Patent term extension for pharmaceutical patents
US, Japan, Korea, EU and Chinese Taipei

Your trainer for today
- Christine Kämmer
- Since 2005 at the EPO
- Asian Patent Information Services
  - Chinese patent information specialist
  - Enquiries on Asian PI
  - CN/TW/HK legal status services
  - Training courses
  - “East meets West” in Vienna
Your trainer for today

- Sofie Leplae
- Since 2007 at the EPO
- Patent Data Services Team
  - INPADOC worldwide legal status database
  - Bulk Data distribution
  - Trainer on Patent Families and Legal Status and general patent information

Introduction

EU

Japan

US

Korea

Chinese Taipei

Useful information
INTRODUCTION: Patent term extension

INTRODUCTION: Definition of Patent Term Extension

- Patent term extension or Patent term restoration is a compensation for compulsory lengthy regulatory approval/market authorisation (testing and clinical trials)
- Hybrid system: basic patent and market authorisation
**INTRODUCTION: Other types of protection**

- **Orphan medicinal products**
  Pharmaceutical companies can benefit from incentives such as fee waivers, scientific assistance for marketing authorisation and the possibility of an EU marketing authorisation with a 10-year market exclusivity period.

- **Bolar provision/exemption**: generic drug manufacturers may already engage in clinical trials before expiry of the patent

- **Test data exclusivity leading to market exclusivity**: protection of clinical trial data

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**CN: Ongoing developments**

- currently **no** patent term extensions; not included in upcoming law revision
- plan: term extension (5 years) may be introduced for “innovative drugs for which market authorisation is applied for simultaneously in China and abroad”
- “Healthy China 2030”: core principles (health priority, innovation, scientific development, fairness and justice)
- April 2018: China Drug Administration (CDA) issued Draft Measures
  - plan: extend data exclusivity for clinical drug data
  - to include innovative, orphan and pediatric drugs (6 years) and innovative biological treatment products (12 years)
  - aim: encourage global companies to launch innovative drugs and conduct clinical trials in China
IN: SPCs/PTEs not available

- India currently does not allow extension of patent terms
  - protection of public health
  - promotion of drug accessibility for 1.3 billion Indian residents
  - significant Indian pharma sector with strong domestic generic drug players
- under TRIPS Agreement, India not obliged to grant patent term extensions (one of the flexibilities available under TRIPS)
- India not a signatory of any “TRIPS Plus” regime agreements with requirements to go beyond minimum TRIPS obligations (e.g. FTA with certain jurisdictions)

➢ different stakeholders’ pressure on Indian government remains

EU: Supplementary protection certificate (SPC)
EU regulation and national procedure
EU: EU SPC regulation and national law

- EU Regulation and national law
- Product approval procedure
- Where to find SPC Information
- Future developments

EU: EU regulation

- In 1992 creation of a supplementary protection certificate for medicinal products; entered into force in January 1993 (No 1768/92)
- In 1996 SPC for plant protection products (No 1610/96)
- In 2006 Paediatric extension of 6 months (No 1902/2006)
- In 2009 legislation was codified (No 469/2009)
**EU: Purpose of the SPC regulation**

- putting EU industry on **equal level with US and Japan**
- preserving the **integrity** of the **common market**
  (Italy and France had developed own national law)
- adequate **protection** of pharmaceutical research
- **public health** interests
- **compensation** for long period between filing of patent and market authorization of a product

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**EU: EU Regulation**

- **Pharmaceutical and plant patents**
- **SPC only granted to patent holder(s)** of basic patent (at the time of SPC grant), NOT to different authorisation holder or licensee
- **Conditions** for obtaining an SPC:
  1. Product must be protected by a **basic patent**
  2. **Valid market authorisation** must already exist
  3. **SPC for the product cannot already exist**
  4. The **valid market authorisation** is the **first place to place the product on the market**
- **Paediatric extension:**
  - Only if an SPC is granted (Negative term SPC!)
  - Agreed completed Paediatric Investigation Plan
**EU: Third party observations, opposition and appeal**

- Majority of countries allow for third party observations *
- With the exception of Denmark, no country allows for opposition to SPCs.
- Appeals:

  **Article 18**

  **Appeals**

  The decisions of the authority referred to in Article 9(1) or of the bodies referred to in Articles 15(2) and 16(2) taken under this Regulation shall be open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents.


* Source: Study on the legal aspects of supplementary protection certificates in the EU, European Commission, EU publication, 2018

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**EU: SPC fee structure – national law**

20.2.15 Payment of fees (EURO)

<table>
<thead>
<tr>
<th>Country</th>
<th>Filings on MS application</th>
<th>1st year</th>
<th>2nd year</th>
<th>3rd year</th>
<th>4th year</th>
<th>5th year</th>
<th>Based on examination fees in SPC (where applicable)</th>
<th>Additional information</th>
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<td>300</td>
<td>2,450</td>
<td>2,450</td>
<td>2,450</td>
<td>2,450</td>
<td>2,450</td>
<td>4,920</td>
<td>6th year (extension) + 520</td>
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<td>550</td>
<td>600</td>
<td>600</td>
<td>600</td>
<td>600</td>
<td>600</td>
<td>1,200 (in full with 6th year) or (if not paid separately)</td>
<td></td>
</tr>
<tr>
<td>Denmark</td>
<td>420</td>
<td>940</td>
<td>940</td>
<td>940</td>
<td>940</td>
<td>940</td>
<td>470</td>
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</table>
| Estonia | 400                      | 500      | 500      | 500      | 500      | 500      | Decision fees under section 27 of the Finnish Patents Act 490 and annual fees for each year or part of it, 990.332
| France  | 520                      | 940      | 940      | 940      | 940      | 940      | 470                                              |                        |
| Germany | 100                      | 2,100    | 2,100    | 2,100    | 2,100    | 2,100    | 4,200                                            | 6th year (extension) + 520 |
| Greece  | 250                      | 1,200    | 1,200    | 1,200    | 1,200    | 1,200    | 1,200                                            |                        |
| Iceland | 150                      | 1,300    | 1,300    | 1,300    | 1,300    | 1,300    | 1,300                                            |                        |
| Ireland | 400                      | 940      | 940      | 940      | 940      | 940      | 470                                              |                        |
| Luxembourg | 450       | 600      | 600      | 600      | 600      | 600      | 191 (for establishment fees) + 700 for appeals, 300 for fee for administrative ex-examination 3,552 |

Source: Table 20.2.16 in Study on the legal aspects of supplementary protection certificates in the EU, European Commission, EU publication, 2018

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* Source: Study on the legal aspects of supplementary protection certificates in the EU, European Commission, EU publication, 2018
EU: European regulatory system for medicines

- **Centralized** authorisation procedure
  - “European Medicines Agency” compulsory for some medicines
    (for e.g. new active ingredients for HIV, diabetes ...)

- **National** authorisation procedure
  - mutual recognition procedure in EEA (including Switzerland)
  - decentralised procedure

The European Medicines Agency (EMA) is a decentralised agency of the European Union (EU) responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU.

**Single marketing authorisation application**

**Compulsory for:**
- Human medicines containing a new active substance to treat: (human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS); cancer; diabetes; neurodegenerative diseases; auto-immune and other immune dysfunctions; viral diseases.
- Medicines derived from biotechnology processes, such as genetic engineering; advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines;
- Orphan medicines (medicines for rare diseases);
- Veterinary medicines for use as growth or yield enhancers.


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**EU: EPARs – European Public Assessment reports**

**What we publish on medicines and when**

**Table of contents**

- Applications for centralised marketing authorisation
- Changes to centralised marketing authorisations
- EU information
- Other relevant documents and publications

The European Medicines Agency (EMA) publishes information on human medicines at various stages of their lifecycles, from early development through initial evaluation to post-authorisation changes, safety reviews and withdrawals of authorisation. EMA has published a guide to the different forms of information stakeholders can expect to see, including what content can be expected from centralised authorisations, including the publication times and locations:

- **EMA information on human medicines**
- **For the Committee for Medicinal Products for Human Use (CHMP) and the Humanitarian Use of Medicines Committee (HUMC)**: EMA publishes meeting highlights to communicate information of major public interest, usually the day after their meetings have ended.

As a matter of good practice, marketing authorisation holders, applicants and third parties should wait until EMA communication is published before publishing their own communication related to the committee’s decisions.

In line with Good Pharmacovigilance Practice (GVP) Module IX, EMA gives advance notice of its safety-related publications to national competent authorities, the European Commission and the concerned marketing authorisation holders.

Marketing authorisation holders are also obliged to inform the agency and relevant national competent authorities of any serious unlicensed information on the safety of medicines.

EU: Table of all EPARs for human and veterinary medicine

EU: National authorities


National competent authorities (human)

The European Medicines Agency works closely with the national competent authorities of the Member States of the European Union (EU) and the European Economic Area (EAA), responsible for human medicines.

The national competent authorities are primarily responsible for the authorisations of medicines available in the EU that do not pass through the centralised procedure.

They also supply thousands of European experts who serve as members of the Agency’s scientific committees, working parties or in assessment teams supporting their members.

For more information on how the Agency works together with the national competent authorities, see European medicines regulatory network.

List of national competent authorities in the EEA

<table>
<thead>
<tr>
<th>Country</th>
<th>Name</th>
<th>Contact details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>Austrian Agency for Health and Food Safety</td>
<td>+43 1 604 44 0</td>
</tr>
<tr>
<td>Belgium</td>
<td>Federal Agency for Medicines and Health Products</td>
<td>2018 Brussels, Belgium</td>
</tr>
</tbody>
</table>
EU: National authority: example Belgium

https://banquededonneesmedicaments.fagg-afmps.be

EU: Procedure

Application

- patent
- product

Scenario 1

- basic patent granted
- first market authorisation + 6 months

Scenario 2

- first market authorisation
- basic patent granted + 6 months

Paediatric Investigation Plan

Extension

When?

with SPC application or when SPC pending not later than 2 years before expiry of SPC
EU: Duration of an SPC

Duration of SPC protection: maximum of 5 years
- date of first Market Authorisation in the EEA*
- date of filing of corresponding patent
- 5 years

maximum of 15 years of exclusivity from the time the product gets the market authorization

EU: Expiry date of SPC

<table>
<thead>
<tr>
<th>Country</th>
<th>Filing of the basic patent</th>
<th>Expiry date basic patent</th>
<th>Start date SPC</th>
<th>Latest expiry date SPC</th>
<th>Latest expiry date SPC paediatric extension</th>
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<tr>
<td>Austria, Croatia, Czech Republic, Denmark, Finland, Germany, Hungary, Latvia, Lithuania, Portugal, Romania, Spain, Sweden</td>
<td>15.10.2015</td>
<td>15.10.2035</td>
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<td>15.10.2040</td>
<td>15.04.2041</td>
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<td>France, Luxembourg</td>
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<td>14.10.2035 (at midnight)</td>
<td>15.10.2035</td>
<td>14.10.2040</td>
<td>14.04.2041</td>
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<tr>
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<td>15.10.2040 (excluded)</td>
<td>15.04.2041</td>
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<td>14.10.2040 (5 years from the legal term of the patent)</td>
<td>14.04.2041</td>
</tr>
</tbody>
</table>

Source: Study on the legal aspects of supplementary protection certificates in the EU. Final report – Study. Published: 2018-05-31
https://publications.europa.eu/en/publication-detail/-/publication/6845fac2-6547-11e8-ab9c-01aa75ed71a1
### EU: EP national entry sources at the EPO

#### EP NATIONAL ENTRY SOURCES AT THE EPO (INCLUDING VALIDATION/EXTENSION INFORMATION)

<table>
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<tr>
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<th>EPC member state</th>
<th>EP information</th>
<th>Legal information</th>
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<td>Albania</td>
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<td>AT</td>
<td>Austria</td>
<td>yes</td>
<td>no</td>
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<td>BE</td>
<td>Belgium</td>
<td>only EP/BE ****</td>
<td>yes ** in EP application</td>
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<td>BG</td>
<td>Bulgaria</td>
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<td>no</td>
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<tr>
<td>CH</td>
<td>Switzerland</td>
<td>yes</td>
<td>yes 65.2017 anniversary of filing</td>
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<td>CY</td>
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<tr>
<td>FI</td>
<td>Finland</td>
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**Notes:**
- Data on exact EXPRIATION of protection (90 years from filing, i.e., before or after)

[https://www.epo.org/searching-for-patents/data/coverage/regular.html](https://www.epo.org/searching-for-patents/data/coverage/regular.html)

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### EU: Example SPC procedure at the national offices

#### The procedure

**How to obtain the certificates?**
To obtain a supplementary protection certificate for a medicinal product, an application under Article 6(3) must be filed with the Office for Intellectual Property.
To obtain a supplementary protection certificate for a geometrically or functionally defined product, an application under Article 6(4) must be filed with the Office for Intellectual Property.

**Content of the request**

The request must contain:

- The name of the medicinal product or the product and a description of the product as well as the detailed specification of the product and the manner in which the product is to be manufactured;
- The name, address and contact details of the applicant;
- The application for a supplementary protection certificate for a medicinal product under Article 6(3) must also include the following information:
  - A declaration that the product is not protected by a patent or by a supplementary protection certificate;
  - Information on the marketing authorization of the medicinal product.

**Cost**

The fee for a supplementary protection certificate is determined by the Office for Intellectual Property and is indicated in the supplementary protection certificate application form.

**Granting and publication**

The Office for Intellectual Property will grant the certificate after receiving the application and verifying all the information. The certificate will be published in the Official Journal of the EPO.

EU: Example Liraglutide (Novo Nordisk)

EP 0944648
Filed 22.08.1997
Granted 14.03.2007
First marketing authorization date
30/06/2009 - EU/1/09/529/001

EU: Example Liraglutide (Novo Nordisk)

EP 0944648
Filed 22.08.1997
Granted 14.03.2007

First marketing authorization date
30/06/2009 - EU/1/09/529/001

SPC application in Belgium
2009C/050
Filing 30/10/2009
Grant 02/02/2010
Expiration date 22/08/2022

SPC application in the UK
SPC/GB09/058
Filing 11/12/2009
Grant 11/03/2011
Expiration date 21/08/2022

SPC application in the Netherlands
300422
Filing 22/10/2009
Grant 16/02/2010
Expiration date 21/08/2022

SPC application in the CH/LI C00944648/01
Filing 21/05/2010
Grant 31/10/2012
Expiration date 21/08/2022

EU: Paediatric investigation plan (PIP)

Use this search to find information on specific human, veterinary and herbal medicines published on the European Medicines Agency’s (EMA) website. Alternatively, you can use the site-wide search in the header above to search across all the content on the EMA website. The regulatory sections of the website contain information on medicines under evaluation, medicine shortages, medication errors, medicines for use outside the European Union (EU) and post-authorisation safety studies.

European Patent Office
**EU: Where to find data on Patents and SPC’s?**

- National intellectual property registers: all EU members, Norway and Switzerland (except for Croatia, Cyprus and Malta)

- INPADOC worldwide legal status database available in Espacenet and GPI

- Commercial databases: for e.g.
  - Cabinet Alice de Pastor (CAP) database, recently bought by ENIGMA marketing research
### EU: National Patent Registers

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<th>First authorisation (Product: Liraglutide – Victoza)</th>
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<td>12209000079/4</td>
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<td>NL</td>
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<td>02/02/2010</td>
<td>22/08/2022</td>
</tr>
</tbody>
</table>

### EU: Espacenet

#### Inpadoc Legal Status

- **Inpadoc Legal status:**
  - **Inpadoc legal status:** (Inpadoc patent family)

#### Inpadoc Patent Family

- **Inpadoc Patent Family:**
  - **Simple Patent Family**
## EU: INPADOC legal status

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<tr>
<th>Event Code</th>
<th>Code Description</th>
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<td>SUPPLEMENTARY PROTECTION CERTIFICATE FILED</td>
<td>20100531G</td>
</tr>
<tr>
<td>REG GB CTFF</td>
<td>SUPPLEMENTARY PROTECTION CERTIFICATE FILED</td>
<td>20100120G</td>
</tr>
<tr>
<td>REG AT ESZA</td>
<td>APPLICATION FILED FOR A CERTIFICATE OF PROTECTION (E- SERIES)</td>
<td>20100111G</td>
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<tr>
<td>REG NL AC1</td>
<td>APPLICATION FOR A SUPPLEMENTARY PROTECTION CERTIFICATE</td>
<td>20100104G</td>
</tr>
<tr>
<td>REG DE V448</td>
<td>APPLICATION OF SPC</td>
<td>20091230G</td>
</tr>
<tr>
<td>REG FI SPCF</td>
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<td>20091229G</td>
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<td>REG DK CTFF</td>
<td>APPLICATION FOR SUPPLEMENTARY PROTECTION CERTIFICATE (SPC) FILED</td>
<td>20091221G</td>
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<td>REG SE SPCF</td>
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<td>REG IE SPCF</td>
<td>REQUEST FOR GRANT OF SUPPLEMENTARY PROTECTION CERTIFICATE</td>
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<td>REG FR CP</td>
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</table>

### INPADOC classification scheme v. 1.0

- **GPI**: National filing (SPC) application or filing of an application for a supplementary protection certificate
- **SPC**: Application for a supplementary protection certificate
- **SPCF**: Supplementary protection certificate filed
- **CTFF**: Supplementary protection certificate application filed
- **AC1**: Application for a supplementary protection certificate
- **V448**: Application of SPC
- **ESZA**: Application for a certificate of protection (E-SERIES)
- **CP**: Certificate of protection
- **REQUEST**: Request for grant of supplementary protection certificate
- **APPLICATION**: Application filed
- **FILED**: Filing date

European Patent Office
**EU: Legal status codes and categories**

<table>
<thead>
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<th>Code</th>
<th>Description</th>
<th>Legal status</th>
<th>Protection beyond IP right term</th>
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**EU: categories for INPADOC events available in New Espacenet**

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European Patent Office

https://www.epo.org/searching-for-patents/data/coverage/weekly.html
EU: Future ... SPC Manufacturing waiver

Export manufacturing waiver for SPCs


This initiative proposes to introduce an exception to let EU firms manufacture certain pharmaceuticals for export to non-EU markets during the term of the SPC.

EU: SPC and effects of the Brexit

EU: SPC and Unitary Patent Package

- The 'patent package' that lays the ground for the creation of unitary patent protection in the EU does not explicitly provide for a 'unitary SPC'.

- To ensure that companies which choose unitary patent protection can benefit from the SPC extension, the European Commission is working on the articulation of unitary patent protection and SPC legislation.

US: Patent term extension (PTE)
US: Background


- Paediatric exclusivity attaches to the END of all existing marketing exclusivity and patent periods.

- Waxman-Hatch exclusivity, orphan exclusivity, and patent periods run concurrently.

NOTE: 35 U.S.C. §154(b): This legislation provides certain deadlines that, if not met by the USPTO, result in an automatic “adjustment” of the term of an individual patent. In particular, each day of USPTO delay results in one additional day of patent term.

US: Patents eligible for term extension

- The patent must claim a drug product, or method of using a drug product where that product has been subject to regulatory review

- Only one patent can be extended upon an approval;

- in the event multiple patents cover that product; the proprietor must choose one

- the request can be filed by the applicant or its agent (for e.g. licensee)

- maximum extension: 5 years

- total effective patent term after the extension of not more than 14 years
**US: Main authorities**

- [USPTO](https://www.uspto.gov/)
- [FDA](https://www.fda.gov/)
- [USDA](https://www.usda.gov/)

**Basic Patent Granted**

Request for Patent Term Extension within 60 days

USPTO

Defining Eligibility

Defining Term

FDA/USDA

Patent Term Extension

**US: Procedure for the product Selzentry (maraviroc)**

**US 6667314 Granted 23.03.2003**

PTE Application under 35 USC 156 filed within 60 days after approval by regulatory agency and before expiration of patent

Initial letter Re: PTE Application to regulating agency
US: Procedure

Letter from FDA confirming the time limit; New Drug Approval (NDA) 022128 for Maraviroc: 6.8.2007

Second letter to regulating agency to determine regulatory review period

Transaction for FDA Determination of Regulatory Review Period: Total length 1524 days;
US: Procedure

Notice in Federal Register

European Patent Office

US: Procedure

Notice of Final Determination-Eligible

European Patent Office
**US: Procedure**

![Patent Term Extension Certificate for 73 days](image)

**US: Search example**

- **US PAIR**
- Orange Book (FDA) – Patent Linkage concept
- INPADOC worldwide legal status database
US: US Pair

Public Patent Application Information Retrieval

https://portal.uspto.gov/pair/PublicPair

U.S.: Patent Linkage

Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)

https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm
**U.S.: Orange book**

![Image of Orange Book](image_url)

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European Patent Office
### U.S.: Orange book

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

#### Authority:
- European Patent Office

#### U.S.: Orange book

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### U.S.: Inpadoc Legal Status database – legal codes

#### Authority:
- European Patent Office

#### U.S.: Inpadoc Legal Status database – legal codes

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