

Using Patents to Identify Emerging Trends in Biomedical Engineering

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Abstract

Patents are a rich source of information for educating students on emerging fields in biomedical engineering. Since 80% of the information in patents is not published elsewhere, faculty should seriously consider including patent instruction in their courses. Patents may be the first and only place that innovations are detailed. Protecting patent rights may preclude presenting and publishing cutting edge information in journal articles and conference papers. This paper covers U.S. issued patents and published applications as well as world patents and applications. Free databases available on the World Wide Web will be emphasized. Classification systems that are discussed include United States, International, and European. Known inventors and assignees are also discussed. Search examples are shown.

Introduction

Students regularly review journal articles and conference papers in undergraduate education programs for state-of-the-art information. Patents are required to include information that is “new, novel, and non-obvious.” This cutting edge information is usually not published in journal articles and conference papers. Since 80% of the information in patents¹ is not published elsewhere, faculty should seriously consider including patent instruction in their courses. Literature reviews of many topics may be incomplete without using patents. U.S. and world patents are relevant.

The definition for a patent is based on a country’s laws or regulations. The definition provided by the United States Patent and Trademark Office states:

A patent is a property right granted by the Government of the United States of America to an inventor “to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States” for a limited time in exchange for public disclosure of the invention when the patent is granted.²

An application is filed in the name of the actual inventor. An inventor’s employment contract usually requires that the rights be assigned to the employer. The employer is called the assignee. Many patents are also filed by independent inventors. An inventor is strongly encouraged to seek legal counsel and have a registered patent attorney or agent file the application.

Staff members at the United States Patent and Trademark Office are responsible for the examination and issue of patents. Faculty members are encouraged to consult the detailed information provided by the USPTO for preparing lectures on patents. There are many print and online publications on the Office web site, including frequently asked questions.³ Two FAQs that are especially helpful include questions on “patents” and those provided by the “General Information Services Division.” New patent users are encouraged to review special pages for Independent Inventors⁴ and First Time Visitors.

Michael Lechter,⁵ a patent attorney, has joined with many colleagues to provide an excellent survey of patents for engineers and scientists. This book includes in depth information that engineers find very helpful for understanding the patenting process. Changes in U.S. patent law in 1995 and 1999 are not reflected in the book.

U.S. utility and design patents issued after June 8, 1995 are effective for 20 years from date of application. Before June 8, 1995, utility and plant patents are effective for 17 years from date of issue. Maintenance fees are paid on utility patents at 3 ½ years, 7 years, and 13 ½ years. Design patents are effective for 14 years from date of issue. Rights normally end when the term ends. This allows the invention to go into the public domain. In the United States, inventors or their assignees may apply for extensions in some cases, for example, pharmaceuticals that have taken long periods of time for approval by the Food and Drug Administration.

Since 2001, U.S. patent applications have been published 18 months after filing date. This is especially true for applications that are filed outside the United States. Inventors who file only in the U.S. may choose not to have their applications published. Most inventors are permitting their applications to be published.

World Patents

The global intellectual property atmosphere greatly influences the scientific and engineering community. As a result, students should be familiar with world patents. One’s patent rights are protected in a country when an inventor files an application, meets the requirements of that country, and is issued a patent. To protect rights outside the United States, one must complete the requirements of that country. A Patent Cooperation Treaty (PCT) application may be filed at the USPTO for patent rights in many countries. The final requirements must also be met in each country. Most patents issued outside the United States are valid for 20 years from application. Most countries publish applications 18 months after filing.

The World Intellectual Property Organization and the European Patent Office are key players in the world patent scene. WIPO is an organization of 179 member countries. Its primary mission is the protection of intellectual property, i.e. patents, trademarks, and copyrights. One sees some of the work of WIPO in a patent document. The standards used for Country Codes, Kind Codes, and INID [International agreed Number for the Identification of (bibliographic) Data] codes make it easier to identify specific information and parts of patent documents. WIPO staff members are responsible for the preliminary search of the PCT application. Patent records from many countries are a part of the European Patent Organization’s esp@cenet database. Patents that share a common priority application number are linked together in one record.

Publishing Considerations Related to Patents

Faculty and students who are writing journal articles, conference papers, and theses should understand how these publications may limit the ability to obtain a patent. Differences among countries should be expected. United States law is based on first-to-invent while other countries are based on first-to-file. The importance of documenting one's work in a laboratory notebook is highly recommended.

In the United States, a patent must be filed within a year of publication:

In order for an invention to be patentable it must be new as defined in the patent law, which provides that an invention cannot be patented if: "(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent," or "(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country more than one year prior to the application for patent in the United States . . ."⁶

If one wants to file a patent outside the United States, many sources recommend that no publication or presentation should be done before filing. Faculty members are encouraged to consult the university intellectual property office or patent attorney before publication or presentation. In 1995, the U.S. introduced the new provisional patent application. This may help with the publication quandary but it is not a cure-all. A non-provisional application must be filed within a year.

Patents and the Curriculum

The best place to find the emerging trends is the newly published applications or issued patents. An actual search of the patent databases is recommended. Two freely available web sites are U.S. Patent Office web site for Patent Full-Text and Full-Page Image Databases:⁷ Issued Patents and Patent Applications. The European Patent Office offers its excellent esp@cenet⁸ database.

Design projects may be an appropriate place to introduce patents. Faculty members in the School of Mechanical Engineering at Purdue University have included a basic introduction to patents and their subject classification in sophomore level design classes for many years. This introduction is done by a skilled librarian who has extensive experience with the topic. Students in Biomedical Engineering may also gain additional knowledge for their design projects.

Assignments Involving Library Materials

Short assignments involving patents may start with newspaper articles, directories, journal articles, and conference papers. Newspaper articles and selected publications may discuss specific new medical devices. Rob Stein⁹ has written a recent newspaper article titled; "Patients Find Technology Easy to Swallow" in the *Washington Post* described a new device. He describes the technology as a "M2A disposable diagnostic capsule. Also called the "gut cam," the device is the first of its kind -- a self-contained, miniature, disposable color video system designed to travel painlessly through the digestive system."

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Journal articles and conference papers on patents are not numerous. A survey of several bibliographic databases makes one quickly realize that journal articles and conference papers do not frequently cover patents. Table 1 shows the results of this search:

Table 1: (biomedical or medicine or medical) and patent*

Database (Coverage)	Results
<i>INSPEC</i> (1970-date)	193 records
<i>COMPENDEX</i> (1983-date)	125 records
<i>Current Contents</i> (recent year)	100 records

Medline (1966-date) shows 2778 articles were Patents is a subject term. *Chemical Abstracts* is an excellent for world-wide coverage of chemical patents but may not be that useful for biomedical patents.

Given these very mediocre results, the author advises instructors to introduce free patent databases provided by the United States Patent and Trademark Office and the European Patent Office.

Directories may be helpful. For example the *Medical Device Register*¹⁰ contains a product directory and supplier profiles. This directory can be helpful for identifying assignees and products but should not be viewed as a comprehensive directory.

Other opportunities may exist to review medical devices in Food and Drug Administration databases of premarket approvals¹¹ and premarket notifications (501K).¹² The information contained in *Recently Approved Devices*¹³ links to the *New Device Approval*. This explains how the product works, when it should be used and not used. After reviewing the related FDA databases and publications, a student should have leads to the inventors, assignees, and product information. Since the patent number is typically not listed in device databases, it is necessary to use inventors, assignees, and product keywords to retrieve patents from patent databases. Drugs listed in the FDA's Electronic Orange Book¹⁴ often contain the patent numbers.

Free Databases or World Wide Web

Three major free databases are available on the web from the U.S. Patent and Trademark Office and the European Patent Organization. These databases allow limited keyword searching as well as inventor and assignee information. Classification systems are also very good for describing the content of the claims. If one searching for keywords results are incomplete.

United States Patent Grants and Published Applications are available on the Web site of the USPTO. Full-text images of most U.S. publications are available as TIFF images and are printed one page at a time. The web databases contain full-text searching for patents (1976-date) and applications (2001-date). Table 2 shows the opening USPTO search patent screen:

Table 2

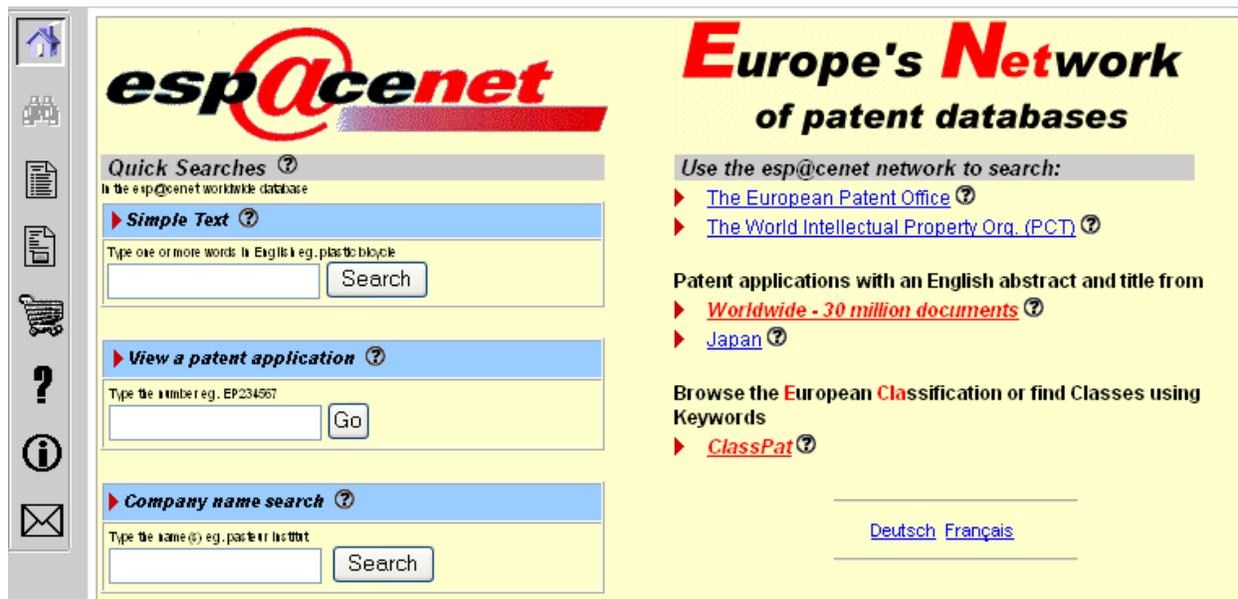
Patent Full-Text and Full-Page Image Databases

Issued Patents (full-text since 1976, full-page images since 1790)	Patent Applications (published since 15 March 2001)
<ul style="list-style-type: none"> ● Quick Search ● Advanced Search ● Patent Number Search ● NEW Access Full-Page Images Directly! ● Database Notices and Status ● Database Contents ● Help 	<ul style="list-style-type: none"> ● Quick Search ● Advanced Search ● Publication Number Search ● Help

Patent and Trademark Depository Libraries¹⁵ have access to patents and applications on DVD. A complete patent may be printed very quickly and easily at a PTDL. Libraries also have search software on DVD. Some of which is not available on the web.

The European Patent Office hosts the esp@cenet site that contains patents from many countries. The years covered by each country varies. Keywords from the title and abstracts are available for some records. esp@cenet includes issued patents and published applications. From the opening screen of esp@cenet,¹⁶ choose *Worldwide - 30 million documents*. Table 3 shows the opening screen:

Table 3



A typical searcher tends to use keyword searching as the only technique for identifying patents. Keywords often limit retrieval and miss relevant patents. Searching by classification enhances retrieval and locates many relevant patents.

Classification Systems

Classification systems are an integral part of patent retrieval. Concepts are often detailed in the classification system. The United States Patent and Trademark Office developed its own U.S. Patent Classification System while the World Patent Organization is responsible for the International Patent Classification. The European Patent Organization has modified the IPC for its use in the European Classification System.

A series of numbers or letters and numbers are used to identify classification systems used with patents. These classification systems typically delineate the content of a patent based on its claims. Table 4 shows examples of patent classifications for endoscopes:

Table 4. Classification Examples

System	Terminology	Example
U.S. Patent Class	Class/Subclass	600/101
International Class	Section Class Subclass Group Subgroup	A61B1/005
European Class	Section Class Subclass Group Subgroup	A61B1/005D

1. **U.S. Patent Classification** has search tools that are helpful for determining the classification. Among these are the *Index to the Patent Classification System*, *Manual of Classification*, and *Classification Definitions*. These are available in print and on the web. The web version links the *Index*, *Manual of Classification*, and *Definitions*. For endoscopes, the *Index* shows the following:

```

Endoscope
Diagnostic specula ..... 600 / 101+
Surgical cutter ..... 606 / 45
  
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The *Manual of Classification* uses a hierarchical system and shows great detail. It is divided into Classes and Subclasses. Class 600 is subdivided by Main Lines in capital letters. These are further outlined by dots. One dot is subdivided by two dots, etc. Table 5 shows a portion of Class 600:

Table 5: Class 600 Surgery (partial)

This Class 600 is considered to be an integral part of Class 128 (see the Class 128 schedule for the position of this Class in schedule hierarchy). This Class retains all pertinent definitions and class lines of Class 128.

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101      ENDOSCOPE
102      . With chair, table, holder, or other support
103      . With monitoring of components or view field
104      . With tool carried on endoscope or auxillary channel therefore
105      .. Urogenital resectoscope
106      .. Having tool moving or stopping means
107      ... Having tool raising platform
108      .. Laser
  
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101 ENDOSCOPE
 109 . With camera or solid state imager
 110 .. Having signal wires
 111 .. Stereoscopic
 112 .. Means for coupling camera or imager
 113 . With additional scope
 114 . With guide means for body insertion
 115 .. Inflatable cuff or balloon
 116 . With inflatable balloon
 117 . With means for indicating position, depth or condition of
 endoscope
 118 . With control or monitoring of endoscope functions
 119 . With shield to protect operator (e.g., splatter protection)
 120 . Having endotracheal intubation means on endoscope
 121 . With protective sheath
 122 .. For camera or handle
 123 .. For auxiliary channel
 124 .. With means to assist covering or uncovering of sheath
 125 .. With locking or retaining means for sheath
 126 . With foot pedal control for endoscope operation
 127 . With non-optical distal tip attachment
 128 . With particular shaft cross-section
 129 . With particular distal tip configuration
 130 . With particular arrangement of internal elements (e.g.,
 shaft reducing)
 131 . With particular operating handle design (e.g., for comfort)
 132 . Universal cord connector device for endoscope functions
 133 . Sterilizable
 134 . Having means to protect user, patient, or endoscope from
 electrical discharge
 135 . Urological
 136 . Having separable shaft
 137 . Having rotatable shaft
 138 . Having rigid tube structure
 139 . Having flexible tube structure
 140 .. Plural layers
 141 .. Articulated segments
 142 ... Pivotaly connected
 143 .. Having shape memory retaining material component
 144 .. With adjustable rigidity
 145 .. With bend detecting means (e.g., endoscope tracking)
 146 .. With bending control means
 147 ... With removable control knob
 148 ... With braking means
 149 ... With wire tension control (e.g., slack absorbing)
 150 ... With deflection recovery
 151 ... Having temperature sensitive shape memory retaining material
 152 ... Fluid or electrical control means
 153 . Having auxiliary channel
 154 .. Channel seal (e.g., forceps stopcock)
 155 .. With interior cleaning means
 156 .. Fluid channel (e.g., suction, irrigation, aspiration)
 157 ... With window cleaning means
 158 ... With air or water supply means
 159 ... With valve construction or valve control means
 160 . Having imaging and illumination means
 161 .. Strain relief means on optical element
 162 .. Ocular (e.g., eyepiece)
 163 ... With focusing
 164 ... Angled or offset on endoscope shaft
 165 ... Plural
 166 .. Stereoscopic
 167 .. Focusing
 168 .. Magnifying
 169 .. Fog prevention

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101         ENDOSCOPE
170         .. Side viewing distal end
171         .. Oblique viewing distal end
172         .. Interchangeable optical system
173         .. View field altering means
174         .. Articulated optical coupler
175         .. Distal optical attachment
176         .. Having particular distal lens or window
177         ... For improved illumination
178         .. Light source
179         ... Lamp in shaft
180         ... With light intensity control
181         .. With filter, masking, diaphragm, or aperture plate
182         .. Light transmitting fibers or arrangements
183         . Tissue division viewing (e.g., carpal tunnel, plantar
           fasciotomy)

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Definitions are available for classes and subclasses. The definition also gives cross-references to other classes and subclasses.

2. **International Patent Classification**¹⁷ is commonly used in many countries around the world. WIPO outlines the history of the IPC and describes its 7th edition. It consists of eight sections, 120 classes, 628 subclasses and approximately 69,000 groups. Although it is used extensively throughout the world, editions have changed over time and this affects the classification and retrieval of patents in countries that have adopted the IPC. One IPC classification is assigned to each U.S. patent. In other countries, several classifications are assigned. The Catchword Index to the IPC is a starting place to identify the IPC. Here is the classification for:

ENDOSCOPES

[A61B 1/00](#)
[A61B 10/00](#)
[A61B 17/32](#)

Catchword then hotlinks to one of the classifications, e.g. A61B 1/00

The classification is hierarchical and includes a series of letters and numbers:¹⁸

Section:	A
Section Title:	Human Necessities
Class	61
Subclass:	B
Group:	1/00 Main Group

Table 6 shows the background on Section/Class A61:

Table 6

A 61 MEDICAL OR VETERINARY SCIENCE; HYGIENE

A 61 B DIAGNOSIS; SURGERY; IDENTIFICATION (analysing biological material [G01N](#), e.g. [G01N 33/48](#); obtaining records using waves other than optical waves, in general [G03B 42/00](#))

Note

This subclass covers instruments, implements, and processes for diagnostic, surgical and person-identification purposes, including obstetrics, instruments for cutting corns, vaccination instruments, finger-printing, psycho-physical tests.

Subclass Index

MEDICINAL METHODS (NON-SURGICAL)	A61B 1/00 , A61B 5/00 , A61B 17/00
INSTRUMENTS FOR PSYCHO-PHYSICAL TESTS	A61B 5/00
MEDICAL INSTRUMENTS	
For auscultation and diagnostics	A61B 5/00 to A61B 10/00
For medical examination of the interior of cavities or tubes of the body and the eyes	A61B 1/00 , A61B 3/00
Aids for examination and care of the mouth	A61B 1/00 , A61B 13/00
SURGICAL INSTRUMENTS, DEVICES OR METHODS	A61B 17/00 ; A61B 18/00
OTHER INSTRUMENTS, IMPLEMENTS OR ACCESSORIES FOR SURGERY OR DIAGNOSIS	A61B 19/00

This is a portion of the group for **Diagnosis; Psycho-physical tests** that shows the hierarchical systems of dots. A group with a single dot is a subgroup of 1/00. Those with two dots are a subgroup of those with one dot.

- 1/00 Instruments for performing medical examinations of the interior of cavities or tubes of the body by visual or photographic inspection, e.g. endoscopes** (examination of body cavities or body tracts using ultrasonic, sonic or infrasonic waves [A61B 8/12](#); instruments, e.g. endoscopes, for taking a cell sample [A61B 10/00](#); endoscopic cutting instruments [A61B 17/32](#); surgical instruments using a laser beam being directed along or through a flexible conduit [A61B 18/22](#)); **illuminating arrangements therefor** (for the eyes [A61B 3/00](#)) **[4]**
- 1/002 . having rod-lens arrangements ([A61B 1/055](#) takes precedence) **[6]**
- 1/005 . Flexible endoscopes **[6]**
- 1/008 . . Articulations **[6]**
- 1/01 . . Guiding arrangements therefor **[6]**
- 1/012 . characterised by internal passages or accessories therefor **[6]**
- 1/015 . . Control of fluid supply or evacuation **[6]**
- 1/018 . . for receiving instruments **[6]**
- 1/04 . combined with photographic or television appliances **[2]**
- 1/045 . . Control thereof **[6]**
- 1/05 . . characterised by the image sensor, e.g. camera, being in the distal end portion **[6]**
- 1/055 . . having rod-lens arrangements **[6]**
- 1/06 . with illuminating arrangements
- 1/07 . . using light-conductive means, e.g. optical fibres **[6]**

There are no definitions for the IPC. The author assumes that the number following the subgroup title, i.e. **[6]** identifies the IPC edition that setup the subgroup.

3. European Classification System¹⁹ is an extension of the International Classification System and is under “constant revision.” An index is available but is awkward to use. Some notes are also available.

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The European Classification for A61 B is shown below:

A	HUMAN NECESSITIES
A61	MEDICAL OR VETERINARY SCIENCE; HYGIENE
A61B	DIAGNOSIS; SURGERY; IDENTIFICATION (analysing biological material G01N , e.g. G01N33/48 ; obtaining records using waves other than optical waves, in general G03B42/00)

A further breakdown of A61B reveals that the system is more detailed than the IPC:

A61B1/00	as above
A61B1/00B	[N: with light conducting means, e.g. fibre optics (A61B1/04 to A61B1/06 take precedence; light guides per se G02B6/00)]
A61B1/00D	[N: comprising a channel for guiding instruments (control of instruments A61B1/018)] [C9807]
A61B1/00F	[N: Coupling devices (medical aspects of connections A61M39/00 ; coherent light guides formed by bundles of fibres G02B6/06 , G02B6/08 , G02B23/26 ; details of coupling devices H01R13/00)]
A61B1/00J	[N: with means for preventing contamination, e.g. by sanitary sheath]
A61B1/00N	[N: for percutaneous insertion into the body] [C9507]
A61B1/00R	[N: with stereoscopic vision] [N9507]
A61B1/00T	[N: with focusing features] [N9507]
A61B1/002	having rod-lens arrangements (A61B1/055 takes precedence) [N9711]
A61B1/005	Flexible endoscopes [N9711]
A61B1/005B	[N: with controlled bending of insertion part (tip steering of catheters A61M25/01C10 ; articulated or flexible manipulators B25J1/02)] [N9711] [C9902]
A61B1/005B2	[N: with illuminating arrangements] [N9711]
A61B1/005B2B	[N: combined with imaging means, e.g. video camera] [N9902]
A61B1/005B4	[N: Constructional details of control elements, e.g. handles (A61B1/005D takes precedence)] [N9711] [C9902]
A61B1/005B4B	[N: using distributed actuators, e.g. artificial muscles] [N9902]
A61B1/005B6	[N: Constructional details of insertion parts, e.g. vertebral elements] [N9902]
A61B1/005B6B	[N: the insertion parts being asymmetric, e.g. for unilateral bending mechanisms] [N9902]
A61B1/005D	[N: using shape-memory elements] [N9711]
A61B1/008	Articulations [N: (A61B1/005B6 takes precedence)] [N9711] [C9902]
A61B1/01	Guiding arrangements therefor [N9711]
A61B1/012	characterised by internal passages or accessories therefor [N9711]
A61B1/015	Control of fluid supply or evacuation [N9711]
A61B1/018	for receiving instruments [N9711]
A61B1/04	combined with photographic or television appliances [N: (camera adapters G03B17/48)]
A61B1/04B	[N: using light conducting means, e.g. fibre optics (light guides per se G02B6/00)]
A61B1/04D	[N: using television camera, e.g. CCD camera (A61B1/05 takes precedence)]
A61B1/04D4	[N: with illuminating arrangements providing two or more colours, e.g. by filtering]
A61B1/045	Control therefor [N9711]
A61B1/05	characterised by the image sensor, e.g. camera, being in the distal end portion [N: (A61B1/005B2B takes precedence)] [C9902]
A61B1/055	having rod-lens arrangements [N9711]
A61B1/06	with illuminating arrangements [N: not otherwise provided for in group A61B1/00] [C9711]
A61B1/07	using light-conductive means, e.g. optical fibres

Searching Techniques

One should search both the U.S. and esp@cenet Web sites. Often patents are filed in Europe before they are filed in the United States. The reader should check search help on each system. For example, a M2A capsule with a camera that is swallowed and used to identify problems in the digestive system. The technology uses an endoscope.

One of the inventors is: Iddan Gavriel. The assignee (applicant) is Given Imaging. Since other inventors may be involved, these may be added to the search. There may be a previous assignee.

These situations need to be considered when designing a search:

Inventor	Iddan Gavriel
Assignee	Given Imaging
IPC	A61B1/05
EC	A61B1/05
EC	A61B1/005B2B
US Class	600/109
Title	“in vivo” and camera\$

U.S. Classification is used on the USPTO Web site. The search system is very flexible for newer patents but uses only classification and patent number before 1976. IPC and EC are both used in esp@cenet. One can not search both classification systems at the same time. Sample searches from both systems will be shown in the conference presentation.

Conclusion

Patents are an important source of information for biomedical engineers. Knowledge of intellectual property is necessary to for the development of new medical devices. This paper has introduced faculty and students to the system of United States and world patents. The examples shown give readers basic information about databases, classification systems, and searching techniques. The information provided is a starting point for inclusion of patents in the biomedical curriculum.

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¹ “Patents as a Technological Resource.” In *Technological Assessment and Forecast: eight report*, 25-37. Washington, D.C. U.S. Patent and Trademark Office, Dept. of Commerce, 1977.

² United States Patent and Trademark Office. *What is a patent?* Arlington, Virginia: USPTO. 12/3/2002. 13 January 2003. <<http://www.uspto.gov/web/offices/com/iip/data.htm#Patent>>

³ United States Patent and Trademark Office. *Additional FAQs on the USPTO Website*. 8/2/2002. 13 January 2003. <<http://www.uspto.gov/web/patents/faqs.htm>>

⁴ United States Patent and Trademark Office. *Independent Inventors Resources*. 12/3/2002. 13 January 2003. <<http://www.uspto.gov/web/offices/com/iip/>>

⁵ Lechter, Michael, et al. *Successful Patents and Patenting for Engineers and Scientists*. New York, IEEE Press, 1995.

⁶ United States Patent and Trademark Office. *Novelty And Non-Obviousness, Conditions For Obtaining A Patent*. 4/4/02. 13 January 2003. <<http://www.uspto.gov/web/offices/pac/doc/general/index.html#novelty>>

⁷ United States Patent and Trademark Office. *Patent Full-Text and Pull-Page Image Databases: Issued Patents and Patent Applications*. 11/19/02. 15 January 2003. <<http://www.uspto.gov/patft/index.html>>

⁸ European Patent Office. esp@cenet. 15 January 2002. <<http://ep.espacenet.com>>

⁹ Stein, Rob. "Patient Finds Technology Easy to Swallow." *Washington Post*. December 30, 2002. Page A01. 25 March 2003. <<http://www.washingtonpost.com/ac2/wp-dyn?pagename=article&node=&contentId=A52179-2002Dec29¬Found=true>>

¹⁰ *Medical Device Register® : The Official Directory of Medical Suppliers*. 2 volumes. Los Angeles: A Canon Communicatons LLC Publication, 2002.

¹¹ U.S. Food and Drug Administration. Center for Devices and Radiological Health. *PMA Database*. Updated 1/6/03. Accessed 1/13/03. <<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>>

¹² U.S. Food and Drug Administration. Center for Devices and Radiological Health. *501K Database*. Updated 1/6/03. Accessed 1/13/03. <<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>>

¹³ U.S. Food and Drug Administration. Center for Devices and Radiological Health. *CDRH Consumer Information: Recently Approved Devices*. Updated 1/6/03. Accessed 1/13/03. <<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/MDA/mda-list.cfm?list=3>>

¹⁴ Center for Drug Evaluation and Research. U.S. Food and Drug Administration. *Electronic Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*. 11/27/02. 13 January 2003. <<http://www.fda.gov/cder/ob/default.htm>>

¹⁵ United States Patent and Trademark Office. *Patent and Trademark Depository Library Program: Complete PTDL List*. 10/15/02. 14 January 2003. <http://www.uspto.gov/web/offices/ac/ido/ptdl/ptdlib_1.html>

¹⁶ European Patent Office. *Search in patents throughout the world*. 15 January 2003. <ep.espacenet.com>

¹⁷ WIPO. *Introduction to the IPC on the Internet*. 14 January 2002. <<http://www.wipo.int/classifications/en/>>

¹⁸ Ibid. *Guide to IPC*.

¹⁹ European Patent Organization. <http://12.espacenet.com/espacenet/ecla/index/index.htm>