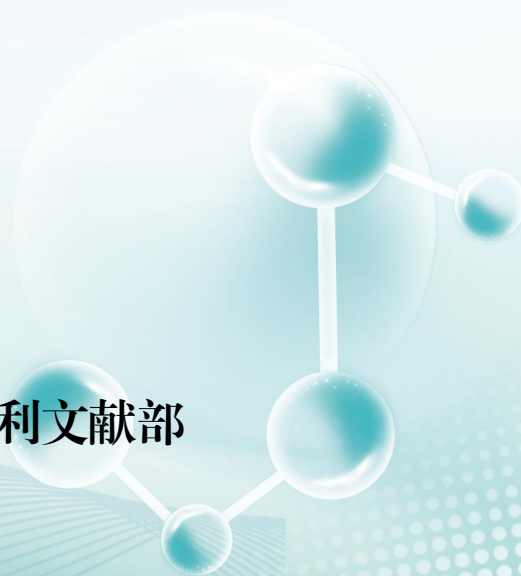




# 各国药品专利权 期限延长信息查询汇编

（第二篇）

国家知识产权局专利局 专利文献部





## 如何查询美国药品专利权期限延长信息

### 前言

为了保护药品专利权人合法权益，鼓励新药研究和促进高水平仿制药发展，近年来我国先后建立了药品专利纠纷早期解决机制和药品专利期限补偿制度。2020年第四次专利法修改时，在第四十二条中增加第三款，规定为补偿新药上市审评审批占用的时间，对药品专利权给予期限补偿，并对最长的补偿期限做了限制。修改后的《专利法实施细则》和《专利审查指南》，对补偿条件等做了细化规定和解释。

药品专利权期限补偿是我国第四次专利法修改引入的新制度，受到社会广泛关注。新药研发成本高、周期长、风险大，需要依赖专利权来保护市场，获得合理利润。同时，由于药品的特殊性，药品上市需要经过药品监督管理部门的严格审批。这就意味着，即便药品发明已获得专利授权，在获得药品上市许可之前，该专利在相当长的时间内仍无法实施，客观上缩短了专利权的保护期限。为了激励新药研发，很多国家对药品专利给予专利权期限延长，补偿原研药上市审批周期过长而导致的专利保护期的损失。

为了方便社会公众及时准确地掌握药品专利权的期限信息，国家知识产权局专利局专利文献部特编写各国药品专



专利权期限延长信息查询系列汇编。该汇编共分为 3 篇，本期为第二篇，将主要介绍如何查询与美国药品相关的专利信息，以及专利权期限延长信息等。后续本汇编将持续推出。

### **一、如何查找药品专利权期限延长（PTE）的审批决定**

美国于 1984 年通过《药品价格竞争与专利期补偿法》（即 Hatch-Waxman 法案），引入专利权期限延长制度，对专利权人在药品上市审批过程中所占用的专利权期限给予补偿。原研药公司递交新药上市许可申请时，需向美国食品药品监督管理局（FDA）提供与该药品相关的专利信息，而社会公众可以通过《经治疗等效性评价批准的药品》（俗称“橙皮书”）查阅该药品名下登记的专利号、专利到期日等相关信息。新药上市审批后，如果符合专利权期限延长的规定条件，则由美国专利商标局做出相应的专利权期限延长的决定。

在药品专利权期限延长的审批决定中，美国专利商标局会明确指出专利权期限延长的具体天数。审批决定可通过 Patent Center 查询系统查阅。

#### **（一）访问 Patent Center 查询系统**

登录美国专利商标局网站 [www.uspto.gov](http://www.uspto.gov)，在首页“patents”栏目下，页面右侧出现的工具栏中，选择“Patent Center”，点击进入，无需注册即可使用。

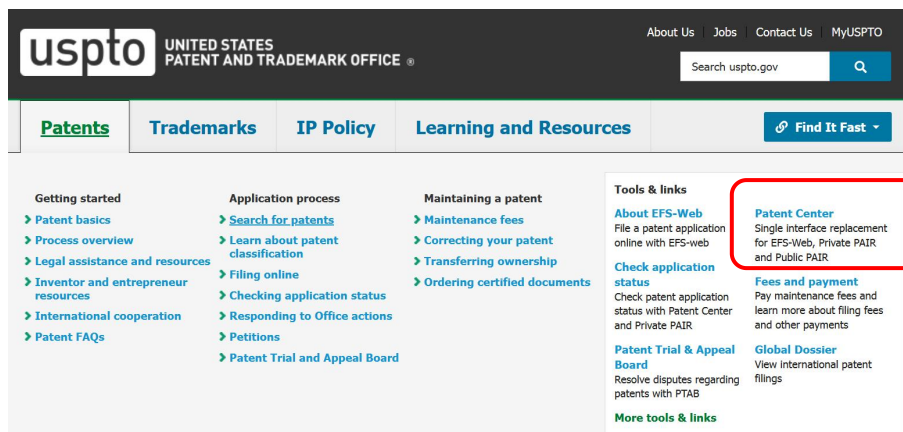


图 1 USPTO 官网

## (二) 查阅药品专利权期限延长的审批决定

在 Patent Center 查询系统中通过药品专利的申请号或专利号进行检索，然后在检索结果页面左侧栏目中选择“Documents & Transactions”，从案卷列表中查阅代码为 TERM.PTO.C（Patent Term Extension Certificate）的文件，即为专利权期限延长的审批决定。



图 2 Patent Center 首页



**Patent Center**

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**10/245,122 | 03822.000010.: LACTAM-CONTAINING COMPOUNDS AND DERIVATIVES THEREOF AS FACTOR XA INHIBITORS** PUBLIC VIEW

<b>Application #</b> 10/245,122	<b>Confirmation #</b> 6870	<b>Attorney Docket #</b> 03822.000010.	<b>Patent #</b> <a href="#">6,967,208</a> <a href="#">Download PDF</a> <a href="#">Text</a> Issued - 11/22/2005	<b>Filing or 371 (c) date</b> 09/17/2002
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**Application Data**

**Documents & Transactions**

**Continuity**

**Patent Term Adjustment**

**Foreign priority**

**Fee payment history**

**Address & Attorney/Agent Information**

**Supplemental Content**

**Assignments**

**Display References**

**Application data**

**Application type**  
Utility

**Examiner**  
BRUCK KIFLE

**Group art unit**  
1624

**Class/subclass**  
514/212.080

**AIA (first inventor to file)**  
No

**Entity status**  
Regular Undiscounted

**Earliest publication #**  
[US 2003-0191115 A1](#)  
[Download PDF](#) [Text](#)

**Earliest publication date**  
10/09/2003

**Assignee for publication**  
-

**Confirmation #**  
6870

**Intl. registration # (Hag)**  
-

**Intl. registration public**  
-

图 3 Patent Center 结果显示页面

例如，查阅药品 ELIQUIS 艾乐妥®（阿派沙班）相关专利 US6967208 的药品专利权期限延长的审批决定。查阅 Patent Term Extension Certificate 文件后可以看到 USPTO 认定的 PTE 延长期限为 1526 天。

**Documents & transaction history**

Documents Transactions

None selected

Showing 1 to 173 of 173 entries

Mail room date	Doc code	Doc description	Pages	Quick download	File size (KB)	
04/23/2021	SOL.NTC.SUIT	Report on the filing or determination of an action regarding a patent	8	<a href="#">Preview</a> <a href="#">PDF</a>	480	<input type="checkbox"/>
09/11/2018	COCOUT	Certificate of Correction - Post Issue Communication	1	<a href="#">Preview</a> <a href="#">PDF</a>	60	<input type="checkbox"/>
09/06/2018	COCX	Supervisory Patent Examiner Response - Return for Certificate of Correction	2	<a href="#">Preview</a> <a href="#">PDF</a>	120	<input type="checkbox"/>
09/04/2018	COCOUT	Certificate of Correction - Post Issue Communication	1	<a href="#">Preview</a> <a href="#">PDF</a>	60	<input type="checkbox"/>
03/27/2018	SOL.NTC.SUIT	Report on the filing or determination of an action regarding a patent	1	<a href="#">Preview</a> <a href="#">PDF</a>	60	<input type="checkbox"/>
08/30/2017	TERM.PTO.C	Patent Term Extension Certificate	2	<a href="#">Preview</a> <a href="#">PDF</a>	120	<input type="checkbox"/>
06/15/2017	SOL.NTC.SUIT	Report on the filing or determination of an action regarding a patent	1	<a href="#">Preview</a> <a href="#">PDF</a>	60	<input type="checkbox"/>
06/08/2017	LET.	Miscellaneous Incoming Letter	3	<a href="#">Preview</a> <a href="#">PDF</a>	180	<input type="checkbox"/>
06/08/2017	N417	Electronic Filing System Acknowledgment Receipt	2	<a href="#">Preview</a> <a href="#">PDF</a>	120	<input type="checkbox"/>
05/09/2017	TERM.PTO.NFD	Notice of Final Determination-Eligible	3	<a href="#">Preview</a> <a href="#">PDF</a>	180	<input type="checkbox"/>

图 4 Patent Center 结果显示页面-PTE 审批决定



图 5 US6967208 的 PTE 审批决定

## 二、如何查找专利权期限调整（PTA）的信息

药品专利权期限延长（PTE）是对药品上市审批所占用的时间的一种补偿。除此之外，美国专利商标局对专利在授权过程的不合理延迟的时间也会给予补偿，即专利权期限调整（PTA）。因此，药品相关专利的专利权可能出现两种期限延长，一是专利权期限延长（PTE），二是专利权期限调整（PTA）。

用户可以在专利说明书的扉页上查阅，或通过 Patent Center 查询系统查阅专利权期限调整的具体天数。





例如，查阅药品 Stelara 喜达诺®（乌司奴单抗）相关专利 US6902734 的专利权期限调整天数。在专利说明书的扉页中显示，该专利的专利权期限延长了 360 天。


 US006902734B2	
(12) <b>United States Patent</b> <b>Giles-Komar et al.</b>	(10) <b>Patent No.: US 6,902,734 B2</b> (45) <b>Date of Patent: Jun. 7, 2005</b>
<hr/>	
(54) <b>ANTI-IL-12 ANTIBODIES AND COMPOSITIONS THEREOF</b>  (75) Inventors: <b>Jill Giles-Komar</b> , Downingtown, PA (US); <b>David M. Knight</b> , Berwyn, PA (US); <b>David Peritt</b> , Bala Cynwyd, PA (US); <b>Bernard Scallon</b> , Collegeville, PA (US); <b>David Shealy</b> , Downingtown, PA (US)  (73) Assignee: <b>Centocor, Inc.</b> , Malvern, PA (US)  <div style="border: 1px solid red; padding: 2px;">         (*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 360 days.       </div> (21) Appl. No.: <b>09/920,262</b>  (22) Filed: <b>Aug. 1, 2001</b>  (65) <b>Prior Publication Data</b>	<b>OTHER PUBLICATIONS</b>  A. U. Gubler et. al (Coexpression of Two Distinct Genes is Required to Generate Secreted Bioactive Cytotoxic Lymphocyte Maturation Factor) Proc. Natl. acad. Sci. USA. vol. 88. pp 4143-4147- (May 1991) Immunology.  A. U. Gubler et. al (Clonic and Expression of Cytotoxic Lymphocyte Maturation Factor (CLMF) a Heterodimeric Lymphokine That Potentiates NR. LAK NA D T-Cell Responses) Abstracts Journal of cellular Biochemistry Supplement 15 F: 70 (1991).  Alvin S. Stern et.al-(Purification to Homogeneity and Partial Characterization of Cytotoxic Lymphocyte Maturation Factor from Human B-Lymphoblastoid Cells) (Jun. 11, 1990) F. Hoffmann La Roche Inc. Nutley NJ USA. Proc. National Acad. Sci. USA (vol. 87, pp 6808-6812- Sep. 1990- Immunology).  M. Gately et. al. (Regulation of Human Lymphocyte Proliferation by a Heterodimeric Cytokine IL-12 (Cytotoxic Lymphocyte Maturation Factor) vol. 147- 874-882 No. 3. (Aug. 1, 1991).(The Journal of Immunology).

图 6 US6902734 专利说明书扉页中的 PTA 信息

在 Patent Center 查询系统中查询药品专利权的信息，在检索结果页面左侧栏目中选择“Patent Term Adjustment”，即可查阅专利权期限调整的天数和计算过程。

例如，药品 ELIQUIS 艾乐妥®（阿派沙班）相关美国专利 US6967208 的专利权期限调整时长为 139 天。



Patent Center

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10/245,122 | 03822.000010.: LACTAM-CONTAINING COMPOUNDS AND DERIVATIVES THEREOF AS FACTOR XA INHIBITORS PUBLIC VIEW

Application #	Confirmation #	Attorney Docket #	Patent #	Filing or 371 (c) date
10/245,122	6870	03822.000010.	6,967,208 <a href="#">Download PDF</a> <a href="#">Text</a> Issued - 11/22/2005	09/17/2002

Application Data

Documents & Transactions

Continuity

Patent Term Adjustment

Foreign priority

Fee payment history

Address & Attorney/Agent Information

Supplemental Content

Assignments

Display References

Application data

Application type

Utility

Examiner

BRUCK KIFLE

Group art unit

1624

Class/subclass

514/212.080

AIA (first inventor to file)

No

Entity status

Regular Undiscounted

Earliest publication #

US 2003-0191115 A1  
[Download PDF](#) [Text](#)

Earliest publication date

10/09/2003

Assignee for publication

-

Confirmation #

6870

图 7 US6967208 的 PTA 信息

10/245,122 | 03822.000010.: LACTAM-CONTAINING COMPOUNDS AND DERIVATIVES THEREOF AS FACTOR XA INHIBITORS

Public view Maintenance Fee Storefront Global Dossier

Application #	Attorney Docket #	Patent #	Status	Filing or 371 (c) date
10/245,122	03822.000010.	6,967,208 <a href="#">Download PDF</a> Issued - 11/22/2005	Patented Case - 11/02/2005	09/17/2002

Patent Term Adjustment

A Delays	B Delays	C Delays	Overlapping Days	Non-Overlapping USPTO Delays	PTO Manual Adjustments	Applicant Delays	Total patentTerm Adjustments
214 days	0	0	0	214 days	0	75 days	↑ 139 days

Patent Term Adjustment History

Number	Date	Contents Description	PTO (Days)	APPL (Days)	Start
79	11/22/2005	Patent Issue Date Used in PTA Calculation	214	0	78
78	12/22/2004	Issue Fee Payment Verified		0	0

图 8 US6967208 的 PTA 天数

### 三、如何查找药品专利权期限延长的请求信息

应社会需求，美国专利商标局在官网上专门开辟网页介绍药品专利权期限延长信息，专栏的网址为 <https://www.uspto.gov/patents/laws/patent-term-extension/patent-terms-extended-under-35-usc-156>。美国专利商



标局在网页中公布近 5 年内提交的药品专利权期限延长请求的汇总表，每季度更新一次。公众可以便利地获知权利人就哪些药品相关专利提交了药品专利权期限延长（PTE）的请求。

汇总表中给出了专利申请号、专利号、PTE 请求的提交日、药品的商品名、FDA/USDA 编号等信息，表中还提供了 Patent Center Link，可通过链接直接进入 Patent Center 查阅相关信息。

[Home](#) > [Patents](#) > [Laws](#) > [Patent Term Extension](#) > Applications for patent term extension and patent terms extended under 35 U.S.C. § 156

## Applications for patent term extension and patent terms extended under 35 U.S.C. § 156

Applications for patent term extension under 35 U.S.C. § 156 may be filed for patents on certain human drugs, food or color additives, medical devices, animal drugs, and veterinary biological products to restore to the terms of those patents some of the time lost while awaiting premarket government approval from a regulatory agency. See the [Manual of Patent Examining Procedure \(MPEP\) section 2750 et seq.](#) for more information. The USPTO plans to update the list of applications for patent term extension and list of patent terms extended under 35 U.S.C. § 156 on a quarterly basis.

### List of applications for patent term extension

The following spreadsheet is a list of all applications for patent term extension under 35 U.S.C. § 156 that have been filed within the past five years. The status of each application, including disposition—such as granted, denied, withdrawn, pending—may be determined by reviewing the electronic file wrapper in [Patent Center](#). Patents that have received certificates of patent term extension are identified in the list further down this web page.

[PTE applications during last five years \(updated through February 2025\) \[MS Excel\]](#)

### List of patent terms extended under 35 U.S.C. § 156

**NOTE:** This list is for informational purposes only and is not intended to have legal effect. Furthermore, this list does not include patents that have been extended only under § 156(e)(2) or § 156(d)(5) (patents that have only received an interim extension). A copy of the certificate of extension should be included in the "correction" section of the patent's images. All patent images can be found in the [Patent Full Text and Image Database](#).

[PTE certificates issued \(updated through February 2025\) \[MS Excel\]](#)

Please note that nearly all patent term extension applications are available in [Patent Center](#).

For further information, contact Ali Salimi at (571) 272-0909 or [ali.salimi@uspto.gov](mailto:ali.salimi@uspto.gov), or Raul Tamayo at (571) 272-7728 or [raul.tamayo@uspto.gov](mailto:raul.tamayo@uspto.gov).

Additional information concerning patent expiration dates of human drug products can be obtained from the Food and Drug Administration's Center for Drug Evaluation and Research. The Patent and Exclusivity Addendum of the "Orange Book," the [Approved Drug Products with Therapeutic Equivalents Evaluations](#) [↗](#), includes an alphabetical listing of human drug products according to generic name with related patent information.

Additional information concerning patent expiration dates of animal drug products can also be obtained from the Food and Drug Administration's Center for Veterinary Medicine. The Patent Information section of the "Green Book," which documents [Approved Animal Drug Products](#) [↗](#), includes a listing by application number of animal drug products with the trade name, patent number, and patent expiration date.

图 9 药品专利权期限延长信息的专栏



	A	B	C	D	E	F
	U. S. Application	U. S. Patent No.	Patent Center Link	PTE Application Filing Date	Trade Name Identified in PTE Application	FDA/USDA Designated Number*
1						
2	13138669	8,815,301	<a href="#">13138669</a>	3/6/2020	MONOFERRIC (ferric derisomaltose)	
3	16178943	10,414,831	<a href="#">16178943</a>	3/6/2020	MONOFERRIC (ferric derisomaltose)	
4	09534968	6,953,476	<a href="#">09534968</a>	3/11/2020	Reducer	
5	10743470	7,335,799	<a href="#">10743470</a>	3/11/2020	NEXLETOL (bempedoic acid)	
6	14026816	8,858,612	<a href="#">14026816</a>	3/11/2020	Reducer	
7	13559168	9,084,765	<a href="#">13559168</a>	3/12/2020	BARHEMSYS (amisulpride)	
8	11869250	7,572,897	<a href="#">11869250</a>	3/17/2020	TEPEZZA (teprotumumab-trbw)	
9	10509770	7,423,050	<a href="#">10509770</a>	3/19/2020	REYVOW (lasmiditan)	
10	13447007	8,410,088	<a href="#">13447007</a>	3/20/2020	TAZVERIK (tazemetostat)	
11	09938670	7,678,146	<a href="#">09938670</a>	3/25/2020	Bulkamid Urethral Bulking System	
12	10872231	7,758,497	<a href="#">10872231</a>	3/25/2020	Bulkamid Urethral Bulking System	
13	09938667	7,780,958	<a href="#">09938667</a>	3/25/2020	Bulkamid Urethral Bulking System	
14	14884167	RE45,969	<a href="#">14884167</a>	4/1/2020	AcrySof IQ Vivuity (extended vision intraocular lens)	

图 10 USPTO 受理的 PTE 请求的汇总表 (2025 年 2 月更新)

四、如何查找所有给予药品专利权期限延长的专利信息

在药品专利权期限延长信息的专栏，还会定期更新获批药品专利权期限延长的专利汇总表。汇总表中给出了美国专利商标局批准的所有药品专利权期限延长的信息，包括专利号、药品的商品名、最初的专利权终止日和给予 PTE 的天数等相关信息。公众可以非常便利地了解哪些药品专利被给予了药品专利权期限延长（PTE）。

	Patent No.	Tradename of Product (generic name, if applicable)	Original Expiration Date*	Period of Extension Granted
1				
1033	9,572,856	GIAPREZA (angiotensin II)	2020/11/23	240 days
1034	9,580,461	LUMOXITI (moxetumomab-pasudotox-tdfk)	2023/3/3	162 days
1035	9,586,978	MAVYRET (glecaprevir and pibrentasvir)	2030/6/10	149 days
1036	9,597,230	iStent inject Trabecular Micro-Bypass System	2027/2/24	318 days
1037	9,610,106	BARRICAID (anular closure device)	2027/4/19	675 days
1038	9,662,338	QELBREE (viloxazine extended-release capsules)	2033/2/7	784 days
1039	9,745,373	VYEPTI	2032/5/21	637 days
1040	9,827,251	BYFAVO	2031/11/17	798 days
1041	10,155,821	ENHERTU (fam-trastuzumab deruxtecan nxki)	2033/10/10	71 days
1042	10,383,961	DETECTNET (copper Cu 64 dotatate injection)	2032/8/23	313 days

图 11 药品专利权 PTE 汇总表 (2025 年 2 月更新)

撰    稿：杨  策

审    核：赵  欣

版面设计：招润捷