Europäisches Patentamt
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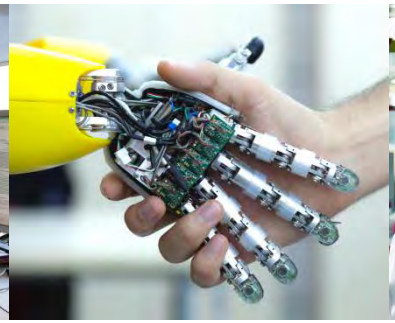
Patent term extension for pharmaceutical patents

EU, Japan, Korea and US





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PD 5.4 Patent Information

27 March 2019

Contents

- Introduction: Patent term extension
- EU
- Korea
- Japan
- Other Asian countries
- US

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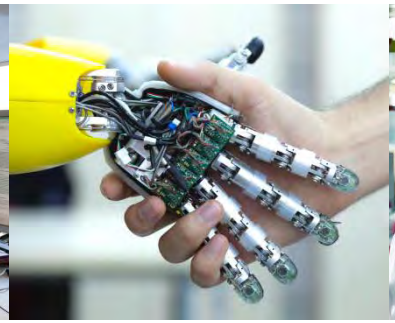
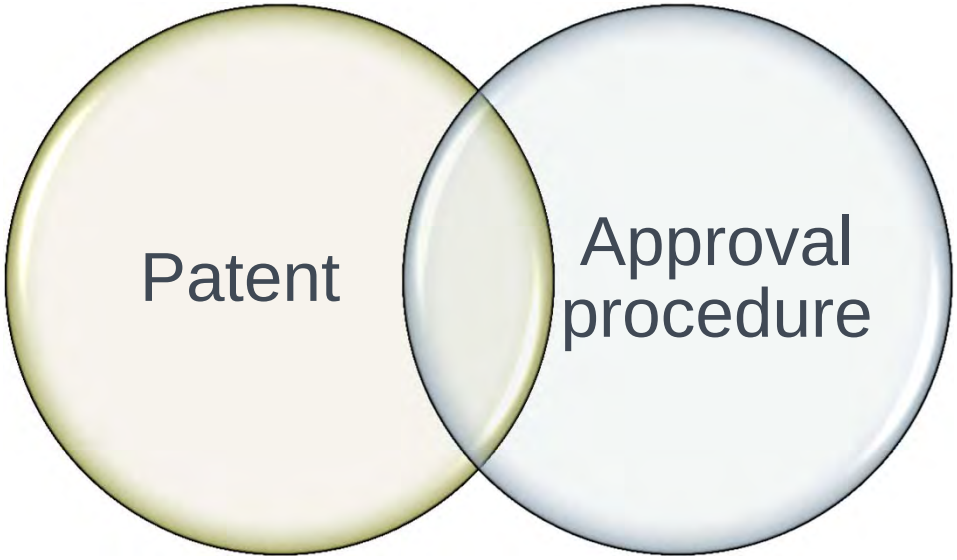
INTRODUCTION:
Patent term extension





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: Countries with Patent term extension for medicinal products/patents

- EU, EEA (Iceland, Norway, Liechtenstein) and Switzerland
- UK (after the Brexit)
- Israel
- US
- Canada
- Japan
- Korea
- Chinese Taipei
- Australia
- New Zealand
- Russia
- Singapore
- ? China
- …

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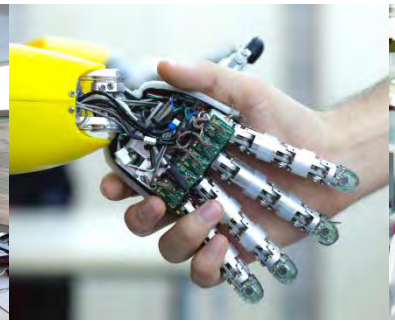
EU: Supplementary protection certificate (SPC)

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)

Council regulation (EEC) No 1768/92 concerning the creation of a supplementary protection certificate for medicinal products

Regulation (EC) No 1610/96 of the European Parliament and of the Council concerning the creation of a supplementary protection certificate for plant protection products

Regulation (EC) No 1902/2006 of the European Parliament and of the Council of 20 December 2006 amending Regulation 1901/2006 on medicinal products for paediatric use (Text with EEA relevance)

Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (Codified version) (Text with EEA relevance)

EU: Purpose of the EU 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

EU: EU Regulation - content

- **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 (not in GR, LT, CH) *
- 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.

From: Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (Codified version) (Text with EEA relevance)

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

EU: SPC fee structure – national law

20.2.16 Payment of fees (EURO)

Country	Filing an SPC application	1st year	2nd year	3rd year	4th year	5th year	Request for extension of duration	Additional information
Austria	363	2,611	3,029	3,448	3,864	4,282	258	
Croatia*	Adm. fee 20 + coverage charges 400	1,500	2,000	2,400	2,800	3,200	330	In case of late payment (grace period 6 months), the specified amounts double
Czech Republic *	191	994	1,070	1,147	1,223	1,299	-	
Denmark *	403 Paed. ext. – 336	685	685	685	685	685	403 (re-establishment fee)	Fee for appeal: 537; fee for administrative re-examination: 2,012
Finland	500	900	900	900	900	900	500	Decision fee under section 71a of the Finnish Patents Act: 450 and annual fee for each year or part of it: 900
France	520	940	940	940	940	940	470	
Germany	300	2,650	2,940	3,290	3,650	4,120	100 (if filed with SPC request) 200 (if filed separately)	6th year (extension) – 4520
Greece	250	1,200	1,300	1,400	1,500	1,800		Filing fees for duration of the validity of an SPC for paediatric medicines 6 months extension – 1200

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

EU: SPC Numbers 1990-2015

Table 19: SPCs by country

Country	Total Patents	SPC Applications	SPC Grants	SPC Refusals
Austria	2,636	774	618	78
Belgium	2,671	752	496	91
Bulgaria	863	181	105	20
Croatia	506	79	19	1
Czech Republic	1,146	272	165	33
Denmark	2,411	742	596	126
Estonia	628	145	121	6
Finland	1,853	571	385	19
France	2,845	775	582	135
Germany	2,923	942	560	219
Greece	2,308	531	455	23
Hungary	1,218	338	177	60
Iceland	363	101	66	8
Ireland	2,211	669	486	100
Italy	2,692	771	722	55
Latvia	967	211	155	15
Lithuania	911	201	119	11
Luxembourg	2,484	658	656	7
Netherlands	2,648	782	668	134
Norway	978	387	324	32
Poland	931	213	74	41
Portugal	2,137	542	421	68
Romania	1,167	234	126	15
Slovak Republic	1,020	203	147	21
Slovenia	1,120	282	254	26
Spain	2,709	643	535	165
Sweden	2,632	770	630	117
Switzerland	2,717	631	539	66
UK	2,797	807	566	134
Total	52,492	14,207	10,767	1,826

Kyle, Margaret. “Economic Analysis of Supplementary Protection Certificates in Europe”. 2017, table 19 page 24.

EU: European regulatory system for medicines

- **Centralized** authorisation procedure
  - “European Medicines Agency” (EMA)
  - Brexit: Relocation to Amsterdam
  - Brexit: UK to become 3rd country on 30 March 2019

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

https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines

EU: Product authorisation - single marketing authorisation "European Medicines Agency" (1995)

https://www.ema.europa.eu/en

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.

EU: EPARs – European Public Assessment reports

What we publish on medicines and when

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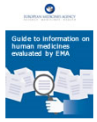
Table of contents

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 types of information stakeholders can expect on this website about centrally and non-centrally authorised medicines, including the publication times and location:

Guide to information on human medicines evaluated by EMA

For the Committee for Medicinal Products for Human Use (CHMP) and the Pharmacovigilance Risk Assessment Committee (PRAC), EMA publishes **meeting highlights** to communicate information of **major public interest**, usually the day after their meetings have ended.

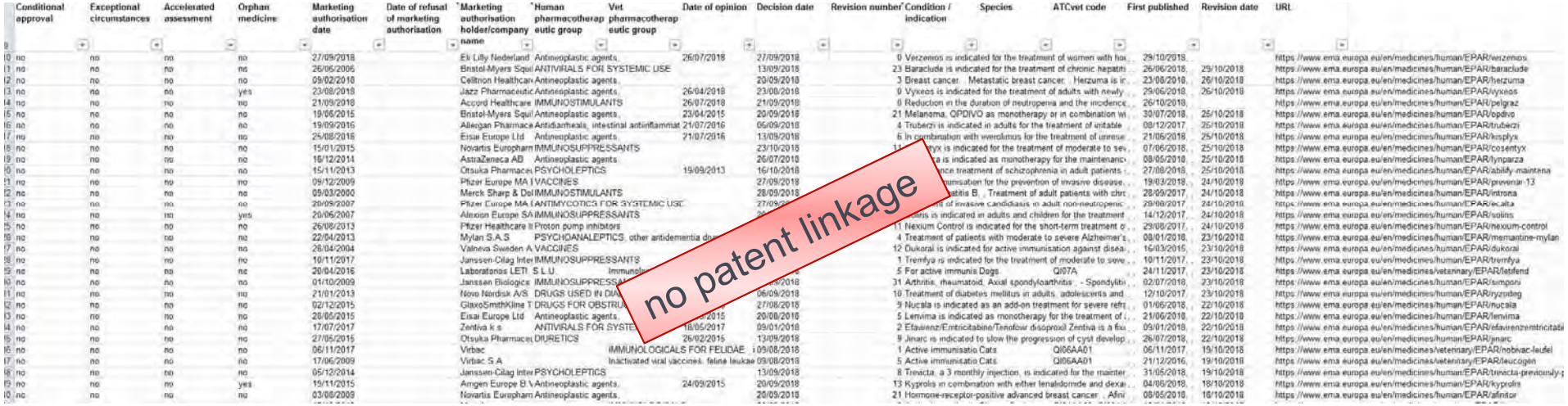
As a matter of good practice, marketing authorisation holders, applicants and third parties should **wait until EMA communication is published** before publishing their own communication related to the committee's outcome.

In line with Good Pharmacovigilance Practice (GVP) Module XV, 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 their intention to publish information on the safety of medicines.

https://www.ema.europa.eu/en/medicines/what-we-publish-medicines-when

EU: Table of all EPARs for human and veterinary medicine



	Conditional approval	Exceptional circumstances	Accelerated assessment	Orphan medicine	Marketing authorisation date	Date of refusal of marketing authorisation	Marketing authorisation holder/company name	Human pharmacotherapeutic group	Vet pharmacotherapeutic group	Date of opinion	Decision date	Revision number	Condition / indication	Species	ATCvet code	First published	Revision date	URL
10	no	no	no	no	27/09/2018		Eli Lilly Nederland	Antineoplastic agents		26/07/2018	27/09/2018	0	Verzenios is indicated for the treatment of women with hor			29/10/2018		https://www.ema.europa.eu/en/medicines/human/EPAR/verzenios
11	no	no	no	no	26/06/2006		Bristol-Myers Squi	ANTIVIRALS FOR SYSTEMIC USE			13/09/2018	23	Baraclude is indicated for the treatment of chronic hepatiti			26/06/2018	29/10/2018	https://www.ema.europa.eu/en/medicines/human/EPAR/baraclude
12	no	no	no	no	09/02/2018		Celltrion Healthcare	Antineoplastic agents			20/09/2018	3	Breast cancer. . Metastatic breast cancer. . Herzuma is ir			23/08/2018	26/10/2018	https://www.ema.europa.eu/en/medicines/human/EPAR/herzuma
13	no	no	no	yes	23/08/2018		Jazz Pharmaceutic	Antineoplastic agents		26/04/2018	23/08/2018	0	Vyxeos is indicated for the treatment of adults with newly			29/06/2018	26/10/2018	https://www.ema.europa.eu/en/medicines/human/EPAR/vyxeos
14	no	no	no	no	21/09/2018		Accord Healthcare	IMMUNOSTIMULANTS		26/07/2018	21/09/2018	0	Reduction in the duration of neutropenia and the incidence			26/10/2018		https://www.ema.europa.eu/en/medicines/human/EPAR/pelgraz
15	no	no	no	no	19/06/2015		Bristol-Myers Squi	Antineoplastic agents		23/04/2015	20/09/2018	21	Melanoma. OPDIVO as monotherapy or in combination wi			30/07/2018	25/10/2018	https://www.ema.europa.eu/en/medicines/human/EPAR/opdivo
16	no	no	no	no	19/09/2016		Allergan Pharmace	Antidiarrheals, intestinal antiinflammat		21/07/2016	06/09/2018	4	Trubeizi is indicated in adults for the treatment of irritable			08/12/2017	25/10/2018	https://www.ema.europa.eu/en/medicines/human/EPAR/trubeizi
17	no	no	no	no	25/08/2016		Eisai Europe Ltd	Antineoplastic agents		21/07/2016	13/09/2018	6	In combination with vercitinos for the treatment of unrese			21/06/2018	25/10/2018	https://www.ema.europa.eu/en/medicines/human/EPAR/lenvima
18	no	no	no	no	15/01/2015		Novartis Europharm	IMMUNOSUPPRESSANTS			23/10/2018	14	tyx is indicated for the treatment of moderate to sev			07/06/2018	25/10/2018	https://www.ema.europa.eu/en/medicines/human/EPAR/cosentyx
19	no	no	no	no	16/12/2014		AstraZeneca AB	Antineoplastic agents			26/07/2018	7	a is indicated as monotherapy for the maintenanc			08/05/2018	25/10/2018	https://www.ema.europa.eu/en/medicines/human/EPAR/lynparza
20	no	no	no	no	15/11/2013		Otsuka Pharmaceu	PSYCHOLEPTICS		19/09/2013	16/10/2018	12	nce treatment of schizophrenia in adult patients			27/08/2018	25/10/2018	https://www.ema.europa.eu/en/medicines/human/EPAR/abilify-maintena
21	no	no	no	no	09/12/2009		Pfizer Europe MA I	VACCINES			27/09/2018	19	munisation for the prevention of invasive disease			19/03/2018	24/10/2018	https://www.ema.europa.eu/en/medicines/human/EPAR/prevenar-13
22	no	no	no	no	09/03/2000		Merck Sharp & Dol	IMMUNOSTIMULANTS			28/09/2018	20	atitis B. . Treatment of adult patients with chr			28/09/2017	24/10/2018	https://www.ema.europa.eu/en/medicines/human/EPAR/introna
23	no	no	no	no	20/09/2007		Pfizer Europe MA I	ANTIMYCOTICS FOR SYSTEMIC USE			27/09/2018	12	s of invasive candidiasis in adult non-neutropenic			29/08/2017	24/10/2018	https://www.ema.europa.eu/en/medicines/human/EPAR/ecalta
24	no	no	no	yes	20/06/2007		Alexion Europe SA	IMMUNOSUPPRESSANTS			20/09/2018	20	is is indicated in adults and children for the treatment			14/12/2017	24/10/2018	https://www.ema.europa.eu/en/medicines/human/EPAR/soliris
25	no	no	no	no	26/06/2013		Pfizer Healthcare I	Proton pump inhibitors			27/09/2018	11	Nexium Control is indicated for the short-term treatment o			29/08/2017	24/10/2018	https://www.ema.europa.eu/en/medicines/human/EPAR/nexium-control
26	no	no	no	no	22/04/2013		Mylan S.A.S	PSYCHOANALEPTICS, other antidementia dru			27/09/2018	4	Treatment of patients with moderate to severe Alzheimer's			08/01/2018	23/10/2018	https://www.ema.europa.eu/en/medicines/human/EPAR/memantine-mylan
27	no	no	no	no	26/04/2004		Valneva Sweden A	VACCINES			27/09/2018	12	Dukoral is indicated for active immunisation against diseas			16/03/2015	23/10/2018	https://www.ema.europa.eu/en/medicines/human/EPAR/dukoral
28	no	no	no	no	10/11/2017		Janssen-Cilag Inter	IMMUNOSUPPRESSANTS			23/10/2018	1	Tremfya is indicated for the treatment of moderate to seve			10/11/2017	23/10/2018	https://www.ema.europa.eu/en/medicines/human/EPAR/tremfya
29	no	no	no	no	20/04/2016		Laboratorios LETI	S.L.U. Immunolo			27/09/2018	5	For active immunis Dogs	QI07A		24/11/2017	23/10/2018	https://www.ema.europa.eu/en/medicines/veterinary/EPAR/latifend
30	no	no	no	no	01/10/2009		Janssen Biologics	IMMUNOSUPPRESSA			6/2018	31	Arthritis, rhaumatoid, Axial spondyloarthritis: . - Spondylitis			02/07/2018	23/10/2018	https://www.ema.europa.eu/en/medicines/human/EPAR/simponi
31	no	no	no	no	21/01/2013		Novo Nordisk A/S	DRUGS USED IN DIA			06/09/2018	10	Treatment of diabetes mellitus in adults, adolescents and			12/10/2017	23/10/2018	https://www.ema.europa.eu/en/medicines/human/EPAR/ryzodeg
32	no	no	no	no	02/12/2015		GlaxoSmithKline T	DRUGS FOR OBSTRU			27/08/2018	9	Nucala is indicated as an add-on treatment for severe refr			01/06/2018	22/10/2018	https://www.ema.europa.eu/en/medicines/human/EPAR/nucala
33	no	no	no	no	26/05/2015		Eisai Europe Ltd	Antineoplastic agents		5/2015	20/08/2018	5	Lenvima is indicated as monotherapy for the treatment of i			21/06/2018	22/10/2018	https://www.ema.europa.eu/en/medicines/human/EPAR/lenvima
34	no	no	no	no	17/07/2017		Zentiva k.s.	ANTIVIRALS FOR SYSTE		18/05/2017	09/01/2018	2	Efavirenz/Emtricitabine/Tenofovir disoproxil Zentiva is a fix			09/01/2018	22/10/2018	https://www.ema.europa.eu/en/medicines/human/EPAR/efavirenzemtricitabi
35	no	no	no	no	27/05/2015		Otsuka Pharmaceu	DIURETICS		26/02/2015	13/09/2018	9	Jinarc is indicated to slow the progression of cyst develop			26/07/2018	22/10/2018	https://www.ema.europa.eu/en/medicines/human/EPAR/jinarc
36	no	no	no	no	06/11/2017		Virbac	IMMUNOLOGICALS FOR FELIDAE		05/08/2018	09/08/2018	1	Active immunisatio Cats	QI06AA01		06/11/2017	19/10/2018	https://www.ema.europa.eu/en/medicines/veterinary/EPAR/nobivac-leufel
37	no	no	no	no	17/06/2009		Virbac S.A	Inactivated viral vaccines, feline leukae		09/08/2018	09/08/2018	5	Active immunisatio Cats	QI06AA01		21/12/2016	19/10/2018	https://www.ema.europa.eu/en/medicines/veterinary/EPAR/leucogen
38	no	no	no	no	05/12/2014		Janssen-Cilag Inter	PSYCHOLEPTICS			13/09/2018	8	Trevicta, a 3 monthly injection, is indicated for the mainter			31/05/2018	19/10/2018	https://www.ema.europa.eu/en/medicines/human/EPAR/trevicta-previously-p
39	no	no	no	yes	19/11/2015		Amgen Europe B.V	Antineoplastic agents		24/09/2015	20/09/2018	13	Kyprolis in combination with either lenalidomide and dexar			04/06/2018	18/10/2018	https://www.ema.europa.eu/en/medicines/human/EPAR/kyprolis
40	no	no	no	no	03/08/2009		Novartis Europharm	Antineoplastic agents			20/09/2018	21	Hormone-receptor-positive advanced breast cancer. . Afini			08/05/2018	18/10/2018	https://www.ema.europa.eu/en/medicines/human/EPAR/afinitor

no patent linkage

Link to Assessment report

EU: National authorities

https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human
https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-veterinary

National competent authorities (human)

Share

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 (EEA) responsible for human medicines.

The national competent authorities are primarily responsible for the authorisation of medicines available in the EU that do not pass though 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 EMA works together with the national competent authorities, see European medicines regulatory network.

List of national competent authorities in the EEA

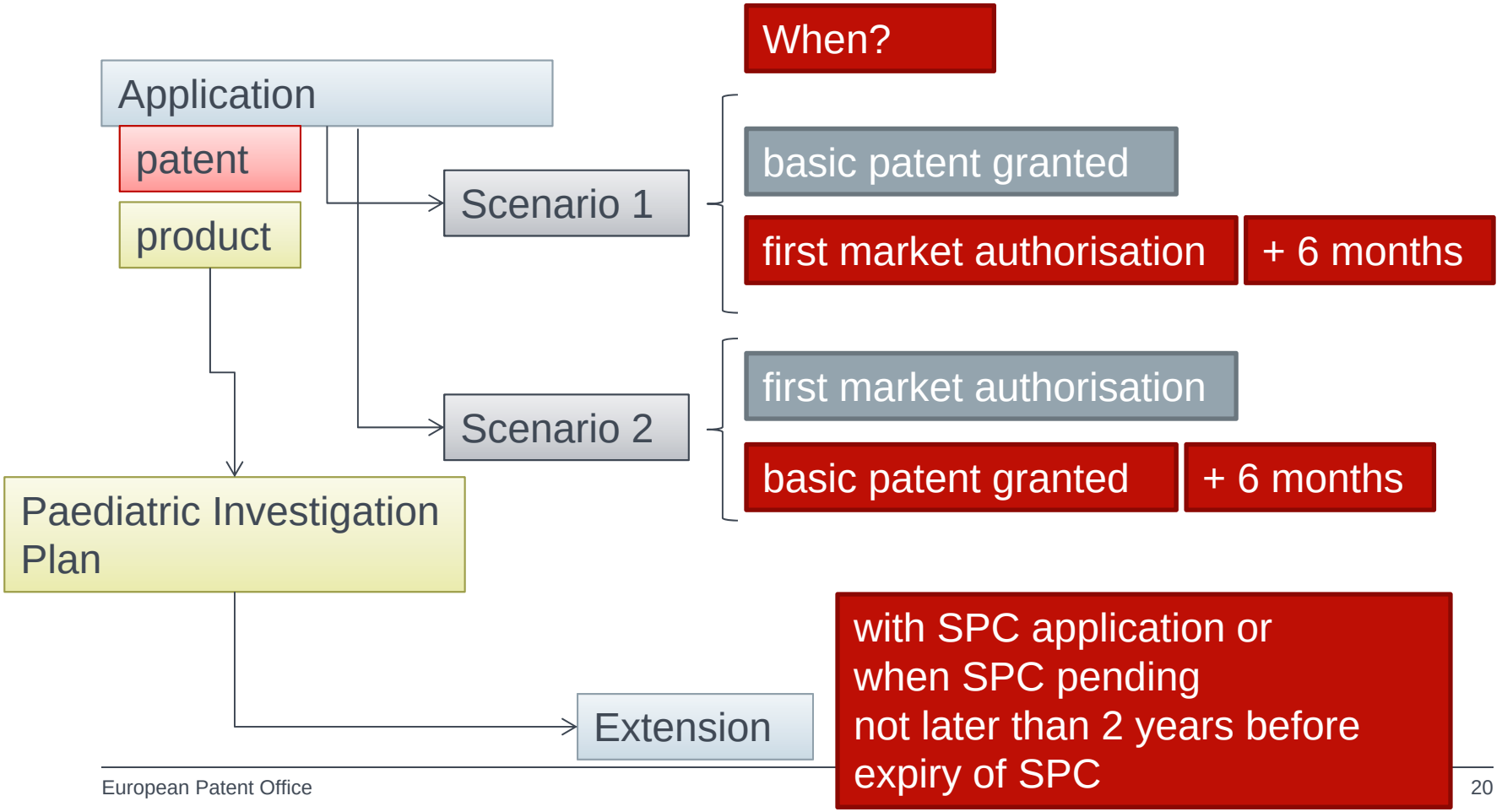
Country	Name	Contact details	
Austria	Austrian Agency for Health and Food Safety	Spargelfeldstraße 191 1220 Wien Austria Tel. +43 5 0555-0 Fax +43 5 0555-22019 www.ages.at	AGES Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH
Belgium	Federal Agency for Medicines and Health Products	Eurostation building, block 2 place Victor Horta, 40/ 40 1060 Brussels Belgium Tel. +32 2 524 7111 E-mail: info.medicines@fagg-afmps.be www.fagg-afmps.be/	famhp

https://www.afmps.be/fr

EU: National authority: example Belgium

https://banquededonneesmedicaments.fagg-afmps.be

EU: Procedure



EU: Duration of an SPC

Duration of SPC protection: maximum of 5 years

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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

Country	Filing of the basic patent	Expiry date basic patent	Start date SPC	Latest expiry date SPC	Latest expiry date SPC paediatric extension
Austria, Croatia, Czech Republic, Denmark, Finland, Germany, Hungary, Latvia, Lithuania, Portugal, Romania, Spain, Sweden	15.10.2015	15.10.2035	16.10.2035	15.10.2040	15.04.2041
France, Luxembourg	15.10.2015	14.10.2035 at midnight	15.10.2035	14.10.2040	14.04.2041
Greece	15.10.2015	16.10.2035	17.10.2035	16.10.2040	16.04.2041
Ireland, Netherlands	15.10.2015	14.10.2035	15.10.2015	14.10.2015	14.04.2041
Italy	15.10.2015	15.10.2035 (excluded)	15.10.2035	15.10.2040 (excluded)	15.04.2041
Poland	15.10.2015	15.10.2035	15.10.2035	15.10.2040	15.04.2041
Serbia	15,10.2015	15.10.2035 (included)	16.10.2035	15.10.2040 (included)	15.04.2041
Slovak Republic	15.10.2015	15.10.2035	16.10.2035	16.10.2040	16.04.2041
Switzerland	15.10.2015	14.10.2035 at midnight	15.10.2035	-	-
UK	15.10.2015	14.10.2035	15.10.2035	14.10.2040 (expiry 5 years from the legal term of the patent)	14.04.2041

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)

This table shows how information on EP national entry is propagated in EPO databases and where/how you can find it

					Bibliographic information			Legal information			
	Country code	EPC member state	EPC member since	London agreement	New document number for translation of entry to national phase publication	EPO's kind code for translation publication	Translation publication available in DOCDB/patent family	Legal status events for national entry publication available in INPADOC	Post-grant information available in EP Register	Federated register service available in EP Register	NEW: Date of exact EXPIRATION OF PROTECTION (20 years from filing: on, before or after)
1	AL	Albania	01 May 2010	yes	no	no	no	no	yes	no	no
2	AT	Austria	01 May 1979		yes	T1-T9	yes **	EP application	yes	yes 01.2016	anniversary of filling
3	BE	Belgium	07 October 1977		only EP/BE ****	T1, T2****	yes**** **	EP application	yes	yes 11.2017	anniversary of filling
4	BG	Bulgaria	01 July 2002		no	no	no	no	yes	yes 05.2017	anniversary of filling
5	CH	Switzerland	07 October 1977	Article 1(1)	EP	no	EP	EP application	yes	yes 02.2016	1 day before anniversary
6	CY	Cyprus	01 April 1998		yes	T1, T2	yes ***	no	yes	no	no
7	CZ	Czech Republic	01 July 2002		no	no	no	no	yes	yes	anniversary of filling
8	DE	Germany	07 October 1977	Article 1(1)	EP	no	EP	EP application	yes	yes 08.2018	anniversary of filling
9	DK	Denmark	01 January 1990	yes	only EP/DK*	T1-T7	yes	EP application	yes	no	anniversary of filling
10	EE	Estonia	01 July 2002		yes	B1-B9	yes	EP application	yes	no	1 day before anniversary
11	ES	Spain	01 October 1986		yes	T1-T9	yes	EP application	yes	yes 09.2016	anniversary of filling
12	FI	Finland	01 March 1996	yes	yes	T1-T7	no	EP application	yes	yes 03.2016	anniversary of filling

https://www.epo.org/searching-for-patents/data/coverage/regular.html

EU: Example SPC procedure at the national offices

economie

The procedure

How to obtain the certificate?

To obtain a supplementary protection certificate for a **medicine**, a request form (DOC, 109.5 Kb) must be filed with the Office for Intellectual Property.

To obtain a supplementary protection certificate for a **phytopharmaceutical product**, a request form (DOC, 106 Kb) must be filed with the Office for Intellectual Propert.

The request may be filed in French, Dutch or German.

Content of the request

The request file must contain:

1. The request form for a SPC addressed to the relevant Minister (2 copies);
2. A copy of the market authorisation (MA) issued in Belgium which identifies the product, the number and the date of the authorisation as well as a summary of the product characteristics as of the date on which the SPC request was filed;
3. If the MA was issued in Belgium prior to another market authorisation in the European Union, information on the identity of the product for which authorisation was issued and the legal basis of this authorisation as well as a copy of the publication of the authorisation in the Official Journal;
4. Where applicable, the proxy authorisation given to a representative of the requesting party (accredited patent agent, attorney, employee etc.).

Most of the data listed above may be provided after the request is filed. However, a **filing date for the request** may not be attributed unless the following minimum data and documents have been provided:

- A declaration of the request for a certificate;
- Information on the requesting party's identity;
- Information on the basic patent.

Cost

Official taxes must be paid for an SPC request and for its continuance.

Granting and publication

Once all the administrative formalities have been carried out, the certificate is issued as quickly as possible. This certificate enters into force on the day the patent expires. The SPC file is also made public except for documents regarding the MA and other documents which the patent holder prefers to keep confidential. The delivery of the certificate is mentioned in the Compendium and in the Patent Register. Any change to the certificate, such as a transfer or a license, must be submitted to the Office for Intellectual Property and mentioned in the Register.

https://economie.fgov.be/en/themes/intellectual-property/patents/supplementary-protection

national rules

economie

FEDERAL PUBLIC SERVICE
Economy, S.M.E.s., Self-employed & Energy

Intellectual Property Office

SUPPLEMENTARY PROTECTION CERTIFICATE FOR MEDICINAL PRODUCTS AND FOR PLANT PROTECTION PRODUCTS

CIRCULAR ON THE DATE OF THE AUTORISATION TO PLACE THE PRODUCT ON THE MARKET

This circular establishes the rules applicable before the Intellectual Property Office for determining the date of the authorisation to place a medicinal product or a plant protection product on the market. The purpose of this circular is to simplify and harmonize the different authorization regimes. As from 01/06/2016, these provisions apply to all current and future SPC applications.

The concept of 'the date of the authorisation to place the product on the market' occurs in Articles 7 and 13 of the Regulation (EC) n° 469/2009 of 6 May 2009 concerning the supplementary protection certificate for medicinal products and in Articles 7 and 13 of the Regulation (EC) n°1610/96 of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products.

Article 7, §1, stipulates that : « *The application for a certificate shall be lodged within six months of the date on which the authorisation referred to in Article 3(b) to place the product on the market [as a medicinal product] [as a plant protection product] was granted.* ».

Article 13, § 1, stipulates that: « *The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the Community, reduced by a period of five years.* ».

The date taken into account for the different authorisations to place the product on the market (MA) is the following:

1. **Date of MA for a medicinal product granted by the European Commission**

   The date of the MA is the date of notification of the decision granting the marketing authorisation. This date is published in the Official Journal of the European Union.

2. **Date of MA for a medicinal product granted by the Federal Agency for medicines and health products (FAMHP)**

   The date of the MA is either the starting date of the validity period of the marketing authorisation, or the date of signature of the MA, if this date is later.

3. **Date of MA for a plant protection product granted by the Federal Public Service Health**

   The date of the MA is either the starting date of the validity period of the marketing authorisation, or the date of signature of the MA, if this date is later.

The circular of 22 September 2003 on the SPC grant procedures for medicinal products and for plant protection products is repealed at the date of 1 June 2016.

Brussels, 07/04/2016,

Stefan DRISQUE
Advisor

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

Federated register: EP0944648

Refine search | ST36 | Espacenet | Submit observations | Report error | Print

GLP-1 DERIVATIVES

Application No.	Publication No.	Applicant	IPC
EP97935509	EP0944648	NOVO NORDISK A/S	C07K14/605 A61K38/26

Only designated contracting states and extension states providing the Federated Register Service are listed below.

	Status	Application No.	Publication No.	Proprietor	Invalidation date	Not in force since	Renewal fees last paid	Record last updated
AT	Patent expired	EP97935509	EP0944648	NOVO NORDISK A/S	12.09.2017	22.08.2017	—	—
BE	—	EP97935509	EP0944648	NOVO NORDISK A/S	22.08.2017	22.08.2017	20.07.2016	07.02.2018
CH/LI	Patent not in force	EP97935509	EP0944648	NOVO NORDISK A/S	21.08.2017	21.08.2017	—	26.06.2017
DE	Patent not in force	EP97935509	EP0944648	Novo Nordisk A/S, 2880 Bagsvaerd, D...	—	—	—	24.08.2017
ES	Patent lapsed	E97935509	ES2283025	NOVO NORDISK A/S	29.11.2017	23.08.2017	27.07.2016 Latest annual fee paid 20	—
FI	Patent expired	EP97935509	EP0944648	NOVO NORDISK A/S	—	22.08.2017	21.07.2016	31.10.2016
GB	Patent expired	EP97935509	EP0944648	NOVO-NORDISK A/S	—	21.08.2017	26.07.2016 Latest annual fee paid 20	—
GR	Patent expired	EP97935509	GR3051947	NOVO NORDISK A/S	06.09.2017	23.08.2017	25.07.2016	06.09.2017
IE	Patent expired	EP97935509	EP0944648	NOVO NORDISK A/S	28.09.2017	28.09.2017	21.07.2016	28.09.2017
LT	Patent not validated	EP97935509	EP0944648	NOVO NORDISK A/S	—	—	—	18.04.2016
LU	Patent lapsed	EP97935509	EP0944648	NOVO NORDISK A/S	—	22.08.2007	—	08.06.2018
NL	—	EP97935509	EP0944648	NOVO NORDISK A/S	22.08.2017	22.08.2017	21.07.2016	05.01.2018
PT	Patent expired	EP97935509	EP0944648	NOVO NORDISK A/S	22.08.2017	—	01.08.2016 Paid for year 20	23.08.2013
RO	No data provided by the national patent office for this patent							
SE	Patent not in force	EP97935509	EP0944648	NOVO NORDISK A/S	—	—	26.07.2016 Latest annual fee paid 20	31.10.2016
SI	No data provided by the national patent office for this patent							

https://register.epo.org/application?number=EP97935509&lng=en&tab=federated

Authorisation details

Product details

Name	Victoza
Agency product number	EMEA/H/C/001026
Active substance	liraglutide
International non-proprietary name (INN) or common name	liraglutide
Therapeutic area (MeSH)	Diabetes Mellitus, Type 2
Anatomical therapeutic chemical (ATC) code	A10BJ02

Publication details

Marketing-authorisation holder	Novo Nordisk A/S
Revision	18
Date of issue of marketing authorisation valid throughout the European Union	30/06/2009
Contact address	Novo Allé DK-2880 Bagsvaerd Denmark

https://www.ema.europa.eu/en/medicines/human/EPAR/victoza

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

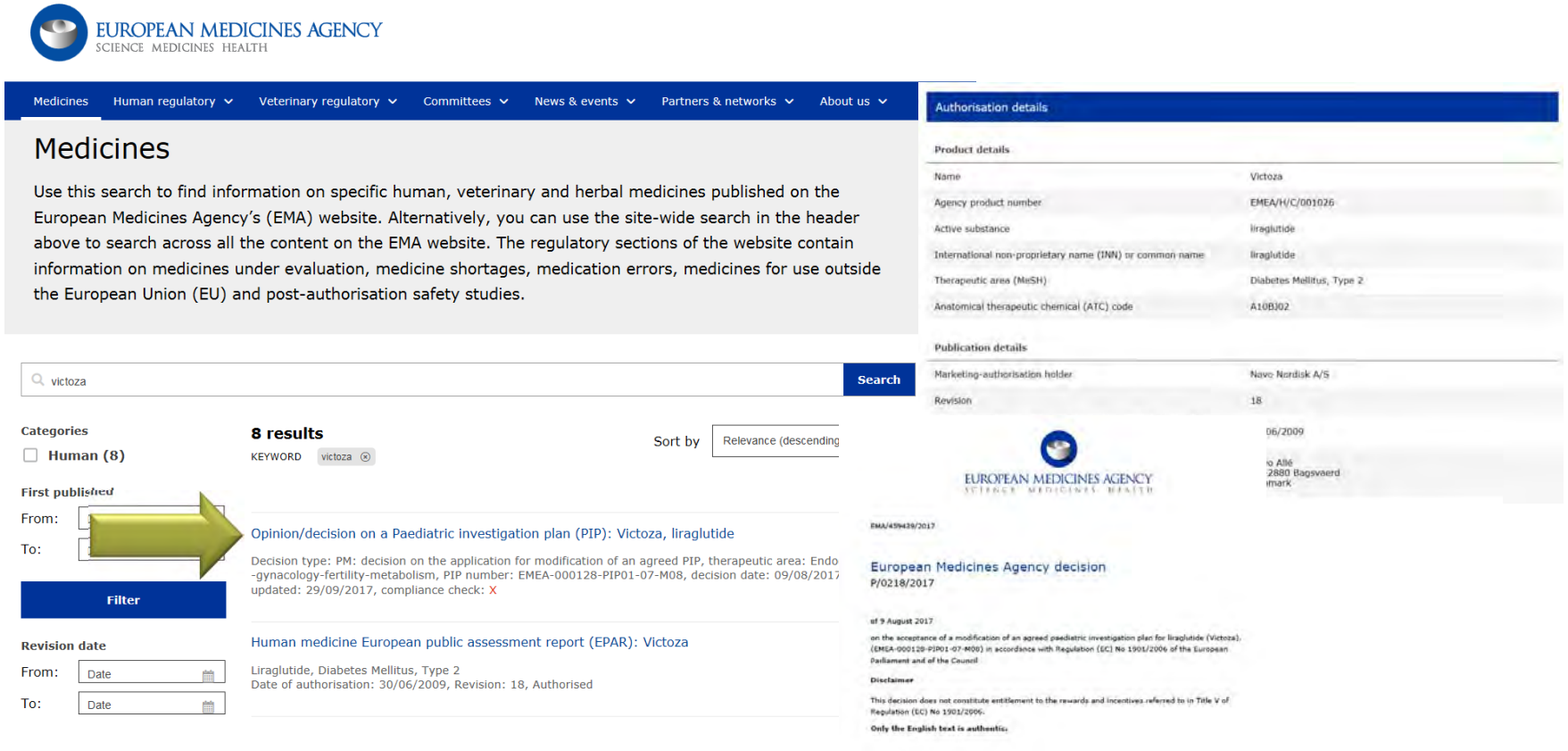
SPC application in Belgium
2009C/050
Filing 30/10/2009
Grant 02/02/2010
Expiration date 22/08/2022
http://bpp.economie.fgov.be/fo-eregister-view/search/detailsType/2009CSLASH050/SPC

SPC application in the UK
SPC/GB09/058
Filing 11/12/2009
Grant 11/03/2011
Expiration date 21/08/2022
http://mijnoctrooi.rvo.nl/fo-eregister-view/search/detailsType/300422/SPC

SPC application in the Netherlands
300422
Filing 22/10/2009
Grant 16/02/2010
Expiration date 21/08/2022
http://mijnoctrooi.rvo.nl/fo-eregister-view/search/detailsType/300422/SPC

SPC application in the CH/LI C00944648/01
Filing 21/05/2010
Grant 31/10/2012
Expiration date 21/08/2022
https://www.swissreg.ch/srclient/faces/jsp/spc/sr300.jsp?language=en&section=spc&id=C00944648%2F01

EU: Paediatric investigation plan (PIP)



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

Federated register: EP0944648

Refine search | ST36 | Espacenet | Submit observations | Report error | Print

GLP-1 DERIVATIVES

Application No.	Publication No.	Applicant	IPC
EP97935509	EP0944648	NOVO NORDISK A/S	C07K14/605 A61K38/26

Only designated contracting states and extension states providing the Federated Register Service are listed below.

	Status	Application No.	Publication No.	Proprietor	Invalidation date	Not in force since	Renewal fees last paid	Record last updated
AT	Patent expired	EP97935509	EP944648	NOVO NORDISK A/S	12.09.2017	22.08.2017	---	---
BE	---	EP97935509	EP0944648	NOVO NORDISK A/S	22.08.2017	22.08.2017	20.07.2016	07.02.2018
CH/LI	Patent not in force	EP97935509	EP0944648	NOVO NORDISK A/S	21.08.2017	21.08.2017	---	28.08.2017
DE	Patent not in force	EP97935509	EP944648	Novo Nordisk A/S, 2880 Bagsvaerd, D...	---	---	---	24.08.2017
ES	Patent lapsed	E97935509	ES2283025	NOVO NORDISK A/S	29.11.2017	23.08.2017	27.07.2016 Latest annual fee paid: 20	---
FI	Patent expired	EP97935509	EP0944648	NOVO NORDISK A/S	---	22.08.2017	21.07.2016	31.10.2018
GB	Patent expired	EP97935509	EP0944648	NOVO-NORDISK A/S	---	21.08.2017	26.07.2016 Latest annual fee paid : 20	---
GR	Patent expired	EP97935509	GR3061947	NOVO NORDISK A/S	06.09.2017	23.08.2017	25.07.2016	06.09.2017
IE	Patent expired	EP97935509	EP0944648	NOVO NORDISK A/S	28.09.2017	28.09.2017	21.07.2016	28.09.2017
LT	Patent not validated	EP97935509	EP0944648	NOVO NORDISK A/S	---	---	---	18.04.2016
LU	Patent lapsed	EP97935509	EP0944648	NOVO NORDISK A/S	---	22.08.2007	---	08.06.2018
NL	---	EP97935509	EP0944648	NOVO NORDISK A/S	22.08.2017	22.08.2017	21.07.2016	05.01.2018
PT	Patent expired	EP97935509	EP944648	NOVO NORDISK A/S	22.08.2017	---	01.08.2016 Paid for year 20	23.08.2013
RO	*No data provided by the national patent office for this patent*							
SE	Patent not in force	EP97935509	EP0944648	NOVO NORDISK A/S	---	---	26.07.2016 Latest annual fee paid: 20	31.10.2018
SI	*No data provided by the national patent office for this patent*							

Responsibility for the accuracy or quality of the data displayed lies entirely with the national patent office concerned, including but not limited to the completeness and fitness of the information for specific purposes.
For complete and authoritative information, please refer to the appropriate national patent register, e.g. by clicking the relevant country code.

National patent registers

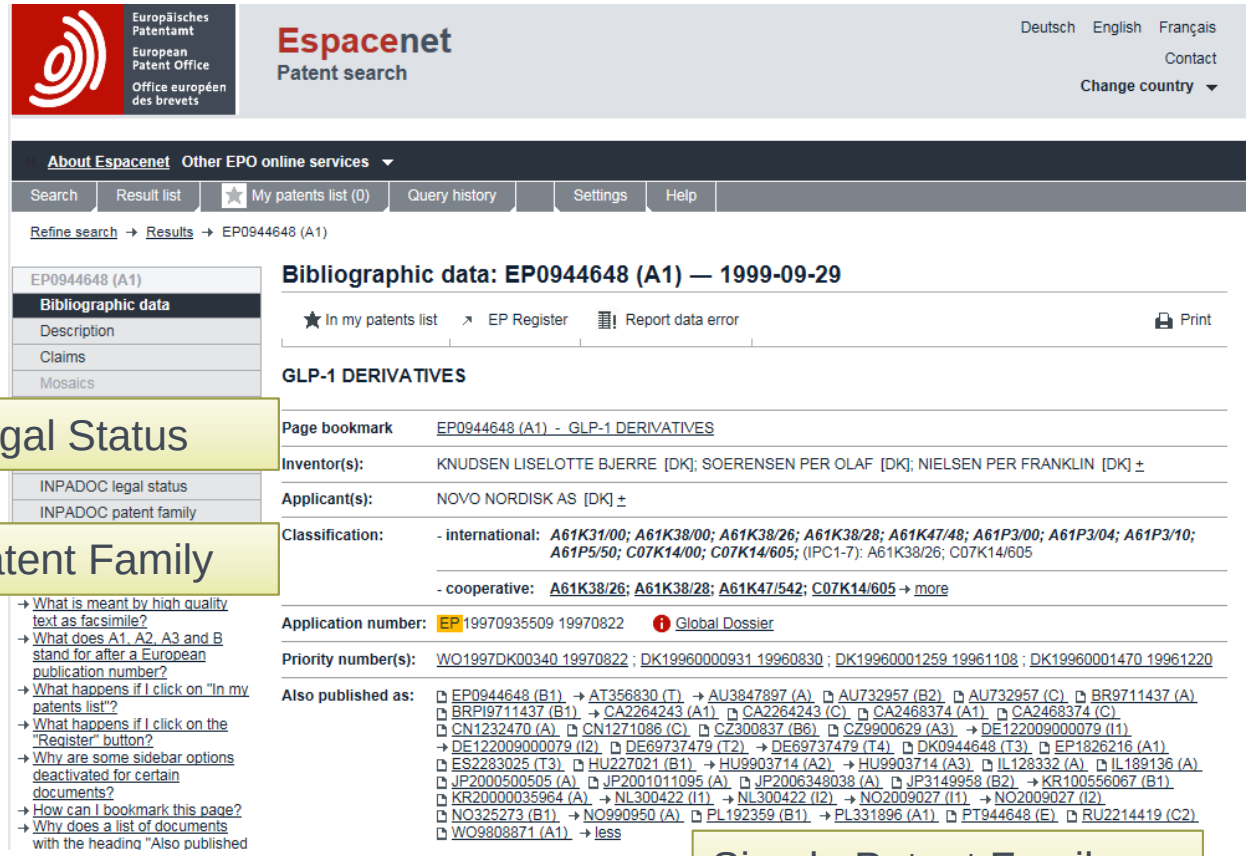
Designated contracting states AT | BE | CH | DE | DK | ES | FI | FR | GB | GR | IE | IT | LI | LU | NL | PT | SE

Extension states AL | LT | LV | RO | SI

EU: National Patent Registers

CC	SPC Number (for EP0944648)	First authorisation (Product: Liraglutide – Victoza)	filed	grant	max validity
AT	SPC 48/2009		23/11/2009	19/12/2014	22/08/2022
BE	2009C/050	EU/1/09/529/001-005 30/06/2009	23/10/2009	02/02/2010	22/08/2009
CH/LI	C00944648/01	SWISSMEDIC 59329 11/12/2009	21/05/2010	31/10/2012	21/08/2022
DE	122009000079.6	EU/1/09/529/001-005 30/06/2009	27/05/2010	16/06/2011	22/08/2022
DK	CA 2009 00041		29/10/2009		
ES	C200900054	EU/1/09/529/001-005 30/06/2009	06/11/2009	18/04/2011	22/08/2022
FI	C20090043	EU/1/09/529/001-005 30/06/2009	29/12/2009	27/04/2012	22/08/2022
FR	FR09C0054	EU/1/09/529/001-005 30/06/2009	23/10/2009	01/04/2011	21/08/2022
GB	SPC/GB09/058	EU/1/09/529/001-005 30/06/2009	11/12/2009	11/03/2011	21/08/2022
GR	20090800031	EU/1/09/529/001-005 30/06/2009	22/10/2009	27/04/2010	23/08/2022
IE	2009/034	EU/1/09/529/001-005 30/06/2009	02/11/2009	27/10/2010	21/08/2022
IT	132009901790907	EU/1/09/529/001-005 30/06/2009	07/12/2009	17/03/2010	22/08/2022
LU	No information				
NL	300422	EU/1/09/529/001-005 30/06/2009	22/10/2009	16/02/2010	21/08/2022
PT	383	EU/1/09/529/001-005 30/06/2009	26/10/2009	04/06/2010	22/08/2022
SE	SE 0990038-2	EU/1/09/529/001-005 30/06/2009	04/11/2009	02/02/2010	22/08/2022

EU: Espacenet



Inpadoc Legal Status

Inpadoc Patent Family

Simple Patent Family

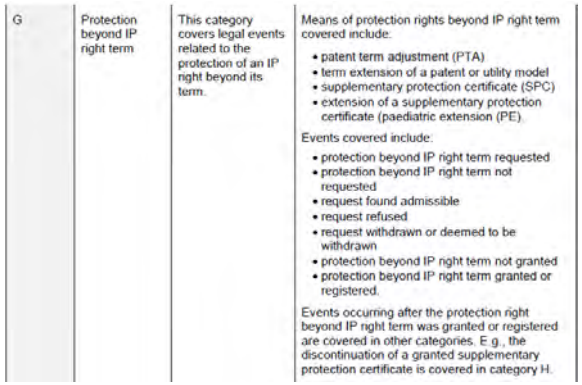
EU: INPADOC legal status

Event date :	2009/10/23
Event code :	REG FR CP
Code Expl.:	SUPPLEMENTARY CERTIFICATE OF PROTECTION FILED
SPC NUMBER :	09C0054
FILING DATE :	20091023
FURTHER INFORMATION :	PRODUCT NAME: LIRAGLUTIDE; REGISTRATION NO/DATE: EU/1/09/529/001 20090630
Event date :	2009/12/04
Event code :	REG FR CR
Code Expl.:	SUPPLEMENTARY CERTIFICATE OF PROTECTION LAID OPEN TO THE PUBLIC (EEC REGULATION OF 18 JUNE 1992)
SPC NUMBER :	09C0054
FILING DATE :	20091023
FURTHER INFORMATION :	PRODUCT NAME: LIRAGLUTIDE; REGISTRATION NO/DATE IN FRANCE: EU/1/09/529/001 DU 20090630; REGISTRATION NO/DATE AT EEC: EU/1/09/529/001 DU 20090630
Event date :	2009/12/04
Event code :	REG FR CP
Code Expl.:	SUPPLEMENTARY CERTIFICATE OF PROTECTION FILED
Event date :	2009/12/09
Event code :	REG IE SPCF
Code Expl.:	REQUEST FOR GRANT OF SUPPLEMENTARY PROTECTION CERTIFICATE
SPC NUMBER :	SPC034/2009
FILING DATE :	20091102
FURTHER INFORMATION :	SPC034/2009: 20091102
Event date :	2009/12/15
Event code :	REG SE SPCF
Code Expl.:	APPLICATION FOR SUPPLEMENTARY PROTECTION CERTIFICATE FILED
SPC NUMBER :	0990038-2
FILING DATE :	20090630
FURTHER INFORMATION :	0990038-2, 20090630

EU: INPADOC legal status – events on SPC filing (GPI)

REG CH SPCF	20100531	G	SPCF	SUPPLEMENTARY PROTECTION CERTIFICATE FILED
REG GB CTFF	20100120	G	CTFF	SUPPLEMENTARY PROTECTION CERTIFICATE FILED
REG AT ESZA	20100115	G	ESZA	APPLICATION FILED FOR A CERTIFICATE OF PROTECTION (E-SERIES)
REG NL AC1	20100104	G	AC1	APPLICATION FOR A SUPPLEMENTARY PROTECTION CERTIFICATE
REG DE V448	20091230	G	V448	APPLICATION OF SPC
REG FI SPCF	20091229	G	SPCF	SUPPLEMENTARY PROTECTION CERTIFICATE APPLICATION FILED
REG DK CTFF	20091221	G	CTFF	APPLICATION FOR SUPPLEMENTARY PROTECTION CERTIFICATE (SPC) FILED
REG SE SPCF	20091215	G	SPCF	APPLICATION FOR SUPPLEMENTARY PROTECTION CERTIFICATE FILED
REG IE SPCF	20091209	G	SPCF	REQUEST FOR GRANT OF SUPPLEMENTARY PROTECTION CERTIFICATE
REG FR CP	20091023	G	CP	SUPPLEMENTARY CERTIFICATE OF PROTECTION FILED

[INPADOC classification scheme v. 1.0]

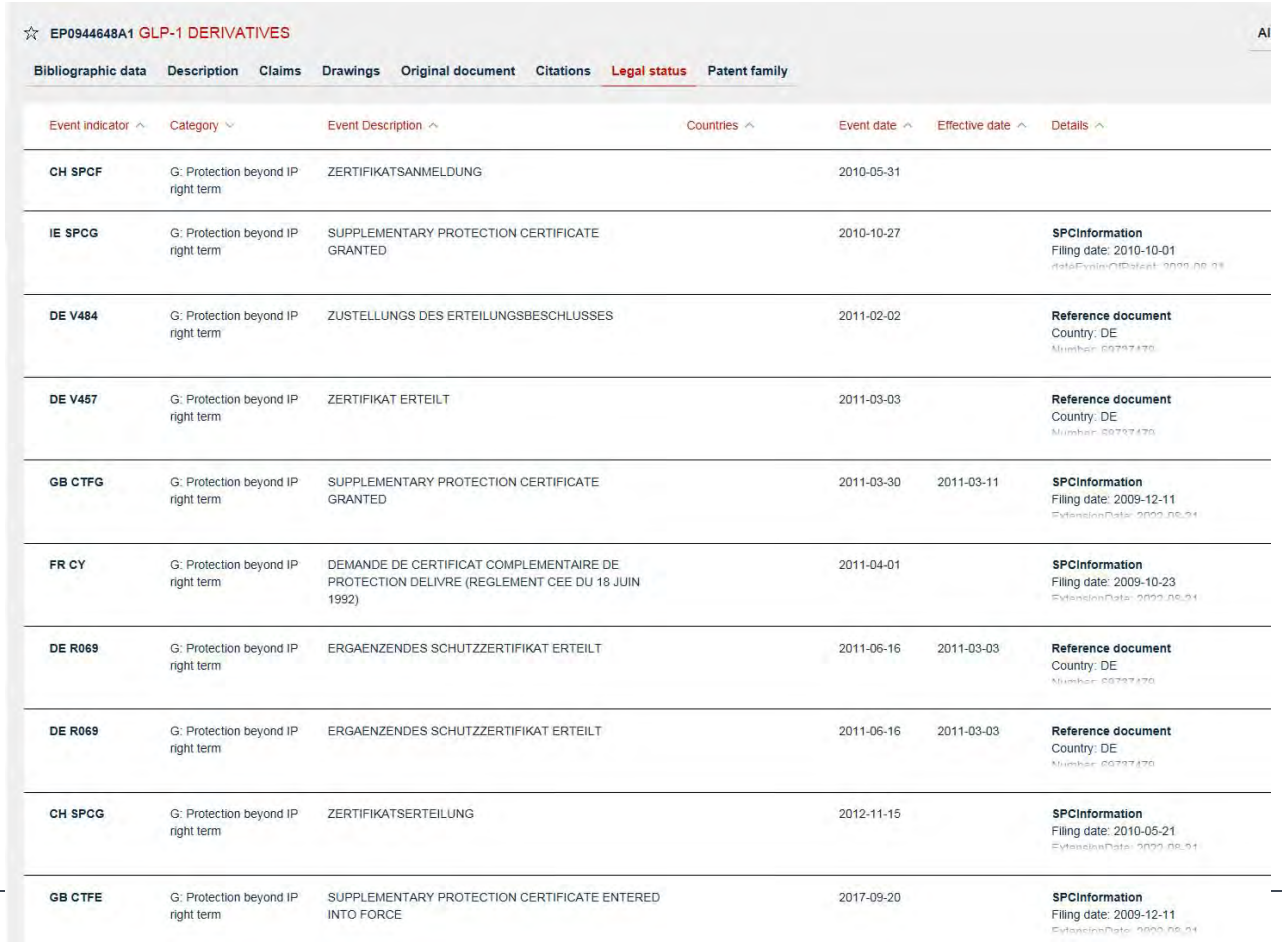


G	Protection beyond IP right term	This category covers legal events related to the protection of an IP right beyond its term.	Means of protection rights beyond IP right term covered include: • patent term adjustment (PTA) • term extension of a patent or utility model • supplementary protection certificate (SPC) • extension of a supplementary protection certificate (paediatric extension (PE). Events covered include: • protection beyond IP right term requested • protection beyond IP right term not requested • request found admissible • request refused • request withdrawn or deemed to be withdrawn • protection beyond IP right term not granted • protection beyond IP right term granted or registered. Events occurring after the protection right beyond IP right term was granted or registered are covered in other categories. E.g., the discontinuation of a granted supplementary protection certificate is covered in category H.

EU: Legal status codes and categories

163	NL	SPCD	SUPPLEMENTARY PROTECTION CERTIFICATE REJECTED	G	PROTECTION BEYOND IP RIGHT TERM
164	NL	SPCE	FILING FOR A PAEDIATRIC EXTENSION OF A SUPPLEMENTARY PROTECTION CERTIFICATE	G	PROTECTION BEYOND IP RIGHT TERM
165	NL	SPCF	APPLICATION FOR A SUPPLEMENTARY PROTECTION CERTIFICATE	G	PROTECTION BEYOND IP RIGHT TERM
166	NL	SPCG	GRANT OF A SUPPLEMENTARY PROTECTION CERTIFICATE	G	PROTECTION BEYOND IP RIGHT TERM
167	NL	SPCY	PAEDIATRIC EXTENSION OF SUPPLEMENTARY PROTECTION CERTIFICATE REJECTED	G	PROTECTION BEYOND IP RIGHT TERM
168	NL	SPCZ	GRANT OF EXTENSION OF A SUPPLEMENTARY PROTECTION CERTIFICATE	G	PROTECTION BEYOND IP RIGHT TERM
169	NL	XC	OTHER COMMUNICATIONS CONCERNING SUPPLEMENTARY PROTECTION CERTIFICATES	G	PROTECTION BEYOND IP RIGHT TERM
170	NO	SPCE	APPLICATION TO EXTEND A SUPPLEMENTARY PROTECTION CERTIFICATE (SPC)	G	PROTECTION BEYOND IP RIGHT TERM
171	NO	SPCF	FILING OF SUPPLEMENTARY PROTECTION CERTIFICATE	G	PROTECTION BEYOND IP RIGHT TERM
172	NO	SPCG	GRANTED SUPPLEMENTARY PROTECTION CERTIFICATE	G	PROTECTION BEYOND IP RIGHT TERM
173	NO	SPCH	EXTENSION OF A SUPPLEMENTARY PROTECTION CERTIFICATE (SPC) GRANTED	G	PROTECTION BEYOND IP RIGHT TERM
174	NO	SPCK	CHANGE IN THE VALIDITY PERIOD OF AN SPC	G	PROTECTION BEYOND IP RIGHT TERM
175	NO	SPCW	WITHDRAWAL, REJECTION OR DISMISSAL OF SUPPLEMENTARY PROTECTION CERTIFICATE	G	PROTECTION BEYOND IP RIGHT TERM

EU: categories for INPADOC events available in New Espacenet



☆ EP0944648A1 GLP-1 DERIVATIVES

Bibliographic data | Description | Claims | Drawings | Original document | Citations | Legal status | Patent family

Event indicator	Category	Event Description	Countries	Event date	Effective date	Details
CH SPCF	G: Protection beyond IP right term	ZERTIFIKATSANMELDUNG		2010-05-31		
IE SPCG	G: Protection beyond IP right term	SUPPLEMENTARY PROTECTION CERTIFICATE GRANTED		2010-10-27		SPCInformation Filing date: 2010-10-01
DE V484	G: Protection beyond IP right term	ZUSTELLUNGS DES ERTEILUNGSBESCHLUSSES		2011-02-02		Reference document Country: DE
DE V457	G: Protection beyond IP right term	ZERTIFIKAT ERTEILT		2011-03-03		Reference document Country: DE
GB CTFG	G: Protection beyond IP right term	SUPPLEMENTARY PROTECTION CERTIFICATE GRANTED		2011-03-30	2011-03-11	SPCInformation Filing date: 2009-12-11
FR CY	G: Protection beyond IP right term	DEMANDE DE CERTIFICAT COMPLEMENTAIRE DE PROTECTION DELIVRE (REGLEMENT CEE DU 18 JUIN 1992)		2011-04-01		SPCInformation Filing date: 2009-10-23
DE R069	G: Protection beyond IP right term	ERGAENZENDES SCHUTZZERTIFIKAT ERTEILT		2011-06-16	2011-03-03	Reference document Country: DE
DE R069	G: Protection beyond IP right term	ERGAENZENDES SCHUTZZERTIFIKAT ERTEILT		2011-06-16	2011-03-03	Reference document Country: DE
CH SPCG	G: Protection beyond IP right term	ZERTIFIKATSERTEILUNG		2012-11-15		SPCInformation Filing date: 2010-05-21
GB CTFE	G: Protection beyond IP right term	SUPPLEMENTARY PROTECTION CERTIFICATE ENTERED INTO FORCE		2017-09-20		SPCInformation Filing date: 2009-12-11

EU: Future ... SPC Manufacturing waiver

Export manufacturing waiver for SPCs

On 28 May 2018, the Commission adopted a proposal for a regulation to amend Regulation (EC) No 469/2009 on supplementary protection certificates for medicinal products.

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

https://ec.europa.eu/growth/content/brexit-%E2%80%93-guidance-stakeholders-impact-field-supplementary-protection-certificates-medicinal_en

EU: SPC and Unitary Patent Package

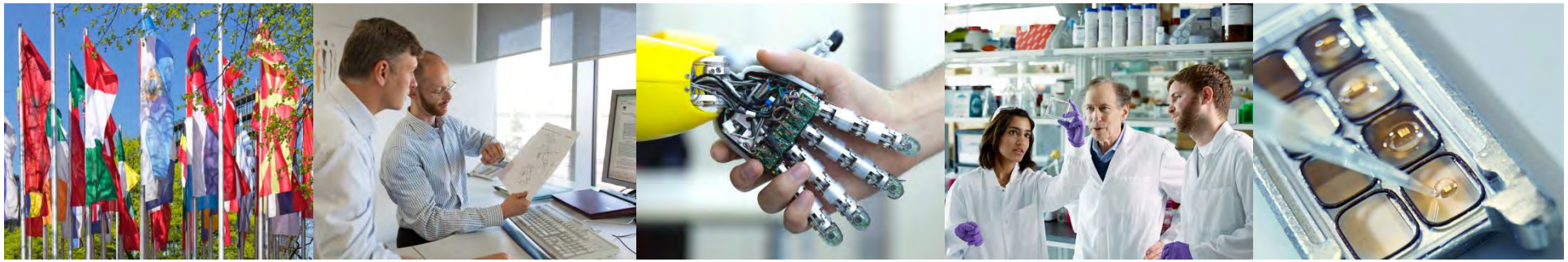
- The 'patent package' that lays the ground for the creation of unitary patent protection in the EU does not explicitly provide for a 'unitary SPC'.

- 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.

AND NOW… KOREA

Europäisches Patentamt
European Patent Office
Office européen des brevets

US: Patent term extension (PTE)



US: Background

- **1984** Drug Price Competition and Patent Term Restoration Act - Patent Terms Extended Under 35 U.S.C. §156

- 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.

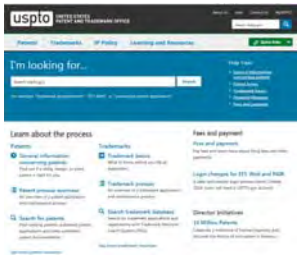
https://www.uspto.gov/patent/laws-and-regulations/patent-terms-extended
https://www.uspto.gov/web/offices/pac/mpep/mpep-9015-appx-l.html#d0e303884

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



https://www.uspto.gov/

https://www.fda.gov/default.htm
https://www.usda.gov/

Product

basic patent granted

Product approval

request for Patent term extension

within 60 days

USPTO

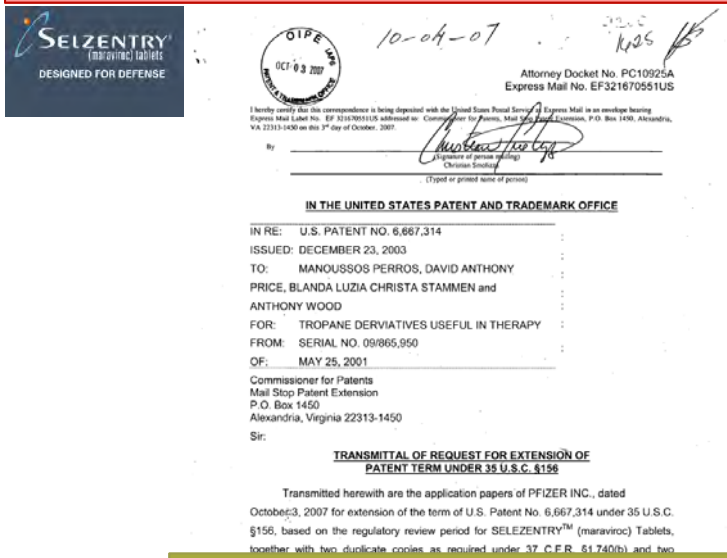
defining eligibility
defining term

FDA/USDA

Patent term extension

US: Procedure for the product Selzentry (maraviroc)

US 6667314 Granted 23.03.2003



10-04-07

Attorney Docket No. PC10925A
Express Mail No. EF321670551US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE: U.S. PATENT NO. 6,667,314
ISSUED: DECEMBER 23, 2003
TO: MANOUSSOS PERROS, DAVID ANTHONY PRICE, BLANDA LUZIA CHRISTA STAMMEN and ANTHONY WOOD
FOR: TROPANE DERVIATIVES USEFUL IN THERAPY
FROM: SERIAL NO. 09/865,950
OF: MAY 25, 2001

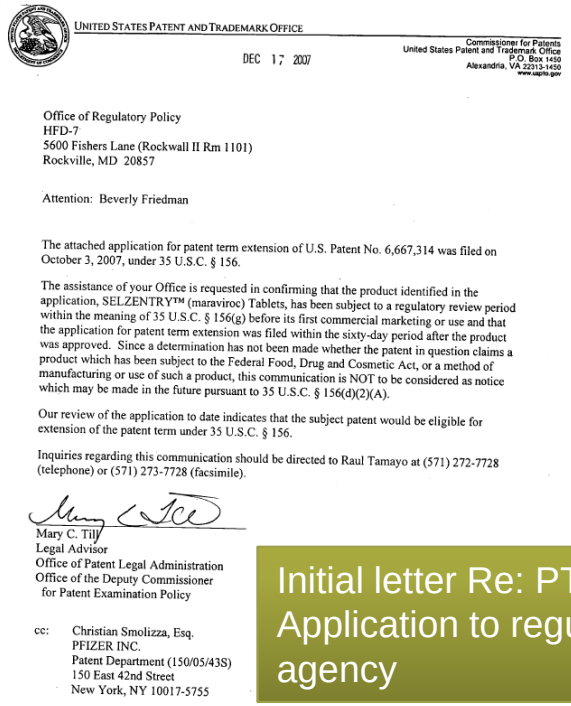
Commissioner for Patents
Mail Stop Patent Extension
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

TRANSMITTAL OF REQUEST FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. §156

Transmitted herewith are the application papers of PFIZER INC., dated October 3, 2007 for extension of the term of U.S. Patent No. 6,667,314 under 35 U.S.C. §156, based on the regulatory review period for SELEZENTRY™ (maraviroc) Tablets,

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



UNITED STATES PATENT AND TRADEMARK OFFICE

DEC 17 2007

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Office of Regulatory Policy
HFD-7
5600 Fishers Lane (Rockwall II Rm 1101)
Rockville, MD 20857

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 6,667,314 was filed on October 3, 2007, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, SELZENTRY™ (maraviroc) Tablets, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

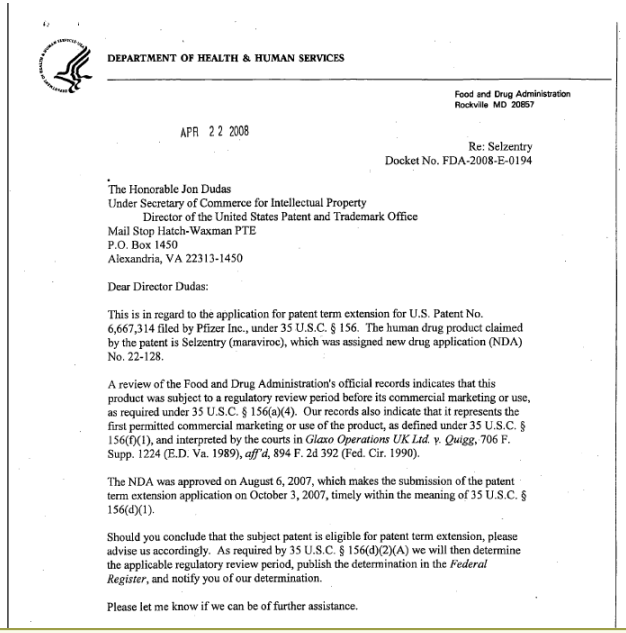
Inquiries regarding this communication should be directed to Raul Tamayo at (571) 272-7728 (telephone) or (571) 273-7728 (facsimile).

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Christian Smolizza, Esq.
PFIZER INC.
Patent Department (150/05/43S)
150 East 42nd Street
New York, NY 10017-5755

Initial letter Re: PTE Application to regulating agency

US: Procedure



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 22 2008

Re: Selzentry
Docket No. FDA-2008-E-0194

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 6,667,314 filed by Pfizer Inc., under 35 U.S.C. § 156. The human drug product claimed by the patent is Selzentry (maraviroc), which was assigned new drug application (NDA) No. 22-128.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in *Glaxo Operations UK Ltd. v. Quigg*, 706 F. Supp. 1224 (E.D. Va. 1989), *aff'd*, 894 F. 2d 392 (Fed. Cir. 1990).

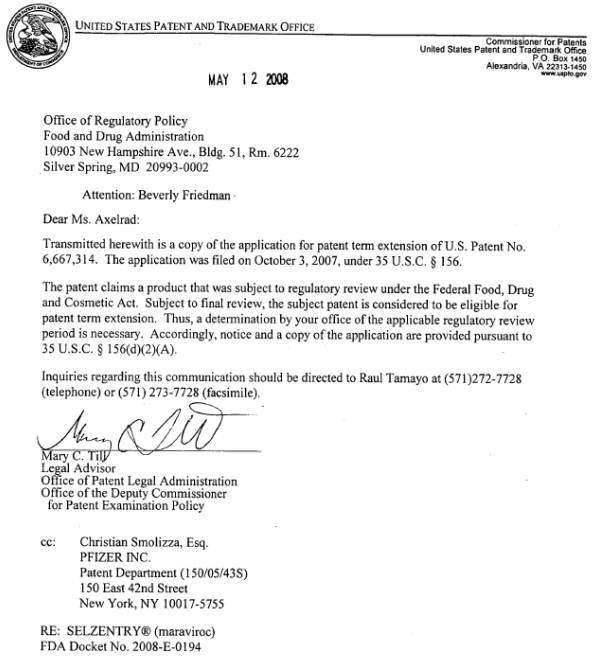
The NDA was approved on August 6, 2007, which makes the submission of the patent term extension application on October 3, 2007, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

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



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAY 12 2008

Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

Dear Ms. Axelrad:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 6,667,314. The application was filed on October 3, 2007, under 35 U.S.C. § 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term extension. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

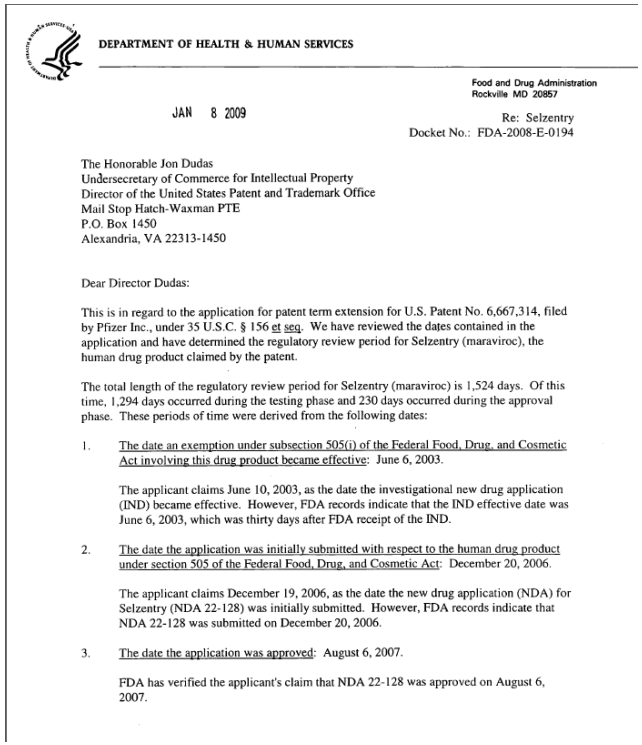
Inquiries regarding this communication should be directed to Raul Tamayo at (571)272-7728 (telephone) or (571) 273-7728 (facsimile).

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Christian Smolizza, Esq.
PFIZER INC.
Patent Department (150/05/43S)
150 East 42nd Street
New York, NY 10017-5755

RE: SELZENTRY® (maraviroc)
FDA Docket No. 2008-E-0194

US: Procedure



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 8 2009

Re: Selzentry
Docket No.: FDA-2008-E-0194

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 6,667,314, filed by Pfizer Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Selzentry (maraviroc), the human drug product claimed by the patent.

The total length of the regulatory review period for Selzentry (maraviroc) is 1,524 days. Of this time, 1,294 days occurred during the testing phase and 230 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: June 6, 2003.

   The applicant claims June 10, 2003, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 6, 2003, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: December 20, 2006.

   The applicant claims December 19, 2006, as the date the new drug application (NDA) for Selzentry (NDA 22-128) was initially submitted. However, FDA records indicate that NDA 22-128 was submitted on December 20, 2006.

3. The date the application was approved: August 6, 2007.

   FDA has verified the applicant's claim that NDA 22-128 was approved on August 6, 2007.

Dudas - Selzentry
Patent No. 6,667,314
Page 2

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Christian Smolizza, Esq.
Pfizer Inc.
Patent Department 150/05/43S
150 East 42nd Street
New York, NY 10017-5755

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

US: Procedure

approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biologic product MIRCERA (methoxy polyethylene glycol-epoetin beta). MIRCERA is indicated for the treatment of anemia associated with chronic renal failure, including patients on dialysis and patients not on dialysis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for MIRCERA (U.S. Patent No. 6,583,272) from Hoffmann-La Roche Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 22, 2008, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of MIRCERA represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for MIRCERA is 2,140 days. Of this time, 1,565 days occurred during the testing phase of the regulatory review period, while 575 days occurred during the approval p

were deriv

1. *The d section 505 and Cosm* became effective: January 6, 2002. The applicant claims January 3, 2002, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 6, 2002, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262)*: April 19, 2006. The applicant claims April 18, 2006, as the date the biologics license application (BLA) for MIRCERA (BLA B125164/0) was initially submitted. However, FDA records indicate that BLA B125164/0 was submitted on April 19, 2006.

3. *The date the application was approved*: November 14, 2007. FDA has verified the applicant's claim that BLA B125164/0 was approved on November 14, 2007.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by April 13, 2009. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 10, 2009. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Notice in Federal Register

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–E–0194]

Determination of Regulatory Review Period for Purposes of Patent Extension; SELZENTRY

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for SELZENTRY and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical drug becomes til the approval proval phase starts ission of an the human drug ues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product SELZENTRY (maraviroc). SELZENTRY is indicated for combination antiretroviral treatment of adults infected with only CCR5-tropic HIV–1 detectable, who have evidence of viral replication and HIV–1 strains resistant to multiple antiretroviral agents. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for SELZENTRY (U.S. Patent No. 6,667,314) from Pfizer Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 22, 2008, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of SELZENTRY represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for SELZENTRY is 1,524 days. Of this time, 1,294 days occurred during the testing phase of the regulatory review period, while 230 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: June 6, 2003. The applicant claims June 10, 2003, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 6, 2003, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: December 20, 2006. The applicant claims December 19, 2006, as the date the new drug application (NDA) for SELZENTRY (NDA 22–128) was initially submitted. However, FDA records indicate that NDA 22–128 was submitted on December 20, 2006.

3. *The date the application was approved*: August 6, 2007. FDA has verified the applicant's claim that NDA 22–128 was approved on August 6, 2007.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 73 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by April 13, 2009. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 10, 2009. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 2, 2009.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E9–2813 Filed 2–9–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–E–0112]

Determination of Regulatory Review Period for Purposes of Patent Extension; VETMEDIN

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for VETMEDIN and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that animal drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA recently approved for marketing the animal drug product VETMEDIN (pimobendan). VETMEDIN is indicated for the management of the signs of mild, moderate, or severe (modified NYHA Class II, III, or IV) congestive heart failure in dogs due to atrioventricular valvular insufficiency or dilated cardiomyopathy. VETMEDIN is indicated for use with concurrent therapy for congestive heart failure (e.g., furosemide, etc.) as appropriate on a case-by-case basis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for VETMEDIN (U.S. Patent No. 5,364,648) from Dr. Karl Thomae GmbH, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 9, 2008, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of VETMEDIN represented the first permitted commercial marketing or use of the product. Shortly thereafter,

US: Procedure

Department of Health and Human Services — Public Health Service

SEP 30 2009

Food and Drug Administration
Rockville, MD 20857

Re: Selzentry
Docket No. FDA-2008-E-0194

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the patent term extension application for U.S. Patent No. 6,667,314 filed by Pfizer Inc. under 35 U.S.C. § 156. The patent claims Selzentry (maraviroc), new drug application (NDA) 22-128.

In the February 10, 2009, issue of the Federal Register (74 Fed. Reg. 6638), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before August 10, 2009, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Jane A. Axelrad

FDA Final Eligibility Letter

cc: Christian Smolizza, Esq.
Pfizer Inc.
Patent Department 150/05/43S
150 East 42nd Street
New York, NY 10017-5755

Notice of Final Determination-Eligible

UNITED STATES PATENT AND TRADEMARK OFFICE

FEB 23 2010

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Christian Smolizza, Esq.
Pfizer Inc.
Patent Department (150/05/43S)
150 East 42nd Street
New York, NY 10017-5755

In Re: Patent Term Extension
Application for
U.S. Patent No. 6,667,314

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 6,667,314, claims of which cover the human drug product SELZENTRY® (maraviroc), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 73 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of a request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 73 days.

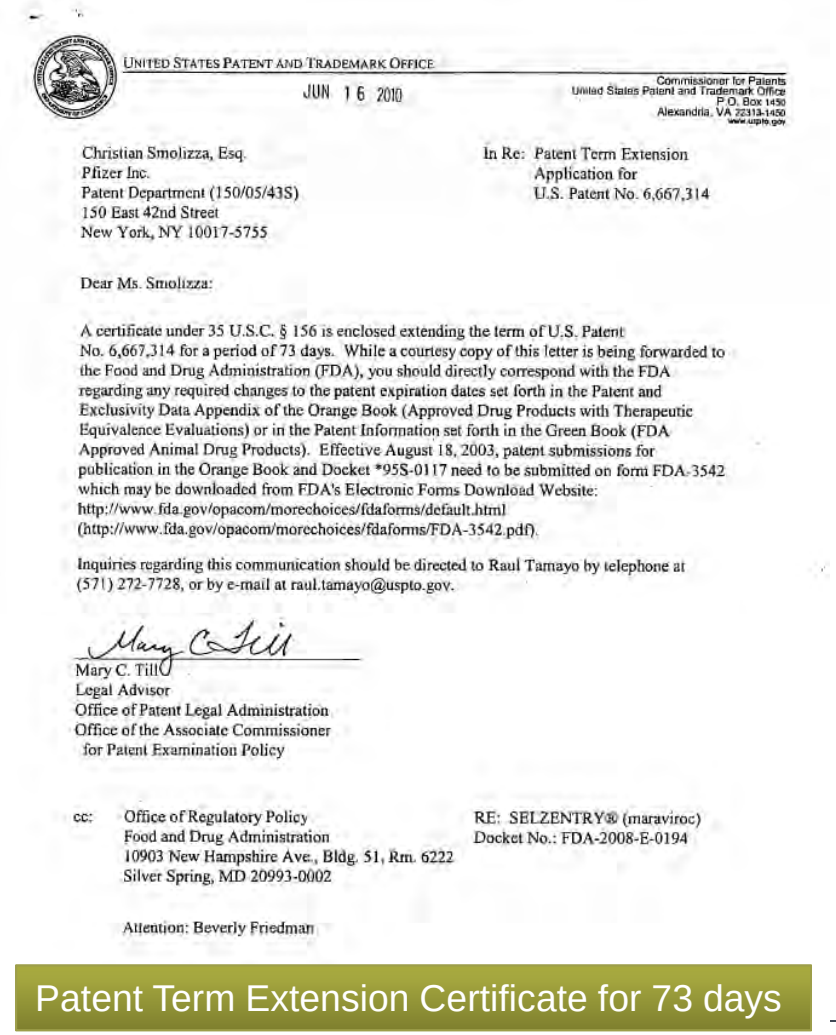
The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of February 10, 2009 (74 Fed. Reg. 6638), would be 776 days. Under 35 U.S.C. § 156(c):

Period of Extension = ½ (Testing Phase) + Approval Phase
= ½ (1,294 - 201) + 230
= 776 days (2.1 years)

Since the regulatory review period began June 6, 2003, before the patent issued (December 23, 2003), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From June 6, 2003, to and including December 23, 2003, is 201 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation, because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 776 days, would extend the patent from May 25, 2021, to July 10, 2023, which is beyond the 14-year limit (the approval date is August 6, 2007, thus the 14 year limit is August 6, 2021). The period of

US: Procedure



UNITED STATES PATENT AND TRADEMARK OFFICE

JUN 16 2010

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Christian Smolizza, Esq.
Pfizer Inc.
Patent Department (150/05/43S)
150 East 42nd Street
New York, NY 10017-5755

In Re: Patent Term Extension
Application for
U.S. Patent No. 6,667,314

Dear Ms. Smolizza:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 6,667,314 for a period of 73 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to Raul Tamayo by telephone at (571) 272-7728, or by e-mail at raul.tamayo@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

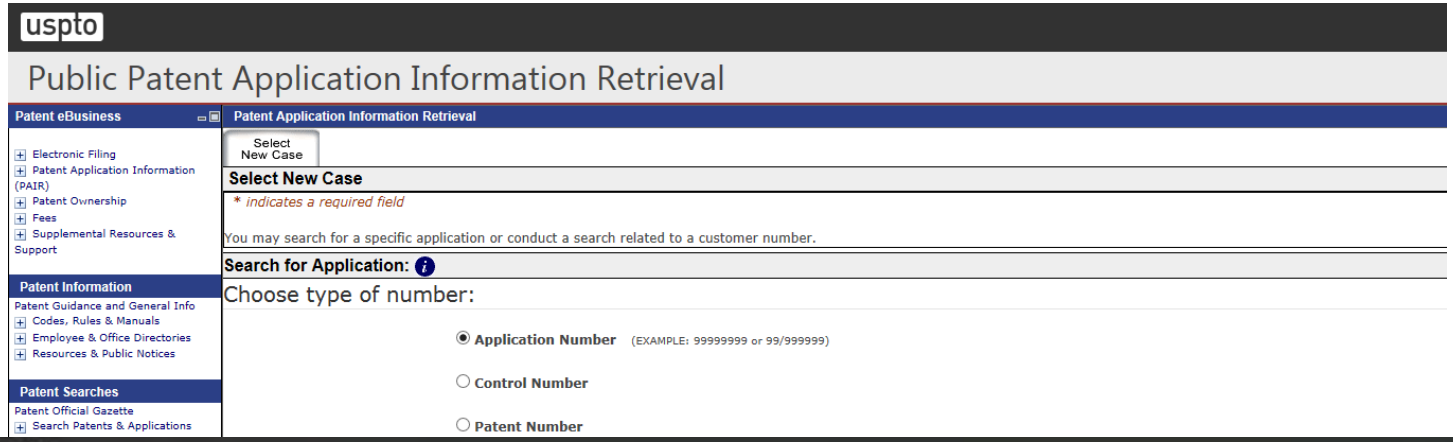
RE: SELZENTRY® (maraviroc)
Docket No.: FDA-2008-E-0194

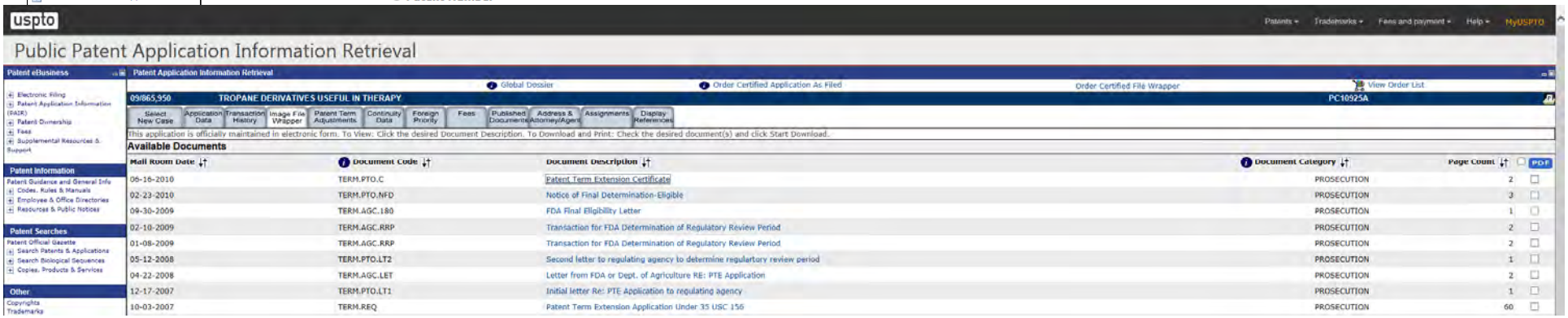
Patent Term Extension Certificate for 73 days

US: Search example

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

US: US Pair

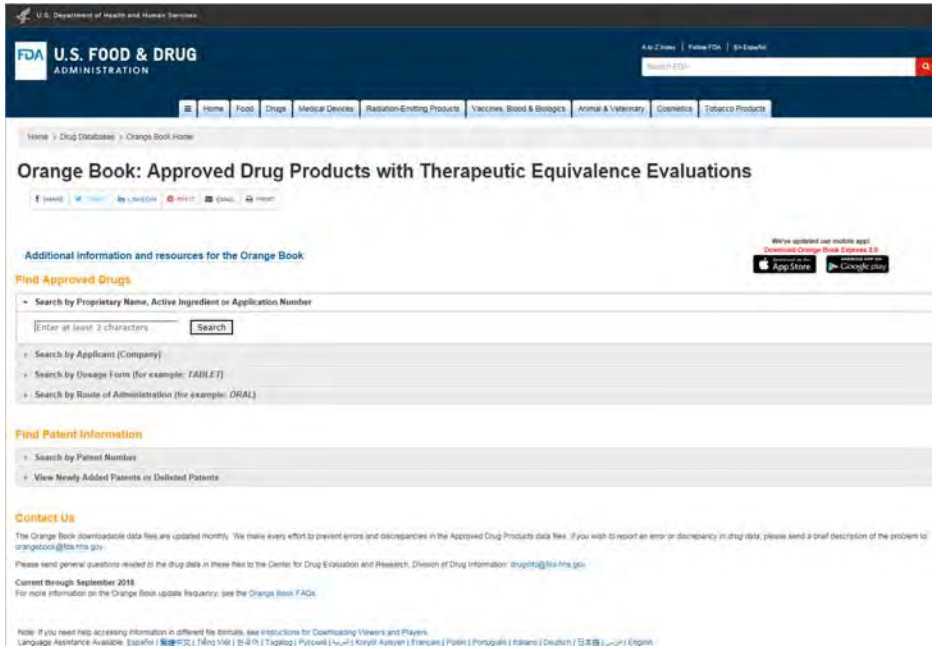




https://portal.uspto.gov/pair/PublicPair

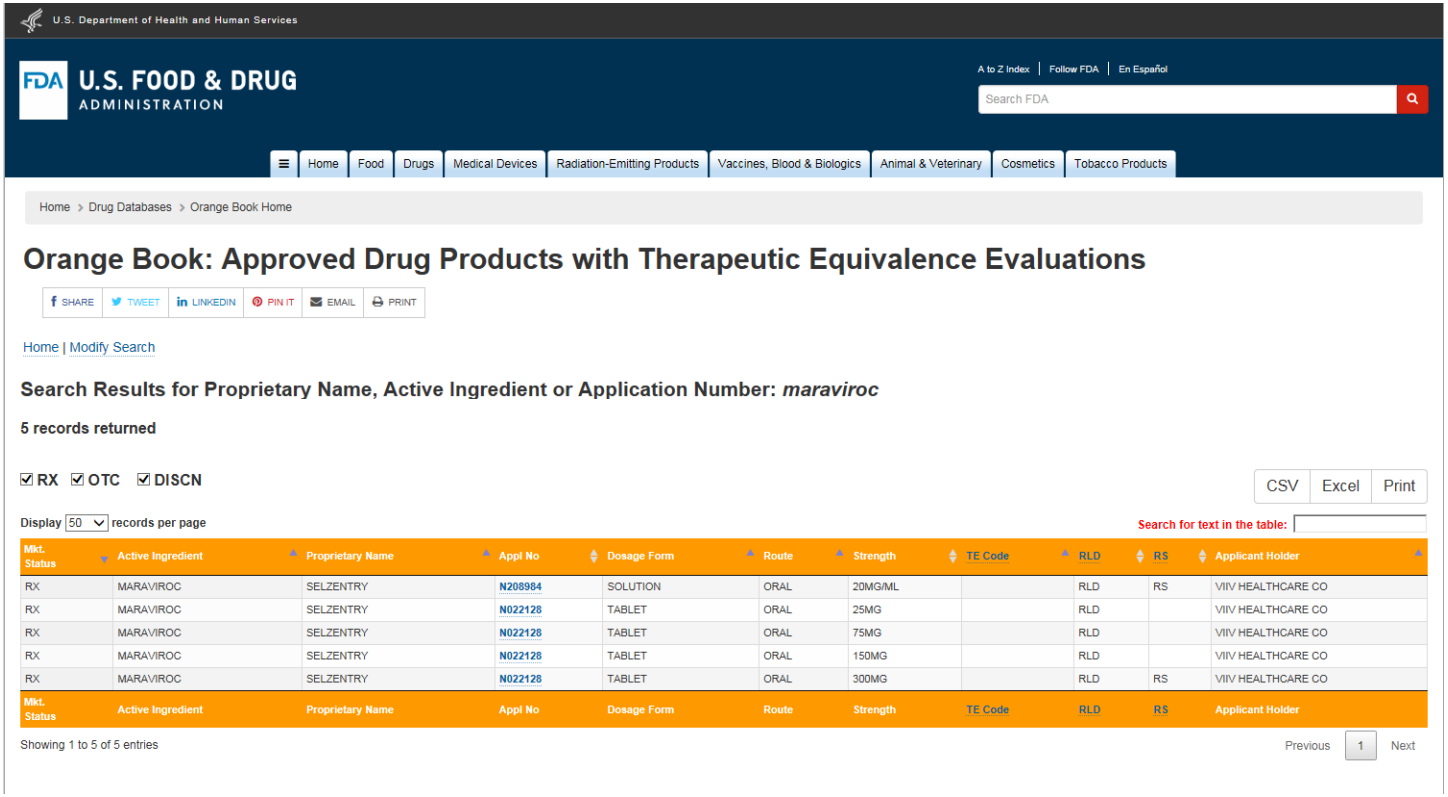
U.S.: Patent Linkage

Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)



https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm

U.S.: Orange book



U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

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Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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Search Results for Proprietary Name, Active Ingredient or Application Number: *maraviroc*

5 records returned

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Search for text in the table:

Mkt. Status	Active Ingredient	Proprietary Name	Appl No	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	MARAVIROC	SELZENTRY	N208984	SOLUTION	ORAL	20MG/ML		RLD	RS	VIIV HEALTHCARE CO
RX	MARAVIROC	SELZENTRY	N022128	TABLET	ORAL	25MG		RLD		VIIV HEALTHCARE CO
RX	MARAVIROC	SELZENTRY	N022128	TABLET	ORAL	75MG		RLD		VIIV HEALTHCARE CO
RX	MARAVIROC	SELZENTRY	N022128	TABLET	ORAL	150MG		RLD		VIIV HEALTHCARE CO
RX	MARAVIROC	SELZENTRY	N022128	TABLET	ORAL	300MG		RLD	RS	VIIV HEALTHCARE CO
Mkt. Status	Active Ingredient	Proprietary Name	Appl No	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder

Showing 1 to 5 of 5 entries

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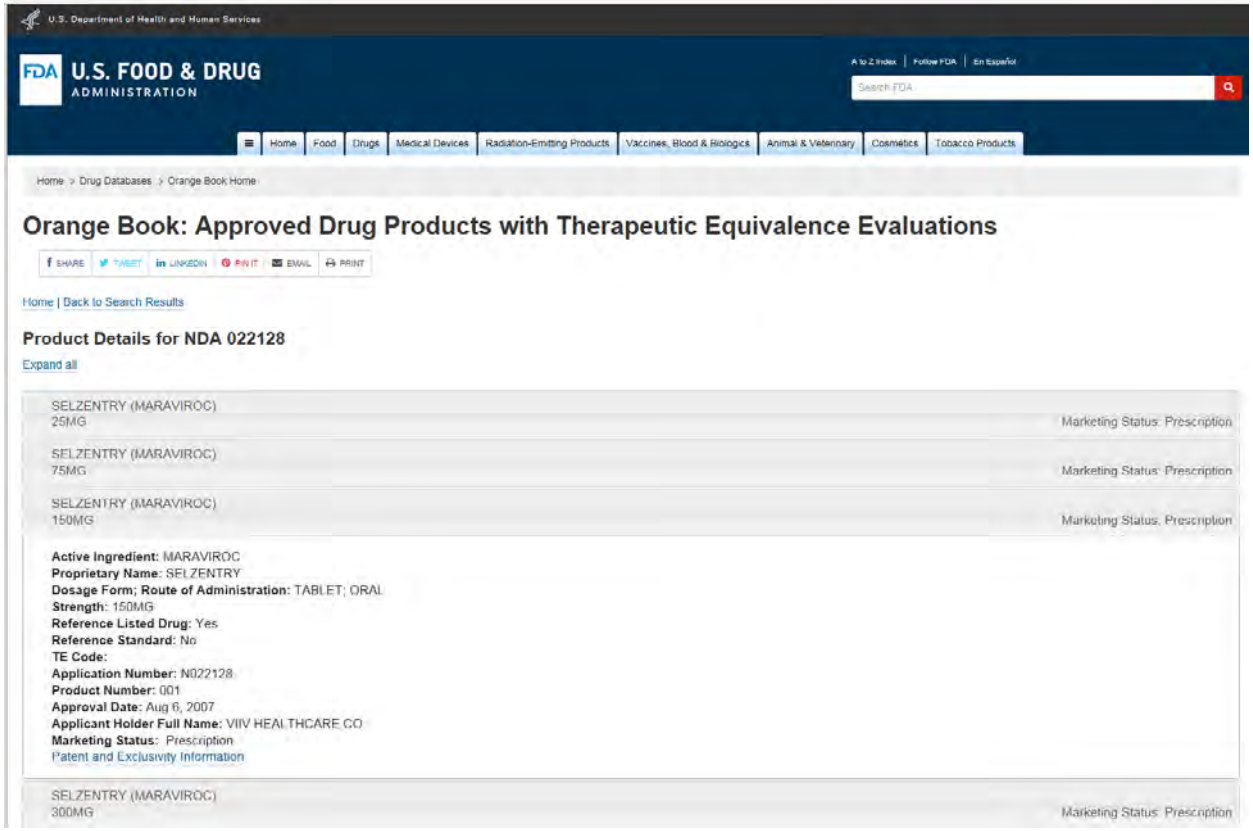
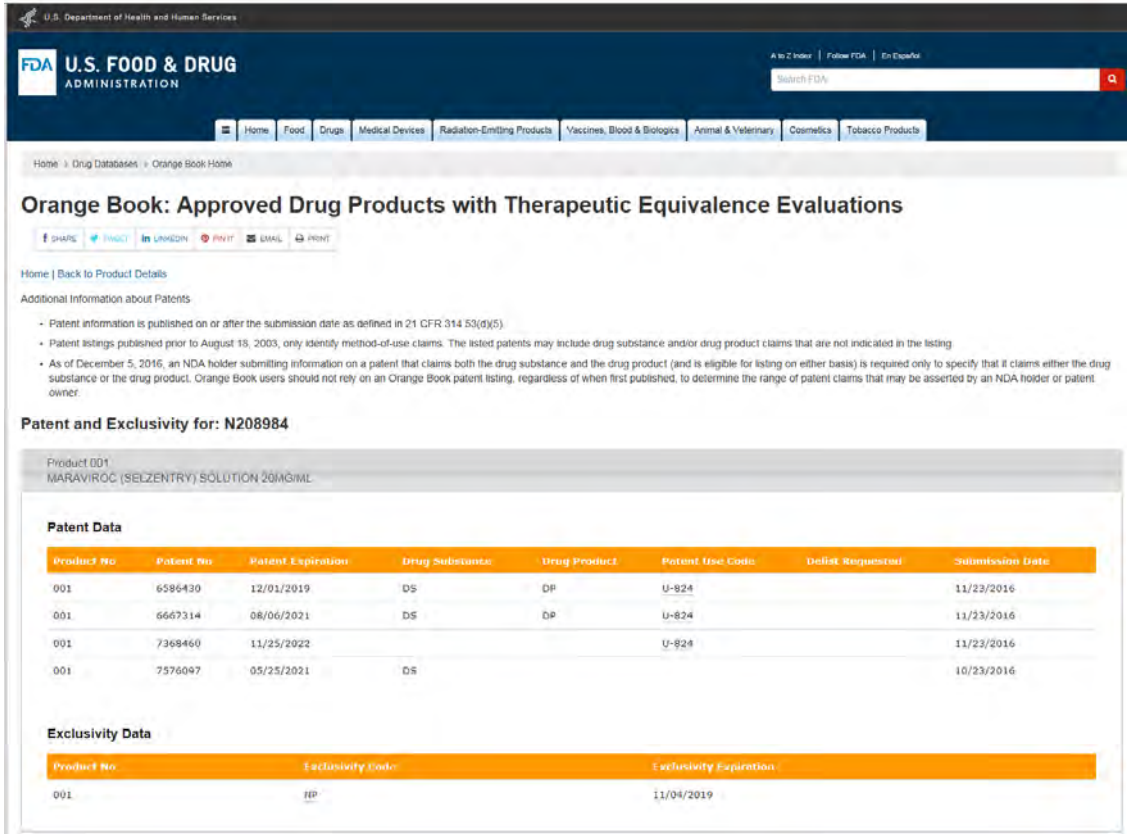
U.S.: Orange book



U.S.: Orange book



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Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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Additional Information about Patents

- Patent information is published on or after the submission date as defined in 21 CFR 314.53(d)(5).
- Patent listings published prior to August 18, 2003, only identify method-of-use claims. The listed patents may include drug substance and/or drug product claims that are not indicated in the listing.
- As of December 5, 2016, an NDA holder submitting information on a patent that claims both the drug substance and the drug product (and is eligible for listing on either basis) is required only to specify that it claims either the drug substance or the drug product. Orange Book users should not rely on an Orange Book patent listing, regardless of when first published, to determine the range of patent claims that may be asserted by an NDA holder or patent owner.

Patent and Exclusivity for: N208984

Product 001
MARAVIROC (SELZENTRY) SOLUTION 20MG/ML

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	6586430	12/01/2019	DS	DP	U-824		11/23/2016
001	6667314	08/06/2021	DS	DP	U-824		11/23/2016
001	7368460	11/25/2022			U-824		11/23/2016
001	7576097	05/25/2021	DS				10/23/2016

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
001	NP	11/04/2019

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

US	PTEF	APPLICATION FOR A PATENT TERM EXTENSION	G	PROTECTION BEYOND IP RIGHT TERM
US	PTEG	GRANT OF A PATENT TERM EXTENSION	G	PROTECTION BEYOND IP RIGHT TERM
US	PTER	REJECTION OF A REQUEST FOR PATENT TERM EXTENSION (FOR EG. INELIGIBLE, DISMISSAL, WITHDRAWAL, ETC)	G	PROTECTION BEYOND IP RIGHT TERM

Authority	Event Code	First Date Gazette	Last Date Gazette	First Application			First Date Filed	Last Application			Last Date Filed	No. Events
US	PTEF	28-09-1984	05-10-2018	US	53628166	A	22-03-1966	US	201615019009	A	09-02-2016	1555
US	PTEG	18-04-1986	10-09-2018	US	70037568	A	25-01-1968	US	201615019009	A	09-02-2016	821
US	PTER	26-07-1985	12-06-2018	US	28674172	A	08-09-1972	US	201113334288	A	22-12-2011	159

U.S.: Events in Espacenet

Event date :	2007/05/17
Event code :	FPAY
Code Expl.:	+ FEE PAYMENT
PAYMENT YEAR :	4
Event date :	2007/10/03
Event code :	PTEF
Code Expl.:	APPLICATION FOR A PATENT TERM EXTENSION
FILING DATE :	20071003
EXPIRY DATE :	20210525
FURTHER INFORMATION :	PRODUCT NAME: SELZENTRY (MARAVIROC); REQUESTED FOR 73 DAYS
Event date :	2010/06/11
Event code :	PTEG
Code Expl.:	+ GRANT OF A PATENT TERM EXTENSION
FILING DATE :	20071003
EXPIRY DATE :	20210525
EXTENSION DATE :	20210806
FURTHER INFORMATION :	PRODUCT NAME: SELZENTRY (MARAVIROC)

https://worldwide.espacenet.com/publicationDetails/inpadoc?CC=US&NR=2002013337A1&KC=A1&FT=D&ND=3&date=20020131&DB=&locale=en_EP#

Questions

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