THE USE OF PATENT INFORMATION FOR RESEARCH PURPOSES AND EXPLOITATION OF RESULTS

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HUMAN TECHNOPOLE

4-DAYS FULL IMMERSION TRAINING ON TECHNOLOGY TRANSFER IN LIFE SCIENCES

OVERVIEW (PART I)

INTRODUCTION

A. PATENT BASICS

B. CONTENT & FORMAT OF PATENT DOCUMENTS

C. PATENT INFORMATION (PATINFO) SEARCH BASICS

D. FEATURES OF PATINFO DATABASES

E. PATINFO SEARCH SCOPES & STRATEGIES

F. PATINFO ALTERNATIVE SOURCES

G. PRESENTATION OF CASE STUDY

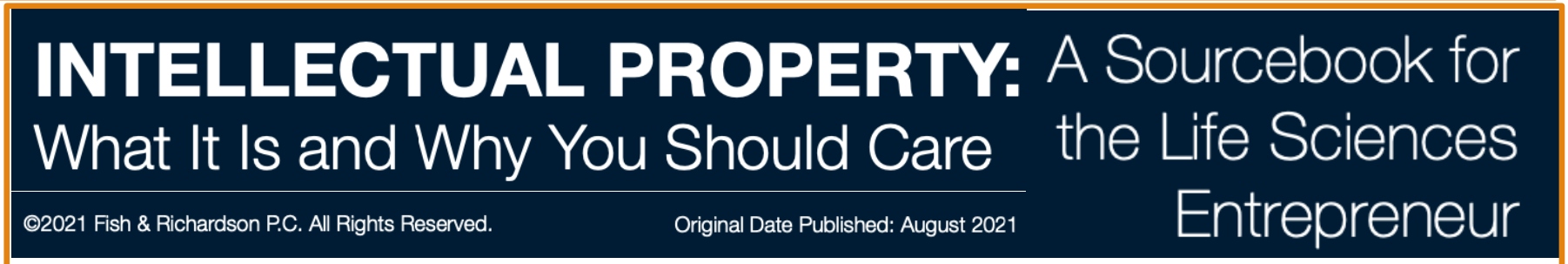
INTRODUCTION: Innovation, Patent, & Tech Transfer (1)

Understanding Patent Preparation and Prosecution

Matthew S. Rudd, JD, and William E. McCracken, JD

A patent can be a useful tool for protecting intellectual property. A well-written patent can keep competitors from copying successful products and can also help lure potential investors. At the same time, rattling the proverbial patent saber may lead to royalty in- come from licensing agreements. Successfully litigating a claim for patent infringement can cripple a competitor, solidify your market position, bring in significant awards from damages, and even lead to further licensing agreements.

Effective January 2010



Patents encourage technological innovation. By requiring applicants to publicly disclose all elements of their inventions, the patent system creates a searchable technology database that everyone can access, which essentially means inventors don't have to start at square one when seeking to improve an existing technology. At the corporate level, patents allow companies to protect the novel aspects of their products, provide a basis for negotiating with competitors, and instil confidence in investors, among many other benefits. In these ways, patents reward research and development efforts and encourage investment in them.

INTRODUCTION: Innovation, Patent, & Tech Transfer (2)

Guidelines for Preparing Patent Landscape Reports 2015

World Intellectual Property Organization (WIPO)

by Anthony Trippe, Patinformatics, LLC

Patent Landscape Reports (PLRs) support informed decision-making (...) in various areas of technology, (...) With the institution of patent (*information)* analytics, and PLRs, it is possible for these critical decisions to be made with data-driven, evidence-based approaches that deliver informed choices, and mitigate the associated to the decision risks. PLRs can be used as instruments to inform public policy makers in strategic decisions to related to R&D investment, prioritization, technology transfer or local manufacturing. Patent information can and is increasingly being used as a tool to inform public policy: Policymakers dealing with innovation have increasingly focused on patent system.

Benefits to the use of patent analytics and PLRs:

- Innovation Policy – Providing evidence of the emerging trends in technology
- Investment Opportunity – Identifying the technologies that may create a new market
- Competitor Intelligence – Profiling your competitors using their patent portfolios
- Knowledge Transfer – Analyzing the flow of knowledge and collaborations
- Geographical Profiling – Comparing markets between countries and regions

INTRODUCTION: The IP Network (1)

Patents ..... 20 years — Registration (Filing) — Expiring date

Utility models ..... from 7 to 10 years — Registration (Filing) — Expiring date

Databases ..... 15 years — Creation — Expiring date

European IPR Helpdesk

Your Guide to IP in Europe

The essentials of IP protection in Europe

www.iprhelpdesk.eu.

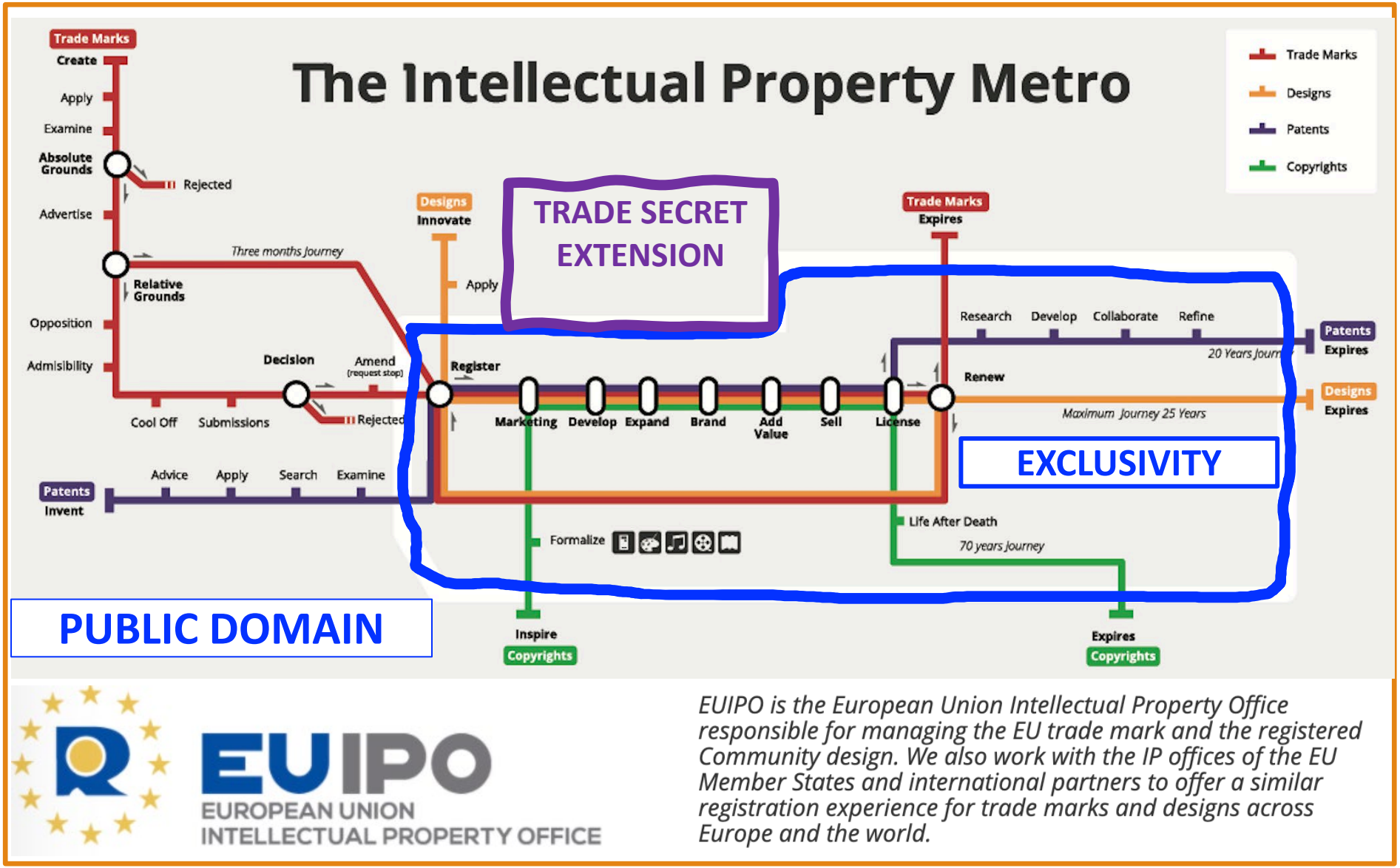
Trade marks ..... 10 years — Registration — 10 years x ∞ — Renewals

Industrial designs 5 years — Registration (Filing) — 5 years x (max. 4 times) — Renewals (optional) — Expiring date (max. 25 years)

Domain names ..... max. 10 years — Registration — 10 years x ∞ — Renewals

Copyright ..... Life of the author — Creation of the work — Death of the author (+70 years)

INTRODUCTION: The IP Network (2)



EUIPO
EUROPEAN UNION
INTELLECTUAL PROPERTY OFFICE

EUIPO is the European Union Intellectual Property Office responsible for managing the EU trade mark and the registered Community design. We also work with the IP offices of the EU Member States and international partners to offer a similar registration experience for trade marks and designs across Europe and the world.

PATENT BASICS: Patent Rights

- Patent rights are granted by state authorities to company or a person (applicant or patentee) to provide with a legally enforceable monopoly over inventions of industrial interest:
  - ✓ Products, uses, methods, technologies (not services)
  - ✓ In any domain (biology, chemistry, mechanics, electronics)
  - ✓ To be used as a strategic and financial instrument (for transactions, licenses, etc.)

- Such rights are obtained and fully enforceable if:
  - ✓ The patent application is actually published and granted as a patent
  - ✓ If the invention as defined in the is officially declared as patentable (novel, inventive, supported by text) and other formal/law criteria at national level are fulfilled (e.g. standards for patent eligibility in ICT or pharma/biotech may differ considerably)
  - ✓ Only in countries where a patent is granted (territorial effects)
  - ✓ For variable period of time (in general no more than 20 years)
  - ✓ If all administrative, formal, fee, and legal requirements are fulfilled

PATENT BASICS: Patent Geography & Jurisdictions

- Patent rights are generally fully enforceable on the basis of patent in a given jurisdiction as a ”negative right”:
  - ✓ The patent owner has to file a legal suit against an «infringer»
  - ✓ The court judges if this latter person or entity should pay damages, since the invention, as defined in the Claims, was produced, sold, used, and/or imported without paying a licence or acquiring the patent rights from the owner in that country

- There is nothing such as a «World Patent» or a «EU patent»:
  - ✓ National patent offices examine & grant national patents, following their own rules and patentability criteria
  - ✓ European patents are managed by the EU-independent EPO (European Patent Office) issuing patents that can be validated in any/all EU countries and some other countries (e.g. Switzerland, Norway, Iceland, Turkey, etc.)

PATENT BASICS: International Patent Systems (1)

- Main systems that allow simplifying international patent protection

WIPO
Making IP Work

WIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

Core functions
Multilateral law-making
IP laws
Policy negotiations

Policy – *Page 4*

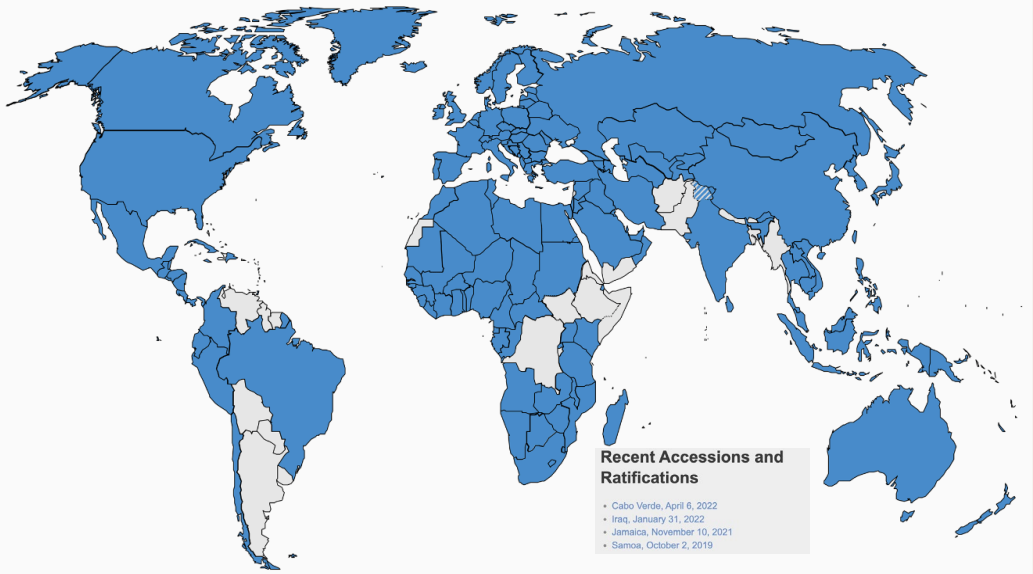
Public tools
Treaties

Core functions
IP filing services
Dispute resolution

Services – *Page 8*

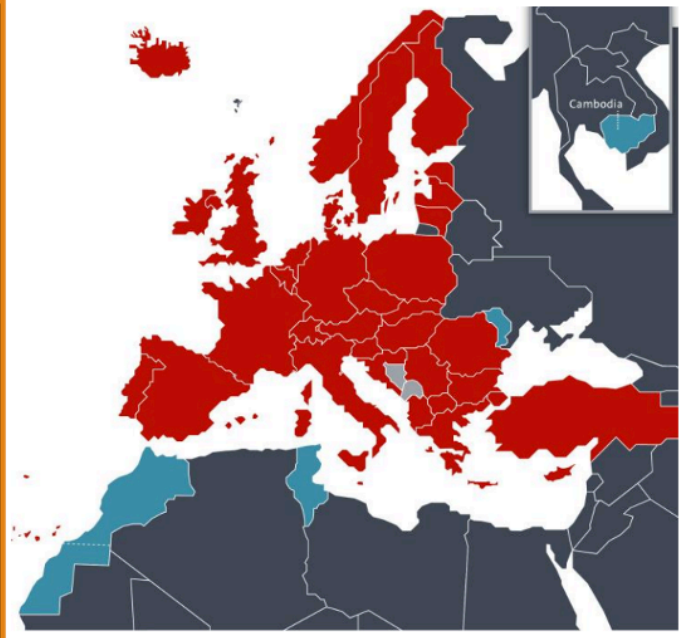
Public tools
PCT System (patents)
Madrid System (trademarks)
Hague System (designs)
Lisbon System (GIs)

The PCT now has 156 Contracting States



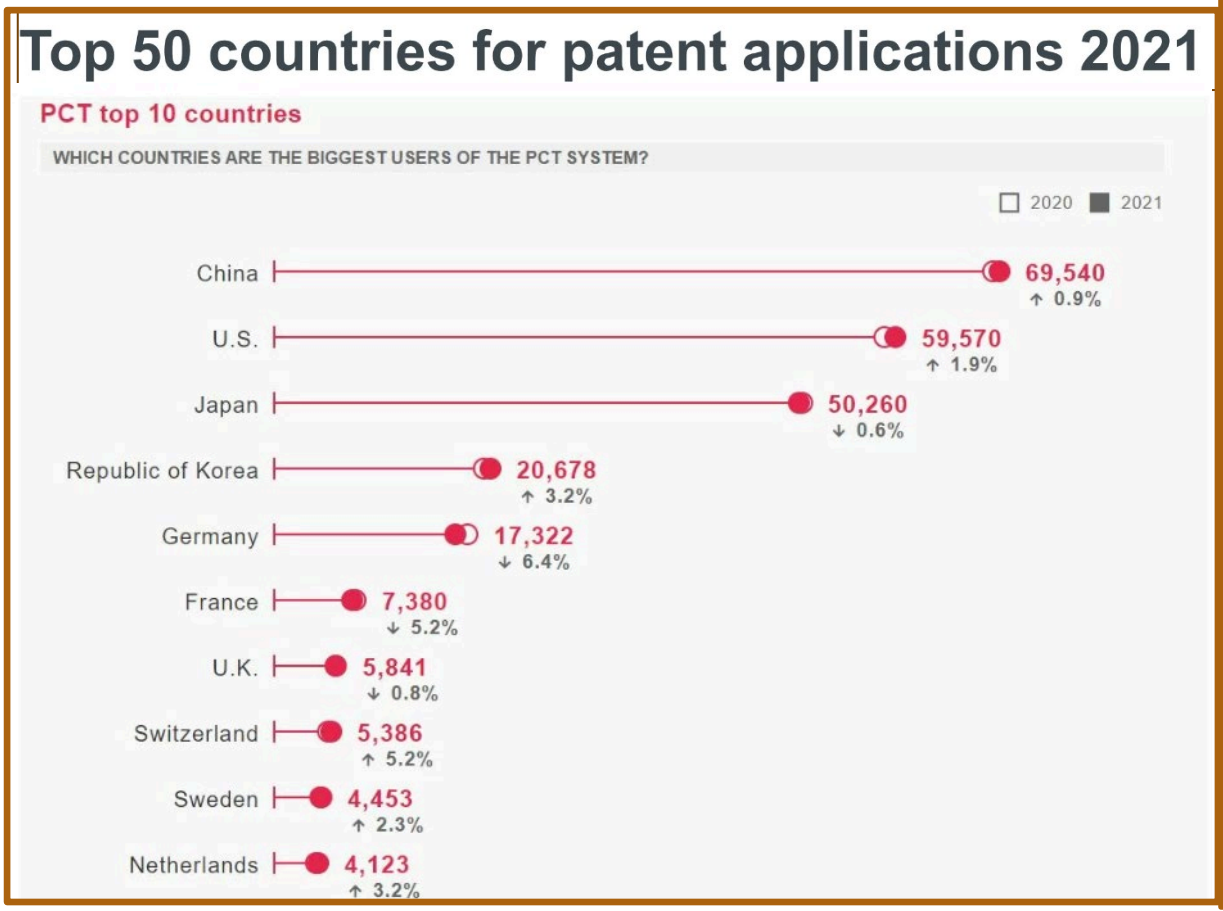
Europäisches Patentamt
European Patent Office
Office européen des brevets

The European Patent Office (EPO) examines European patent applications, enabling inventors, researchers and companies from around the world to obtain protection for their inventions in up to 44 countries through a centralised and uniform procedure that requires just one application.



PATENT BASICS: International Patent Proceedings (2)

- Such systems are actually used in different manners by applicants in different technical domain and/or from different countries



		2021	Change
1	United States	46 533	+5.2%
2	Germany	25 969	+0.3%
3	Japan	21 681	-1.2%
4	P.R. China	16 665	+24.0%
5	France	10 537	-0.7%
6	R. Korea	9 394	+3.4%
7	Switzerland	8 442	+3.9%
8	Netherlands	6 581	+3.1%
9	United Kingdom	5 627	-1.2%
10	Sweden	4 954	+12.0%
11	Italy	4 919	+6.5%
12	Denmark	2 642	+9.2%
13	Belgium	2 485	+3.3%
14	Austria	2 317	+0.5%
15	Finland	2 111	+11.2%
16	Canada	2 083	+18.4%
17	Spain	1 954	+8.9%

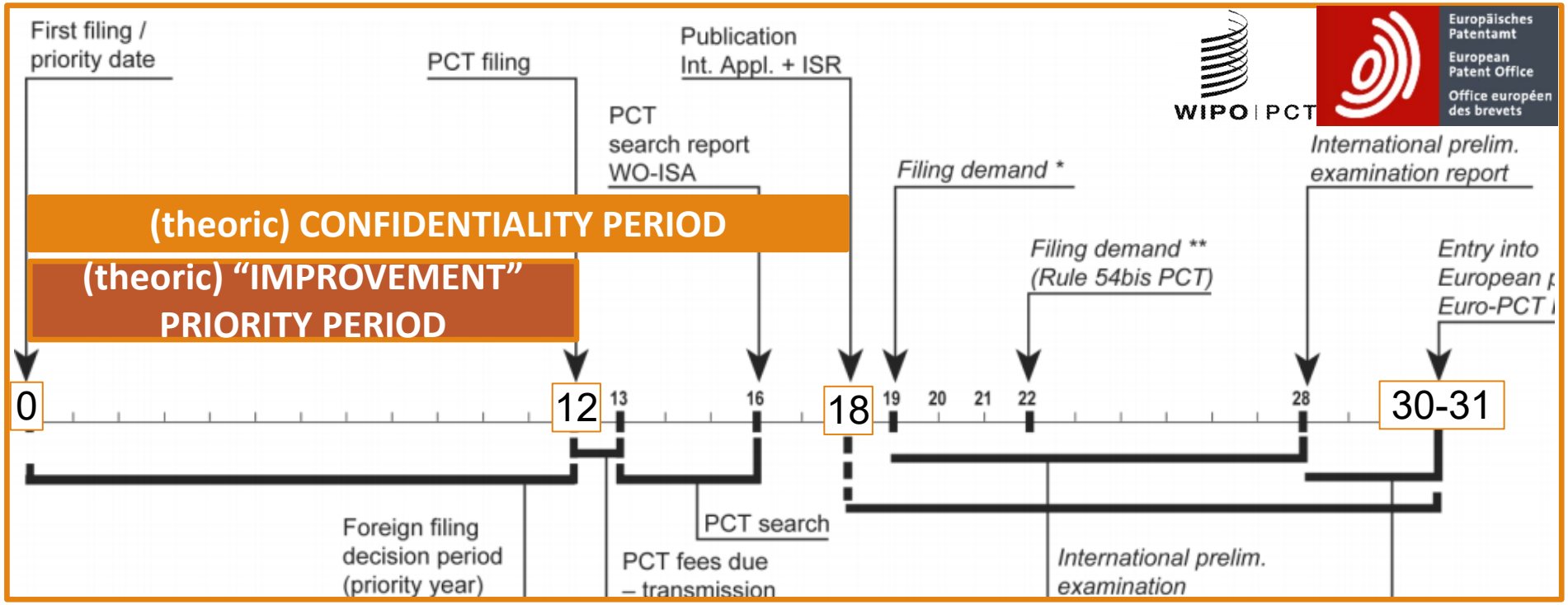
PATENT BASICS: Filing, Publication, & Examination (1)

- A patent application is examined with respect to:
  - ✓ Firstly for formal examination requirements (language, fees, text, figures, biological sequence & deposits etc.) applicable to whole application and then for claim patentability (eligibility, novelty, inventiveness, sufficiency)
  - ✓ Firstly for the publication as application before its grant (unless examination is accelerated), and then for the re-publication as a granted patent including the claims that have full legal effect (if renewal fees are paid)

- Country-specific requirements or policies still matter a lot:
  - ✓ For publication, examination, maintenance, and enforcement of patent rights in such country
  - ✓ After publishing the application, each patent office decides how/when/which patent information is made public through own website within the national patent register

PATENT BASICS: Filing, Publication, & Examination (2)

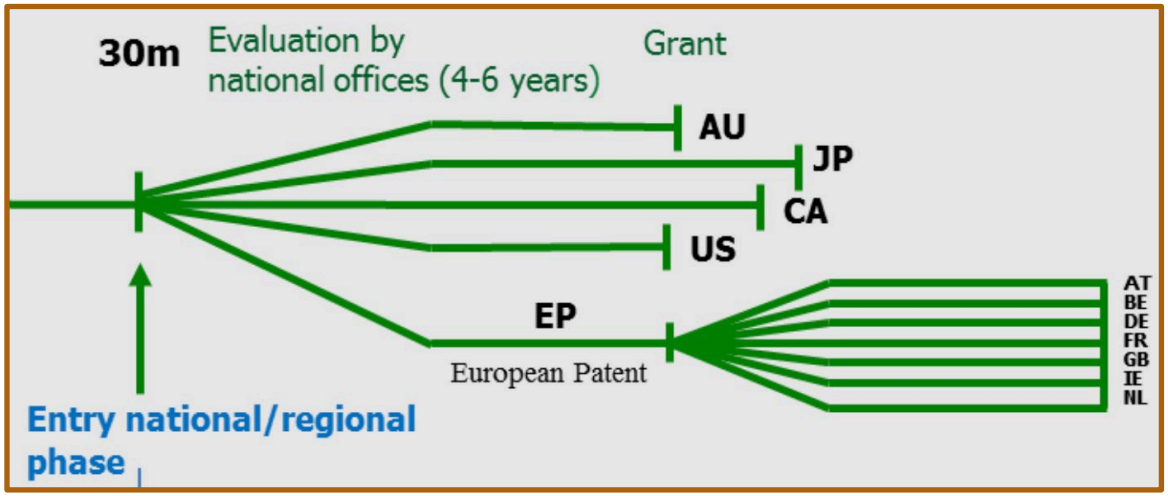
- It is possible to modify a patent application up to 12 months, before its publication at 18 months and (under PCT system) starting substantive examination at regional/national patent office but applicants are still given the opportunity to proceed in many ways depending on needs, available resources, competition, etc., also by means parallel national patent filings that are prosecuted at a faster pace (and sometimes granted more easily)



PATENT BASICS: Filing, Publication, & Examination (3)

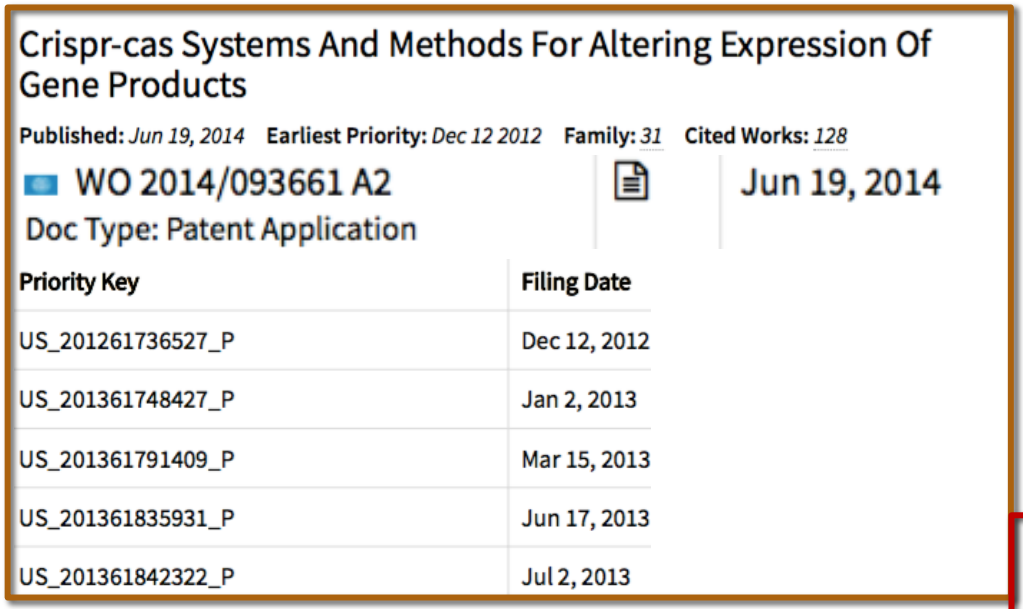
- Priority and PCT systems delay costs and formalities to generate a series of country-specific patent applications that may lead to:
  - ✓ Independently published, examined, and granted patents (in USA, Japan, China, Italy, etc.) and/or
  - ✓ in EPO member country, a single patent that may be converted, without further examination, into separate national patents to be validated in each European country (at variable costs)

- Such multiple patent documents (as applications or granted patents) that share initial filing data form a patent family



PATENT BASICS: Filing, Publication, & Examination (4)

- A PCT, EP, or other appl. in a patent family can be translated in one or more languages, but claims only may change across jurisdictions before re-publication as application or granted patents (and whatever may happen later , such as after oppositions)



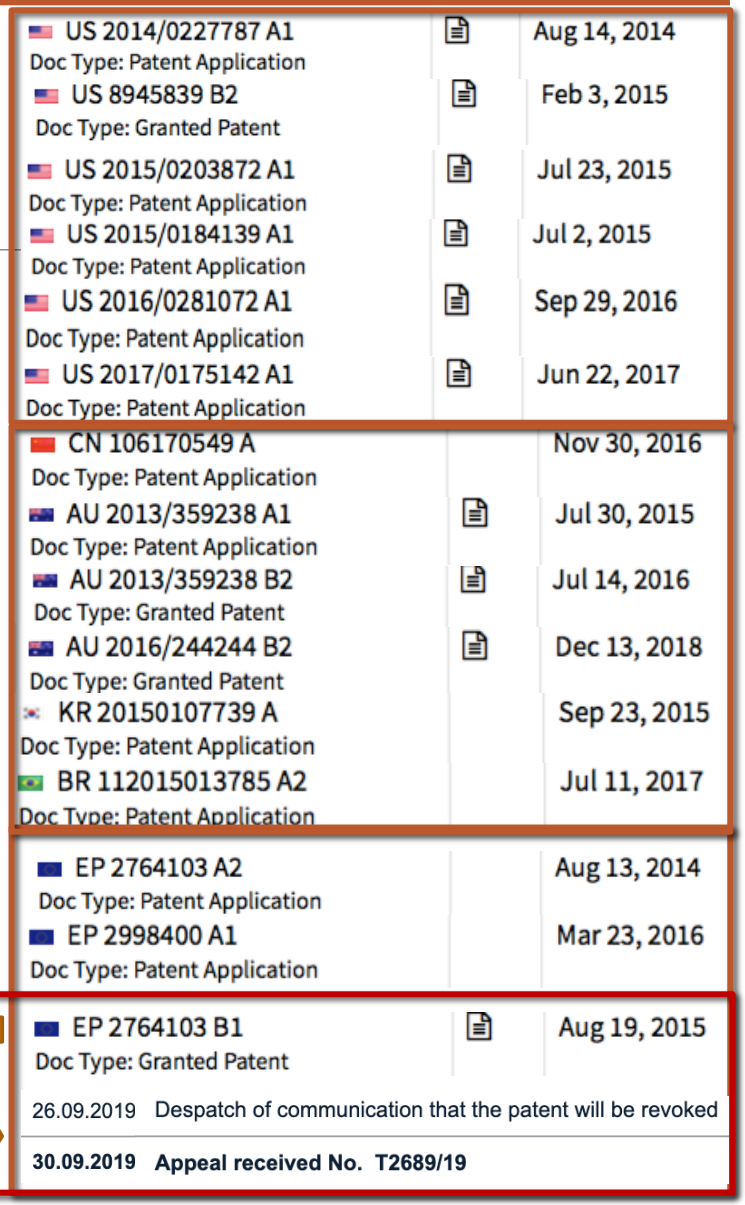
Crispr-cas Systems And Methods For Altering Expression Of Gene Products

Published: *Jun 19, 2014* **Earliest Priority:** *Dec 12 2012* **Family:** *31* **Cited Works:** *128*

WO 2014/093661 A2 — Jun 19, 2014

Doc Type: Patent Application

Priority Key	Filing Date
US_201261736527_P	Dec 12, 2012
US_201361748427_P	Jan 2, 2013
US_201361791409_P	Mar 15, 2013
US_201361835931_P	Jun 17, 2013
US_201361842322_P	Jul 2, 2013



US 2014/0227787 A1 — Aug 14, 2014
Doc Type: Patent Application

US 8945839 B2 — Feb 3, 2015
Doc Type: Granted Patent

US 2015/0203872 A1 — Jul 23, 2015
Doc Type: Patent Application

US 2015/0184139 A1 — Jul 2, 2015
Doc Type: Patent Application

US 2016/0281072 A1 — Sep 29, 2016
Doc Type: Patent Application

US 2017/0175142 A1 — Jun 22, 2017
Doc Type: Patent Application

CN 106170549 A — Nov 30, 2016
Doc Type: Patent Application

AU 2013/359238 A1 — Jul 30, 2015
Doc Type: Patent Application

AU 2013/359238 B2 — Jul 14, 2016
Doc Type: Granted Patent

AU 2016/244244 B2 — Dec 13, 2018
Doc Type: Granted Patent

KR 20150107739 A — Sep 23, 2015
Doc Type: Patent Application

BR 112015013785 A2 — Jul 11, 2017
Doc Type: Patent Application

EP 2764103 A2 — Aug 13, 2014
Doc Type: Patent Application

EP 2998400 A1 — Mar 23, 2016
Doc Type: Patent Application

EP 2764103 B1 — Aug 19, 2015
Doc Type: Granted Patent

26.09.2019 Despatch of communication that the patent will be revoked

30.09.2019 Appeal received No. T2689/19

PATENT BASICS: Filing, Publication, & Examination (5)

- The grant of patent rights involves a series of actions that are performed by applicant/owner(s), patent offices, and third parties over some years:
  - ✓ Filing of patent appl. in one or more national Patent Offices that can be improved over a period of 12mts (priority rights/applications)
  - ✓ The preliminary search and examination of claims with publication of patent application and priority filing(s) by patent office(s) within 18mts from the first priority appl. (no copyright)
  - ✓ Completing proceedings to start substantive examination
  - ✓ The substantive examination of the (claims of) patent application
  - ✓ Providing amended claims, arguments, and/or post-filing evidences
  - ✓ Decision to (refuse or) grant a patent in one or more countries
  - ✓ Completion of grant proceedings (paying fees, filing translations, etc.)
  - ✓ Publication of the granted patent
  - ✓ Maintaining the patent rights (by paying annuity fees, monitoring and eventually suing other entities for alleged infringement)
  - ✓ Filing observations during examination of patent applications and/or challenging granted patent rights at patent office or at courts

PATENT BASICS: Filing, Publication, & Examination (6)

- The disclosure & claim requirements for chemical and biological entities in patent documents have led to defining specific policies that apply to the filing, publication, and examination:
  - ✓ For biologicals, formatting protein/DNA/RNA sequences as sequence listing using an international patent standard (WIPO ST.26)
  - ✓ For cells, depositing samples at institutions that are recognized by patent offices using a specific procedure (under the Budapest treaty)
  - ✓ For chemicals, making use of general formula that define alternative chemical groups in one or more positions (Markush structures)

- Such specific policies make more complex and may expand the scope of the patent rights (and consequently of the search & analysis of relevant information) so that some experience and expertise is needed, also in view of:
  - ✓ Uneven use by applicants and variable practices at patent offices
  - ✓ Different choices that are made and found acceptable for some "borderline" situations (e.g. peptides, antibodies, mutated cell lines)

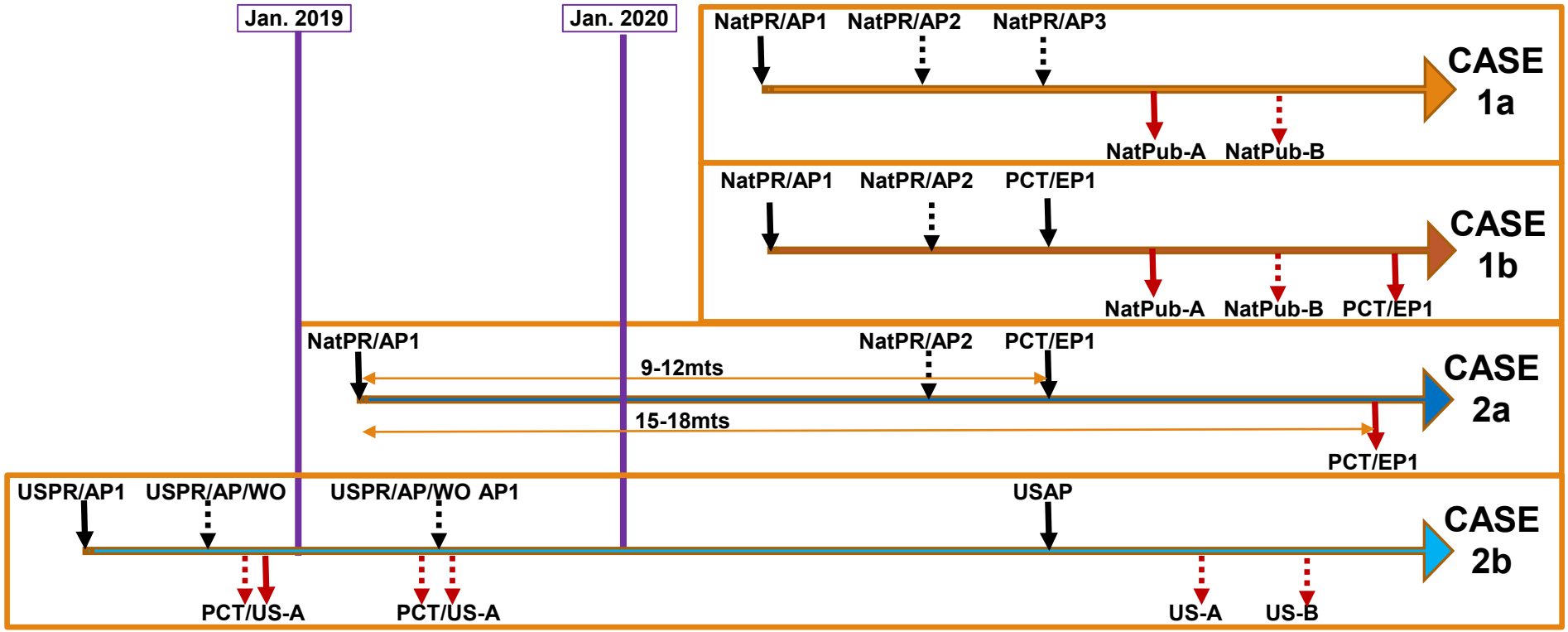
PATENT BASICS: Filing, Publication, & Examination (7)

- The patent office may have specific policies related to:
  - ✓ Anticipated publication of information related to a patent filing well before the statutory 18mts deadline (e.g. UK, Australian, and other patent office publishing title, inventors, applicant, filing date/no. in their own patent bulletin within weeks from filing)
  - ✓ No information about examination process until grant (as in Chinese and other Asian patent offices)

- Applicants in a given country and/or technical domain may pursue patent proceedings in less conventional manner that affect the access to information related to patent rights and strategies:
  - ✓ For PCT appl., choosing one of the nine admissible language of filing & publication other than English
  - ✓ Filing, prosecuting, and getting patent granted in the country where the company owning/licensing the patent is located and/or have most important activities (or competitors)

PATENT BASICS: Filing, Publication, & Examination (8)

- Analysis of patent publications should also take into account the potentially different filing strategies, previously pending applications, and opportunistic approaches when drafting patent applications, as in the case of COVID-related patent filings since Jan. 2020



PATENT CONTENTS & FORMAT: Patent Vs. Article (1)

- Patent documents share features of scientific articles but they are differently presented and/or ordered, over a much larger number of pages, evolving over time (for claims only), maybe not written in own language or English, and consequently their search and analysis may be:
  - ✓ ”unappealing” and complex for scientific readers
  - ✓ Requiring specific approaches for searching & analysing them

- The patent document is also the result of a collective work:
  - ✓ The inventor(s), a concept more restrictive than author (contributing to the concept of invention, not in executing the related experiments)
  - ✓ The applicant(s), being the inventor(s), but more often the employer(s), providing direct instructions about specific contents and/or wording
  - ✓ The patent attorneys, who represent applicant(s) at patent office and draft, amend and/or translate patent documents
  - ✓ The patent examiners, who evaluate patentability and may request /allow only specific amendments to the claims

PATENT CONTENTS & FORMAT: Patent Vs. Article (2)

Scientific Article	Vs.	Patent Document
➢ Drafted by researchers, coming from same/different entities		➢ Drafted by an "informal" team (attorneys, inventors, managers)
➢ Drafts can be fully modified after feed-back from reviewers		➢ "Drafts" can be filed during 12mts, then only claims can be amended
➢ Journal-specific requirements for text & figure publication (e.g. length, colors, tables, suppl. files)		➢ Publication requirements are less restrictive on some aspects (e.g. size), more on others (e.g. no colors)
➢ Publication date depending from reviewers, publishers, authors		➢ Published after 18mts from 1st filing in specific weekdays (Tue for US, Wed for EPO, Thu for PCT)
➢ A publication, generally in English, is followed by other articles with new data, other authors, citing later references etc.		➢ Redundant, "frozen" publications in each country, translated in various languages and/or wit different claims
➢ Pubmed search & access, often subscription for full-text access		➢ Freely available & searchable, highly diversified search & analysis tools

PATENT CONTENTS & FORMAT: Overview (1)

- The patent office acts initially as any publisher, with own policies and requirements for accepting & publishing a file as a patent application:
  - ✓ First page contains bibliographic information and relevant dates (from applicant or patent office) and Patent classification (from patent office)
  - ✓ Description (or specification) contains sections describing the invention in the form of text, tables, technical (chemical/biological) information, figure legends, means to use invention, examples describing the experimental results, and references
  - ✓ Claims contain the "synthetic" legal definition of the invention
  - ✓ Figures (all at the end, only black & white, specific text formats)
  - ✓ Preliminary search/examination data (from patent office)

- NO limit in number of pages, figures, claims but to be noticed:
  - ✓ Translation costs & some fees increase proportionally
  - ✓ Biological sequences are grouped and reformatted in a separate file (sequence listing) with the consequent increase of page number

PATENT CONTENTS & FORMAT: Overview (2)

- Some free articles provides scientific audiences with guidance for reading and making the best use of patent documents

EXPERT OPINION ON THERAPEUTIC PATENTS, 2018
VOL. 28, NO. 4, 277–280
https://doi.org/10.1080/13543776.2018.1438409

EDITORIAL

Tips for reading patents: a concise introduction for scientists

Kate E. Donald[a], K. M. Mohibul Kabir[b] and William A. Donald[b]

1. Tip 1: know the difference between patents and patent applications
2. Tip 2: get your bearings
3. Tip 3: read the abstract
4. Tip 4: jump to the examples
5. Tip 5: read the claims
6. Tip 6: check the dates
7. Tip 7: patents are not subject to the scientific method and peer review

Patents undergo an examination process by patent examiners who will assess whether a patent application complies with the legal requirements for a patent in a given country. However, it is important to note that the data contained in patent applications and/or patents are not subject to peer review and the scientific method. The validity of the scientific data (if assessed at all) will not typically be considered unless challenged in patent validity proceedings. Thus, we suggest that the data reported in patents be viewed with this process in mind.

Overall, we hope this informal introduction to patent reading will encourage more scientists and students to read the patent literature and make use of the cutting-edge research disclosed in patents and patent applications.

New Biotechnology 40 (2018) 133–139
Contents lists available at ScienceDirect
New Biotechnology
journal homepage: www.elsevier.com/locate/nbt

Meeting Report

Intellectual property rights derived from academic research and their role in the modern bioeconomy—A guide for scientists

Jan B. Krauss*, David Kuttenkeuler

New BIOTECHNOLOGY 60 (2021) 124–129
Contents lists available at ScienceDirect
New BIOTECHNOLOGY
journal homepage: www.elsevier.com/locate/nbt

When to file for a patent? The scientist's perspective

Jan Krauß *, David Kuttenkeuler

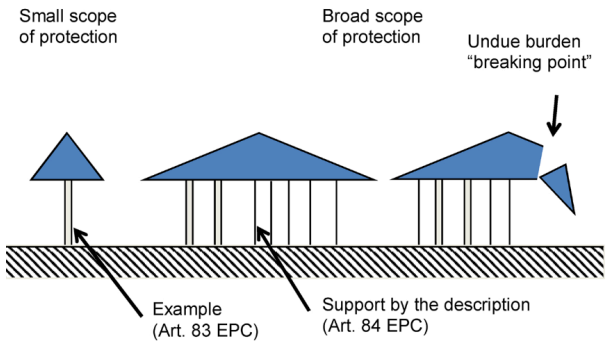
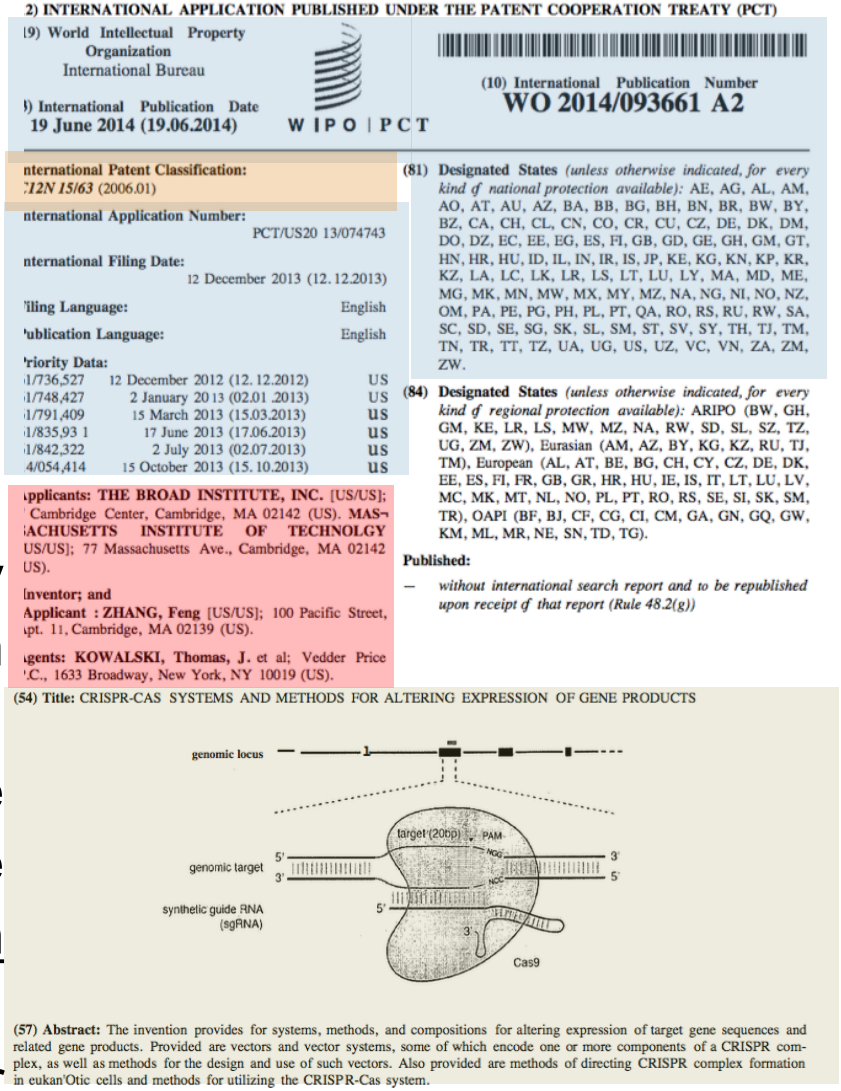


Fig. 1. Schematic overview of the enablement and written description requirements.

PATENT CONTENTS & FORMAT: First Page Info (1)

- Any PCT appl. first page:
  - ✓ Patent filing codes, dates, states
  - ✓ One or more classification codes
  - ✓ Official title, abstract, main figure
  - ✓ The names of inventor(s), applicant(s), patent attorney(s)

- To be noticed:
  - ✓ Title and abstract are generally shorter, much less informative than scientific articles
  - ✓ Patent classification codes are determined by patent offices on the basis of the content of <u>claims which are searched for relevant prior art</u>
  - ✓ Names/dates are those declared or defined at filing



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

(9) World Intellectual Property Organization
International Bureau

(10) International Publication Number
WO 2014/093661 A2

) International Publication Date
19 June 2014 (19.06.2014)

W I P O | P C T

nternational Patent Classification:
C12N 15/63 (2006.01)

nternational Application Number:
PCT/US20 13/074743

nternational Filing Date:
12 December 2013 (12. 12.2013)

'iling Language: English

'ublication Language: English

'riority Data:

1/736,527	12 December 2012 (12. 12.2012)	US
1/748,427	2 January 2013 (02.01 .2013)	US
1/791,409	15 March 2013 (15.03.2013)	US
1/835,93 1	17 June 2013 (17.06.2013)	US
1/842,322	2 July 2013 (02.07.2013)	US
4/054,414	15 October 2013 (15. 10.2013)	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, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, 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, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, 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, 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).

Published:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

Applicants: THE BROAD INSTITUTE, INC. [US/US]; Cambridge Center, Cambridge, MA 02142 (US). **MAS¬ACHUSETTS INSTITUTE OF TECHNOLGY** US/US]; 77 Massachusetts Ave., Cambridge, MA 02142 US).

Inventor; and
Applicant : ZHANG, Feng [US/US]; 100 Pacific Street, apt. 11, Cambridge, MA 02139 (US).

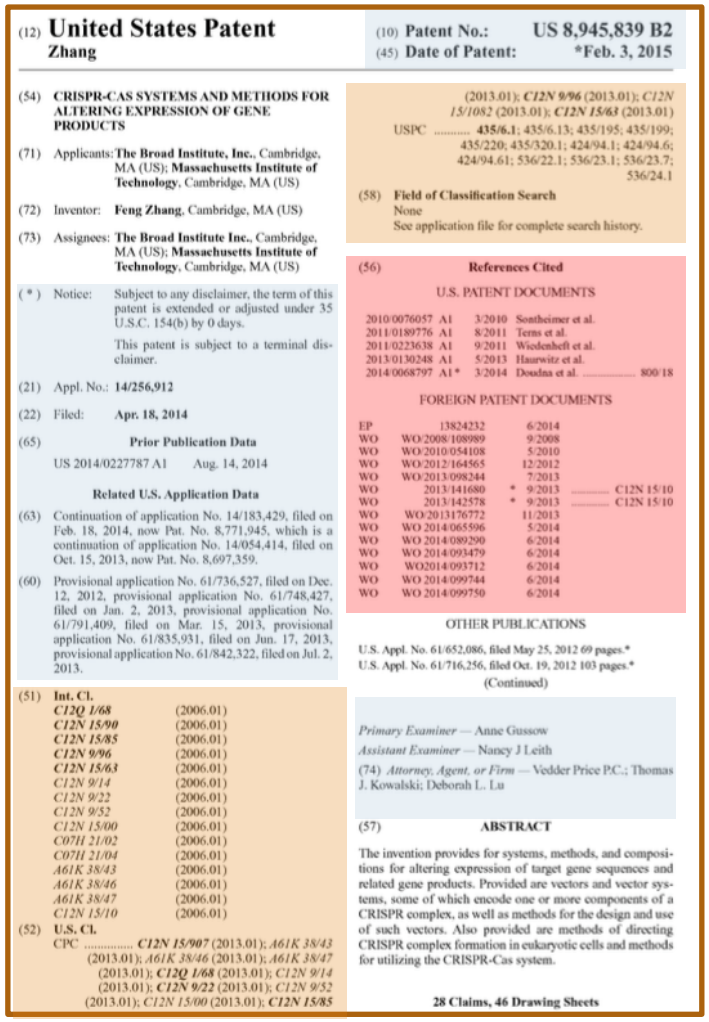
Agents: KOWALSKI, Thomas, J. et al; Vedder Price P.C., 1633 Broadway, New York, NY 10019 (US).

(54) **Title:** CRISPR-CAS SYSTEMS AND METHODS FOR ALTERING EXPRESSION OF GENE PRODUCTS

(57) **Abstract:** The invention provides for systems, methods, and compositions for altering expression of target gene sequences and related gene products. Provided are vectors and vector systems, some of which encode one or more components of a CRISPR complex, as well as methods for the design and use of such vectors. Also provided are methods of directing CRISPR complex formation in eukan'Otic cells and methods for utilizing the CRISPR-Cas system.

PATENT CONTENTS & FORMAT: First Page Info (2)

- EP&US documents present specific, additional information in 1st page about relevant prior art, proceedings, and classifications at a patent office



(12) **United States Patent**
Zhang

(10) **Patent No.: US 8,945,839 B2**
(45) **Date of Patent: *Feb. 3, 2015**

(54) **CRISPR-CAS SYSTEMS AND METHODS FOR ALTERING EXPRESSION OF GENE PRODUCTS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/256,912**

(22) Filed: **Apr. 18, 2014**

(65) **Prior Publication Data**

US 2014/0227787 A1 Aug. 14, 2014

Related U.S. Application Data

(63) Continuation of application No. 14/183,429, filed on Feb. 18, 2014, now Pat. No. 8,771,945, which is a continuation of application No. 14/054,414, filed on Oct. 15, 2013, now Pat. No. 8,697,359.

(60) Provisional application No. 61/736,527, filed on Dec. 12, 2012, provisional application No. 61/748,427, filed on Jan. 2, 2013, provisional application No. 61/791,409, filed on Mar. 15, 2013, provisional application No. 61/835,931, filed on Jun. 17, 2013, provisional application No. 61/842,322, filed on Jul. 2, 2013.

(51) **Int. Cl.**

C12Q 1/68	(2006.01)
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C12N 9/96	(2006.01)
C12N 15/63	(2006.01)
C12N 9/14	(2006.01)
C12N 9/22	(2006.01)
C12N 9/52	(2006.01)
C12N 15/00	(2006.01)
C07H 21/02	(2006.01)
C07H 21/04	(2006.01)
A61K 38/43	(2006.01)
A61K 38/46	(2006.01)
A61K 38/47	(2006.01)
C12N 15/10	(2006.01)

(52) **U.S. Cl.**

CPC ***C12N 15/907*** (2013.01); *A61K 38/43* (2013.01); *A61K 38/46* (2013.01); *A61K 38/47* (2013.01); ***C12Q 1/68*** (2013.01); *C12N 9/14* (2013.01); ***C12N 9/22*** (2013.01); *C12N 9/52* (2013.01); *C12N 15/00* (2013.01); ***C12N 15/85***

(2013.01); ***C12N 9/96*** (2013.01); *C12N 15/1082* (2013.01); ***C12N 15/63*** (2013.01)

USPC **435/6.1**; 435/6.13; 435/195; 435/199; 435/220; 435/320.1; 424/94.1; 424/94.6; 424/94.61; 536/22.1; 536/23.1; 536/23.7; 536/24.1

(58) **Field of Classification Search**
None
See application file for complete search history.

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(Continued)

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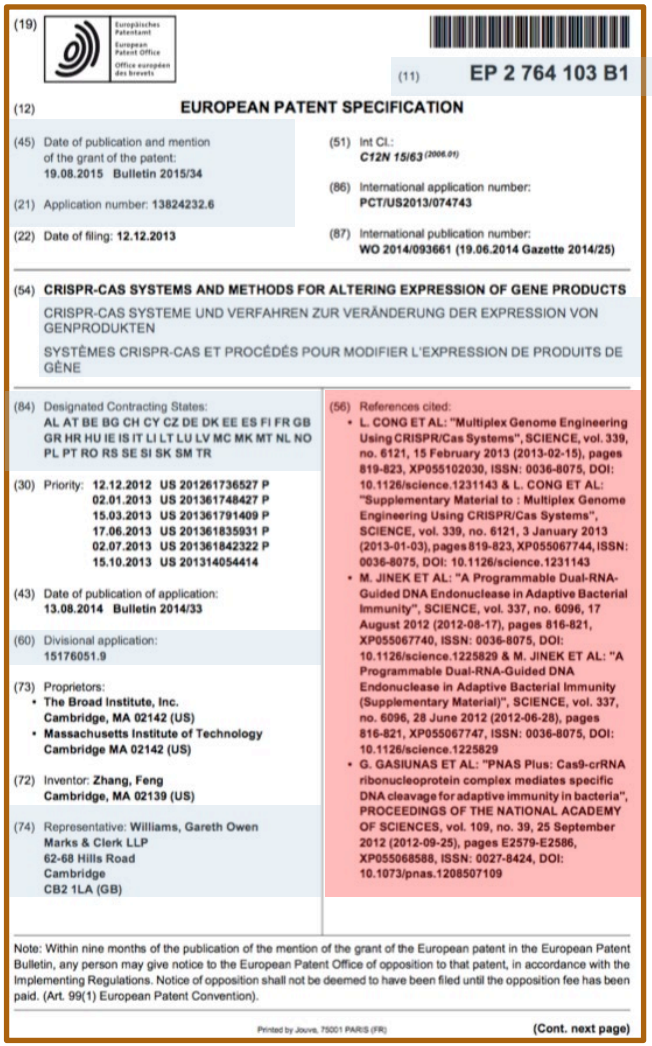
(57) **ABSTRACT**

The invention provides for systems, methods, and compositions for altering expression of target gene sequences and related gene products. Provided are vectors and vector systems, some of which encode one or more components of a CRISPR complex, as well as methods for the design and use of such vectors. Also provided are methods of directing CRISPR complex formation in eukaryotic cells and methods for utilizing the CRISPR-Cas system.

28 Claims, 46 Drawing Sheets



(19) Europäisches Patentamt / European Patent Office / Office européen des brevets

(11) **EP 2 764 103 B1**

(12) **EUROPEAN PATENT SPECIFICATION**

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(51) Int Cl.:
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(54) **CRISPR-CAS SYSTEMS AND METHODS FOR ALTERING EXPRESSION OF GENE PRODUCTS**

CRISPR-CAS SYSTEME UND VERFAHREN ZUR VERÄNDERUNG DER EXPRESSION VON GENPRODUKTEN

SYSTÈMES CRISPR-CAS ET PROCÉDÉS POUR MODIFIER L'EXPRESSION DE PRODUITS DE GÈNE

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

(30) Priority: **12.12.2012 US 201261736527 P**
02.01.2013 US 201361748427 P
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(43) Date of publication of application:
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(60) Divisional application:
15176051.9

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- **L. CONG ET AL: "Multiplex Genome Engineering Using CRISPR/Cas Systems", SCIENCE, vol. 339, no. 6121, 15 February 2013 (2013-02-15), pages 819-823, XP055102030, ISSN: 0036-8075, DOI: 10.1126/science.1231143 & L. CONG ET AL: "Supplementary Material to : Multiplex Genome Engineering Using CRISPR/Cas Systems", SCIENCE, vol. 339, no. 6121, 3 January 2013 (2013-01-03), pages 819-823, XP055067744, ISSN: 0036-8075, DOI: 10.1126/science.1231143**
- **M. JINEK ET AL: "A Programmable Dual-RNA-Guided DNA Endonuclease in Adaptive Bacterial Immunity", SCIENCE, vol. 337, no. 6096, 17 August 2012 (2012-08-17), pages 816-821, XP055067740, ISSN: 0036-8075, DOI: 10.1126/science.1225829 & M. JINEK ET AL: "A Programmable Dual-RNA-Guided DNA Endonuclease in Adaptive Bacterial Immunity (Supplementary Material)", SCIENCE, vol. 337, no. 6096, 28 June 2012 (2012-06-28), pages 816-821, XP055067747, ISSN: 0036-8075, DOI: 10.1126/science.1225829**
- **G. GASIUNAS ET AL: "PNAS Plus: Cas9-crRNA ribonucleoprotein complex mediates specific DNA cleavage for adaptive immunity in bacteria", PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES, vol. 109, no. 39, 25 September 2012 (2012-09-25), pages E2579-E2586, XP055068588, ISSN: 0027-8424, DOI: 10.1073/pnas.1208507109**

Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

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(Cont. next page)

PATENT CONTENTS & FORMAT: Background

- This initial section should provide an overview of what is known and considered relevant by the inventors/applicants on the subject of the invention in an objective & complete manner (extremely variable size, from few lines to several pages)
- It contains citations of previous patent/scientific literature and any publication that, together with those cited in other sections, are consolidated in a final reference list
- To be noticed:
  - ✓ Background and reference list should convey a clear message to the examiner about what was known/achieved so far but, unfortunately, often these sections are not complete/fully consistent with the scope of claims, taking the risk of “misunderstandings” with examiner
  - ✓ Patent offices perform their own search anyway, but In USA, “duty of candor” requires to disclose all that is known, done by anyone, or later identified (e.g. at other patent offices), if not the patent may be revoked

PATENT CONTENTS & FORMAT: Summary, Description

- These sections provide:
  - ✓ The general features and uses of the invention, with text supporting the word-by-word the text of claims and explaining which technical limitations or problems are solved by the claimed invention
  - ✓ How to exploit the invention in different contexts, by expanding or adapting some features of the claimed invention to the actual or potential uses, also by taking into account guidance from the literature, other patents, products on the market, etc.

- Toughest, longest reading for the academics (may be skipped), but:
  - ✓ Specific wording/acronyms can be defined here as applicable for interpreting their use/meaning all over the patent document
  - ✓ This section is usually the longest one, wherein patent attorneys generally make use of long lists, broad statements, references to books, copy/pasted text from reviews, templates etc… making this section very heterogenous

PATENT CONTENTS & FORMAT: Examples

- This section:
  - ✓ Provides readers with the data generated by inventors with detailed materials & methods that would allow reproducing them
  - ✓ Includes conclusions based on literature & invention-related data
  - ✓ May be structured as M&M, Results, Discussion sub-sections

- Most important sections for technical scopes, but to be noticed that:
  - ✓ Elements within examples can be used for supporting claims during examination (post-filing evidences can be used, submitted, but not formally integrated during such later phase)
  - ✓ Demonstration by a third party that this information is incomplete or incorrect may lead to patent revocation
  - ✓ Generally separated from the rest but to be checked also with respect to cited figures, and separate “description of figure/drawing” section
  - ✓ Too many patent attorneys copy/paste files from inventors, without checking consistency/completeness or alerting inventors of potential risks during patent examination

PATENT CONTENTS & FORMAT: Figures, Tables

- These different elements are dealt in different manners:
  - ✓ Tables are embedded and numbered in the text (generally in Examples)
  - ✓ Figures (graphs, drawings) are B/W only and form a separate patent file
  - ✓ Legends form a specific section in text (often longer than in articles)
  - ✓ Photos and flowcharts are generally avoided but allowable as figures if useful for explaining the invention and text has correct size & language
  - ✓ Biological sequences, chemical structures, cell lines should be clearly referenced with an official code (e.g. name, deposit/access numbers)
  - ✓ Chemical structures can be found in figures, tables, text, and/or claims
  - ✓ Biological sequences can be found in figures, tables (less commonly explicitly listed in text, and/or claims) and separate sequence listing file

- As the Examples, important for technical scopes, but to be noticed:
  - ✓ Limiting their number or compacting the (non)text elements may reduce cost & increase usefulness (but following the format rules)
  - ✓ Not always well reviewed by patent attorneys and patent office (typos, errors may be later corrected but under strict specific rules)

PATENT CONTENTS & FORMAT: Claims (general issues)

- Claims are the legally relevant and often "dynamic" content:
  - ✓ Defining breadth of patent rights and of patentability examination (according to prior publications and national patent laws)
  - ✓ Together with official abstract, forming the real abstract of a patent document (but changing over time and from country)
  - ✓ To be interpreted according to the rest of the patent application
  - ✓ Drafted, modified, and interpreted by patent attorneys, patent examiners /judges… not an easy reading for average inventors

- To be noticed:
  - ✓ During the substantive examination may be (extensively) modified before/after grant, depending on national patent laws, applicant's interests & strategies, etc. but only with the approval of patent offices, and confirmed by applicant (and maybe never granted)
  - ✓ Variable number, length, format, category, and complexity (from one in few lines to hundreds in several pages), with several sub-cases
  - ✓ NO graphic elements (with exception of chemical structures)

PATENT CONTENTS & FORMAT: Claims (categories)

- The Claims are generally distinguished in categories:
  - ✓ Products that are defined by functionally & structurally linked components (in mechanics, electronics, or chemical compositions) or chemical structures, directly or indirectly (nucleic acids and proteins)
  - ✓ Products that are too complex (e.g. cells, alloys, or biological/chemical mixtures) may be defined by functional and/or production features, origin, purity, dimensions, shape, percentage of identity, etc.
  - ✓ Compositions that contain mixtures of well-defined products (each one having different chemical nature, functions, etc.) may be defined by the ratio, percentage, concentration of components
  - ✓ Industrial, medical, cosmetic, or other industrial uses/methods employing such products, alone or combined (e.g. in devices)
  - ✓ Process and technologies for manufacturing such products and performing the related methods/uses (e.g. medical dosages/regimens)
- Product, “compositions-of-matter” claims are generally those strategically and economically most valuable but often more difficult to be granted

PATENT CONTENTS & FORMAT: Beyond Text (1)

- WIPO publishes a PCT appl. adding further **PatInfo** files relating to:
  - ✓ The preliminary examination, listing the search criteria and databases, the most relevant publications for evaluating patentability and main arguments against/in favour of patentability of the claims as initially filed (but to be reviewed and confirmed at national stage)
  - ✓ Any other file that is required for formal or substantive examination and provided by the applicant at/after filing, including commentaries and/or amendments to the claims as initially filed and the previous appl. that have been used for establishing priority rights

- Many of major patent office also provide users with such **PatInfo** files but some knowledge of the specific patent office rules is needed since only a minority of documents and procedural events may be actually relevant for the scope of the search, at least for the more legal/business aspects
  - ✓ Ownership/licensing matters
  - ✓ Payment of fees and other formalities affecting pendency/enforcement
  - ✓ Arguments, case law & documents in favour/against claim patentability

PATENT CONTENTS & FORMAT: Beyond Text (2)

- Once entered national/regional proceedings (or when directly filing at national/regional level), additional **PatInfo** files relating to:
  - ✓ The substantive examination files, with other prior art citations, arguments and documents against/in favour of patentability of claims as further amended, and decisions about refusing/granting the patent
  - ✓ Any other file that is required for formal or substantive examination and maintenance of the patent as pending or granted, including signed forms about inventors/applicant/licensee, fee payments, actions by 3rd parties, post-filing/publication/grant events, legal issues, case law, etc.

- However, the accessibility and searchability of such additional **PatInfo** files at web patent register are very different from patent office to patent office:
  - ✓ Language, user's registration, file format, and update issues
  - ✓ National rules giving full/partial/no access to examination dossier
  - ✓ Information about fee payment and legal events incomplete/scattered
  - ✓ Effectiveness of web interface and search criteria actually available

PATENT CONTENTS & FORMAT: Beyond Text (3)

- The preliminary examination leads to the publication of a categorized list of most relevant publications for evaluating patentability and main arguments against/in favour of patentability of the claims as initially filed (but to be reviewed and confirmed during substantive examination (not in PCT phase)

A. CLASSIFICATION OF SUBJECT MATTER
INV. C12N15/63
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
C12N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, BIOSIS, EMBASE, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	L. CONG ET AL: "Multiplex Genome Engineering Using CRISPR/Cas Systems", SCIENCE, vol. 339, no. 6121, 15 February 2013 (2013-02-15), pages 819-823, XP055102030, ISSN: 0036-8075, DOI: 10.1126/science.1231143 Abstract; the whole document page 820, left-hand column	1-27

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

* Special categories of cited documents :
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 June 2014	10/06/2014

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Seroz, Thierry

(10) International Publication
WO 2014/093661

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Statement

Novelty (N)	Yes: Claims	3, 16
	No: Claims	1, 2, 4-15, 17-27
Inventive step (IS)	Yes: Claims	
	No: Claims	1-27
Industrial applicability (IA)	Yes: Claims	1-27
	No: Claims	

1. Novelty (Article 33(2) PCT)

Documents D1 (Supplementary Materials for D1) discloses a vector system comprising all features listed in claim 14. Moreover, the multiple chimeric RNA polynucleotides are used to provide a multiplexed system and include at least one NLS in the proximity of a terminus of the CRISPR enzyme. Furthermore, the first regulatory element is a polymerase III promoter and the second regulatory element is a polymerase II promoter. The CRISPR enzyme is the Cas9 enzyme that has been codon optimized for expression in mammalian cells.

The said vector system is used in a method of altering the expression of a gene of interest in a defined genomic locus, namely the human *EMX1* locus.

Therefore, in view of D1, **claims 1, 2, 4-15, 17-27** lack novelty.

2. Inventive step (Article 33(3) PCT)

The embodiments set forth in claims 3 and 16 are merely some of the several straightforward possibilities which the skilled person would select, in accordance with circumstances, without requiring any inventive skill.

Therefore, **claims 3 and 16** are not inventive over D1.

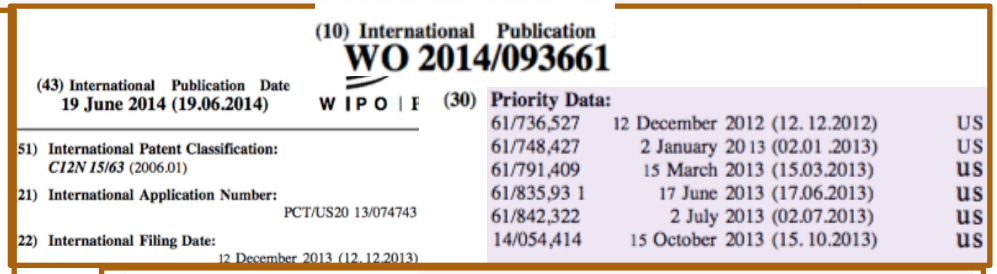
PATENT CONTENTS & FORMAT: Beyond Text (4)

- WIPO publishes a PCT appl. any other file that is required for formal or substantive examination and provided by the applicant at/after filing, including and commentaries/amendments to the claims as initially filed and the previous appl. that have been used for establishing priority rights, or commentaries that have been filed by 3rd parties after publication

https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2014093661

PCT Biblio. Data | Description | Claims | Drawings | National Phase | Patent Family | Notices | Documents

19.06.2014	Initial Publication without ISR (A2 25/2014)	PDF 143 p.
19.06.2014	(RO/102) Notification Concerning Payment of Prescribed Fees	PDF 2 p.
19.06.2014	Priority Document	PDF 293 p.
19.06.2014	Replacement, Substitute sheets (Rule 26)	PDF 21 p.
19.06.2014	Priority Document	PDF 322 p.
19.06.2014	Priority Document	PDF 306 p.
19.06.2014	Priority Document	PDF 127 p.
19.06.2014	Priority Document	PDF 405 p.
19.06.2014	(RO/106) Invitation to Correct Defects in the International Application	PDF 4 p.
19.06.2014	Priority Document	PDF 298 p.



(10) International Publication
WO 2014/093661

(43) International Publication Date
19 June 2014 (19.06.2014)

WIPO | PCT

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C12N 15/63 (2006.01)

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PCT/US20 13/074743

(22) International Filing Date:
12 December 2013 (12. 12.2013)

(30) Priority Data:

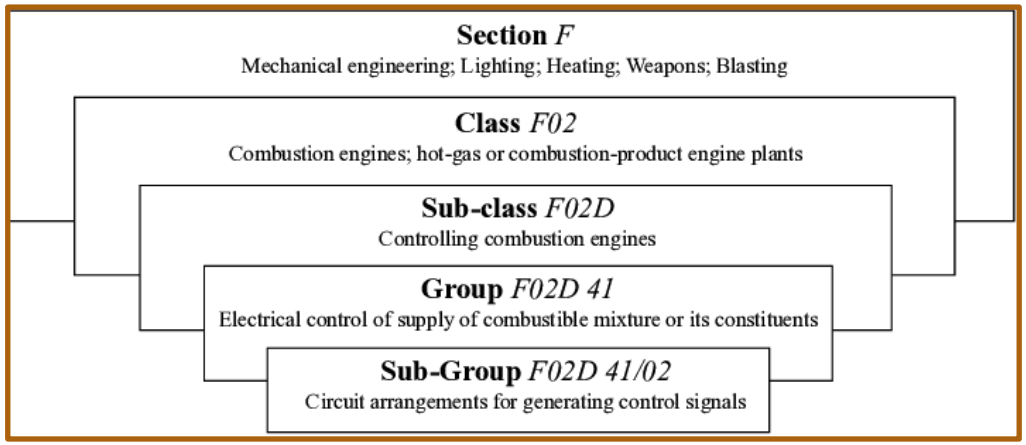
61/736,527	12 December 2012 (12. 12.2012)	US
61/748,427	2 January 20 13 (02.01 .2013)	US
61/791,409	15 March 2013 (15.03.2013)	US
61/835,93 1	17 June 2013 (17.06.2013)	US
61/842,322	2 July 2013 (02.07.2013)	US
14/054,414	15 October 2013 (15. 10.2013)	US

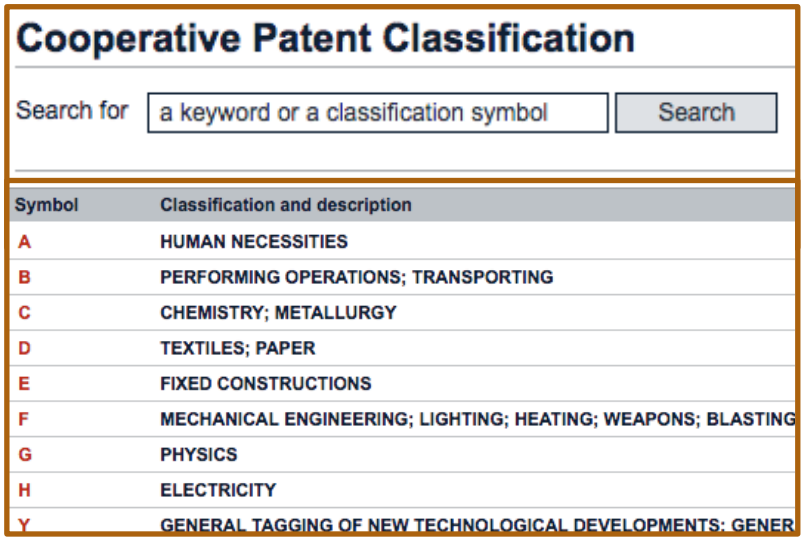
16.06.2015	(IB/373) International Preliminary Report on Patentability Chapter I	PDF 6 p.
12.06.2015	(ISA/237) Written Opinion of the International Searching Authority	PDF 5 p.
12.06.2015	Written Opinion of the International Searching Authority (replaced)	PDF 5 p.
28.04.2015	Additional comments submitted with observation	PDF 1 p.
28.04.2015	Third Party Observation	PDF 9 p.
25.09.2014	(ISA/210) International Search Report	PDF 6 p.

PATENT CONTENTS & FORMAT: Patent Classification(1)

- All patent applications that have been searched receive from patent office two types of patent classification alphanumerical codes:
  - ✓ International Patent Classification (IPC), at publication
  - ✓ Cooperative Patent Classification (CPC), generally later

- The systems share many codes but
  - ✓ The number of assigned IPC/CPC codes may vary considerably among patent documents, patent offices, and technical domains
  - ✓ CPC codes are generally more, more updated and precise,
  - ✓ Some IPC-only codes are still useful





PATENT CONTENTS & FORMAT: Patent Classification(2)

- The IPC/CPC codes defines products or uses using own logics and rules

PREPARATIONS FOR MEDICAL, DENTAL, OR TOILET PURPOSES (devices or methods specially adapted for bringing pharmaceutical products into particular physical or administering forms A61J 3/00; chemical aspects of, or use of materials for deodorisation of air, for disinfection or sterilisation, or for bandages, dressings, absorbent pads or surgical articles A61L; {compounds per se C01, C07, C08, C12N} ; soap compositions C11D; {micro-organisms per se C12N})	S D i !	A61K ☐
▼ **Preparations for dentistry** (teeth cleaning preparations A61K 8/00, A61Q 11/00; {dental prostheses A61C 13/00; apparatus or methods for oral or dental hygiene A61C})	D i	A61K 6/00 ☐
▼ **Cosmetic or similar toilet preparations** (casings or accessories for storing or handling of solid or pasty toilet or cosmetic substances A45D 40/00)	D i !	A61K 8/00 ☐
▼ **Medicinal preparations characterised by special physical form** (nuclear magnetic resonance contrast preparations or magnetic resonance imaging contrast preparataions A61K 49/18; preparations containing radioactive substances A61K 51/12)	D i	A61K 9/00 ☐
▼ **Medicinal preparations containing organic active ingredients**	D i	A61K 31/00 ☐
▼ **Medicinal preparations containing inorganic active ingredients**	D	A61K 33/00 ☐
▼ **Medicinal preparations containing materials or reaction products thereof with undetermined constitution**	D i	A61K 35/00 ☐
▼ **Medicinal preparations of undetermined constitution containing material from algae, lichens, fungi or plants, or derivatives thereof, e.g. traditional herbal medicines** {(antigens from pollen A61K 39/36)}	D i	A61K 36/00 ☐
▼ **Medicinal preparations containing peptides** (peptides containing beta-lactam rings A61K 31/00; cyclic dipeptides not having in their molecule any other peptide link than those which form their ring, e.g. piperazine-2,5-diones, A61K 31/00; ergot alkaloids of the cyclic peptide type A61K 31/48; containing macromolecular compounds having statistically distributed amino acid units A61K 31/74; medicinal preparations containing antigens or antibodies A61K 39/00; medicinal preparations characterised by the non-active ingredients, e.g. peptides as drug carriers, A61K 47/00)	D i	A61K 38/00 ☐
▼ **Medicinal preparations containing antigens or antibodies** (materials for immunoassay G01N 33/53)	D i	A61K 39/00 ☐

PATENT CONTENTS & FORMAT: Patent Classification(3)

- A specific topic may be defined by IPC/CPC for different features, as a product may be defined by different words in different languages

WIPO IP PORTAL | MENU | WIPO Pearl | HELP | ENGLISH | LOGIN | WIPO

COVID-19 GLOSSARY

AR مرض كوفيد-19

DE Covid-19
ES enfermedad por coronavirus 2019, *(syn.)* covid-19
FR COVID-19, *(syn.)* Covid-19, covid-19
JA 新型コロナウイルス感染症, *(syn.)* COVID-19
KO 코로나바이러스감염증-19
PT doença do coronavírus 2019, *(syn.)* COVID-19
RU коронавирусная болезнь 2019 года, *(syn.)* COVID-19
ZH 2019 冠状病毒病, *(syn.)* COVID-19

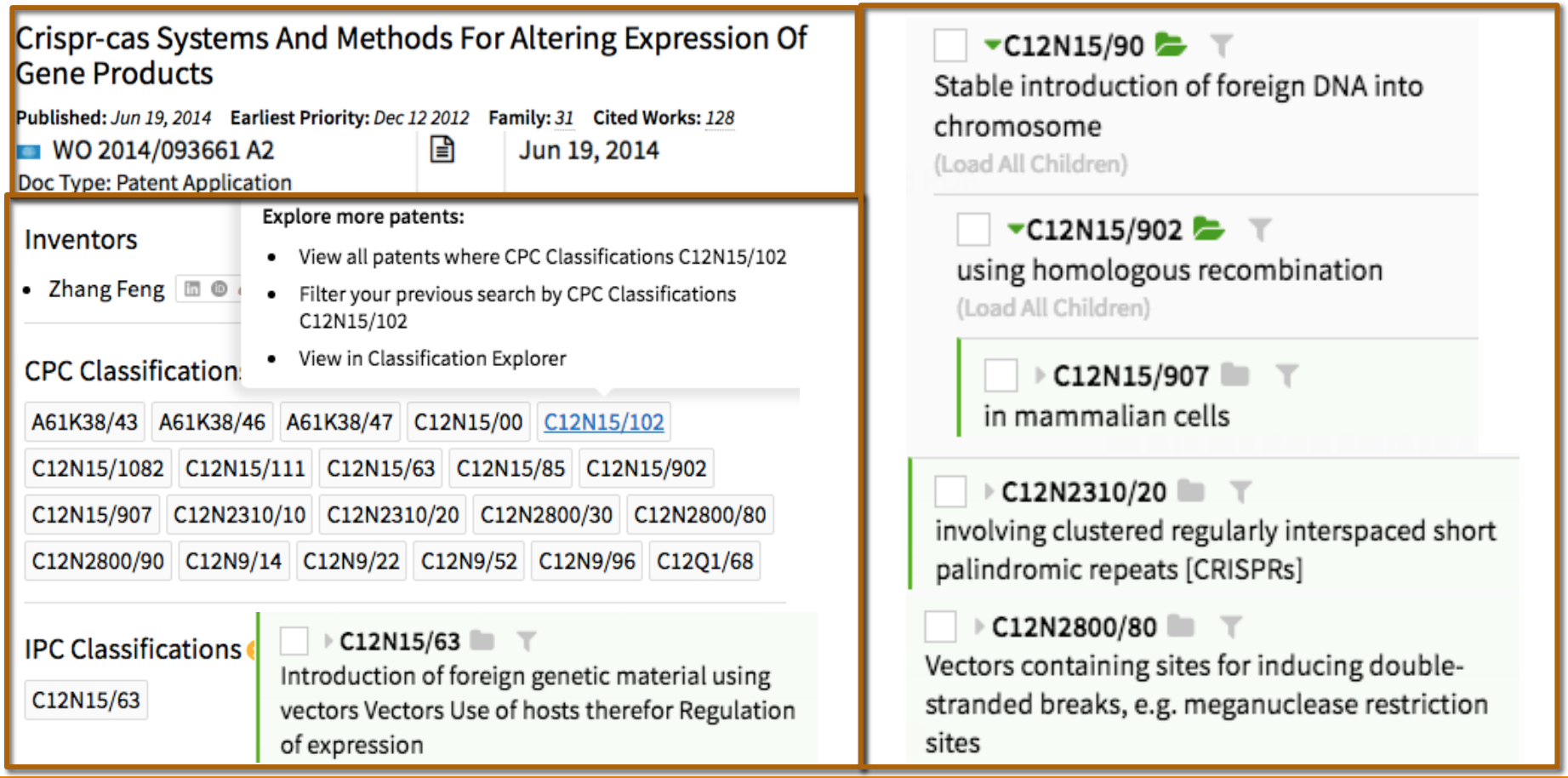
AR لقاح

DE Impfstoff, *(syn.)* Vakzine
ES vacuna
FR vaccin
JA ワクチン
KO 백신
PT vacina
RU вакцина
ZH 疫苗

A61K 39/00	**Medicinal preparations containing antigens or antibodies** (materials for immunoassay G01N 33/53)	D
A61K 39/12	• Viral antigens	
A61K 39/215	•• Coronaviridae, e.g. avian infectious bronchitis virus	
C12N 2770/00	**ssRNA Viruses positive-sense** (not used)	
C12N 2770/00011	• ssRNA Viruses positive-sense	
C12N 2770/20011	•• Coronaviridae	
C12N 2770/20034	••• Use of virus or viral component as vaccine, e.g. live-attenuated or inactivated virus, VLP, viral protein	
A61P 31/00	**Antiinfectives, i.e. antibiotics, antiseptics, chemotherapeutics**	
A61P 31/12	• Antivirals	
A61P 31/14	•• for RNA viruses	

PATENT CONTENTS & FORMAT: Patent Classification(2)

- The combination of correct IPC/CPC codes with classical keywords may help focusing the search but:
  - ✓ Not 100% consistently assigned, even in the same technical domain
  - ✓ Precision of definitions may differ among product/process/uses



PATINFO SEARCH BASICS: Overall PatInfo Diversity

- Previous section has shown how PatInfo may be found in many formats and how it can be modified and increase over time, distinguishing three main domains that partially overlap:
  - ✓ Technical contents and documentation
  - ✓ Legal documentation and geographical status
  - ✓ Entities/people that create, own, commercially exploit, evaluate, infringe, and/or challenge the patent rights

- Text, figures, sequences, chemicals and other elements of the patent application as filed and later translated
- References as cited by applicant, patent offices, challengers
- Technical submissions at different stages of proceedings
- Claims as initially filed, then modified, pending and/or translated until grant in one or more patent offices
- Choice of jurisdictions, examination strategy, and of representatives where patent protection is sought
- Payment of fees, formalities; legal arguments, case law, and status of main/divisional applications at different stages

Applicant
Patentee
Assignee
Licensor
Licensee
Inventor
Infringer
Opponent
Attorney
Examiner
Judge

PATINFO SEARCH BASICS: Technical PatInfo (1)

- Technical contents and documentation can be searched in patent documents using combinations of criteria that are elaborated on the basis of the features of the (potentially claimed) products, processes, methods and/or uses of interest, taking into account :
  - ✓ Specific, alternative names (scientific/commercial names, technical jargon, acronyms, non-English names, use of Arab/Roman numbers, Latin/Greek/Asian symbol, official standards/units, etc.)
  - ✓ How and where such names may found associated/near to each other and/or to common technical concepts or wording
  - ✓ If/which patent classification codes may be appropriate

- Main issues that make Technical PatInfo searches time consuming:
  - ✓ Chemicals and biologicals requiring structure and/or sequence search methods, with large documents and datasets to browse
  - ✓ Information within tables, figures, non-readable PDF files
  - ✓ Potential inconsistencies and errors among / within texts
  - ✓ Non-English texts (uneven efficacy of automated translation)

PATINFO SEARCH BASICS: Technical PatInfo (2)

- Different approaches for searching technical contents in patent documents can be elaborated depending on:
  - ✓ The complexity, scope, and urgency of the tasks
  - ✓ Technical knowledge of those performing the search
  - ✓ The access to commercial databases that are more effective, at least in some situations, to free patent databases
  - ✓ The importance to identify the network of cited/citing references to perform patentability and/or strategic evaluations

- Potential solutions that facilitate Technical PatInfo searches:
  - ✓ Make some initial technical readings to understand main topics
  - ✓ Perform preliminary searches to identify key criteria, entities, and most common locations of keywords in patent documents
  - ✓ Exploit this knowledge to compare sets of documents using IPC/CPC codes and proceed to “cascade” reference searches
  - ✓ Focus the search on most relevant patent offices (WIPO, EPO, USPTO) and/or jurisdictions (for market size and/or domain)

PATINFO SEARCH BASICS: Technical PatInfo (3)

- The potential, hardly anticipated bias needs to be attentively evaluated

Knowledge **2022**, 2, 487–507. https://doi.org/10.3390/knowledge2030029

Article

Investigating the Impacts of Misspellings in Patent Search by Combining Natural Language Tools and Rule-Based Approaches

Davide Russo [1,*], Christian Spreafico [1], Simone Avogadri [1] and Andrea Precorvi [2]

[1] Department of Management, Information and Production Engineering, University of Bergamo, 24044 Dalmine, Italy

Table 1. Misspellings' classification.

Accidental		Voluntary
Accidental Ignorance	**Accidental Typographic**	
Phonetically Plausible Misspelling Knok/knock	Thumbo, Twypo, Writo Bicylce, receive' as 'recieve	Typosquatting gogole.com (accessed on 28 July 2022)
Difficult Words (i.e., latin origins) Diarrhoea	Speako ate/eight	Neologisms Wake cup
Misuse and Orthographic errors than" and "then	Format conversion Universit?/università	Atomic misspellings prostate instead of prostrate
Compound (Hyphen or dash) email or e-mail	Transliteration of texts from non-latin alphabets Ko = co = cho	

Table 4. Keywords (correct and with misspellings) used to search patents about BRAYTON CYCLE.

Keywords		Results (N° Patents)
Correct keyword	BRAYTON CYCLE	5395
Keywords with misspellings	BRAITON CYCLE	10
	BRAY-TON CYCLE	33
	BRYTON CYCLE	57
	BRIGHTON CYCLE	96
	BRETTON CYCLE	99
	BRITTON CYCLE	4
	BREE TON CYCLE	1

Table 6. Keywords (correct and with misspellings) used to search patents about BICYCLE.

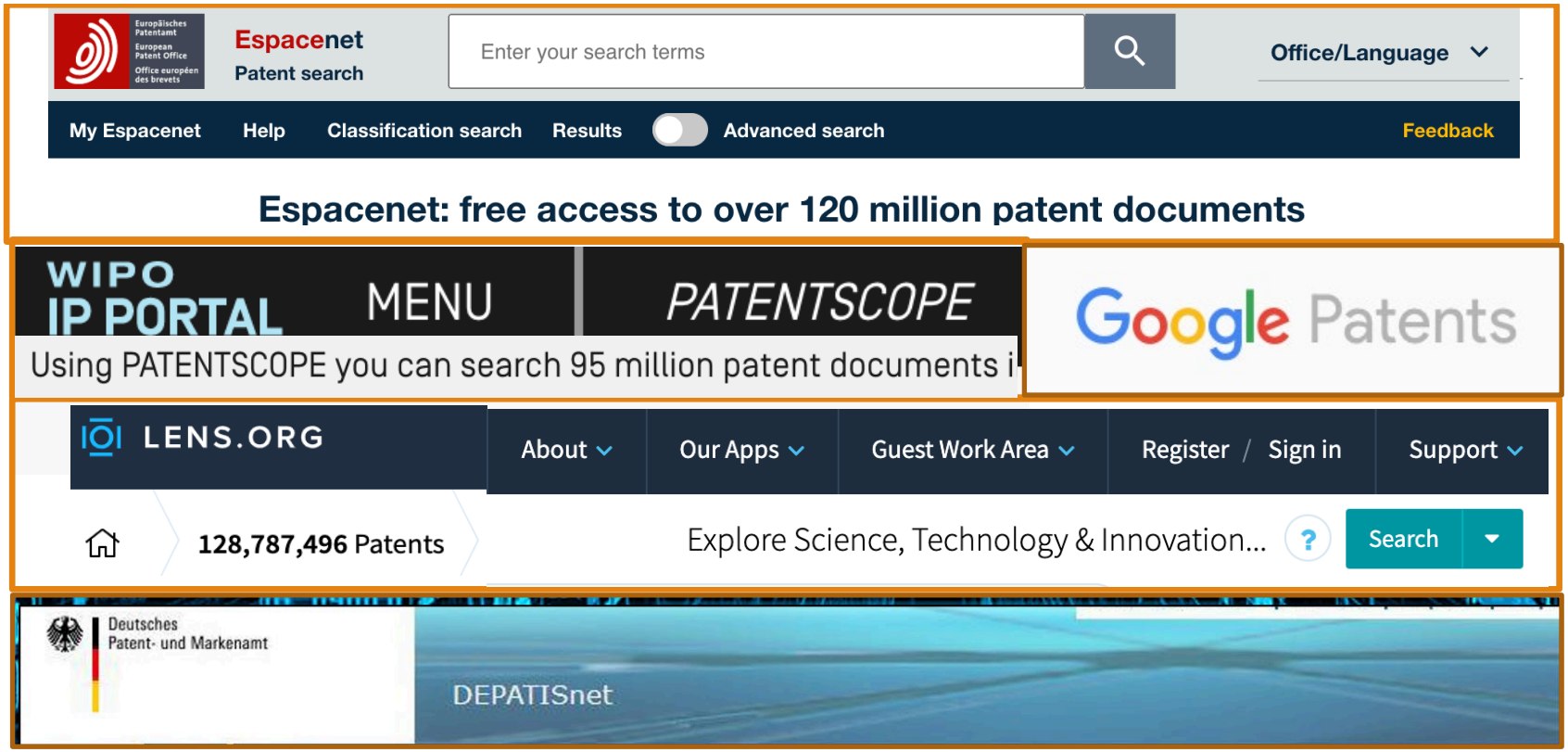
Keywords		Results (N° Patents)
Correct keyword	BICYCLE	188,699
Keywords with misspellings providing more patents (>100 each)	BICY	823
	BICYLE	417
	BYCYCLE	132
	BI-CYCLE	128
	BI CYCLE	128
	BICI	126
	BYCICLE	117
	ABICYCLE	109

Table 9. Keywords (correct and with misspellings) used to search patents about CO_2 and CARBON DIOXIDE.

Keywords		Results (N° of Patents)
Correct keyword	CO_2	536,459
Keywords with misspellings	CO 2; CO-2; CO.2; CO_2-; CO_2~; CO_2; CO.2; CO_2; CO–2; CO:2	831,022
	C02 (Zero instead of O)	76,624
	C0 2; C0-2; C0.2; C02-; C02~; $C0_2$; C0.2; C0_2; C0–2; C0:2	118,156
	Cθ2 (Teta instead of O)	2288
	Cθ 2; Cθ-2; Cθ.2; Cθ2-; Cθ2~; $Cθ_2$; Cθ.2; Cθ_2; Cθ–2; Cθ:2	3982
	CO sub 2; CO.sub.2; CO.sub_2; CO sub_2	20,482
	C0 sub 2; C0.sub.2; C0.sub_2; C0 sub_2	25
Correct keyword	CARBON DIOXIDE	1,164,394
Keywords with misspellings providing more patents (>1000 each)	DIOXIDE CARBON	42,424
	CARBON OXIDE	31,867
	CARBONDIOXIDE	4279
	CARBON DIOXID	2888
	CARBON DI OXIDE	1990

PATINFO SEARCH BASICS: Technical PatInfo (4)

- The different free or commercial patent databases propose own approach & dataset to help identifying relevant Technical PatInfo



PATINFO SEARCH BASICS: Technical PatInfo (5)

- The patent databases may be compared by different criteria but these comparisons differ over time, technical domain, and according to own personal preferences

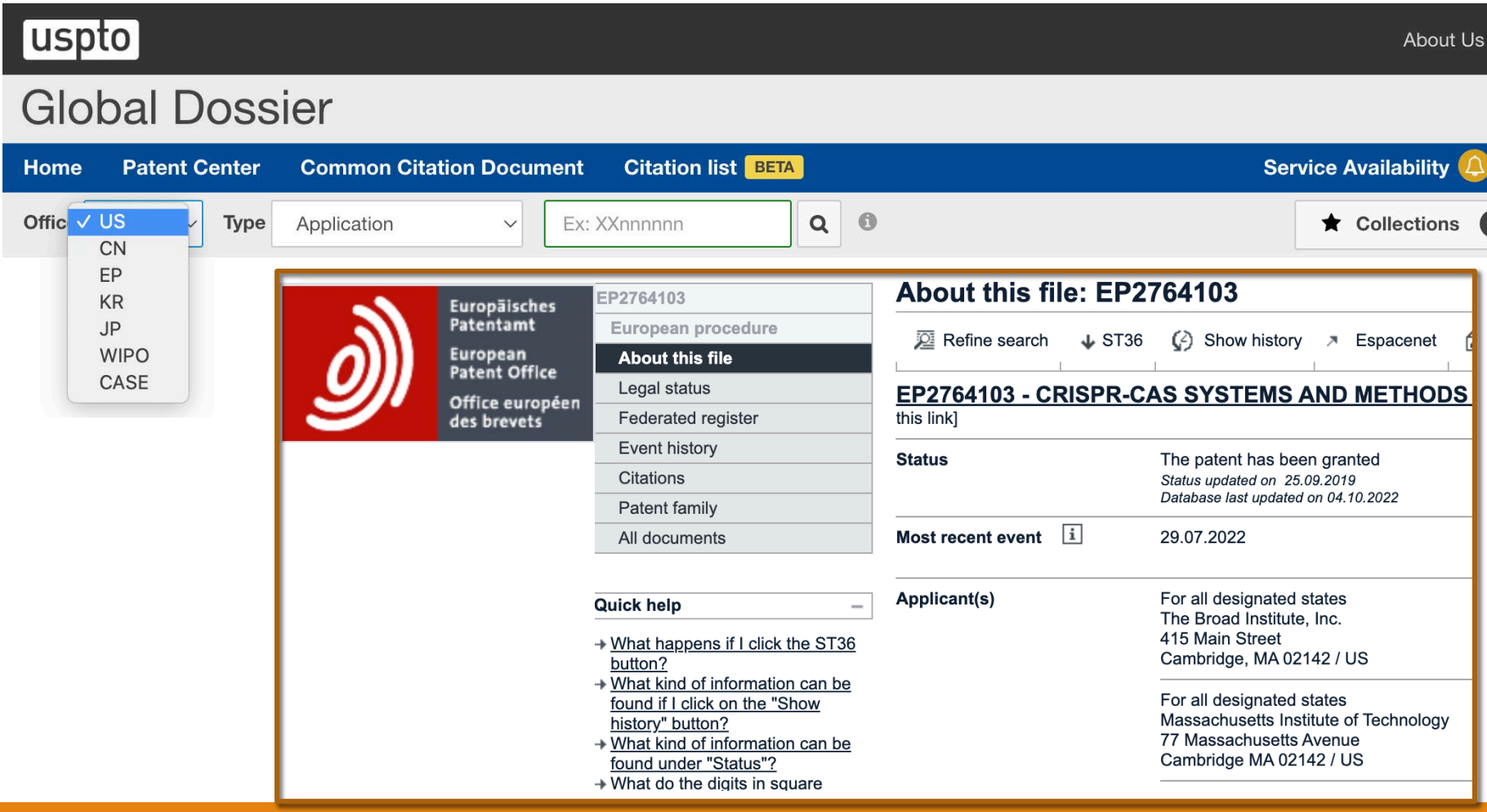
PATINFO SEARCH BASICS: Legal PatInfo (1)

- This type of search requires some basic knowledge of patenting process, in general and for main patent offices:
  - ✓ Concepts of patent family, patentability, formal & substantive examination, post-filing/publication/grant events & documents
  - ✓ Relevant dates, fees, and obligations that affect examination and legal effects of patent proceedings
  - ✓ How finding and extracting relevant documents from patent office website (where possible)

- Main issues that make Legal PatInfo searches difficult :
  - ✓ Legal understanding requires the support of patent attorney(s)
  - ✓ Several, large documents searchable by type/title and not content (requiring the use of effective PDF converting software)
  - ✓ Non-English texts and difference in patent proceedings, dates, fees among patent offices (also evolving over the time)
  - ✓ Uneven completeness, update, searchability of Information as made available by patent offices in their website

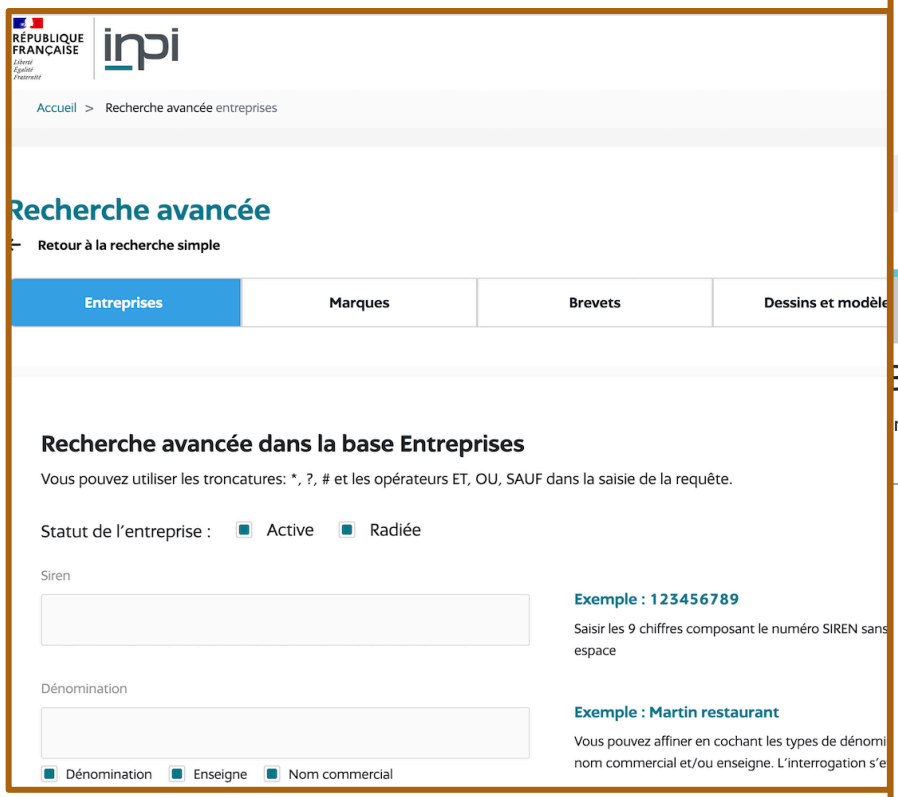
PATINFO SEARCH BASICS: Legal PatInfo (2)

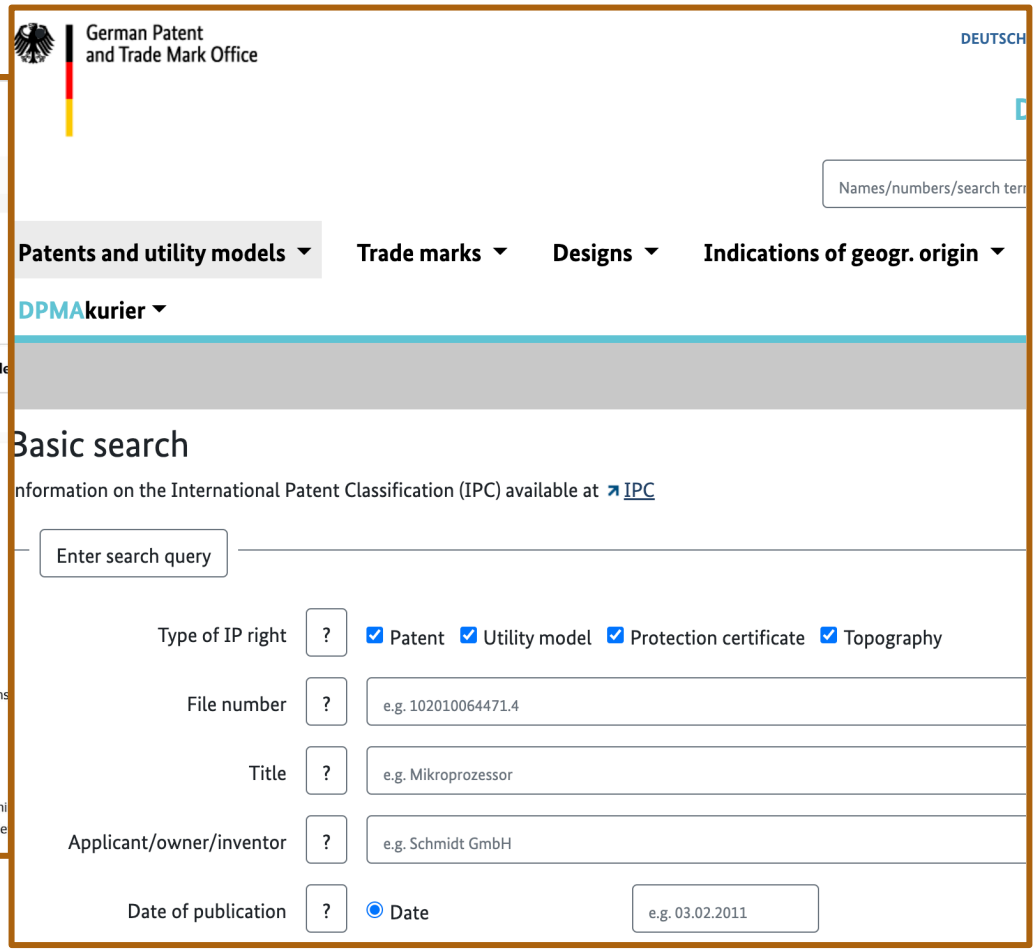
- A few official websites provide users with multi-jurisdiction access to parallel patent but findings need to be cross-checked at each patent office, in order to avoid major errors that would affect conclusions



PATINFO SEARCH BASICS: Legal PatInfo (3)

- Exemplary websites for national patent registries may be French and German ones, with several search criteria & English-based access





PATINFO SEARCH BASICS: Legal PatInfo (4)

- The Italian patent register is (slowly) improving

PATINFO SEARCH BASICS: Commercial PatInfo

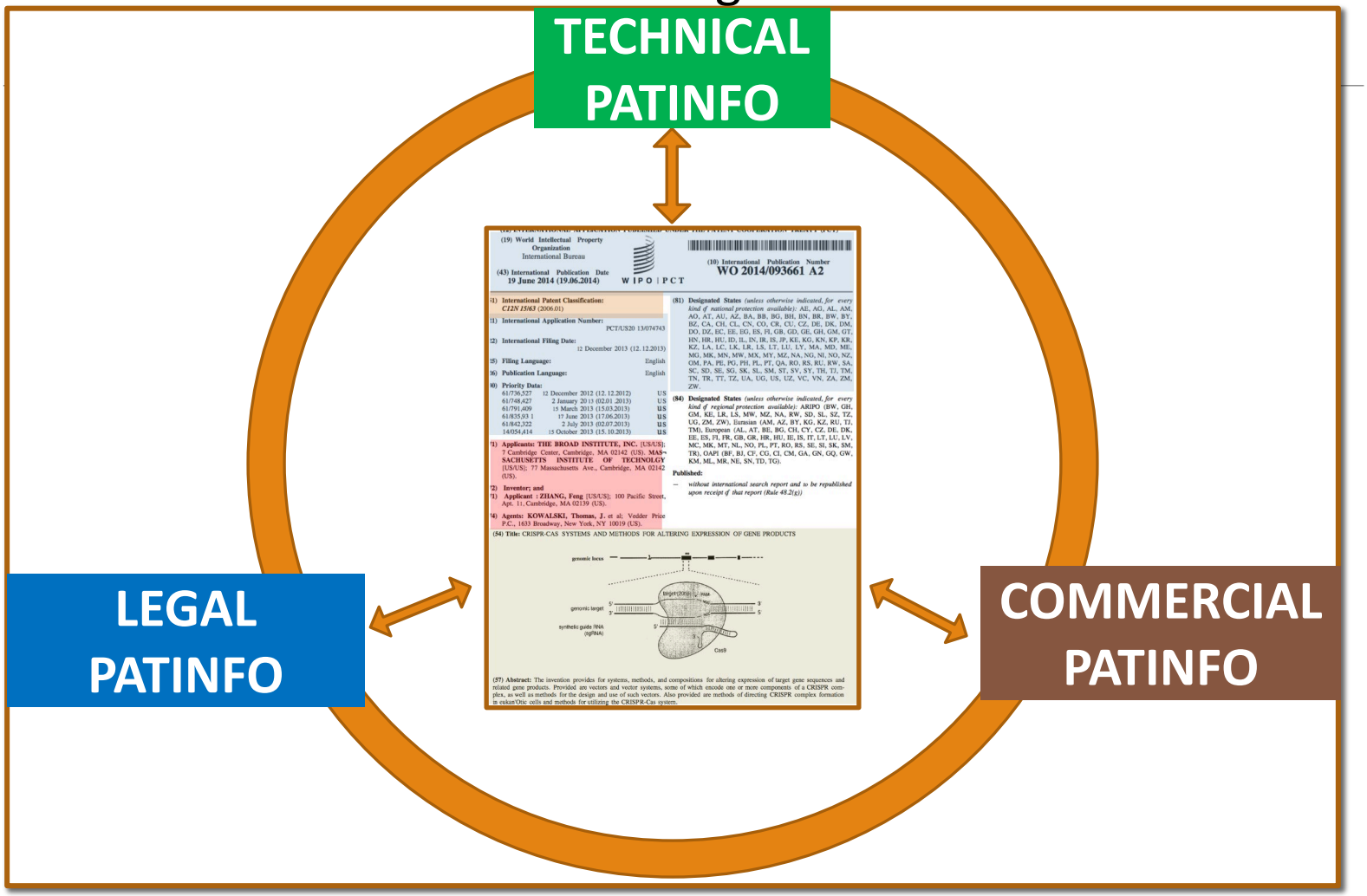
- Assigning correctly the relationship between one or more entities and specific patent rights may be difficult for several reasons:
  - ✓ Undisclosed contractual relationships among the entities about control, exclusivity, cross-licensing, exploitation of patent rights
  - ✓ Individuals actually acting as “strawmen” for companies
  - ✓ Potential legal/commercial differences among jurisdictions, branches
  - ✓ Uneven content and obligation of official patent registers

(Co-) Applicant Patentee Assignee Licensor Licensee Infringer Opponent

- Potential solutions that facilitate Commercial PatInfo searches:
  - ✓ Make the best use of Technical and Legal PatInfo searches for extracting relevant names
  - ✓ Check such names across databases and jurisdictions
  - ✓ Make searches in “alternative” sources of PatInfo such as company websites, scientific information, Linkedin/Twitter webpages, documentation filed for financial reasons that are required to be disclosed to the public, or by using Google Advanced Search features

PATINFO SEARCH BASICS: A global view of PatInfo

- The patent application or the granted patent is at the centre of a network of information each having own relevance and features



COFFEE BREAK

PATINFO DATABASES: Overview (1)

- The websites of main (inter)national authorities provide any user with a large amount of PI and tools for competitive intelligence:
  - ✓ Databases easier to search at no cost, access to PDF files
  - ✓ Guidance through webinars, fact sheets, FAQ sections, etc.
  - ✓ Access to laws, courts decisions, examination proceedings

- Basic criteria for choosing & using PatInfo databases:
  - ✓ Complexity of search strategies, downloading features
  - ✓ Coverage (how often it is updated and how far it goes in the past)
  - ✓ Overall usability (in saving / combining searches and PatInfo details)
  - ✓ Search language that allow combining ranges, variants, operators
  - ✓ Access to original/readable PDF and identification of keyword context
  - ✓ Means to analyze, categorize, pre-select the search hits

- Intermediation through nationally authorized representatives is needed for:
  - ✓ Patent drafting, filing & examination, fee payments
  - ✓ Interpretation of national/International law effects
  - ✓ The overall patent strategy with respect to competitors

PATINFO DATABASES: Overview (2)

- The listed basic criteria are intended for improving recall & precision and optimize the search according to its scope and the different PatInfo formats that can be exploited and combined effectively in a given domain:
  - ✓ Text-/table-based
  - ✓ Relevant dates & names
  - ✓ Patent Classification codes
  - ✓ Graphs, photographs, drawings
  - ✓ Biological sequences & chemical structures

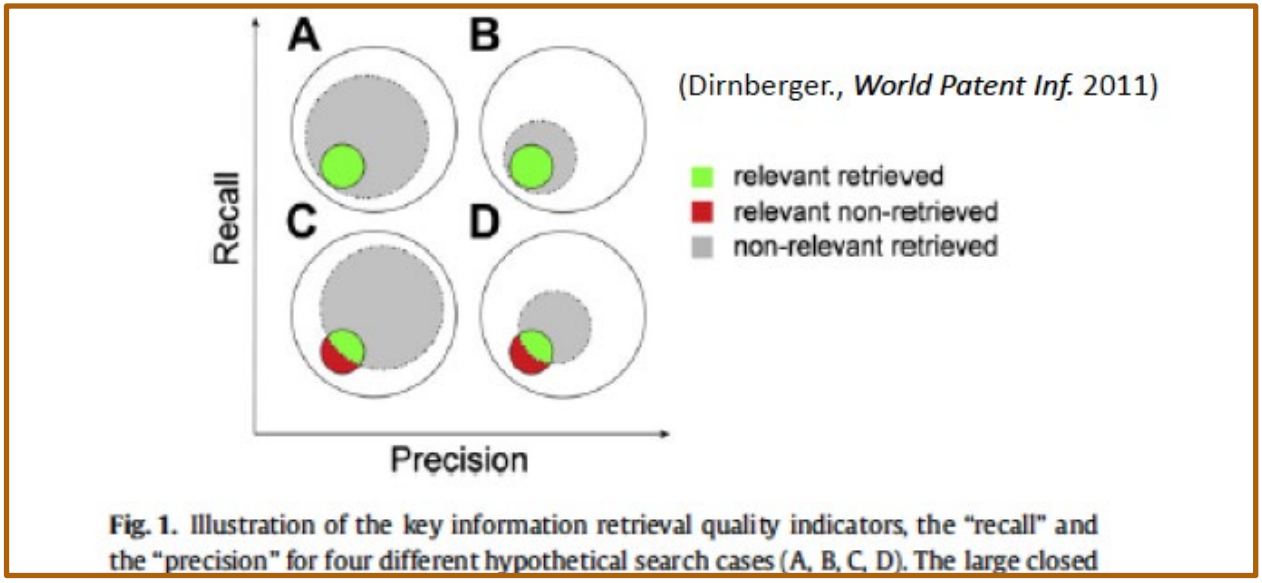
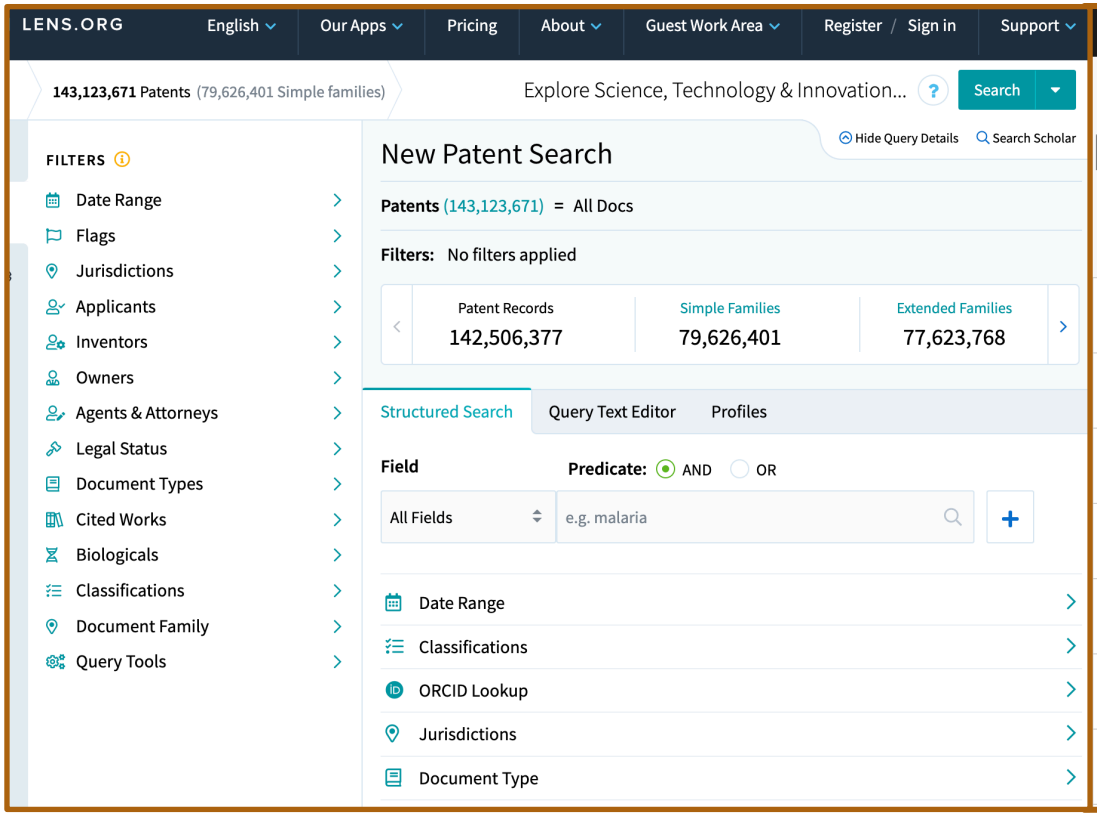
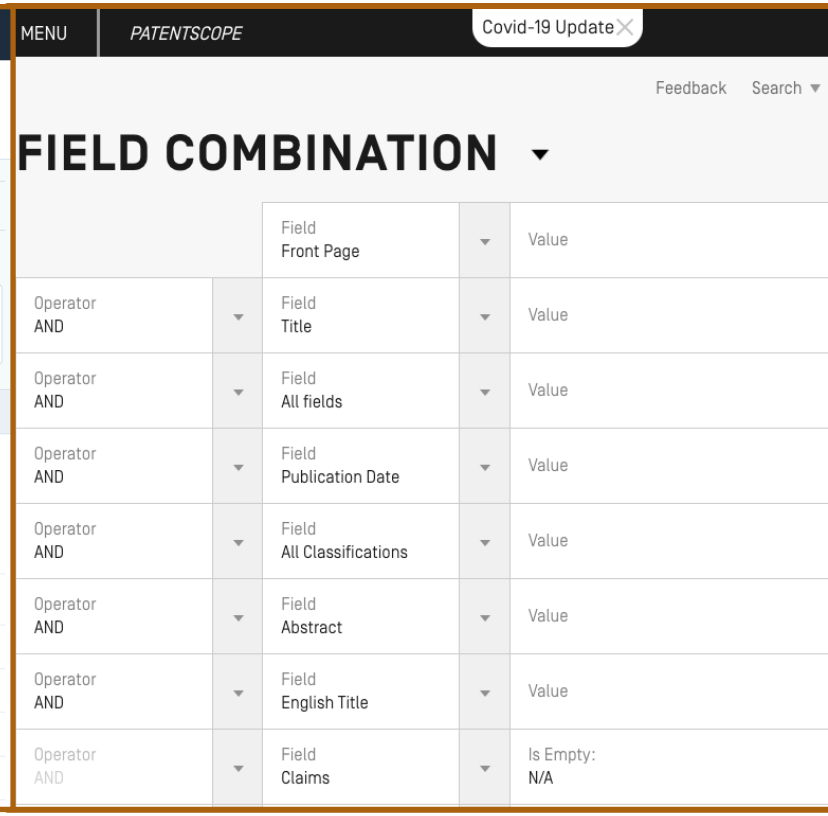


Fig. 1. Illustration of the key information retrieval quality indicators, the "recall" and the "precision" for four different hypothetical search cases (A, B, C, D). The large closed

PATINFO DATABASES: PatentScope & Lens (1)

- Patentscope & Lens appear as outstanding PatInfo source for most users
- Though, it remains important to compare the different search results using different search strategies and PatInfo databases





PATINFO DATABASES: PatentScope & Lens (2)

- Common, useful features in Patentscope & Lens
  - ✓ Coverage of main patent offices (WO, EP, US) and beyond
  - ✓ Claim & full-text searching, using complex search syntax
  - ✓ Extensive choice of standard Legal/Commercial PatInfo criteria
  - ✓ Many data browsing/sorting/filtering criteria (also in claims)
  - ✓ Alerting and data export functions
  - ✓ Good analytical functions (within own workspace)
  - ✓ Good help files, regularly improved, webinars, and error checking
- Some free PatInfo database present uneven quality/interest
  - ✓ National Patent office are good for coverage, but uneven user-friendliness (e.g. limited search criteria, download features)
  - ✓ Google Patents have some nice search/viewing features but incomplete/unclear coverage for jurisdictions other than USA
- It remains important to compare the different search results using different search strategies and PatInfo databases

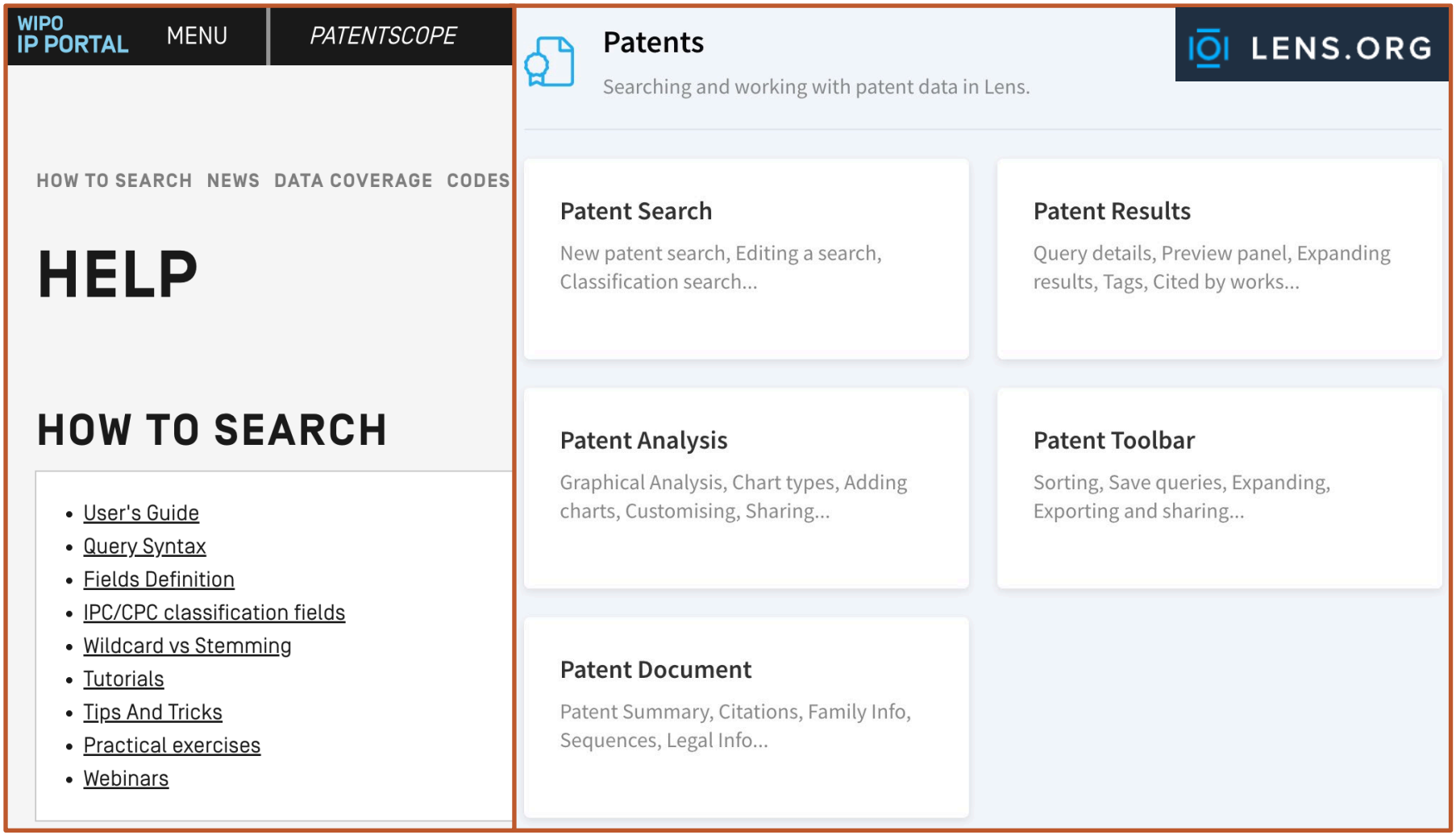
PATINFO DATABASES: PatentScope & Lens (3)

- Strength in Patentscope Vs. Lens
  - ✓ More regularly updated, more “old” & verified data
  - ✓ More precise procedural information with related links
  - ✓ Efficient online translation system
  - ✓ Simpler navigation across hits, clearer & cleaner views
  - ✓ Links & search features for chemical compounds

- Strength in Lens Vs. Patentscope
  - ✓ Better representation of patent families and of patent status
  - ✓ Direct access to readable PDF, more data downloadable as csv files
  - ✓ Title, abstract, claims, patent classifications in the same page
  - ✓ Links among patent & scientific documents (cited/citing)
  - ✓ Simpler way to add/modify criteria for focusing searches
  - ✓ Searches can be limited to granted patents only
  - ✓ Links & search features for DNA/protein sequences
  - ✓ Integration of CPC and criteria linking inventors, applicants, institutions

PATINFO DATABASES: PatentScope & Lens (4)

- Patentscope & Lens have detailed help files but different approaches

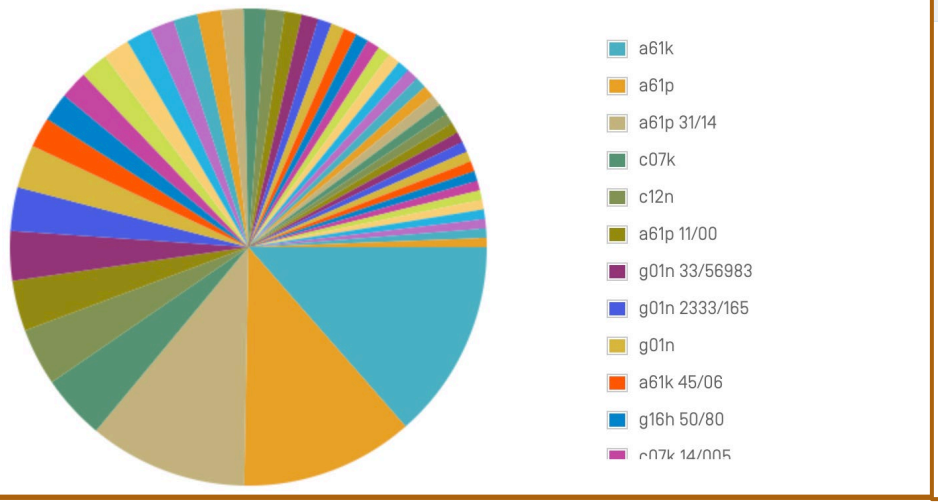


PATINFO DATABASES: PatentScope & Lens (5)

- Patentscope & Lens have different formats and functions for data analysis

WIPO IP PORTAL | MENU | *PATENTSCOPE* | HELP | EN_AB:(covid)

Countries		Applicants		IPC code		CPC code		Publication Dates		Filing Dates	
PCT	1,105	PFIZER INC	26	A61K	1,804	a61k	727	2020	549	2019	3
India	766	THE REGENTS OF THE UNIVERSITY OF CALIFORNIA	23	A61P	1,313	a61p	631	2021	1,821	2020	1,442
China	736			G01N	509	a61p 31/14	577	2022	1,435	2021	1,924
United States of America	586	INSERM (INSTITUT NATIONAL DE LA SANTÉ ET DE LA RECHERCHE MÉDICALE)	21	C07K	481	c07k	236			2022	409
Australia	156			C12N	444	c12n	209				
Russian Federation	108	LOVELY PROFESSIONAL UNIVERSITY	17	A61B	413	a61p 11/00	184				
				G16H	392	g01n 33/56983	180				
				G06Q	301						

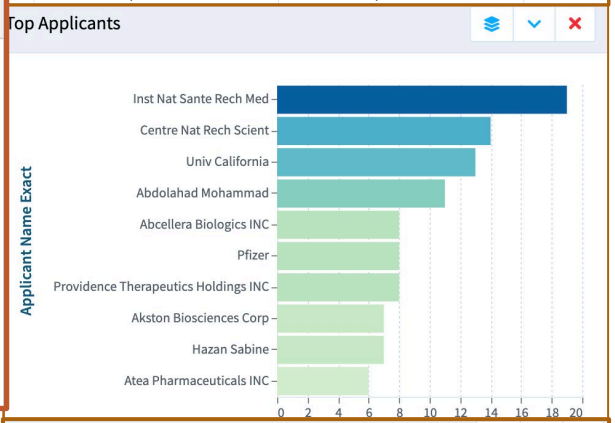


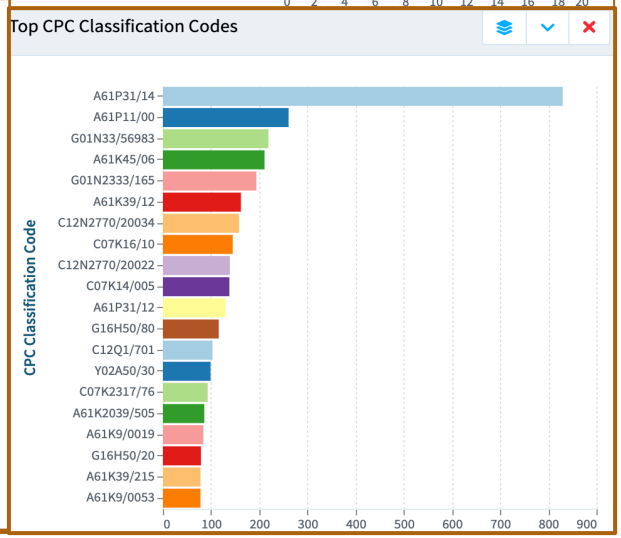
Patents (2,441) = Abstract: covid

Filters: No filters applied

LENS.ORG

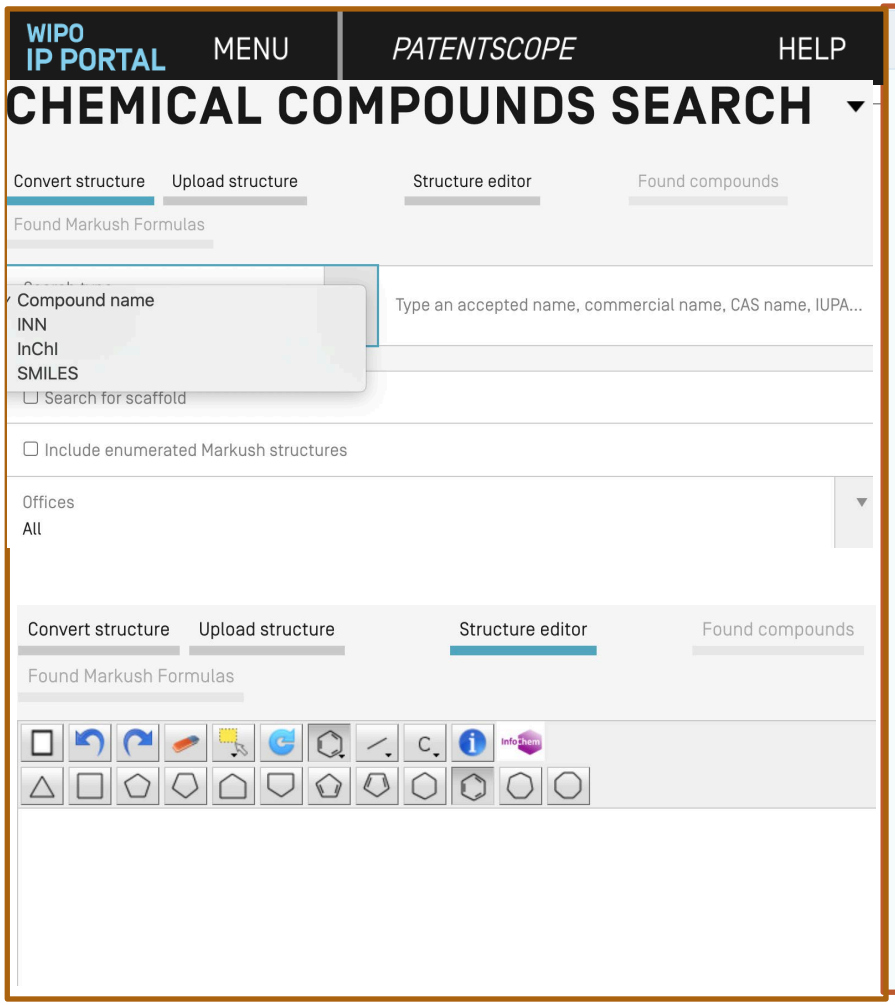
Patent Records	Simple Families	Exte
2,441	1,977	

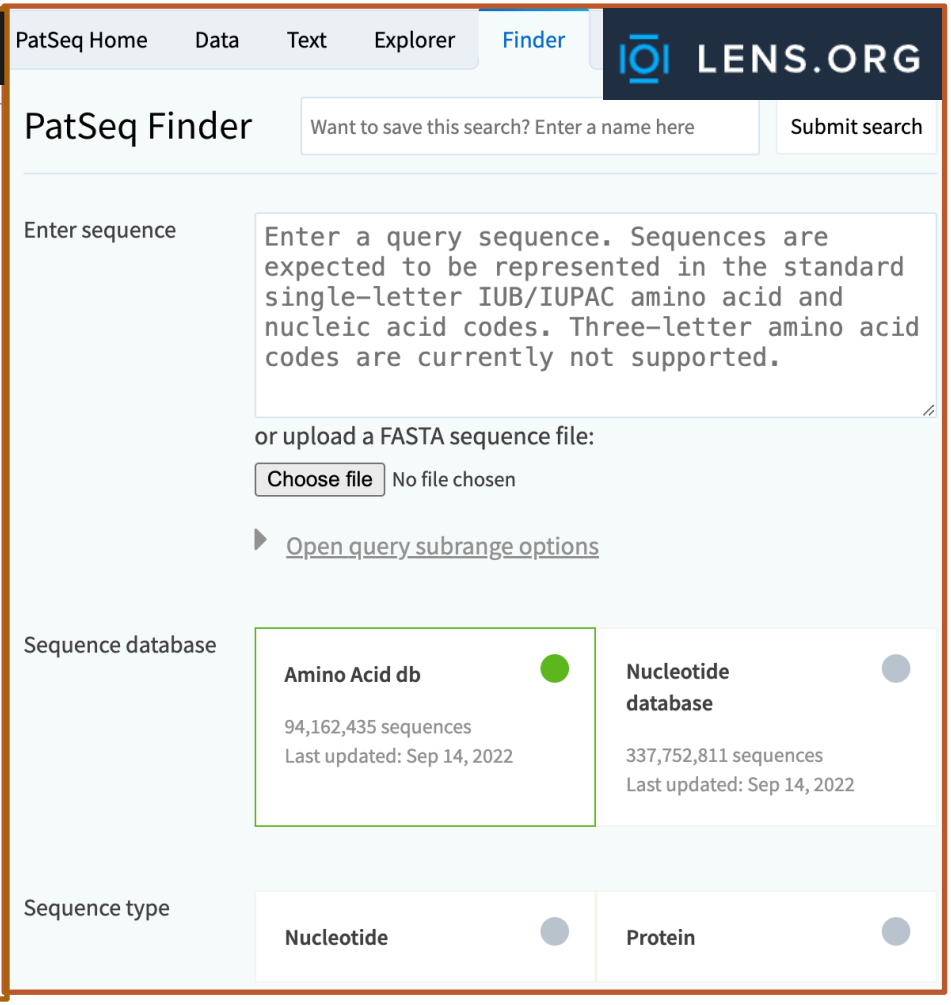




PATINFO DATABASES: PatentScope & Lens (6)

- Patentscope & Lens have different chemical & biologicals search features





PATINFO DATABASES: PatentScope & Lens (7)

- Patentscope & Lens have post-processing & analysis functions that are based upon the data export/analysis functions (e.g. saving csv/xls files, graphical representations, sorting & browsing), so that users can:
  - ✓ Review patent documents in a detailed manner, e.g. by exploiting links to other documents (Lens) or translation systems (Patentscope)
  - ✓ Focus on technical content & figures in the earliest (English) patent document for each patent family to compare search hits
  - ✓ Compare with scientific / commercial publications from same inventors/entity, integrating the content of pre- and post-filing publications (and maybe anticipating future patent filings)
- Patentscope & Lens help communicating and using PatInfo analysis with colleagues, management, external collaborators, investors, partners, etc.
  - ✓ Generating summaries with links to PDF of cited search hits
  - ✓ Identifying criteria and frequency for repeating the search within both patent & scientific literature

PATINFO DATABASES: PatentScope & Lens (8)

- Each of Patentscope & Lens have different way to extract, export and summarize the results of a srch

WIPO IP PORTAL MENU | PATENTSCOPE HELP

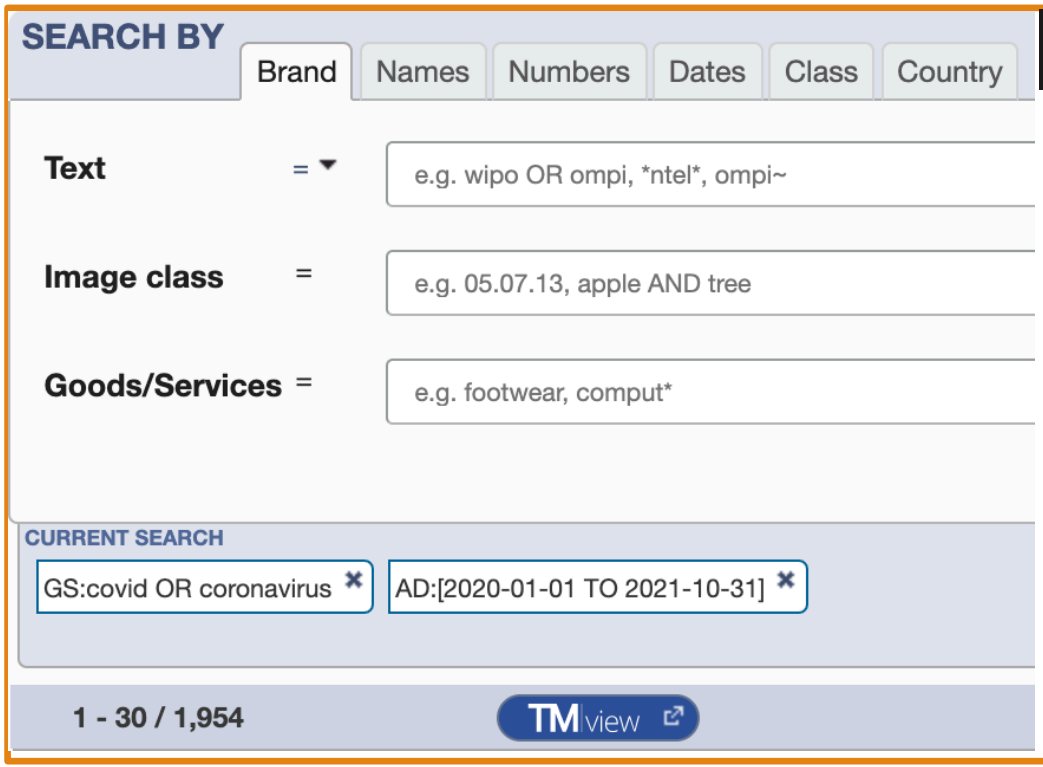
Application Id	Application Number	Application Date	Publication Date	Country	Title	Abstract	I P C	Applicants
WO2022122883	PCT/EP2021/084929	09.12.2021	16.06.2022	WO	LYSOSOMAL ACID LIPASE VARIANTS AND USES THEREOF	The present invention relates to variants of lysosomal acid lipase (LAL) and uses thereof.	C12N 9/20	GENETHON; INSERM (INSTITUT NATIONAL DE LA SANTÉ ET DE LA RECHERCHE MÉDICALE); UNIVERSITE D'EVRY VAL D'ESSONNE; UNIVERSITE
WO2022122733	PCT/EP2021/084602	07.12.2021	16.06.2022	WO	NEW GENE THERAPY FOR THE TREATMENT OF DUCHENNE MUSCULAR DYSTROPHY	The present invention concerns a method of treating Duchenne muscular dystrophy (DMD) in a human, comprising systemically administering by intravascular injection a gene therapy product that comprises an adeno-associated viral (AAV) vector of serotype 8, which harbors a nucleic acid sequence encoding a human ΔR4-R23/ΔCT microdystrophin.	A61K 48/00; A61P 21/00; C12N 15/86; A61K 38/17	GENETHON
WO2022069598	PCT/EP2021/076882	29.09.2021	07.04.2022	WO	ENHANCING UTROPHIN EXPRESSION IN CELL BY INDUCING MUTATIONS WITHIN UTROPHIN REGULATORY ELEMENTS AND THERAPEUTIC USE THEREOF	The invention relates to a composition for enhancing utrophin expression in cell by inducing mutations within a target sequence comprising a utrophin repressor binding site using a gene editing enzyme	C12N 15/113; C12N 15/11; A61K 31/7105	GENETHON; UNIVERSITE D'EVRY VAL D'ESSONNE; INSERM (INSTITUT NATIONAL DE LA SANTÉ ET DE LA RECHERCHE MÉDICALE)
WO2022053630	PCT/EP2021/074964	10.09.2021	17.03.2022	WO	PEPTIDE-MODIFIED AAV CAPSID	The invention relates to a peptide-modified AAV capsid with improved tropism, in particular increased muscle tropism and/or reduced liver tropism. The invention relates also to the derived recombinant AAV vector particle packaging a gene of interest, and its use in	C12N 7/00; A61K 48/00; C12N 15/864; C07K 14/015; C07K 14/005; C12N 15/86	GENETHON; INSERM (INSTITUT NATIONAL DE LA SANTÉ ET DE LA RECHERCHE MÉDICALE); UNIVERSITE D'EVRY VAL D'ESSONNE
WO2022043280	PCT/EP2021/073309	23.08.2021	03.03.2022	WO	C-TERMINAL TRUNCATED GDE FOR THE	The present invention relates to a functional C-terminal	C12N 9/10; C12N 9/44; A61K	GENETHON; INSERM (INSTITUT NATIONAL DE LA

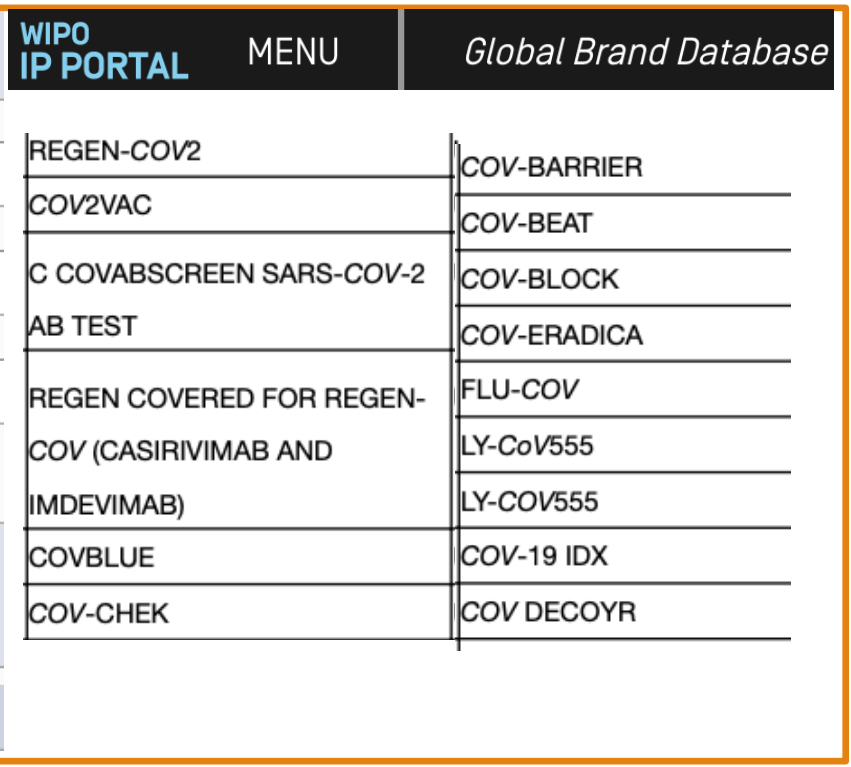
LENS.ORG

#	Jurisdiction	Kind	Display Key	Lens ID	Publication Date	Publication Year	Application Number	Application Date	Priority Numbers	Earliest Priority Dat	Title
584	ZA	B	ZA 202100202 B	024-491-775-064-051	26/01/2022	2022	ZA 202100202 A	12/01/2021	US 201862768731 P;;E	17/07/2018	COMPOSITIONS AND METHODS FOR INCREASING
262	ZA	B	ZA 201507315 B	097-719-788-072-436	30/05/2018	2018	ZA 201507315 A	02/10/2015	FR 1353306 A;;FR 201	11/04/2013	SELECTIVE GENE THERAPY EXPRESSION SYSTEM
591	WO	A1	WO 2022/122883 A1	074-015-683-488-486	16/06/2022	2022	EP 2021084929 W	09/12/2021	EP 20306524 A	09/12/2020	LYSOSOMAL ACID LIPASE VARIANTS AND USES TI
4	WO	A1	WO 2022/122733 A1	107-268-125-359-699	16/06/2022	2022	EP 2021084602 W	07/12/2021	US 202063122703 P	08/12/2020	NEW GENE THERAPY FOR THE TREATMENT OF DU
465	WO	A1	WO 2022/069598 A1	030-726-027-286-071	07/04/2022	2022	EP 2021076882 W	29/09/2021	EP 20306112 A	29/09/2020	ENHANCING UTROPHIN EXPRESSION IN CELL BY I
476	WO	A1	WO 2022/053630 A1	009-743-189-831-937	17/03/2022	2022	EP 2021074964 W	10/09/2021	EP 20306005 A	10/09/2020	PEPTIDE-MODIFIED AAV CAPSID
535	WO	A1	WO 2022/043280 A1	030-727-544-867-688	03/03/2022	2022	EP 2021073309 W	23/08/2021	EP 20192377 A	24/08/2020	C-TERMINAL TRUNCATED GDE FOR THE TREATMEN
522	WO	A1	WO 2022/008711 A1	198-507-008-957-469	13/01/2022	2022	EP 2021069133 W	09/07/2021	EP 20305796 A	10/07/2020	A NOVEL MUSCLE-SPECIFIC PROMOTER
539	WO	A1	WO 2022/003211 A1	087-311-486-345-409	06/01/2022	2022	EP 2021068553 W	05/07/2021	EP 20305757 A	03/07/2020	METHOD FOR ENGINEERING NOVEL HYBRID AAV C
509	WO	A3	WO 2021/255245 A3	047-487-690-865-389	10/02/2022	2022	EP 2021066626 W	18/06/2021	EP 20315308 A	19/06/2020	GENE THERAPY EXPRESSION SYSTEM ALLOWING
544	WO	A2	WO 2021/255245 A2	136-380-347-428-92X	23/12/2021	2021	EP 2021066626 W	18/06/2021	EP 20315308 A	19/06/2020	GENE THERAPY EXPRESSION SYSTEM ALLOWING

PATINFO DATABASES: Patent Vs. Trademarks (1)

- Trademark have distinct filing, grant, enforcement, and use compared to patents but companies worldwide may file “clusters” of trademarks around a product or a technology that are published even before the publication of the related patent applications,, as it happened for trademarks covering goods or services related to Covid or Coronavirus





PATINFO DATABASES: Patent Vs. Trademarks (2)

- Trademark filing history may anticipate the actual clinical development and marketing of the related goods or services even by several months

VAXZEVRIA

EUIPO Trademark

Name and address of the applicant
AstraZeneca UK Limited
1 Francis Crick Avenue, Cambridge Biomedical C
Cambridge CB2 0AA

Date of the registration
2021-04-01
(210)
Serial number of the application
018352979
(220)
Date of filing of the application
2020-12-11

5 Pharmaceutical preparations and substances.

COMIRNATY

EUIPO Trademark

Name and address of the applicant
BioNTech SE
An der Goldgrube 12
D-55131 Mainz
ALEMANIA

Date of the registration
2020-10-07
Serial number of the application
018247442
Date of filing of the application
2020-05-30

5 Vaccines for human use.

SOBERANA

EUIPO Trademark

Name and address of the applicant
INSTITUTO FINLAY DE VACUNAS
Avenida 21, Número 19810, entre 198 y 200
Atabey, Playa, La Habana 11600
CUBA

Date of the registration
2021-03-06
(210)
Serial number of the application
018315237
(220)
Date of filing of the application
2020-09-30

5
Pharmaceuticals; Vaccines.

SEARCH SCOPES & STRATEGIES: Introduction

- The occasional, non-professional user of patent information may take advantage of free patent searching websites to establish structured review of patent publications ("patent landscaping"):
  - ✓ Identifying the inventors/entities having the most technically relevant and/or intense patent activities in a given technical domain
  - ✓ Initial search input should be in the format of a selection of technical keywords related to products and relevant uses, and/or names of potential "target" authors, institutions, companies
  - ✓ Graphical representations (over time, grouping hits by different criteria) should be elaborated

- Ideally, an initial search should lead to the following outputs:
  - ✓ An xls file with basic details, possibly a more structured document for internal use (at best, even as basis for drafting a patent application or an article)
  - ✓ An optimized patent search strategy to be used as regular (monthly, quarterly) alerting system for new relevant hits

SEARCH SCOPES & STRATEGIES: Good Practices (1)

- Preparing the PatInfo search
  - ✓ Identifying synonyms/acronyms (even with common typos) and/or known inventors/applicant for relevant products/uses to be included in the search strategies
  - ✓ Making a first search in title/abstract and/or main English-publishing jurisdictions (WO/EP/US) to get as many as possible relevant criteria (applicants/inventors, keywords, patent classification codes)

- Performing the PatInfo search
  - ✓ Into both Lens & Patentscope (saving search strategies)
  - ✓ Applying various search criteria combinations (e.g. product keywords in title/abstract only, use keywords also in claims)
  - ✓ Being ready to adapt search criteria (e.g. extending search to citing/cited scientific & patent documents, including relevant names of applicant, inventors, and/or combining with recurrent IPC or CPC patent classification codes) before expanding the search in more jurisdictions and/or in other PatInfo databases

SEARCH SCOPES & STRATEGIES: Good Practices (2)

- Only the regular, professional user of patent information can start searching from free patent searching websites and then extending deeper searches into (non-)commercial database to perform the most complete & legal-/business-relevant searches:
  - ✓ Patentability of filed/granted claims (by a client or competitor)
  - ✓ Legal relevance of filed/granted claims by others for commercial exploitation of a (non-)patented product/method by the client (commonly named as "Freedom-to operate" searches), in particular for due diligence activities

- The results of these searches needs to be:
  - ✓ Evaluated by a patent attorney to evaluate risks/opportunities, and if any action is needed (e.g. trying to invalidate or negotiating the transfer or license-in/out of a patent family, re-considering the use of a technology or material, an experimental plan, or an investment)
  - ✓ Updated regularly, in view of own/competitors' activities, and compared with results obtained using alternative criteria

SEARCH SCOPES & STRATEGIES: Good Practices (3)

- The search strategies should also take into consideration both:
  - ✓ Nature of the invention and of the related means (in particular for chemicals and biologicals and their related medical uses)
  - ✓ The patent strategies ("Life Cycle Management) in a given domain

Entrepreneurial patent management in pharmaceutical startups

Marcus Holgersson[1], marhol@chalmers.se, Tai Phan[2] and Thomas Hedner[2]

PERSPECTIVE Drug Discovery Today • Volume 21, Number 7 • July 2016

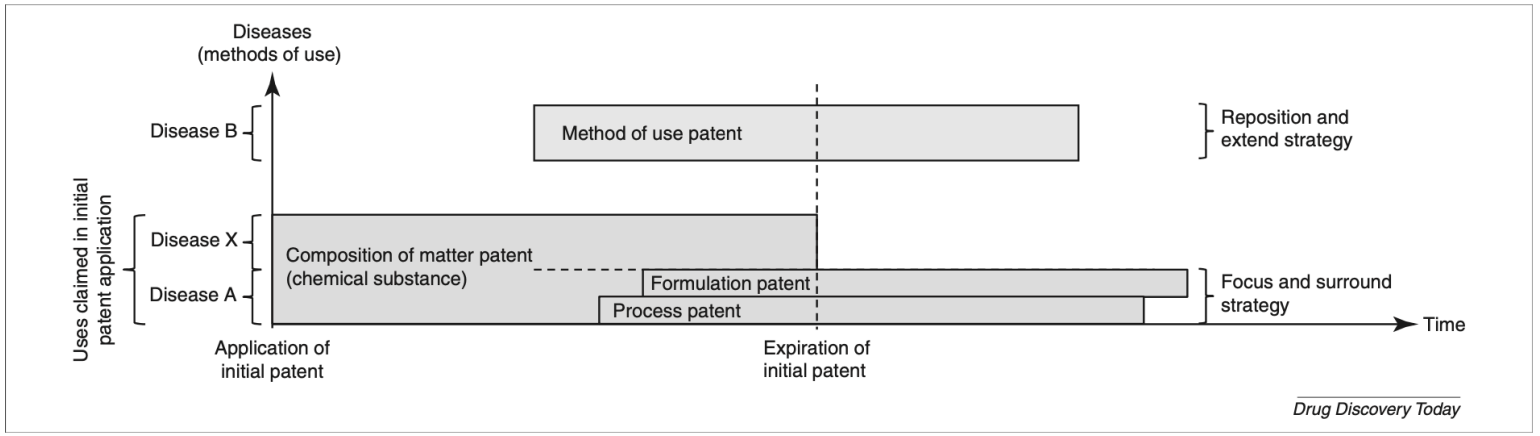


FIGURE 1

Examples of pharmaceutical patent strategies. In the focus and surround strategy an early broad patent of the chemical substance is complemented with formulation patents and process patents to strengthen and extend (in time) the patent protection related to the specific drug. In the reposition and extend strategy a new use for a previously known substance is protected by a method of use patent, thereby extending the protection time of the substance for that specific use.

SEARCH SCOPES & STRATEGIES: Categories (1)

Guidelines for Preparing Patent Landscape Reports

2015

Guidelines prepared for the

World Intellectual Property Organization (WIPO)

by Anthony Trippe, Patinformatics, LLC

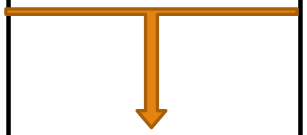
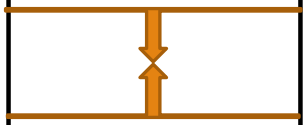
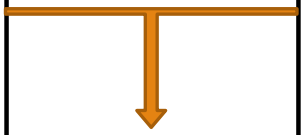
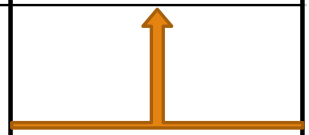
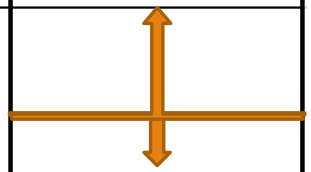
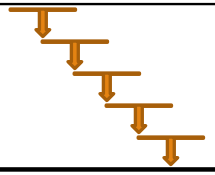
4.4. Publicly accessible supplementary information associated with patent applications
- 4.4.1. File wrappers and prosecution history
- 4.4.2. Maintenance information
- 4.4.3. Assignment information
- 4.4.4. Litigation
- 4.4.5. Patent Families

4.5. Sources of patent information
- 4.5.1. National Patent Offices
- 4.5.2. Free Online Sources
- 4.5.3. Commercial Sources

4.6. Reports associated with patent information
- 4.6.1. Landscape
- 4.6.2. Map
- 4.6.3. Watch or Alerts
- 4.6.4. Freedom-to-Operate / Clearance
- 4.6.5. Patentability / Prior-Art
- 4.6.6. Validity
- 4.6.7. General Statistics

5. Objectives and Motivations for Generating Patent Landscape Reports
- 5.1. Objectives behind Patent Landscape Reports
  - 5.1.1. To support governmental policy discussions
    - 5.1.1.1. Global Efforts
    - 5.1.1.2. Regional Efforts
    - 5.1.1.3. National Efforts
    - 5.1.1.4. Technology transfer and licensing
    - 5.1.1.5. Research and development decision making
  - 5.1.2. Business or corporate uses
    - 5.1.2.1. Competitor monitoring
    - 5.1.2.2. Technology monitoring
    - 5.1.2.3. Mergers and acquisitions
- 5.2. Motivations for generating Patent Landscape Reports
  - 5.2.1. Who is the report intended for?
  - 5.2.2. How does it save the client time?
  - 5.2.3. How does it add value to the decision making process?
  - 5.2.4. How will the user evaluate the effectiveness of the report?

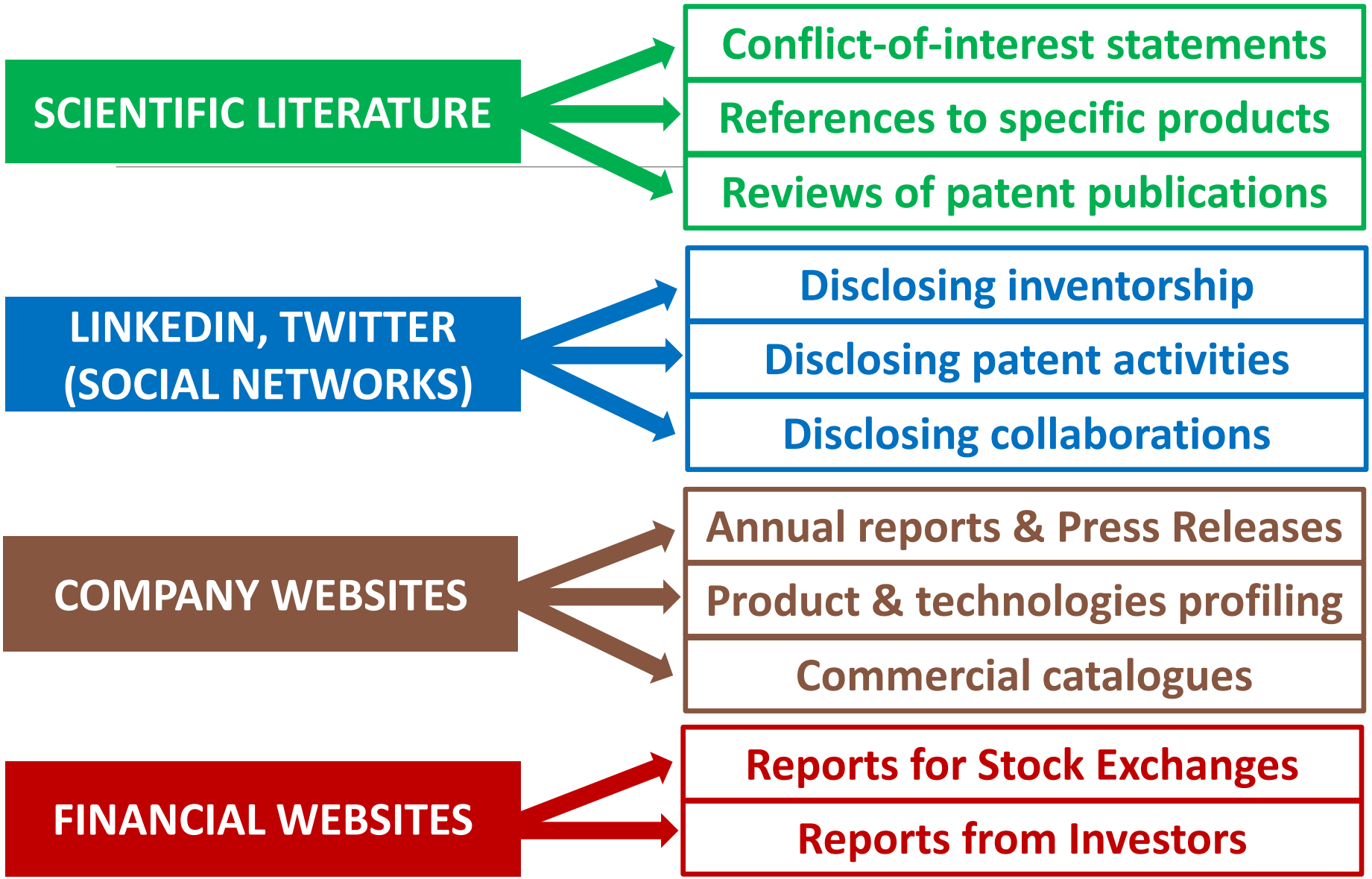
SEARCH SCOPES & STRATEGIES: Categories (2)

SEARCH TYPE	PATINFO TYPE			TIME RANGE
	TECHNICAL	LEGAL	COMMERCIAL	
Patent Landscaping	+++	+	++	
Patent Trends	+(++)	+(++)	+(++)	
Company Profiling	++(+)	+++	+++	
Patentability/ Validity	+++	+	+(+)	
Freedom-To-Operate	+++	+++	+++	
Patent Monitoring	+(++)	+(++)	+(++)	

ALTERNATIVE PATINFO: Introduction

- In general, companies, institutions, and investigators/inventors share a common interest in promoting their patent-related activities (and thus in disclosing PatInfo) with respect to:
  - ✓ Private investors, public funders (present or future)
  - ✓ Own organization, employees, collaborators
  - ✓ Technical/business competitors
  - ✓ Present/potential clients, competitors, licensees, licensors
  - ✓ Financial authorities requiring the fulfillment of legal obligations
- In biotech/pharma domain, these self-promotional activities are even more needed, and somehow common, given:
  - ✓ The complexity, time, and investments that are required to have a product/service validated before having any actual commercial activity
  - ✓ The expectations from stake/stockholders, authorities, competitors
  - ✓ The patent-related possibilities to get high levels of a market shares, return-on-investment, visibility, employment for a longer time.

ALTERNATIVE PATINFO: Main Categories



ALTERNATIVE PATINFO: Scientific literature (COI; 1)

- In recent years, main/most life sciences journals require authors to provide reviewers/readers with separate statements indicating if/how one or more authors have specific financial interest that may have affected the manner in which such publication has been drafted, but:
  - ✓ No real, effective control on the reviewer's/publisher's side
  - ✓ Uneven, poor guidance to authors about which personal/company interests should be considered as "conflicting" for scientific audience
  - ✓ Poor searchability in literature database, unless by reviewing the full-text article or journals that give access to this information as separate field in PubMed database (a growing but still limited practice)
- The actual frequency of Technical/Legal/Commercial PatInfo within Conflict-of-interest (COI) statement is hard to be evaluated precisely and systematically but COVID emergency has prompted both authors and publishers to be more proactive and precise in their role as discloser

ALTERNATIVE PATINFO: Scientific literature (COI; 2)

- The COI declaration of competing interest may be used to "mine" or anticipate patent filings still to be published, but content and format is not uniform, even in the same journal and/or in articles from same authors
- Such declaration from same authors may evolve, and still useful if no patent-related COI is present

NATURE COMMUNICATIONS | (2020)11:6121 | https://doi.org/10.1038/s41467-020-19819-1

Development of a multi-antigenic SARS-CoV-2 vaccine candidate using a synthetic poxvirus platform

Flavia Chiuppesi[1], Marcela d'Alincourt Salazar[1], Heidi Contreras[1], Vu H. Nguyen[1], Joy Martinez[1],

Competing interests

Funds were allocated to Don J. Diamond by the City of Hope (COH) for research that resulted in the development of multi-antigenic SARS-CoV-2 vaccine using a synthetic poxvirus platform discussed in this publication. While unknown whether publication of this report will aid in receiving grants and contracts, it is possible that this publication will be of benefit to COH. COH had no role in the conceptualization, design, data collection, analysis, decision to publish, or preparation of the manuscript. Don J. Diamond is a co-inventor on two patent applications that were submitted by COH to the USPTO prior to submission of this manuscript for consideration at Nature Communications. Both patent applications are in provisional status and have not yet converted to utility applications that have an official USPTO application number. One patent application covers the design and construction of the synthetic MVA platform, and another patent application covers the development of a COVID-19 vaccine. Felix Wussow is a co-inventor of the same two provisional patent applications that apply to Don J. Diamond.

Approaches and Challenges in SARS-CoV-2 Vaccine Development

Gabriel Dagotto,[1,2,5] Jingyou Yu,[1,2,5] and Dan H. Barouch[1,2,3,4,*]

DECLARATION OF INTERESTS

Correspondence and requests for materials should be addressed to D.H.B. (dbarouch@bidmc.harvard.edu). D.H.B. is a co-inventor on provisional vaccine patents (62/969,008; 62/994,630) that have been licensed.

NATURE COMMUNICATIONS | (2020)11:5413 | https://doi.org/10.1038/s41467-020-19231-9 |

Structural basis for potent neutralization of SARS-CoV-2 and role of antibody affinity maturation

Nicholas K. Hurlburt[1], Emilie Seydoux[1], Yu-Hsin Wan[1], Venkata Viswanadh Edara[2], Andrew B. Stuart[1], Junli Feng[1], Mehul S. Suthar[2], Andrew T. McGuire[1,3], Leonidas Stamatatos[1,3] & Marie Pancera[1,4]✉

Competing interests

The authors declare no competing interests. A provisional patent application (U.S. Provisional Application number 63/016268) has been filed on the SARS-CoV-2-specific monoclonal antibodies isolated herein.

ALTERNATIVE PATINFO: Scientific literature (COI; 3)

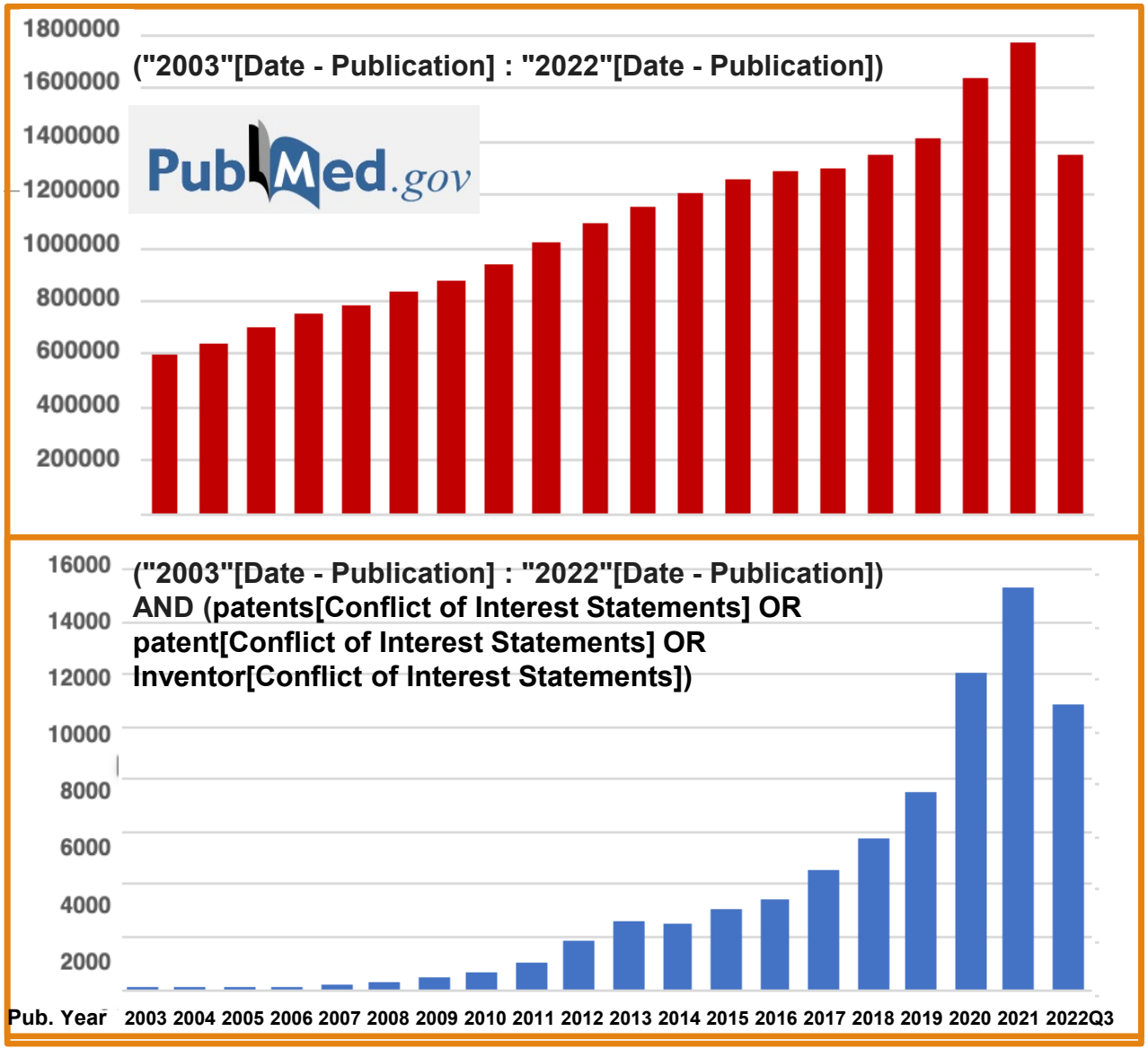
- This type of "hidden" patent disclosure are relatively frequent in COVID articles, especially in some high profile journals or preprint servers

Top 10 journals for COVID articles (WHO Covid-19 global literature database; Sept. 2021)	
MedRxiv	14876
SSRN	5081
BioRxiv	4439
British Med. Jour.	2693
PLoS One	2430
Sustainability	1519
Am. J. Resp. Crit. Care Med.	1419
Cureus	1271
Scientific Reports	1200
J Med Virol	1160

Top 10 journals for COVID articles with PatInfo-disclosing COI (own data; Sept. 2021)	
BioRxiv	94
Nature Communications	50
Cell	40
Nature	34
MedRxiv	29
Scientific Reports	25
Science	21
Cell Reports	18
Immunity	17
PLoS One	17

ALTERNATIVE PATINFO: Scientific literature (COI; 4)

- The PubMed records that are indexed with patent-related issues in the COI statements is still a minority (<1%) but increasing

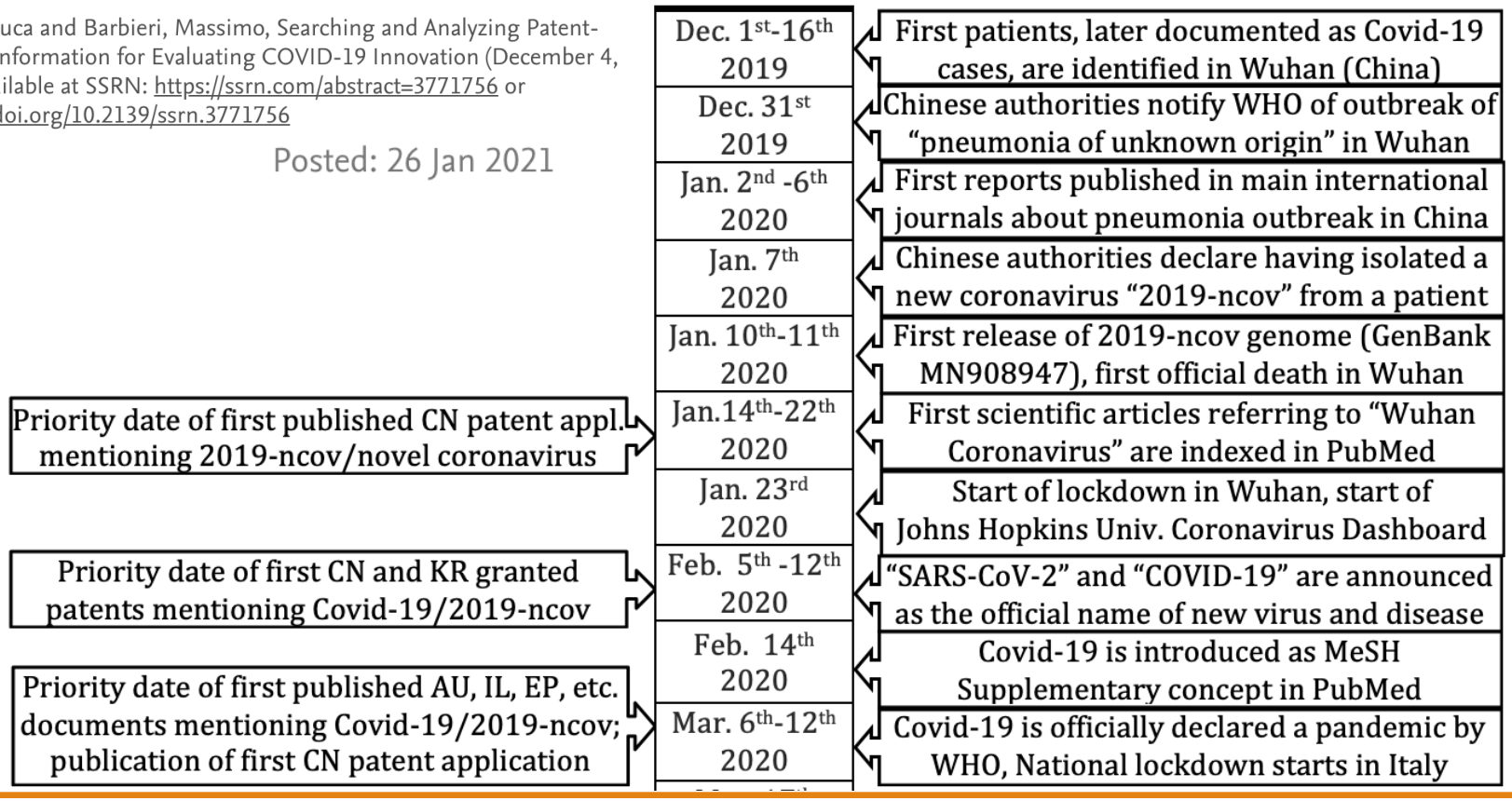


ALTERNATIVE PATINFO: Scientific literature (COI; 5)

- Relevant PatInfo in a publication (in COI statement or elsewhere) may be aligned with events during the early days of pandemic, showing the "reactivity" of applicants, at least in some countries (to be considered for future searches)

Falciola, Luca and Barbieri, Massimo, Searching and Analyzing Patent-Relevant Information for Evaluating COVID-19 Innovation (December 4, 2020). Available at SSRN: https://ssrn.com/abstract=3771756 or http://dx.doi.org/10.2139/ssrn.3771756

Posted: 26 Jan 2021



ALTERNATIVE PATINFO: Scientific literature (COI; 6)

(10) International Publication Number
WO 2021/045836 A1

(43) International Publication Date
11 March 2021 (11.03.2021)

(22) International Filing Date:
25 June 2020 (25.06.2020)

(30) Priority Data:

63/004,312	02 April 2020 (02.04.2020)	US
63/014,687	23 April 2020 (23.04.2020)	US
63/025,949	15 May 2020 (15.05.2020)	US
63/034,865	04 June 2020 (04.06.2020)	US

(71) Applicant: REGENERON PHARMACEUTICALS,

ANTI-SARS-COV-2-SPIKE GLYCOPROTEIN ANTIBODIES AND ANTIGEN-BINDING FRAGMENTS

> Science. 2020 Aug 21;369(6506):1010-1014.
doi: 10.1126/science.abd0827. Epub 2020 Jun 15

Studies in humanized mice and convalescent humans yield a SARS-CoV-2 antibody cocktail

Competing interests: Regeneron authors own options and/or stock of the company. This work has been described in one or more pending provisional patent applications. G.C., W.O., A.J.M., N.S., G.D.Y., and C.A.K. are officers of Regeneron. **Data and materials availability:** The structure of SARS-CoV-2 RBD in complex with REGN10933 and REGN10987 Fabs has been deposited in Protein Data Bank

- How a US company, active in antibody-based therapeutics, has coordinated COVID scientific, R&D, patent filing activities

Apr. 2nd- Jun. 4th 2020 initial patent filings

↓

Jun. 15th 2020 first scientific publication

↓

Jun. 25th -Jul. 20th 2020 definitive PCT, US, European, Canadian, Singapore patent filings

↓

Sep. 25th 2020 grant of first US patent (first official patent publication)

↓

Mar. 11th 2021 Publication of PCT appl.

↓

Mar. 23th - Apr. 13th 2021 grant of two additional US patents (further US appl. already filed)

ALTERNATIVE PATINFO: Scientific literature (Content; 1

- In addition (or not) to PatInfo in COI statement, authors may refer to:
  - ✓ Materials or findings that come from patent documents (very rarely)
  - ✓ Data that are extracted and compared from patent databases with respect to a given product, technology, country, etc. (e.g. over time)

- Two main issues:
  - ✓ There are some journals that are specialized in publishing PatInfo analyses (as in the series "*Recent Patents in...*") but the quality of such articles is quite uneven (indeed, if an article is in a domain of interest, it may useful to have a look and extract inventors, companies, names of compounds, publication numbers, etc. to start PatInfo searches from)
  - ✓ Even more respected journals that publish articles reviewing PatInfo have unclear/inconsistent reviewing & acceptance criteria

NATURE BIOTECHNOLOGY VOLUME 35 NUMBER 3 MARCH 2017 210

Evidence of insufficient quality of reporting in patent landscapes in the life sciences

James A Smith, Zeeshaan Arshad, Hannah Thomas, Andrew J Carr & David A Brindley

Despite the importance of patent landscape analyses in the commercialization process for life science and healthcare technologies, the quality of reporting for patent landscapes published in academic journals is inadequate.

Patent documents are an exceptionally rich source of information that can and should be mined and analyzed for a number of purposes. (...). However, without adequate reporting, the full value of such analyses will not be realized, and even the most rigorous and elegant investigations may be limited in reach because they simply cannot be reproduced and critically evaluated.

ALTERNATIVE PATINFO: Scientific literature (content; 2

- Only a few articles (unfortunately) present PatInfo data with sufficient level of completeness and details about different entities and their activities

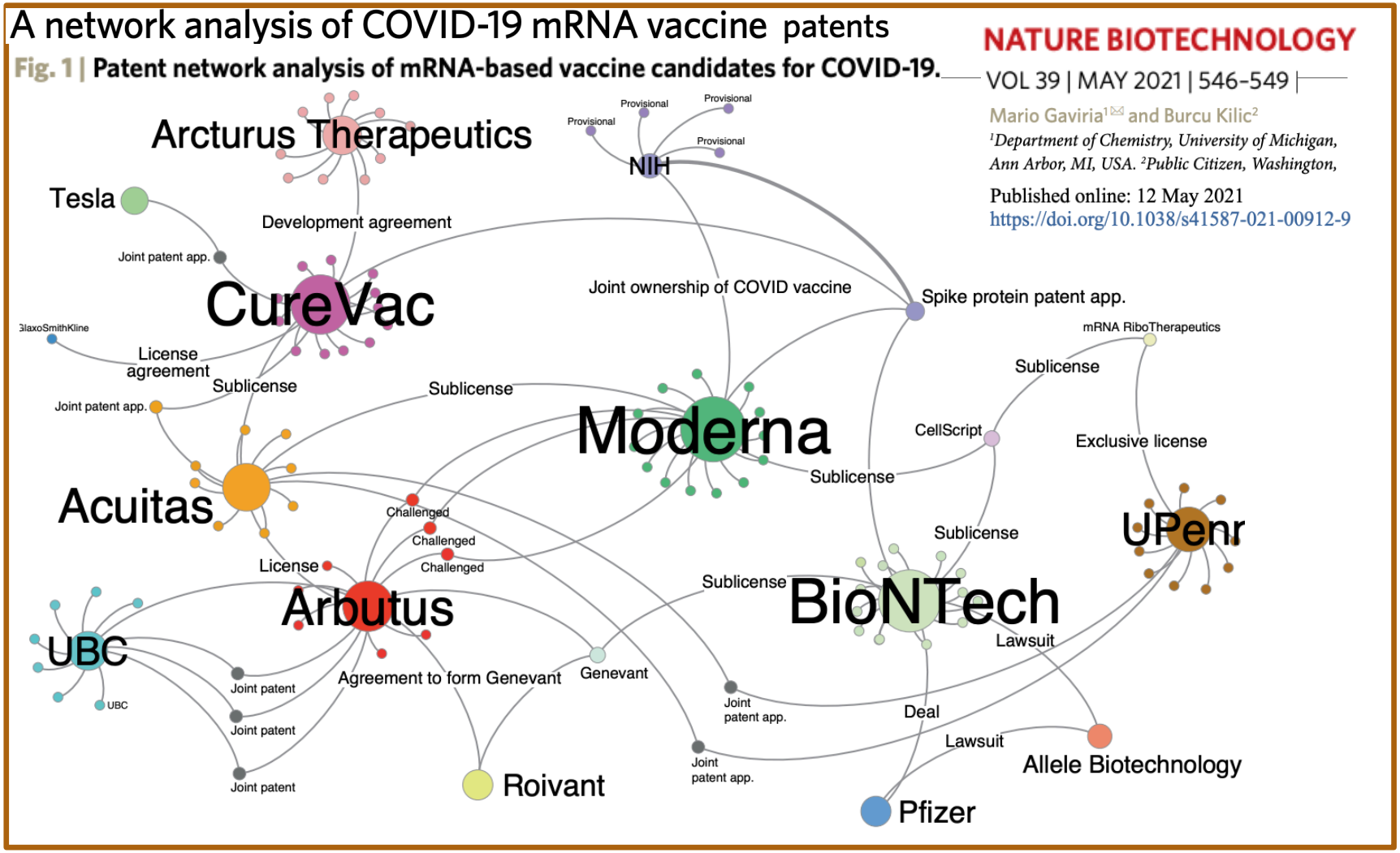
A network analysis of COVID-19 mRNA vaccine patents

NATURE BIOTECHNOLOGY
VOL 39 | MAY 2021 | 546–549

Mario Gaviria[1]✉ and Burcu Kilic[2]
[1]Department of Chemistry, University of Michigan, Ann Arbor, MI, USA. [2]Public Citizen, Washington,

Published online: 12 May 2021
https://doi.org/10.1038/s41587-021-00912-9

Fig. 1 | Patent network analysis of mRNA-based vaccine candidates for COVID-19.

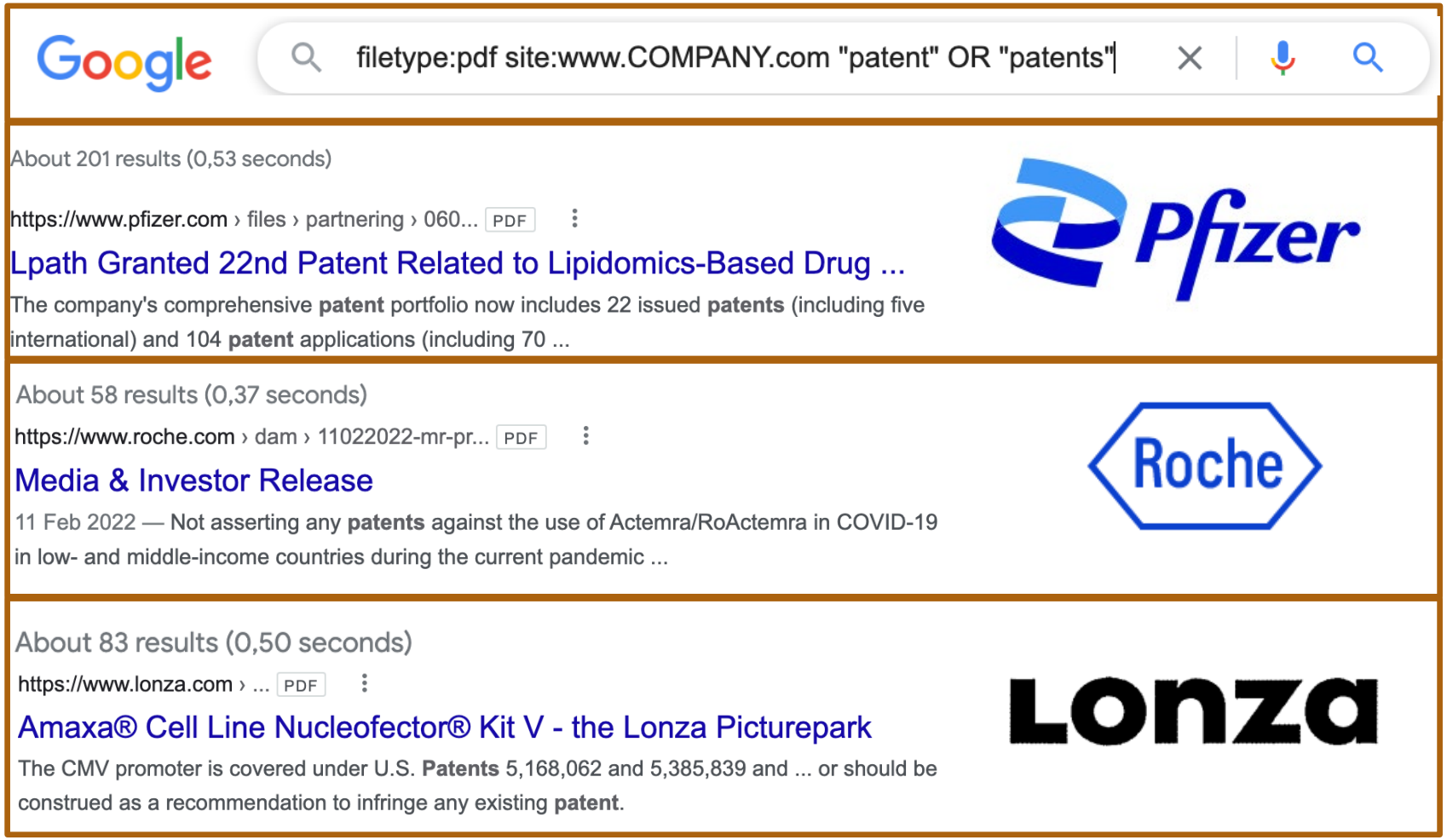


ALTERNATIVE PATINFO: Company websites

- The PatInfo quality and quantity within company or institutional website is extremely variable, due to several reasons:
  - ✓ Family business or company on US stock exchange market
  - ✓ Legal obligation or general practices at country level
  - ✓ Company policy about Intellectual Property, trade secret
- In addition to annual reports, many other documents can be found:
  - ✓ Product catalogs associating an item to pending/granted patents
  - ✓ Listing patent documents associated to a given technology
  - ✓ Press releases about patent granting, co-development/licensing agreements, having lost/won a patent lawsuit, etc.
  - ✓ Searchable listing of patent filings by country, technology, product
- If such PatInfo is not put in evidence within a dedicated section of the company/institution website, Google Advanced Search features can be your best friends

ALTERNATIVE PATINFO: Company websites

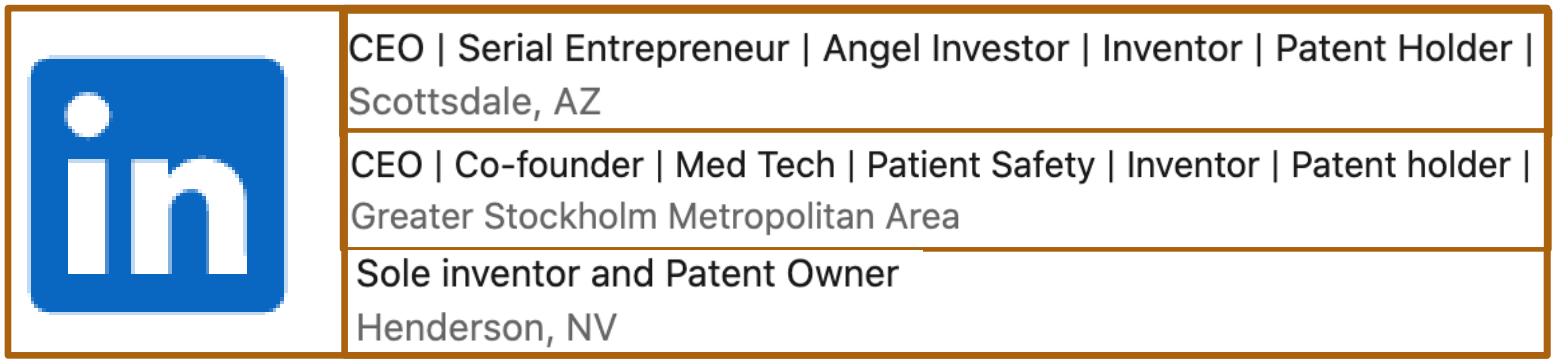
- The Google Advanced Search features allow search by date, type of page/file, but also within a website



ALTERNATIVE PATINFO: Social Networks

- As in any other domain, social networks have also changed the way people, companies, and institutions communicate also with respect to their patent-related activities, however:
  - ✓ At the level of companies and institutions, press releases and other communication including PatInfo that are published in the official website may be notified in the parallel social network accounts
  - ✓ At the level of specific person, references to inventorship or contribution to patent filings may be presented in own profile or post (even though the employer may not have been informed first) to promote own skills and achievements

- LinkedIn and Twitter profiles can be reviewed at this scope



ALTERNATIVE PATINFO: Financial & SEC documents (1

- Companies that raise funds for their development have to communicate regularly to present/future investors about achievements and next projects and sometimes such disclosures not only are made public but also may be more detailed than those in company website for instance:
  - ✓ When offering stocks and obligations through official authorities, such as SEC (Securities and Exchange Commission, USA) accounts
  - ✓ When profiled by analysts at investment banks, rating agencies, venture capital funds, etc. as potential target for (dis)investment
- The level and type of PatInfo details greatly varies from company to company from document to document, and from type of institutions reporting the information obtained directly from the companies but it may be interesting also to check for entities that are not actually object of the report but they collaborate, are licensor/licensee, or have other type of relationship the quoted company

ALTERNATIVE PATINFO: Financial & SEC documents (2

- Various advisory/investment entities publish reports including PatInfo that are collected by them through interviews, web searches, etc.

EDISON HEALTHCARE INSIGHT

Edison is an investment research and advisory company, with offices in North America, Europe, the Middle East and AsiaPac. The heart of Edison is our world renowned equity research platform and deep multi-sector expertise. At Edison Investment Research, our research is widely read by international investors,

Arovella Therapeutics (ALA)

INVESTMENT SUMMARY

Arovella Therapeutics (ALA) is a biotechnology company focused on developing therapies to treat cancer and conditions that affect the central nervous system. Its most advanced product is ZolpiMist, an oro-mucosal spray version of Ambien for the treatment of insomnia, which is partnered in certain regions with Teva and STADA Pharmaceuticals Australia. ALA recently in-licensed an invariant natural killer T (iNKT) cell therapy platform that can be used in conjunction with chimeric antigen receptors to target blood cancers. There are a number of potential benefits of CAR-iNKT, including the prospect of being an allogeneic 'off-the-shelf' therapy, significantly simplifying the manufacture of the therapy and its delivery to patients. In December 2021, ALA in-licensed patent rights for a monoclonal antibody that targets the Dickkopf-1 (DKK1) peptide, which is expressed in the tumour cells of multiple myeloma and other types of cancer. ALA plans to combine the DKK1 targeting

SymBio Pharmaceuticals (4582)

INVESTMENT SUMMARY

SymBio is a speciality pharma focused on Asia-Pacific markets and has the Japanese rights to multiple formulations of Treakisym (bendamustine). Treakisym iv was approved for r/r low-grade NHL/MCL in 2010, for CLL and first-line low-grade NHL/MCL in 2016 and for r/r DLBCL in 2021. SymBio has in-licensed liquid formulations for injection that will give Treakisym patent protection to 2031; a clinical trial is underway of the rapid-infusion liquid formulation. The company filed an IND in March 2021 to begin Phase II studies for the anti-viral drug brincidofovir (in-licensed from Chimerix) for pediatric adenovirus infections and received a fast track designation by the US FDA in April 2021.

Newron Pharmaceuticals (NWRN)

INVESTMENT SUMMARY

Newron is developing evenamide (30mg twice per day) as an add-on to treat poorly managed and resistant schizophrenia. A potentially pivotal Phase II/III study (008A) is underway and could report by Q422. Further US studies will be needed. Newron hopes to partner evenamide for larger indications and to sell the product directly for clozapine-resistance. H121 results showed Xadago royalties of €2.65m, up 6.5% versus H120. Newron had cash plus loan facilities at end June totalling €36.9m plus Xadago royalties to fund it into 2023.

INDUSTRY OUTLOOK

Xadago is marketed as an add-on to levodopa therapy in PD. It is sold by Zambon in Europe and by Supernus in the United States. The additional study on a dyskinesia indication should start in Q122 and could eventually boost US sales. Generic manufacturers have notified the FDA of their intention to file generic Xadago products. Newron is contesting these filings. After 2022, Xadago is protected by a set of patents, which expire no earlier than 2027 if upheld.

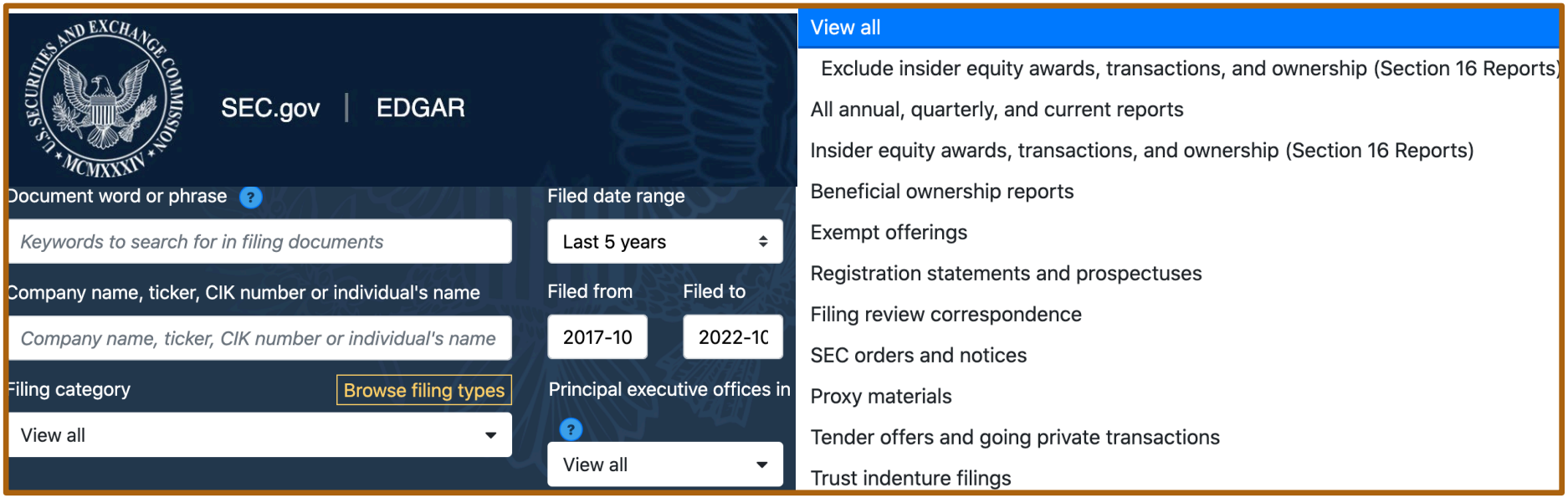
Medlab Clinical (MDC)

INVESTMENT SUMMARY

Medlab's proprietary platform, NanoCelle, is a patented nanomicellar formulation that can improve the delivery of drugs. Medlab's lead product is NanaBis, a combination of THC and CBD (1:1) cannabinoids encapsulated in NanoCelle particles, which enable a convenient buccal spray formulation. A recent breakthrough was Medlab's announcement that it had successfully produced a synthetic version of NanaBis, which will allow it to move away from

ALTERNATIVE PATINFO: Financial & SEC documents (3

- The SEC website has a particularly well-structured search engine for identifying documents filed by companies in US stock market
  - ✓ In addition to yearly/quarterly report, the disclosed documents may be also manufacturing, co-development, supply agreements having details on the management of background/foreground patent matters
  - ✓ However, the search may be time-consuming, in particular if document coding is not clear to the searcher



ALTERNATIVE PATINFO: Financial & SEC documents (4

UNITED STATES SECURITIES AND EXCHANGE COMMISSION FORM 20-F
ANNUAL REPORT for the fiscal year ended Dec. 31, 2020 (Mar. 31 2021)

Commission file number: 001-39081

BioNTech SE

Our **platform patent filings relevant to Our COVID-19 vaccine (BNT162b2),** collectively, the "BNT162b2 Platform Filings", include certain mRNA Structure Filings relating to features (…), including filings which **are jointly owned by BioNTech RNA and TRON ("*TRanslationale ONkologie Univ. Johannes Gutenberg- Universität Mainz gemeinnützige GmbH*")(…)** pending BNT162b2 Platform Filings, if issued, would have **20-year terms extending into the late-2020s to the early-2040s**.

We also have undertaken various **patent filings specifically related to BNT162b2** structure, composition, formulation, packaging, use and/or manufacture, or the BNT162b2 Platform Filings, including filings that have arisen through collaboration with third parties such as Pfizer. Such filings relevant to our COVID-19 vaccine, if issued, **would have 20-year terms that would extend into early 2040s**; there are presently no issued patents within the BNT162b2 Platform Filings.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION FORM 20-F
ANNUAL REPORT for the fiscal year ended Dec. 31, 2020 (Feb. 26th 2021)

moderna

We have built a substantial IP estate that includes numerous patents and patent applications related to the development and commercialization of mRNA vaccine and therapeutic development candidates, (…) our **solely-owned patent portfolio** consists of more than 145 issued or allowed U.S. patents or patent applications and more than 125 (…) patents in jurisdictions outside of the U.S. (..) have **expiry dates extending out to 2033 and at least 2041-2042** for (…) more recently filed patent applications.

We have filed **several patent applications covering our COVID-19 vaccine** (…) that include a PCT appl., two U.S. patent appl., 7 pending U.S. provisional patent appl., and patent applications filed in Argentina and Taiwan (..) filed **from Jan. through May 2020**. U.S. government has rights in certain of foregoing patent appl.. U.S. Patent No. (…) claims to lipid nanoparticle-encapsulated mRNA encoding betacoronavirus spike protein (...) also featured in a European patent appl. (…) filed in **October 2015**

ALTERNATIVE PATINFO: Financial & SEC documents (5

Exhibit 4.57

CONFIDENTIAL
Execution version

THE SYMBOL "[***]" DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

AMENDED & RESTATED
DEVELOPMENT AGREEMENT

This amended and restated development agreement (this ***Agreement***) is effective as of July 7, 2021 (the ***Effective Amendment Date***) and entered into by and between Sanofi, having a place of business at 54, rue La Boétie, 75008 Paris, France (***Sanofi***), and BioNTech RNA Pharmaceuticals GmbH, having a place of business at An der Goldgrube 12, 55131 Mainz, Germany (***Biontech***). Sanofi and Biontech shall each individually be referred to herein as a ***Party***, and shall be referred to together as the ***Parties***.

RECITALS

A. On November 2 nd, 2015, as amended by an amendment letter dated December 14th, 2017, the Parties entered into a Collaboration and License Agreement (the ***License Agreement***) with the desire to collaborate in the research, development and commercialization of RNA-based therapeutics for the treatment of cancer.

B. Under the License Agreement, a Mixture named Licensed Product #1 (as further defined below) has been approved by the Joint Steering Committee as a Licensed Product Candidate in accordance with Section 2.8 of the License Agreement.

4.10.2 The Parties shall [***] share [***] (i) the costs for preparing and filing (a) the Formulation Priority Application and any other priority patent application(s) filed within [***] of the Formulation Priority Application, (b) PCT application(s) claiming priority to the Formulation Priority Application, and (c) national/ regional stage entries of PCT application(s) claiming priority to the Formulation

Priority Application; and (ii) application filing fees for non-divisional application(s) filed in non-PCT contracting states that claim priority to the Formulation Priority Application ((i) and (ii) the ***Shared Formulation Patent Costs***). [***] Sanofi shall have the right (but not the obligation) to file and validate Formulation Patents in additional countries at its costs, in the name of Biontech. Except for the Shared Formulation Patent Costs, Sanofi shall bear the Prosecution and Maintenance costs of Formulation Patents for which it controls Prosecution and Maintenance pursuant to Section 4.2.3 above. Except for the Shared Formulation Patent Costs, Biontech shall bear the Prosecution and Maintenance costs for Formulation Patents for which it controls Prosecution and Maintenance.

4.11 Patent Enforcement

4.11.1 Each Party (***Enforcing Party***) shall have the first right (but not the obligation), at its sole discretion, to control the enforcement or otherwise abate the infringement of any Patent Rights Prosecuted and Maintained by it in accordance with Section 4.2 above. [***].

4.11.2 [***]

4.9 With respect to the Co-Development Patents and CMC Patents, each Party shall (a) provide the other Party with written notice reasonably in advance of: (i) any filing of such Patent Rights for which it controls the Prosecution and Maintenance pursuant to Section 4.2 above; and (ii) any other substantive submissions and correspondence to patent office(s) with respect to the Prosecution and Maintenance of such Patent Rights; (b) provide the other Party with any final drafts of any application for such Patent Right to be filed or such substantive submission or correspondence (such application, submissions and correspondence, the ***Patent Documentation***) reasonably in advance of its filing or submission and consider in good faith the incorporation of reasonable comments by the other Party thereon; (c) provide the other Party with a copy of all Patent Documentation once it has been filed or otherwise submitted; (d) provide the other Party with copies of any substantive communications received from patent office(s) with respect to such Patent Rights; (e) notify the other Party of any: (i) [***] and (f) provide the other Party with written notice as early as possible (in any event, no later than [***] prior to abandoning any such

6.6 Joint Patent Committee

6.6.1 Each Party shall designate [***] shall constitute the joint patent committee (***Joint Patent Committee***). Each Party may replace its Joint Patent Committee [***] upon notice to the other Party.

6.6.2 The Joint Patent Committee shall be responsible for:

(a) review and approval of Prosecution and Maintenance decisions regarding Formulation Patents as per Section 4.10.1;

(b) review and approval of Patent Documentation related to Formulation Patents as per Section 4.10.1;

(c) reconciliation of Shared Formulation Patent Costs.

6.6.3 [***]

CASE STUDY: Genethon & Telethon (introduction; 1)

- These two entities present themselves as promoting medical innovation also by transferring technologies and through licensing, promoting the use of patent protection in their own or funded activities

Telethon multi-round call for research projects 2021 – 2024

Telethon Grantees are required to ensure that the patentable results arising from Telethon-funded research projects are duly protected through the interaction and cooperation with their Host Institutions' Technology Transfer Office before any disclosure of said results, as this may facilitate the full realization of their translational potential. In light of the above, the Grantee expressly undertakes to communicate manuscripts and abstracts to the Technology Transfer Office (or other relevant office) of the Host Institution before submission for publication, to allow the necessary assessments on patentability and activities for protection through patent application filing or other intellectual property rights. Grantees and/or their Host Institutions must promptly inform Telethon via written communication of any new patent filings and execution of agreements with for-profit entities related to Telethon's funded research.

CASE STUDY: Genethon & Telethon (introduction; 2)

FONDAZIONE Telethon

Al via IAMA Therapeutics, che svilupperà un nuovo candidato farmaco per le disfunzioni del neurosviluppo

La startup nasce dall'esperienza decennale di due gruppi di ricerca dell'Istituto Italiano di Tecnologia (IIT) di Genova, quelli di "Brain Development and Disease e Molecular Modeling and Drug Discovery", guidati rispettivamente da Laura Cancedda e **Marco De Vivo**. Il lavoro del team, diretto dai due ricercatori e **supportato anche da Fondazione Telethon**, ha visto i primi risultati pubblicati sulla prestigiosa rivista "Nature Medicine" nel 2015. L'attività di ricerca in seguito è maturata nella scoperta del nuovo candidato farmaco che ha trovato spazio in un'altra importante pubblicazione su Chem nel 2020. Per le sue peculiarità IAMA-6 è stato quindi protetto da un **brevetto**, che vede coinvolti a fianco dell'IIT **anche Fondazione Telethon**, Università di Genova e Università di Bologna.

SEC.gov | EDGAR

COLLABORATIVE DEVELOPMENT AGREEMENT

No. 013135-1MTUB-00

This COLLABORATIVE DEVELOPMENT AGREEMENT (the "**Agreement**"), effective as of January 24, 2014 (the "**Effective Date**"), is made by and between Audentes Therapeutics, Inc., a Delaware corporation, having a place of business at 101 Montgomery Street, Suite 2650, San Francisco, CA 94104, USA ("**Audentes**") and Genethon, a French not-for-profit organization organised under the French law of July 1, 1901, having a principal place of business at 1bis rue de l'Internationale, 91002 EVRY Cedex, France ("**Genethon**").

4.1 Background Intellectual Property.

(a) Genethon hereby grants to Audentes a royalty-free, fully paid-up, worldwide, sublicenseable (through multiple tiers), exclusive (including as to Genethon) license under its Background Intellectual Property, for the sole purpose of making, using, importing, selling, offering for sale and otherwise discovering, researching, developing or commercializing Products. Notwithstanding the above, the license granted in this Section 4.1(a) shall be subject to the following:

(i) With respect to [*], the licenses granted to Audentes under this Section 4.1(a) shall be limited to Genethon's co-ownership share and subject to the rights of the co-owners identified in Exhibit D-1. The Parties agree that (a) Genethon shall [*], and (b) any co-ownership agreement Genethon may enter into with such co-owners shall [*] and (c) subject to the foregoing sub-clause (h), Audentes shall [*].

(ii) With respect to [*], the licenses granted to Audentes under this Section 4.1(a) shall be subject to the rights of the co-owner identified in Exhibit D-2, provided that Genethon shall use [*] efforts to [*].

(iii) With respect to [*], Genethon hereby grants to Audentes an option to obtain a sublicense under the terms set forth in Exhibit E under that certain Patent License Agreement entered into by Genethon with the United States Department of Health and Human Services (the "**HHS**") on June 22, 2012 (such agreement, a copy of which has been provided to Audentes subject to confidentiality obligations, the "**HHS Patent License Agreement**") for the sole purpose of making, using, importing, selling, offering for sale and otherwise discovering, researching, developing or commercializing Products following a technology transfer under Section 2.4(b) or 2.4(c); it being understood that such option to obtain a sublicense is subject to HHS's reasonable prior written approval in, accordance with Section 4.1 of the HHS Patent License Agreement. Audentes may exercise such option at any time following the Effective Date upon delivery of written notice to

CASE STUDY: Genethon & Telethon (introduction; 3)

- The PatInfo associated to two entities will be reviewed by making use of
  - ✓ Searches and tools in Patentscope & Lens
  - ✓ Additional data from other exemplary websites
  - ✓ Links to official patent documentation

- The PatInfo will be consolidated and represented using
  - ✓ Excel files
  - ✓ Standard/re-elaborated graphical representations

CASE STUDY: Genethon & Telethon

- For Technical/Legal PatInfo searching, enter in Google
  - ✓ Patentscope search
  - ✓ Lens search patent
  - ✓ Epo register search patent
  - ✓ Ipc patent search
  - ✓ Cpc patent search
  - ✓ Globaldossier search patent
  - ✓ UIBM search patent
  - ✓ Depatisnet search patent

- For Commercial PatInfo, enter in Google
  - ✓ pubmed advanced search
  - ✓ Globalbrand search
  - ✓ sec edgar search

Conclusions

For details about methodologies, data, graphics, and references presented today, please contact me at

LFALCIOLA@SCIBILIS.BE

LinkedIN (search luca falciola bruxelles patent)

THANKS FOR YOUR ATTENTION!