How to conduct patent searches for medicines

A step-by-step guide
How to conduct patent searches for medicines

A step-by-step guide


I. World Health Organization, Regional Office for South-East Asia.

II. World Health Organization, Regional Office for the Western Pacific.

# Contents

**Acknowledgements** .................................................................................................................. v

**List of abbreviations and acronyms** ......................................................................................... vi

1. **Introduction** .......................................................................................................................... 1
   1.1 Format of the guide ............................................................................................................... 3

2. **The patent system and patent information** ......................................................................... 5
   2.1 Multilateral treaties on patents ........................................................................................ 5
       2.1.1 The TRIPS Agreement ............................................................................................. 5
       2.1.2 The Paris Convention and priority period ................................................................. 6
       2.1.3 The Patent Cooperation Treaty .................................................................................. 6
   2.2 Types of patent filing and protection .................................................................................. 7
       2.2.1 National patent filings ............................................................................................. 7
       2.2.2 Regional patent filings ............................................................................................. 7
       2.2.3 International patent applications .............................................................................. 7
   2.3 Patent information .............................................................................................................. 8
       2.3.1 Understanding information in a patent specification ............................................. 9
   2.4 Where to obtain patent information ................................................................................ 21
   2.5 How patent information is arranged ................................................................................ 22

3. **Types of patents on medicines** ............................................................................................ 25

4. **How to find patents on medicines** ..................................................................................... 27
   4.1 Sources linking medicines and patent information ....................................................... 28
       4.1.2 Introduction of the US FDA Orange Book .............................................................. 29
       4.1.3 Introduction of the Health Canada Patent Register ............................................. 30
   4.2 How to find patents listed in the Orange Book and Health Canada Patent Register .......... 32
       4.2.1 Using the Orange Book .......................................................................................... 32
       4.2.2 Using the Health Canada Patent Register .............................................................. 36
4.3 Obtaining copies of patent documents listed in the Orange Book and Health Canada Patent Register

4.3.1 Using esp@cenet to obtain US and Canadian patent documents

4.4 Limitations of relying on the Orange Book and Health Canada Patent Register to identify patents

4.5. Search techniques for expanding on Orange Book and Health Canada patent listings

4.5.1 Keyword searching

4.5.2 Searching by applicant/assignee and inventor name(s)

4.5.3 Searching by patent classification

4.5.4 Citation searching

4.5.5 Searching by date ranges

5. How to find patents in developing countries

5.1 Using online patent databases

5.2 Using official patent office journals

5.3 Obtaining patent information from national/regional patent offices using priority data

5.4 Obtaining patent specifications from national/regional patent offices

5.5. Ensuring patent information is up to date

6. Evaluating patent information for public health needs

Appendices

I Paris Convention for the Protection of Industrial Property

II PCT Contracting States

III Patent Office Databases and Electronic Journals/Gazettes
Acknowledgements

This guide has been written by Tahir Amin for the WHO Regional Office for South-East Asia and the WHO Regional Office for the Western Pacific. It was field tested by Ujjwal Kumar, and technically reviewed and edited by Karin Timmermans.

It has benefited from comments and suggestions by Dr Suchart Chongprasert, Food and Drug Administration, Thailand; Dr Carlos M. Correa, University of Buenos Aires, Argentina; Prof. Peter Drahos, Australia National University, Australia; Dr Aaron Kesselheim, Harvard Medical School, United States; Dr Jakkrit Kuanpoth, University of Wollongong, Australia; Ms Leena Menghaney, Médecins Sans Frontières, India; and Ms Priti Radhakrishnan, Co-Director, Initiative for Medicines, Access & Knowledge, United States.

Screen captures of patent data made available to the public through the Internet have been accessed from:

- Health Canada (http://www.patentregister.ca/);
- Indian Patent Office (http://ipindia.nic.in/ipirs/patentsearch.htm);
- Philippines Patent Office (http://patents.ipophil.gov.ph/PatSearch/);
- United States Food and Drug Administration (http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm);
- European Patent Office (http://ep.espacenet.com/); and

These screen captures are current as of 13 May 2010. Patent websites are subject to change and redesign, and may depart from the form represented here.
### List of abbreviations and acronyms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARV</td>
<td>antiretroviral</td>
</tr>
<tr>
<td>EPO</td>
<td>European Patent Office</td>
</tr>
<tr>
<td>INN</td>
<td>international non-proprietary name</td>
</tr>
<tr>
<td>INPADOC</td>
<td>international patent documentation centre collection</td>
</tr>
<tr>
<td>IPC</td>
<td>International Patent Classification</td>
</tr>
<tr>
<td>LDCs</td>
<td>least developed countries</td>
</tr>
<tr>
<td>NDA</td>
<td>new drug application</td>
</tr>
<tr>
<td>NDS</td>
<td>new drug submission</td>
</tr>
<tr>
<td>PCT</td>
<td>Patent Cooperation Treaty</td>
</tr>
<tr>
<td>SNDS</td>
<td>supplement to a new drug submission</td>
</tr>
<tr>
<td>TRIPS</td>
<td>Agreement on Trade-Related Aspects of Intellectual Property</td>
</tr>
<tr>
<td>US FDA</td>
<td>United States Food and Drug Administration</td>
</tr>
<tr>
<td>USPTO</td>
<td>United States Patent and Trademark Office</td>
</tr>
<tr>
<td>WIPO</td>
<td>World Intellectual Property Organization</td>
</tr>
<tr>
<td>WTO</td>
<td>World Trade Organization</td>
</tr>
</tbody>
</table>
The globalization of intellectual property protection on medical products changes how developing country health authorities and procurement bodies make their decisions with respect to purchasing medicines. Whereas previously the decision to procure more cost-effective generic versions of medicines may not have required the consideration of intellectual property protection, that is no longer the case.

Under the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), Member States of the World Trade Organization (WTO) with developing country status were required to start examining patent applications and providing patent protection on medicines either by 1 January 2000 or by 1 January 2005. Many developing countries implemented patent protection on medicines much earlier than the required deadline. Today, patents on medicines are being granted in developing countries, and medicines under patent are entering the market.

This change in the patent laws of developing countries now requires local health authorities and procurement bodies to establish in advance of purchasing decisions whether patent(s) on a particular medicine have been filed, granted, lapsed or expired. Having such information in hand can help to decide whether more cost-effective medicines can be procured from alternative sources without the risk of patent infringement.

1 A number of developing countries also introduced data exclusivity into their regulatory systems. This means that data submitted by a pharmaceutical company to national regulatory authorities for obtaining marketing approval of a medicine could not be used to approve generic versions of the same drug for at least a period of five years. This guide does not address how to determine whether data exclusivity impacts the procurement of generic medicines. In order to determine whether data exclusivity applies, the reader should refer to national legislation and the relevant national regulatory authority.

2 Least developed countries (LDCs) are not required to implement patents for pharmaceuticals until 2016. However, some LDCs may have already implemented TRIPS standards for pharmaceuticals within their patent laws.
Equally significant, access to patent information can also help ensure that countries engage with patent owners at a much earlier stage to explore possibilities for making medicines that are or could come under patent protection more affordable. Moreover, such information can help countries decide whether they should exercise the flexibilities available under TRIPS and the Doha Declaration (i.e. compulsory licensing and government use) to procure or produce local lower-priced generic versions.

In practice, obtaining relevant and accurate patent information on medicines, particularly in developing countries, is not without difficulties. This is due to a number of reasons:

- the technical language of patent specifications;
- the lack of reference to international non-proprietary names (INNs) or the commercial name of the product in patent specifications;
- the information is not up to date or is inaccurate;
- a drug may be covered by more than one patent;
- the information is not easily obtainable from the national patent office; and
- even where information is accessible, patent searches are subject to the frequent disclaimer that they may not reveal all the relevant patents.

Despite these constraints, patent information is increasingly being made available electronically. Freely accessible resources and methods that are not overly technical are available to help identify if relevant patents exist on medicines. Such methods, while not exhaustive, can nevertheless help health authorities and procurement agencies to identify pharmaceutical patents at the national level.

The purpose of this guide is to provide a starting point for health authorities, procurement bodies and others to identify whether patents relating to a pharmaceutical product exist in the country of interest.

The methods detailed in this guide use free resources that are available on the Internet. As patent searching is not an exact art, it is impossible for any guide to cover all the potential variables that a search may involve. The mechanics and effectiveness of a patent search are mainly determined by the depth of the user's knowledge of the subject matter, continuous iteration, and trial and error. This guide is therefore by no means intended to be a comprehensive guide; it merely is a starting point.

It is important to note that this guide does not discuss how to assess the claims of a patent in order to determine whether the purchase or production of a generic version of a medicine is prevented. Such an assessment would
require the services of a patent lawyer and a person with the relevant scientific background.

The intended purpose of this guide is to provide health authorities, procurement bodies and other interested parties with the basic tools to start obtaining critical information on patents covering a particular medicine in the country of interest. By doing so, decision-making on procurement issues could be made more effective and accurate.

1.1 Format of the guide

This guide is arranged into the following chapters.

Chapter 2 provides a basic introduction to the patent system and patent information. This chapter introduces the various treaties covering patents, the different types of patents (i.e. national and regional patents, and international patent applications) and key concepts (e.g. priority periods). It also explains how to read a patent document and how patent information is administered, including the arrangement of equivalent and corresponding patents in databases (patent families).

The purpose of this chapter is to provide readers who have little or no understanding of the patent system and related concepts with the necessary background information to carry out a meaningful search. Readers who fall into this category are advised to review this chapter first before moving to the practical parts of the guide.

As most medicines are protected by more than one patent, Chapter 3 of the guide familiarizes readers with the different types of patents that may exist in relation to a particular product.

Chapter 4 describes the various practical steps for conducting a search. Given the difficulties in identifying and matching patents to relevant products, the method adopted in this guide starts from the information about patents on medicines provided through the United States Food and Drug Administration (US FDA) Orange Book and the Health Canada Patent Register. Providing step-by-step examples, this chapter demonstrates how to extract patent information on medicines from the Orange Book and Health Canada.

As the Orange Book and Health Canada registers do not provide listings of all patents relating to marketed medicines, Chapter 4 also provides techniques for expanding a search using keywords, patent classifications, assignee/applicant and inventor name, citations and date ranges.

Applying the techniques discussed in Chapter 4, Chapter 5 explains how to find equivalent and corresponding patents in other countries using
available databases, or other methods when information is not available electronically.

Chapter 6 concludes by briefly discussing the steps that need to be taken following a search to determine whether there is freedom to procure or manufacture generic medicines.
Before commencing a patent search, it is necessary to have a grasp of:

- the various multilateral agreements governing the modern patent system and the concept of priority;
- the different ways of filing and obtaining patent protection;
- how patent information is administered; and
- how patent documents are structured.

Readers not familiar with the above should read this chapter first before proceeding through the remaining chapters of the guide.

### 2.1 Multilateral treaties on patents

Contrary to popular belief, there is no single global patent that provides protection in all countries. Patents are territorial rights that are granted in accordance with the national patent laws of a particular country. There are, however, various multilateral agreements that attempt to provide a degree of harmonization within the patent system. These are discussed briefly below.

#### 2.1.1 The TRIPS Agreement

The most comprehensive of these frameworks is the TRIPS Agreement. TRIPS requires Member States of the WTO to implement minimum levels of intellectual property protection1. This includes providing for product and process patents in all fields of technology, and a minimum patent term of 20 years. However, countries are permitted some flexibility in determining what amounts to an invention and in deciding their own standards of patentability. Therefore, an invention that has been patented under the laws of one country may not be considered patentable in another country.

---

1 Least developed countries (LDCs) are not required to implement patents for pharmaceuticals until 2016.
It should be noted that granted patents might subsequently be invalidated in part or in full. Alternatively, granted patents may lapse due to failure to pay maintenance fees. The renewal period varies from country to country.

Aside from TRIPS, two other key international agreements that create a degree of harmonization within the patent system are the Paris Convention and the Patent Cooperation Treaty. The key elements of these legal frameworks for the purpose of this guide are discussed below.

2.1.2 The Paris Convention and priority period

In 1883, the Paris Convention created the first multilateral framework for intellectual property rights. As of 15 October 2009, 173 countries are signatories to the Convention (see Appendix I). One of the principal concepts introduced by the Convention is the priority system.

Under the priority system, an inventor may, within 12 months of the first patent application (the priority application) disclosing an invention in a member country, apply for protection for the same invention in other member countries. This 12-month period is known as the priority period. Subsequent applications filed within the 12-month priority period will enjoy the same filing date (known as the priority date) as the first application. These later applications will also enjoy priority status over all other applications, acts and disclosures relating to the same invention that are filed after the priority date. The withdrawal or abandonment of the first application (the priority application), or the revocation of the first patent (the priority patent) does not affect the priority status of the subsequent applications that rely on the earlier patent.

The Convention permits applicants to claim "multiple priorities" or "partial priorities". Therefore, later applications filed within the priority period may claim priority from more than one earlier application, which cover different features of the invention. Partial priority exists where the later applications combine subject matter for which priority is claimed with elements of the invention for which there is no priority application.

2.1.3 The Patent Cooperation Treaty

The Patent Cooperation Treaty (PCT) came into being in 1970 and is open to states that are party to the Paris Convention. As of 15 May 2010, there were 142 contracting parties to the PCT (see Appendix II).

The PCT (also commonly referred to as the international patent system) makes it possible for an applicant who is a national or resident of a contracting
A step-by-step guide

state to apply for patent protection for an invention in more than one country through a single application. The PCT filing system is discussed in more detail below (see Section 2.2.3).

2.2 Types of patent filing and protection

As already indicated above, patent rights are territorial. There are different routes to filing and obtaining patent protection in a country.

2.2.1 National patent filings

A patent application that is filed with the national patent office is typically referred to as a national filing. It will be examined and granted according to the patent law of that country. The patent will only be enforceable in the country(ies) where it was filed and granted.

The initial application (the priority application) may be followed by further patent applications for the same invention in other countries within the 12-month priority period.

2.2.2 Regional patent filings

In some regions, countries have come together and created regional patent conventions that harmonize the administration of patents. These regional conventions allow applicants to file a single application with a regional patent office, designating the contracting states that they wish to seek protection in. The regional patent office will administer, and in some cases (the European Patent Office (EPO) and the African Intellectual Property Organization (OAPI)), conduct the examination and issuing of the patent.

Regional patents have the same effect as national patent rights in the designated Member States. In some cases, for example a European patent, the patent is granted as a bundle of national rights.

The current regional patent conventions and their respective regional patent offices are: the European Patent Convention and the EPO; the Harare Protocol on Patents and Industrial Design (Harare Protocol) and the African Regional Industrial Property Organization (ARIPO); the Bangui Agreement relating to OAPI; the Eurasia Patent Convention and the Eurasian Patent Office (EAPO). The Member States of each of these regional patent conventions can be found on the relevant organizational websites.

2.2.3 International patent applications

Under the PCT system, an international application makes it possible for an applicant who is a national or resident of a contracting state to apply
for patent protection for an invention in more than one country through a single application.

The application can be filed through either the national patent office of the contracting state where the applicant is resident or through the International Bureau of the World Intellectual Property Organization (WIPO). Applicants resident in a contracting state that is party to a regional patent convention may file the international application at the respective regional patent office.

If the applicant does not withdraw an international application it will be published under an international publication number by WIPO's International Bureau 18 months from the date of filing or from the priority date, if any. The applicant then has up to 30 months (31 months in some countries) from the date of the priority application upon which the international application is based to decide whether to pursue national protection for the invention in each of the countries designated, or only in a few. By selecting to pursue the international application in a particular country, the application enters what is termed the national phase. The single international application thus becomes a national application in each of the designated states and is published as such in each country’s patent office journal. Each of those national applications will then be examined by the respective national patent office.

### 2.3 Patent information

An applicant must describe the invention and the subject matter for which patent protection is sought in the patent specification.

Once the specification has been filed through one of the filing systems discussed above, the receiving patent office will administer the application. Unless the applicant withdraws the application, in most countries the first time that the patent specification and its filing details become public is 18 months after the priority date of the first application (the priority application).

Thereafter, the application is given a substantive examination to determine whether the invention meets the requirements of patentability as defined under the country’s national law. During the examination of an application or due to a pre-grant opposition by a third party, the subject matter claims and description in the specification may be revised. Therefore, it is necessary to track an application through examination to grant (or refusal) in order to obtain the final subject matter that a patent covers.

---

3 However, not all countries undertake a substantive examination.
2.3.1 Understanding information in a patent specification

A patent specification consists of various pieces of information that can be used for the purpose of searching.

The format of patent documents (the specifications) and the information contained therein are largely the same from one patent office to another. This information generally falls into three categories:

- bibliographic data, which usually appears on the front page of a patent specification;
- technical information, which includes the description of the invention; and
- legal information, referred to as the claims, which define the scope of protection sought.

Bibliographic data

With the exception of a few differences between patent authorities, the fields of information appearing on the cover page of a patent document will generally be the same. Below is a summary of the most common fields of information that appear in the bibliographic data.

- **Application number:** A unique number given to each patent application filed.

  In the case of US patents, there may be additional numbers that reveal earlier related applications from which the current application derives. These earlier applications are known as “continuation applications”, “continuation-in-part applications” or “provisional applications”. It is worth noting that the numbers of continuation applications, continuation-in-part applications and provisional applications will often form the priority data for subsequent filings in other countries.

- **Patent number:** A unique number given to each granted patent.

- **Document kind codes:** An alphanumeric code used to distinguish the particular status of a published application or patent. The code will follow a publication number or patent number (e.g. A1 or B1). See Box 1 below for further information on kind codes.

- **Filing date:** The date the application was filed and accepted by the relevant patent office. This is the date that the 20 years of patent protection will run from, if the patent is granted.
- **Priority data:** Includes the application number(s), date(s) and two-letter code of the country where the first application(s) filed for the invention from which priority is claimed were made. The priority date(s) given is also the date from which the invention will be protected, if the patent is granted.

- **Publication number:** This is the number given to an application when it is first published in an official patent office journal (usually 18 months after the priority date). In some countries the publication number will remain the same as the original application number.

- **Publication date:** The date the application/specification was first published (usually 18 months after the priority date).

- **Date of patent/Date of publication of the grant of the patent:** The date that the patent was published as granted.

- **International Patent Classification:** Code that represents the field of technology to which the subject matter of the patent relates. All published patents will be classified using a standard classification system, the International Patent Classification (IPC) system. For further information on patent classification systems, see Box 2 below.

- **Applicant/Proprietor/Assignee:** The name of the individual or company that is applying for protection of an invention. In the United States, if there has been a legal assignment of the invention prior to a patent application being filed, the field "Assignee" in a US patent document represents the applicant. This field also provides the business address or city where the applicant is based.

- **Inventor(s):** The name of the person(s) who invented the subject matter claimed in the patent application and their address.

- **Representative/Agent:** The name and address of the patent attorney or lawyer that is on record as handling the application on behalf of the applicant.

- **Designated States:** For PCT and European patents, this field displays the designated countries where protection may be sought. The designated countries are displayed using two-letter codes created by WIPO.

The list of designated states provided at the time of the 18-month publication will reflect the states that the applicant included at the
time of filing the application. However, as discussed above, it is possible that an applicant may not proceed to pursue the application in every designated country.

- **Divisional application:** Refers to related application(s) that are descended from (or “divided out” from) a previous application, which is known as a parent application. A divisional application will usually be filed where the parent application claims more than one invention. Also, where the parent application has been refused by a patent office during examination or opposition, an applicant may file one or more divisional applications covering the same or virtually the same subject matter as the parent application in order to have another chance at obtaining a patent. An example of a granted European patent with two related divisional patent applications is shown in Figure 2. By searching for the divisional application numbers provided in the bibliographic data of the parent patent document, users can obtain information about these additional patents.

In some countries, e.g. India, the bibliographic data of a parent application will not provide details of any related divisional applications. However, the bibliographic data of the divisional application (which would have to be found through conducting searches as described in Chapter 4) will show the details of the related parent application.

- **References cited:** These relate to prior patent documents or non-patent literature relating to the subject matter of the application disclosed by the applicant or identified by the patent office examiner during examination of the application.

- **Title:** Provides a brief indication of the nature of the subject matter of the patent.

- **Abstract:** Provides a summary of the subject matter of the patent application or patent. Some abstracts may include a diagram.

Figures 1 to 3 illustrate how bibliographic data is presented on the front page of a US, European and PCT patent specification.

In some countries, the bibliographic data for a patent specification may not appear on the front page of a patent specification. Instead, the data is provided in the official patent office journal when the application is published after 18 months. Figure 4 illustrates how bibliographic data is presented in the Official Journal of the Indian Patent Office.
Figure 1: Example of bibliographic data as presented on the front page of a US patent specification.
**Figure 2:** Example of bibliographic data as presented on the front page of a European patent specification filed through the PCT.

- **Date of publication of grant of patent**
- **Application number and date of filing**
- **Title in languages of the EPO**
- **Designated states and extension of patent to new Member States of the E.U.**
- **Priority data**
- **Publication of application after entering national phase for the EPO**
- **Details of divisional applications relating to this application**
- **Applicant**
- **Inventors**
- **Publication number and kind code for status of application**
- **International classification code**
- **International application number from which application derives**
- **International publication details**
- **Legal representative for applicant**
- **Prior art cited by applicant or examiner**

### Example of a European Patent Specification

**EP 0998480 B1**

**Title:** NUCLEOTIDE ANALOG COMPOSITION AND SYNTHESIS METHOD

**Applicant:** GILEAD SCIENCES, INC., Foster City, CA 94404 (US)

**Inventors:**
- MUNGER, John, D., Jr., Alisoa, CA 92653 (US)
- RCHOFF, John, C., Mountain View, CA 94040 (US)
- SCHULTZE, Lisa, M., San Carlos, CA 94070 (US)

**Priority data:**

- **Priority:** 25.07.1997 US 599972
- **Priority:** 29.07.1997 US 599977

**International classification code:**

- **Classification:** C07F 6/651, A61K 9/31/675
- **Classification:** C07F 1/625A

**Publication of application after entering national phase for the EPO:**

- **Date of publication:** 10.05.2000 Bulletin 2000/15

**References cited:**

- **EP-A-0 265 665**
- **EP-A-0 064/003**

**Prior art cited by applicant or examiner:**

- SISCHOPHENSER, K. - SH(PO)_{3}FMPA. An orally bioavailable prodrug of the anti-HIV agent FMPA + 693 CONFERENCE ON RETROVIRUSES AND OPPORTUNISTIC INFECTIONS, WASHINGTON, DC, US, JAN 25-30, 1997 (abstract 914) ZEPPO23/3495

**Note:** Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid (Art. 98(1) European Patent Convention).
How to conduct patent searches for medicines

Figure 3: Example of bibliographic data as presented on the front page of a PCT patent specification

Figure 4: Example of bibliographic data as presented in the Official Journal of the Indian Patent Office

9. Application No. 896/DEL/2002 A
(22) Date of filing of Application : 06/Mar/2002
(54) Title of the invention : Nucleotide Analog Composition.

(51) International classification: C 07 D 473/00; C 12 P 17/00
(30) Priority Date:
(31) Document No. : M/053,777; 08/908,752
(33) Country : UNITED STATES OF AMERICA; UNITED STATES OF AMERICA


(71) Name of the Applicant:
GILEAD SCIENCES, INC.
Address of the Applicant:
333 LAKESIDE DRIVE, FOSTER CITY, CALIFORNIA 94404
UNITED STATES OF AMERICA

(72) Name of the Inventor:
JOHN DUCAN MUNGER, JR.,
JOHN CHRISTIAN ROHLFF
LISA MARIE SCHULTZE

Abstract:
The invention provides a composition comprising bis(POC)PMPA and fumaric acid (1:1). The composition is useful as an intermediate for the preparation of antiviral compounds, or is useful for administration to patients for antiviral therapy or prophylaxis. The composition is particularly useful when administered orally. The invention also provides methods to make PMPA and intermediates in PMPA synthesis. Embodiments include lithium t-butoxide, 9-(2-hydroxypropyl) adenine and diethyl p-toluenesulfonfylmethoxyphosphonate in an
Box 1. Kind Codes

As patent documents change in their content between publication and grant, patent authorities classify the different versions using kind codes. Kind codes will follow the application or granted patent number e.g. EP 0996622 (A1) or EP 0996622 (B1). Although there is some harmonization in the document kind codes used by the different patent authorities, they can vary.

For example, most patent offices will use the document kind code "A" to indicate that a patent application is published for the first time and is either unexamined or under examination. The document kind code "A" may be followed by a numeral, e.g. "A1", "A2" or "A3".

A1 indicates the publication of a PCT or European patent (referred to as an EP patent) with a search report through the International Search Authority (under the auspices of WIPO).

A2 indicates the publication of a PCT or EP patent without an International Search Authority search report.

A3 indicates the publication of a PCT or EP with an International Search Authority search report for a patent previously documented as A2.

B1 indicates a granted EP patent. B2 indicates a granted EP patent with revisions. To obtain the final granted patent claims for an EP, one needs to download the patent that is suffixed with letters "B1" or "B2".

The United States also uses the kind code B for granted patents. Other countries using the kind code B for a granted patent include Indonesia and Viet Nam. China and a number of other countries use the letter "C".

NB: Published PCT applications only appear as applications—thus, they will never be referenced by the kind codes "B" or "C" (which signify that a patent has been granted). However, when a PCT application enters into the national phase and matures into a granted patent in a designated country, that country’s patent database or publication will indicate its status by either the kind code "B" or "C".

For specific details on country kind codes, see: http://www.delphion.com/help/kindcodes or http://www.cas.org/expertise/cascontent/caplus/patcoverage/patkind.html
Box 2. The Patent Classification System

Although the different patent authorities maintain their own classification schemes, the most widely used system is the IPC administered by WIPO. The IPC contains about 70,000 entries (classification symbols) that can be used to classify patent documents. The different classifications are arranged into the following eight sections with a hierarchical structure:

Section A – Human Necessities
Section B – Performing Operations; Transporting
Section C – Chemistry; Metallurgy
Section D – Textiles; Paper
Section E – Fixed Constructions
Section F – Mechanical Engineering; Lighting; Heating; Weapons; Blasting
Section G – Physics
Section H – Electricity

Each of the above sections contains subsections. For example, Section A (Human Necessities) contains the following subsections: Agriculture; Foodstuffs; Tobacco; Personal or Domestic Articles; Health; Life Saving; Amusement.

Each section/subsection is divided into classes, represented by the letter of the section followed by a two-digit number. Example: A61 includes technologies relating to “Medicine or Veterinary Science; Hygiene”.

Classes are further divided into subclasses, represented by a capital letter. Examples: A61K for “Preparations for Medical, Dental, or Toilet Purposes” and A61P for “Therapeutic Activity of Chemical Compounds or Medicinal Preparations”.

The subclass is further broken down into subdivisions called “groups”, also known as the “main group” within the hierarchical structure. The main group can be identified by a two-digit-number. Example: A61P 31 for “Antibiotics, antiseptics, chemotherapeutics”.

The main group is further divided into subgroups. The subgroup is separated from the main group number by a forward oblique stroke followed by a one- to three-digit number. Example: A61P 31/18 for “HIV” and A31P 33/06 for “Antimalarials”.

Pharmaceutical products are usually classified under A61K, A61P and/or C07.

The IPC system can also be searched electronically online at: http://www.wipo.int/classifications/ipc/ipc8/?lang=en

Although the IPC is widely used, different patent authorities may have their own classification systems. The European and US Patent Offices are two such examples. They are useful to know for the purpose of this guide, given that many pharmaceutical product patents originate from these regions.

The European Classification (ECLA) system builds on the IPC system and contains some 134,000 groups. The ECLA system can be searched online at: http://v3.espacenet.com/eclasrch.

Technical information

Following the bibliographic data, a patent specification will provide the technical information relating to the subject matter of the invention. This section, often referred to as the body of the patent specification, consists of a written and diagrammatic description of the invention.

The technical section of a patent specification will usually include the following subsections:

- **Field of the invention**: Describes in one or two sentences the subject matter of the invention and its benefits.
- **Background of the invention**: Sets out any previous disclosures known to the applicant/patentee at the time of filing the patent that may be relevant to the subject matter of the invention. Depending on the particular requirements of the patent office in question, the applicant provides information about earlier related patent(s) or literature(s). The section will then usually describe the object of the invention and the problem it seeks to solve, and how it represents an advance over what was previously known.
- **Summary of the invention**: Briefly explains the main subject matter of the invention. The summary may also make reference to related embodiments—i.e. a particular implementation or method of carrying out the invention—of the main claim.
- **Brief description of the drawing/figures**: Any figures or drawings needed to explain the invention will be briefly described under this subsection. In most cases any figures/drawings will appear at the end of the patent document after the claims section (see page 20).
- **Detailed description of the invention**: Provides the technical details of the invention and how it may be used. The description should be detailed enough to allow a third party to be able to carry out the invention.
- **Examples**: Demonstrate various workings of the invention. They can range from examples explaining which process to use to make the invention, to data showing how the invention provides improvements (such as stability or bioavailability) over other or earlier known forms of the subject matter for which a patent is being claimed.

Figures 5 and 6 illustrate how the technical information in a patent specification may be presented.

Depending on the user’s knowledge of the subject matter to be searched and the type of database used, it may be possible to search for terms that only appear in the body of the specification. Using such a search method may provide a more comprehensive set of results than searching only the bibliographic data, title or abstract of a patent document. Such search techniques will be discussed further in Chapter 4.
Figure 5: Example of technical information in a patent specification
Figure 6: Examples given in a patent specification explaining the invention

EP 0 598 480 B1

Rockville, MD) and manufacturer’s Coulometer Instructions. The amount of BPFPE used in the assay, about 50-100 mg, was measured using a fireproof analytical balance (Sartorius Model RC2/20, equivalent). A typical batch contained less than 1.0% w/w water.

[0068] BPFPE crystals were analyzed by infrared spectroscopy using a Perkin-Elmer model 1650 FT-IR spectrophotometer according to the manufacturer’s instructions. KBr (Aldrich, IR grade) was dried overnight at 60°C under vacuum before use. A translucent pellet containing about 10% by weight (about 5 mg) of BPFPE crystals and about 90% by weight (50 mg) of dried KBr was prepared by grinding the two powders together to obtain a fine powder. IR spectroscopy has been described (see, e.g., U.S. Pharmacopeia, vol. 22, 1994 method 197, U.S.P. Pharmacopeial Convention, Inc., Rockville, MD; Horowitz, M.T., et al., Organic Chemistry, 2nd ed., Allyn and Bacon, Inc., Boston, p 410-412, 1973). The spectrophotometer sample chamber was purged for at least 5 minutes with high purity nitrogen gas at about 6 psi to reduce carbon dioxide absorbance interference to ≤2% in a background scan prior to scanning with the sample. BPFPE crystals exhibited an infrared absorption spectrum in potassium bromide with characteristic bands present in potassium compounds at approximately 2534 (C=O), 3107-3205 (N-H, C-N, N=O), 2988-2939 (aliphatic C-H), 1759 (aryl carbon C=O), 1678 (aromatic C=C), 1020 (aromatic C=O), 1120 (phosphonate P=O) and 1102 (C-O-C).

[0069] The solubility of BPFPE in different solvents was examined. BPFPE was found to be generally more soluble in polar solvents, which are typically used in the invention methods and embodiments. BPFPE solubility in dimethylformamide was 428 mg/mL, and BPFPE solubility in acetonitrile was 15-100 mg/mL. BPFPE solubility in acetonitrile, acetonitrile-acetone and deionized water (pH 3.3) was about 3-15 mg/mL. BPFPE had a low solubility in CHCl₃, diethyl ether and hexane.

[0070] BPFPE crystals were analyzed by ultraviolet spectroscopy using a Hewlett-Packard model 8456A diode array spectrophotometer according the manufacturer’s instructions. The amount of BPFPE used in the assay, about 25 mg, was measured using a five place analytical balance (Sartorius, Model RC210C, equivalent) and HPLC or spectrophotometric grade solvents. The mole absorbency of 10 µg/mL BPFPE at pH 6.0 in 0.01 M potassium phosphate buffer was 14900 μM⁻¹ cm⁻¹ and 15015 μM⁻¹ cm⁻¹ at 270 nm in 0.01 N HCl or 15 µg/mL BPFPE (100 µg/mL) in methanol had a λmax at about 267 nm.

[0071] BPFPE crystals were not hygroscopic when kept at 92% relative humidity and at room temperature for up to 37 days. BPFPE has a pH of 3.8 as determined by potentiometric titration.

Example 2

[0072] Chlorine enrichment of (R)-PMPA, (R,L)-PMPA.HCl (2.0 g, about 93% R isomer) was suspended in a flask containing water (100 mL) and the pH was adjusted to 7.1 using HCl or NaOH as needed. The solution was warmed to 40 °C and the pH was adjusted to about 6.0. The pH was then adjusted to 3.1, and the solution was seeded with (R)-PMPA. The solution was allowed to cool to room temperature and left for about 2 hours. The solids were collected on a coarse glass filter, washed with cold water (15 mL) and then washed with acetone (10 mL). The resulting PMPA consisted of 98.9% of the (R) isomer. No chlorine enrichment of the (S) isomer was observed when similar protocols were performed using 2.5 g of (S,L)-PMPA (about 92% (S)-isomer) and 25 mL of water. Chlorine enrichment of the (S) isomer to 99.6% (R)-isomer was observed when a similar protocol was performed using 0.758 g of (R,L)-PMPA (about 93% (R)-isomer) and 10 mL of water.

Example 3

[0073] The solid state chemical stability of cBPFPE and bis(D-carboxy)PMPA-citrate salt was compared by analyzing each compound after storage under different conditions. The results showed that BPFPE powder was unexpectedly more stable to storage at elevated temperature and relative humidity.

<table>
<thead>
<tr>
<th>Conditions</th>
<th>temp*</th>
<th>BPFPE%</th>
<th>mono(DPMPA)</th>
<th>bi(DPMPA)</th>
<th>mono(DPMPA)</th>
<th>bi(DPMPA)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>fumarate%</td>
<td>citrate%</td>
<td>fumarate%</td>
<td>citrate%</td>
</tr>
<tr>
<td>40°C, 75%**</td>
<td>0</td>
<td>99.6</td>
<td>1.0</td>
<td>99.0</td>
<td>1.0</td>
<td>99.0</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>98.3</td>
<td>1.7</td>
<td>98.0</td>
<td>1.7</td>
<td>98.0</td>
</tr>
<tr>
<td></td>
<td>50</td>
<td>98.1</td>
<td>2.9</td>
<td>98.9</td>
<td>2.9</td>
<td>98.9</td>
</tr>
<tr>
<td></td>
<td>60</td>
<td>97.7</td>
<td>2.3</td>
<td>97.0</td>
<td>2.3</td>
<td>97.0</td>
</tr>
</tbody>
</table>

* days, ** relative humidity.
Legal information

The claims defining the legal rights over the invention will be found at the end of the patent specification (see Figure 7). Understanding the scope of the claims and the subject matter it covers is necessary to assess whether there is freedom to procure or manufacture generic versions of a particular medicine.

As the laws regarding claim construction may differ from country to country, the topic of claims analysis is beyond the scope of this guide. It is suggested that once a particular patent(s) has been identified, a patent lawyer/attorney and/or a pharmaceutical chemist who is familiar with construing the claims of a patent in accordance with national laws should be engaged, in order to determine the exact scope of the claims.

**Figure 7:** Example of patent claims

We claim:

1. A composition of formula (I)

   \[ \begin{align*}
   & B \quad \text{O} \\
   & \text{OR} \quad \text{H} \quad \text{O} \\
   & \text{CH}_3 \\
   & \text{OR} \quad \text{HO} \quad \text{O} \\
   & \text{CH}(\text{CH}_3) \quad \text{CH}(\text{CH}_3) \\
   \end{align*} \]

15 wherein B is adenosine-9-yl and R independently is —H or —CH\(_2\)-O—C(O)—O—CH(CH\(_3\))\(_2\), but at least one R is

1. The composition of claim 1 wherein both R are

2. The composition of claim 1 wherein the composition is a crystalline solid.

3. The composition of claim 1 wherein the compound is enriched or resolved at the carbon atom chiral center (*).

4. The composition of claim 1 having an X-ray powder diffraction spectrum peak using Cu-K\(\alpha\) radiation, expressed in degrees 20 at about 25.0.

5. A composition comprising the composition of claim 1 and an acceptable excipient.

6. A composition comprising a lithium alkoxide and a 9-(2-hydroxypropyl)adenine solution.

7. A composition comprising an (R,S)-PMPA solution at a pH of about 2.7–3.5 wherein the solution has less than about 0.1 g/mL (R,S)-PMPA and wherein about 90–94% of the PMPA is in the (R) configuration.
2.4 Where to obtain patent information

How patent data and specifications are obtained varies from country to country. A number of developed country patent offices provide free online access to patent information, including both bibliographic data and related patent documents. Although most of the free online databases only cover information relating to patents in developed countries, there are exceptions.

The EPO’s online database (esp@cenet) provides access to selected patent information and specifications from other national patent offices.\(^4\) WIPO’s patent database (Patentscope) provides access to international patent documents (PCT applications) as well as selected information on whether those applications have entered the national phase.\(^5\)

There are a growing number of developing country patent offices that now have patent databases that can be searched freely. However, many if not all of these databases only provide limited data with no online access to the full patent specification. In some countries, there may be separate databases that have to be searched and cross-referenced in order to obtain complete information. For example, the Indian Patent Office has two separate databases, one for published patent applications and one for granted patents. Also, many of these databases are only searchable in the national language. Once the details of a particular patent are found from a search of one of these databases, a request has to be made to the patent office itself to obtain a copy of the full patent document. In some cases, such as in India, payment of an official fee will be necessary.

Where a national patent office does not provide an online searchable database, it is possible to obtain information on patents by manually searching the official journal (or gazette) of the relevant patent office. Unlike online searching, manually searching patent office journals/gazettes is a laborious and time-consuming task. Patent offices normally have an official journal/gazette in one form or another within which details of all patent applications\(^6\) and granted patents will be presented. The journal/gazette may either be available for download from the particular national patent office website or can be purchased for an official fee. In some cases, it may be necessary to visit the patent office to search the records on-site. As journals/gazettes will not include the full patent document, it will be necessary to request this from patent office once the relevant application or granted patent has been found.

\(^4\) http://ep.espacenet.com/
\(^5\) http://www.wipo.int/pctdb/en/
\(^6\) As explained above, patent applications usually will be published 18 months after the priority date.
For a list of free online databases or journals provided by national/regional patent offices and the type of patent information they offer, see Appendix III.

In addition to patent office databases, there are a number of commercial and non-profit databases that provide patent information online.

The commercial databases offer a subscription-based service and tend to provide more comprehensive coverage. For example, Thompson Reuters’ Derwent World Patent Index provides patent information from 41 patent offices around the world. However, even though such databases provide information that may not be available from the databases of the EPO and WIPO, they still lack data from most developing countries.

The non-profit databases are usually limited to patent information from Europe, Japan, the United States and WIPO. Nevertheless, as explained in Chapters 4 and 5, these databases can be useful to obtain full electronic copies of EPO, PCT and US patent documents that are not available from the national patent office databases.

### Box 3. Examples of non-profit patent databases

- BigPatents India: http://india.bigpatents.org/
- Freepatentsonline: http://www.freepatentsonline.com/
- Google Patents: http://www.google.com/patents
- IP.com: http://ip.com/
- Patent Lens: http://www.patentlens.net/patentlens/structured.html
- PriorSmart: http://www.priorsmart.com/

### 2.5 How patent information is arranged

With the ever-increasing volume of patent information and improvements in patent search technology, various concepts have been developed to make searching more thorough. One such concept is the **patent family**. A patent family can be defined in various ways.

Broadly, a patent family arises when several patent documents around the world claim the same priority or priorities from the first patent application(s) filed for an individual invention. As a result, all the patents sharing the same priority or priorities become related **family members**. Therefore, depending on the database used, a search against one member of a patent family can reveal other members of the family from around the world.
Although a patent family may reveal a list of patents that share the same priority patent(s), it does not mean that the patent documents and their claims will be the same. The narrowest definition of a patent family is one including documents that have exactly the same priorities and claims. Patent documents that have the exact same priorities are usually referred to as equivalents. The feature *Also published as* in the esp@cenet database will highlight patents that are considered to be equivalent.

A broader and more comprehensive patent family is where the patents will be directly or indirectly linked by the priority, but the body of all listed patent documents and their claims will not be the same. For example, such a patent family would include patents that cover different aspects of the invention deriving from one or more of the priority claims, as well as ones that have been divided out from other applications. The EPO’s database esp@cenet uses this more comprehensive patent family system, called the International Patent Documentation Centre Collection (INPADOC).

The information provided in patent families will likely have missing or incorrect information; this is due to delays in receiving information from the participating national patent offices. Therefore, to make sure of the actual status of a patent in a particular country, users should double check with the relevant national patent office.

For the purpose of demonstrating examples in this guide, the INPADOC patent family system will be used.
Types of patents on medicines

The patent system is designed to provide one patent for one invention. Therefore, if Company X invents a new chemical compound, Company X may be entitled to a single patent to protect the newly invented compound and how it is manufactured. If Company X then also discovers new forms of the compound, invents new ways to deliver or manufacture the compound, in each case Company X may be entitled to a separate patent for each claimed invention.

Most of today’s marketed pharmaceutical products consist of relatively small chemical molecules. Others derive from biological material (i.e. biotechnology drugs or biologicals). Whether the medicine in question is a chemical or biological product, several patents are likely to have been filed and/or granted to protect it.

In the case of non-biological pharmaceutical products, a single medicine may be covered by separate patents claiming:

- the chemical compound (the active ingredient or base compound);
- polymorphic forms of the compound;
- salts, esters, ethers, enantiomers, metabolites and other derivative compounds;
- formulations and compositions of the compound, e.g. capsule, tablet and oral solutions;
- different dosage forms;
- one or more indications (uses) for the medicine;
- a combination of the compound with other active ingredients;
- processes and methods for manufacturing the active ingredient, polymorphic forms, derivative compounds and formulations/compositions.¹

Biological medicinal products, such as vaccines, are also usually covered by more than one patent. Typically there will be separate patents covering the protein sequence and/or combinations of proteins of a virus-like particle, followed by subsequent patents covering compositions and formulations (i.e. adjuvants and excipients).

It is worth noting here, that while it is important to identify as many of the different patents as possible that may relate to a particular medicine, some patents are more important than others in terms of whether they will block the procurement or local manufacture of more affordable generic versions.

In the case of non-biological pharmaceutical products, for example, a patent claiming the base chemical compound will likely prevent any use of the same compound. Such a patent would, most likely, prevent any production, importation or sale of formulations or dosage forms that include that base compound. Where there exists only a patent claiming a particular salt or polymorph of the base compound, then it is possible that a local manufacturer may be able to use an alternative salt or polymorph of the compound (provided it meets regulatory requirements). Similarly, if the patent covering the base compound has expired or was never filed in a country, but patents covering formulations of the compound exist, it may still be possible to procure or manufacture alternative formulations. However, only by consulting a local patent lawyer/attorney and/or pharmaceutical chemist and analysing the scope of the claims of a patent will it be possible to determine whether more affordable generic versions can be procured or manufactured without infringing the patent(s).

Chapters 4 and 5 discuss some basic search techniques for identifying the different patents that may exist in relation to a pharmaceutical product.
The remaining chapters of this guide focus on basic tools and techniques for finding patents on pharmaceutical products.

As mentioned in the introduction, obtaining relevant and accurate patent information on medicines, in particular in developing countries, is not without its difficulties. To help overcome some of these difficulties, this guide uses a stepwise approach. The steps, which are summarized in Box 4, will be explained in more detail in this chapter and in Chapter 5. Although this method may not always yield results, it should in most cases help users get a broad sense of the patents that exist in relation to a particular product, and ideally, obtain key information.

Box 4: Summary of steps illustrated in this guide to search for patents on medicines

**Step 1**
The first step is to identify patents that relate to marketed medicines. One efficient way of obtaining this information is through public databases made available online by the US FDA (the Orange Book) and Health Canada (Patent Register). These databases match some key US and Canadian patent numbers to medicines that are marketed in these countries, but that may also be sold in other countries (see Sections 4.1 and 4.2 and 4.4).

**Step 2**
Once US and/or Canadian patent(s) number(s) relating to a medicine have been identified, the next step is to obtain the bibliographic details of the patent(s). It is also recommended to obtain the specification(s) of the US and/or Canadian patent(s) found. Having access to the bibliographic data and full details of the identified patents is not only useful for identifying priority data relevant to equivalent patents filed in other countries, but also for finding keywords that may be used to expand the search to other related patents. Section 4.3 describes the steps for obtaining bibliographic data and specifications of US and/or Canadian patents using the EPO’s esp@cenet database.
**Step 3**

As the Orange Book and Health Canada Patent Register do not provide information on all relevant patents relating to a particular medicine, further searches are necessary. Section 4.5 explains how to expand patent searches using various techniques including keywords, applicant/assignee name, patent classification, citations and date range information. This section also introduces readers to the WIPO public database, Patentscope, which offers more search fields than other public databases and provides information on international patent applications, as well as national phase data. The techniques discussed are demonstrated using different national patent office databases.

**Step 4**

Taking the techniques and information obtained through steps 1 to 3, the next step is to apply them to finding patents in the country of interest. Chapter 5 provides various examples of how to search for patents in other countries that are equivalent to those filed or granted in the United States, Canada or through the PCT. This chapter also provides examples of keyword and applicant/assignee name searching using patent databases of different countries. Finally, as many countries do not provide searchable online databases, Chapter 5 discusses methods for finding patent information from patent office journals.

### 4.1 Sources linking medicines and patent information

Despite the growing number of databases providing online patent information, one of the major problems when searching for patents on medicines is matching the relevant patent(s) to a particular product.

When inventors/companies discover a new compound or derivative that forms the basis of a medicine, a patent will be filed immediately to protect the invention. This means that the initial patent covering the basic active ingredient will be filed well before the World Health Organization has provided it with an INN or modified INN (INN(M)), which becomes the generic name of the new molecule. As a result, searches using the generic name of a medicine will normally not retrieve the basic patent protecting the active ingredient of a product. It is also not possible to search using a brand name of a product, as patents covering active ingredients are filed before medicines are commercialized and brand names are assigned.

A similar problem usually exists in relation to subsequent patents covering the final formulation of a product. It is common for patent applicants not to include the INN, INN(M) or brand name in the specification, even when it is available.
A useful method and first step for overcoming the problem of identifying which patents may relate to a particular medicine is to use the US FDA’s Orange Book and the Health Canada Patent Register. Both the United States and Canada operate a system linking patent data to regulatory approval. As a result the United States and Canadian regulatory agencies maintain public databases providing lists of approved drugs and their related patents.¹

The workings of the Orange Book and Health Canada Patent Register, and the types of patents listed, are discussed in more detail below.

### 4.1.2 Introduction of the US FDA Orange Book

As required under US regulatory law (commonly known as the Hatch-Waxman Act), all new drugs that are approved for marketing in the United States have to be listed in the Orange Book. In addition, the company seeking to market a new drug must provide information regarding any relevant patent (including patents owned by third parties) that might be used to protect the medicine for listing in the Orange Book.² This information should include the expiry date of those patents. The data must be submitted either with the new drug application (NDA) if the patent has already been issued, within 30 days of the approval of the NDA, or if the concerned patent application is still pending, within 30 days of the issuance of the patent.³

The Orange Book requires that patents covering the following subject matter be listed by applicants of a new drug/NDA⁴:

- Active ingredient (the active drug substance, including the polymorphic form used in the NDA)
- Formulation and compositions (the end product for the purpose of human use)
- Method of approved use and treatment
- Product-by-process if the end product is novel and is the subject matter of the NDA

---

¹ The linking of patents to the regulatory approval of medicines means that regulatory agencies are prevented from granting approval to generic versions of medicines where the originator company has a valid patent listed. Although such linkage systems may aid the transparency of patent information relating to medicines, they can be the subject of misuse and litigation and lead to delays in generic versions entering the market. Countries may want to consider these drawbacks when deciding whether to introduce such linkage. It should be noted that linking patents to regulatory approval of generic medicines is not mandated by TRIPS or any other multilateral agreement.

² Federal Food, Drug and Cosmetic Act 21 USC §355(b)(1)

³ Federal Food, Drug and Cosmetic Act 21 USC §355(c)(2)

⁴ Federal Food, Drug and Cosmetic Act 21 C.F.R §314.53(b)(1)
By contrast, patents covering the following subject matter are not permitted to be listed:

- Processes for making the product
- Metabolites
- Intermediate compounds used during the process of making the active ingredient
- Product-by-process patents covering an end product that is not novel and is not the subject matter of the NDA

While regulatory requirements do not prevent the listing of biologicals and their patents (i.e. vaccines), they are rarely entered into the Orange Book.

An electronic version of the Orange Book is available at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm

### 4.1.3 Introduction of the Health Canada Patent Register

The Patented Medicines (Notice of Compliance) Regulations (PM(NOC) Regulations) govern the types of pharmaceutical patents originator manufacturers may file with a New Drug Submission (NDS) or Supplement to a New Drug Submission (SNDS). It is worth noting here that the regulations stress that originator manufacturers may file patents relating to a NDS or SNDS, thereby making patent listing optional.

Relevant patents that the originator would like to have listed should be submitted at the time of filing an NDS or SNDS or within 30 days of issuance of the patent. The patents submitted with an NDS or SNDS are reviewed by the Minister of Health and added to the Health Canada Patent Register if considered relevant. The types of patents that are relevant for listing with an NDA or SNDS are ones claiming:

- An approved medicinal ingredient.

A medicinal ingredient can be chemical or biological in nature, including the ingredient’s chemical equivalents. Therefore, the definition includes claims for different polymorphs of the medicinal ingredient. However, different chemical forms of a medicinal ingredient (e.g. salts, esters, isomers/enantiomers, hydrates or solvates) are not eligible for listing.

---

5 PM(NOC) Regulations s4(5) and s4(6)
6 PM(NOC) Regulations s4(2)(a)
7 PM(NOC) Regulations s2
A step-by-step guide

A formulation or dosage form. A claim for a formulation means a claim for a substance that is a mixture of medicinal and non-medicinal ingredients in a drug, and which is administered in a particular dosage form. A claim for the dosage form means a claim for a delivery system for administering a medicinal ingredient in a drug or a formulation of a drug that includes within its scope that medicinal ingredient of the formulation.

An approved use of a medical ingredient. A claim for the use of a medicinal ingredient means a claim for the use of the medicinal ingredient for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms.

Patents covering the following subject matter are not eligible for listing on the Health Canada Patent Register:

- Processes for making the product
- Metabolites
- Intermediate compounds used during the process of making the active ingredient
- Different chemical forms of a medicinal ingredient (e.g. salts, esters, isomers/enantiomers, and hydrates or solvates)

Health Canada allows for the listing of biologicals, and unlike the Orange Book, patents relating to some biotech drugs and vaccines are included in the register.

The Health Canada Patent Register can be accessed online at: http://www.patentregister.ca/
4.2 How to find patents listed in the Orange Book and Health Canada Patent Register

4.2.1 Using the Orange Book

Step 1
Enter the URL: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm to access the electronic Orange Book search options as shown in Figure 8.

The electronic Orange Book allows users to search for listed drugs and their related patents through five different options. Unless the relevant NDA application number or patent number is already known, for specific queries, it is suggested users search under the option Active Ingredient or Proprietary Name.

Step 2
By clicking on one of the search options (shown in Figure 8), the user will be directed to a new page where the relevant term can be entered in the search box. For illustration, the option Active Ingredient and the generic name “abacavir” is used in Figure 9. Ensure that the option Rx (Prescription Drug Products) is selected.

Step 3
The search for the active ingredient abacavir should retrieve information relating to marketed forms of the drug (see Figure 10).

Figure 8: US FDA Electronic Orange Book search options
**Figure 9:** US FDA Electronic Orange Book active ingredient search

![Figure 9](image1.png)

**Figure 10:** US FDA Electronic Orange Book active ingredient search results

![Figure 10](image2.png)

Click on any one of these numbers to access the page linking to patent data for the relevant product.
The information provided includes:

- **Appl No**: the NDA application number for marketing approval.
- **Active ingredient**: the active ingredient(s) of the marketed product.
- **Dosage form/Route**: the route for administering the drug.
- **Strength**: the amount of active ingredient in the dosage form.
- **Proprietary name**: the brand name of the product as sold in the United States.
- **Applicant**: the proprietor of the marketed product.

To access the page that links to the patent data relating to the marketed product(s), click on any one of the numbers provided under the column Appl No.

**Note**: Although the example shown in Figure 10 lists products combining more than one active ingredient, the patent listings (shown in Figure 12) are likely to only include patents covering each individual active ingredient.

**Example**: For the product Epzicom® (abacavir sulfate and lamivudine), only individual patents for the two active ingredients will likely be provided, and not any patents covering the combination of the two ingredients. (For discussion and examples of how to conduct further searches for other patents including patents on combinations, see Section 4.5 and Chapter 5.)

**Step 4**

Having clicked on a link under the column Appl No, as shown in Figure 10, a page repeating information relating to the marketed product will appear.

In addition to the marketing approval information, a link is provided to view patent and exclusivity data for the drug (see Figure 11). Click on the link View to proceed to the page containing patent listings.

**Step 5**

The next page should provide the patent(s) listed by the proprietor in relation to the marketed product.

The key items of information provided are the patent number (US) and the patent expiration date (US) (see Figure 12).

All the patent numbers obtained (see list in Figure 12) should be noted down, as it will be necessary to obtain the patent specification for each one (see Section 4.3) in order to identify its subject matter and relevance.
Figure 11: US FDA Electronic Orange Book patent information link

![Image of patent information link][Image]

Click here to view patent listing

Figure 12: US FDA Electronic Orange Book patent listings for abacavir

![Image of patent listings][Image]

**Patent and Exclusivity Search Results from query on Appl No 020978 Product 001 in the OB_Rx list.**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>N020978</td>
<td>001</td>
<td>5034304</td>
<td>Dec 18, 2011</td>
<td>Y</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N020978</td>
<td>001</td>
<td>5034306*PED</td>
<td>Jan 16, 2012</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N020978</td>
<td>001</td>
<td>5098500*PED</td>
<td>Dec 26, 2009</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N020978</td>
<td>001</td>
<td>6234540</td>
<td>May 14, 2018</td>
<td>Y</td>
<td>Y</td>
<td>U - 65</td>
<td></td>
</tr>
<tr>
<td>N020978</td>
<td>001</td>
<td>6234540*PED</td>
<td>Nov 14, 2018</td>
<td></td>
<td></td>
<td>U - 65</td>
<td></td>
</tr>
<tr>
<td>N020978</td>
<td>001</td>
<td>6641843</td>
<td>Feb 4, 2020</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**There is no unexpired exclusivity for this product.**

**Additional Information:**

1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).
2. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. These patents may not be flagged with respect to other claims which may apply.
4.2.2 Using the Health Canada Patent Register

Step 1

Enter the URL: http://www.patentregister.ca/ to access the Health Canada Patent Register. The front page of the Health Canada website provides users the choice of two languages to work in, English and French. Click on the preferred choice. (For illustration, the examples provided here are in English.)

The user will then access the patent register search page as shown in Figure 13.

Health Canada provides three main search options:

- By medicine (i.e. the generic name of the active ingredient in the drug)
- By brand name
- By patent number

Unlike the Orange Book, the Health Canada Patent Register provides a drop-down menu list of medicines and brand names on the register, from which users can choose the product of interest. Searches may only be conducted using one option at a time (i.e. by Medicine or Brand Name).

Step 2

The search results will display the brand name, strength of the dosage used in the marketed product, dosage form, DIN (drug identification number) and patent number(s) related to the product (see Figure 14).

All the patent numbers thus obtained (see list in Figure 14) should be noted down, as it will be necessary to obtain the patent specification for each one (see Section 4.3) in order to identify its subject matter and relevance.

To obtain more detailed information such as the filing and expiry date(s) of the listed Canadian patents, users can click on the links provided under the column-heading DIN (see Figure 15).
Figure 13: Health Canada Patent Register search page

Drop down menu of generic and brand names listed on Health Canada and an option to search by patent number.

Figure 14: Health Canada Patent Register search results for abacavir

Click here to access more detailed information about the listed Canadian patents (see Fig. 15).

Granted Canadian patent numbers.
Figure 15: Health Canada Patent Register detailed patent information for abacavir
4.3 Obtaining copies of patent documents listed in the Orange Book and Health Canada Patent Register

Once the patent numbers from the Orange Book and/or Health Canada have been obtained, it is recommended that a full copy of the US and/or Canadian patent document be retrieved. This is so that the subject matter covered by each listed patent can be identified.

Two other key reasons for obtaining copies of the relevant US or Canadian patent(s) before embarking on more expansive searches and locating related patent(s) in other countries are:

- A significant number of patents on medicines claim priority from filings first made in the United States. As will be discussed in Chapter 5, in some cases, matching patents from other countries with those in the Orange Book is made easier when the priority number is known.

  Matching priority data from Canadian patent documents can sometimes be a much simpler process than from US patent documents. This is because priority claims are often based on a continuation, continuation-in-part or provisional application number made in the United States, and not on the actual US patent application number. As continuation, continuation-in-part or provisional application numbers are usually found in the main text of a US patent document, rather than in the bibliographic data on the front page, it can be more time efficient to view the front page of a Canadian patent for the priority data.

- Despite their technical nature, reviewing the body of a patent document and claims of the US and/or Canadian patent can be useful for learning about the product and the science behind it. Adopting this practice can also help in identifying key terms or specific chemical names used by applicants that might be helpful when trying to conduct further patent searches related to the product. This will be discussed in more detail below (see Section 4.5).

The most straightforward way to obtain US and Canadian patent information is through the respective online patent office databases:


Both databases provide a basic search option whereby users can insert the relevant patent number into a field. However, neither allows users to download complete PDF versions of patent documents.
4.3.1 Using esp@cenet to obtain US and Canadian patent documents

To obtain complete PDF versions of patent documents, the patent database of the European Patent Office (EPO), esp@cenet, can be used. Esp@cenet maintains bibliographic data for patents from over 90 countries and regions, including Canada and the United States. The esp@cenet database also allows users to download complete PDF versions of patent documents from a number of countries, including Canada and the United States.

The following steps demonstrate how to download a PDF version of US or Canadian patent document from esp@cenet:

Step 1
Enter the URL: http://ep.espacenet.com/ to access the main page of esp@cenet (see Figure 16).

Click on the option Number Search to be directed to the databases and search options.

Step 2
The Number Search page is divided into two parts (see Figure 17).

Database
Under the heading Database, the user is provided with the option Select a Patent Database. The drop-down menu provides the following database options:

- EP esp@cenet—this database enables users to search European patents published by the EPO over the last 24 months. European patent publications older than 24 months should be searched using the Worldwide database.
- Worldwide—allows users to search for published patent information from over 90 countries.
- WIPO—provides access to patent applications published by WIPO in the last 24 months.

For the purpose of searching Canadian and US patents, select the Worldwide database.
A step-by-step guide

**Figure 16:** Front page of esp@cenet

![Front page of esp@cenet](image)

**Figure 17:** Esp@cenet number search

![Esp@cenet number search](image)
**Enter number**

Beneath the option *Select a Patent Database* is a search field marked *Number*. This is the field for entering the number of the patent to be searched.

Insert the patent number(s) obtained through the Orange Book and/or Health Canada in the search field. Ensure there is no space between the country code and patent number. For illustration, the first patent number (US patent No. 5034394) from the Orange Book listing for abacavir shown in Figure 12 is used. This patent number should be entered as US5034394.

The search field accepts application, publication (including granted published patents) or priority numbers, with or without a country code prefix. To retrieve more precise results, it is suggested that users include a country code prefix. It is possible to search up to four publication numbers at a time.

**Step 3**

The search should return a list of results comprising basic bibliographic data and a link for US patent No.5034394 (see Figure 18).

Click on the title of the patent (in this example *Therapeutic nucleosides*) to access more detailed data and the option for downloading a complete copy of the specification and claims.

**Step 4**

Esp@cenet should then display a page comprising bibliographic data and a number of other information options relating to US patent No. 5034394 (see Figure 19).

To download the complete patent document for US patent No. 5034394, click on the tab *Original document*.

A prompt may appear asking the user to save the file. However, as this option only downloads the first page of the patent document, press *Cancel* and then click on the link *Save Full Document* as shown in Figure 20. Another prompt will appear requesting a number code to be entered. Enter the number code provided and another window will appear asking the user to *Open* or *Save* the file. Press either option and the complete version of the patent document will be opened/saved (see Figure 21).
Figure 18: Esp@cenet number search result list for US patent No. 5034394

Click on the title of the patent to access more detailed data and to download the patent document.

Figure 19: Esp@cenet bibliographic data and patent document download option for US patent No. 5034394

View the text of the technical information and claims

Click here to download a complete PDF version of the patent document

Priority data, as formatted for esp@cenet
Figure 20: Esp@cenet link to download full PDF version of a patent document

Note: As shown in Figure 19, it is possible to obtain priority information for the patent in view from the bibliographic data.

However, the format of the priority numbering in esp@cenet’s bibliographic data is often different from how it is recorded by other national patent offices. As a result, it may be difficult to make a direct match when using other patent office databases or reviewing patent office journals.

Example: the priority number for US patent No. 5034394 is presented as GB19880015265 in esp@cenet, but is referenced as GB8815265 in other databases. Downloading the original patent document is usually helpful to overcome such differences.

The tabs Description and Claim, as shown in Figure 19, allow users to review the text of the technical information and claims of the patent in view without having to download the complete document. Where the text and claims are not available in English, esp@cenet will either provide the text of an equivalent patent that is in English, or provide users the option to translate the text.
Once the patent data and complete specification have been obtained, through esp@cenet, for a patent listed in the Orange Book and/or Health Canada, the user should have sufficient information to find related patents in other countries. Methods and techniques for locating equivalent and related patents in other countries are discussed in Chapter 5.

However, before proceeding to Chapter 5 it is important to note that there are limitations to relying solely on the Orange Book and Health Canada to find all potential patents that may impact procurement or local manufacturing decisions. The following sections discuss these limitations and suggest additional search techniques that may be used to fill those gaps.

**Figure 21:** Front page of the complete patent document for US patent No. 5034394 as downloaded from esp@cenet

![Front page of the complete patent document](image-url)
4.4 Limitations of relying on the Orange Book and Health Canada Patent Register to identify patents

The Orange Book and the Health Canada Patent Register do not cover all medicines marketed globally, but only products approved and sold in the United States and Canada. As a result a number of medicines and their related patents may be missing. For example, many if not all drugs for neglected diseases such as malaria, sleeping sickness and Chagas disease are unlikely to appear given that there is no commercial market for such products in Canada and the United States. Many fixed-dose combinations of antiretrovirals (ARVs) may also be missing. Although products that fall under the category of biologicals (i.e. vaccines and biotech drugs) are largely missing from the Orange Book, they do appear to be listed on Health Canada. However, there is no certainty that all such products will be included.

Second, only granted patents can be listed on the Orange Book and Health Canada. Therefore, there will be situations where an NDA, NDS or SNDS has been approved, but the related patent is still pending. Such patents will not be included in the Orange Book or Health Canada Patent Register until they are granted. Indeed, it may be the case that the relevant patent will not be granted in the United States or Canada, but nevertheless it may have been filed and granted in another country. An example of such a scenario may be a patent for a new formulation for an already marketed drug.

Third, the FDA’s maintenance of the Orange Book is only administrative and does not include ensuring that listings are accurate. Also, there is no obligation on companies to provide information on process patents or on patents for intermediates of a product. As for Health Canada, originators are not under any obligation to list patents with an NDS or SNDS. Even where companies list relevant patents on Health Canada, as for the Orange Book, they are not permitted to list patents covering processes, metabolites and intermediate compounds. Therefore, interested parties seeking information on such patents will need to conduct further searches (see Section 4.5 and Chapter 5). Such information will be particularly important for local manufacturers who may need to identify the relevant process and intermediate patents in order to be sure the processes used do not infringe any patent.

4.5. Search techniques for expanding on Orange Book and Health Canada patent listings

As more and more patent information is becoming digitized in online databases with different data fields, there are a number of techniques that may used to conduct more expansive searches. These techniques can be particularly important for identifying patents covering new formulations and combinations
of existing medicines whose key patents (as identified in the Orange Book or Health Canada) may not have been filed in other countries.

The search techniques discussed here are using:

- Keywords (text queries)
- Applicant(s)/Assignee(s) and inventor name(s)
- Patent classification
- Citations and reference to earlier patents
- Date ranges

It is worth mentioning again, because patent searching is a continually iterative process, the search techniques described here have to be refined throughout the search process for the best results. This means using any one or more of the techniques at a time in different data fields to obtain a broad or narrow set of results. Through this process, the searcher should be able to retrieve patents that may be relevant to a particular medicinal product. However, unlike patents listed in the Orange Book or Health Canada, the patents identified through the above techniques will ultimately have to be evaluated for relevance through an expert analysis of the claims.

4.5.1 Keyword searching

Keyword/text queries are searches using words that may appear in a patent document describing the subject matter, technology or problem that the claimed invention is designed to solve.

A keyword could for example be:

- the initial code name given to a drug during the research stage (e.g. TMC 278 for rilpiverine)
- the INN of an active ingredient (e.g. abacavir)
- a technology used in formulation (e.g. melt-extrusion)
- a disease the invention works against (e.g. malaria or HIV)

Most online patent databases allow for some form of keyword searching. However, databases may vary in terms of the word search operators (Boolean operators) and truncation limiters (wildcards) available for use. Tables 1 and 2 provide examples of the more common operators available in patent databases. However, not all databases offer all these operators. There may also be differences in whether the database permits users to search only the bibliographic data or also the technical information and claims of a patent specification. As many developing country patent office databases do not yet provide online access to the text of complete patent documents, in such cases it will only be possible to search the bibliographic data.
Table 1: Word/Boolean operators found in patent databases

<table>
<thead>
<tr>
<th>Boolean Operator</th>
<th>Function</th>
</tr>
</thead>
</table>
| AND              | Retrieves records containing both the words searched. The use of AND provides a narrow search.  
*Example*: ritonavir AND lopinavir would capture all data/specifications including both these terms. |
| ANDNOT (or NOT)  | Retrieves records containing only one of the words searched. The use of ANDNOT or NOT serves to provide a narrow search.  
*Example*: ritonavir ANDNOT lopinavir would capture all data/specifications including only the term ritonavir but not lopinavir. |
| OR               | Retrieves records containing either of the words searched, or both. The use of OR serves to broaden a search.  
*Example*: ritonavir OR lopinavir would capture all data/specifications including either ritonavir, or lopinavir, or both ritonavir and lopinavir. |
| XOR              | Retrieves records containing either of the words searched, but not both. Provides for a narrow search.  
*Example*: ritonavir XOR lopinavir would capture all data/specifications including either ritonavir or lopinavir, but not both ritonavir and lopinavir. |
| NEAR             | Retrieves records containing all words searched, within a certain number of words of each other. In most databases, NEAR is equivalent to within 10 words.  
*Example*: artemisinin NEAR malaria would capture data/specifications containing both words within a given number of words from each other. |
| ADJ              | Retrieves all words searched that appear next to one another in the order specified or within a prescribed number of words. |
| WITH             | Retrieves all words searched that appear within the same sentence. |
| SAME             | Retrieves all words searched that appear in the same paragraph. |

Table 2: Truncation symbols found in patent databases

<table>
<thead>
<tr>
<th>Truncation symbols</th>
<th>Function</th>
</tr>
</thead>
</table>
| *                  | Truncation symbols serve to shorten the principal root (or stem) of a word. This technique captures an unlimited or prescribed number of characters in front (left truncation) or behind (right truncation) of the principal root of a word, enabling the user to expand the scope of a search.  
*Example*: arte* would capture all data/documents including artemisinin, artemisinic acid, artemether, artesunate, arteether, artemotil. |
| ?                  | |
| $                  | |
| %                  | |
In addition to Boolean operators, some databases also permit the use of Nested Queries or Nesting. Nested queries use parentheses to specify the order in which the search terms in conjunction with Boolean operators should be interpreted. Words appearing within the parentheses will be read first followed by the terms outside of the parentheses.

*Example:* (ritonavir OR lopinavir) AND HIV will capture all data/specifications with the words ritonavir and/or lopinavir plus HIV.

*Example:* artemisinin AND (malaria OR protozoan) will capture all data/specifications with the word artemisinin and either the word malaria or protozoan.

It may also be possible to search for phrases within data/documents by surrounding a group of words in quotation marks. This technique allows users to search for multi-word phrases without having to specify each word separately.

*Example:* “ritonavir lopinavir”

The effectiveness of a keyword search is often dependent on how much knowledge the searcher has of the relevant subject matter. For example, reviewing the specifications of patents listed on the Orange Book and/or Health Canada, or scientific literature about a particular product, can help improve keyword searches. This is because patents or literature written by the applicant often use particular keywords that may also appear in subsequent patents. Therefore, it is advisable to do as much background reading as possible about a particular medicine before embarking on a keyword search.

As will be shown in the examples at the end of this section and in Chapter 5, carrying out keyword searches is extremely useful and important for two reasons. First, as already mentioned, they can be used to locate patents not listed in the Orange Book or Health Canada. Additionally, such searches can be useful to locate patents equivalent to those listed in the Orange Book or Health Canada in a third country’s online patent office database that does not provide an option to search by priority data.

### 4.5.2 Searching by applicant/assignee and inventor name(s)

Most developing country online patent office databases allow users to search by applicant/assignee or inventor name(s).

This option can be useful when little prior information is available about a particular medicine. For example, searching by applicant/assignee can provide a broad set of results from which a searcher may be able to locate
some relevant patents. Such searches can also provide an understanding of the patenting activities of a specific company.

Alternatively, combining a keyword search with an applicant/assignee or inventor name can narrow a set of results (see examples below).

It is important to note that a single applicant may appear under different names as a result of abbreviation or a misspelling. To help avoid missing important data/specifications, additional searches should make use of the keyword searching techniques discussed above.

4.5.3 Searching by patent classification

As already discussed in Chapter 2 (see Box 2, page 16) all patent documents and claimed inventions are individually classified into technology groups and hierarchical sub-groups according to a standardized system.

Most patent databases allow users to search by classification. However, searching by classification is only useful if accompanied by a keyword, an applicant/assignee or inventor name. Simply searching using a classification code for pharmaceutical products alone would retrieve too many records.

4.5.4 Citation searching

Patent documents will often contain references (citations) to earlier patents or literature disclosed by an applicant as known prior art or found by a patent examiner during examination. For example, patent Y claiming a new formulation of the drug abacavir might cite patent X, which first disclosed the base compound for the drug.

Databases that allow the text of specifications to be searched will usually allow for what are known as backward and forward citation searching. Using the example above, if patent X is cited by patent Y, this would be known as a backward citation. Patent Y would be considered a forward citation of patent X.

Citation searching can be invaluable for demonstrating the evolving patent landscape of a particular drug. As mentioned above, there are likely to be several patents filed on one medicine and chances are they will cite some of the related patents. Using patent information from the Orange Book (most citations for pharmaceutical patents will be to either US or EU patents) and patent families, it may be possible to conduct citation searches to locate subsequent patents that may claim an improvement. Coupled with keywords and applicant/assignee details, citation searches can be narrowed to meet a desired result. This particular search technique can also help identify alternative terms about a technology for conducting further searches.
One note of caution with citations in patent documents; applicants and examiners may not cite all relevant patents or may cite earlier patents that are irrelevant.

References to earlier patents and literature usually appear in the section of the patent document titled *Background to the Invention or Description*. As a result, backward citation searching is only possible if the patent database allows the complete patent document to be searched. For an illustration of citation searching, see example 4.4 on page 63.

### 4.5.5 Searching by date ranges

As patent documents contain filing dates, publication dates and priority dates, it is possible to search using a range of dates in some databases.

Databases that offer the ability to search by a range of dates may use different operators. Typical operators are: greater than (>), less than (<), greater than or equal to (>=), less than or equal to (<=) and unequal to (<>). WIPO’s Patentscope database uses the operator -> to specify a range of dates, e.g. 20000101->20090101 (between 1 January 2000 and 1 January 2009).

Combining a date range alongside another data field, such as applicant name or a keyword, can be helpful when trying to narrow a set of records to a particular period.

The following examples illustrate some of the above techniques using the Patentscope, esp@cenet and the Indian Patent Office databases. These databases have been selected because they allow users to search by one or more of the techniques discussed. WIPO’s Patentscope database holds records of PCT applications dating back to 1978 and allows for searches using several search fields. Patentscope also allows users to search the text of PCT patent specifications, download PCT patent specifications, and access useful information concerning national phase data of PCT applications. Esp@cenet offers similar search features to Patentscope, but is not limited only to PCT applications. See also Box 3 (page 22) and Appendix III for other online databases that offer free access.

**Example 4.1 – Search for “abacavir” using WIPO’s Patentscope database**

*Step 1*

To access the structured search page of Patentscope, enter the URL: http://www.wipo.int/pctdb/en/search-struct.jsp
The structured search page provides a choice of 33 data fields that a user can select to form the basis of a search. Patentscope also provides 11 search fields that can be used for any one search.

In the search field next to the data field Description (which allows users to search the main body of patent specifications in the database), enter the term abacavir (see Figure 22).

As of the time of writing, the search returns a list of 2068 records (see Figure 23).

**Figure 22:** Patentscope search for “abacavir” using description data field

**Figure 23:** Patentscope search results for “abacavir” using description data field
**Step 2**

The initial search results provide a broad set of results, but can be narrowed as desired.

For example, by adding an applicant name (e.g. Glaxo), to the original search for the term abacavir (see Figure 24), the search (at the time of writing) returns only 28 results (see Figure 25).

**Figure 24:** Patentscope search for “abacavir” using description field and applicant name

![Patentscope search for “abacavir” using description field and applicant name](image)

**Figure 25:** Patentscope search results for “abacavir” using description field and applicant name

![Patentscope search results for “abacavir” using description field and applicant name](image)
Alternatively, it is possible to narrow the results further to target patent documents that include the term abacavir in the claims. This can be done by selecting the data field \textit{Claims} and adding the term abacavir in the associated search field (see Figure 26). The results of the search then narrow to seven hits (see Figure 27).

\textbf{Figure 26:} Patentscope search for “abacavir” using description, claim data fields and applicant name

\textbf{Figure 27:} Patentscope search results for “abacavir” using description, claim data fields and applicant name
Click on the link for the application of interest to view further details.

**Step 3**

After one has clicked on the link for the application of interest, Patentscope takes the user to a page providing the bibliographic data of the patent (see Figure 28). In addition to the bibliographic data, Patentscope provides various tabs where users can access the following information:

- **Description**—provides access to the text of the patent document, which includes the technical information, examples and other descriptions relating to the claimed invention (see Figure 29).

- **Claims**—provides access to the original claims filed for the application (see Figure 30). As international applications will be examined by the national patent offices of the countries designated in the application, these claims may be amended or refused entirely.

- **National phase**—provides details of selected countries where the international application has entered the national phase, and the current status (see Figure 31).

If the listed country has an online patent database, WIPO may provide a direct link to the national phase application. As will be discussed further in Chapter 5, this can be a useful way to identify if a patent exists in one of the designated states of an international application. However, **only information from countries that make their data available to WIPO will be listed.** Also, as with all databases, the information may not always be up to date.

Note: Although not mentioned in Patentscope, it is worth noting that the US national phase application of this PCT application was abandoned. As a result, this patent will not be granted in the United States and will not appear in the Orange Book. Also, the national phase application in Canada (application No. 2330391) does not appear among the patents listed for abacavir in Health Canada as shown in Figure 14 above. Furthermore, the application for a European Patent was withdrawn, whereas in New Zealand it was granted as patent No. 507745.

- **Notices**—provides information on any amendments made to the application after publication.

- **Documents**—provides access to PDF versions of the international patent document and the related International Search Authority report.
Figure 28: Patentscope bibliographic data for PCT application No. WO/1999/055372
A step-by-step guide

**Figure 29:** Patentscope description for PCT application No. WO/1999/055372

**Figure 30:** Patentscope claims for PCT application No. WO/1999/055372
**Figure 31:** Patentscope national phase data for PCT application No. WO/1999/055372
Example 4.2 – Search for patent applications using “HIV protease” or applicant name “Abbott” in the Indian Patent Office online database

**Step 1**

Enter the following URL to access the Indian Patent Office online database: http://ipindia.nic.in/ipirs/patentsearch.htm

Select the option *Published Patent Applications* which appears in the left-hand side of the screen. (NB: The Indian Patent Office provides a separate option for searching granted patents. For a discussion on how to search for granted patents in India, see Chapter 5).

After clicking the option *Published Patent Applications*, two further options will appear, one for a *Quick Search*, the other for an *Advanced Search*.

The *Quick Search* only allows users to search one search field at a time, e.g. either *Applicant Name* or *Abstract* or *Journal Number*.

For this example, the option *Advanced Search* is used. The Advanced Search option provides eight data fields and two search fields for searching. The Boolean operators available are *AND*, *OR* and *AND NOT*. Under the option *Location* users have the option to search applications filed with the four branches of the IPO or by a specific branch (i.e. Chennai, Delhi, Kolkata and Mumbai).

Select one of the data fields from the drop-down menu. For this example the data field *Abstract* is chosen. Enter the words *HIV Protease* in the opposite search field.

To conduct a broad search, select the Boolean operator *OR*.

From the second of the two data fields, select the option *Applicant Name*. Insert the name *Abbott* in the search field (see Figure 32).

**Figure 32:** Indian Patent Office search for “HIV protease” or applicant name “Abbott”
Step 2

The search should return all patent publications that contain the words *HIV Protease* within the abstract or the applicant name Abbott (see Figure 33).

Given the general nature of the words *HIV Protease* and use of the Boolean operator *OR*, the search returns a broad set of results—197 in this case (see Figure 33). As the Indian Patent Office database only provides a relatively limited number of search and data fields, conducting broad searches may be necessary to capture the patents of interest.

To view the bibliographic details of the patents listed, click on the application number, as shown in Figure 33. The bibliographic details of the application will be presented as shown in Figure 34.13

**Figure 33:** Indian Patent Office search results for “HIV Protease” or applicant “Abbott”

---

13 As of this writing, the Indian Patent Office database does not provide the option to view the full specification of a published application. Copies of patent applications, published 18 months after the priority date, can be requested from the relevant patent office branch where the application was filed, on payment of an official fee. In the case of the example provided in Figure 34, as the application was filed with the Chennai branch, any request for the specification must be made to that office.
Example 4.3 – Search using IPC classification code A61P 33/18 for HIV and applicant name “Tibotec” using esp@cenet database

Step 1
Enter the URL: http://ep.espacenet.com/ to access the front page of esp@cenet.

Click on the option Advanced Search to access the database search options (see Figure 35).

Select Worldwide for the patent database. Enter the applicant name (i.e. Tibotec) in the search field next to the data field marked Applicant(s). In the search field next to the data field International Patent Classification (IPC), insert the IPC code A61P33/18 for HIV (see Figure 36).
How to conduct patent searches for medicines

Figure 35: Front page of esp@cenet database

Click here to access Advanced search

Figure 36: Esp@cenet advanced search for IPC classification code “A61P31/18” and applicant name “Tibotec”

Select Worldwide patent database

Enter applicant name

Enter IPC classification code
**Step 2**

The search will retrieve all patents available in esp@cenet in the name of Tibotec with the IPC classification code for chemical compounds with therapeutic activity relating to HIV (see Figure 37).

The bibliographic data, complete patent documents (where available) and patent family data can be viewed by clicking on the title of a particular patent (using the steps described in Section 4.3 of this guide).

Searching by *sub-class* and *Applicant name* is useful for obtaining broad coverage of a company’s patent portfolio in a particular therapeutic class.

**Example 4.4 – Citation search using WIPO’s Patentscope database**

**Step 1**

Select a patent number for a product from the Orange Book, using the steps described in Section 4.2.1 (Figures 8-12).

For the purpose of this example, US patent No. 5935946 for the active ingredient tenofovir disoproxil fumarate is used (see Figure 38).

Proceed to the structured search page of WIPO’s Patentscope database, as demonstrated in example 4.1 (Figure 22).

Insert the number 5935946 in the search field next to the data field *Description* (see Figure 39). As mentioned above, citations to earlier patents appear only in the patent document itself. For this reason, the search has to be conducted using the data field *Description*.

**Step 2**

Figure 40 shows international patent applications citing US patent No. 5935946.

Results 3 and 4 of the search show two applications by Gilead Sciences that appear to cover a combination of products. Neither of these patents features in the Orange Book listings shown in Figure 38.

By clicking on the title and selecting the tab *Description*, users can review the body of the specification and the earlier cited patents, which will be highlighted in the text. As Figure 41 shows, PCT application No. WO 2004/064845 cites US patent No. 5935946 and other relevant patents that may not be listed in the Orange Book (e.g. US patent No. 6069249).

As will be discussed further in Chapter 5, once the information from an international patent has been found there are various methods for identifying whether similar or related patents exist in a country of interest.
**Figure 37:** Esp@cenet advanced search results for IPC classification code “A61P31/18” and applicant name “Tibotec”
**Figure 38:** Orange Book patent listings for tenofovir disoproxil fumarate

![Patent and Exclusivity Search Results from query on Appl No:01356 Product 001 in the OB Rx list.](image1)

- Select a patent number

**Figure 39:** Patentscope citation search for US patent No. 5935946

![Patentscope citation search for US patent No. 5935946](image2)

- Ensure the data field Description is selected
Figure 40: Patentscope search results for international patents citing US patent No. 5935946
A step-by-step guide

**Figure 41:** Patentscope description for international publication No. WO 2004/06484

67

Citation of earlier patents
How to find patents in developing countries

Locating patents in developing countries that are equivalent or related to those found in the Orange Book, the Health Canada Patent Register or through the extended searches described in Chapter 4 is not a straightforward process.

One reason is that the patent family and national phase data available in esp@cenet and Patentscope do not cover all countries where the patent may have been filed. Only information that the EPO or WIPO has been able to obtain from countries will be available. Also, there are only a handful of online searchable databases or patent journals provided by developing country patent offices (see Appendix III). Even where developing country patent offices offer an online searchable database, the data fields that are available to be searched are not as extensive as in esp@cenet or Patentscope. For example, there may not be a search field whereby the user can search by priority number. Key data may be omitted, incorrectly inputted or out of date, all of which can lead to an unsuccessful search. Finally, as complete specifications and claims for patents filed or granted in developing countries are rarely available online, in many cases they will have to be requested directly from the concerned national or regional patent office.

Ultimately, even if patent information for a particular developing country is available online, in most cases the search process will inevitably end with having to request a patent document from the relevant national or regional patent office.

Despite these limitations, in a number of developing countries it may still be possible to identify whether a patent exists using information available on the Internet. Having such information in hand can make the step of obtaining the relevant patent document from the national or regional patent office a much simpler process.
5.1 Using online patent databases

The following examples illustrate how to use patent information identified in Chapter 4 to check for equivalent or related patents in other countries.

Example 5.1: Using esp@cenet to find patents in other countries

For this example, refer to Figures 8-12 (Section 4.2.1) and Figures 16-21 (Section 4.3.1), which demonstrated how to locate patent listings for abacavir in the Orange Book and to obtain the patent document for US patent No. 5034394 using esp@cenet. Continuing from that example, the following steps set out some techniques for searching for patents in other countries that are equivalent or related to US patent No. 5034394.

Step 1

Having located US patent No. 5034394 on esp@cenet, it is now possible to view patents that are considered equivalent or which share the same priority application in other countries.

To view patents that are considered to be equivalent to US patent No. 5034394, esp@cenet provides a list under the heading Also published as (see Figure 42). For some records that have a large number of equivalent patents available, esp@cenet provides a link titled more>> which allows users to expand the list of equivalent patents available in esp@cenet (see Figure 42). By clicking on the thumbnail of the PDF logo, the user can download the patent document for a particular patent, if available, by following the steps shown in Figures 19 and 20.

As explained in Section 2.5, to view a broader and more comprehensive patent family for U.S patent No. 5034394, users should click on the option View INPADOC patent family (see Figures 43 and 44). Developing countries and regional patent organizations included in the INPADOC patent family may include Argentina, ARIPO (AP), Brazil (BR), China (CN), Colombia (CO), Indonesia (IN), Mexico (MX), OAPI (OA) and South Africa (ZA). However, the country information available in esp@cenet varies from patent to patent. Also, users should remember that the specifications and claims of the patents listed in the INPADOC patent family might not be exactly the same as for US patent No. 5034394.

Repeating steps 3 and 4 of section 4.3.1 (Figures 18–20), click on the link of the country of interest to view the bibliographic data and related patent document for each patent. By way of example, Figure 45 provides the bibliographic data for ARIPO patent number AP196A, Figure 46 the front page of the patent document for AP196A, and Figure 47 an extract of the claims from AP196A.
A step-by-step guide

Figure 42: Esp@cenet equivalent patent and INPADOC patent family links for US patent No. 5034394

Click on thumbnails to view equivalent patents

Click on the link more >> to view expanded list (as shown in Figure 43)

Figure 43: Esp@cenet equivalent patent list for US patent No. 5034394

Click here to view INPADOC patent family list (shown in Figure 44)
How to conduct patent searches for medicines

Figure 44: Esp@cenet INPADOC patent family for US patent family No. 5034394
Figure 45: Esp@cenet bibliographic data page for ARIPO patent No. AP196A

Click here to obtain legal status of AP196A.
NB: The legal status of applications may not always be available.
How to conduct patent searches for medicines
**Step 2**

If the relevant patent information is located in esp@cenet’s INPADOC patent family, it is necessary to check its legal status. This can be done by clicking on the tab **INPADOC Legal Status** as shown in Figure 45. The status of a patent will usually be indicated by one or more of the following terms depending on the country and stage of examination:

- **Assignment**—indicates the patent has been assigned and provides the current and previous proprietor.
- **Publication**—indicates that the application has been published (18 months after the priority or filing date).
- **Request of examination as to substance**—indicates that the applicant has requested examination of the application.
- **Granted**—indicates that the patent has been granted.
- **Certificate of Correction**—applies to US patents, indicating that an error in the patent specification has been rectified.
- **Supplementary Patent Certificate (SPC) Filed/Granted**—applies to European patents, indicating the application or grant of extension of the patent term.¹
- **Extension of Patent Term**—applies to US patents, indicating that the term of the patent has been extended beyond 20 years.²

However, for other countries the legal status of a patent application may not always be available or may not be up to date. It is recommended that the legal status and/or final claims as granted and shown in esp@cenet always be checked with the relevant national or regional patent office.

**Example 5.2: Using national databases to locate patents-Philippines**

Where esp@cenet INPADOC does not list the country of interest, it may be possible to locate the patent using a national patent office database (see **Appendix III** for online databases made available by national patent offices).

---

¹ Supplementary Patent Certificates (SPC) are available for products that have a basic patent in force that constitutes the active ingredient or a combination of active ingredients of a medicinal product (Articles 1 and 3 of Regulation (EC) No 469/2009). SPCs take effect at the end of the lawful term of the basic patent (20 years) and may not exceed a period of five years unless an extension is granted—in which case the extension of the SPC will be for an additional six months (Article 13). Extensions are granted when an authorized medicinal product that is protected by a patent has completed all the studies required in compliance with an agreed paediatric investigation plan (Article 36 of Regulation (EC) No 1901/2006). The INPADOC Legal Status screen provides information on SPCs of European patents using PRS (patent register service) codes. The current PRS codes can be obtained by entering the URL: [http://www.epo.org/patents/patent-information/raw-data/useful-tables.html](http://www.epo.org/patents/patent-information/raw-data/useful-tables.html) and clicking on the link **Table of all PRS codes available for SPCs**.

² Extensions of patent terms relate to patents that claim a product, a method of using a product or a method of manufacturing (USC 35 s156).
For example, the Intellectual Property Office of the Philippines provides an online searchable database called PhilPAT.

**Step 1**

Enter the URL: http://patents.ipophil.gov.ph/PatSearch/ and select the *Advanced Search* option.

The Advanced Search page provides five search and data fields (see Figure 48). The Boolean operators used by PhilPAT are AND and OR. PhilPAT also allows users to choose between searching for *All Occurrences* of a word or *As Separate Word*. As there are different types of patents (i.e. inventions and utility models), PhilPAT provides a drop-down menu under the heading *Category* from which the searcher can select the relevant type of patent. For pharmaceutical/biotech patents, the relevant option would be *Invention*. Alternatively the setting can be left as *All*, but this may return a wider set of results depending on the terms searched.

PhilPAT is one of the national patent office databases that enables users to search by priority data. When searching by priority number it may be necessary to input the priority number in various formats to obtain a result.

Select the option *Priority Number* and enter the priority number for US patent No. 5034394, e.g. 8815265 (see Figure 48).

**Figure 48:** PhilPAT database search by priority number 8815265
The search retrieves one result with the priority number 8815265 (see Figure 49). Click on the title of the patent *Therapeutic Nucleosides* to review the patent information (see Figure 50). Note that PhilPAT only provides access to the bibliographic data. To view the patent specification and claims, and to know whether the patent has been renewed, a request would have to be made to the Intellectual Property Office of the Philippines.

**Figure 49:** PhilPAT database search results for priority number 8815265

![PhilPAT database search results for priority number 8815265](image)

**Figure 50:** PhilPAT bibliographic data for Philippines patent No. 30647

![PhilPAT bibliographic data for Philippines patent No. 30647](image)
Step 2

Patent databases may not always retrieve all records for a particular search. There can be many reasons for this. For example, the priority number that is being searched may have been entered incorrectly or the database’s search function is not accurate. To obtain a more complete set of results, additional searches should always be conducted.

In the case of this example, searching the PhilPAT database using the title of the US patent No. 5034394 (i.e. *Therapeutic Nucleosides*) returns a number of other patents (see Figures 51 and 52).

**Figure 51**: PhilPAT database search for “Therapeutic Nucleosides”
Figure 52: PhilPAT database search results for “Therapeutic Nucleosides”

Figure 53: PhilPAT bibliographic data for Philippines patent No. 1198938847
By reviewing each patent it transpires that Philippines patent No. 1198938847 also claims priority from 8815265 (see Figure 53). Notably, patent No. 1198938847 has the same filing date but a different date of grant than patent No. 30647 (see Figure 50). In this case, as the filing dates are identical, these patents should expire at the same time.

**Figure 54:** Patentscope bibliographic data for international patent publication No. WO 2004/064845
Example 5.3: Checking for PCT national phase data in esp@cenet

This example continues from Example 4.4 on pages 63-67.

Step 1

Figure 40 on page 66 displays the Patentscope search results for international applications citing US patent No. 5935946.

Using international publication number WO 2004/064845 as an example, click on the title of the patent as shown in Figure 40 to access the bibliographic data and patent information (see Figure 54).

As mentioned above (Example 4.1, step 3), Patentscope provides national phase data for those countries that make their patent information available to WIPO. Click on the tab National Phase to view the national phase data for WO 2004/064845. Figure 55 shows that WO 2004/064845 has entered the national phase in the following designated developing countries: China, Mexico, Viet Nam and South Africa.

Figure 55: Patentscope national phase data for international patent publication No. WO 2004/064845
Using the reference numbers provided in Patentscope, users can contact the respective national patent office to obtain further information.

**Step 2**

Patentscope only provides limited national phase data. If the country of interest is not listed but was designated in the international patent application, it will be necessary to conduct further searches using other tools.

One way to do this is through esp@cenet’s INPADOC patent family, which may provide information about additional countries where WO 2004/064845 may have entered into the national phase.

Select the option *Number Search* from esp@cenet’s main page (see Figures 16 and 17). Using the Worldwide patent database, enter publication number WO2004064845, without any spaces or special characters (as shown in Figure 56).

The search yields one result. As shown in Figures 18 and 42-44, click on the title of the patent to access the bibliographic data and INPADOC patent family link. Click on the INPADOC patent family link to view the patent family.

The only additional information provided by esp@cenet in relation to a developing country is that W2004/064845 may have entered the national phase in Brazil (see Figure 57). However, on reviewing the bibliographic data (see Figure 58), it is apparent that the Brazilian national phase application may stem from a related international patent WO2004/064846, which shares the same priority numbers as WO2004/064845.

**Figure 56:** Esp@cenet number search for WO 2004/064845
Figure 57: Esp@cenet INPADOC patent family results for international patent number WO 2004/064845

Click here to access bibliographic data for Brazil

Figure 58: Esp@cenet bibliographic data for Brazilian national phase application No. PI 0406760

Compare priority data with information provided in Patentscope (shown in Figure 54). NB: The format of the priority number in esp@cenet may be different from that provided in Patentscope. E.g. the priority number US 20030440308 is written as 60/440,308 in Patentscope.
Example 5.4: Using national databases to locate PCT national phase applications - India

Step 1

An alternative method for identifying whether an international patent has entered the national phase and/or has been granted in a designated country is by using an online database provided by a national/regional patent office.

Using India as an example, the first step is to search the Indian Patent Office database of published patent applications (see Example 4.2 on page 59 for details on how to access the database). Select the data field Applicant Name and insert the applicant details (i.e. Gilead) as provided in the Patentscope record shown in Figure 54. Then select the Boolean operator AND, and the data field Abstract. In the search field, enter a distinctive term from the abstract of WO 2004/064845 as provided in Patentscope. For this example, the word tenofovir has been selected (see Figure 59).

As of this writing, the search retrieved four results (see Figure 60). The first two results share the same title as WO 2004/064845, i.e. Compositions and Methods for Combination Antiviral Therapy. Reviewing the bibliographic data of the two applications informs the searcher that Application No. 3383/DELNP/2005 derives from international publication number WO 2004/064845 (see Figure 61).

Figure 59: Indian Patent Office search for national phase application relating to WO 2004/064845
**Figure 60:** Indian Patent Office search results for national phase application relating to WO 2004/064845

**Figure 61:** Indian Patent Office bibliographic data for national phase application No. 3383/DELNP/2005 (deriving from WO 2004/064845)

International patent application and publication data confirms that this application derives from WO 2004/064845
Step 2

To establish whether a patent has been granted in India, return to the home page of the Indian Patent Office’s website (URL: http://ipindia.nic.in/ipirs/patentsearch.htm). Click on the option Application Status. Enter the national phase application number 3383/DELNP/2005 as shown in Figure 62. The search reveals that application No. 3383/DELNP/2005 has been abandoned under Section 21(1) of the Indian Patents Act (see Figure 63). It is important to note, when checking the status of an application, that there may be errors in the database. Hence, negative results are not conclusive. To be prudent, it is always worth requesting in writing confirmation of the status of an application from the patent office.

Figure 62: Indian Patent Office search for application status of application No. 3383/DELNP/2005 (deriving from WO 2004/064845)

Figure 63: Indian Patent Office search results for application status of application No. 3383/DELNP/2005 (deriving from WO 2004/064845)
It is also recommended to check in the granted patent database. This is done to double check in case of errors in the Application Status database and to verify whether the patent has been granted.

To search for patents granted in India, at the URL mentioned above, click on the option Granted Patents. Select the option Advanced Search. A new page will appear providing data and search field options mirroring the search options for published patent applications discussed in Example 4.2 on page 59. Following the process described in Example 4.2, select the data field Application Number and enter the application number 3383/DELNP/2005 in the text box. If the patent is granted, the granted patent number and other bibliographic data will be displayed. In this case, the search confirms that the patent has not been granted (see Figure 64).

**Figure 64**: Indian Patent Office granted patents search result for application No. 3383/DELNP/2005 (deriving from WO 2004/064845)

---

### 5.2 Using official patent office journals

Where patent information for the country of interest is not available in an online searchable database, an alternative but time-consuming method for locating patents is to review the official patent office journal (also referred to as gazette or bulletin) of the relevant national (or regional) patent office.

---

3 It is possible to view the entire specification and claims of granted patents in India, in HTML format.
All national and regional patent offices should provide some form of official office journal where applications and granted patents are published for public viewing. Official patent office journals are usually made available in hard copies or on a CD, and released at intervals. For example, the Intellectual Property Organisation of Pakistan usually releases its journal for published patent applications every seven days. Publication details of patents will typically be in the local language of the country or in the language in which legal proceedings are conducted.

Official patent journals can be obtained by mail from a patent office following payment of a subscription fee. Alternatively, it is possible to visit a patent office and search hard copies of journals on-site.

However, there is a small but growing number of countries that provide access to their patent journals online in a PDF or Word format (see Appendix III). Although search options in PDFs and Word documents are extremely limited and each journal will have to be reviewed individually, their availability in an electronic format does make searching easier.

It should be noted, journals available in electronic form might only begin from a particular year. Therefore, it may still be necessary to contact the national (or regional) patent office directly for details of patents that were published prior to the start of the online availability of journals. Also, some journals will only provide a minimum amount of information, such as the applicant name and title of the patent. Despite the fact that some journals only offer limited information, it may be possible to obtain further details about the relevance of a patent using some of the techniques discussed in Chapter 4.

The following example demonstrates how searching online patent office journals may be useful for identifying patents of interest.

**Example 5.5: Official Patent Gazette of the Intellectual Property Organisation of Pakistan**

*Step 1*

Enter the following URL to access electronic versions of the official patent gazette for published applications by Intellectual Property Organisation of Pakistan: http://www.ipo.gov.pk/Patent/PatentGazzette.aspx

As it is not possible to identify in advance the specific issue of the journal/gazette in which a patent of interest may have been published, it will be necessary to go through each one. While this is a time-consuming exercise, for countries that do not provide a searchable online database, this is the only way to identify relevant patents on medicines.
Click on the gazette of interest to download the PDF file (see Figure 65). Once the PDF version of the gazette is downloaded, it is possible to review the new applications for patents published in Pakistan (see Figure 66).

**Figure 65**: Intellectual Property Organisation of Pakistan Patents Gazette notifications

Click on a link to download the PDF version of a particular gazette

NB: The Intellectual Property Organisation of Pakistan also provides electronic documents, which list basic information for patents granted. The documents can be downloaded here: http://www.ipo.gov.pk/Patent/PatentGranted.aspx

**Step 2**

Figure 66 shows an extract from the official patent gazette of Pakistan published on 2 February 2008.
**Figure 66:** Extract from the Official Patents Gazette of Pakistan
2 February 2008

<table>
<thead>
<tr>
<th>Patent No.</th>
<th>Inventor/Company</th>
<th>Title of the patent application</th>
<th>Abstract</th>
</tr>
</thead>
</table>
| 252/1997 F. Hoffman-La Roche AG, Switzerland | “A physiologically active polyethylene glycol (PEG) – interferon (IFN) α conjugate” | (A61K, 47/48, C07K, 14/52)  
139345 | Physiologically active PEG-IFNα conjugates having a formula as follows: |
| 554/1997 Chiesi Farmaceutici SPA, Italy | “Ala-aminoacid amide” | (A61K, 3/165)  
139346 | The present invention relates to serjamide, glycaminamide, alaninamide and phenylalaninamide derivatives of formula I |
139347 | |
Using Application No. 139345 by F. Hoffmann La Roche for *A physiologically active polyethylene glycol (PEG) – interferon (IFN) conjugate* as an example, a person with knowledge of the field may be able to determine the subject matter of this patent by simply looking at the chemical structure provided.

If the information provided in the gazette is limited, further details that could help identify the subject matter of the patent may be obtained by searching for equivalent patent documents through esp@cenet or Patentscope. This would mean using the techniques discussed in Chapter 4, but now in inverse order—working back from the limited national data (gazette) to obtain the equivalent or related patents filed in other countries.

For this example, the esp@cenet database is used. Access the **Advanced Search** option for esp@cenet as shown in Figure 35.

Using the information provided for Pakistan application No. 139345, conduct a keyword search as shown in Figure 67. Note that the results of the search will depend on the terms selected. In the example shown here, a keyword search against the words *physiologically*, *conjugate* and the applicant name *Hoffmann* returns one result (see Figure 68).

**Figure 67:** Esp@cenet advanced search for keywords “Physiologically”, “Conjugate” and Applicant Name “Hoffmann”
Click on the title of the patent retrieved to review the bibliographic details (see Figure 69). As can be seen from the bibliographic details of the patent retrieved, the English title and abstract appear to relate to Pakistan application No. 139345. As the patent retrieved is for the Czech Republic (CZ), to obtain access to a patent document in English, click on the INPADOC patent family link.

From the INPADOC patent family list click on the title of the patent for Canada as shown in Figure 70. Although the title of the Canadian patent is not identical to Pakistan application No. 139345, the abstract is. It would appear that Canadian patent No. 2203480 (shown in Figure 71) might cover identical or similar subject matter, though of course this can only be determined once the patent document for application No. 139345 is obtained. Nonetheless, this exercise can be a useful way to obtain an impression of the subject matter that the published application may cover. This process can also help one to decide whether it is necessary to obtain a copy of the complete specification for the patent.
Figure 69: Esp@cenet bibliographic data for Czech Republic patent publication No. 9701679

Figure 70: Esp@cenet INPADOC patent family for Czech Republic patent publication No. 9701679
To access the full patent document for Canadian application No. 2203480, follow the steps discussed in Figures 19 and 20.

**Step 3**

Where the INPADOC patent family lists a Canadian patent (as in the example above), using this information to search the Health Canada Patent Register may help verify which marketed medicine the patent relates to.

To access the Health Canada Patent Register, follow step 1 described in Section 4.2.2. Enter Canadian patent No. 2203480 in the search field next to *Patent Number* (see Figure 13).

The search reveals that Canadian patent No. 2203480 is listed for the marketed product Pegasis® (peginterferon alfa-2a injection), used to treat hepatitis C (see Figure 72). Click on the links under *DIN* to obtain further product and patent details.
5.3 Obtaining patent information from national/regional patent offices using priority data

Where patent information for a developing country is not available using the techniques discussed above, it may be possible to locate patents using priority data. For example, by providing the priority number(s) for a patent relating to an Orange Book listing, a patent office may be able to match it to a patent filed locally.

It is worth noting that some developing country patent authorities may lack the resources to deal with specific requests or do not have systems in place to locate patents. For those countries where obtaining information is difficult, an alternative route is to use the service of a local patent lawyer. Although there is a cost involved, local patent lawyers can be helpful in retrieving patent information. However, it is important to check the credentials of local patent lawyers to ensure they are able to carry out the task required. A useful starting point is to search the Internet for legal services guides that rate law firms in the area of intellectual property around the world.
5.4 Obtaining patent specifications from national/regional patent offices

Once a patent is located using one of the methods described above, the next step is to obtain a copy of the concerned patent document to review the claims as filed and granted in the country of interest. Although having the patent numbers and basic bibliographic data may imply that a patent on a particular medicine exists in a country, it is still necessary to review the actual content of the relevant national patent to determine its scope.

Given that only a limited number of developing country patent offices provide online access to the full text of patent documents, in many instances it will be necessary to make a request directly to the relevant patent office. As patent claims can be refused partially or entirely during examination, or even after grant (e.g. as a result of a revocation), it is important to track the status of a patent once located. In a number of countries, this may require paying separate official patent office fees for a copy of the patent application as filed as well as for a certified copy of the final granted patent.

5.5. Ensuring patent information is up to date

Patents holders are required to pay renewal fees to maintain a patent. The timing of the payment of renewal fees varies from country to country, ranging from once a year to every four years. In some countries a renewal fee will also be due during the application phase in order to keep the patent application alive on the register. Depending on the status of the patent and the laws governing renewal payments, failure to pay the required renewal fee could result in the patent becoming abandoned or revoked. Note that patent laws may allow applicants or patent holders a grace period of six or more months after the due date for renewal within which to make payment. As many of the online patent databases may not be accurate in terms of providing whether an applicant or patent holder has paid the required renewal fees, it is worth checking with the national or regional patent office on an annual basis.

The status of patents may also change as a result of an opposition or revocation action. Although a patent may have been granted and renewed, it can still be revoked if a third party successfully invalidates it (through legal proceedings).

Therefore, whichever method is used to obtain patent information, it is imperative that the information is kept up to date.
The mere existence of a patent application or granted patent should not be taken as blocking the path to procuring or manufacturing generic versions of a medicine. For example, a patent covering a particular formulation, dosage form or process may not be infringed when an alternative dosage form of the same medicine is procured, or when a different production process is used. Only after the claims of the relevant patent(s) have been analysed will it be possible to assess this.

This guide only looks at how to find patents on medicines. The subject of patent claim interpretation and construction goes beyond the scope of this guide, and involves specialist subject areas; it is especially complex given the fact that laws and practices vary from one country to the next. For this reason, when analysing a patent, a lawyer familiar with the patent law of the country in question should be consulted. It is also recommended that persons skilled in the specific subject matter of the patent be involved.

It is worth bearing in mind, even where a patent or patent application calls into question whether a generic version of a medicine can be manufactured or procured, a number of options may be available. When there is reason to believe that the patent does not meet patentability requirements, one option may be to file an opposition or revocation action to ensure patent is not granted or is invalidated if already granted. Many patent laws allow for such interventions by third parties where there is evidence to suggest that a patent should not be or should not have been granted. However, such proceedings can take considerable time and expertise, and are dependent on whether there is sufficient evidence for challenging a patent.

Another option is negotiating directly with the patent holder, either for a reduction in the price of the medicine, or for a voluntary license to enable local manufacturing of the product. Compulsory licenses and government use authorizations are also options that are permitted under the TRIPS Agreement and that are available in most national patent laws.
Numerous considerations come into play when making decisions on whether there is freedom to procure or manufacture generic versions of a particular medicine. However, a fundamental part of the decision-making process is knowing which medicines are covered by patents. It is hoped that this guide will provide a useful starting point for navigating the various databases and obtaining the required patent information.
## Appendix I

### Paris Convention for the Protection of Industrial Property

Paris Convention (1883), revised at Brussels (1900), at Washington (1911), at The Hague (1925), at London (1934), at Lisbon (1958) and at Stockholm (1967), and amended in 1979 (Paris Union)

**Status on October 15, 2009**

<table>
<thead>
<tr>
<th>State</th>
<th>Date on which State became party to the Convention</th>
<th>Latest Act(^1) of the Convention to which State is party and date on which State became party to that Act</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albania</td>
<td>October 4, 1995</td>
<td>Stockholm: October 4, 1995</td>
</tr>
<tr>
<td>Algeria</td>
<td>March 1, 1966</td>
<td>Stockholm: April 20, 1975(^2)</td>
</tr>
<tr>
<td>Andorra</td>
<td>June 2, 2004</td>
<td>Stockholm: June 2, 2004</td>
</tr>
<tr>
<td>Angola</td>
<td>December 27, 2007</td>
<td>Stockholm: December 27, 2007</td>
</tr>
<tr>
<td>Antigua and Barbuda</td>
<td>March 17, 2000</td>
<td>Stockholm: March 17, 2000</td>
</tr>
<tr>
<td>Armenia</td>
<td>December 25, 1991</td>
<td>Stockholm, Articles 13 to 30: October 8, 1980</td>
</tr>
<tr>
<td>Australia</td>
<td>October 10, 1925</td>
<td>Stockholm, Articles 1 to 12: September 27, 1975</td>
</tr>
<tr>
<td>Austria</td>
<td>January 1, 1909</td>
<td>Stockholm, Articles 13 to 30: August 25, 1972</td>
</tr>
<tr>
<td>Bahamas</td>
<td>July 10, 1973</td>
<td>Stockholm, Articles 13 to 30: March 10, 1977</td>
</tr>
<tr>
<td>Barbados</td>
<td>March 12, 1985</td>
<td>Stockholm: March 12, 1985</td>
</tr>
<tr>
<td>Belgium</td>
<td>July 7, 1884</td>
<td>Stockholm: February 12, 1975</td>
</tr>
<tr>
<td>Belize</td>
<td>June 17, 2000</td>
<td>Stockholm: June 17, 2000</td>
</tr>
<tr>
<td>Benin</td>
<td>January 10, 1967</td>
<td>Stockholm: March 12, 1975</td>
</tr>
<tr>
<td>Bhutan</td>
<td>August 4, 2000</td>
<td>Stockholm: August 4, 2000</td>
</tr>
<tr>
<td>Bosnia and Herzegovina</td>
<td>March 1, 1992</td>
<td>Stockholm: March 1, 1992</td>
</tr>
<tr>
<td>Brazil</td>
<td>July 7, 1884</td>
<td>Articles 1 to 12: November 24, 1992</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>June 13, 1921</td>
<td>Stockholm, Articles 13 to 30: March 24, 1975(^3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Articles 1 to 12: May 19 or 27, 1970(^3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Articles 13 to 30: May 27, 1970</td>
</tr>
<tr>
<td>State</td>
<td>Date on which State became party to the Convention</td>
<td>Latest Act(^1) of the Convention to which State is party and date on which State became party to that Act</td>
</tr>
<tr>
<td>---------------------------</td>
<td>---------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Burkina Faso</td>
<td>November 19, 1963</td>
<td>Stockholm: September 2, 1975</td>
</tr>
<tr>
<td>Cameroon</td>
<td>May 10, 1964</td>
<td>Stockholm: April 20, 1975</td>
</tr>
<tr>
<td>Canada</td>
<td>June 12, 1925</td>
<td>Stockholm, Articles 1 to 12: May 26, 1996</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stockholm, Articles 13 to 30: July 7, 1970</td>
</tr>
<tr>
<td>Chad</td>
<td>November 19, 1963</td>
<td>Stockholm: September 26, 1970</td>
</tr>
<tr>
<td>Chile</td>
<td>June 14, 1991</td>
<td>Stockholm: June 14, 1991</td>
</tr>
<tr>
<td>China(^a)</td>
<td>March 19, 1985</td>
<td>Stockholm: March 19, 1985</td>
</tr>
<tr>
<td>Comoros</td>
<td>April 3, 2005</td>
<td>Stockholm: April 3, 2005</td>
</tr>
<tr>
<td>Congo</td>
<td>September 2, 1963</td>
<td>Stockholm: December 5, 1975</td>
</tr>
<tr>
<td>Côte d’Ivoire</td>
<td>October 23, 1963</td>
<td>Stockholm: May 4, 1974</td>
</tr>
<tr>
<td>Cuba</td>
<td>November 17, 1904</td>
<td>Stockholm: April 8, 1975</td>
</tr>
<tr>
<td>Cyprus</td>
<td>January 17, 1966</td>
<td>Stockholm: April 3, 1984</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>January 1, 1993</td>
<td>Stockholm: January 1, 1993</td>
</tr>
<tr>
<td>Democratic People’s Republic of Korea</td>
<td>June 10, 1980</td>
<td>Stockholm: June 10, 1980</td>
</tr>
<tr>
<td>Denmark(^b)</td>
<td>October 1, 1894</td>
<td>Stockholm, Articles 1 to 12: April 26 or May 19, 1970(^2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stockholm, Articles 13 to 30: April 26, 1970(^1)</td>
</tr>
<tr>
<td>Djibouti</td>
<td>May 13, 2002</td>
<td>Stockholm: May 13, 2002</td>
</tr>
<tr>
<td>Dominica</td>
<td>August 7, 1999</td>
<td>Stockholm: August 7, 1999</td>
</tr>
<tr>
<td>Dominican Republic</td>
<td>July 11, 1890</td>
<td>The Hague: April 6, 1951</td>
</tr>
<tr>
<td>Ecuador</td>
<td>June 22, 1999</td>
<td>Stockholm: June 22, 1999</td>
</tr>
<tr>
<td>Egypt</td>
<td>July 1, 1951</td>
<td>Stockholm: March 6, 1975</td>
</tr>
<tr>
<td>Estonia</td>
<td>August 24, 19946</td>
<td>Stockholm: August 24, 1994</td>
</tr>
<tr>
<td>Finland</td>
<td>September 20, 1921</td>
<td>Stockholm, Articles 1 to 12: October 21, 1975</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stockholm, Articles 13 to 30: September 15, 1970</td>
</tr>
<tr>
<td>France(^7)</td>
<td>July 7, 1884</td>
<td>Stockholm: August 12, 1975</td>
</tr>
<tr>
<td>Gabon</td>
<td>February 29, 1964</td>
<td>Stockholm: June 10, 1975</td>
</tr>
<tr>
<td>Germany</td>
<td>May 1, 1903</td>
<td>Stockholm: September 19, 1970</td>
</tr>
<tr>
<td>State</td>
<td>Date on which State became party to the Convention</td>
<td>Latest Act(^1) of the Convention to which State is party and date on which State became party to that Act</td>
</tr>
<tr>
<td>-----------------------</td>
<td>--------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Greece</td>
<td>October 2, 1924</td>
<td>Stockholm: July 15, 1976</td>
</tr>
<tr>
<td>Guatemala</td>
<td>August 18, 1998</td>
<td>Stockholm: August 18, 1998</td>
</tr>
<tr>
<td>Guinea</td>
<td>February 5, 1982</td>
<td>Stockholm: February 5, 1982</td>
</tr>
<tr>
<td>Guyana</td>
<td>October 25, 1994</td>
<td>Stockholm: October 25, 1994</td>
</tr>
<tr>
<td>Haiti</td>
<td>July 1, 1958</td>
<td>Stockholm: November 3, 1983</td>
</tr>
<tr>
<td>Holy See</td>
<td>September 29, 1960</td>
<td>Stockholm: April 24, 1975</td>
</tr>
<tr>
<td>Hungary</td>
<td>January 1, 1909</td>
<td>Stockholm, Articles 1 to 12: April 26 or May 19, 1970(^3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stockholm, Articles 13 to 30: April 26, 1970(^2)</td>
</tr>
<tr>
<td>Iceland</td>
<td>May 5, 1962</td>
<td>Stockholm, Articles 1 to 12: April 9, 1995</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stockholm, Articles 13 to 30: December 28, 1984</td>
</tr>
<tr>
<td>India</td>
<td>December 7, 1998</td>
<td>Stockholm: December 7, 19982</td>
</tr>
<tr>
<td>Indonesia</td>
<td>December 24, 1950</td>
<td>Stockholm, Articles 1 to 12: September 5, 1997</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stockholm, Articles 13 to 30: December 20, 1979(^2)</td>
</tr>
<tr>
<td>Iran (Islamic Republic of)</td>
<td>December 16, 1959</td>
<td>Stockholm: March 12, 1999(^2)</td>
</tr>
<tr>
<td>Iraq</td>
<td>January 24, 1976</td>
<td>Stockholm: January 24, 1976</td>
</tr>
<tr>
<td>Ireland</td>
<td>December 4, 1925</td>
<td>Stockholm, Articles 1 to 12: April 26 or May 19, 1970(^2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stockholm, Articles 13 to 30: April 26, 1970</td>
</tr>
<tr>
<td>Israel</td>
<td>March 24, 1950</td>
<td>Stockholm, Articles 13 to 30: April 26, 1970</td>
</tr>
<tr>
<td>Italy</td>
<td>July 7, 1884</td>
<td>Stockholm, Articles 12 to 15: April 26 or May 19, 1970(^3)</td>
</tr>
<tr>
<td>Jamaica</td>
<td>December 24, 1999</td>
<td>Stockholm: December 24, 1999</td>
</tr>
<tr>
<td>Japan</td>
<td>July 15, 1899</td>
<td>Stockholm, Articles 1 to 12: October 1, 1975</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stockholm, Articles 13 to 30: April 24, 1975</td>
</tr>
<tr>
<td>Jordan</td>
<td>July 17, 1972</td>
<td>Stockholm: July 17, 1972</td>
</tr>
<tr>
<td>Kazakhstan</td>
<td>December 25, 1991</td>
<td>Stockholm: December 25, 19912</td>
</tr>
<tr>
<td>Kenya</td>
<td>June 14, 1965</td>
<td>Stockholm: October 26, 1971</td>
</tr>
<tr>
<td>Kyrgyzstan</td>
<td>December 25, 1991</td>
<td>Stockholm: December 25, 19912</td>
</tr>
<tr>
<td>Lao People’s Democratic Republic</td>
<td>October 8, 1998</td>
<td>Stockholm: October 8, 1998(^2)</td>
</tr>
<tr>
<td>Latvia</td>
<td>September 7, 1993(^3)</td>
<td>Stockholm: September 7, 1993</td>
</tr>
<tr>
<td>Lebanon</td>
<td>September 1, 1924</td>
<td>London: September 30, 1947</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stockholm, Articles 13 to 30: December 30, 1986(^2)</td>
</tr>
<tr>
<td>Libyan Arab Jamahiriya</td>
<td>September 28, 1976</td>
<td>Stockholm: September 28, 1976(^2)</td>
</tr>
<tr>
<td>State</td>
<td>Date on which State became party to the Convention</td>
<td>Latest Act of the Convention to which State is party and date on which State became party to that Act</td>
</tr>
<tr>
<td>---------------------</td>
<td>---------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Liechtenstein</td>
<td>July 14, 1933</td>
<td>Stockholm: May 25, 1972</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>June 30, 1922</td>
<td>Stockholm: March 24, 1975</td>
</tr>
<tr>
<td>Malawi</td>
<td>July 6, 1964</td>
<td>Stockholm: June 25, 1970</td>
</tr>
<tr>
<td>Malaysia</td>
<td>January 1, 1989</td>
<td>Stockholm: January 1, 1989</td>
</tr>
<tr>
<td>Mali</td>
<td>March 1, 1983</td>
<td>Stockholm: March 1, 1983</td>
</tr>
<tr>
<td>Malta</td>
<td>October 20, 1967</td>
<td>Stockholm, Articles 13 to 30: December 12, 1977</td>
</tr>
<tr>
<td>Mauritania</td>
<td>April 11, 1965</td>
<td>Stockholm: September 21, 1976</td>
</tr>
<tr>
<td>Mexico</td>
<td>September 7, 1903</td>
<td>Stockholm: July 26, 1976</td>
</tr>
<tr>
<td>Monaco</td>
<td>April 29, 1956</td>
<td>Stockholm: October 4, 1975</td>
</tr>
<tr>
<td>Mongolia</td>
<td>April 21, 1985</td>
<td>Stockholm: April 21, 1985</td>
</tr>
<tr>
<td>Montenegro</td>
<td>June 3, 2006</td>
<td>Stockholm: June 3, 2006</td>
</tr>
<tr>
<td>Morocco</td>
<td>July 30, 1917</td>
<td>Stockholm: August 6, 1971</td>
</tr>
<tr>
<td>Mozambique</td>
<td>July 9, 1998</td>
<td>Stockholm: July 9, 1998</td>
</tr>
<tr>
<td>Namibia</td>
<td>January 1, 2004</td>
<td>Stockholm: January 1, 2004</td>
</tr>
<tr>
<td>Netherlands</td>
<td>July 7, 1884</td>
<td>Stockholm: January 10, 1975</td>
</tr>
<tr>
<td>New Zealand</td>
<td>July 29, 1931</td>
<td>London: July 14, 1946</td>
</tr>
<tr>
<td>Niger</td>
<td>July 5, 1964</td>
<td>Stockholm: March 6, 1975</td>
</tr>
<tr>
<td>Nigeria</td>
<td>September 2, 1963</td>
<td>Lisbon: September 2, 1963</td>
</tr>
<tr>
<td>Norway</td>
<td>July 1, 1885</td>
<td>Stockholm: June 13, 1974</td>
</tr>
<tr>
<td>Oman</td>
<td>July 14, 1999</td>
<td>Stockholm: July 14, 1999</td>
</tr>
<tr>
<td>Pakistan</td>
<td>July 22, 2004</td>
<td>Stockholm: July 22, 2004</td>
</tr>
<tr>
<td>Panama</td>
<td>October 19, 1996</td>
<td>Stockholm: October 19, 1996</td>
</tr>
<tr>
<td>Peru</td>
<td>April 11, 1995</td>
<td>Stockholm: April 11, 1995</td>
</tr>
<tr>
<td>Philippines</td>
<td>September 27, 1965</td>
<td>Lisbon: September 27, 1965</td>
</tr>
<tr>
<td>Poland</td>
<td>November 10, 1919</td>
<td>Stockholm, Articles 13 to 30: July 16, 1980</td>
</tr>
<tr>
<td>Portugal</td>
<td>July 7, 1884</td>
<td>Stockholm: April 30, 1975</td>
</tr>
<tr>
<td>Qatar</td>
<td>July 5, 2000</td>
<td>Stockholm: July 5, 2000</td>
</tr>
<tr>
<td>Romania</td>
<td>October 6, 1920</td>
<td>Stockholm, Articles 1 to 12: April 26 or May 19, 1970</td>
</tr>
</tbody>
</table>

How to conduct patent searches for medicines
<table>
<thead>
<tr>
<th>State</th>
<th>Date on which State became party to the Convention</th>
<th>Latest Act of the Convention to which State is party and date on which State became party to that Act</th>
</tr>
</thead>
<tbody>
<tr>
<td>Russian Federation</td>
<td>July 1, 1965&lt;sup&gt;1,11&lt;/sup&gt;</td>
<td>Stockholm, Articles 1 to 12: April 26 or May 19, 1970&lt;sup&gt;3,11&lt;/sup&gt;</td>
</tr>
<tr>
<td>Rwanda</td>
<td>March 1, 1984</td>
<td>Stockholm: March 1, 1984</td>
</tr>
<tr>
<td>Saint Kitts and Nevis</td>
<td>April 9, 1995</td>
<td>Stockholm: April 9, 1995</td>
</tr>
<tr>
<td>Saint Lucia</td>
<td>June 9, 1995</td>
<td>Stockholm: June 9, 1995</td>
</tr>
<tr>
<td>Sao Tome and Principe</td>
<td>May 12, 1998</td>
<td>Stockholm: May 12, 1998</td>
</tr>
<tr>
<td>Saudi Arabia</td>
<td>March 11, 2004</td>
<td>Stockholm: March 11, 2004</td>
</tr>
<tr>
<td>Senegal</td>
<td>December 21, 1963</td>
<td>Stockholm, Articles 1 to 12: April 26 or May 19, 1970&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
<tr>
<td>Senegal&lt;sup&gt;12&lt;/sup&gt;</td>
<td>April 27, 1992</td>
<td>Stockholm: April 27, 1992</td>
</tr>
<tr>
<td>Seychelles</td>
<td>November 7, 2002</td>
<td>Stockholm: November 7, 2002</td>
</tr>
<tr>
<td>Sierra Leone</td>
<td>June 17, 1997</td>
<td>Stockholm: June 17, 1997</td>
</tr>
<tr>
<td>Slovakia</td>
<td>January 1, 1993</td>
<td>Stockholm: January 1, 1993</td>
</tr>
<tr>
<td>South Africa</td>
<td>December 1, 1947</td>
<td>Stockholm: March 24, 1975&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
<tr>
<td>Spain</td>
<td>July 7, 1884</td>
<td>Stockholm: April 14, 1972</td>
</tr>
<tr>
<td>Sudan</td>
<td>April 16, 1984</td>
<td>Stockholm: April 16, 1984</td>
</tr>
<tr>
<td>Suriname</td>
<td>November 25, 1975</td>
<td>Stockholm: November 25, 1975</td>
</tr>
<tr>
<td>Swaziland</td>
<td>May 12, 1991</td>
<td>Stockholm: May 12, 1991</td>
</tr>
<tr>
<td>Sweden</td>
<td>July 1, 1885</td>
<td>Stockholm, Articles 1 to 12: October 9, 1970</td>
</tr>
<tr>
<td>Switzerland</td>
<td>July 7, 1884</td>
<td>Stockholm, Articles 13 to 30: April 26, 1970</td>
</tr>
<tr>
<td>Syrian Arab Republic</td>
<td>September 1, 1924</td>
<td>Stockholm: December 13, 2002&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td>Thailand</td>
<td>August 2, 2008</td>
<td>Stockholm: August 2, 2008</td>
</tr>
<tr>
<td>Tonga</td>
<td>June 14, 2001</td>
<td>Stockholm: June 14, 2001</td>
</tr>
<tr>
<td>Trinidad and Tobago</td>
<td>August 1, 1964</td>
<td>Stockholm: August 16, 1964</td>
</tr>
<tr>
<td>Tunisia</td>
<td>July 7, 1884</td>
<td>Stockholm: August 12, 1964</td>
</tr>
<tr>
<td>Turkey</td>
<td>October 10, 1925</td>
<td>Stockholm, Articles 1 to 12: February 1, 1995</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stockholm, Articles 13 to 30: May 16, 1976</td>
</tr>
<tr>
<td>State</td>
<td>Date on which State became party to the Convention</td>
<td>Latest Act of the Convention to which State is party and date on which State became party to that Act</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>---------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Uganda</td>
<td>June 14, 1965</td>
<td>Stockholm: October 20, 1973</td>
</tr>
<tr>
<td>United Kingdom13</td>
<td>July 7, 1884</td>
<td>Stockholm, Articles 1 to 12: April 26 or May 19, 1970</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>United Republic of Tanzania</td>
<td>June 16, 1963</td>
<td>Lisbon: Articles 13 to 30: June 16, 1963</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stockholm, Articles 13 to 30: December 30, 1983</td>
</tr>
<tr>
<td>United States of America14</td>
<td>May 30, 1887</td>
<td>Stockholm, Articles 1 to 12: August 25, 1973</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Venezuela (Bolivarian Republic of)</td>
<td>September 12, 1995</td>
<td>Stockholm: September 12, 1995</td>
</tr>
<tr>
<td>Viet Nam</td>
<td>March 8, 1949</td>
<td>Stockholm: July 2, 1976</td>
</tr>
<tr>
<td>Zambia</td>
<td>April 6, 1965</td>
<td>Lisbon: April 6, 1965</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stockholm, Articles 13 to 30: May 14, 1977</td>
</tr>
</tbody>
</table>

(Total: 173 States)

1 "Stockholm" means the Paris Convention for the Protection of Industrial Property as revised at Stockholm on July 14, 1967 (Stockholm Act); "Lisbon" means the Paris Convention as revised at Lisbon on October 31, 1958 (Lisbon Act); "London" means the Paris Convention as revised at London on June 2, 1934 (London Act); "The Hague" means the Paris Convention as revised at The Hague on November 6, 1925 (Hague Act).
2 With the declaration provided for in Article 28(2) of the Stockholm Act relating to the International Court of Justice.
3 These are the alternative dates of entry into force which the Director General of WIPO communicated to the States concerned.
4 The Stockholm Act applies also to the Hong Kong Special Administrative Region with effect from July 1, 1997, and to the Macau Special Administrative Region with effect from December 20, 1999.
5 Denmark extended the application of the Stockholm Act to the Faroe Islands with effect from August 6, 1971.
6 Estonia acceded to the Paris Convention (Washington Act, 1911) with effect from February 12, 1924. It lost its independence on August 6, 1940, and regained it on August 20, 1991.
7 Including all Overseas Departments and Territories.
8 Latvia acceded to the Paris Convention (Washington Act, 1911) with effect from August 20, 1925. It lost its independence on July 21, 1940, and regained it on August 21, 1991.
9 Ratification for the Kingdom in Europe, the Netherlands Antilles and Aruba.
10 The accession of New Zealand to the Stockholm Act, with the exception of Articles 1 to 12, extends to the Cook Islands, Niue and Tokelau.
11 Date of adherence of the Soviet Union, continued by the Russian Federation as from December 25, 1991.
12 Serbia is the continuing State from Serbia and Montenegro as from June 3, 2006.
13 The United Kingdom extended the application of the Stockholm Act to the Isle of Man with effect from October 29, 1983.
14 The United States of America extended the application of the Stockholm Act to all territories and possessions of the United States of America, including the Commonwealth of Puerto Rico, as from August 25, 1973.
## Appendix II

### PCT Contracting States

<table>
<thead>
<tr>
<th>Name of State followed by the two-letter code</th>
<th>Date on which State became bound by the PCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albania AL</td>
<td>4 October 1995</td>
</tr>
<tr>
<td>Algeria DZ</td>
<td>8 March 2000</td>
</tr>
<tr>
<td>Angola AO</td>
<td>27 December 2007</td>
</tr>
<tr>
<td>Antigua and Barbuda AG</td>
<td>17 March 2000</td>
</tr>
<tr>
<td>Armenia AM</td>
<td>25 December 1991</td>
</tr>
<tr>
<td>Australia AU</td>
<td>31 March 1980</td>
</tr>
<tr>
<td>Austria AT</td>
<td>23 April 1979</td>
</tr>
<tr>
<td>Azerbaijan AZ</td>
<td>25 December 1995</td>
</tr>
<tr>
<td>Bahrain BH</td>
<td>12 March 1985</td>
</tr>
<tr>
<td>Barbados BB</td>
<td>25 December 1991</td>
</tr>
<tr>
<td>Belarus BY</td>
<td>30 October 2003</td>
</tr>
<tr>
<td>Belgium BE</td>
<td>14 December 1981</td>
</tr>
<tr>
<td>Belize BZ</td>
<td>17 June 2000</td>
</tr>
<tr>
<td>Benin BJ</td>
<td>26 February 1987</td>
</tr>
<tr>
<td>Bosnia and Herzegovina BA</td>
<td>7 September 1996</td>
</tr>
<tr>
<td>Botswana BW</td>
<td>30 October 2003</td>
</tr>
<tr>
<td>Brazil BR</td>
<td>9 April 1978</td>
</tr>
<tr>
<td>Bulgaria BG</td>
<td>21 May 1984</td>
</tr>
<tr>
<td>Burkina Faso BF</td>
<td>21 March 1989</td>
</tr>
<tr>
<td>Cameroon CM</td>
<td>24 January 1978</td>
</tr>
<tr>
<td>Canada CA</td>
<td>2 January 1990</td>
</tr>
<tr>
<td>Central African Republic CF</td>
<td>24 January 1978</td>
</tr>
<tr>
<td>Chad TD</td>
<td>24 January 1978</td>
</tr>
<tr>
<td>Chile CL</td>
<td>2 June 2009</td>
</tr>
<tr>
<td>China CN</td>
<td>1 January 1994</td>
</tr>
<tr>
<td>Colombia CO</td>
<td>28 February 2001</td>
</tr>
<tr>
<td>Comoros KM</td>
<td>3 April 2005</td>
</tr>
<tr>
<td>Congo CG</td>
<td>24 January 1978</td>
</tr>
<tr>
<td>Costa Rica CR</td>
<td>3 August 1999</td>
</tr>
<tr>
<td>Côte d’Ivoire CI</td>
<td>30 April 1991</td>
</tr>
<tr>
<td>Croatia HR</td>
<td>1 July 1998</td>
</tr>
<tr>
<td>Cuba CU</td>
<td>16 July 1996</td>
</tr>
<tr>
<td>Cyprus CY</td>
<td>1 January 1998</td>
</tr>
<tr>
<td>Czech Republic CZ</td>
<td>1 January 1993</td>
</tr>
<tr>
<td>Democratic People’s Republic of Korea KP</td>
<td>8 July 1980</td>
</tr>
<tr>
<td>Denmark DK</td>
<td>1 December 1978</td>
</tr>
<tr>
<td>Dominica DM</td>
<td>7 August 1999</td>
</tr>
<tr>
<td>Dominican Republic DO</td>
<td>28 May 2007</td>
</tr>
<tr>
<td>Ecuador EC</td>
<td>7 May 2001</td>
</tr>
<tr>
<td>Egypt EG</td>
<td>6 September 2003</td>
</tr>
<tr>
<td>El Salvador SV</td>
<td>17 August 2006</td>
</tr>
<tr>
<td>Equatorial Guinea GQ</td>
<td>17 July 2001</td>
</tr>
<tr>
<td>Estonia EE</td>
<td>24 August 1994</td>
</tr>
<tr>
<td>Finland FI</td>
<td>1 October 1980</td>
</tr>
<tr>
<td>France FR</td>
<td>25 February 1978</td>
</tr>
<tr>
<td>Gabon GA</td>
<td>24 January 1978</td>
</tr>
<tr>
<td>Gambia GM</td>
<td>9 December 1997</td>
</tr>
<tr>
<td>Georgia GE2</td>
<td>25 December 1991</td>
</tr>
<tr>
<td>Germany DE</td>
<td>24 January 1978</td>
</tr>
<tr>
<td>Ghana GH</td>
<td>26 February 1997</td>
</tr>
<tr>
<td>Greece GR</td>
<td>9 October 1990</td>
</tr>
<tr>
<td>Grenada GD</td>
<td>22 September 1998</td>
</tr>
<tr>
<td>Guatemala GT</td>
<td>14 October 2006</td>
</tr>
<tr>
<td>Guinea GN</td>
<td>27 May 1991</td>
</tr>
<tr>
<td>Guinea-Bissau GW</td>
<td>12 December 1997</td>
</tr>
<tr>
<td>Honduras HN</td>
<td>20 June 2006</td>
</tr>
<tr>
<td>Hungary HU</td>
<td>27 June 1980</td>
</tr>
<tr>
<td>Iceland IS</td>
<td>23 March 1995</td>
</tr>
<tr>
<td>India IN</td>
<td>7 December 1998</td>
</tr>
<tr>
<td>Indonesia ID</td>
<td>5 September 1997</td>
</tr>
<tr>
<td>Ireland IE</td>
<td>1 August 1992</td>
</tr>
<tr>
<td>Israel IL</td>
<td>1 June 1996</td>
</tr>
<tr>
<td>Italy IT</td>
<td>28 March 1985</td>
</tr>
<tr>
<td>Japan JP</td>
<td>1 October 1978</td>
</tr>
<tr>
<td>Kazakhstan KZ</td>
<td>25 December 1991</td>
</tr>
<tr>
<td>Kenya KE</td>
<td>8 June 1994</td>
</tr>
<tr>
<td>Kyrgyzstan KG</td>
<td>25 December 1991</td>
</tr>
<tr>
<td>Lao People’s Democratic Republic LA</td>
<td>14 June 2006</td>
</tr>
<tr>
<td>Latvia LV</td>
<td>7 September 1993</td>
</tr>
<tr>
<td>Lesotho LS</td>
<td>21 October 1995</td>
</tr>
<tr>
<td>Liberia LR</td>
<td>27 August 1994</td>
</tr>
<tr>
<td>Libyan Arab Jamahiriya LY</td>
<td>15 September 2005</td>
</tr>
<tr>
<td>Liechtenstein LI</td>
<td>19 March 1980</td>
</tr>
<tr>
<td>Lithuania LT</td>
<td>5 July 1994</td>
</tr>
</tbody>
</table>

---

1. \[\text{PCT Contracting States}\]
2. \[\text{Name of State followed by the two-letter code}\]
3. \[\text{Date on which State became bound by the PCT}\]
<table>
<thead>
<tr>
<th>Name of State followed by the two-letter code</th>
<th>Date on which State became bound by the PCT¹</th>
<th>Name of State followed by the two-letter code</th>
<th>Date on which State became bound by the PCT¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malawi MW..............................24 January 1978</td>
<td>Seychelles SC............................7 November 2002</td>
<td>Malaysia MY2.............................16 August 2006</td>
<td>Sierra Leone SL ......................17 June 1997</td>
</tr>
<tr>
<td>Morocco MA............................8 October 1999</td>
<td>Netherlands NL3..............10 July 1979</td>
<td>Netherland NL2..........................1 January 1993</td>
<td>Sudan SD............................16 April 1984</td>
</tr>
<tr>
<td>Netherlands NL3..............10 July 1979</td>
<td>Norway NO4..........................1 January 1980</td>
<td>Oman OM4.............................26 October 2001</td>
<td>Trinidad and Tobago TT.................10 March 1994</td>
</tr>
<tr>
<td>Nicaragua NI...........................6 March 2003</td>
<td>Peru PE.................................6 June 2009</td>
<td>Peru PE.................................6 June 2009</td>
<td>Turkey TR.............................1 January 1996</td>
</tr>
<tr>
<td>Peru PE.................................6 June 2009</td>
<td>Romania RO5...........................23 July 1979</td>
<td>Romania RO2...........................23 July 1979</td>
<td>United Republic of Tanzania TZ................14 September 1999</td>
</tr>
</tbody>
</table>

1. All PCT Contracting States are bound by Chapter II of the PCT relating to the international preliminary examination.
2. With the declaration provided for in PCT Article 64(5).
3. With the declaration provided for in PCT Article 64(2)(a)(ii).
4. Including all Overseas Departments and Territories.
5. Ratification for the Kingdom in Europe, the Netherlands Antilles and Aruba.
6. Extends to the Isle of Man.
7. With the declarations provided for in PCT Articles 64(3)(a) and 64(4)(a).
8. Extends to all areas for which the United States of America has international responsibility.

(15 May 2010)
## Appendix III

### Patent Office Databases and Electronic Journals/Gazettes

The following is a selection of patent office databases and electronic patent office journals/gazettes available online.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Instituto Nacional Da Propriedade Industrial (Brazil)</td>
<td>To access database, enter code provided. Search fields include: application number, title of the patent, applicant and inventor. Each patent record also includes the status of the patent. The database is in Portuguese <a href="http://pesquisa.inpi.gov.br/MarcaPatente/jsp/servimg/servimg.jsp?BasePesquisa=Patentes">http://pesquisa.inpi.gov.br/MarcaPatente/jsp/servimg/servimg.jsp?BasePesquisa=Patentes</a></td>
<td></td>
</tr>
<tr>
<td>Industria y Comercio Superintendencia Republica de Colombia (Colombia)</td>
<td>Search fields include: application number, priority number, applicant and granted patent number. <a href="http://190.254.15.230/~oparra/externas/datospatente.php">http://190.254.15.230/~oparra/externas/datospatente.php</a></td>
<td></td>
</tr>
<tr>
<td>Cuba</td>
<td>Search fields include: application number, title of the patent, applicant and inventor. To access the database click on the links Bases de Datos and Invenciones. <a href="http://www.ocpi.cu/">http://www.ocpi.cu/</a></td>
<td>Under the link Publicaciones click on the option Boletin Official to access the official journals.</td>
</tr>
<tr>
<td>---------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>Egyptian Patent Office (Egypt)</td>
<td>Search fields include: application number, title of the patent, applicant and inventor. Searches can be conducted in Arabic or English. <a href="http://www.egypo.gov.eg/inner/english/Search_1.html">http://www.egypo.gov.eg/inner/english/Search_1.html</a></td>
<td></td>
</tr>
<tr>
<td>European Patent Office</td>
<td>Options include basic, structured (Boolean) and advanced searching of bibliographic data and text of the specifications. Esp@cenet provides access to patent information from over 80 countries, including patent specifications and status where available. <a href="http://ep.espacenet.com/">http://ep.espacenet.com/</a></td>
<td></td>
</tr>
<tr>
<td>Intellectual Property India (India)</td>
<td>Options include basic and advanced search. Search fields include: abstract, application number, title of the patent, applicant and inventor. The site also offers the status of patent applications and HTML text of granted patents. <a href="http://ipindia.nic.in/ipirs/patentsearch.htm">http://ipindia.nic.in/ipirs/patentsearch.htm</a></td>
<td>Under the heading Publications click on the link Patent Office Journal to access the official journal of published patents. The Official Patent Office Journal is published every 7 days. <a href="http://ipindia.nic.in/ipr/patent/patents.htm">http://ipindia.nic.in/ipr/patent/patents.htm</a></td>
</tr>
<tr>
<td>Korea Intellectual Property Rights Information Service (Republic of Korea)</td>
<td>Provides a general (basic) and advanced search. Search fields include: title, priority date and patentee. Searches can be conducted in English. <a href="http://patent2.kipris.or.kr/pateng/searchLogin.do?next=GeneralSearch">http://patent2.kipris.or.kr/pateng/searchLogin.do?next=GeneralSearch</a></td>
<td>Patent Office Gazettes can be downloaded from the row titled Solicitudes de Patente under the column Ejemplar. To access past gazettes, click the drop down arrow under the column Oficio de Puesta en Circulation. Gazettes are published in Spanish. <a href="http://siga.impi.gob.mx/wb/SIGA/SIGA_avisos_puesta_en_circulacion">http://siga.impi.gob.mx/wb/SIGA/SIGA_avisos_puesta_en_circulacion</a> (It is also possible to view the patent office gazette through the database under the link Busqueda por ejemplar).</td>
</tr>
<tr>
<td>Mexico</td>
<td>Options include basic (Busqueda simple), structured (Busqueda estructurada) and advanced search (Busqueda avanzada). Search fields include: abstract, application number, title of the patent, applicant and inventor. Searches can only be conducted in Spanish. <a href="http://siga.impi.gob.mx/wb/SIGA/SIGA_busqueda_simple">http://siga.impi.gob.mx/wb/SIGA/SIGA_busqueda_simple</a></td>
<td>For patents published after 18 months: <a href="http://www.ipo.gov.pk/Patent/PatentGazette.aspx">http://www.ipo.gov.pk/Patent/PatentGazette.aspx</a> For granted patents: <a href="http://www.ipo.gov.pk/Patent/PatentGranted.asp">http://www.ipo.gov.pk/Patent/PatentGranted.asp</a></td>
</tr>
<tr>
<td>---------------</td>
<td>----------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td>Department of Intellectual Property Thailand (Thailand)</td>
<td>Provides various search options including a quick search, simple search, by classification, patent number and a complex search allowing more than one search field. Searches can be conducted in with Thai or English. <a href="http://patentsearch.moc.go.th/DIPSearch/PatentSearch/SearchSimple.aspx">http://patentsearch.moc.go.th/DIPSearch/PatentSearch/SearchSimple.aspx</a></td>
<td></td>
</tr>
<tr>
<td>World Intellectual Property Organization</td>
<td>Allows users to search over 1.6 million PCT applications. Options include basic, structured (Boolean) and advanced searching of bibliographic data and text of the specifications. The database allows the specifications of PCT applications to be downloaded as well as providing the national phase status of applications where available. <a href="http://www.wipo.int/pctdb/en/">http://www.wipo.int/pctdb/en/</a></td>
<td></td>
</tr>
</tbody>
</table>
Agencies that procure medicines are increasingly faced with questions about the patent status of pharmaceutical products. This is important because these agencies have a responsibility to use their budgets efficiently (for example by procuring generic medicines), but do not want to infringe on intellectual property rights.

Many organizations involved in medicines procurement have limited knowledge of and little experience in establishing whether a particular medicine is under patent in a particular country. This guide describes a step-by-step approach to locating information about patents on medicines, which, though not easily found, is often available on the Internet. Concrete examples are given of how to trace, through the various online databases, whether a patent has been applied for, granted, refused or revoked. Suggestions are also provided for using Internet sources to obtain data (such as priority dates) that can facilitate efforts to identify relevant patents through more traditional means, such as patent office gazettes.