



PROGRAM MATERIALS

Program #33106

May 22, 2023

**Everything You Always Wanted to
Know About Patent Expirations ... But
Were Afraid to Ask!**

Copyright ©2023 by

- **Andrew Berks, Ph.D., J.D. - Gallet Dreyer & Berkey, LLP.**

**All Rights Reserved.
Licensed to Celesq®, Inc.**

Celesq® AttorneysEd Center
www.celesq.com

5301 North Federal Highway, Suite 150, Boca Raton, FL 33487
Phone 561-241-1919

EVERYTHING YOU ALWAYS WANTED TO KNOW ABOUT PATENT EXPIRATIONS . . . BUT WERE AFRAID TO ASK!

Or — when will my patent expire?

Andrew Berks, Ph.D., J.D.

Gallet Dreyer & Berkey LLP

New York, NY

ahb@gdblaw.com

When will my patent expire?

- Agenda
 - Brief history of patents and patent policy
 - Current law
 - Information Sources
 - Effect of provisional patent applications
 - Patent term extensions
 - Shortening patent life – why and how
 - Maintenance fees – keeping patents alive

A short history of patents

- Statute of Monopolies in England (1623). Allowed a 14-year term for a new invention.
- This was an exclusionary right. A patent owner can exclude others from practicing the claimed invention, i.e., a patent confers no right to practice an invention.
- Patents were a cutting-edge social policy in the 18th century. Incorporated by founding Fathers into the US Constitution, and the first patent act was in 1790 – one of the first things the new Congress did.

Patents Incorporated into US Constitution



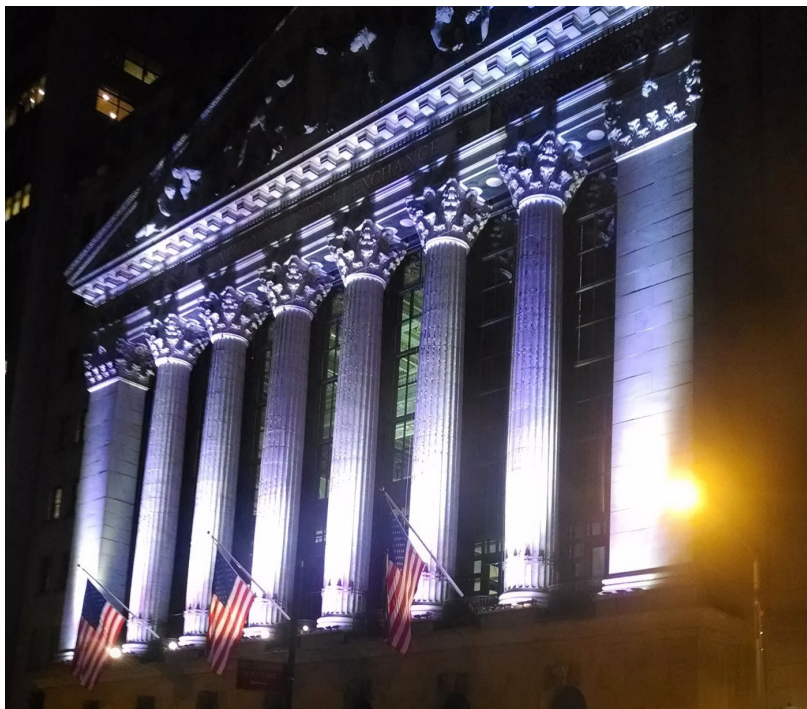
- US constitution Art I §8 cl. 8: To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries;
- This was adopted without debate at the Constitutional Convention

History Cont'd

- General idea: patents encourage the advancement of new technology by giving an exclusionary period in exchange for a full disclosure of the invention.*
- There have been several patent acts since 1790.
- In the US, the current patent scheme was created in 1952 but key elements were reworked in 1995 and in the American Invents Act (2011).
- Patent statutes in 35 U.S.C.
- Patent rules are in 37 C.F.R.

**Univ. Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 922 (Fed. Cir. 2004)

Overarching Concept of Patents



- Quid pro quo: in exchange for a full disclosure of a new invention, the inventors (or their assignees) get a **limited** period of exclusivity where the patent owner can prevent others from practicing the invention.
- This is an economic incentive to make new inventions. The patent owner may be able to enjoy profits from the period of exclusivity.

Patents are an asset

- Patents are an asset that can be bought, sold, and licensed.
- Because patents have a presumption of validity, once issued there is a high bar to overturning a patent.
- Patents have analogies to real property
- Licensing a patent is similar to renting real property. A licensee gets to use the patent in exchange for “rent” – which may be royalty payments or other financial arrangements.
- A transfer of a patent is called an “assignment”
- The USPTO keeps a register of patent assignments and other encumbrances, just like a county land office.

20-year Rule

- So what is the length of the limited period?
- **20 years** from the earliest non-provisional patent application filing date
- Also part of patent policy: an invention must be novel, not obvious, and fully described. It must also be patentable subject matter. These are all big subjects not discussed here.
- This is universally accepted. Almost every sovereign country allows patents and almost all use the 20-year expiry rule.



Are patents worthwhile?

- I would argue that the great technological advances of the 19th and 20th centuries were largely driven by strong patent policies in the major industrialized countries (US, England, France, Germany)
- Look at any technological advance and you will likely find many patents as the technology developed.
- This is ongoing in the 21st century.
- So the answer to this question is YES



Patent Expirations

- Patent expiries were set at 17 years from the date of grant in 1861.
- This rule ended for patent applications filed on or after June 8, 1995.
 - Patent terms were brought into compliance with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement in the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) of 1994 (TRIPS Agreement Art. 33).

Old Law



- There were two big problems with the old 17-year rule.
 - Patent applicants could “game” the system by keeping a patent application in prosecution for many years, by delaying issuance, which could in effect increase the term of protection. Keep in mind only valid patents in force can be enforced.
 - It is possible there may even be patent applications in the USPTO today, 28 years after 1995, that were filed under the pre-GATT provisions and will expire 17 years from grant—if they ever issue.
 - Most other countries had switched to a 20-year from date of filing patent term. By 1995, the US was an outlier with the 17-year rule.

New Rule – Patent Life is 20 years

- There were two big changes on June 8, 1995
- (1) Patent expiry changed to 20 years from the earliest effective non-provisional filing date.
 - The issue date no longer was part of the calculation of the patent expiration date.
 - 35 U.S.C. §154(a)
 - This rule is in effect in essentially all countries worldwide.
- (2) Provisional patent applications were created.
- These provisions only affected patent applications filed on or after June 8, 1995.
 - For patent applications filed prior to June 8, 1995, the patent expiration was 17 years from grant or 20 years from the earliest filing date – whichever was later.
 - So for many years after 1995, patent attorneys had to really look hard at patent applications to figure out the correct expiration date.

What is the Effective Filing Date?

- The earliest non-provisional filing date effective in the US.
 - The first patent application filed under 35 U.S.C. §111(a) or as a PCT patent application
- Child patent applications like continuations, divisionals, and continuations-in-part do not reset the earliest non-provisional filing date.
- A PCT patent application is a non-provisional patent application, so normally counts as a US non-provisional filing date.
 - PCT applications must contain claims and be properly formatted
 - PCT patent applications are expected to meet the substantive requirements of patent law
 1. Patentable subject matter
 2. Novel and inventive (non-obvious)
 3. Meet the written description requirement (sufficiency of disclosure)



Sources of Information

- Official sources are the best resource for determining patent status including critical dates like patent filing dates.
- Patent offices of all major countries maintain a website with official information.
- In the US, this is Patent Center
 - <https://patentcenter.uspto.gov/>
- There is an older system, called “PAIR” (patent application information retrieval) that is being phased out. The public PAIR is no longer available. There is a “private PAIR” that requires a USPTO account that is still available.
- Having a USPTO account makes additional features available in Patent Center.
- Non-experts do not need a USPTO account
- Once a patent application is published, it becomes available in Patent Center
- WIPO - PATENTSCOPE

The screenshot shows the USPTO Patent Center website. The browser address bar displays <https://patentcenter.uspto.gov>. The website header includes the USPTO logo and navigation links for Patents, Trademarks, Fees and payment, Contact Us, MyUSPTO, and Sign in. The main navigation bar contains Home, New submission, Existing submissions, Petitions, Post grant, Search, and Patent Center Help.

The main content area features a light blue background with a list of announcements:

- **Filing a new non provisional 111(a) application?** Starting June 30, 2023, specification, claims and abstracts not filed in DOCX format will incur a non-DOCX surcharge of up to \$400 for this filing type. See the [Federal Register notice](#) for more information.
- Extended through June 30, 2023, exclusively in Patent Center, applicants have the option to upload a backup (auxiliary) PDF version of their application with their DOCX version. There are no fees associated with this auxiliary PDF. See the [Federal Register notice](#) for more information.

Attend a [DOCX training webinar](#) or visit the [DOCX information page](#) to learn more about filing in DOCX format.

- Patents with an issue date on or after April 18, 2023 are issued as [electronic patent grants \(eGrants\)](#)
- On April 12, 2023 the Office will transition all current Private PAIR e-Office Action participants to Patent Center e-Office Action. Visit the [e-Office Action](#) information page for additional information.
- Any known issues and workarounds for Patent Center can be found on the [Patent Center information page](#).

Search for a patent application

Search by application number, patent number, PCT number, publication number or international design registration number.

Application # Search



US 20230140672A1

(19) **United States**(12) **Patent Application Publication**
KLASEK et al.(10) **Pub. No.: US 2023/0140672 A1**(43) **Pub. Date: May 4, 2023**(54) **HUMIDIFIER FOR RESPIRATORY
APPARATUS**(71) Applicant: **ResMed Pty Ltd**, Bella Vista (AU)(72) Inventors: **Paul Jan KLASEK**, Sydney (AU);
Alexander VIRR, Gosford (AU);
Nathan John ROW, Sydney (AU);
Ronald James HUBY, Sydney (AU);
Jack Wei CHENG, Sydney (AU)(21) Appl. No.: **17/991,667**(22) Filed: **Nov. 21, 2022****Related U.S. Application Data**

(63) Continuation of application No. 15/710,893, filed on Sep. 21, 2017, which is a continuation of application No. 11/936,822, filed on Nov. 8, 2007, now Pat. No. 9,855,398.

(60) Provisional application No. 60/955,222, filed on Aug. 10, 2007.

(30) **Foreign Application Priority Data**

Nov. 8, 2006 (AU) 2006906224

(52) **U.S. Cl.**CPC *A61M 16/1075* (2013.01); *A61M 16/0633* (2014.02); *A61M 16/108* (2014.02); *A61M 16/1085* (2014.02); *A61M 16/109* (2014.02); *A61M 16/1095* (2014.02); *A61M 16/0875* (2013.01); *A61M 16/16* (2013.01); *A61M 16/0003* (2014.02); *A61M 16/0825* (2014.02); *A61M 16/0057* (2013.01); *A61M 16/161* (2014.02); *A61M 16/0066* (2013.01); *A61M 16/06* (2013.01); *A61M 16/0816* (2013.01); *A61M 2016/0027* (2013.01); *A61M 2016/0039* (2013.01); *A61M 2205/14* (2013.01); *A61M 2205/3368* (2013.01); *A61M 2205/3375* (2013.01); *A61M 2205/3569* (2013.01); *A61M 2205/3584* (2013.01); *A61M 2205/3592* (2013.01); *A61M 2205/3633* (2013.01); *A61M 2205/3653* (2013.01); *A61M 2205/6018* (2013.01); *A61M 2205/6054* (2013.01); *A61M 2230/04* (2013.01); *A61M 2205/3334* (2013.01)

(57)

ABSTRACT

A heatable conduit for use in a respiratory apparatus for delivering breathable gas to a patient includes a first segment comprising one or more heater wires and a second segment

Home - Patent Center - USPTO x Patent Public Search Basic | USPTO x 20230140672 - 20230140672

https://patentcenter.uspto.gov 110%

Getting Started MyUSPTO | USPTO Google Maps Translate Mail - Andrew H. Berk... DocketTrak® Patent Vi... Trello BIPL QuickBooks PCT - The Internationa... Home - Patent Center ... Google Patents

An official website of the United States government [Here's how you know](#)

uspto Patents Trademarks Fees and payment Contact Us MyUSPTO [Sign in](#)

Patent Center

Home New submission Existing submissions Petitions Post grant Search Patent Center Help

- **Filing a new non provisional 111(a) application?** Starting June 30, 2023, specification, claims and abstracts not filed in DOCX format will incur a non-DOCX surcharge of up to \$400 for this filing type. See the [Federal Register notice](#) for more information.
- Extended through June 30, 2023, exclusively in Patent Center, applicants have the option to upload a backup (auxiliary) PDF version of their application with their DOCX version. There are no fees associated with this auxiliary PDF. See the [Federal Register notice](#) for more information.

Attend a [DOCX training webinar](#) or visit the [DOCX information page](#) to learn more about filing in DOCX format.
- Patents with an issue date on or after April 18, 2023 are issued as [electronic patent grants \(eGrants\)](#)
- On April 12, 2023 the Office will transition all current Private PAIR e-Office Action participants to Patent Center e-Office Action. Visit the [e-Office Action](#) information page for additional information.
- Any known issues and workarounds for Patent Center can be found on the [Patent Center information page](#).

Search for a patent application

Search by application number, patent number, PCT number, publication number or international design registration number.

Application # 17/991,667

17/991,667 | PTB-4398-2462: HUMIDIFIER FOR RESPIRATORY APPARATUS [PUBLIC VIEW](#)

Application #	Confirmation #	Attorney Docket #	Patent #	Filing or 371 (c) date	Status
17/991,667	3501	PTB-4398-2462	-	11/21/2022	Non Final Action Mailed 03/27/2023

- Application Data**
- Documents & Transactions
- Continuity
- Patent Term Adjustment
- Foreign Priority
- Fee payment history
- Address & Attorney/Agent Information

Application data

Application type	Utility	Earliest publication #	US 2023-0140672 A1 🔗	Intl. registration # (Hague)	-
Examiner	LATOYA M LOUIS	Earliest publication date	05/04/2023	Intl. registration publication date	-
Group art unit	3785	Assignee for publication	-		
Class/subclass	128/203.270	Confirmation #	3501		

Home - Patent Center - USPTO x Patent Public Search Basic | USPTO x 20230140672 - 20230140672 x +

https://patentcenter.uspto.gov/applications/17991667/fw/docs?application= 90% ☆

Getting Started MyUSPTO | USPTO Google Maps Translate Mail - Andrew H. Berk... DocketTrak® Patent Vi... Trello BIPL QuickBooks PCT - The Internationa... Home - Patent Center ... Google Patents

An official website of the United States government [Here's how you know](#)

uspto Patents Trademarks Fees and payment Contact Us MyUSPTO [Sign in](#)

Patent Center Home New submission Existing submissions Petitions Post grant Search Patent Center Help

[Back to home](#) [Order certified copies](#) [Global Dossier](#) [Download](#) [Print](#)

17/991,667 | PTB-4398-2462: HUMIDIFIER FOR RESPIRATORY APPARATUS [PUBLIC VIEW](#)

Application #	Confirmation #	Attorney Docket #	Patent #	Filing or 371 (c) date	Status
17/991,667	3501	PTB-4398-2462	-	11/21/2022	Non Final Action Mailed 03/27/2023

Application Data

Documents & Transactions

Continuity

Patent Term Adjustment

Foreign Priority

Fee payment history

Address & Attorney/Agent Information

Supplemental Content

Assignments

Display References

Documents & transaction history

Documents Transactions

None selected

Showing 1 to 33 of 33 entries

Mail room date	Doc code	Doc description	Pages	Quick download
05/04/2023	NTC.PUB	Notice of Publication	1	Preview PDF
03/29/2023	CTNF	Non-Final Rejection	17	Preview PDF/ XML/ DOCX
03/29/2023	SRFW	Search information including classification, databases and other search related notes	1	Preview PDF
03/29/2023	FWCLM	Index of Claims	1	Preview PDF
03/29/2023	1449	List of References cited by applicant and considered by examiner	5	Preview PDF

Home - Patent Center - USPTO x Patent Public Search Basic | USPTO x 20230140672 - 20230140672

https://patentcenter.uspto.gov/applications/17991667/continuity?application=

Getting Started MyUSPTO | USPTO Google Maps Translate Mail - Andrew H. Berk... DocketTrak® Patent Vi... Trello BIPL QuickBooks PCT - The Internationa... Home - Patent Center ... Google Patents

An official website of the United States government [Here's how you know](#)

uspto Patents Trademarks Fees and payment Contact Us MyUSPTO [Sign in](#)

Patent Center

Home New submission Existing submissions Petitions Post grant Search Patent Center Help

[Back to home](#) [Order certified copies](#) [Global Dossier](#) [Download](#) [Print](#)

17/991,667 | PTB-4398-2462: HUMIDIFIER FOR RESPIRATORY APPARATUS [PUBLIC VIEW](#)

Application #	Confirmation #	Attorney Docket #	Patent #	Filing or 371 (c) date	Status
17/991,667	3501	PTB-4398-2462	-	11/21/2022	Non Final Action Mailed 03/27/2023

Application Data

Documents & Transactions

Continuity

Patent Term Adjustment

Foreign Priority

Fee payment history

Address & Attorney/Agent Information

Supplemental Content

Assignments

Display References

Continuity

Parent data

Application #	Description	Parent application #	Filing or 371 (c) date	Status	Patent #	AIA
17/991,667	is a Continuation of	15/710,893	09/21/2017	-	-	No
15/710,893	is a Continuation of	11/936,822	11/08/2007	Patented	9855398	No
11/936,822	Claims priority from a provisional application	60/955,222	08/10/2007	Expired	-	-

Child data

Application #	Filing or 371 (c) date	Status	Patent #	AIA	Description	Parent application #
18/143,590		-	-	-	is a Continuation in-part of	17/991,667

Non-provisional Filing Date in a PCT Patent Application

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization

International Bureau

(43) International Publication Date
24 June 2021 (24.06.2021)



(10) International Publication Number
WO 2021/126870 A1

(51) International Patent Classification:

A61K 31/192 (2006.01) *A61P 25/16* (2006.01)
A61K 31/216 (2006.01) *A61P 25/28* (2006.01)
A61K 31/575 (2006.01)

(21) International Application Number:

PCT/US2020/065145

(22) International Filing Date:

15 December 2020 (15.12.2020)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/948,756 16 December 2019 (16.12.2019) US
63/030,793 27 May 2020 (27.05.2020) US
16/940,102 27 July 2020 (27.07.2020) US

(71) Applicant: **AMYLYX PHARMACEUTICALS INC.**
[US/US]; 43 Thorndike Street, Cambridge, Massachusetts
02141 (US).

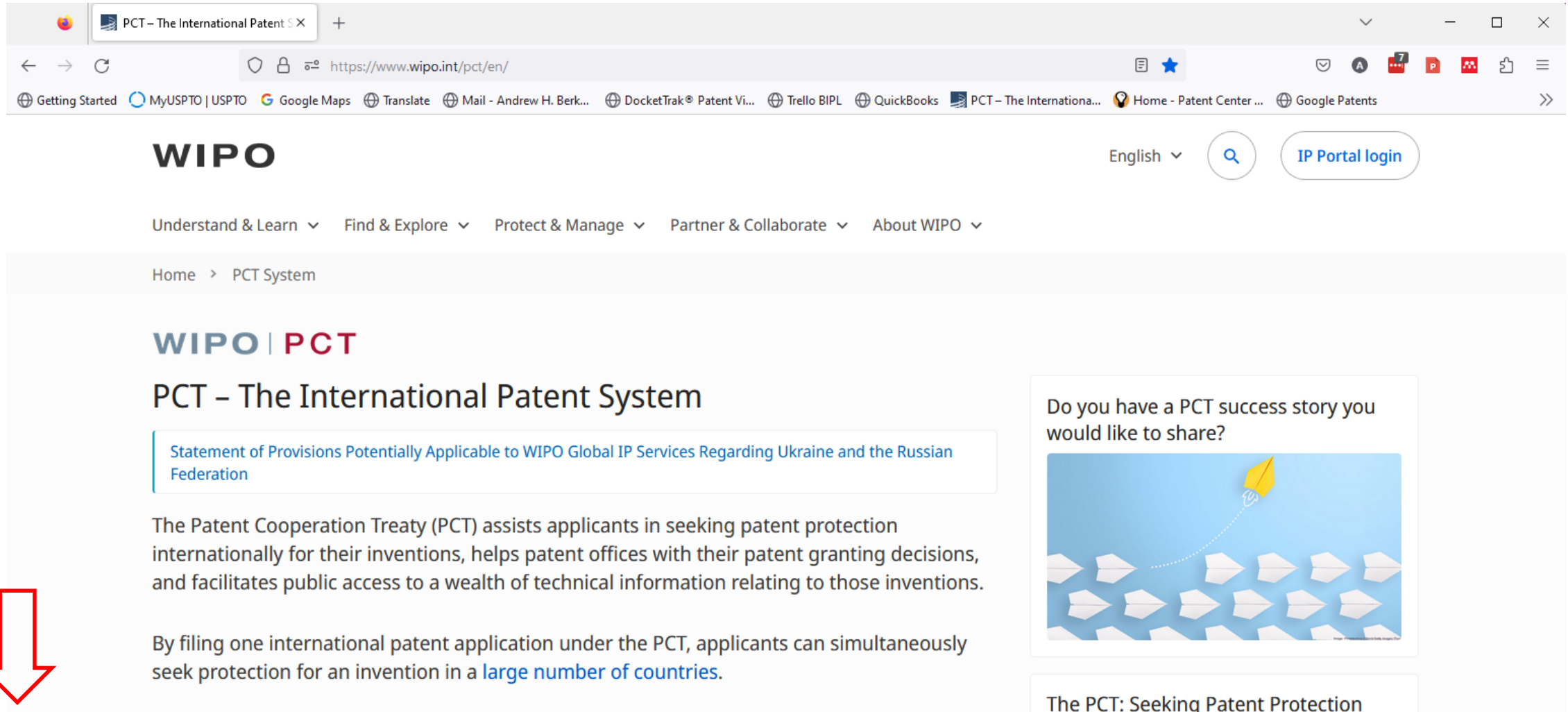
(72) Inventors: **COHEN, Joshua**; 43 Thorndike Street, Cam-
bridge, Massachusetts 02141 (US). **KLEE, Justin**; 43
Thorndike Street, Cambridge, Massachusetts 02141 (US).

(74) Agent: **GARCIA, Todd E.** et al.; Fish & Richardson P.C.,
P.O. Box 1022, Minneapolis, Minnesota 55440-1022 (US).

(81) Designated States (*unless otherwise indicated, for every
kind of national protection available*): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ,
CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO,
DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN,
HR, HU, ID, IL, IN, IR, IS, IT, JO, JP, KE, KG, KH, KN,
KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD,
ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO,
NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW,
SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN,
TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every
kind of regional protection available*): ARIPO (BW, GH,
GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ,
UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,
TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK,
EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,
MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
KM, ML, MR, NE, SN, TD, TG).

PATENTSCOPE – Official PCT Database



The screenshot shows the WIPO PCT website interface. At the top, there is a navigation bar with the WIPO logo on the left, a language dropdown set to 'English', a search icon, and an 'IP Portal login' button. Below this is a horizontal menu with categories: 'Understand & Learn', 'Find & Explore', 'Protect & Manage', 'Partner & Collaborate', and 'About WIPO'. The breadcrumb trail reads 'Home > PCT System'. The main heading is 'WIPO | PCT' followed by 'PCT – The International Patent System'. A highlighted link reads 'Statement of Provisions Potentially Applicable to WIPO Global IP Services Regarding Ukraine and the Russian Federation'. The main text explains that the PCT assists applicants in seeking patent protection internationally. A red arrow on the left points to the text 'By filing one international patent application under the PCT, applicants can simultaneously seek protection for an invention in a large number of countries.' On the right, there is a call-to-action box with the text 'Do you have a PCT success story you would like to share?' and an image of a yellow paper airplane flying over a row of white paper airplanes. Below this is a link titled 'The PCT: Seeking Patent Protection'.

WIPO English [IP Portal login](#)

[Understand & Learn](#) [Find & Explore](#) [Protect & Manage](#) [Partner & Collaborate](#) [About WIPO](#)

Home > PCT System

WIPO | PCT


PCT – The International Patent System

[Statement of Provisions Potentially Applicable to WIPO Global IP Services Regarding Ukraine and the Russian Federation](#)

The Patent Cooperation Treaty (PCT) assists applicants in seeking patent protection internationally for their inventions, helps patent offices with their patent granting decisions, and facilitates public access to a wealth of technical information relating to those inventions.

By filing one international patent application under the PCT, applicants can simultaneously seek protection for an invention in a [large number of countries](#).

Do you have a PCT success story you would like to share?



[The PCT: Seeking Patent Protection](#)

PCT Resources

[ePCT \(WIPO IP Portal\)](#)
[ePCT Video Tutorials for Applicants](#)
[PCT Applicant's Guide](#)
[Forms](#)
[Treaty, Regulations and more](#)
[Time Limit Calculator](#)
[Fees \(WIPO Pay\)](#)

Legal

[Treaty, Regulations and Administrative Instructions](#)
[Treaty](#) **PDF**
[Regulations](#) **PDF**
[Administrative Instructions](#) **PDF**

[Guidelines for Authorities and Offices](#)

[Legal Text Index \(July 1, 2022\)](#) **PDF** [Archives](#)

[Reservations and Incompatibilities](#)

[Official Notices \(PCT Gazette\) Collection](#)

[Amendments to the Regulations \(July 1, 2022\)](#) **PPT**
[Archives](#)

[FAQs](#)

[ISA and IPEA Agreements](#)

[PATENTSCOPE](#)
[PATENTSCOPE Resources](#)

States

[PCT Contracting States](#)

[States bound by the Paris Convention but not the PCT](#)

[States Party to PCT/Paris/WTO](#)

[Time Limits for Entering National/Regional Phase](#)

[Types of Protection](#)

[Regional Patents via the PCT](#)

[Restoration of the Right of Priority](#)

[Waivers: Powers of Attorney](#)

[Access to IPER under Rule 94.1\(c\)](#)

[International applications and national security considerations](#)

[IPO Closed Dates](#)

[Unavailability of Electronic Means of Communication](#)

Filing

[▶ All resources](#)

[ePCT \(WIPO IP Portal\)](#)

[Contingency Upload Service \(FAQs\)](#)

[Direct filing with the IB](#)

[Filing sequence listings under ST.26](#)

[PCT eServices](#)

[PCT Applicant's Guide](#)

[PCT-Patent Prosecution Highway Pilot \(PCT-PPH\)](#)

[Collaborative Search and Examination](#)

[Collection of PCT User Strategies](#)

[PCT Time Limit Calculator](#)

Forms

[Request](#) **PDF**

[Demand](#) **PDF**

Fees

[PCT Fee Tables](#) **PDF**

[WIPO Pay](#)

FIELD COMBINATION

	Field	Value	
	Front Page		?
Operator AND	WIPO Publication Number	2021126870	?
Operator AND	Application Number		?
Operator AND	Publication Date		?
Operator AND	English Title		?
Operator AND	All Classifications	Is Empty: N/A	
Operator AND	Licensing availability	<input type="checkbox"/>	



WO2021126870 COMPOSITIONS X

https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2021126870&_cid=P22-LHF2X2-54402-1

Getting Started MyUSPTO | USPTO Google Maps Translate Mail - Andrew H. Berk... DocketTrak® Patent Vi... Trello BIPL QuickBooks PCT - The Internationa... Home - Patent Center ... Google Patents

WIPO Help English IP Portal login

Home > PATENTSCOPE > Search

Feedback Search Browse Tools Settings

1. WO2021126870 - COMPOSITIONS OF BILE ACIDS AND PHENYL BUTYRATE COMPOUNDS

PCT Biblio. Data Description Claims Drawings ISR/WOSA/A17[2][a] National Phase Patent Family Notices Documents

PermaLink Machine translation

Publication Number WO/2021/126870	Title [EN] COMPOSITIONS OF BILE ACIDS AND PHENYL BUTYRATE COMPOUNDS [FR] COMPOSITIONS D'ACIDES BILIAIRES ET DE COMPOSÉS DE PHÉNYLBUTYRATE
Publication Date 24.06.2021	
International Application No. PCT/US2020/065145	
International Filing Date 15.12.2020	
IPC A61K 31/192 2006.1 A61K 31/216 2006.1 A61K 31/575 2006.1 A61P 25/16 2006.1 A61P 25/28 2006.1	

Particle Size Distribution of NaPB and TURSO

Particle Size (µm)	NaPB (Sodium Phenylbutyrate) % Weight	TURSO (Taurursodiol) % Weight
>250	~30	~2
100-250	~55	~25
150-100	~10	~15
100-150	~5	~18
75-100	~2	~18
45-75	~1	~5
30-45	~0	~0
<30	~0	~0

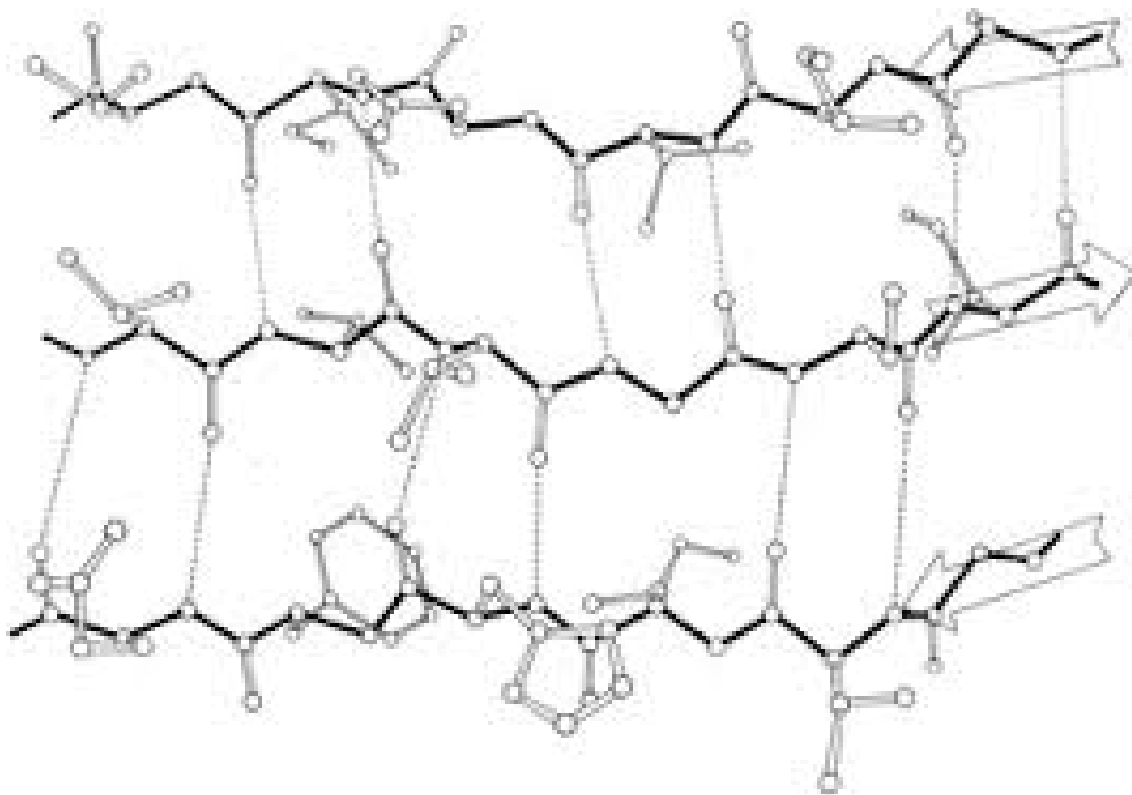
https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2021126870&_cid=P22-LHF2X2-54402-1#detailMainForm:MyTabViewId:DRAWINGS

Provisional Patent Applications – Paris Convention

- Problem: filing patents in other countries.
- Patents are a creature of law and are only valid in the country where granted
- General rule: patent applicants have one year to file a patent application in another country besides their home country.
- Because patents require absolute novelty, inventors need a grace period to file in another country, without the second country considering the original patent application prior art.
- To address this problem the Paris Convention (originally enacted in 1883, amended several times since, most recently in 1979) gives a period of priority of 12 months from the earliest filing date.
- Example: you file a patent application in the US and one year later, you file a patent application in Canada. The Canadian patent examiner cannot assert that the US patent application was prior art because the Canadian patent was filed within the priority period.



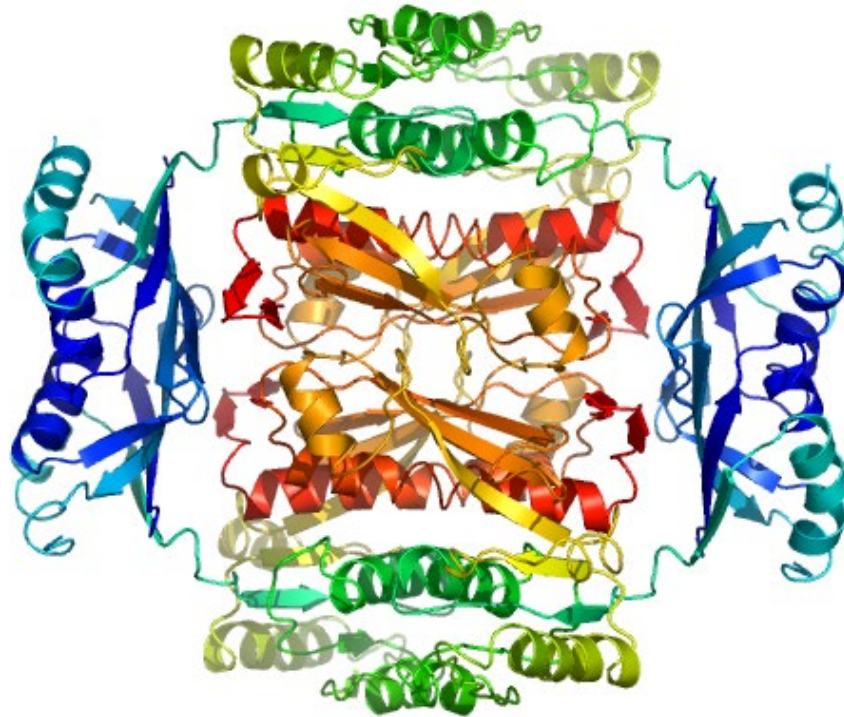
New Problem with 20-year patent life



- The one-year priority is very important. Most inventions are of value in many different countries.
- Problem is that if a patent expires 20 years from filing in your home country, and you have a 12-month period of priority elsewhere, you will get a shorter patent life in your home country than in other countries with 20-year from first filing. In other countries, the expiration will be 21 years from the original filing date.
- Solution: Provisional applications were created!

Provisional Patent Applications

- Created in the US in 1995
- **Provisionals do not count against the 20-year patent expiration clock.**
- **Provisionals have a 12-month life max**



Provisional Patent Appln Timeline

- Typical timeline:



- Key point: a provisional has effect against all other countries.
- So if you file a provisional in the US, it also acts as a provisional in Canada, China, Europe, etc.

More on Provisionals

- The general idea is that a patent applicant files a provisional patent application that has an invention disclosure at a national patent office.
- Provisional patent applications are allowed to be informal. There are no formatting requirements, and claims are not required (unlike regular patent applications).
- The applicant then has 12 months to file a non-provisional patent application anywhere in the world that claims priority to the provisional under the rules of the Paris Convention.
- Provisional patent applications are not examined for novelty and non-obviousness and never issue –
 - **there is no such thing as a granted provisional patent application.**

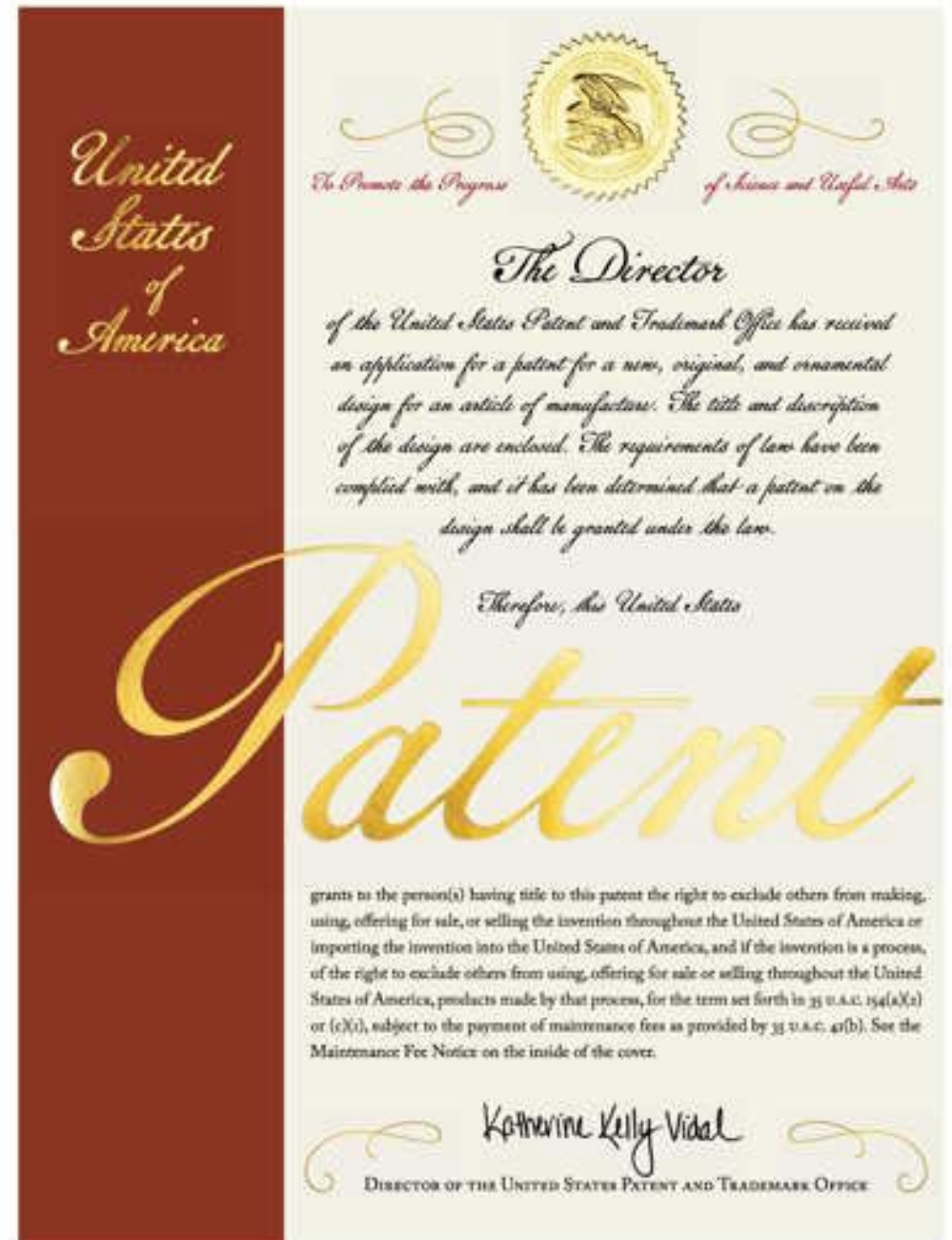
You Got an Issued Patent – Congratulations!

- After you get a patent issued, you cannot put it on the shelf and forget about it and expect it to be in force in 10 years down the road when you discover an infringer.
- Most countries require some kind of ongoing payment to keep a patent in force.
 - Many jurisdictions require annual renewal fees, that often escalate each year.
 - This discourages applicants from keeping patents alive that aren't economically valuable.
 - In many countries (examples: Canada and EPO), annual fees are required even before grant



US Maintenance Fees

- In the US, maintenance fees are required and are due at 3.5 years, 7.5 years, and 11.5 years after the date of issue.
- 6 mos. extension available.
- If the fees aren't paid, the patent will lapse. You cannot sue an infringer for infringement of a lapsed patent.
- Key point: there are service companies that manage these payments. Using them is a good idea.



Patent Term Extensions

- One way of looking at the 20-year patent expiration rule is that it is similar to the old 17-year rule assuming it takes 3 years to get a patent issued, if the applicant and USPTO act diligently
- A big concern when the 20-year rule started in 1995 was that it often took longer than 3 years to get a patent issued through no fault of the applicant. It is not uncommon for a patent application to sit for several years before an examiner picks it up.
- 35 U.S.C. §154(b) was enacted to address this problem, called a “Guarantee of No More Than 3-Year Application Pendency” with a formula for calculating a patent term extension based on delays in patent office and applicant responses.
- These patent term extensions are listed on the front page of an issued patent.
 - Example: US Patent 9,828,164 B2



US009828164B2

(12) **United States Patent**
Denson

(10) **Patent No.:** **US 9,828,164 B2**
(45) **Date of Patent:** **Nov. 28, 2017**

(54) **INTERMODAL CONTAINER AND METHOD
OF CONSTRUCTING SAME**

(56) **References Cited**

(71) Applicant: **Fontaine Engineered Products, Inc.**,
Jasper, AL (US)

U.S. PATENT DOCUMENTS

2,791,463 A 5/1957 Levitt
2,962,323 A 11/1960 McBride

(72) Inventor: **John Clifford Denson**, Birmingham,
AL (US)

(Continued)

(73) Assignee: **Fontaine Engineered Products, Inc.**,
Jasper, AL (US)

FOREIGN PATENT DOCUMENTS

DE 2444523 A1 4/1976
EP 1162058 A1 12/2001

(Continued)

(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 160 days.

OTHER PUBLICATIONS

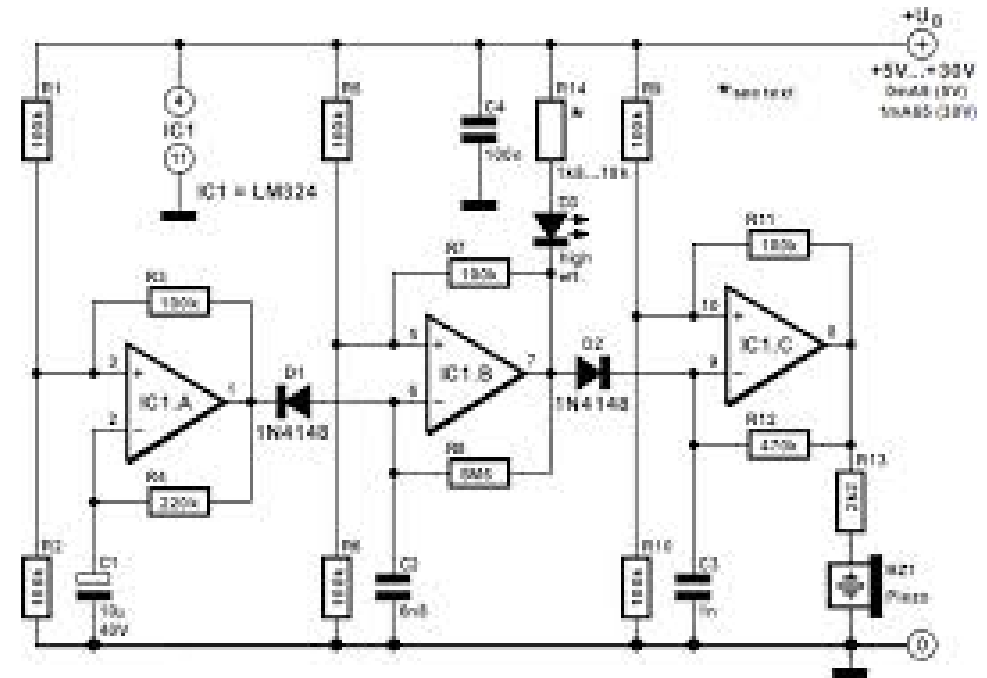
Sec. 156 Patent Term Extension

- 35 U.S.C. §156, created in 1984 in the Hatch-Waxman Act
- Can extend the life of a patent for up to five years for regulatory delays for patents on a product requiring regulatory approval.
- Mainly intended for pharmaceuticals but other types of products subject to regulatory approval may be covered also.
- This was part of the quid pro quo in the H-W Act which gave generics the right to use an invention prior to patent expiration. 35 U.S.C. gives the innovator co.'s a patent term extension to compensate for regulatory delays, which can often take many years.
- These are not listed on the front page of a patent. A patent attorney with experience in this rule needs to find this extension in the online file history of a patent.



Shortening Patent Life

- There are situations where a patent owner wants to shorten the life of a patent
- This is done with a “terminal disclaimer”
- The most common reason for filing a TD is to overcome a “double patenting” rejection
- This happens when a patent examiner alleges a second patent application is obvious over an earlier filed patent.
- Often, an applicant can overcome such a rejection by filing a terminal disclaimer to the second patent application, disclaiming the life of the second patent after the expiration of the first patent.
- Terminal disclaimers made during prosecution are listed in the front page of a patent application



More on Terminal Disclaimers

- Terminal disclaimers can also be filed voluntarily for several reasons.
- A patent owner may be charitable and dedicate an invention to the public as charity
- Sometimes settlements of disputes involve a terminal disclaimer



Patents invalidated in the courts

- Patents have a strong presumption of validity (35 U.S.C §282), but patents are often declared invalid and unenforceable following patent litigation actions.
- Accused infringers typically, as a matter of litigation strategy, argue that (1) the patent is invalid and (2) that they are not actually infringing.
- Invalidity arguments are that the patent is not properly patentable subject matter (§101), that the patent is anticipated or obvious over prior art (§102, 103), and/or that the invention is doesn't meet the written description or definiteness requirements (§112).
- Any of these deficiencies can result in one or more claims of a patent being held invalid and unenforceable prior to the natural expiration of the patent.

Conclusions

- General rule: Patents are valid for 20 years from the earliest non-provisional filing date
- A provisional patent application does not count towards the 20-year expiration clock, but a provisional is only valid for one year.
- Maintenance fees (US) or renewal fees are required in most countries following patent grant
- Several patent term extensions may be available.
- Patent life can be shortened with a terminal disclaimer

Thank you!



About the Speaker



Andrew H. Berks, Ph.D., J.D.
ahb@gdblaw.com
845-558-7245

Gallet, Dreyer, & Berkey LLP
845 Third Ave
New York, NY 10022

Andrew H. Berks builds and protects patent portfolios for his clients. He is a partner at Gallet, Dreyer, & Berkey LLP. Andrew specializes in all aspect of patent matters and IP transactional matters. Andrew's practice includes

- patent strategy and counseling, patent drafting, prosecution, and appeals
- patent opinions including patentability, freedom to operate, non-infringement and patent landscape reviews
- patent litigation
- license agreements and other IP-related contracts
- confidentiality (non-disclosure) agreements
- research and development agreements

Andrew's prior experience includes work at several law firms and corporate environments, including Wyeth Corp., Merck & Co., and Ivax Pharmaceuticals.

Andrew's clients include Fortune 500 corporations, University technology transfer offices, established businesses, foreign companies, entrepreneurs, startups, and individuals. Andrew works in all technology areas, including chemistry, pharmaceuticals, biotechnology, medical devices, mechanical and engineering, and computers and software. Andrew is a graduate of Fordham Law School and has a Ph.D. in organic chemistry from the University of Colorado, Boulder. He has two grown daughters and lives in New York City.

Disclaimer

- This presentation is educational only and does not create a client-attorney relationship.
- This presentation explains how an experienced attorney would approach the topics discussed and is not meant as a “how-to” for inexperienced persons.
- Always consult an experienced attorney for any legal issues you may have.