Japan
**JP: Background**

- introduced in 1988 upon introduction of product patents for pharmaceuticals
- Basis: Article 67 (2) Japan Patent Act
- regulatory approval must be granted to patent holder or licensee
- maximum term: 5 years (until 31 December 1999: min. 2 years)
- several extensions may be requested in parallel
- regulatory approval mandated by Cabinet order (Patent Act Enforcement Order):
  - registration of agrochemicals under Agrochemical Control Act
  - approval of pharmaceuticals and in-vitro diagnostics under Act on Securing the Quality, Effectiveness and Safety of Pharmaceuticals and Medical Devices
- in 2017, around 420 term extensions were requested
JP: Main institutions

Japan Patent Office (JPO)
http://www.jpo.go.jp/

in charge of grant of term extensions

Pharmaceuticals and Medical Devices Agency (PMDA) (founded 2004) under Ministry of Health, Labor and Welfare

in charge of approvals of new drugs

https://www.pmda.go.jp
JP: Patents eligible for term extensions

- patents for pharmaceuticals (both for humans and animals)
- patents for agrochemicals
- not limited to products produced with new substances as active ingredient (= substances whose chemical structure is new), but also for methods to produce these substances, methods to produce pharmaceuticals, in vitro diagnostics products, regenerative medicine products, medical devices
- to encourage inventions in these fields, patent term is extended to compensate patent holders for marketing time lost while developing product and awaiting government approval
**JP: Procedure for the grant of term extensions**

- no mutual information exchange between JPO and PDMA (= no "automatic" term extension after approval of new drugs)
- term extension can be granted only upon request of (all) patent owner(s jointly)
- must be filed within 3 months from disposition designated by Cabinet order, but not later than 6 months before end of the regular patent term
**JP: Challenging a granted term extension**

- Trial for invalidation of term extension may be requested by interested party or examiner at any time in any of the following cases (Art. 125):
  - extension has been registered for an application that did not require a permission to execute the patented invention
  - extension has been registered for an invention that did not receive approval from PMDA
  - registered extension exceeds the period during which the invention was not executable
  - request for extension was not filed by the patent owner

➤ in case of invalidation: term extension deemed never to have existed
JP: Searching information on patent term extensions

Official source: Japan Platform for Patent Information (J-PlatPat)
https://www.j-platpat.inpit.go.jp/web/all/top/BTmTopEnglishPage

- English abstracts, original documents, full text data / machine translation
- Short legal status in English from 1990 on
- Complete legal status information in Japanese (divisionals, post-grant information, opposition, invalidation details)
- Information on patent term extensions in Japanese
- Electronic file inspection in Japanese
JP: Search example (family member of EP 0944648)

40. GLP-1 DERIVATIVES

Inventor: NIELSEN LISELOTTE BJERRM [DK]
NIERSENN PERN FRANKLIN [DK]

Applicant: NOVO NORDISK AS
NOVO NORDISK A/S
BAGSAER D.
(+1)

CPC: A61K32/02 00
A61K38/00
A61K38/20
(+3)

Publication info: H01903714 (A4)
2000-07-29
H01903714 (A3)
2000-07-29
H01903714 (B1)
2010-05-28

Priority date: 1999-06-30

Publication date: 2000-07-29

Event date: 2010/05/26
Event code: FFAY
Code Exp.: RENewed PERINMENT (EVENT DATE IS REINFORMATION DATE OF DATABASE)
FURTHER INFORMATION: JAPANESE INTERMEDIATE CODE: R335221

41. GLUCAGON-LIKE INSULINOTROPIC PEPTIDE ANALOGS, COMPOSITIONS COMPRISING THEM AND USES THEREOF

Inventor: NOVO NORDISK AS [DK]

Applicant: NOVO NORDISK AS
NOVO NORDISK A/S
BAGSAER D.
(+1)

CPC: A61K32/02 00
A61K38/00
A61K38/20
(+3)

Publication info: IL129332 (A)
2002-04-13

Priority date: 1999-06-30

Publication date: 2000-07-29

Event date: 2010/05/26
Event code: FFAY
Code Exp.: RENewed PERINMENT (EVENT DATE IS REINFORMATION DATE OF DATABASE)
FURTHER INFORMATION: JAPANESE INTERMEDIATE CODE: R335221

42. Glaucagon-like insulinotropic peptide analogs, compositions comprising them and uses thereof

Inventor: NOVO NORDISK AS [DK]

Applicant: NOVO NORDISK AS
NOVO NORDISK A/S
BAGSAER D.
(+1)

CPC: A61K32/02 00
A61K38/00
A61K38/20
(+3)

Publication info: H0190137 (A)
2010-05-31

Priority date: 1999-06-30

Publication date: 2000-07-29

Event date: 2010/05/26
Event code: FFAY
Code Exp.: RENewed PERINMENT (EVENT DATE IS REINFORMATION DATE OF DATABASE)
FURTHER INFORMATION: JAPANESE INTERMEDIATE CODE: R335221

43. GLP-1 DERIVATIVES

Inventor: NOVO NORDISK AS [DK]

Applicant: NOVO NORDISK AS
NOVO NORDISK A/S
BAGSAER D.
(+1)

CPC: A61K32/02 00
A61K38/00
A61K38/20
(+3)

Publication info: JP2005005505 (A)
2000-01-18
JP2005005505 (A2)
2001-03-26

Priority date: 1999-06-30

Publication date: 2000-07-29

Event date: 2010/05/26
Event code: FFAY
Code Exp.: RENewed PERINMENT (EVENT DATE IS REINFORMATION DATE OF DATABASE)
FURTHER INFORMATION: JAPANESE INTERMEDIATE CODE: R335221

44. STABILIZED AQUEOUS PEPTIDE SOLUTIONS

Inventor: NOVO NORDISK AS [DK]

Applicant: NOVO NORDISK AS
NOVO NORDISK A/S
BAGSAER D.
(+1)

CPC: A61K32/02 00
A61K38/00
A61K38/20
(+3)

Publication info: JP20030269598 (A)
2003-09-09
JP20030269598 (A2)
2006-04-09

Priority date: 1999-06-30

Publication date: 2000-07-29

Event date: 2010/05/26
Event code: FFAY
Code Exp.: RENewed PERINMENT (EVENT DATE IS REINFORMATION DATE OF DATABASE)
FURTHER INFORMATION: JAPANESE INTERMEDIATE CODE: R335221

FURTHER INFORMATION: JAPANESE INTERMEDIATE CODE: A91
JP: Search example (step I)

2 steps are necessary to find the information on Japanese term extensions:

**Step 1:** Find out the month in which the term extension was registered.

**Step 2:** Determine its duration.

https://www1.j-platpat.inpit.go.jp/
### JP: Number input / document kinds / Japanese years

<table>
<thead>
<tr>
<th>種別</th>
</tr>
</thead>
<tbody>
<tr>
<td>出願番号 (Application number)</td>
</tr>
<tr>
<td>公開番号 (Laid open publication number)</td>
</tr>
<tr>
<td>公表番号 (Laid open publication number)</td>
</tr>
<tr>
<td>公告番号 (Publication number)</td>
</tr>
<tr>
<td>登録番号 (Registration number)</td>
</tr>
<tr>
<td>審判番号 (Trial number)</td>
</tr>
<tr>
<td>出願事件番号 (Trial number)</td>
</tr>
<tr>
<td>優先権主張国番号 (Priority country / number)</td>
</tr>
<tr>
<td>国際出願番号 (International application number)</td>
</tr>
<tr>
<td>国際公開番号 (International publication number)</td>
</tr>
</tbody>
</table>

**Input of numbers**

- **publication numbers**: `Syy-nnnnnn` / `Hyy-nnnnnn` / `yyyy-nnnnnn` (from 2000)
- **patent numbers**: `nnnnnnnn`

- *2-digit Japanese year* / *4-digit Western year* / *serial number*

* **Japanese year conversion rule**: Showa year (S) + 25 = Western year
  Heisei year (H) + 88 = Western year
**JP: Search example (step I) – results screen**

<table>
<thead>
<tr>
<th>Registration number</th>
<th>Post-grant information</th>
</tr>
</thead>
<tbody>
<tr>
<td>3149958 (平13.11.19)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td></td>
</tr>
</tbody>
</table>
JP: Search example (step I) – results screen

*NOTE: Dates given in Japanese years. For explanation on how to convert these into Western years, see slide on number formats.

expiry date after registration: 22 August 2022 (Heisei 34)
date format: yy.mm.dd

term extension granted on 17 November 2010
JP: Search example (step II) – search screen
JP: Search example (step II) – search screen

- Enter date range determined in step 1 (only possible by month)
- Select correct category from drop-down menu (details next slide)
JP: Search example (step II) – search screen

"Registration of an extension of the term of a patent right"
JP: Search example (step II) – search screen

results of the search: 11 documents

click to go to results screen
JP: Details on request / grant of term extension

Date of registration of term extension: 17 November 2010 (in Japanese years)

Duration of extension: 5 years

Registration/patent no.

Further details (active ingredients etc.)

年 = year
月 = month
日 = day
Korea
**KR: Background**

- introduced in 1987 upon introduction of product patents for pharmaceuticals
- two kinds of “term extensions” in Korea:
  - patent term extensions (PTE)
  - patent term adjustments (PTA)
- about 600 term extensions have been requested in Korea since 1999
KR: Main authorities

Korean Patent Office (KIPO)

in charge of approvals of new drugs

in charge of grant of term extensions

Ministry of Food and Drug Safety (MFDS)

http://www.mfds.go.kr/eng
KR: Patents eligible for term extension

- pharmaceutical patents (medicines requiring marketing approval)
- agrochemical patents (agrochemicals/raw materials requiring registration)
- pharmaceuticals: limitation to products with new substances as active ingredient (= substances whose chemical structure is new)
  - not permitted for new uses or existing drugs or new combinations of existing ingredients
KR: Patents eligible for term extension

- Only one extension per patent permitted
  - in case of several approvals for several active ingredients in a patent: extension only for one approval (applicant's choice)
  - in case of several approvals for same active ingredient in a patent: extension only for first approval
  - in case several patents are related to same approval: term extension permitted for each patent
KR: Procedure for grant of term extension

- no mutual information exchange between KIPO and MFDS
  (= no "automatic" term extension after approval of new drugs)
- term extension granted only upon request of patent holder
- market approval must be granted to patent holder or licensee
- request must be filed within 3 months from approval, but not later than 6 months before the end of the original patent term
- maximum term of extension: 5 years
I: Challenging a granted term extension

- trial for invalidation of term extension may be requested by interested party or examiner at any time in any of the following cases (Art. 134):
  - extension has been registered for an application that did not require a permission to execute the patented invention
  - extension has been registered for an invention that did not receive approval from MFDS
  - registered extension exceeds period during which the invention was not executable
  - request for extension was not filed by the patent owner

- in case of invalidation: term extension deemed never to have existed
KR: Patent term adjustments (PTA)

- introduced in 2012 as provision of Korea-US Free Trade Agreement
- patents in all technical fields filed on or after 15 March 2012
- time compensation for delays in granting procedure (if caused by the patent office)

Scope:
- number of days beginning on the day after 4 years from filing date or 3 years from examination request (whichever is later)
- ending on day of registration
- reduced by days attributable to applicant (e.g. time period for filing opinions, amendments etc.)
Requests for PTA included in INPADOC legal status (Code A102)
KR: Searching information on patent term extensions

Official source:
Korean Intellectual Property Rights Information Service
KIPRIS, by Korean Patent Office (KIPO)
http://eng.kipris.or.kr

- most information available in English
- data on Korean patents and utility models from 1948 to date
- Korean full texts for publications since ca. 1980
- comprehensive English legal status from ca. 1948 on
- data on register information and trial proceedings
- updated daily
**KR: Search example (family member of EP 0944648)**

### Family List: EP 0944648 (A1) — 1999-09-29

<table>
<thead>
<tr>
<th>Application(s) for: EP 0944648 (A1)</th>
</tr>
</thead>
</table>

#### 51. DERIVATIVES OF GLP-1 ANALOGS

**Inventor:**

**Applicant:**

**CPC:**

**IPC:**

**Publication info:**

#### 52. GLP-1 DERIVATIVES OF GLP-1 AND EXCLUSION WITH PROTRACTED PROFILE OF ACTION

**Inventor:**

**Applicant:**

**CPC:**

**IPC:**

**Publication info:**

#### 53. GLP-1 DERIVATIVE

**Inventor:**

**Applicant:**

**CPC:**

**IPC:**

**Publication info:**

#### 54. GLP-1 DERIVATIVES

**Inventor:**

**Applicant:**

**CPC:**

**IPC:**

**Publication info:**

---

**INPADOC legal status: KR 200000035964 (A) — 2000-06-26**

**Legal status of KR 200000035964 (A) — 2000-06-26**

- **Event code:** AE01
  - **Code Exp.:** REQUEST FOR EXAMINATION
  - **Event date:** 2002/07/06
  - **Event code:** EP02
  - **Code Exp.:** NOTIFICATION OF REASON FOR REFUSAL
  - **Event date:** 2005/05/28
  - **Event code:** EP03
  - **Code Exp.:** DECISION TO GRANT OR RENUNCIATION OF PATENT RIGHTS
  - **Event date:** 2009/05/32
  - **Event code:** GRNT
  - **Code Exp.:** WRITTEN DECISION TO GRANT
  - **Event date:** 2015/01/06
  - **Event code:** A101
  - **Code Exp.:** APPLICATION TO EXTEND TERM OF PATENT RIGHT BY PERMIT
  - **Event date:** 2016/01/08

---

**European Patent Office**

28
KR: Search example (family member of EP 0944648)

Global Dossier contains machine-translated information on claims covered by term extension, compounds, period of registration etc.

Extended period: “4 year June 20”

Cross-check with KIPRIS for further details!
KR: Advanced search mask in KIPRIS (number search)

Change publication number format to: **10200035964** and enter into “Unex. Pub. No.” field in KIPRIS (10 is for “patents”)

http://engpat.kipris.or.kr/engpat/searchLogina.do?next=MainSearch
**Status “Registered”:** patent still in force

**Click to see further details**

**Purpose:** Provided are derivatives of GLP-1 and analog thereof having a lipophilic substituent which have interesting pharmacological properties, in particular they have a more protracted profile of action than GLP-1(7-37).

**Constitution:** A GLP-1 derivative, a pharmaceutical composition comprising a GLP-1 derivative and a pharmaceutically acceptable vehicle or carrier are provided wherein at least one amino acid residue of the parent peptide has a lipophilic substituent attached with the proviso that if only one lipophilic substituent is present and this substituent is
Term extension information is under “Registr. Details” (patent register)

Expected expiry date including granted patent term extension: **14 March 2022**

Term extension granted on 30 March 2011, for indicated claims

Extended period: **4 years, 6 months, 20 days**
KR: Details on request / grant of term extension

Details on term extension under "etc. Full Text"

Request

Grant

Claims covered by term extensions

Detailed information on approval by MFDS (approval date, active ingredient etc.)
“Judgment” contains all trial proceedings (including invalidation of term extension) related to a certain patent.

Trials for invalidation of term extension.
Chinese Taipei
**TW: Background**

- introduced in 1994 (PTE only available for patents filed on or after 23 January 1994)
- 1997: “Regulations Governing Patent Term Extensions” issued jointly with regulatory authorities on pharmaceuticals and agrochemicals
- 2013: substantial revision of patent term extension practice
- 1 April 2018: revised “Regulations for Ratifying Patent Term Extension” (broader definition of 'first market approval'; limitation of scope of extension to specific ingredients stated in market approval; expanded explanation of “periods of delay attributable to applicant”)
In charge of grant of term extensions

in charge of approvals / registrations

Taiwan Intellectual Property Office (TIPO)

TIPO, Taiwan Intellectual Property Office (TIPO)

http://www.tipo.gov.tw

in charge of approvals / registrations

http://www.fda.gov.tw

FDA under Ministry of Health and Welfare (for pharmaceuticals)


Council of Agriculture (COA) (for agrochemicals)

https://www.tipo.gov.tw

in charge of grant of term extensions

European Patent Office
TW: Patents eligible for term extension

- pharmaceutical and agrochemical patents (Patent Act, Article 53)
- product patents, manufacturing process patents and use patents
- extension only allowed in cases where regulatory approval for exploiting the patent is required by other acts or regulations
**TW: Procedure for grant of term extension**

- only one extension per patent permitted
- term extension granted upon **request of patent holder** or exclusive **licensee** (must have recorded the relevant licensing agreement with TIPO)
- regulatory approval must be granted to patent holder or licensee
- request must be filed within **3 months** from first regulatory approval, but no later than **6 months** before the end of the original patent term
- maximum extension: **5 years** (minimum of 2 years was dropped in 2013)
request for cancellation possible by any party prior to expiration of extended term on the following grounds:
- obtaining market approval not required for practising the patent
- patent holder / licensee never obtained the market approval
- extension period exceeds period during which patent could not be practised
- application for patent term extension was not filed by patent holder
- market approval as basis for extension was not the first market approval or used for another term extension
- drug granted term extension is a veterinary medicine

in case of invalidation: term extension deemed never to have existed
**TW: Searching information on patent term extensions**

- bibliographic data, original documents, citations, text data / MT tool,
- post-grant English legal status information since 1976
- pre-grant legal status and gazette data provided by machine translation
- links to online file wrapper in TIPONet (bilingual)
- English version: updated monthly, time lag: 3 months
- Chinese version: B doc. on 1\textsuperscript{st} /11\textsuperscript{th} /21\textsuperscript{st} day; A doc. on 1\textsuperscript{st} /16\textsuperscript{th} day

**Official source:**
TWPAT, provided by Intellectual Property Office (TIPO)
[www.twpat.tipo.gov.tw](http://www.twpat.tipo.gov.tw)
TW: Search example (family member of US2002013337)
**TW: Search example (family member of US2002013337)**
TW: Search example – TWPAT database

Patent term extension information can be retrieved via the English language interface of TWPAT. The information is created by an online machine translation tool.

https://twpat6.tipo.gov.tw/tipotwoc/tipotwekm
**TW: Search example – search screen**

[Image of a patent search screen]

- **Quick Search**
  - **Patent Type:** [Selected: Granted Inventions]
  - **Certification Number:** [Input: TW301600]
  - **Search** button

[Link: https://twpat6.tipo.gov.tw/tipotwoc/tipotwekm]
**TW: Number formats / Republican years**

申請號 application number → (y)yytnnnnn (ex.: 092124725)
公開號 unexamined publication number → yyyytnnnnn (ex.: 200300001, since 2002)
公告號 grant number → tnnn (ex.: 1250537, after 2004)

**Types of right (t)**

<table>
<thead>
<tr>
<th>Application numbers</th>
<th>Grant numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 for invention</td>
<td>I for invention</td>
</tr>
<tr>
<td>2 for utility model</td>
<td>M for utility model</td>
</tr>
<tr>
<td>3 for design</td>
<td>D for design</td>
</tr>
</tbody>
</table>

**y = Republican year**

**y = Western year**

**t = type of patent right**

**n = serial number**

*Conversion rule for Republican years*

Republican year + 1911 = Western year
(Example: Republican year 105 = 2016)
**TW: Search example – results screen**

access the machine-translated «transaction data»
**TW: Details on request / grant of term extension**

- **Term extension granted for 3 years and 125 days,** until 22 September 2024 (all dates given in Republican years)
- **Information on grant of term extension** (published in gazette on 21 August 2010)
- **Date of first regulatory approval** (12 January 2009)
- **Date of request of term extension** (26 February 2009)

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<tr>
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<td>Volume 37, Number 24 (2010/08/21) Announcement of cases during the extension period granted patent</td>
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<td>08/01/12</td>
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<td>08/02/26</td>
<td></td>
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<tr>
<td><strong>Patent Title</strong></td>
<td>Treatment with tropane derivatives</td>
<td></td>
</tr>
<tr>
<td><strong>Patentee and address</strong></td>
<td>Pfizer, Inc. (USA)</td>
<td></td>
</tr>
<tr>
<td><strong>Number of First Permit</strong></td>
<td>Health Department transfusion medicine Zi No. 024-027</td>
<td></td>
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<tr>
<td><strong>Core Decision</strong></td>
<td>Granted extension case 3 years 125 days during the patent disclosure, ending on September 22, 113.</td>
<td></td>
</tr>
<tr>
<td><strong>Scope of Patent</strong></td>
<td>Maraviroc and its antiretroviral agents as an active ingredient used in combination with other antiretroviral drugs to treat HIV infection with only CCR5 tropism, the antiviral drugs have received treatment, it has proven resistant to multiple antiretroviral drugs and at the same time there is obviously a pharmaceutical composition for viral replication in adult patients, the</td>
<td></td>
</tr>
<tr>
<td><strong>Extension Approved</strong></td>
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</tbody>
</table>
TW: Search example – legal status / expiry date

“patent right change” gives the basic legal status information

expiry date after term extension: 22 September 2024
Useful information
## Summary - Patent term extension at a glance

<table>
<thead>
<tr>
<th></th>
<th>EU</th>
<th>Japan (JP)</th>
<th>Korea (KR)</th>
<th>US</th>
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<tr>
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<tr>
<td><strong>restoration/extension</strong></td>
<td>Up to 5 years. Combined with patent conveys a maximum of 15 years of effective protection</td>
<td>Up to 5 years</td>
<td>Up to 5 years</td>
<td>Up to 5 years. Combined with patent conveys a maximum of 14 years of effective protection</td>
<td>Up to 5 years</td>
</tr>
<tr>
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<tr>
<td></td>
<td>plant patents</td>
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<td></td>
<td>veterinary patents</td>
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<tr>
<td><strong>Filing of a patent term</strong></td>
<td>request must be filed within 6 months from first approval date in the EEA* or within 6 months from grant date of patent</td>
<td>request must be filed within 3 months from disposition designated by Cabinet order, but not later than 6 months before the end of the regular patent term</td>
<td>request must be filed within 3 months from approval, but not later than 6 months before the end of the original patent term</td>
<td>request must be filed within 60 days from approval date</td>
<td>request must be filed within 3 months from first regulatory approval, but no later than 6 months before the end of the original patent term</td>
</tr>
<tr>
<td>*Exception: CH</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

*Exception: CH
EPO patent information webinars

Regular webinars offered free-of-charge by EPO
Useful information – Asiainfo search guides

Detailed step-by-step guides on searching official sources from CN, TW, JP, KR, RU...

www.epo.org/asia
Useful links – patent laws and regulations

- TW: www.tipo.gov.tw (English → Patents → “Laws&Regulations”)
References

- “Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe” by Copenhagen Economics, May 2018
- “Effects of supplementary protection mechanisms for pharmaceutical products” by technopolis group, May 2018.