as precise as what is required to define the invention) is as important as considering the possibilities which are the most suitable for conducting an effective search [44].

## 4. Claims in the field of biomaterials

### 4.1. Some cases

In the following section, the different steps required during the search process as discussed above and some examples of claims found in patents will be illustrated.

Types of claim wording that can often be seen in European patent applications in the field of biomaterials are the following:

**Example 1**. "A catheter balloon manufactured by blow moulding a polymer whose 100% modulus is 5–18 MPa, wherein the balloon has a film thickness of 30–80 μ and a 50% modulus in the longitudinal direction of 30–140 MPa", or

**Example 2**. "A polymeric stent manufactured from a polymer having a glass transition temperature ($T_g$) and a melting temperature ($T$), wherein the polymer has a temperature of about $T_g + 0.2 (T_m - T_g)$ when the polymer is being radially expanded so as to both increase radial stiffness and enhance fracture toughness.", or

**Example 3**. "A composition for use in forming a polymeric stent for insertion into a vessel comprising between 10 and 98% of a first monomer composed of an aliphatic ester C1–C50 of acrylic acid which when homopolymerized has a glass transition temperature lower than about 25 °C; and a second monomer having sites of unsaturation and capable of copolymerization with the first monomer, the second monomer when homopolymerized having a glass transition temperature greater than 25 °C, said monomers when polymerized in the presence of a crosslinker form a polymer having a glass transition temperature of less than about 25 °C″.

Interpretation by the skilled reader provides a clearer idea of what is in fact meant by said claims. But what about the chemical and/or physical properties of the claimed subject-matter mentioned under cases 1–3? Is it acceptable to ignore them? Are they to be taken into account as limiting technical features and how is it possible to distinguish the product they are referring to from that of the prior art?

It is a common practise in industry as well as the academic world, that product development is not more focused in the development of new polymers defined by new monomer units, but much more by the development of new properties of well known polymers. This is done by combining different polymers, i.e. blends of polymers or by introducing dispersed phases of non-polymeric nature in order to improve the mechanical properties of polymers and polymeric systems. In fact, instead of developing a completely new polymer based on new monomers, the mixing of different existing polymers provides a flexible and cost-efficient route to obtain new materials. This is achieved by optimizing the mixing and compounding equipments in order to influence their properties and characteristics. Alternative tools are also developed in mixing and compounding polymers such as controlled phase separation, temperature, diffusion or chemically induced phase separation, flow control of the mixtures [45]. Since the prediction of the mechanical properties of the resulting polymers proves to be complicated to assess, most of the development done on polymer chemistry is in fact based on trial and error.

Therefore, it is important to keep in mind that many polymers are defined by their physical and/or chemical properties and therefore, said technical features cannot be ignored. The question when it comes to novelty of said claims is more whether said physical and/or chemical properties are intrinsic properties of the polymer or whether they are obtained through a specific process or method leading in fact to a polymer with new properties.

In brief and of course, subject to a case by case application, should a prior art document to the same polymers exist, it will be considered by the searcher at the European Patent Office that the physical and/or chemical characteristics claimed are intrinsic properties of said polymer and therefore, a lack of novelty will be raised. It will be left to the applicant to provide arguments in order to overcome said objections.

The technical analysis as presented above is important in order to do a proper analysis of an application related to polymers in view of novelty and inventive step. On top of possible clarity objections under Article 84 EPC, an applicant may face a serious objection of a lack of disclosure under Article 83 EPC. For the search phase this can even result in an incomplete search report under Rule 63 EPC [46–48].

### 4.2. Possible search strategy based on an example in the field of biopolymers

“A catheter balloon manufactured by blow moulding a polyether polyurethane whose 100% modulus (elasticity) is 5–18 MPa, wherein the balloon has a film thickness of 30–80 μ and a 50% modulus in the longitudinal direction of 30–140 MPa.”

It is difficult to give specific guidance as to what one should search in such a case, because no hard and fast rule can be laid down, but we aim here to give a few pointers.

#### 4.2.1. Claims and invention analysis

A first approach consists in identifying the different concepts and the keywords that describe each concept. In the above example, the concept of the invention covers the technical field of catheter balloons made of a polymer. While the catheter balloon is characterised by its film thickness and its 50% modulus in the longitudinal direction, the polymer is only defined by a specific 100% modulus range.

This information can be summarised as follow:

Technical field: catheter balloon
Technical feature EF1: polyether polyurethane
Technical feature EF2: 100% modulus of 5–18 MPa
Technical feature EF3: film thickness
Technical feature EF4: 50% modulus in the longitudinal direction

An important aspect to the analysis of the claim, especially in situations where several parameters or physical properties are involved, is to understand the link between such parameters, how they influence each other and which are the ones which actually solve the problem of the invention.

In this particular situation the invention mentions that properties of the polyether polyurethane in terms of 100% modulus and the 50% modulus in the longitudinal direction related to the balloon both contribute to the ability of the balloon to follow along bended blood vessels.

Moreover, the analysis of the description of the invention indicates that blow moulding is one of the methods traditionally used for the manufacture of catheter balloons. The invention stresses that the essential feature related to the balloon is its film thickness of 30–80 mm. Since the invention does not make the link that a blow moulding process will automatically lead to a film having the desired thickness mentioned above, the feature related to the process (“blow moulding”) will not be searched on a first approach and emphasis will be put on the thickness of the film. The process feature “blow moulding” does not need to be searched since it appears from the description to be inherent in the general definition of the polyether polyurethane described in the claim.

The application reveals that the requirements of the polyether polyurethane in terms of 100% modulus range (5–18 MPa) have a direct impact on the 50% modulus in the longitudinal direction of the balloon. Therefore, in view of the application, most likely, a balloon made of polyether polyurethane having a 100% modulus of 5–18 MPa will be characterised by a 50% modulus in the longitudinal direction of 30–140 MPa.

The last important feature of the invention concerns the polyether polyurethane and its specific 100% modulus range of 5–18 MPa. The invention mentions, among others, one possible approach for preparing polyether polyurethane having such properties and refers also to a trade name.

#### 4.2.2. Search concepts

This combined analysis of the claim in terms of technical features and its subjects will help the searcher to determine the search concepts and identify the features, keywords and classes that will be used during the search (search strategy).

Each search concept represents a distinct aspect of the invention and each search concept corresponds to one or more essential features of the invention. In the present case, the search concepts can be identified as follows:

Search concept 1: catheter balloon
Search concept 2: polyether polyurethane
Search concept 3: 100% modulus
Search concept 4: film thickness

Once the search concepts have been identified, keywords and classes have to be found for each search concept. The search concept should be described as completely as possible using keywords and synonyms. (Note: synonyms can be found on the internet but also some tools available for the EPO searcher EPOQUE, database EUREG for retrieving synonyms and for the translation of terms).

#### 4.2.3. Search tools and search table

The establishment of a search table [26] is often used to collect, organise and display those search concepts. The main advantage of such a table allows getting a global overview of the main elements involved in the search.

Each concept is allotted with classes, keywords and synonyms. In our specific case, the search table may be filled in as in Table 1:

Each column relates to a search concept of the invention. The table is completed with classes, keywords and synonyms relevant to the individual search concepts.

If necessary, the search can be extended beyond the EPOQUE patent databases to other databases such as internet [49–51], non-patent literature or the Registry file of Chemical Abstract database. In our specific example, the CAS RN for polyethylene polyurethane may offer an additional element when searching in the CA database.

#### 4.2.4. The search strategy

The search approach is defined by a combination of fields from the search table. The various possible search approaches have been detailed in section 3.5 of this paper. Each of these search approaches has their strengths and limitations and each search approach is likely to find something the others missed. Consequently, one of the tasks of the searcher is to combine the various approaches and to prioritise them with respect to estimated probability of retrieving relevant prior art.

The above search table offers a number of options, among which the following search approaches can be considered:

- A brief search: combining classes A61L29/04 and C08L75/02
- Combination classification/keyword search: selecting class A61L29/04 and looking in fulltext for the search elements relative to polyether polyurethane, film thickness and/or 100% modulus

**Table 1**
An example of a search table created during establishing a search strategy.

| Search concept | Catheter balloon | Polyether polyurethane | 100% modulus | Film thickness |
|---|---|---|---|---|
| Classification units | A61L29/04<br>A61L29/04 + C08l75/02<br>But also:<br>A61M25/10<br>A61M25/10G | C08L75/02 | | |
| Key words | Catheter balloon | Polyether polyurethane | 100% modulus | Film thickness |
| Synonym | Balloon inflating device | PUR, PU | 100% mod. | |
| Acronyms | | PEU | | |
| Abbreviation | | Polyether-based urethane polymer | | |
| Trade name | | Polyether PU | | |

- Keyword search: combining keywords relative to polyether polyurethane and catheter balloon and retrieve in fulltext thickness and/or 100% modulus

A search strategy typically includes the sequence of choosing a set of search elements, running a suitable search statement and analysing the answer set [25]. Based on the results, the search approach may be broadened just by removing one search concept from the search approach or may be narrowed by combining more search concepts.

Another reason to modify and reformulate the search strategy could be that no novelty destroying document has been found. When such a situation arises, the search should then be focused on the features not present in the prior art found in order to provide the basis for an inventive step argumentation [26].

Turning to the example cited above, a search approach based on a combination of classification and keywords allowed the retrieval of, among others, a document related to a catheter balloon having a film thickness in the range of 30–80 nm and made of polyether polyurethane having a 100% modulus within the range of 5–18 MPa.

That document differs from the claim of the invention in that the process involved for preparing the catheter balloon (i.e. blow moulding) is not specified. The feature related to the physical property of the catheter balloon is also absent from that document.

Having these differences in mind, the next step could consists in orienting the search strategy towards polyether polyurethane films in general (i.e. without limitation to any particular medical application) with the aim of retrieving a document establishing a link between the process of preparing the polyether polyurethane film having a specific thickness by blow moulding and the physical properties of that film in terms of 50% modulus in the longitudinal direction.

## 5. Conclusions

Scientists and engineers still have numerous challenges to overcome in the field of polymers related to biomaterials, challenges linked in part to the constant integration and interaction of the materials with the living tissues. Challenges also have to be overcome for the searchers in view of the constant changes in the drafting of patent applications involving steadily more physical or chemical parameters in the definition of their inventions. A reliable search result providing a strong legal certainty in examination will be only ensured if the search tools themselves are developed in order to tackle these changes and make parameters for instance more searchable.

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