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AN INTRODUCTION TO PATENTS

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VENTURE CENTER

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Contents

1. **IP :** History, Origin and Motivation
2. **Invention**
3. **Patents**
4. **Case study**
5. **The Patent Cooperation Treaty (PCT)**

IP: History, Origin and Motivation

500 BCE : Greek
(Monopoly for a particular time period (1yr) over the creations)

257-180 BCE: Rome
A Roman architect and engineer (Vitruvius)
Judged-Literary contest-Exposed IP theft

1-100 BCE: Rome
Discussion on the Ownership Interest for IP Work (Roman Jurist)

Cont.

Year 1421

First Statute passed to protect rights in Florence, Italy: Right to inventors

Year 1474_Italy Statute

Inventors exclusive right to the creation
Incentive mechanism
Recognized right to inventors
Compensation for infringement
Time limit to the inventors right

Cont.

1561-1610 : English crown grant Monopolies
to exercise monopolies over manufacturing and trade of commodities

1624: Statute passed in England
14 years (New invention, Not in Public domain)

1790-US Patent Act Established
Patents allowed for 14 years
For the useful, important and new inventions, with a description

https://onlinellm.usc.edu/blog/history-of-patent-law/

Cont.

Indian Patent system

Based on the British Patent Law of 1852
The Act VI of 1856 on protection of invention to

The Indian Patents & Designs Act, 1911

Consolidation of previous Acts and legislations; brought patent administration under the management of Controller of Patents for the first time; and Made conducive to the national interest

The Patents Act, 1970 is the legislation that till date governs patents in India.

ipindia.gov.in/history-of-indian-patent-system.htm

IP definition, protection and categorization

By definition*: Intellectual property (IP) refers to **creations of the mind**, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce.

Explanation: It confers **property right for "creations of the mind"**

meaning

- One can own it as a private property;
- One can protect it from other (legal right); and
- One can trade it or, even mortgage it.

https://www.wipo.int/about-ip/en/

Cont.

IP Protection in terms of law (Legal right)

- enable people to earn **recognition or financial benefit** from what they invent or create.
- strike the **right balance** between the interests of innovators and the wider public interest.
- foster an environment in which **creativity and innovation** can flourish.

Cont.

Patent: The deal between the State and the inventor

20 years to exclude others from practicing your invention

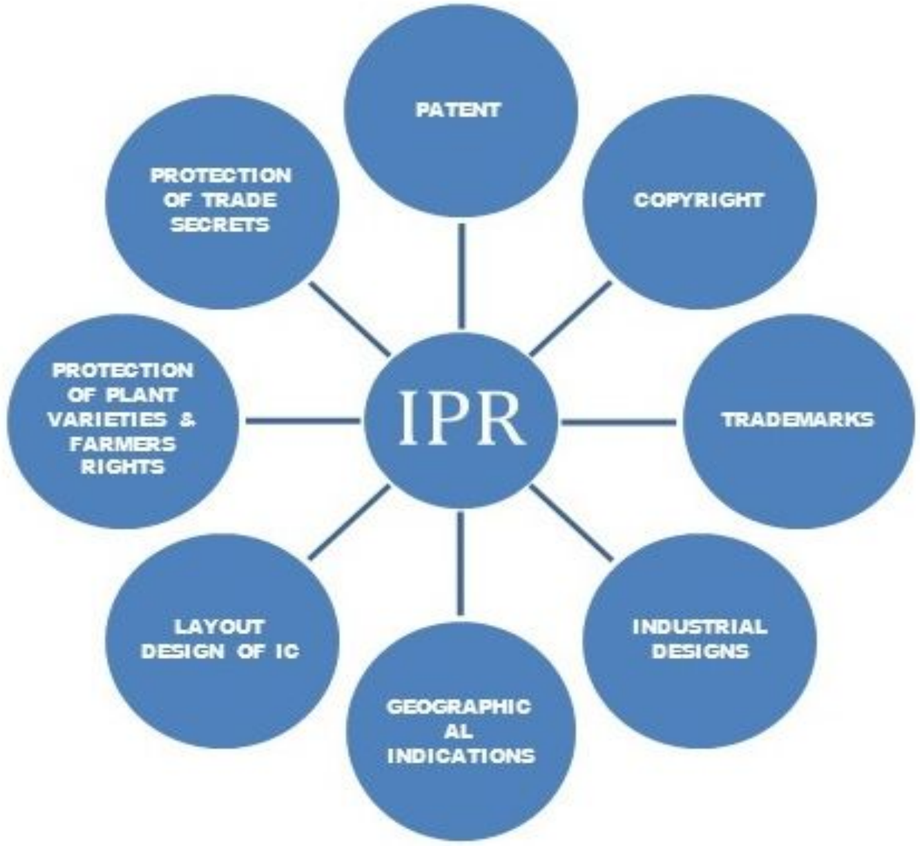
Full disclosure and practice invention in the State

Why the deal?

- To accelerate the process of inventions in society
- To not loose inventions as a society because of non-disclosure
- To induce inventors to practice the invention in the jurisdiction.

Based on slide of VP (http://www.techex.in/)

IP categorization



https://patentsinfo.wordpress.com/ipr/

Cont.

Patent : Type of intellectual property recognized in modern legal systems to protect the inventions.

Trademark is a sign capable of **distinguishing the goods or services** of one enterprise from those of other enterprises.

https://www.wipo.int/edocs/pubdocs/en/wipo_pub_450_2020.pdf

Cont.

Industrial design rights cover those elements of a product that are **aesthetic or ornamental** – the way it looks and feels.

Geographical indication is a sign used on products that have a specific geographical origin and **possess qualities or a reputation that are due to that origin**

https://www.wipo.int/edocs/pubdocs/en/wipo_pub_450_2020.pdf

Cont.

Copyright applies to **the creative expression of ideas** in many different forms – text, still or moving pictures, sound works, three-dimensional shapes such as sculptures and architecture, reference works and collections of data

Trade secret is not publicly disclosed. Information access controlled by CA/NDA.

www.wipo.int/edocs/pubdocs/en/wipo_pub_450_2020.pdf

Cont.

Plant varieties:

a form of intellectual property right granted to the breeder of a new plant variety in relation to certain acts concerning the exploitation of the protected variety.

Lay out designs of Integrated circuit

the layout design (topography) of integrated circuits is protected under a sui generis intellectual property system

https://www.wipo.int/web/patents/topics/integrated_circuits
https://www.wipo.int/edocs/pubdocs/en/wipo_pub_450_2020.pdf

Invention

What is an Invention?

By definition: An invention* can be defined as a product or process that offers a **new way** of doing something, or a new **technical** **solution to a problem**

- Solution to a problem
- New way
- Technical advancement

www.wipo.int/edocs/pubdocs/en/wipo_pub_450_2020.pdf

Cont.

Technical feature?

Compared with the existing prior arts

Technical solution to a problem

Small improvements may be enough

Outcome ?

Product

Service

Technology package

Right to exclude others (Patent)

Patents

Techno-legal document

Issued after the Grant

Published in official Gazette

Pre- prerequisite:

Patent application must be filed

Nature and scope : Jurisdictional right

INTELLECTUAL PROPERTY INDIA

क्रम सं/SL No :02212494

सत्यमेव जयते

पेटेंट कार्यालय,भारत सरकार | The Patent Office, Government Of India

पेटेंट प्रमाण पत्र | Patent Certificate

(पेटेंट नियमावली का नियम 74) | (Rule 74 of The Patents Rules)

पेटेंट सं. / Patent No.	:	434888
आवेदन सं. / Application No.	:	481/MUM/2013
फाइल करने की तारीख / Date of Filing	:	19/02/2013
पेटेंटी / Patentee	:	AGHARKAR RESEARCH INSTITUTE OF MAHARASHTRA ASSOCIATION FOR CULTIVATION OF SCIENCE

प्रमाणित किया जाता है कि पेटेंटी को, उपरोक्त आवेदन में यथाप्रकटित *A METHOD FOR RAPID ISOLATION AND PURIFICATION OF DNA* नामक आविष्कार के लिए, पेटेंट अधिनियम, 1970 के उपबंधों के अनुसार आज तारीख फरवरी 2013 के उन्नीसवें दिन से बीस वर्ष की अवधि के लिए पेटेंट अनुदत्त किया गया है।

It is hereby certified that a patent has been granted to the patentee for an invention entitled *A METHOD FOR RAPID ISOLATION AND PURIFICATION OF DNA* as disclosed in the above mentioned application for the term of 20 years from the 19th day of February 2013 in accordance with the provisions of the Patents Act,1970.

Patent Eligibility

Requirements for patent eligibility

- Novelty
- Inventiveness/Non-obviousness
- Industrial Applicability

#Global requirements

However, every jurisdiction has its exclusion criteria. For Example, **The Indian Patents ACT, 1970** provides section 3 and 4 for the non-patentable subject matter.

Exclusion Criteria (As per the Indian Patent Act)

Section 3. What are not inventions

defined under subsection 3(a) to 3(p)

Section 4. Inventions relating to atomic energy not patentable

No patent shall be granted in respect of an invention relating to atomic energy falling within sub-section (1) of section 20 of the Atomic Energy Act, 1962 (33 of 1962).

https://ipindia.gov.in/writereaddata/Portal/ev/sections/ps3.html

Cont. Section 3. What are not inventions

(a) an invention which is frivolous or which claims anything obviously c**ontrary to well established natural laws**;

(b) an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;

(c) the mere discovery of a **scientific principle or the formulation of an abstract theory or discovery** of any living thing or non-living substance occurring in nature;

Cont.

Section 3. What are not inventions

(d) the mere discovery of a **new form of a known substance** which does not result in the **enhancement of the known efficacy** of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a **known process, machine or apparatus** unless such known process results in a new product or employs at least one new reactant.

Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;

https://ipindia.gov.in/writereaddata/Portal/ev/sections/ps3.html

Cont.

Section 3. What are not inventions

(e) a substance obtained by a **mere admixture** resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;

(f) the **mere arrangement or re-arrangement or duplication of known devices** each functioning independently of one another in a known way;

(h) a **method of agriculture or horticulture**;

Cont.

Section 3. What are not inventions

(i) any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings or any process for a similar **treatment of animals** to render them free of disease or to increase their economic value or that of their products.

(j) plants and animals in whole or any part thereof other than micro organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;

(k) a mathematical or **business method or a computer programme** *per se* or algorithms;

Cont.

Section 3. What are not inventions

(l) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions;

(m) a mere scheme or rule or method of performing mental act or method of playing game;

(n) a presentation of information;

(o) topography of integrated circuits;

(p) an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.

Case study: Invention, Patenting and commercialization

Katalin Karikó and Drew Weissman

University of Pennsylvania, US

(Nobel Laureates 2023)

- for developing effective mRNA vaccines against COVID-19

www.reuters.com/business/healthcare-pharmaceuticals/nobel-medicine-prize-covid-19-vaccine-it-may-be-too-soon-2021-10-01/

Cont.

Technology identification to development

- Nucleoside base modifications i.e. altering mRNA for an effective therapeutics
- Activation of body's protective Immune system, upon administration.
- Covid 19 Vaccine against the Coronavirus (outcome)

Cont.

2005: Karikó and Weissman **discovered that base-modified mRNA can be used to block activation of inflammatory reactions** (*secretion of signaling molecules*) and increase protein production.

2008 and 2010, further research showed that the delivery of mRNA generated with base modifications **markedly increased protein production compared to unmodified mRNA**.

Clinical applications of mRNA ?

Whether the Technology has IP protection?

Cont.

IP protection

RNA Containing Modified Nucleosides and Methods of Use Thereof. # US8278036 (B2)

Claim 1:

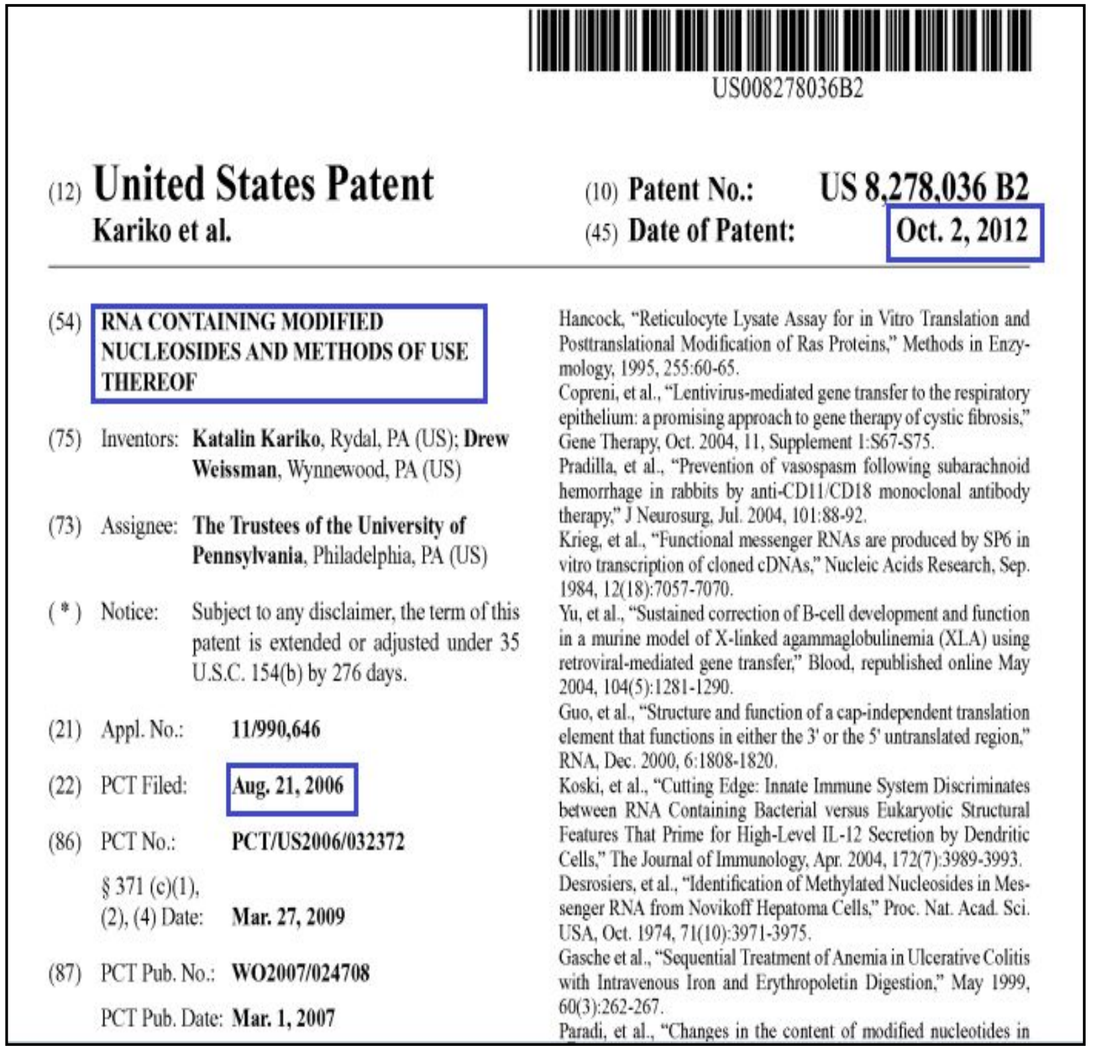
A method for inducing a mammalian cell to produce a protein of interest comprising:

contacting said mammalian cell with

in vitro-synthesized modified RNA

encoding a protein of interest,

wherein said ***in vitro*-synthesized modified RNA comprises the modified nucleoside pseudouridine.**



US008278036B2

(12) **United States Patent**
Kariko et al.

(10) **Patent No.: US 8,278,036 B2**
(45) **Date of Patent: Oct. 2, 2012**

(54) **RNA CONTAINING MODIFIED NUCLEOSIDES AND METHODS OF USE THEREOF**

(75) Inventors: **Katalin Kariko**, Rydal, PA (US); **Drew Weissman**, Wynnewood, PA (US)

(73) Assignee: **The Trustees of the University of Pennsylvania**, Philadelphia, PA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 276 days.

(21) Appl. No.: **11/990,646**

(22) PCT Filed: **Aug. 21, 2006**

(86) PCT No.: **PCT/US2006/032372**

§ 371 (c)(1),
(2), (4) Date: **Mar. 27, 2009**

(87) PCT Pub. No.: **WO2007/024708**

PCT Pub. Date: **Mar. 1, 2007**

Hancock, "Reticulocyte Lysate Assay for in Vitro Translation and Posttranslational Modification of Ras Proteins," Methods in Enzymology, 1995, 255:60-65.

Copreni, et al., "Lentivirus-mediated gene transfer to the respiratory epithelium: a promising approach to gene therapy of cystic fibrosis," Gene Therapy, Oct. 2004, 11, Supplement 1:S67-S75.

Pradilla, et al., "Prevention of vasospasm following subarachnoid hemorrhage in rabbits by anti-CD11/CD18 monoclonal antibody therapy," J Neurosurg, Jul. 2004, 101:88-92.

Krieg, et al., "Functional messenger RNAs are produced by SP6 in vitro transcription of cloned cDNAs," Nucleic Acids Research, Sep. 1984, 12(18):7057-7070.

Yu, et al., "Sustained correction of B-cell development and function in a murine model of X-linked agammaglobulinemia (XLA) using retroviral-mediated gene transfer," Blood, republished online May 2004, 104(5):1281-1290.

Guo, et al., "Structure and function of a cap-independent translation element that functions in either the 3' or the 5' untranslated region," RNA, Dec. 2000, 6:1808-1820.

Koski, et al., "Cutting Edge: Innate Immune System Discriminates between RNA Containing Bacterial versus Eukaryotic Structural Features That Prime for High-Level IL-12 Secretion by Dendritic Cells," The Journal of Immunology, Apr. 2004, 172(7):3989-3993.

Desrosiers, et al., "Identification of Methylated Nucleosides in Messenger RNA from Novikoff Hepatoma Cells," Proc. Nat. Acad. Sci. USA, Oct. 1974, 71(10):3971-3975.

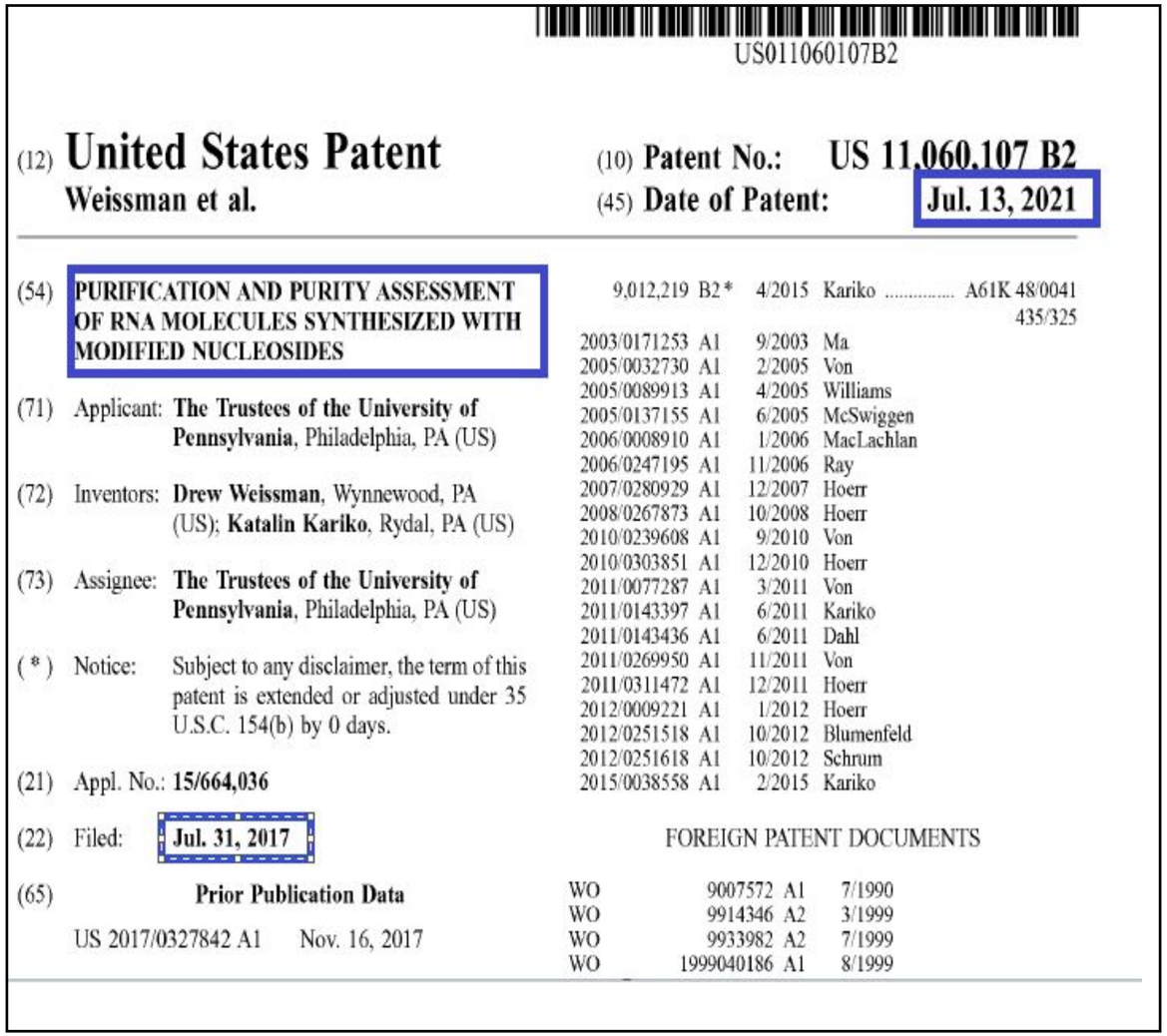
Gasche et al., "Sequential Treatment of Anemia in Ulcerative Colitis with Intravenous Iron and Erythropoletin Digestion," May 1999, 60(3):262-267.

Paradi, et al., "Changes in the content of modified nucleotides in

Cont.

Purification and Purity Assessment of RNA Molecules Synthesized with Modified Nucleosides. # US11060107 (B2)

Claim 1: **A purified preparation of RNA**, the RNA comprising at least o**ne modified nucleoside** selected from the group consisting of a 1-methyl-pseudouridine, m5C, m5U, m6A, s2U, Ψ, and 2′-O-methyl-U,
wherein about 95% to about 99.9% of RNA in the purified preparation is messenger RNA, and
wherein the purified preparation is prepared by subjecting a preparation of messenger RNA to enzymatic digestion with 0.001 units of at least one enzyme elected from the group consisting of
RNase III, RNase V1, Dicer, and Chipper.



US011060107B2

(12) **United States Patent**
Weissman et al.

(10) **Patent No.: US 11,060,107 B2**
(45) **Date of Patent: Jul. 13, 2021**

(54) **PURIFICATION AND PURITY ASSESSMENT OF RNA MOLECULES SYNTHESIZED WITH MODIFIED NUCLEOSIDES**

(71) Applicant: **The Trustees of the University of Pennsylvania**, Philadelphia, PA (US)

(72) Inventors: **Drew Weissman**, Wynnewood, PA (US); **Katalin Kariko**, Rydal, PA (US)

(73) Assignee: **The Trustees of the University of Pennsylvania**, Philadelphia, PA (US)

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

(21) Appl. No.: **15/664,036**

(22) Filed: **Jul. 31, 2017**

(65) **Prior Publication Data**

US 2017/0327842 A1 Nov. 16, 2017

9,012,219	B2 *	4/2015	Kariko	A61K 48/0041 435/325
2003/0171253	A1	9/2003	Ma	
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2005/0089913	A1	4/2005	Williams	
2005/0137155	A1	6/2005	McSwiggen	
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2006/0247195	A1	11/2006	Ray	
2007/0280929	A1	12/2007	Hoerr	
2008/0267873	A1	10/2008	Hoerr	
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2012/0251618	A1	10/2012	Schrum	
2015/0038558	A1	2/2015	Kariko	

FOREIGN PATENT DOCUMENTS

WO	9007572	A1	7/1990
WO	9914346	A2	3/1999
WO	9933982	A2	7/1999
WO	1999040186	A1	8/1999

Cont.

mRNA based Technology was licensed to **Moderna and Pfizer/BioNtech's.**

Other development and Progress

- Lipid nanoparticles (LNP) –Actitus
- 2016: Ongoing Clinical trials : LNP + mRNA based vaccine

Storz, U. The COVID-19 vaccine patent race. *Nat Biotechnol* **40**, 1001–1004 (2022).

https://www.fda.gov/vaccines-blood-biologics/coronavirus-covid-19-cber-regulated-biologics/moderna-covid-19-vaccine

Patent Portfolio by MODERNA TX INC [US]

US 10703789 B2: Modified polynucleotides for the production of secreted proteins (2020-07-07)

Claim 1:

A pharmaceutical composition comprising: a plurality of lipid nanoparticles comprising a cationic lipid, a neutral lipid, a cholesterol, and a PEG lipid, wherein the plurality of lipid nanoparticles has a mean particle size of between 80 nm and 160 nm; and wherein the lipid nanoparticles comprise an mRNA encoding a polypeptide, wherein the mRNA comprises:

(i) at least one 5′-cap structure;

(ii) a 5′-UTR;

(iii) an open reading frame encoding the polypeptide and consisting of nucleotides including N1-methyl-pseudouridine, cytosine, adenine, and guanine;

(iv) a 3′-UTR; and

(v) a poly-A region of least 100 nucleotides in length.

Cont.

US 10702600 B1: Beta coronavirus mRNA vaccine (2020-07-07)

Claim 1:

A composition, comprising: a messenger ribonucleic acid (mRNA) comprising an open reading frame encoding a betacoronavirus (BetaCoV) S protein or S protein subunit formulated in a lipid nanoparticle.

Cont.

US 10064959 B2: Modified nucleosides, nucleotides, and nucleic acids, and uses thereof

Claim 1:

A synthetic messenger ribonucleic acid (mRNA) that is synthesized according to a method comprising the steps of:

a) providing a complementary deoxyribonucleic acid (cDNA) that encodes a pharmaceutical protein of interest;

b) selecting a nucleotide that disrupts a binding of a major groove binding partner with the mRNA, wherein the nucleotide has decreased binding affinity to the major groove binding partner selected from the group consisting of toll-like receptor (TLR) 3, TLR7, TLR8, retinoic acid-inducible gene I (RIG-I), melanoma differentiation-associated gene 5 (MDA5) and laboratory of genetics and physiology 2 (LGP2), and wherein the nucleotide comprises a modification on the major groove face of the nucleobase where an atom of the major groove face of the nucleobase is replaced or substituted with an alkyl group; and

c) contacting the provided cDNA and the selected nucleotide with an RNA polymerase under conditions such that an mRNA transcript is synthesized.

Cont.

US2023108894 (A1) : Coronavirus RNA vaccines

Filing date: 26th Jan 2021

No. of claims - 47 in total (Product, composition and method claims)

Claim 1:

A messenger ribonucleic acid (mRNA) comprising an open reading frame (ORF) that encodes a SARS-CoV-2 spike (S) protein having a double proline stabilizing mutation.

Cont.

Outcome

Covid 19 vaccine

- is an mRNA vaccine composed of
- nucleoside-modified mRNA

(modRNA) encoding a spike protein of SARS-CoV-2, which is encapsulated in lipid nanoparticles.

The Patent Cooperation Treaty (PCT)

A patent application **filing system**

WIPO administers the PCT System,

- an international system that allows applicants to request protection under the Patent Cooperation Treaty in as many signatory states as they wish through a single application
- **146 countries and 4 regional patent systems**

Cont.

Basic Principle:

Rationalized filing and processing for both applicants and Patent Offices

Single application with legal effect in all PCT countries

International and national phases

Preferred route for obtaining patents internationally

- not a patent granting system
- each “designated Office” makes its own decision on patent grant
- Timelines Prescribed

Cont.

Published PCT application

WO2021154763 (A1)

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
05 August 2021 (05.08.2021)

WIPO | PCT

(10) International Publication Number
WO 2021/154763 A1

(51) International Patent Classification:
A61K 39/12 (2006.01) *A61P 11/00* (2006.01)
A61K 39/215 (2006.01) *A61P 31/14* (2006.01)

(21) International Application Number:
PCT/US2021/015145

(22) International Filing Date:
26 January 2021 (26.01.2021)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

62/967,006	28 January 2020 (28.01.2020)	US
62/971,825	07 February 2020 (07.02.2020)	US
63/002,094	30 March 2020 (30.03.2020)	US
63/009,005	13 April 2020 (13.04.2020)	US
63/016,175	27 April 2020 (27.04.2020)	US

(71) Applicant: **MODERNATX, INC.** [US/US]; 200 Technology Square, Cambridge, MA 02139 (US).

(72) Inventors: **STEWART-JONES, Guillaume**; 200 Technology Square, Cambridge, MA 02139 (US). **NARAYANAN, Elisabeth**; 38 Fulkerson Street, Cambridge, MA 02141 (US). **BENNETT, Hamilton**; 200 Technology Square, Cambridge, MA 02139 (US). **CARFI, Andrea**; 200 Technology Square, Cambridge, MA 02139 (US). **METKAR, Mihir**; 200 Technology Square, Cambridge, MA 02139 (US). **PRESNYAK, Vladimir**; 776 Chestnut Street, Manchester, NH 03104 (US).

(74) Agent: **LOCKHART, Helen, C.**; Wolf, Greenfield & Sacks, P.C., 600 Atlantic Avenue, Boston, MA 02210-2206 (US).

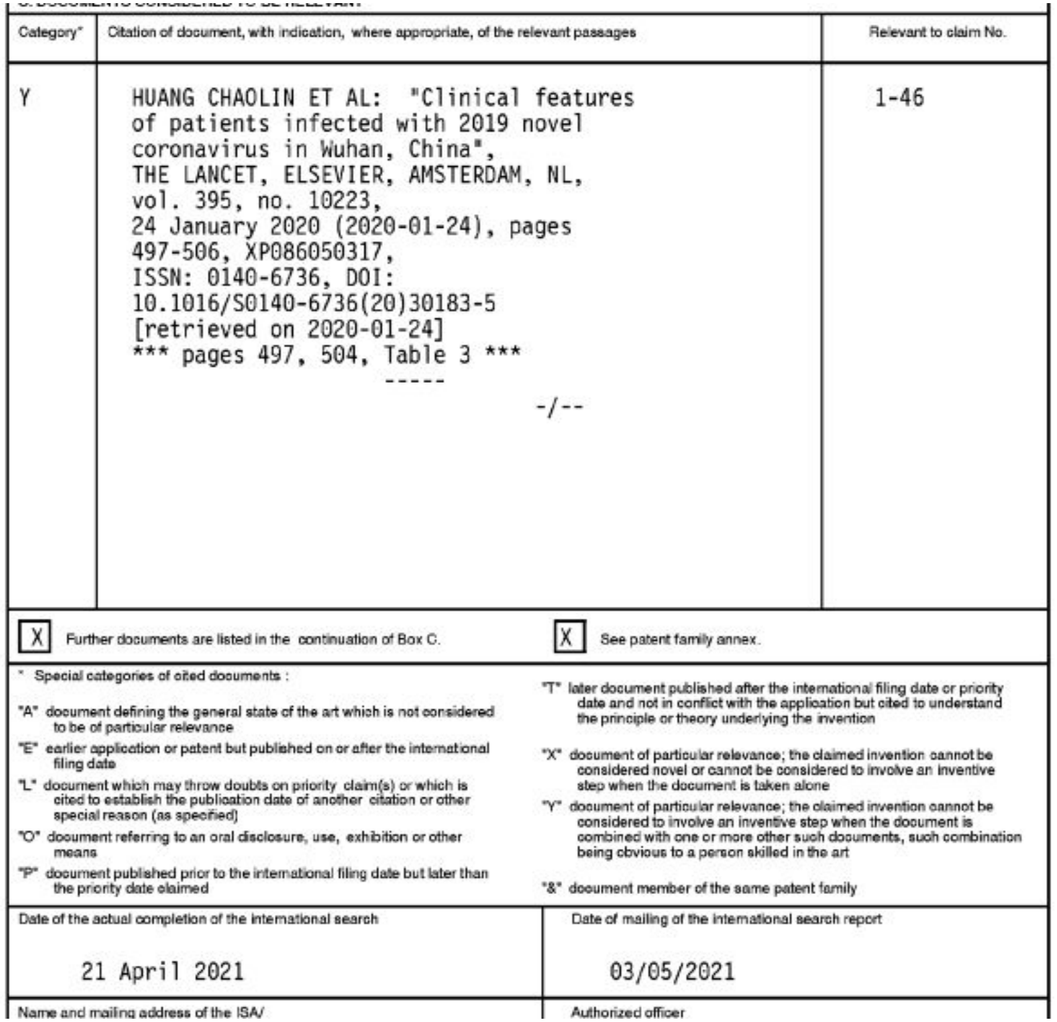
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS,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

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,

Cont.

WO2021154763 (A1)

Applicant gets the patentability search report /written opinion.



Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	HUANG CHAOLIN ET AL: "Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China", THE LANCET, ELSEVIER, AMSTERDAM, NL, vol. 395, no. 10223, 24 January 2020 (2020-01-24), pages 497-506, XP086050317, ISSN: 0140-6736, DOI: 10.1016/S0140-6736(20)30183-5 [retrieved on 2020-01-24] *** pages 497, 504, Table 3 *** ----- -/--	1-46

[X] Further documents are listed in the continuation of Box C. [X] 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
21 April 2021	03/05/2021
Name and mailing address of the ISA/	Authorized officer

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Pune 411008, India

www.techex.in

TechEx.in

Tech Transfer Hub at Venture Center

Supported by NBM - BIRAC

THANK YOU

Technology Identification to the development

COVID-19 vaccinesapproved by the regulatory bodies for use (emergency use authorization). COVID vaccine candidates that are currently being used for inoculations include:

- Pfizer-BionTech
- Moderna Inc
- Oxford-Astrazeneca, developed in India by the Serum Institute of India (SII)
- Sputnik V
- Indian landscape: The Drug Controller General of India (DCGI) has approved two COVID-19 vaccines including **SII's Covishield and Bharat Biotech's Covaxin:**

-