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Get the Most Out of Your Patents: A deep-dive analysis into pharmaceutical patent life cycle management

Created by: Dr. Sarbani Chattopadhyay

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Consultant

- Computational biologist with a PhD in Biochemistry from the University of Calcutta and a LL.M. in European IP and IT Law from the University of Göttingen, Germany.

- As a Consultant at LexisNexis PatentSight, she works with clients across the globe in different technology fields. She specializes in searching and analyzing patents, patent landscaping and benchmarking technologies from a patent perspective.

Today's Discussion: A deep-dive analysis into pharmaceutical patent life cycle management

- Product-to-Patent mapping using Orange Book data
- Insight into fiercely fought patent battles from the prosecution details about key patents.
- The strength and the power provided by the apparent key patent to the patent owner on the basis of the scientifically validated and patented methodology.
- The early predictors indicating the potential contributors to the global pressing needs (e.g., Covid-19 treatment methods).

Rights in the Pharmaceutical Field in USA
Patents vs. Exclusivity

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Patents granted by the USPTO

- Patent rights enable the patent owner to **exclude others**
- Period of patent term: 20 years*.

Exclusivity granted by the FDA

- Exclusivity refers to certain delays and **prohibitions on approval of competitor drugs**
- A **N**ew **D**rug **A**pplication (NDA) or **A**bbreviated **N**ew **D**rug **A**pplication (ANDA) holder is eligible

BOTH are NEGATIVE RIGHTS

- Patents can be issued or expire at any time regardless of the drug's approval status.
- Some drugs have both patent and exclusivity protection while others have just one or neither.
- Patents and exclusivity may or may not run concurrently and may or may not cover the same aspects of the drug product

Orange Book

- Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

The Orange Book information enables direct Product-to-Patent mapping

- FDA will **not publish in the Orange Book** patent information on **unapproved applications** or on **patents beyond the scope** of the Food Drug & Cosmetic Act (i.e., process or manufacturing patents). The patents that FDA regards as covered by the statutory provisions for submission of patent information are:

  - patents that claim the active ingredient(s);
  - drug product patents which include formulation/ composition patents;
  - use patents for a particular approved indication or method of using the product; and
  - certain other patents as detailed on FDA Form 3542.

Product-to-Patent mapping

Focus: Multiple Sclerosis

Multiple sclerosis (MS) is a condition that can affect the brain and spinal cord, causing a wide range of potential symptoms, including problems with vision, arm or leg movement, sensation or balance.

It's a lifelong condition that can sometimes cause serious disability, although it can occasionally be mild.

There's no cure for multiple sclerosis. In many cases, it's possible to treat symptoms. Average life expectancy is slightly reduced for people with MS.

It's most commonly diagnosed in people in their 20s, 30s and 40s although it can develop at any age. It's about 2 to 3 times more common in women than men. MS is one of the most common causes of disability in younger adults.

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https://www.nhs.uk/conditions/multiple-sclerosis/

LexisNexis TotalPatent One®

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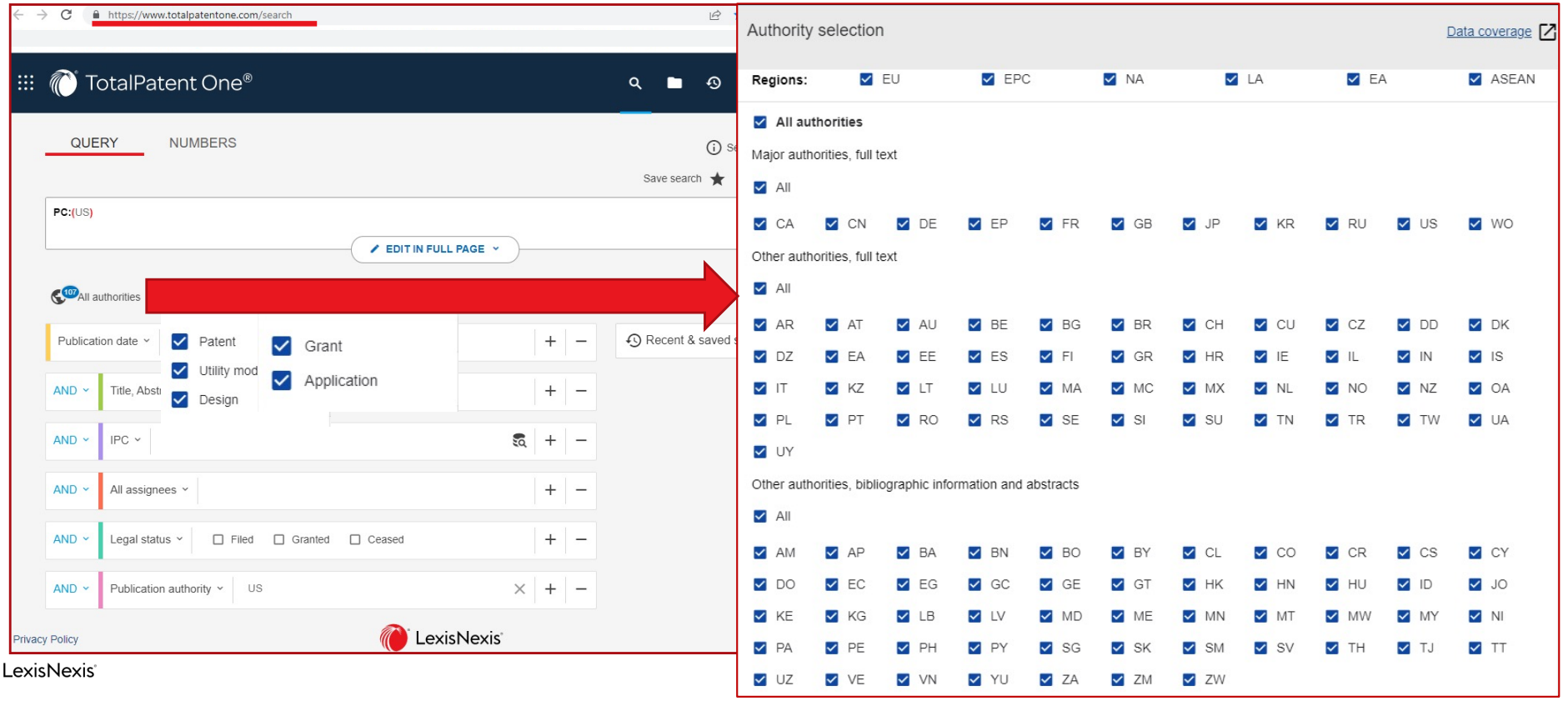
Patent Search in LexisNexis TotalPatentOne®

TotalPatentOne® is a patent search software created by LexisNexis®.



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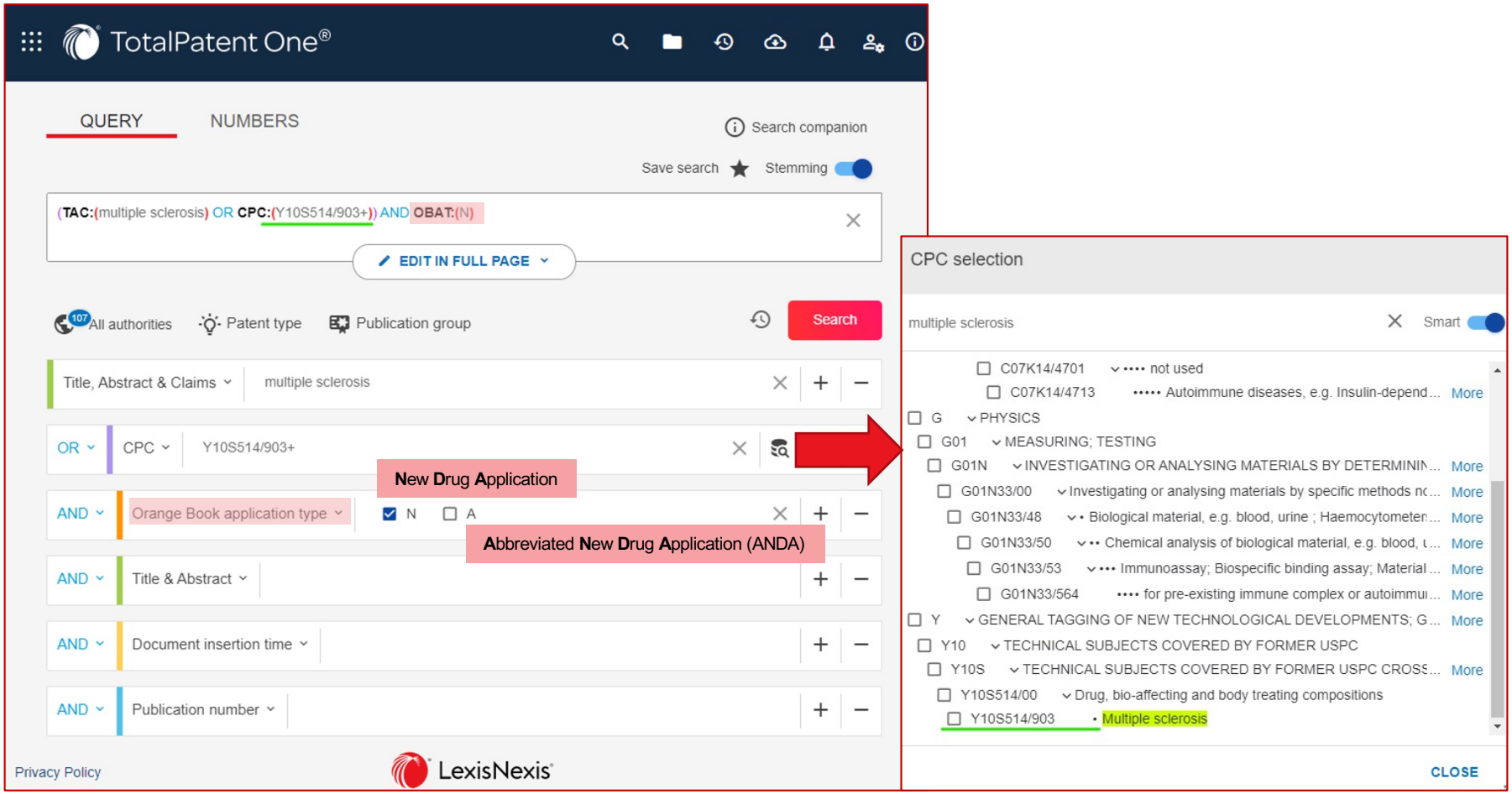
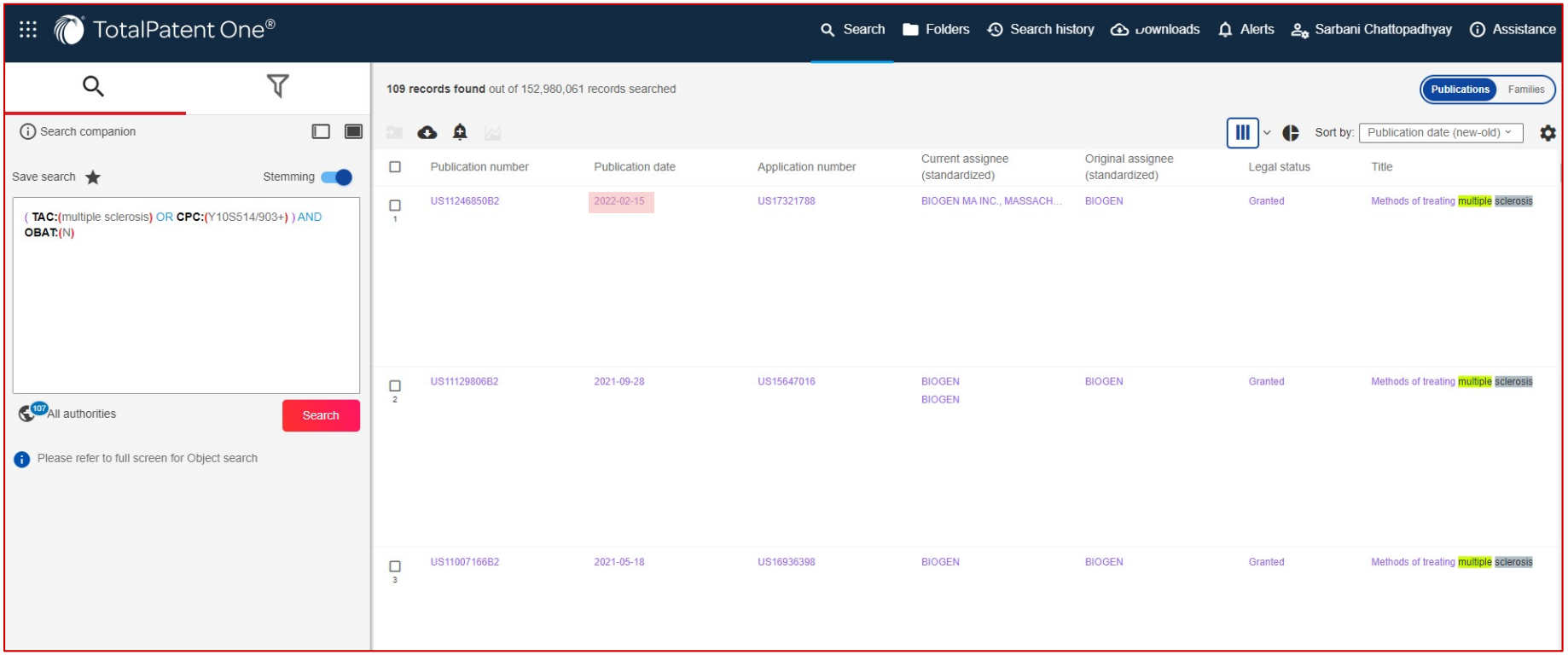
Patent Search in LexisNexis TotalPatentOne® : Multiple Sclerosis



Patent Search in LexisNexis TotalPatentOne®: Multiple Sclerosis



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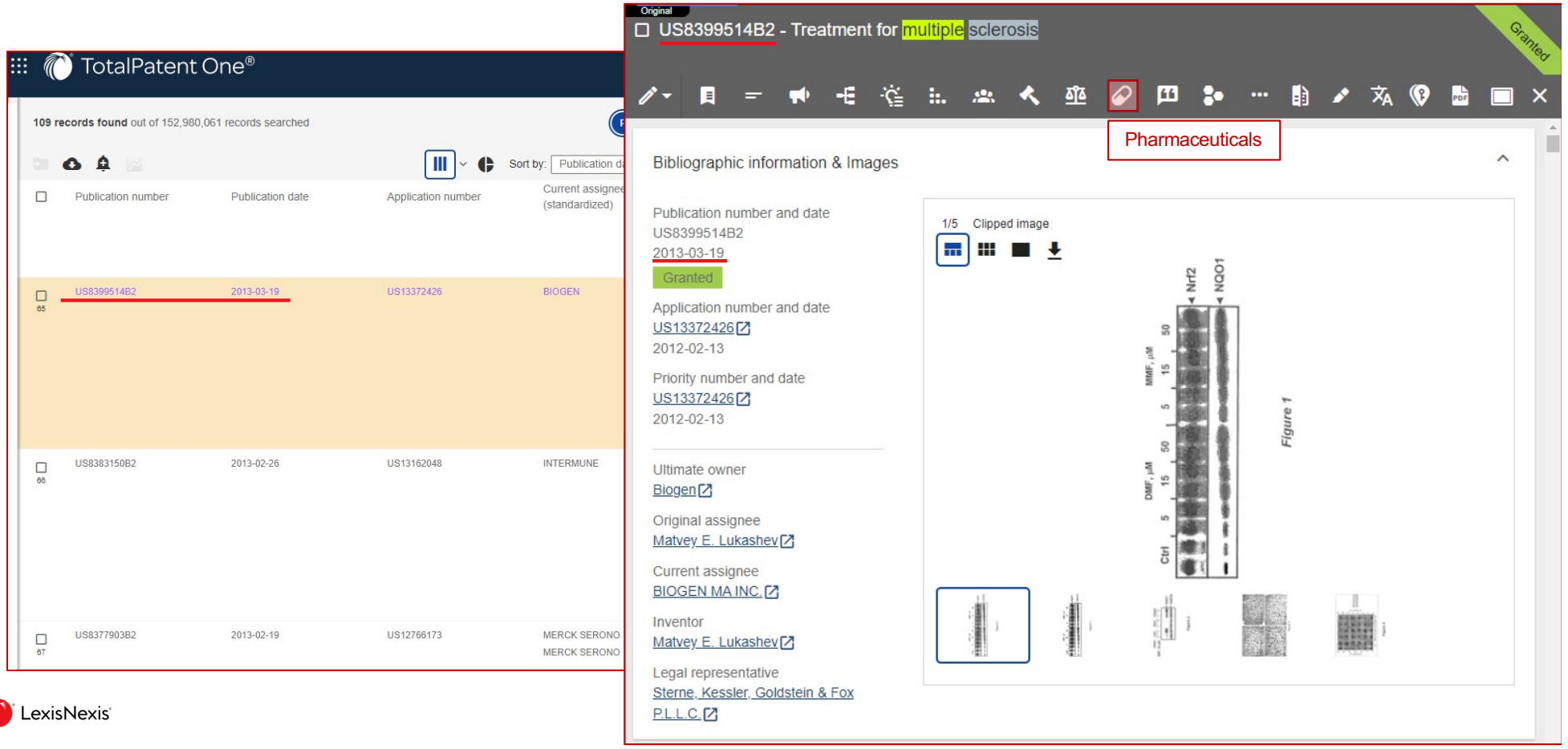
Patent Search in LexisNexis TotalPatentOne®: Multiple Sclerosis



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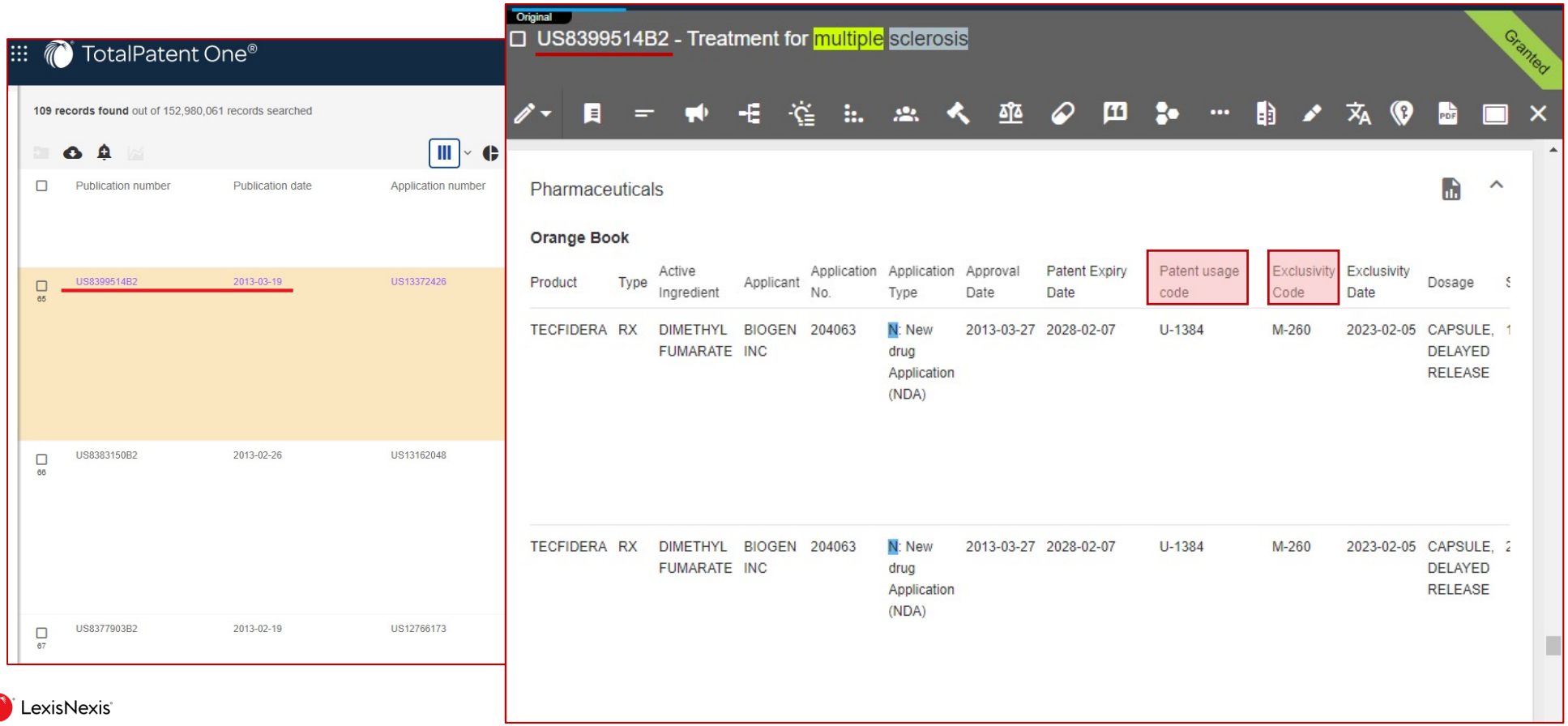
Information: Codes and Definition



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Patent Use Codes and Definitions

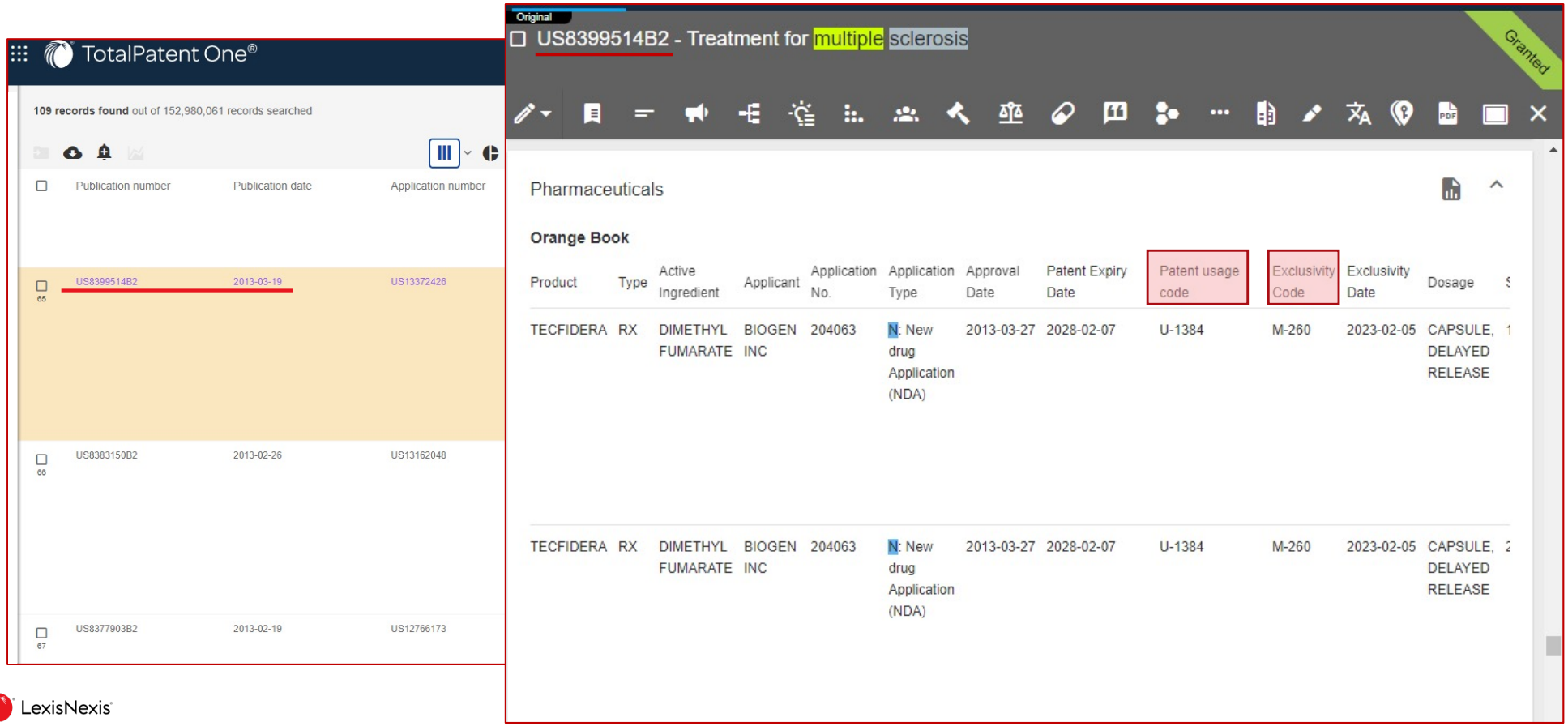
Patent Use Code

Code to designate a use patent that covers the approved indication or use of a drug product. May repeat for multiple applications, multiple products and multiple patents. Format is nnnnnnnnn.

U-1376	TREATMENT OF INFLAMMATORY LESIONS OF NON-NODULAR MODERATE TO SEVERE ACNE VULGARIS
U-1377	IMPROVE RESPIRATORY SYMPTOMS IN CYSTIC FIBROSIS IN PATIENTS WITH PSEUDOMONAS AERUGINOSA
U-1378	TREATMENT OF A NITROGEN METABOLISM DISORDER
U-1379	IMPROVEMENT OF GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS WHO HAVE ONE OR MORE SPECIFIED CARDIOVASCULAR RISK FACTORS
U-1380	IMPROVEMENT OF GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS WHO HAVE ONE OR MORE SPECIFIED CARDIOVASCULAR RISK FACTORS WHEREIN THE PATIENT HAS CARDIOVASCULAR DISEASE
U-1381	USE OF PRASUGREL AND ASPIRIN IN PATIENTS REQUIRING THE REDUCTION OF THROMBOTIC CARDIOVASCULAR EVENTS
U-1382	TREATMENT OF NAUSEA AND VOMITING OF PREGNANCY IN WOMEN WHO DO NOT RESPOND TO CONSERVATIVE MANAGEMENT
U-1383	DOSAGE ADJUSTMENT OF A NITROGEN SCAVENGING DRUG IN THE TREATMENT OF A UREA CYCLE DISORDER
U-1384	METHOD OF TREATING MULTIPLE SCLEROSIS
U-1385	METHOD OF TREATING AN AUTOIMMUNE DISEASE SELECTED FROM AUTOIMMUNE POLYARTHRITIS AND MULTIPLE SCLEROSIS BUT NOT TREATING PSORIATIC ARTHRITIS
U-1386	A METHOD OF INCREASING THE TESTOSTERONE BLOOD LEVEL OF A PERSON IN NEED THEREOF
U-1387	REDUCTION IN RISK OF HOSPITALIZATION IN PATIENTS WITH A HISTORY OF PAROXYSMAL OR PERSISTENT AF WITHOUT SEVERE HEART FAILURE AND WITH ONE OR MORE RISK FACTORS BY ADMINISTRATION TWICE A DAY WITH MORNING AND EVENING MEALS
U-1388	TREATMENT OF PATIENTS WITH A HISTORY OF PAROXYSMAL OR PERSISTENT AF WITHOUT SEVERE HEART FAILURE AND WITH ONE OR MORE RISK FACTORS BY ADMINISTRATION TWICE A DAY WITH MORNING AND EVENING MEALS
U-1389	ELLA IS A PROGESTERONE AGONIST/ANTAGONIST EMERGENCY CONTRACEPTION INDICATED FOR THE PREVENTION OF PREGNANCY FOLLOWING UNPROTECTED INTERCOURSE OR A KNOWN OR SUSPECTED CONTRACEPTIVE FAILURE. ELLA CAN BE TAKEN WITH OR WITHOUT FOOD
U-1390	A METHOD OF INCREASING THE TESTOSTERONE BLOOD LEVEL OF AN ADULT MALE SUBJECT IN NEED THEREOF

https://www.fda.gov/drugs/drug-approvals-and-databases/orange-book-data-files
https://www.accessdata.fda.gov/scripts/cder/ob/results_patent.cfm

Information: Codes and Definition



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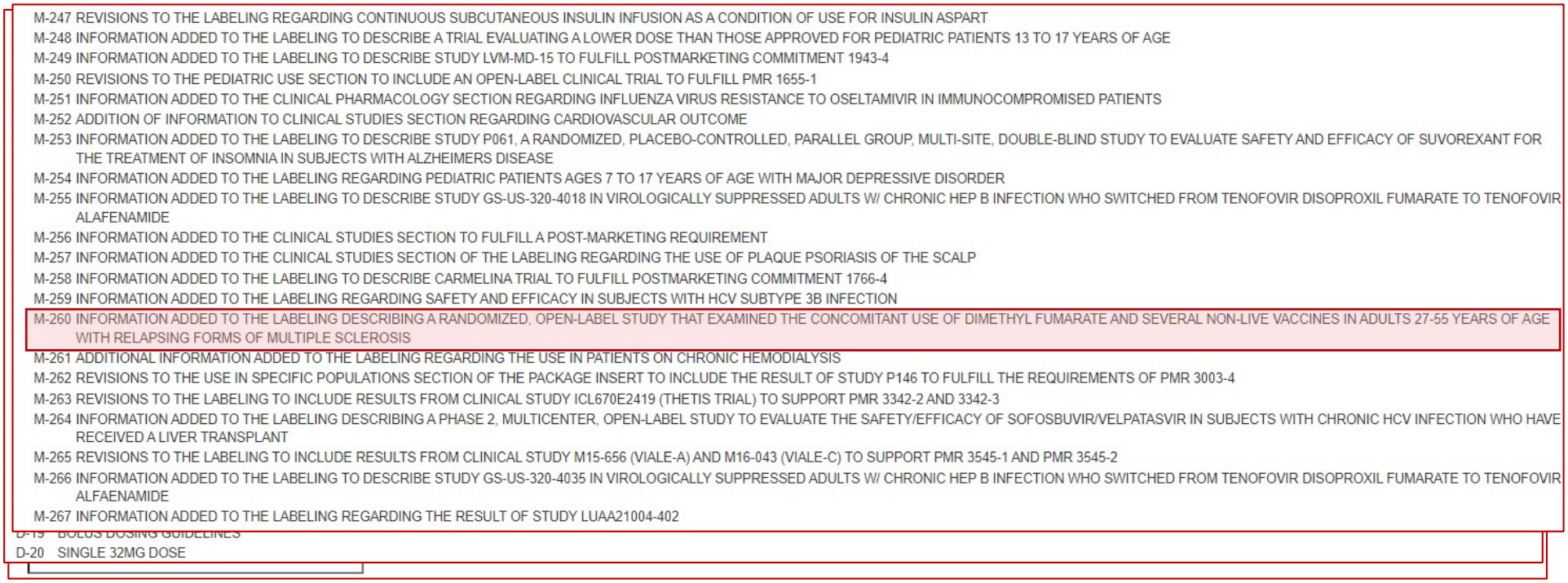
Exclusivity Codes and Definitions

Exclusivity Code:
Code to designate exclusivity granted by the FDA to a drug product. Format is nnnnnnnnn.



M-247 REVISIONS TO THE LABELING REGARDING CONTINUOUS SUBCUTANEOUS INSULIN INFUSION AS A CONDITION OF USE FOR INSULIN ASPART
M-248 INFORMATION ADDED TO THE LABELING TO DESCRIBE A TRIAL EVALUATING A LOWER DOSE THAN THOSE APPROVED FOR PEDIATRIC PATIENTS 13 TO 17 YEARS OF AGE
M-249 INFORMATION ADDED TO THE LABELING TO DESCRIBE STUDY LVM-MD-15 TO FULFILL POSTMARKETING COMMITMENT 1943-4
M-250 REVISIONS TO THE PEDIATRIC USE SECTION TO INCLUDE AN OPEN-LABEL CLINICAL TRIAL TO FULFILL PMR 1655-1
M-251 INFORMATION ADDED TO THE CLINICAL PHARMACOLOGY SECTION REGARDING INFLUENZA VIRUS RESISTANCE TO OSELTAMIVIR IN IMMUNOCOMPROMISED PATIENTS
M-252 ADDITION OF INFORMATION TO CLINICAL STUDIES SECTION REGARDING CARDIOVASCULAR OUTCOME
M-253 INFORMATION ADDED TO THE LABELING TO DESCRIBE STUDY P061, A RANDOMIZED, PLACEBO-CONTROLLED, PARALLEL GROUP, MULTI-SITE, DOUBLE-BLIND STUDY TO EVALUATE SAFETY AND EFFICACY OF SUVOREXANT FOR THE TREATMENT OF INSOMNIA IN SUBJECTS WITH ALZHEIMERS DISEASE
M-254 INFORMATION ADDED TO THE LABELING REGARDING PEDIATRIC PATIENTS AGES 7 TO 17 YEARS OF AGE WITH MAJOR DEPRESSIVE DISORDER
M-255 INFORMATION ADDED TO THE LABELING TO DESCRIBE STUDY GS-US-320-4018 IN VIROLOGICALLY SUPPRESSED ADULTS W/ CHRONIC HEP B INFECTION WHO SWITCHED FROM TENOFOVIR DISOPROXIL FUMARATE TO TENOFOVIR ALAFENAMIDE
M-256 INFORMATION ADDED TO THE CLINICAL STUDIES SECTION TO FULFILL A POST-MARKETING REQUIREMENT
M-257 INFORMATION ADDED TO THE CLINICAL STUDIES SECTION OF THE LABELING REGARDING THE USE OF PLAQUE PSORIASIS OF THE SCALP
M-258 INFORMATION ADDED TO THE LABELING TO DESCRIBE CARMELINA TRIAL TO FULFILL POSTMARKETING COMMITMENT 1766-4
M-259 INFORMATION ADDED TO THE LABELING REGARDING SAFETY AND EFFICACY IN SUBJECTS WITH HCV SUBTYPE 3B INFECTION
M-260 INFORMATION ADDED TO THE LABELING DESCRIBING A RANDOMIZED, OPEN-LABEL STUDY THAT EXAMINED THE CONCOMITANT USE OF DIMETHYL FUMARATE AND SEVERAL NON-LIVE VACCINES IN ADULTS 27-55 YEARS OF AGE WITH RELAPSING FORMS OF MULTIPLE SCLEROSIS
M-261 ADDITIONAL INFORMATION ADDED TO THE LABELING REGARDING THE USE IN PATIENTS ON CHRONIC HEMODIALYSIS
M-262 REVISIONS TO THE USE IN SPECIFIC POPULATIONS SECTION OF THE PACKAGE INSERT TO INCLUDE THE RESULT OF STUDY P146 TO FULFILL THE REQUIREMENTS OF PMR 3003-4
M-263 REVISIONS TO THE LABELING TO INCLUDE RESULTS FROM CLINICAL STUDY ICL670E2419 (THETIS TRIAL) TO SUPPORT PMR 3342-2 AND 3342-3
M-264 INFORMATION ADDED TO THE LABELING DESCRIBING A PHASE 2, MULTICENTER, OPEN-LABEL STUDY TO EVALUATE THE SAFETY/EFFICACY OF SOFOSBUVIR/VELPATASVIR IN SUBJECTS WITH CHRONIC HCV INFECTION WHO HAVE RECEIVED A LIVER TRANSPLANT
M-265 REVISIONS TO THE LABELING TO INCLUDE RESULTS FROM CLINICAL STUDY M15-656 (VIALE-A) AND M16-043 (VIALE-C) TO SUPPORT PMR 3545-1 AND PMR 3545-2
M-266 INFORMATION ADDED TO THE LABELING TO DESCRIBE STUDY GS-US-320-4035 IN VIROLOGICALLY SUPPRESSED ADULTS W/ CHRONIC HEP B INFECTION WHO SWITCHED FROM TENOFOVIR DISOPROXIL FUMARATE TO TENOFOVIR ALAFENAMIDE
M-267 INFORMATION ADDED TO THE LABELING REGARDING THE RESULT OF STUDY LUAA21004-402
D-19 BOLUS DOSING GUIDELINES
D-20 SINGLE 32MG DOSE

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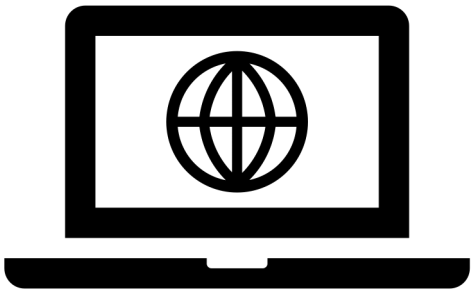
https://www.fda.gov/drugs/drug-approvals-and-databases/orange-book-data-files
https://www.accessdata.fda.gov/scripts/cder/ob/results_exclusivity.cfm



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

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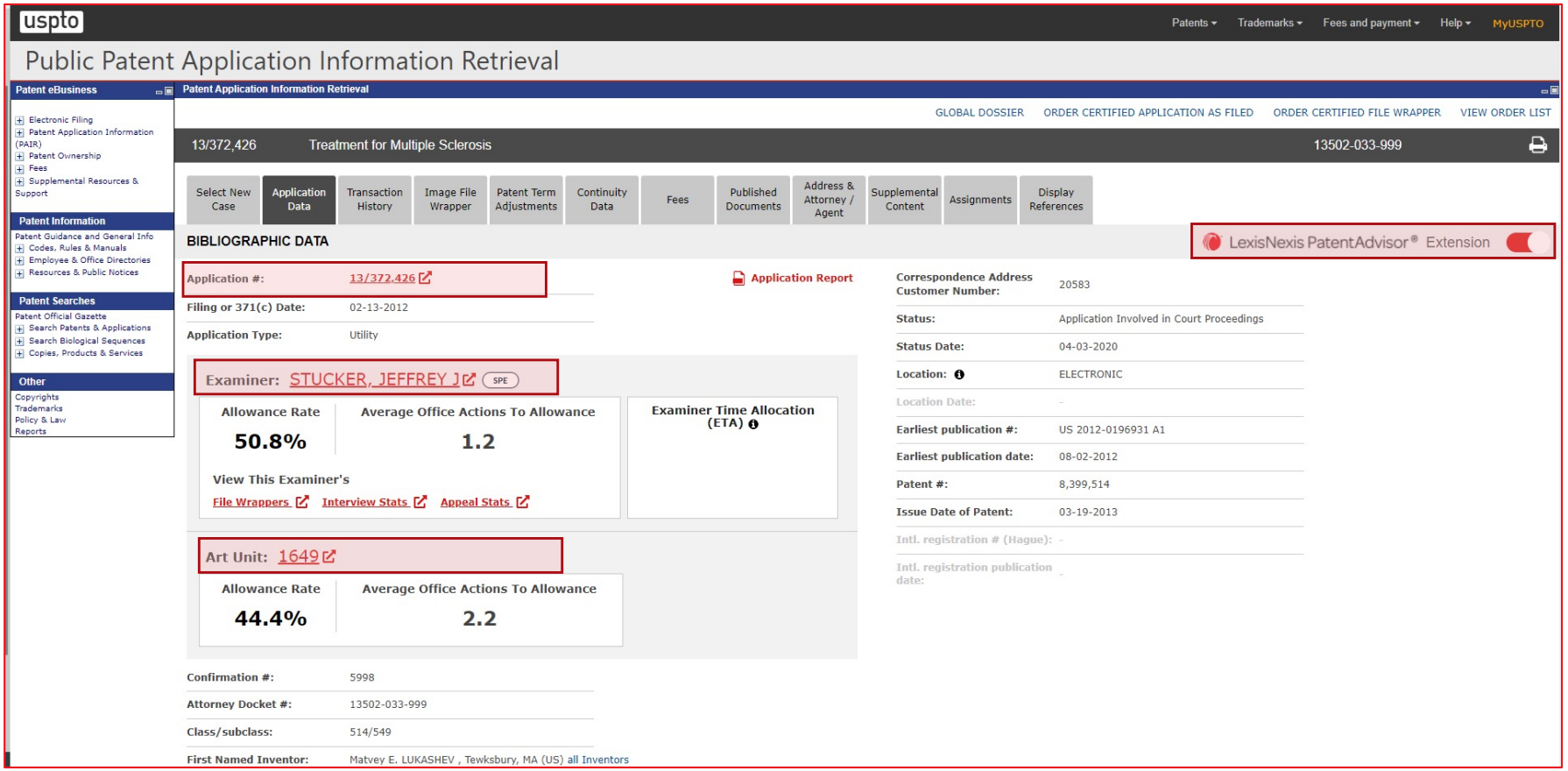
USPTO PAIR Information



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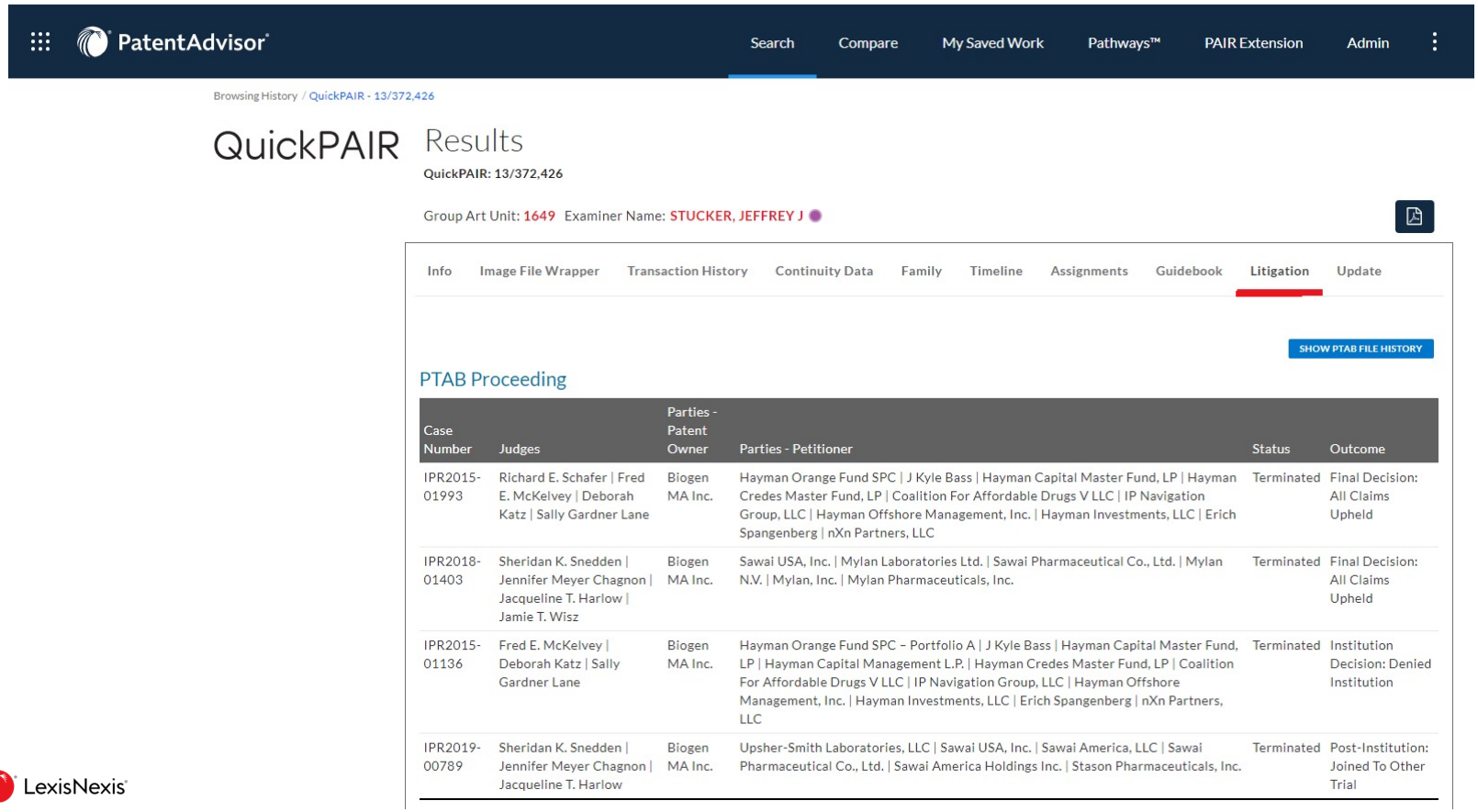
LexisNexis PatentAdvisor® : PTAB Proceedings Information



Case Number	Judges	Parties - Patent Owner	Parties - Petitioner	Status	Outcome
IPR2015-01993	Richard E. Schafer | Fred E. McKelvey | Deborah Katz | Sally Gardner Lane	Biogen MA Inc.	Hayman Orange Fund SPC | J Kyle Bass | Hayman Capital Master Fund, LP | Hayman Credes Master Fund, LP | Coalition For Affordable Drugs V LLC | IP Navigation Group, LLC | Hayman Offshore Management, Inc. | Hayman Investments, LLC | Erich Spangenberg | nXn Partners, LLC	Terminated	Final Decision: All Claims Upheld
IPR2018-01403	Sheridan K. Snedden | Jennifer Meyer Chagnon | Jacqueline T. Harlow | Jamie T. Wisz	Biogen MA Inc.	Sawai USA, Inc. | Mylan Laboratories Ltd. | Sawai Pharmaceutical Co., Ltd. | Mylan N.V. | Mylan, Inc. | Mylan Pharmaceuticals, Inc.	Terminated	Final Decision: All Claims Upheld
IPR2015-01136	Fred E. McKelvey | Deborah Katz | Sally Gardner Lane	Biogen MA Inc.	Hayman Orange Fund SPC – Portfolio A | J Kyle Bass | Hayman Capital Master Fund, LP | Hayman Capital Management L.P. | Hayman Credes Master Fund, LP | Coalition For Affordable Drugs V LLC | IP Navigation Group, LLC | Hayman Offshore Management, Inc. | Hayman Investments, LLC | Erich Spangenberg | nXn Partners, LLC	Terminated	Institution Decision: Denied Institution
IPR2019-00789	Sheridan K. Snedden | Jennifer Meyer Chagnon | Jacqueline T. Harlow	Biogen MA Inc.	Upsher-Smith Laboratories, LLC | Sawai USA, Inc. | Sawai America, LLC | Sawai Pharmaceutical Co., Ltd. | Sawai America Holdings Inc. | Stason Pharmaceuticals, Inc.	Terminated	Post-Institution: Joined To Other Trial

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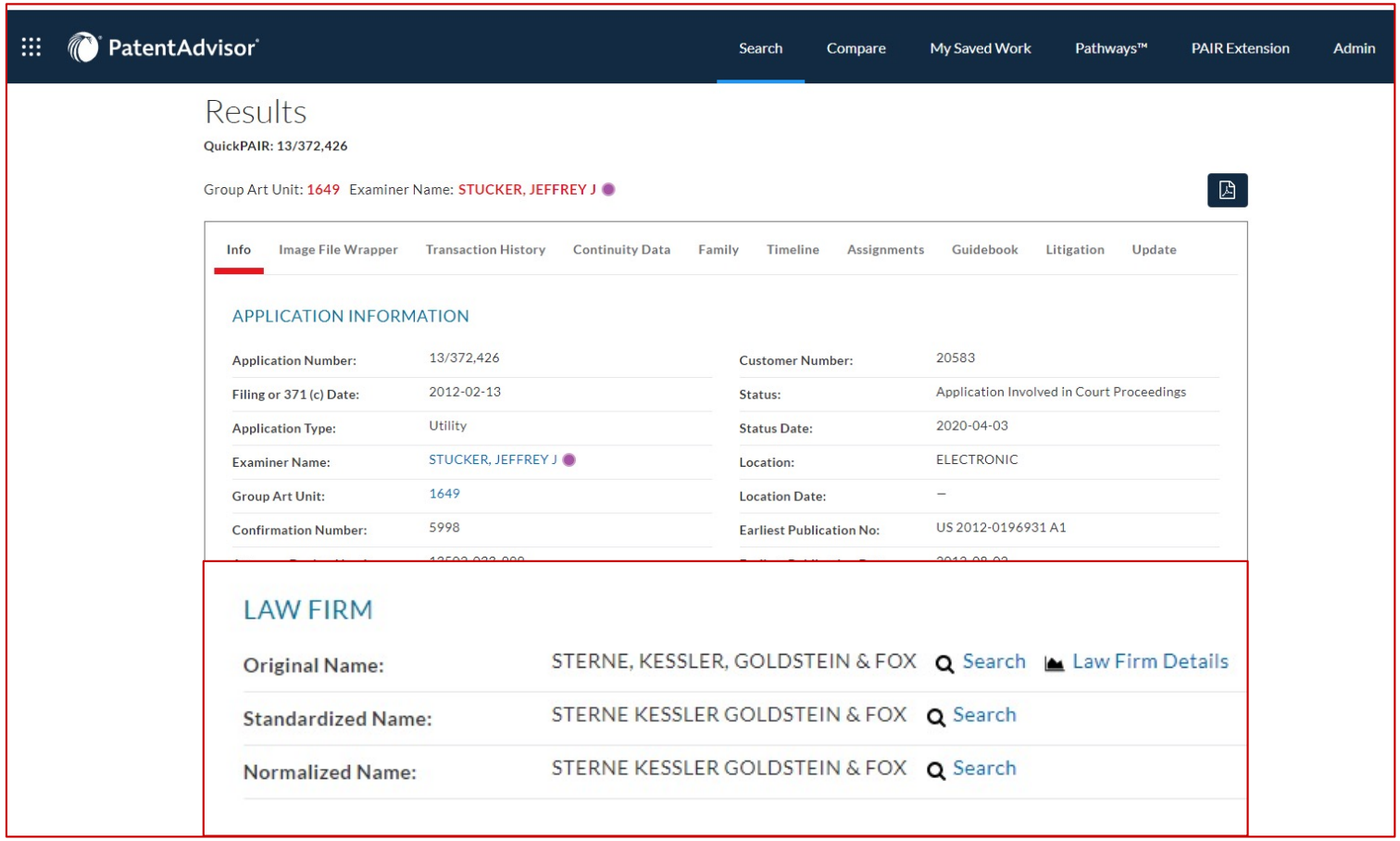
LexisNexis PatentAdvisor® : Law Firm Statistics



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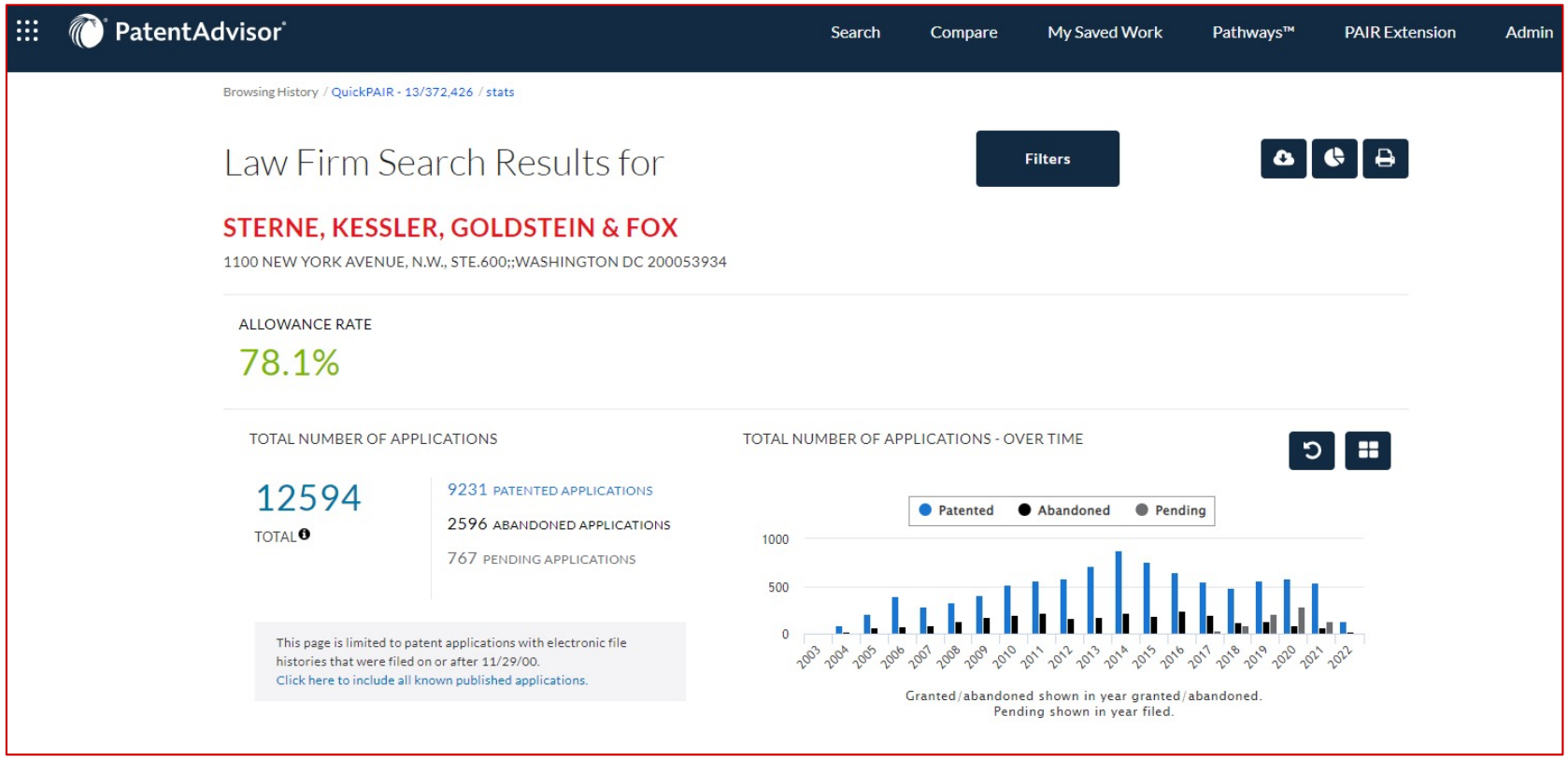
LexisNexis PatentAdvisor® : Law Firm Statistics



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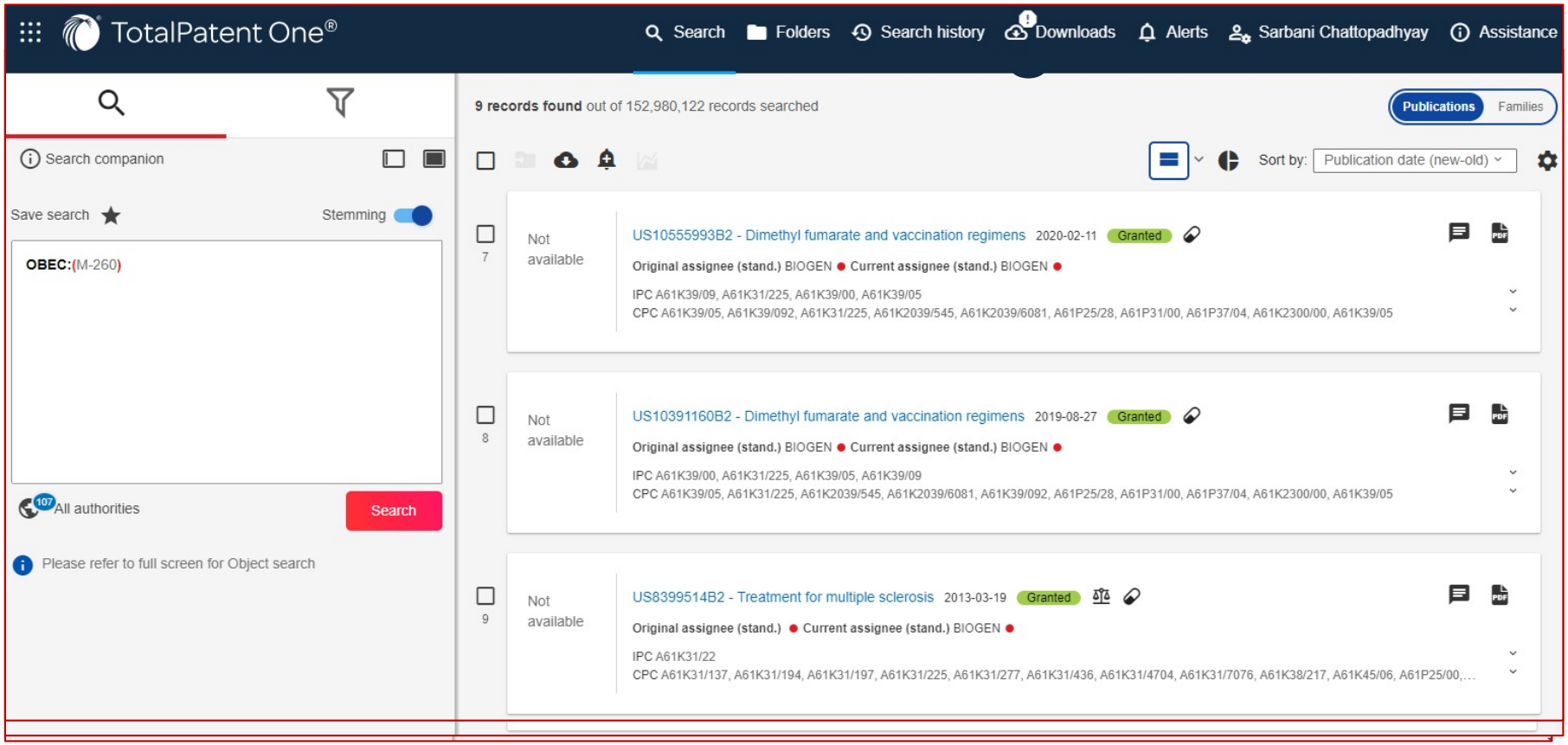
Patent search w.r.t. Exclusivity Codes



TecFidera: Blockbuster drug for Biogen for Relapsing MS

Unlikely Multiple Sclerosis Pill On Track To Become Blockbuster

October 28, 2013 · 3:21 PM ET

There aren't very many drugs that are also, essentially, industrial chemicals available in railroad-car volumes, pharmaceutical chemist Derek Lowe noted on his blog, In The Pipeline, this spring.

Only a few drugs could really be bought in bulk.

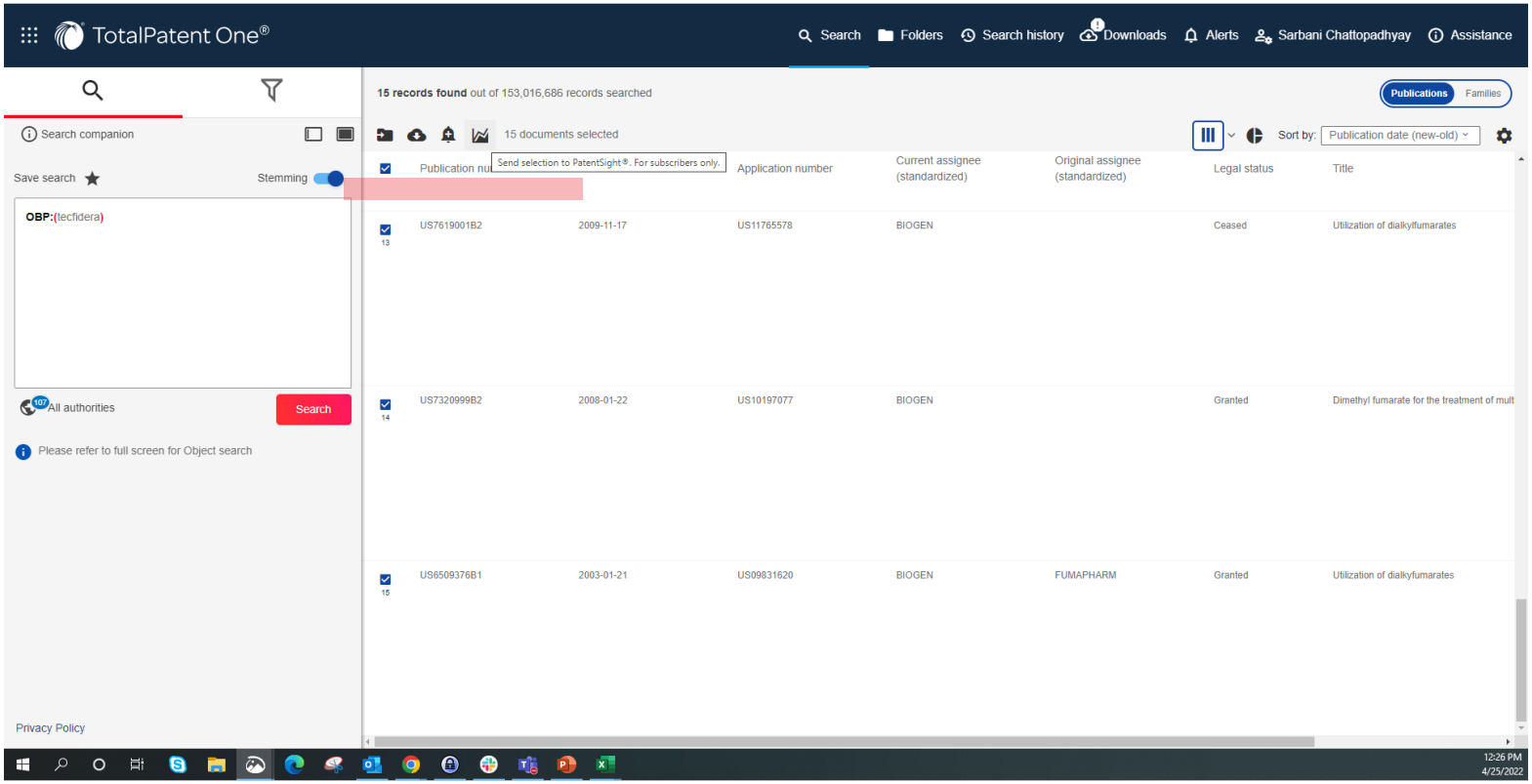
iStockphoto.com

But there are a few. One is lithium carbonate, a staple of glassmaking and ceramic glazes and also the active ingredient in drugs for depression. Another is nitrous oxide, or laughing gas, for anesthesia.

Then there's Tecfidera, or dimethyl fumarate, which was approved by the Food and Drug Administration in March to treat multiple sclerosis. The twice-a-day pill from Biogen Idec was derived from an old, basic chemical: fumaric acid, used industrially to make foods taste sour and to preserve them.

https://www.npr.org/sections/health-shots/2013/10/28/241365414/unlikely-multiple-sclerosis-pill-on-track-to-become-blockbuster?t=1650841331917

Patent search w.r.t. Exclusivity Codes



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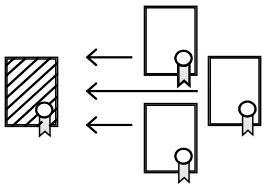
LexisNexis PatentSight Methodology

- The scientifically validated and patented methodology is based on “Simple Patent Family” definition.
- All patent documents with the exactly same priority parameters are grouped into 1 patent family: Hypothesis: The Simple patent family technically covers one single invention.

Technology Relevance

Worldwide citations received from later patents, adjusted for age, patent office practices and technology field

Average value: 1



Market Coverage

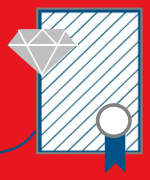
Market size protected by active patents and pending patent applications on a certain invention

Value of granted US patent: 1

X

Competitive Impact

(Individual patent strength)
The relative business value of a patent family



Individual Patent Family

∑

Patent Asset Index™

Innovative strength of a company or portfolio (ability to achieve competitive advantage)!

The **Current Ultimate Owner** is the basis for actuating right to ownership of the patent.

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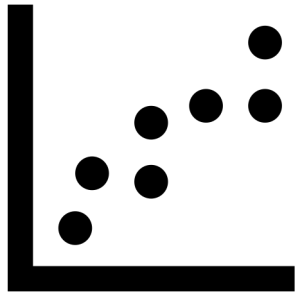
Holger Ernst & Nils Omland (2011): The Patent Asset Index - A New Approach to Benchmark Patent Portfolios. World Patent Information 33(1), 34–41.



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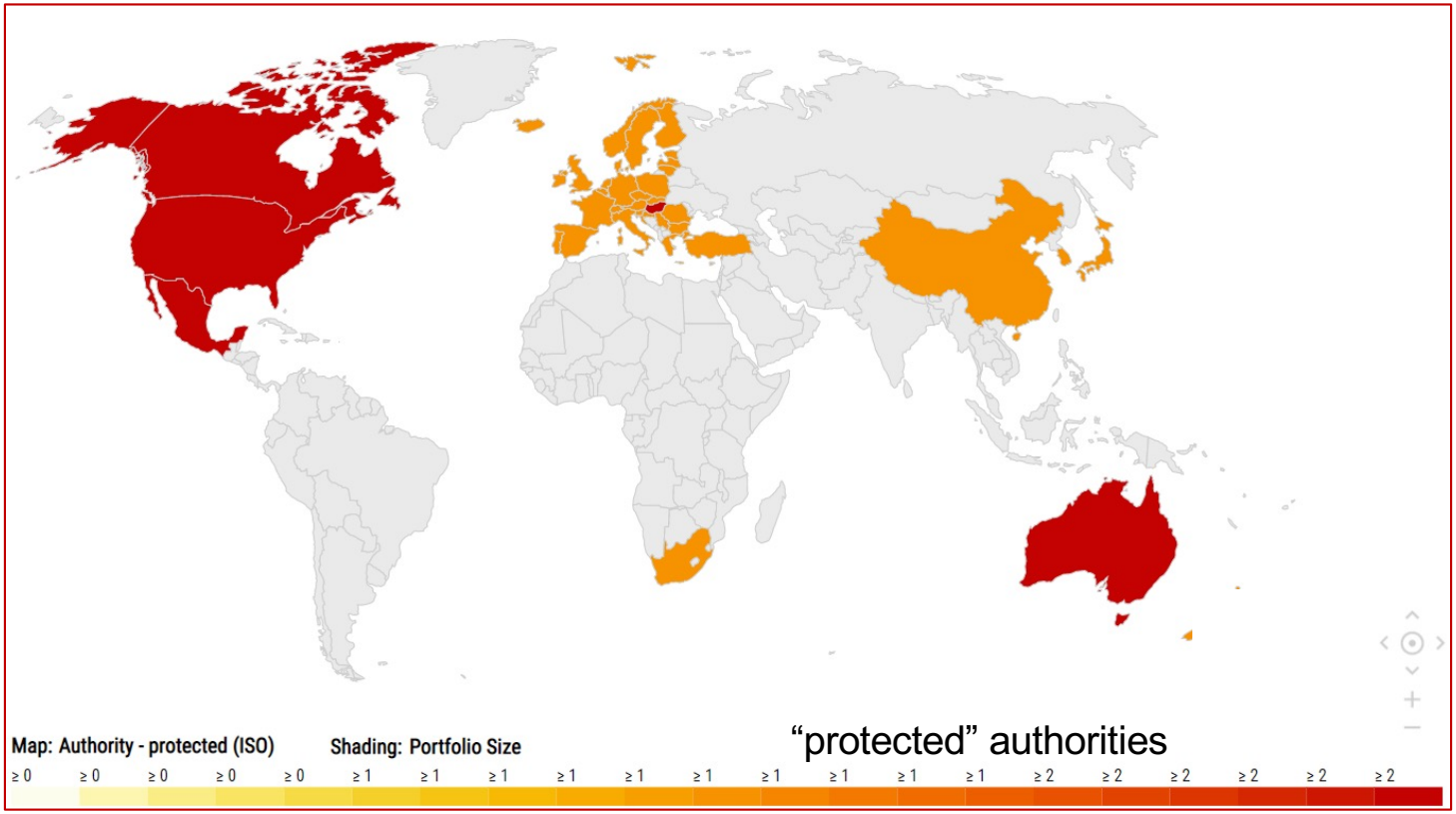
Biogen‘s protection strategy for patents related to (active product): Tecfidera



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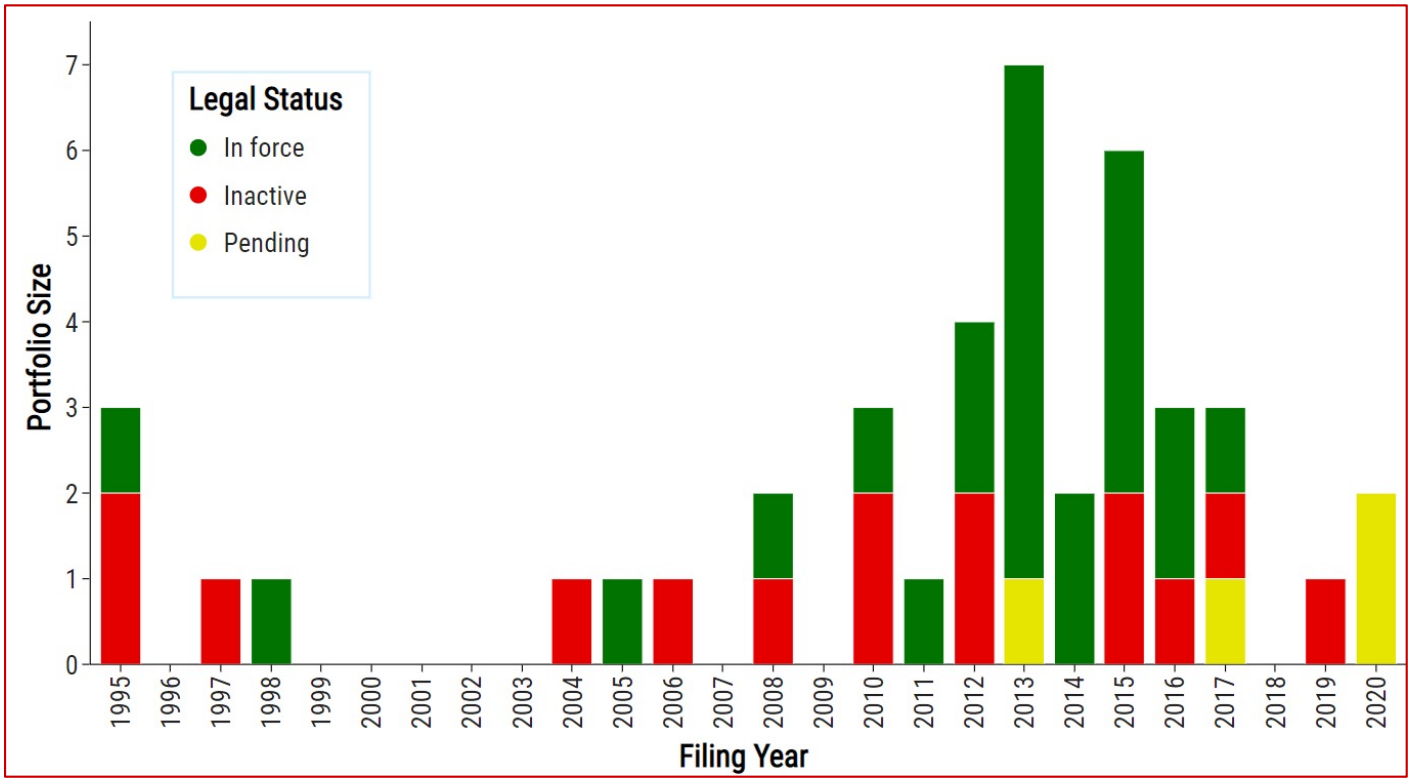
Biogen‘s patents around Tecfidera over the years



“protected” authorities

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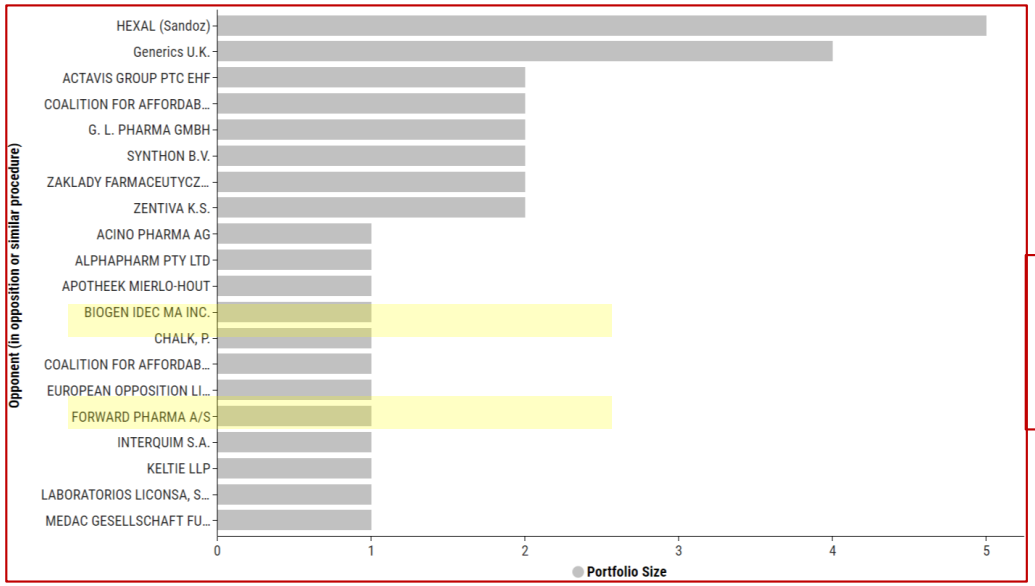
Biogen‘s patents around Tecfidera over the years



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The **Current Ultimate Owner** is the basis for actuating right to ownership of the patent.

- Generic companies like Generics U.K., Organisations like Coalition for Affordable drugs had opposed the Biogen Tecfidera patents.
- Interestingly Biogen Idec is shown as Opponent here.

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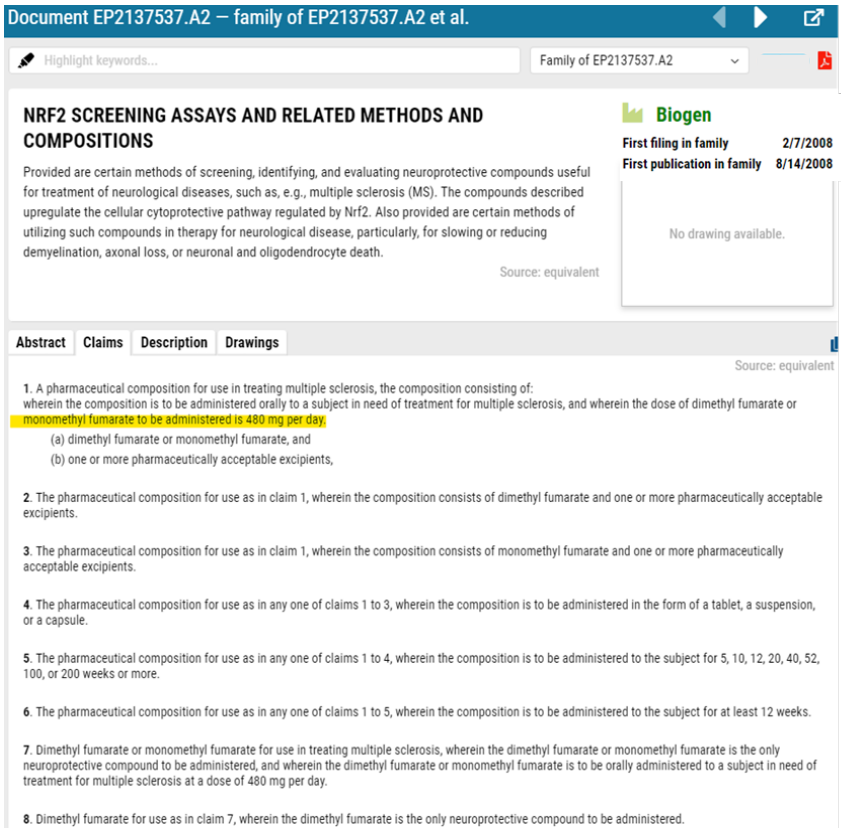
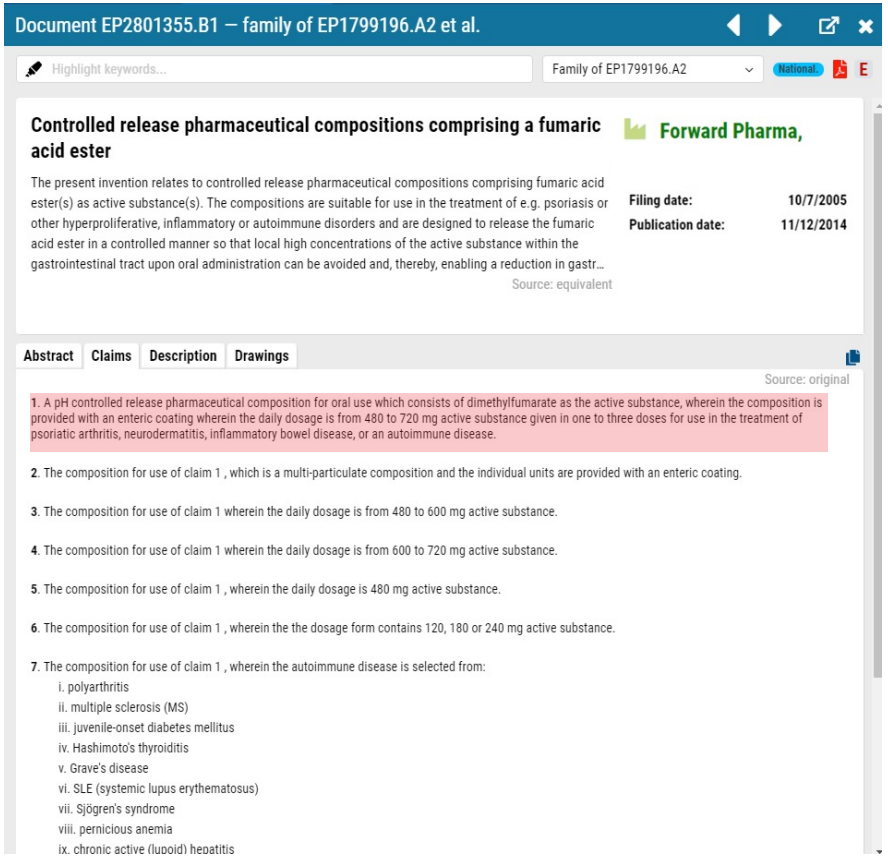
Biogen vs Forward Pharma regarding Tecfidera patents





Biogen vs Forward Pharma regarding Tecfidera patents

MarketWatch • Latest Coronavirus Watchlist Markets Investing Barron's Personal Finance Economy Retir

Biogen's $1.25 billion agreement with Forward Pharma is a very expensive insurance policy on its most valuable drug

Published: Jan. 17, 2017 at 10:46 a.m. ET

By Emma Court

The agreement does not resolve a patent dispute between the two companies

Biogen can now use Forward Pharma's patents to extend the drug's legal protections, Evercore ISI's

Losing a patent dispute could require a company to take its product off the market and pay hefty sums. Decisions for the U.S. and European patent cases are expected this quarter, with a U.S. decision in late March.

Biogen vs Forward Pharma regarding Tecfidera patents

Biogen

OVERVIEW NEWS

BIOGEN AND FORWARD PHARMA AGREE TO ENTER INTO SETTLEMENT AND LICENSE AGREEMENT

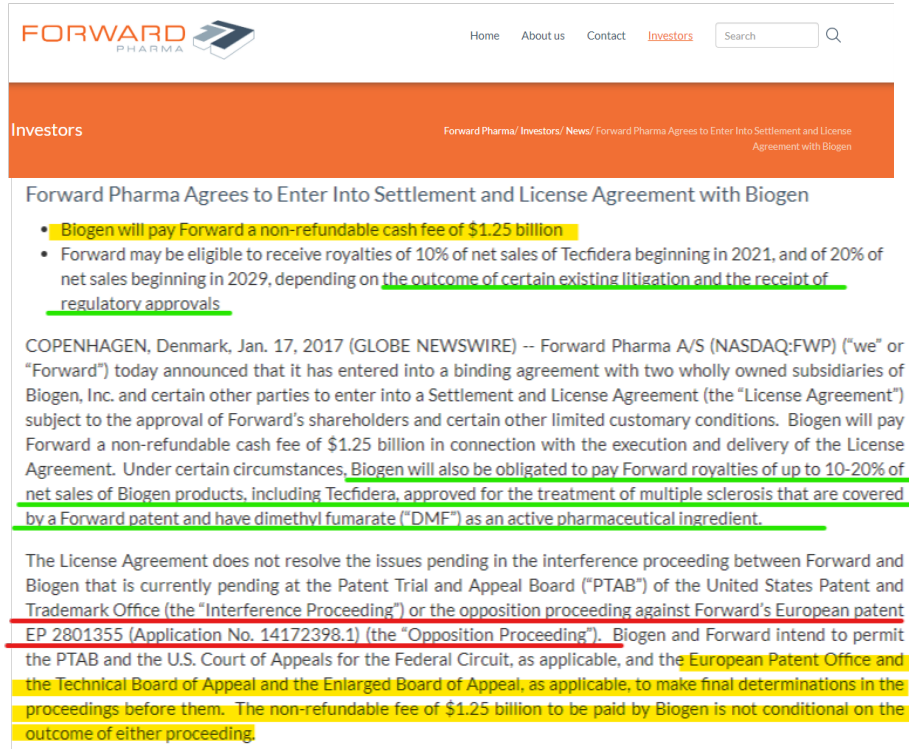
January 17, 2017 at 7:30 AM EST

Biogen to Pay $1.25B in Exchange for License Agreement to Forward Pharma Intellectual Property

Future Payment of Royalties Subject to Resolution of Ongoing Patent Procedures in US and EU

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Biogen Inc. (NASDAQ: BIIB) today announced that it has agreed to enter into a settlement and license agreement with Forward Pharma, subject to the approval of Forward Pharma's shareholders and other customary conditions. The license agreement will provide Biogen an irrevocable license to all intellectual property owned by Forward Pharma.

Upon the effectiveness of the settlement and license agreement, Biogen will provide Forward Pharma a cash payment of $1.25 billion. Under certain circumstances outlined in the agreement, Biogen will pay Forward Pharma royalties on net sales of Biogen products for the treatment of multiple sclerosis that are covered by a Forward Pharma patent and have dimethyl fumarate ("DMF") as an active pharmaceutical ingredient.



FORWARD PHARMA

Home About us Contact Investors Search

Investors

Forward Pharma/ Investors/ News/ Forward Pharma Agrees to Enter Into Settlement and License Agreement with Biogen

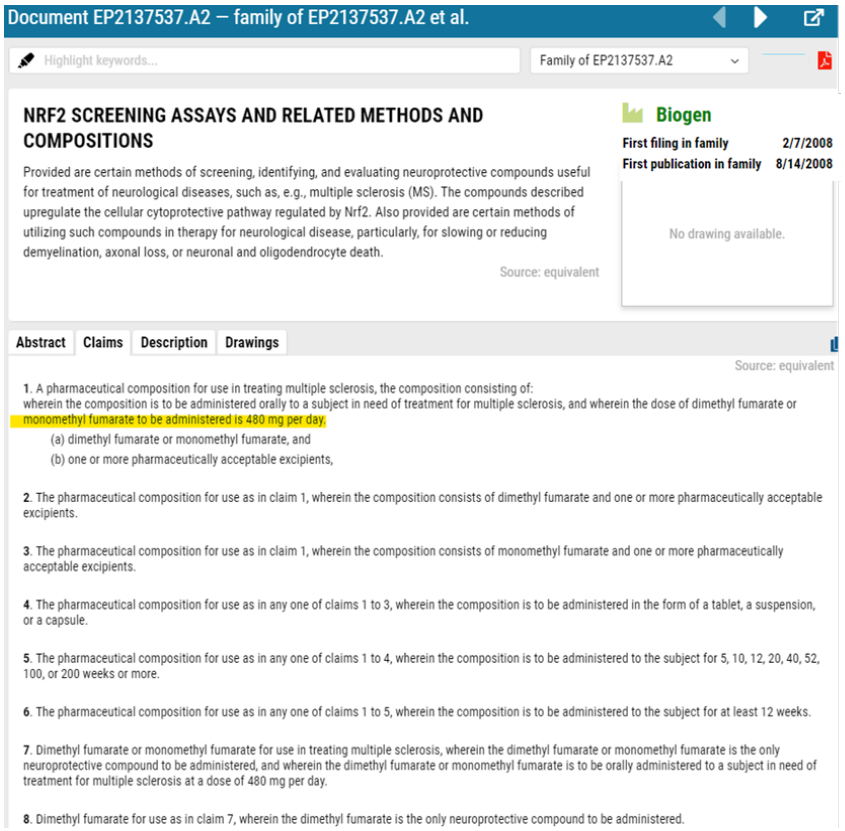
Forward Pharma Agrees to Enter Into Settlement and License Agreement with Biogen

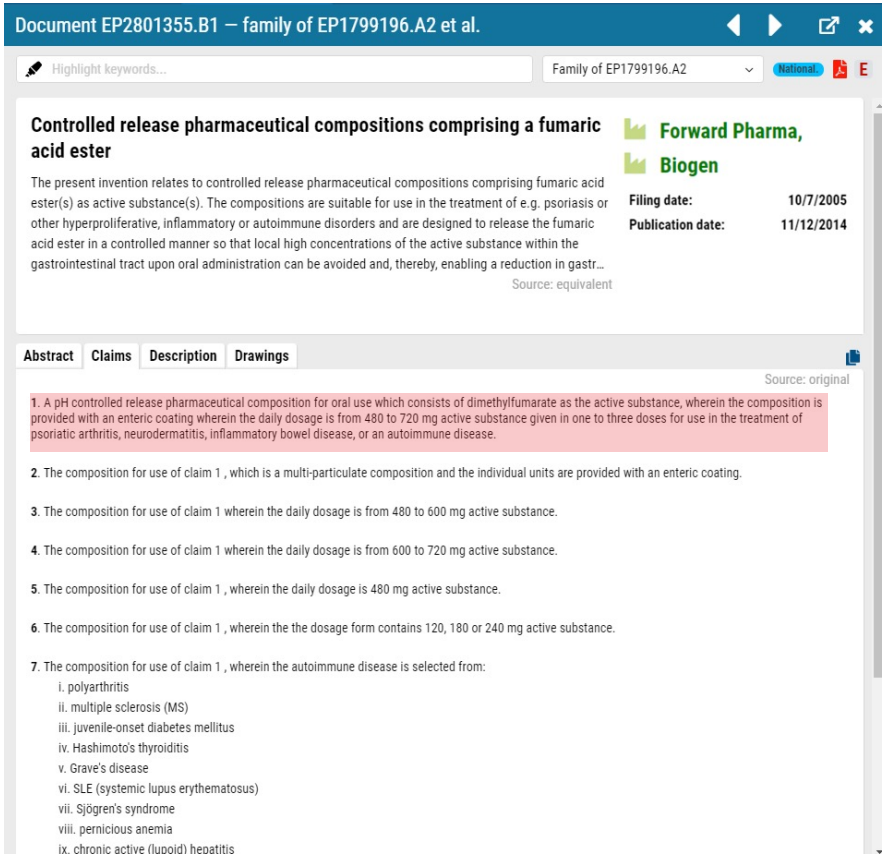
- Biogen will pay Forward a non-refundable cash fee of $1.25 billion
- Forward may be eligible to receive royalties of 10% of net sales of Tecfidera beginning in 2021, and of 20% of net sales beginning in 2029, depending on the outcome of certain existing litigation and the receipt of regulatory approvals

COPENHAGEN, Denmark, Jan. 17, 2017 (GLOBE NEWSWIRE) -- Forward Pharma A/S (NASDAQ:FWP) ("we" or "Forward") today announced that it has entered into a binding agreement with two wholly owned subsidiaries of Biogen, Inc. and certain other parties to enter into a Settlement and License Agreement (the "License Agreement") subject to the approval of Forward's shareholders and certain other limited customary conditions. Biogen will pay Forward a non-refundable cash fee of $1.25 billion in connection with the execution and delivery of the License Agreement. Under certain circumstances, Biogen will also be obligated to pay Forward royalties of up to 10-20% of net sales of Biogen products, including Tecfidera, approved for the treatment of multiple sclerosis that are covered by a Forward patent and have dimethyl fumarate ("DMF") as an active pharmaceutical ingredient.

The License Agreement does not resolve the issues pending in the interference proceeding between Forward and Biogen that is currently pending at the Patent Trial and Appeal Board ("PTAB") of the United States Patent and Trademark Office (the "Interference Proceeding") or the opposition proceeding against Forward's European patent EP 2801355 (Application No. 14172398.1) (the "Opposition Proceeding"). Biogen and Forward intend to permit the PTAB and the U.S. Court of Appeals for the Federal Circuit, as applicable, and the European Patent Office and the Technical Board of Appeal and the Enlarged Board of Appeal, as applicable, to make final determinations in the proceedings before them. The non-refundable fee of $1.25 billion to be paid by Biogen is not conditional on the outcome of either proceeding.

Biogen vs Forward Pharma regarding Tecfidera patents





Biogen vs Forward Pharma regarding Tecfidera patents

Forward Pharma loses European patent case

The European Patent Office has revoked a patent that could have ensured Danish Forward Pharma royalties of US Biogen's multi-blockbuster Tecfidera. Forward Pharma's share price declines by almost 30 percent.

REUTERS

World Business Markets Breakingviews Video More

BRIEF-Forward Pharma Says European Patent Office Has Revoked EP2801355 Patent

1 MIN READ

By Reuters Staff

Jan 29 (Reuters) - Forward Pharma A/S:

* FORWARD PHARMA ANNOUNCES THE DECISION OF THE EUROPEAN PATENT OFFICE IN THE OPPOSITION PROCEEDINGS FOR THE EP2801355 PATENT

* SAYS EUROPEAN PATENT OFFICE HAS REVOKED EP2801355 PATENT FOLLOWING ORAL HEARING IN OPPOSITION PROCEEDINGS Source text for Eikon: Further company coverage:

Forward v. Biogen: Biogen Prevails in MS Drug Patent Appeal in Federal Circuit

Oct 24 (Reuters) - A U.S. appeals court on Wednesday upheld a ruling that patents owned by Biogen Inc covering its blockbuster multiple sclerosis drug Tecfidera are valid, rejecting a challenge by Danish drugmaker Forward Pharma A/S.

The U.S. Court of Appeals for the Federal Circuit said it agreed with a March 2017 ruling by the Patent Trial and Appeal Board that freed Bigoen Inc from future royalty payments to Forward.

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https://www.reuters.com/article/brief-forward-pharma-says-european-paten/brief-forward-pharma-says-european-patent-office-has-revoked-ep2801355-patent-idUKFWN1PO11G

Small Emerging Players targeting Multiple Sclerosis

Underlying hypothesis to identify pathbreaking inventions

- The patents will be cited as relevant prior art for subsequent patent applications in the same field.
- Small players may not be able to protect as extensively across the globe as established big players.
- Small players (start ups) will have a more focused portfolio concentrating on specific technology topic .

LexisNexis PatentSight

- The forward citation-based indicator can provide insights.
- Exclude effect of market coverage.
- "Share in total portfolio size of owner" in Multiple sclerosis related patents can be useful. .

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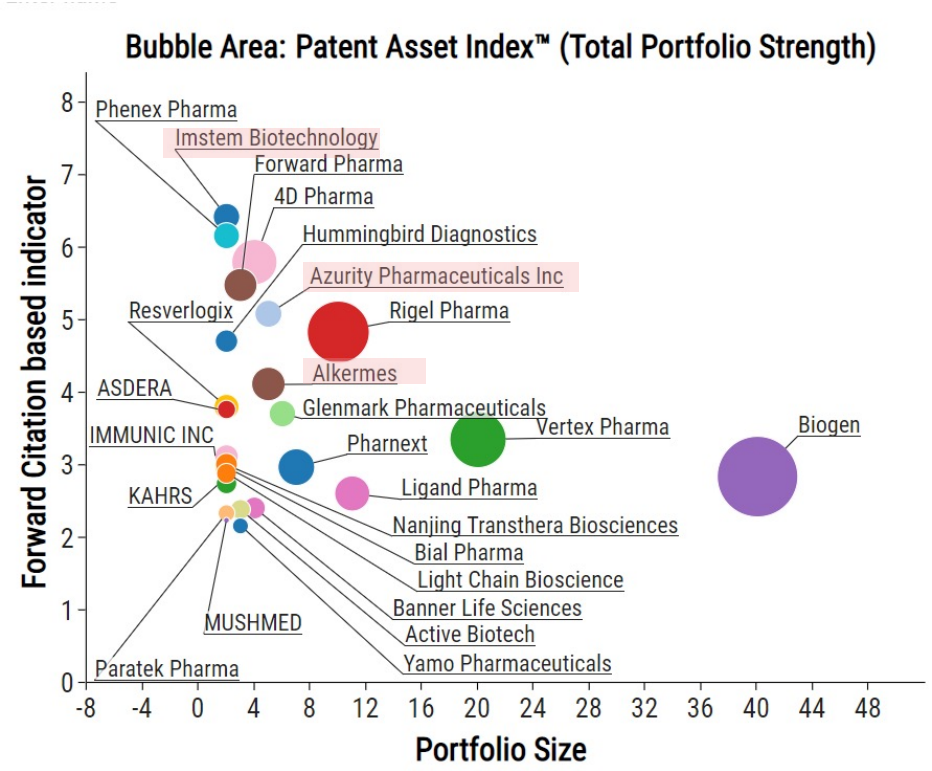
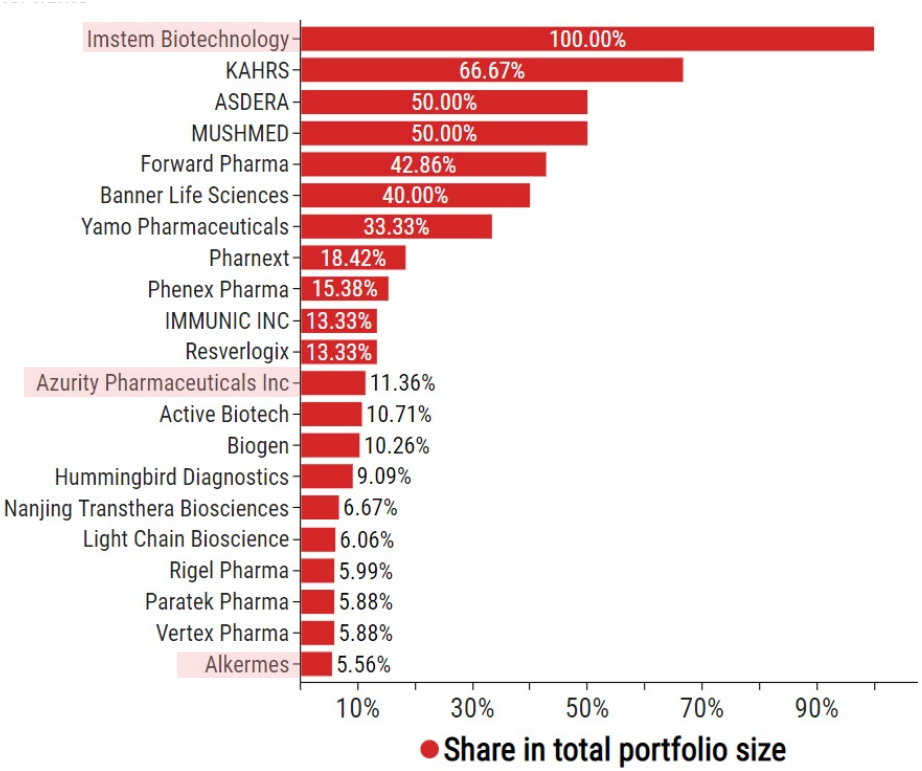
Small Emerging Players targeting Multiple Sclerosis





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News

ImStem Announces First US Multiple Sclerosis Patient Has Been Dosed with its IMS001

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NEWS PROVIDED BY
ImStem Biotechnology, Inc. →
Nov 18, 2021, 08:37 ET

FARMINGTON, Conn., Nov. 18, 2021 /PRNewswire/ -- ImStem Biotechnology, Inc. (Farmington CT), a biopha
company pioneering the development of human embryonic stem cell (ESC) derived mesenchymal stem
through a proprietary method using a trophoblast intermediate stage (termed T-MSC), today announc
the first US multiple sclerosis patient with its lead investigational drug candidate IMS001 at the Shep
Atlanta, GA. IMS001 is an investigational, allogeneic cell product to be administered intravenously to
from MS. We believe this is the first hES-MSC based allogeneic cell therapy accepted for clinical tria
patients with MS. The company plans to continue enrollment in a dose-escalating, open-label stu
safety, tolerability, and exploratory efficacy of single dose of IV IMS001 in subjects with relapsing-
primary progressive MS with treatment failure to prior disease modifying treatments (DMTs).

PHARMA

Azurity bags FDA nod for grape-flavored multiple sclerosis drug

By Nick Paul Taylor • Feb 8, 2022 03:35pm

Biogen and Alkermes Announce FDA Approval of VUMERITY™ (diroximel fumarate) for Multiple Sclerosis

OCTOBER 30, 2019 • NEURODEGENERATIVE DISEASES

– VUMERITY, a New Oral Treatment Option for Relapsing Forms of MS, Offers a Combination of Well-Characterized Efficacy, Safety and Tolerability –

CAMBRIDGE, Mass. and DUBLIN, Ireland, Oct. 30, 2019 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) and Alkermes plc (Nasdaq: ALKS) today announced that the U.S. Food and Drug Administration (FDA) approved VUMERITY™ (diroximel fumarate), a novel oral fumarate with a distinct chemical structure, for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease. Biogen holds the exclusive, worldwide license to commercialize VUMERITY and intends to make it available in the United States in the near future.

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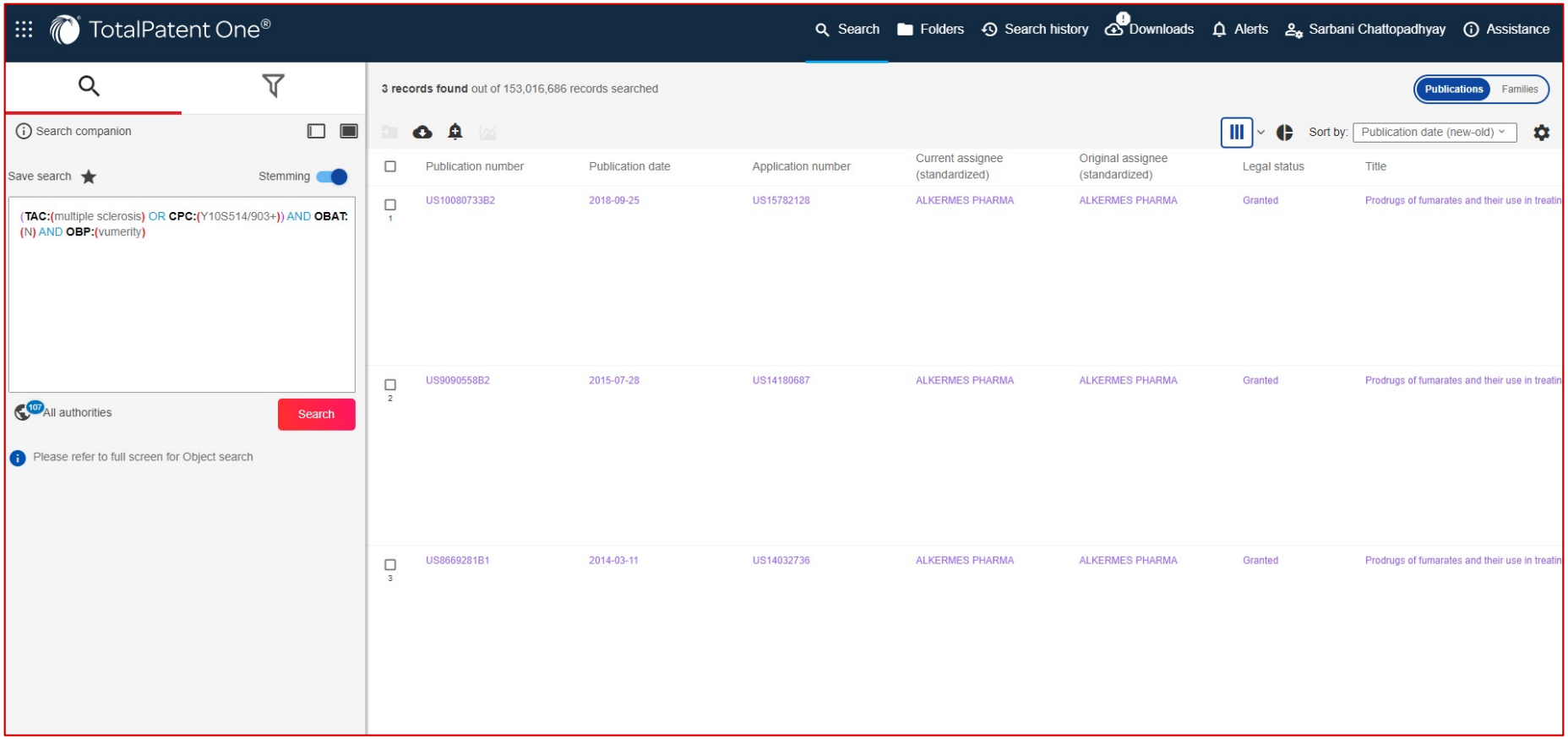
https://www.prnewswire.com/news-releases/imstem-announces-first-us-multiple-sclerosis-patient-has-been-dosed-with-its-ims001-301426858.html

“Vumerity” information in TotalPatentOne



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Multiple Sclerosis and Suicide rate

Suicide in Patients with Multiple Sclerosis: Guidance on Red Flags and Prevention

Comorbid depression is only one of the likely warning signs

SHARE

"Living with multiple sclerosis [MS] can feel like being stuck in quicksand for some patients," notes Cleveland Clinic neurologist Mary Alissa Willis, MD. "They fight a constant battle not to lose ground in the management of some of their symptoms. Suicide can seem like the last bit of control a patient has over his or her body."

https://consultqd.clevelandclinic.org/suicide-in-patients-with-multiple-sclerosis-guidance-on-red-flags-and-prevention/

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Depression, Suicidal Thoughts Prevalent in MS

— Burden equally high in relapsing-remitting and progressive multiple sclerosis

by Judy George, Senior Staff Writer, MedPage Today September 13, 2020

Last Updated September 30, 2020

ADVERTISEMENT

Depression was common in people with multiple sclerosis (MS) and was equally prevalent in patients with relapsing-remitting and progressive forms of the disease, a cross-sectional study showed.

No evidence of group differences between people with progressive MS and relapsing-remitting MS emerged in either depressive symptom severity or suicidal ideation, contrary to the study's hypothesis, reported Lindsey Knowles, PhD, of the University of Washington and the VA Puget Sound Healthcare System in Seattle, at MS Virtual 2020, the joint ACTRIMS-ECTRIMS meeting.

Sustainability & Sustainable Future

Definition

In 1987, the United Nations Brundtland Commission defined sustainability as "**meeting the needs of the present without compromising the ability of future generations to meet their own needs**."

www.un.org/en/academic-impact/sustainability

The United Nations Sustainable Development Goals (SDGs) are targets for global development adopted in September 2015, set to be achieved by 2030. Implementation and success will rely **on countries' own sustainable development policies, plans and programs, and will be led by countries.** The **Sustainable Development Goals (SDGs)** will be a compass for aligning countries' plans with their global commitments.

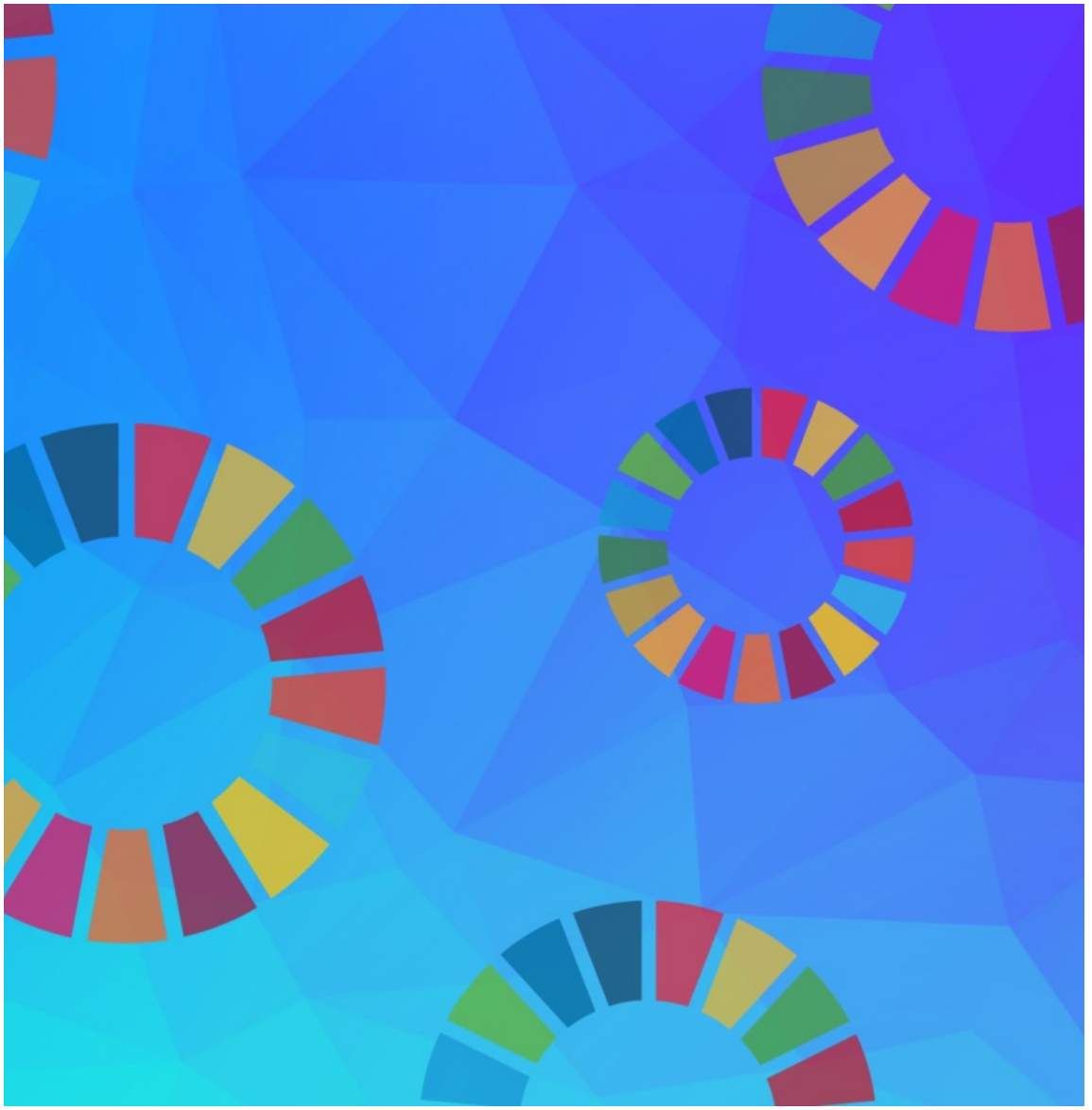
The Sustainable Development Goals (SDGs), also known as the Global Goals, were adopted by the United Nations in 2015 as a universal call to action to **end poverty, protect the planet,** and ensure that by 2030 **all people enjoy peace and prosperity**.

LexisNexis again pioneering to support the United Nations Sustainable Development Goals

RELX is a dedicated signatory of the UN Global Compact which uses the SDGs to chart business participation in achieving these aims.

LexisNexis® RULE OF LAW FOUNDATION

As an active contributor at the United Nations Rule of Law Steering Committee, LexisNexis helped set the UN SDGs in motion.



LexisNexis PatentSight mapped global patents against the United Nations SDGs

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United Nations Sustainable Development Goal 3: Good Health and Well-being

UN SDG 3

https://unstats.un.org/sdgs/metadata/files/Metadata-03-04-02.pdf Last updated: May 2021

SDG indicator metadata

(Harmonized metadata template - format version 1.0)

0. Indicator information

0.a. Goal

Goal 3: Ensure healthy lives and promote well-being for all at all ages

0.b. Target

Target 3.4: By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being

0.c. Indicator

Indicator 3.4.2: Suicide mortality rate

0.d. Series

0.e. Metadata update

May 2021

0.f. Related indicators

NA

4. Other methodological considerations

4.a. Rationale

Mental disorders occur in all regions and cultures of the world. The most prevalent of these disorders are depression and anxiety, which are estimated to affect nearly 1 in 10 people. At its worst, depression can lead to suicide. In 2019, there were over 700,000 estimated suicide deaths worldwide.

Patent Mapping to Targets and Indicators of UN SDG 3 in LexisNexis® PatentSight®

Search Topics	UN SDG Targets	UN SDG Indicators
Cancer Cardiovascular Diseases Chronic Respiratory Diseases Diabetes	3.4 By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being.	3.4.1 Mortality rate attributed to cardiovascular disease, cancer, diabetes or chronic respiratory disease.
Mental Health		3.4.2 Suicide mortality rate.
New Surgical and Diagnostic Methods for Non-communicable Diseases		

ıture
ases
note

4.2

cardiovascular disease, cancer,
/ disease.

Multiple Sclerosis patents map to UN SDGs

Entities investing in innovating and patenting in Multiple Sclerosis contribute to a more Sustainable future.

Patent Analytics in Crisis Response: Covid-19 treatment (not vaccine)

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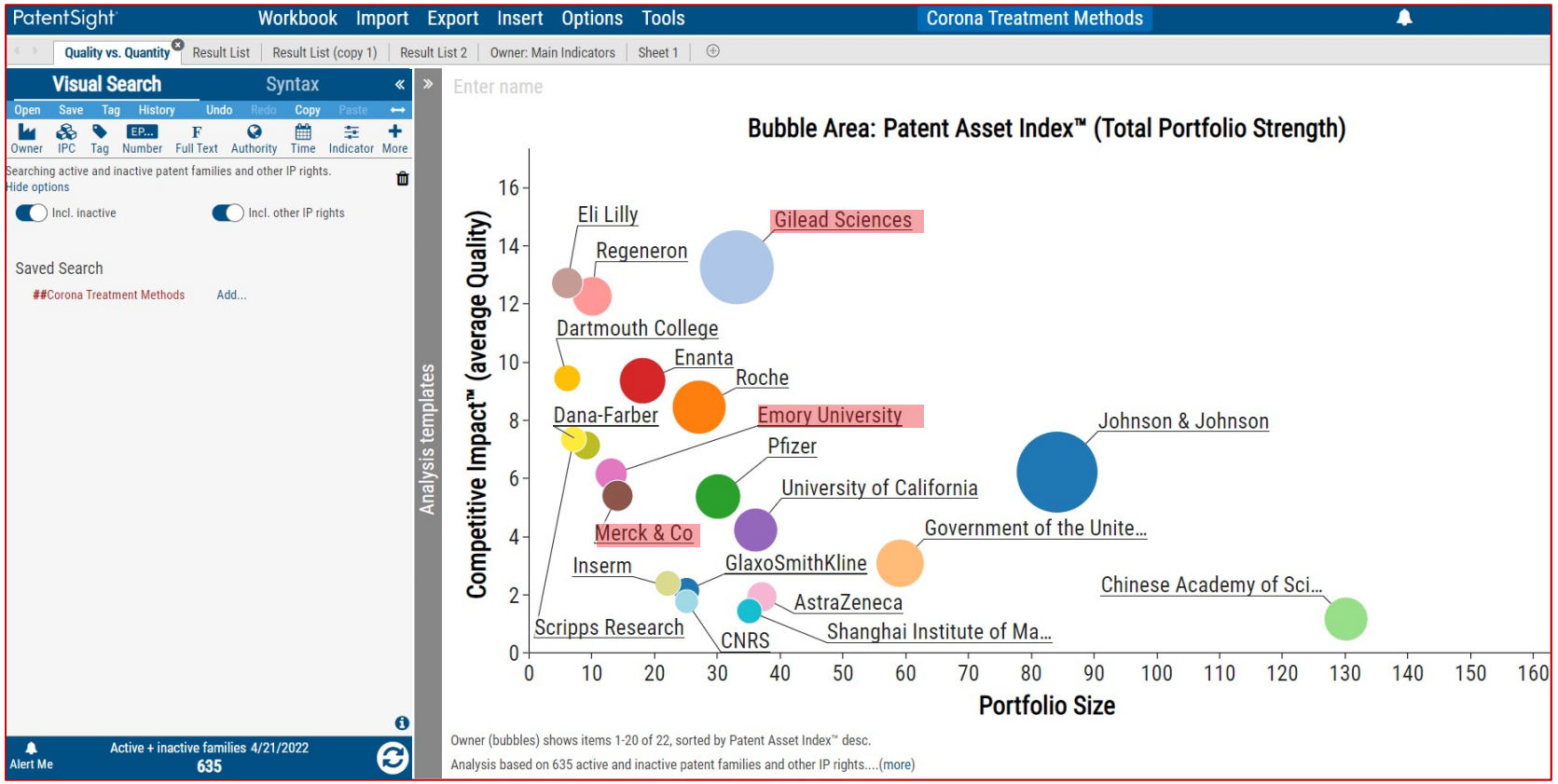
LexisNexis PatentSight: Quality vs. Quantity



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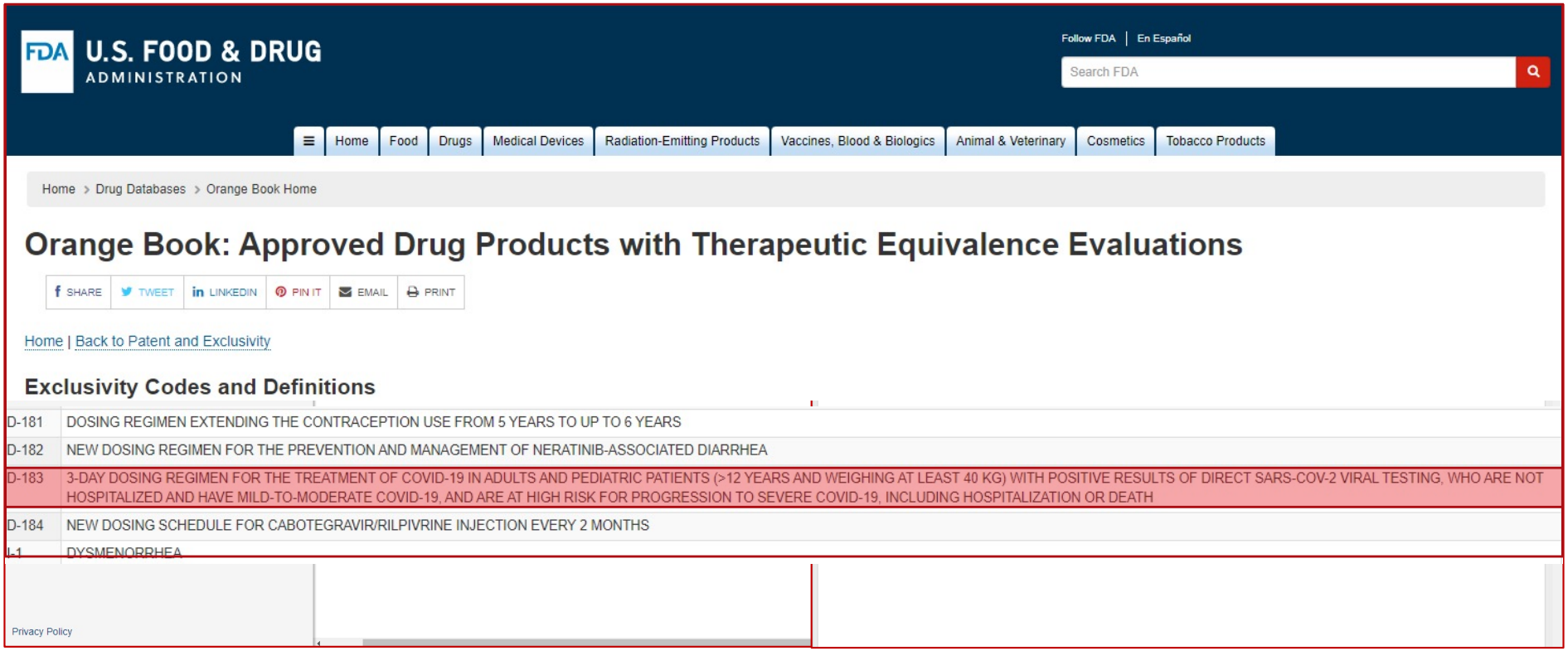
Gilead Sciences in Corona treatment



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Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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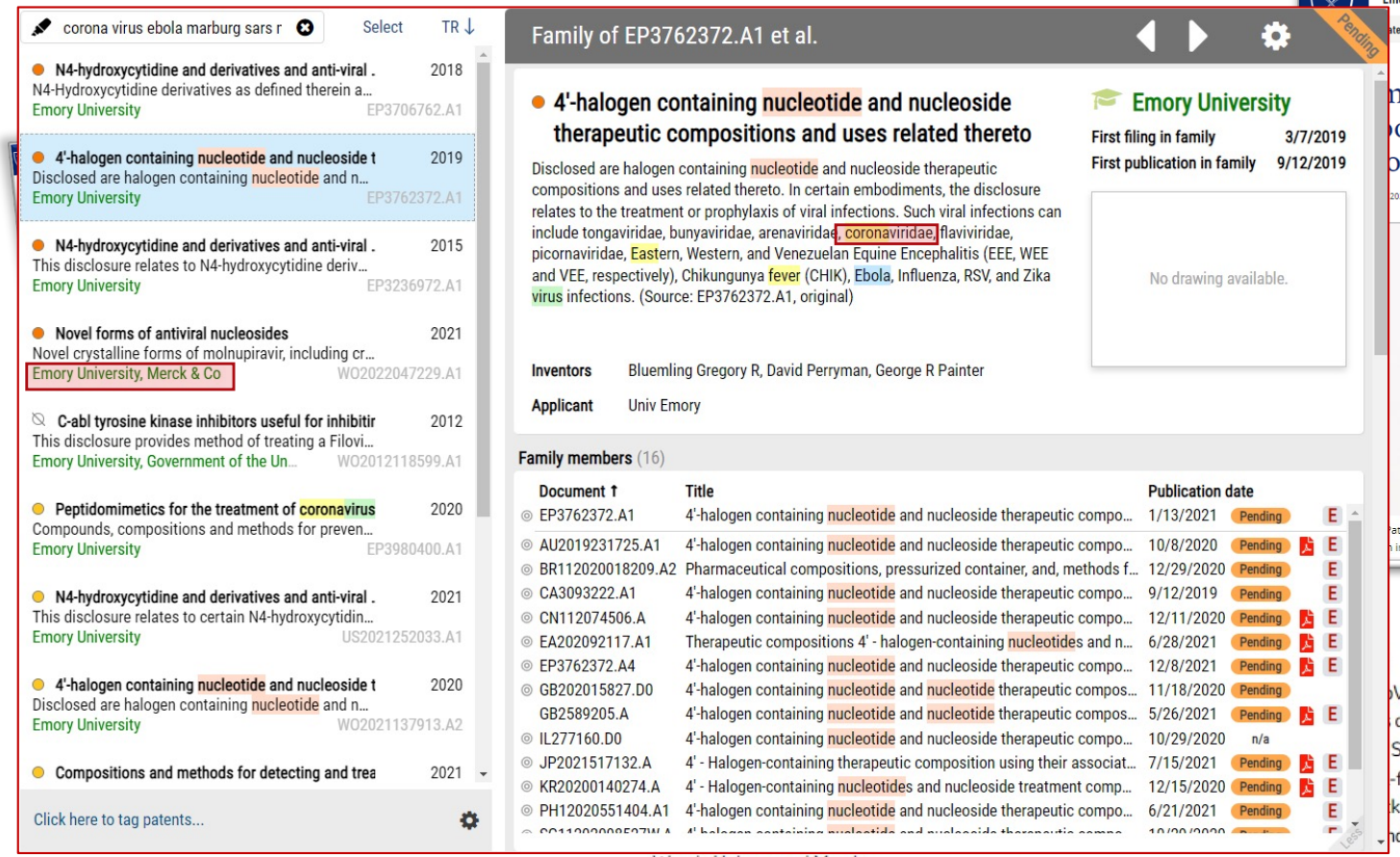
Exclusivity Codes and Definitions

D-181	DOSING REGIMEN EXTENDING THE CONTRACEPTION USE FROM 5 YEARS TO UP TO 6 YEARS
D-182	NEW DOSING REGIMEN FOR THE PREVENTION AND MANAGEMENT OF NERATINIB-ASSOCIATED DIARRHEA
D-183	3-DAY DOSING REGIMEN FOR THE TREATMENT OF COVID-19 IN ADULTS AND PEDIATRIC PATIENTS (>12 YEARS AND WEIGHING AT LEAST 40 KG) WITH POSITIVE RESULTS OF DIRECT SARS-COV-2 VIRAL TESTING, WHO ARE NOT HOSPITALIZED AND HAVE MILD-TO-MODERATE COVID-19, AND ARE AT HIGH RISK FOR PROGRESSION TO SEVERE COVID-19, INCLUDING HOSPITALIZATION OR DEATH
D-184	NEW DOSING SCHEDULE FOR CABOTEGRAVIR/RILPIVRINE INJECTION EVERY 2 MONTHS
I-1	DYSMENORRHEA

Privacy Policy

Emory University & Merck in Corona treatment



Wendy Holman and Merck.

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Thank You!

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Links

- https://www.nhs.uk/conditions/multiple-sclerosis/
- https://www.fda.gov/drugs/drug-approvals-and-databases/orange-book-data-files
- https://www.accessdata.fda.gov/scripts/cder/ob/results_exclusivity.cfm
- https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#exclusivityexpire
- https://www.accessdata.fda.gov/scripts/cder/ob/
- https://www.fda.gov/media/92548/download
- https://www.accessdata.fda.gov/scripts/cder/ob/results_patent.cfm
- https://www.fda.gov/drugs/drug-approvals-and-databases/orange-book-data-files
- https://www.npr.org/sections/health-shots/2013/10/28/241365414/unlikely-multiple-sclerosis-pill-on-track-to-become-blockbuster?t=1650841331917
- https://www.reuters.com/article/brief-forward-pharma-says-european-paten/brief-forward-pharma-says-european-patent-office-has-revoked-ep2801355-patent-idUKFWN1PO11G
- https://consultqd.clevelandclinic.org/suicide-in-patients-with-multiple-sclerosis-guidance-on-red-flags-and-prevention/