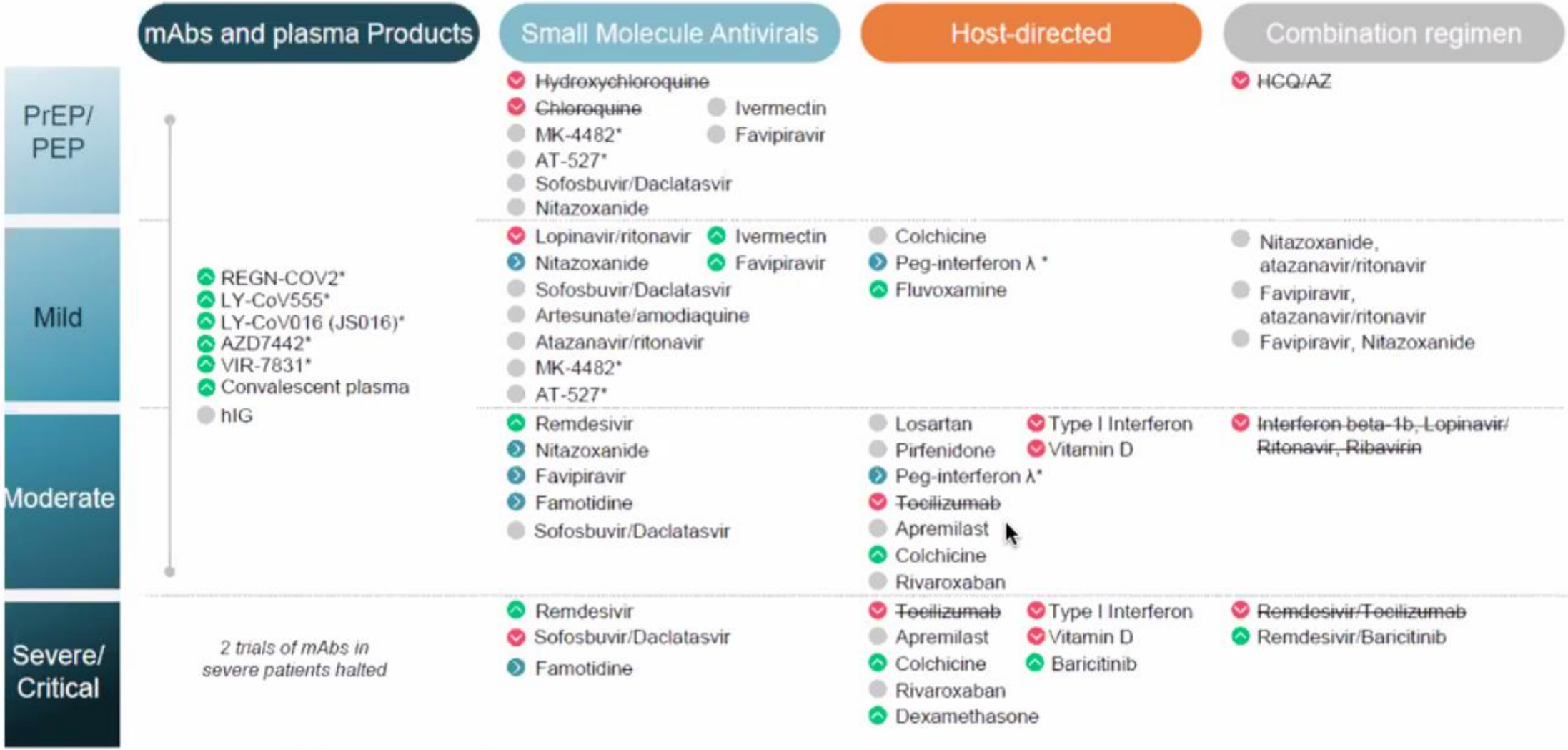
GSIPA2M
GLOBAL SUMMIT ON INTELLECTUAL PROPERTY & ACCESS TO MEDICINES: PATHWAYS TO ACCESS
15-17 January 2018 MARRAKECH- MOROCCO

IP AND COVID-19 RESPONSE

Sergey Kondratyuk



Source : ACT-A consortium

Treatments: Remdesivir

- Access: US government purchased 90%; EU remaining 10%
- Gilead signs voluntary license with companies in Egypt, Pakistan, and India
- 127 Countries

Producer	Product name	Price per 5-day treatment course
Gilead Sciences	Remdesivir	$2,340
Eskayef Pharmaceuticals	Remvir	$960
Hetero	Covifor	$426
Beximco Sciences	Bemsivir	$390
Cipla	Cipremi	$320
Jubliant Life Sciences		$384
Mylan	Desrem	$384
Zydus Cadilla	Remdac	$229

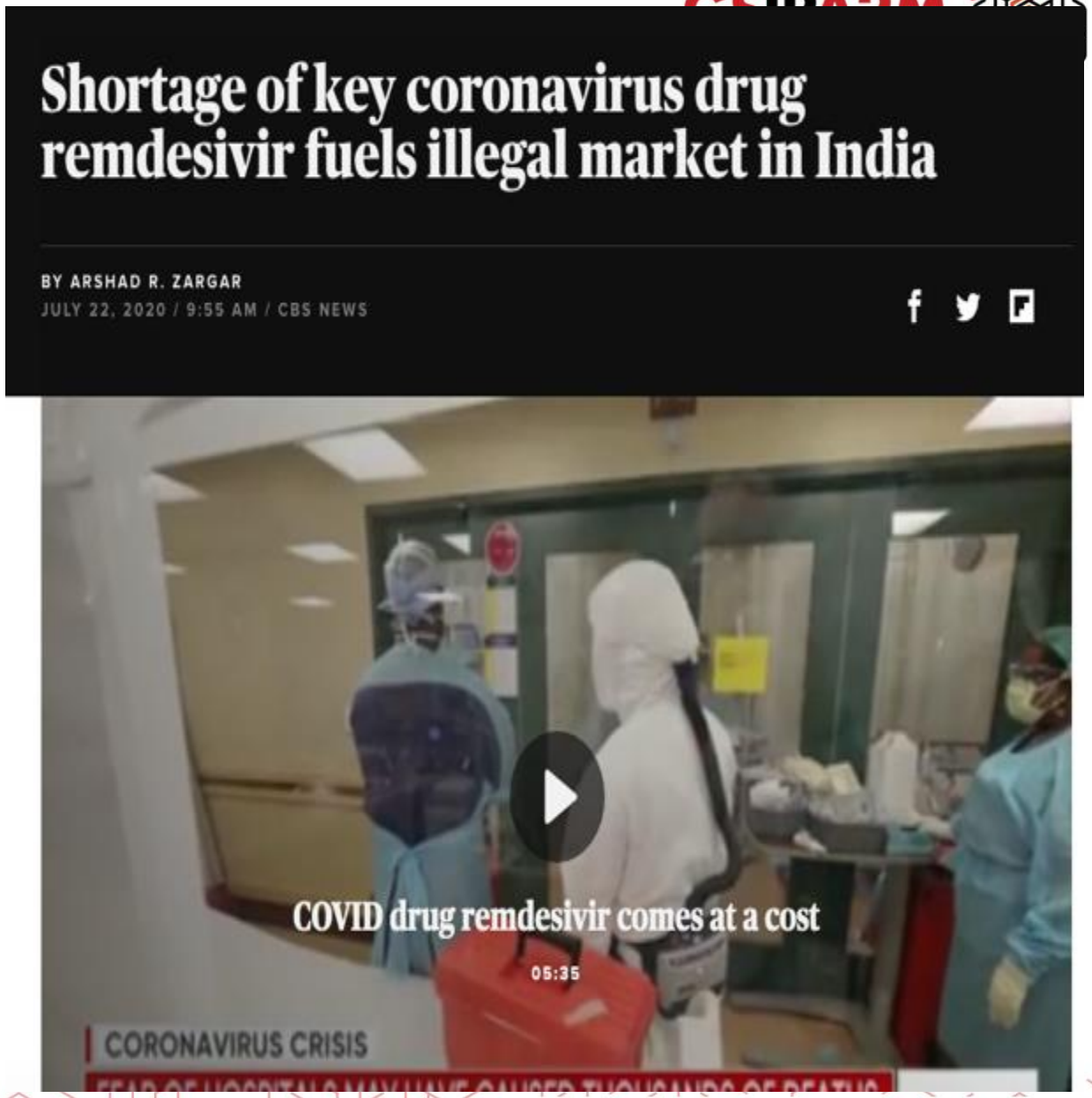


Table 1. Summary of costs of production and lowest/highest prices

Drug	Dose	Highest list price	Lowest list price	Estimated cost price (course)	Estimated cost price (day)
Remdesivir (10 Days)	100 mg IV BD (Day 1) 100 mg IV OD (Days 2–9)	___	___	$9	$0.93
Favipiravir (14 Days)	600 mg BD	___	$231 (China)	$20	$1.45
Lopinavir/ritonavir (14 Days)	400/100 BD	$503 (US)	$9 (Global Fund)* $15 (South Africa)	$4	$0.28
Hydroxychloroquine (14 Days)	400 mg OD	$19 (China)	$2 (India)	$1	$0.08
Chloroquine (14 days)	155 mg OD	$93 (US)	$0.20 (Bangladesh)	$0.30	$0.02
Azithromycin (14 days)	500 mg OD	$63 (US)	$5 (India)	$1.40	$0.10
Sofosbuvir/daclatasvir (14 days)	400/60 OD	$18,610 (US)	$6 (Pakistan)	$5	$0.39
Pirfenidone (28 days)	801 mg TD	$9606 (US)	$100 (India)	$31	$1.09
Tocilizumab (Per dose)	560 mg BD	$3383 (US)	$510 (Pakistan)	___	___

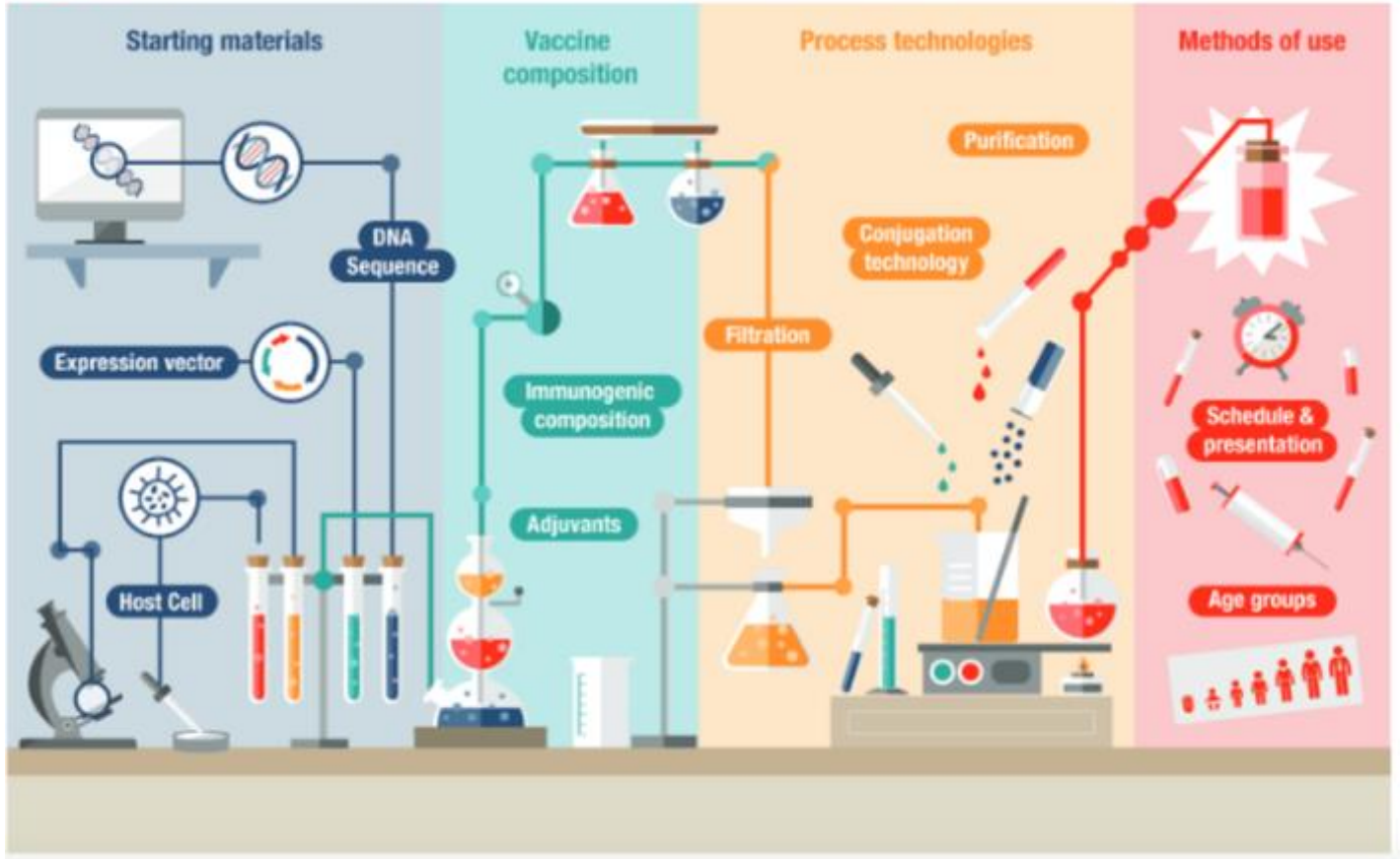
*Median price available to a range of low- and middle-income countries. OD: once daily; BD: two times daily; TD: three times daily; IV: intravenous.

Remdesivir: patenting

Country	Patent Description	Patent Status	Expected Expiry
Brazil	Remdesivir and analogues (Markush structure) & their use as antivirals	Filed	2029
	Remdesivir compound & use of Remdesivir and its analogues for treating paramyxoviridae virus infections	Filed	2031
	Remdesivir and its analogues used for treating Arenaviridae and Coronaviridae virus infections	Filed	2036
China	Remdesivir and analogues (Markush structure) & their use as antivirals	Granted	2029
	Remdesivir and analogues (Markush structure) & their use as antivirals	Granted	2029
	Remdesivir compound & use of Remdesivir and its analogues for treating paramyxoviridae virus infections	Granted	2031
	Remdesivir compound & use of Remdesivir and its analogues for treating paramyxoviridae virus infections	Granted	2031
	Remdesivir and its analogues used for treating Arenaviridae and Coronaviridae virus infections	Filed	2036
India*	Remdesivir and analogues (Markush structure) & their use as antivirals	Granted	2029
	Remdesivir compound & use of Remdesivir and its analogues for treating paramyxoviridae virus infections	Granted	2031
	Remdesivir compound & use of Remdesivir and its analogues for treating paramyxoviridae virus infections	Filed	2031
Russian Federation	Remdesivir and analogues (Markush structure) & their use as antivirals	Granted	2029
	Remdesivir compound & use of Remdesivir and its analogues for treating paramyxoviridae virus infections	Withdrawn	
	Remdesivir compound & use of Remdesivir and its analogues for treating paramyxoviridae virus infections	Granted	2031
	Remdesivir and its analogues used for treating Arenaviridae and Coronaviridae virus infections	Withdrawn	

Patents on Vaccines

Figure 1: Examples of Patent Barriers Throughout the Vaccine Development Process and Beyond



- Vaccine patents tend to start with over-broad claims and then follow-on patents are filed that expire many years after the original patents
- PCV: USD9 – 80 depending on the country; 2019 Serum's USD2 vaccine introduced
- HPV: Prices for the vaccines range from $4.50 per dose at the lowest global price up to $193 per dose in the US private sector. Could be manufactured for as little as $0.50 to $0.60 per dose.

Coronavirus vaccine patent filings (Source: European Patent Office)

Not just patents…trade secrets

- "Often labeled as "confidential information," or "proprietary information," trade secrets actually encompass vast quantities of information needed to discover, test, create, and manufacture diagnostics, treatments, medicines, and vaccines.
- Manufacturing processes, test data, medical formulas, and cell lines and other biological resources, chemical formulas, processes for manufacturing.
- **For vaccines and other biologic medicines, cell lines, genomic information, and other biological material can also be held as trade secrets.**
- **Similarly, data about the effectiveness of medicines and vaccines are trade secrets.**
- **Even "negative information" – information about what does not work – can be a trade secret.**
- **This information is essential to the rapid development of, and access to, safe and effective COVID diagnostics, treatments and vaccines worldwide."**

COVID-19 TRADE SECRETS AND INFORMATION ACCESS: AN OVERVIEW

Posted by David-Levine | Jul 10, 2020 | Academic Resources, AI, Coronavirus

David S. Levine[1]

Associate Professor, Elon University School of Law

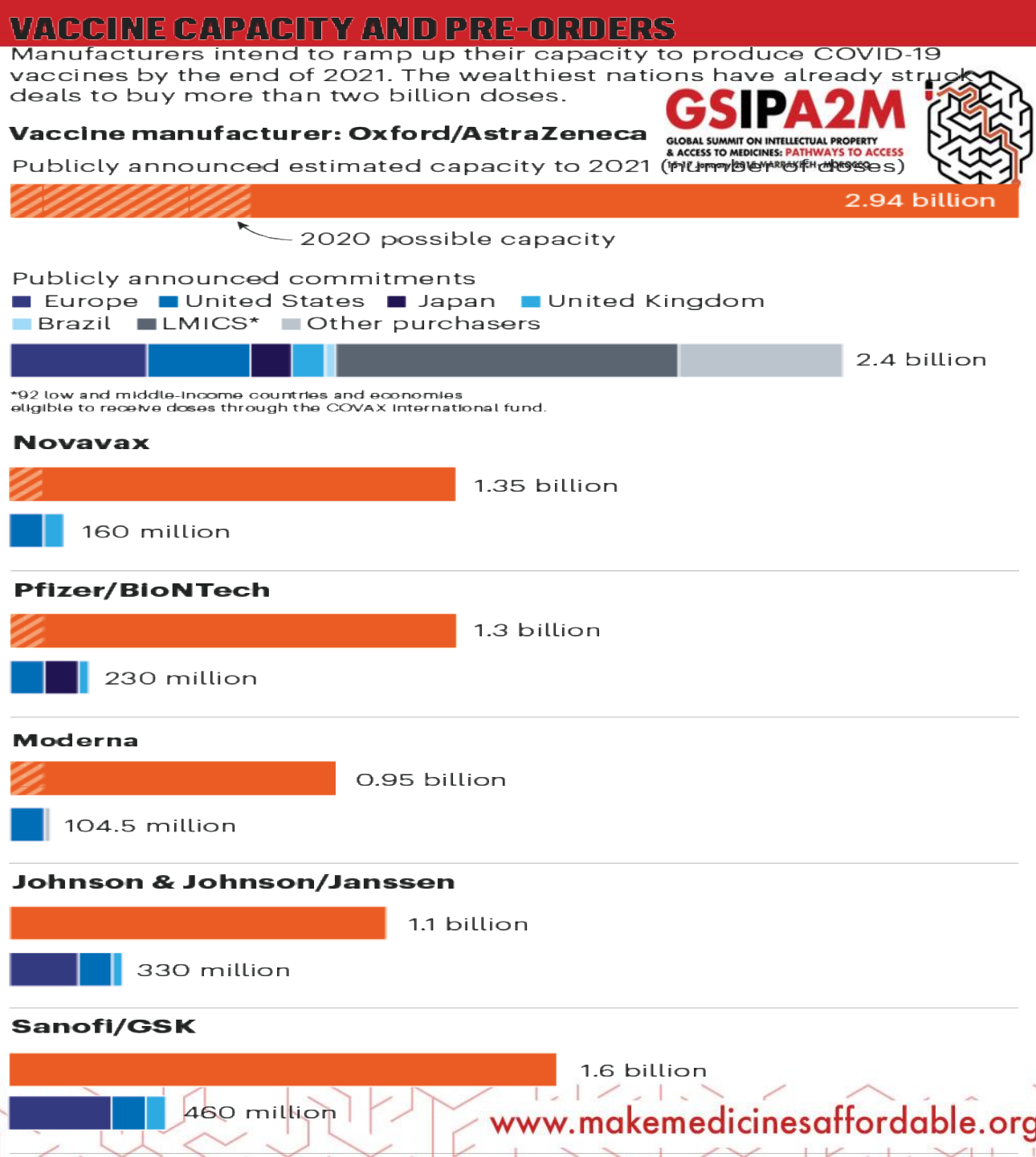
Affiliate Scholar, Center for Internet and Society at Stanford Law School

The unprecedented Covid-19 (Covid) virus has brought to the forefront many challenges associated with exclusive rights, information sharing, and innovation. How do we get effective diagnostics, treatments and vaccines quickly and safely to the public? More specifically, how do we ensure that sufficient quantities are produced, that health products are affordable, and that they are equitably distributed globally? Among many challenges on the road to this outcome is the difficult question of how to handle trade secrets, namely, information that is valuable because others do not know it.

The most famous trade secret is the Coca-Cola formula, but trade secrecy spans a shockingly broad range of critical and life-saving information. Indeed, trade secrets are everywhere in the battle to defeat Covid, from clinical data to pharmaceutical manufacturing processes. For the public at large, Covid trade secrets raise two primary issues: (a) When do you have a Covid trade secret, and (2) Should access to that trade secret extend to competitors, civil society

Inevitable shortages…

- *"As it stands, Pfizer and BioNTech can only produce 50 million doses for 2020 and 1.3bn for 2021 – this is a two-dose vaccine, that means only 25 million can receive it this year and just 650 million people next year." - Global Justice Now*



Inevitable shortages? http://vaxmap.org/

Patents on Vaccines: Licensing…litigation…!

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The Motley Fool

Pfizer, BioNTech, and Regeneron Hit With Patent Lawsuits Over COVID-19 Drugs and Vaccines

Eric Volkman · 10/5/2020

Three top names in the fight against the coronavirus and the COVID-19 disease that can result from it have been sued for patent infringement. The trio includes Regeneron Pharmaceuticals (NASDAQ: REGN), Pfizer (NYSE: PFE), and BioNTech (NASDAQ: BNTX). The plaintiff is privately held Allele Biotechnology and Pharmaceuticals.

nature biotechnology

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News in Brief | Published: 04 September 2020

Moderna loses key patent challenge

Nature Biotechnology **38**, 1009(2020) | Cite this article

6381 Accesses | **60** Altmetric | Metrics

A dispute over a key technology used in Moderna's highly anticipated COVID-19 vaccine came to a head in July when Arbutus Biopharma fended off a claim by the vaccine maker. The patent clash over the delivery system used in Moderna's mRNA-1273 vaccine could hamper the biotech's ability to price the vaccine competitively, as well as affect its margins versus those of other companies developing coronavirus vaccines. Moderna previously held a limited sublicense to Arbutus Biopharma's lipid nanoparticle (LNP) formulation, which is used to deliver messenger RNA drugs into cells. But since 2018, Moderna has filed three inter partes reviews (IPRs) with the US Patent and Trademark Office seeking to invalidate Arbutus's LNP patents. The first two IPRs resulted in wins for Moderna – invalidating one of Arbutus's patents in full and partially invalidating another. However, on 23 July the US Patent

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DARPA letter to KEI confirming investigation of Moderna for failure to report government funding in patent applications

Posted on September 18, 2020 by James Love

On Friday, September 18, 2020, KEI received a letter from the Defense Advanced Research Projects Agency (DARPA) confirming that the agency was investigating Moderna for failure to report government funding in patent applications. The Financial Times and other outlets had previously reported this investigation (see: https://www.keionline.org/moderna), but this letter is the first official notice we have received from DARPA.

Current contract manufacturing agreements

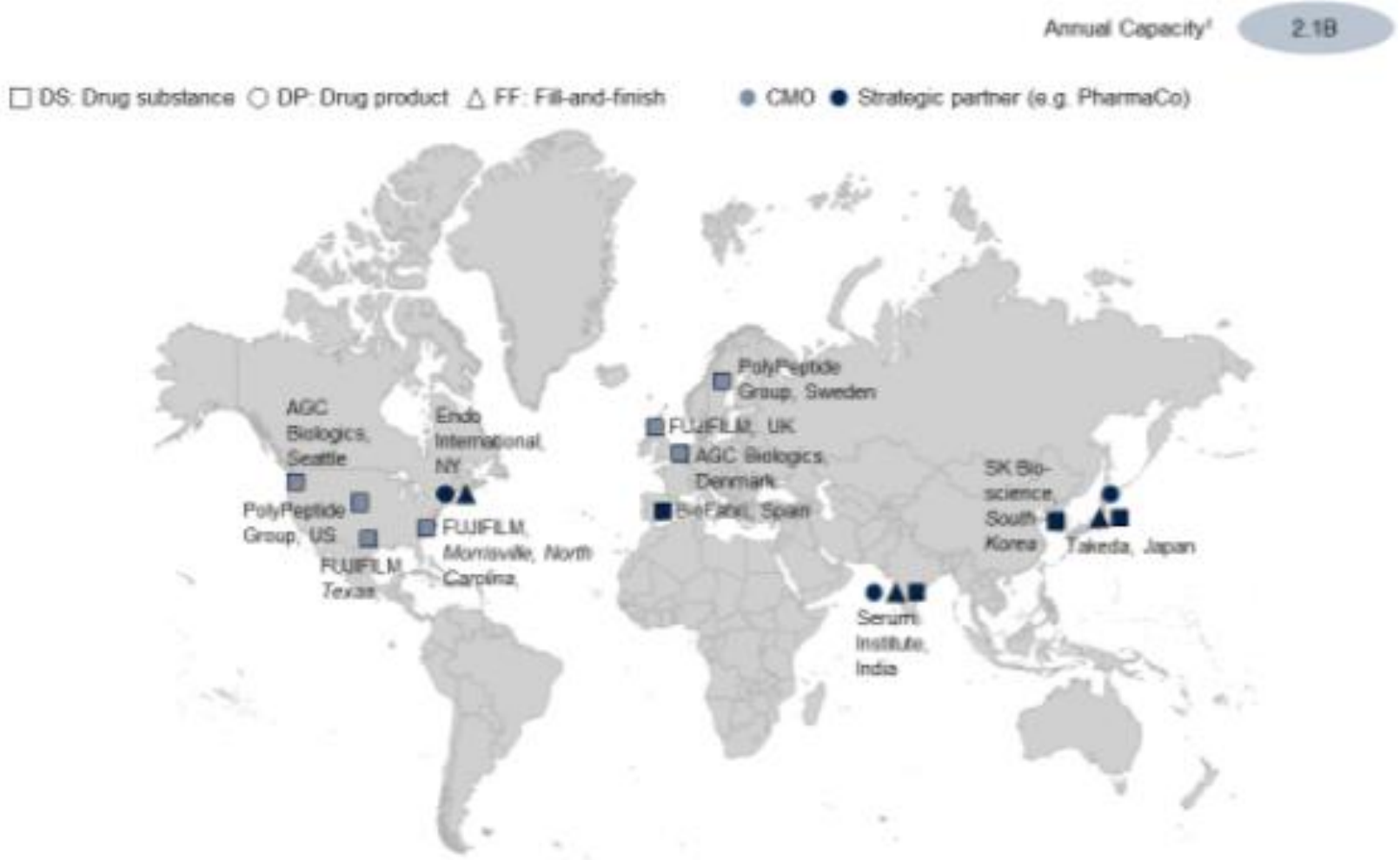
Known Vaccine Manufacturing Capacity – AstraZeneca[2]

1. For COVID-19 vaccine production; no other mRNA vaccines are currently commercially available
2. Reported agreements with 20 contract manufacturing organisations in July 30, 2020 H1 earnings call
Source: Pharmadeals, Catalent, Symbiosis Pharma, Scrip, Fiocruz, Biopharm, Novasep, FiercePharma, mAbxience, Halix, CNB, AMRI, Reuters, Fierce Pharma

Джерело - https://www.dcvmn.org/IMG/pdf/landscape_of_current_c19_supply_chain_manufacturing_capacity_appendix_embargo_9march20.pdf

Current contract manufacturing agreements

Known Vaccine Manufacturing Capacity – Novavax



1 For COVID-19 vaccine production; no other mRNA vaccines are currently commercially available

Source: Pharmadeals, Catalent, Symbiosis Pharma, Scrip, Fiocruz, Biopharm, Novasep, FiercePharma, mAbxience, Halix, GSK, AMRI, Reuters, Fierce Pharma

Джерело - https://www.dcvmn.org/IMG/pdf/landscape_of_current_c19_supply_chain_manufacturing_capacity_appendix_embargo_9march20.pdf

Current contract manufacturing agreements

Known Vaccine Manufacturing Capacity – J&J

Джерело - https://www.dcvmn.org/IMG/pdf/landscape_of_current_c19_supply_chain_manufacturing_capacity_appendix_embargo_9march20.pdf

1 For COVID-19 vaccine production; no other mRNA vaccines are currently commercially available
Source: Pharmadeale, Reuters, Fierce Pharma, FierceBiotech, Aspen, Catalent
DOCUMENT INTENDED TO PROVIDE INSIGHT BASED ON CURRENTLY AVAILABLE INFORMATION FOR CONSIDERATION AND NOT SPECIFIC ADVICE
REFERENCES TO SPECIFIC ORGANISATIONS ARE SOLELY FOR INFORMATIONAL PURPOSES AND DO NOT CONSTITUTE ANY ENDORSEMENT OR RECOMMENDATION

Current contract manufacturing agreements

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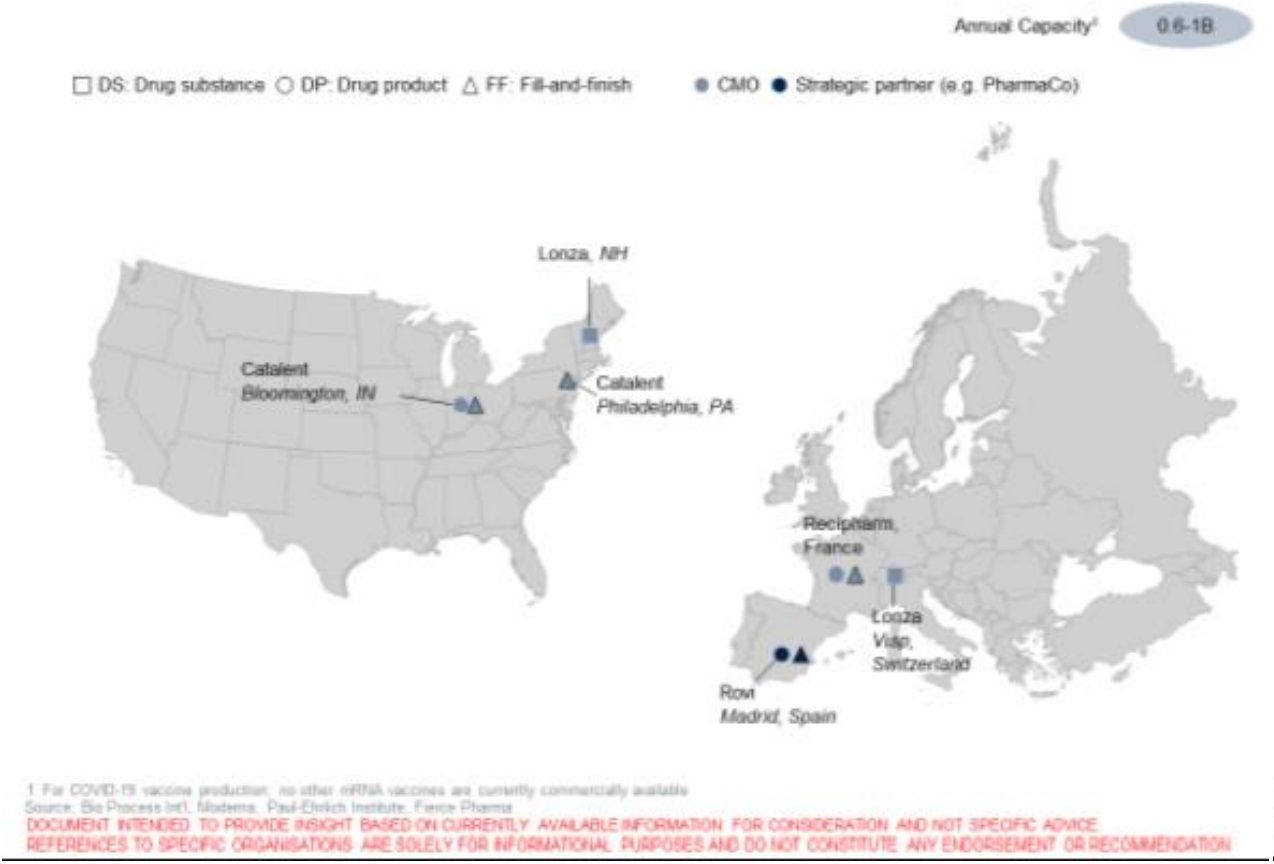
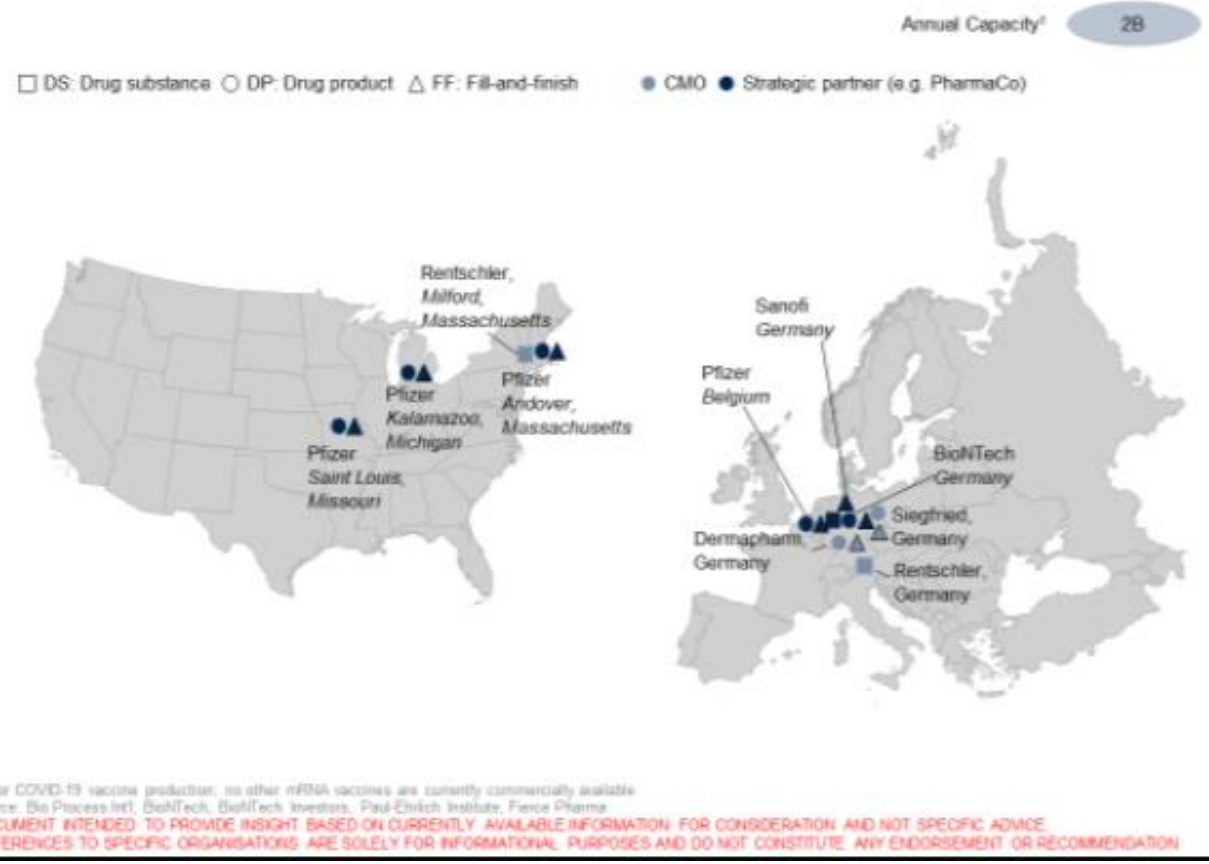
Known Vaccine Manufacturing Capacity – Moderna



1 For COVID-19 vaccine production; no other mRNA vaccines are currently commercially available
Source: Bio Process Intl, Moderna, Paul-Ehrlich Institute, Fierce Pharma
DOCUMENT INTENDED TO PROVIDE INSIGHT BASED ON CURRENTLY AVAILABLE INFORMATION FOR CONSIDERATION AND NOT SPECIFIC ADVICE
REFERENCES TO SPECIFIC ORGANISATIONS ARE SOLELY FOR INFORMATIONAL PURPOSES AND DO NOT CONSTITUTE ANY ENDORSEMENT OR RECOMMENDATION

Known Vaccine Manufacturing Capacity – BioNTech/Pfizer



1 For COVID-19 vaccine production; no other mRNA vaccines are currently commercially available
Source: Bio Process Intl, BioNTech, BioNTech Investors, Paul-Ehrlich Institute, Fierce Pharma
DOCUMENT INTENDED TO PROVIDE INSIGHT BASED ON CURRENTLY AVAILABLE INFORMATION FOR CONSIDERATION AND NOT SPECIFIC ADVICE
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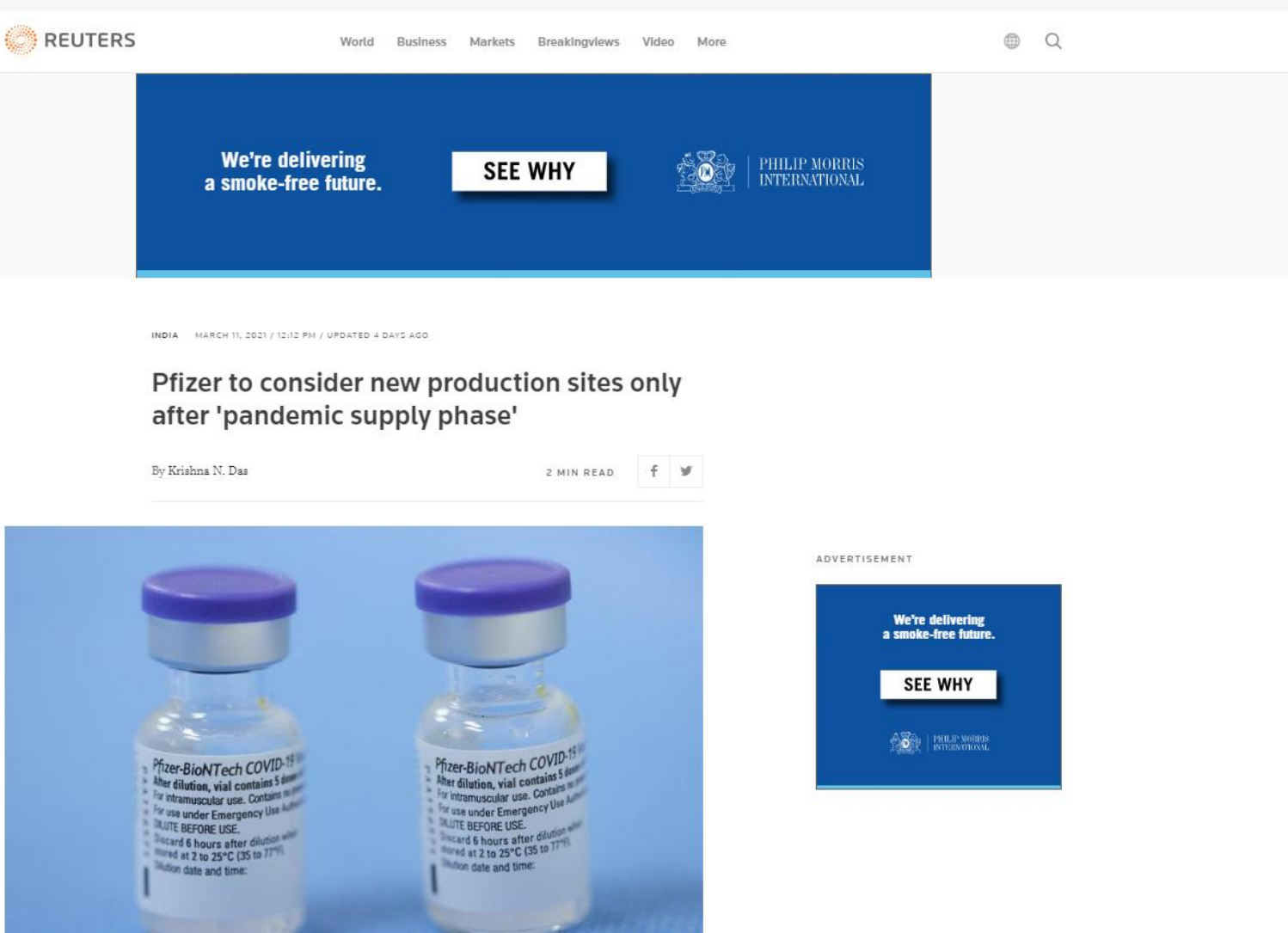
Джерело - https://www.dcvmn.org/IMG/pdf/landscape_of_current_c19_supply_chain_manufacturing_capacity_appendix_embargo_9march20.pdf

Technology transfer

Moderna announced non-prosecution of patent rights back in the summer of 2020, although trade secret protection may be a problem (an alternative explanation is the unwillingness to sue Pfizer over mRNA technology, but in this way the actual non-recognition of Pfizer's rights to mRNA technology)

In February, Pfizer said they had no internal discussion about additional local production. Once the delivery phase during a pandemic is over, then Pfizer will "assess additional options."

JnJ informally denied Canadian Biolyse a voluntary license



Джерело -
https://www.reuters.com/article/health-coronavirus-india-pfizer/pfizer-to-consider-new-production-sites-only-after-pandemic-supply-phase-idUSL4N2L929X?utm_campaign=pharmalittle&utm_medium=email&_hsmi=115341704&_hsenc=p2ANqtz-_RCSz-hqsJTYWSAo0MLUtY3wmnScxpo46F2VU4uloF0GwuW8kDlkS1eOz6StUJRiv6HFIrIu9A1XmlZJ7gp-mVNx3Dag&utm_content=115341704&utm_source=hs_email

Other countries have unused capacity

- In South Africa, where a new variant threw the country into a new crisis, manufacturer Biovac said for several weeks that it was in negotiations, but never reached an agreement with an unnamed manufacturer.
- In Denmark, the Bavarian Nordic plant has available capacity for 200 million doses, but they are still waiting for any news from the manufacturer of the approved vaccine.
- Incepta (Bangladesh) approached Moderna with an offer of its facilities - but they did not respond and only the CEO of Moderna explained in another interview that their engineers are fully loaded with the launch of production in Europe.
- The Canadian company Biolyse asked JnJ for a voluntary license and stated that if it refused, it would require the government to issue a compulsory license for the JnJ vaccine.

Джерело - https://www.csmonitor.com/World/2021/0301/Is-a-vaccine-a-private-patent-or-a-global-public-good

International Initiatives

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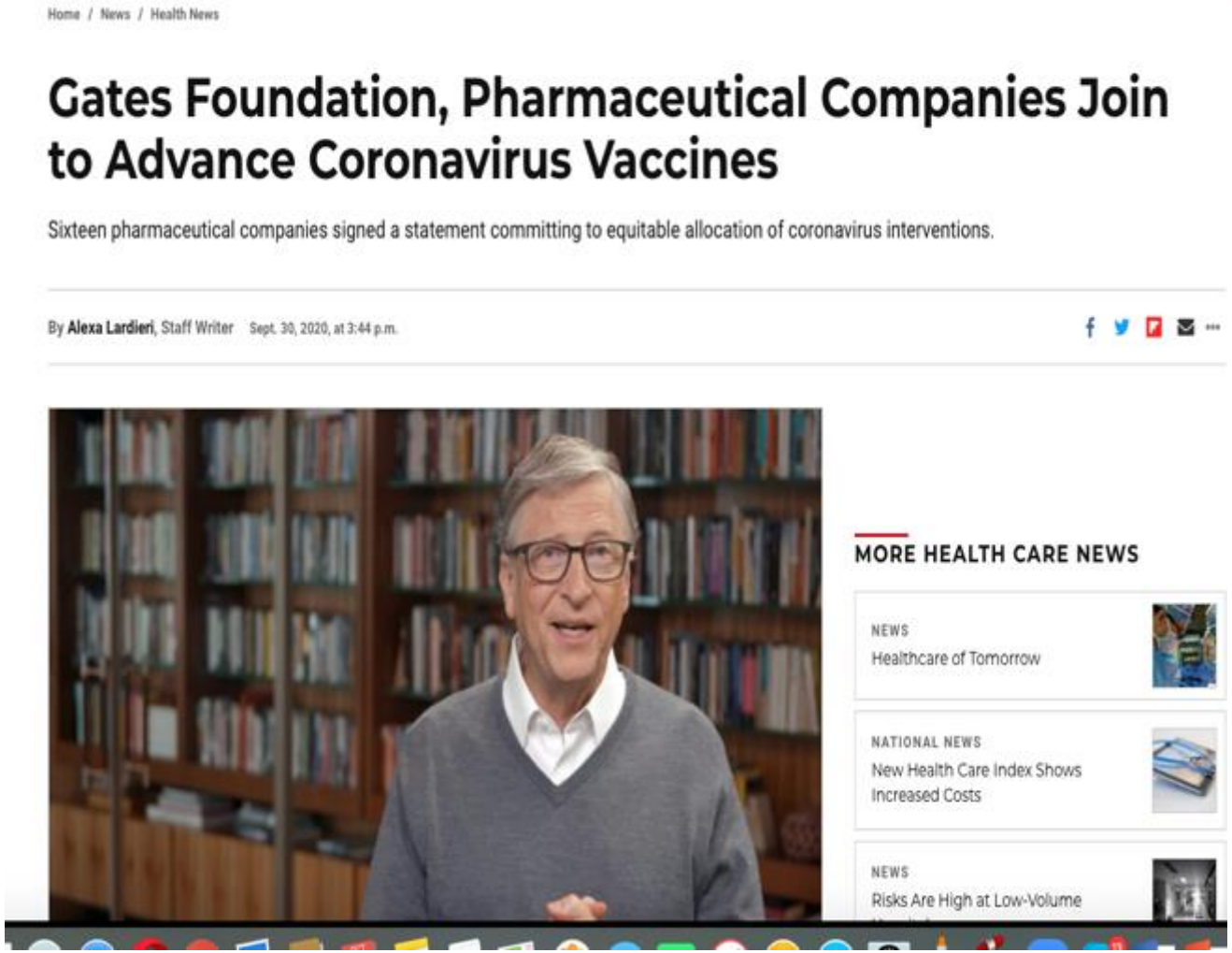
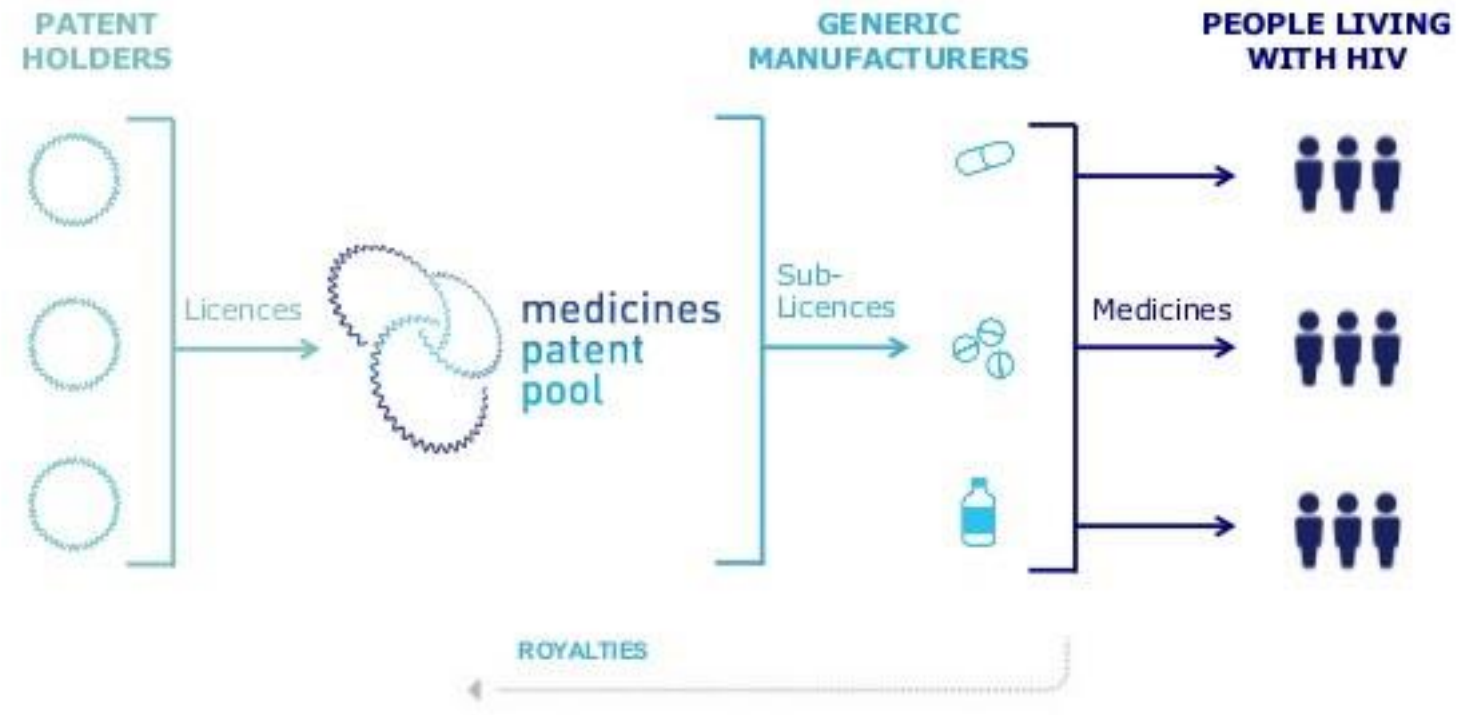
World Health Organization · UNAIDS · PATHFINDERS



Voluntary licensing

medicines patent pool

How the MPP works



Voluntary licensing: C-TAP

TECH ACCESS PARTNERSHIP

COVID Technology Access Pool announced in May 2020.

Grant voluntary licenses on a non-exclusive and global basis to the Patent Pool or other mechanisms and / or do not pursue IP rights as appropriate during a pandemic

- Provide voluntarily knowledge data for broad global manufacturing through the Technology Access Partnership TAP, which is administered by UN Technology Bank or through the Open COVID Pledge Initiative;

UN TECHNOLOGY
UNITED NATIONS TECHNOLOGY BANK FOR LEAST DEVELOPED COUNTRIES

OPEN COVID PLEDGE

Unita
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medicin
patent
pool

Voluntary licensing: C-TAP

12 November 2020

Mobilising the power of collective action against COVID-19 – An Open Pledge from Global Manufacturers of Generic Medicines

As a united group of 18 leading pharmaceutical manufacturing companies from around the world providing treatments to millions, most of whom live in low- and middle-income countries (LMICs), we come together, through this signed pledge to support the fight against COVID-19. We affirm our joint engagement and offer our capacity to develop and supply COVID-19 treatments – re-purposed, new, small molecules and biologics – to those in need.

We strongly believe that collaboration is the only way we can make it past this pandemic. Each of us stands ready to contribute to the fight against COVID-19 through our technical expertise and longstanding experience in manufacturing and distribution of quality-assured medicines. Previously, we have worked together by sourcing active pharmaceutical ingredients from each other and expanding distribution networks for finished formulations. However, this is the first time that we are coming together as a network to lend our strengths to a challenge that the world has not encountered before. Unprecedented problems call for unprecedented solutions.

One thread that connects us, the first signees of this pledge, is the work that we have done with the UN-backed Medicines Patent Pool (MPP) and many other partners in making billions – precisely 15 billion doses – of life-saving HIV and hepatitis C medicines available and affordable in LMICs. MPP's model, with its transparency, non-exclusivity and proven track record, has set the gold standard for public health voluntary licensing.

We are convinced that through a transparent approach, in working together, we can offer more than the sum of our individual capacities. In our mission to fight COVID-19 and prevent millions of unnecessary deaths everywhere, we commit to SUCCESS (Sustainable Universal access through Collaboration, Coordination, Emergency measures, Scale and Speed):

1. **Sustainable**: supporting sustainable access through affordable pricing for COVID-19 treatments and working with MPP to negotiate licences for patented effective COVID-19 therapeutics, as they become available.
2. **Universal access:** complementing the efforts of the innovators, especially in LMICs, to make sure that no one is left behind.
3. **Collaboration**: leveraging our combined geographical footprint – in manufacturing and distribution – to help combat this pandemic.
4. **Coordination**: facilitating access to COVID-19 therapeutics in LMICs by working closely with international agencies such as MPP, that work hand in glove with relevant stakeholders like the World Health Organization, Unitaid, UNICEF, USAID and The Global Fund.
5. **Emergency measures**: exploring the fastest regulatory pathways to speed up access, including the use of emergency procedures during the pandemic or import waivers, as appropriate.
6. **Scale**: dedicating significant amount of manufacturing capacity needed to ensure the demand for COVID-19 therapeutics – re-purposed, new, small molecules and biologics – can be fully met.
7. **Speed**: accelerating development and delivery timelines for new treatments with technology transfer support from MPP and originators, as needed.

Signatories:

1. Adcock Ingram
2. Arene
3. Aurobindo
4. Beximco
5. Celltrion
6. Desano
7. Emcure
8. Hetero
9. Langhua Pharma
10. Laurus Labs
11. Lupin
12. Macleods
13. Mangalam
14. Micro Labs
15. Natco
16. Strides Shasun
17. Sun Pharma
18. Zydus Cadila

Medicines Patent Pool
medicinespatentpool.org

Voluntary licensing: C-TAP

TECH ACCESS PARTNERSHIP

Rejection of the MPP IFPMA model of voluntary licenses such as C-TAP (IFPMA position):

IP is not a barrier to access to drugs,

global licenses and no patent prosecution is a one-size fits all solution, but here we need a tailor-made solution for each country (MPP)

Gilead's bilateral license for remdesivir and Merck on Molnupiravir

https://www.ifpma.org/resource-centre/ifpma-statement-on-the-solidarity-call-to-action-to-realize-equitable-global-access-to-covid-19-health-technologies-through-pooling-of-knowledge-intellectual-property-and-data/

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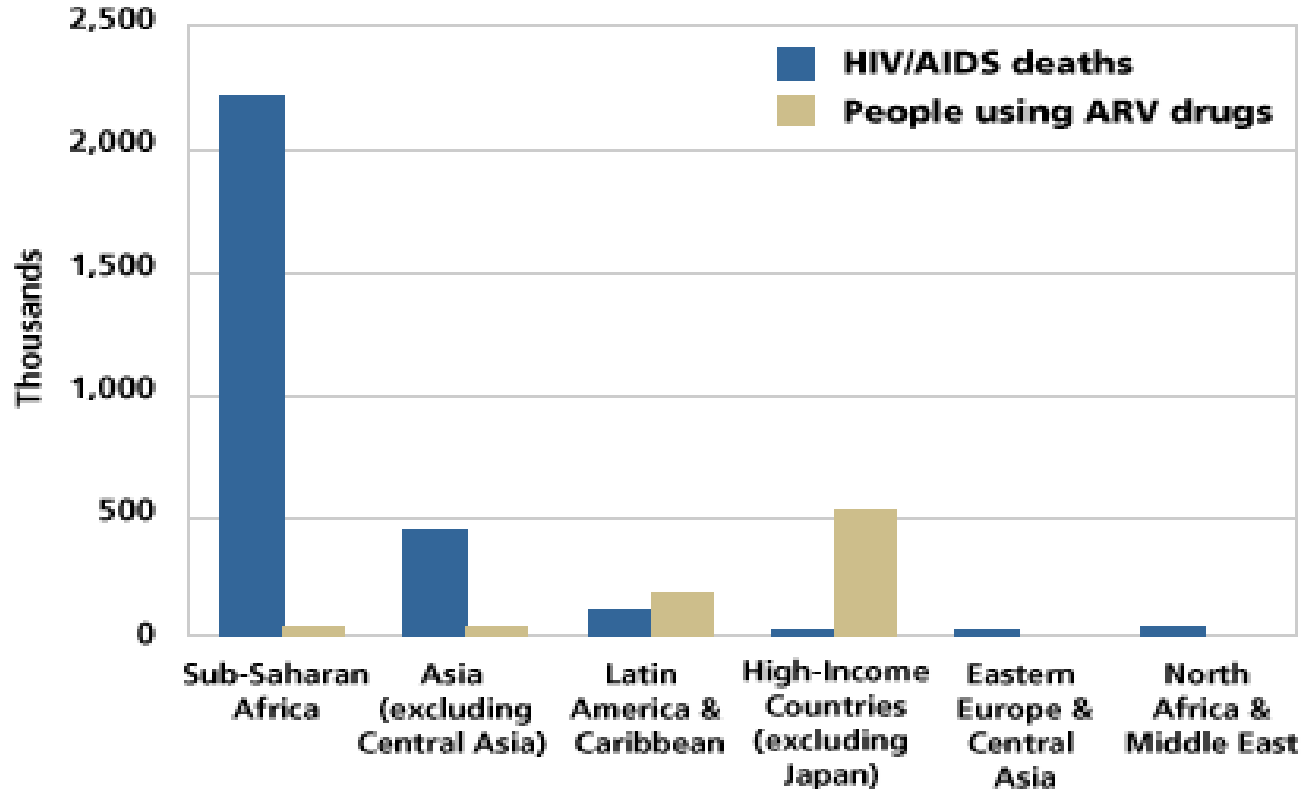
OPEN COVID PLEDGE

medicin patent pool

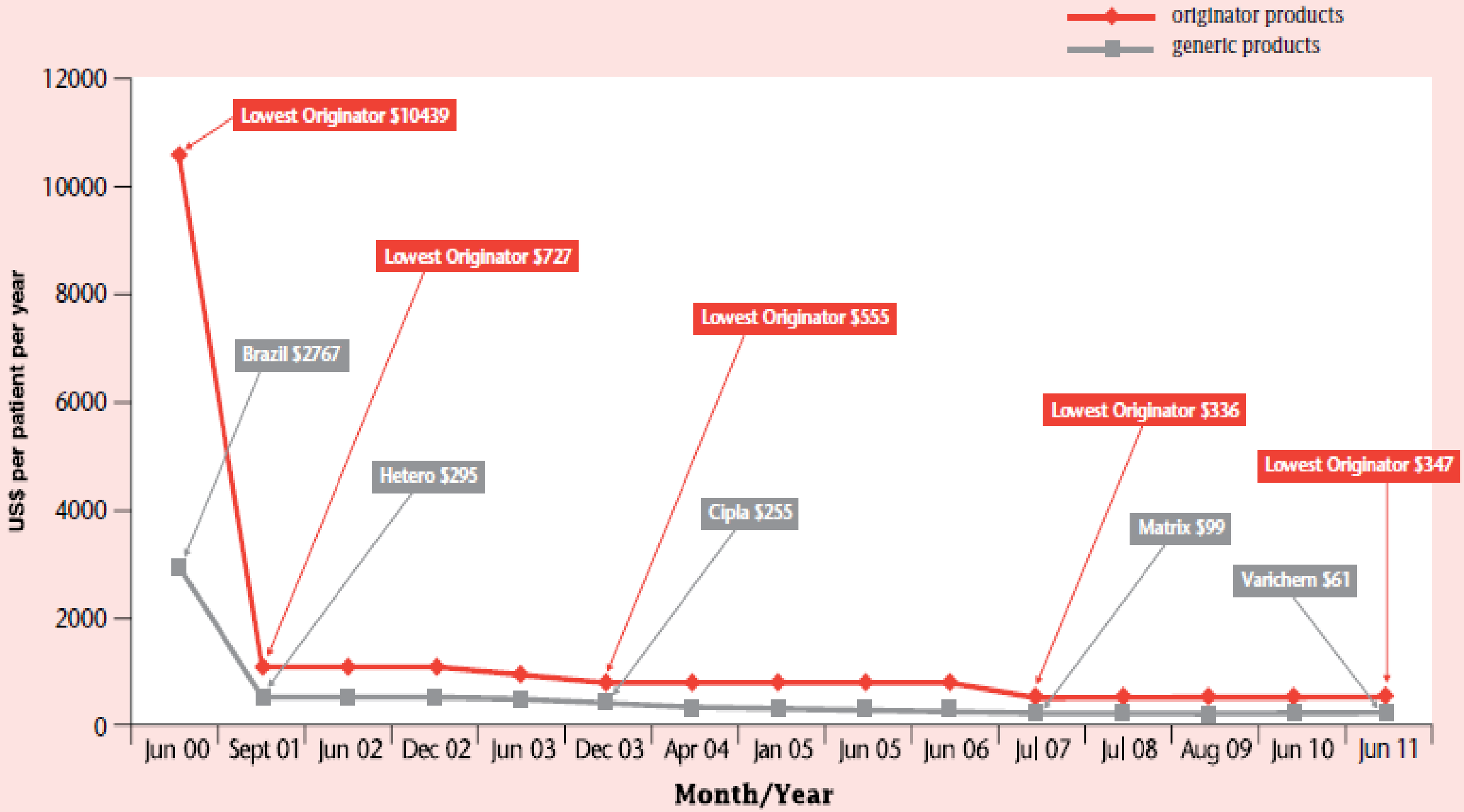
2001: The WTO's TRIPS Agreement and HIV

HIV/AIDS Deaths

HIV/AIDS deaths in 2001, by region, and number of people using antiretroviral drugs by end 2001.



Source:WHO/UNAIDS, 2002


originator products
generic products
12000
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4000
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US$ per patient per year
Lowest Originator $10439
Lowest Originator $727
Lowest Originator $555
Lowest Originator $336
Lowest Originator $347
Brazil $2767
Hetero $295
Cipla $255
Matrix $99
Varichem $61
Jun 00
Sept 01
Jun 02
Dec 02
Jun 03
Dec 03
Apr 04
Jan 05
Jun 05
Jun 06
Jul 07
Jul 08
Aug 09
Jun 10
Jun 11
Month/Year

WHICH MEASURES ARE BEING TAKEN TO ADDRESS MONOPOLIES ON COVID-19 TECHNOLOGIES?

Canada legislative changes due to COVID-19

- Canada has amended its laws to make it easier to issue compulsory licences. Bill C-13, the COVID-19 Emergency Response Act, passed into law on 25th March.
- Along with a range of powers to tackle problems cause by coronavirus, it specifies that if the Federal Minister of Health considers there to be a public health emergency, the Commissioner of Patents may allow the Canadian state to produce, sell and use a patented invention.
- Unlike existing compulsory licensing provisions, the new law allows the government to issue a licence without first negotiating with the rights holder or establishing its own ability to supply a product.
- Patentees must be compensated, but the law states only that they should receive "any amount the Commissioner considers to be adequate remuneration in the circumstances", taking into account the economic value of the permit.
- Licences issued under the new legislation are non-transferable and will be cancelled if the state of national emergency comes to an end.
- The provision expires at the end of September 2020, after which no patent permit can be granted.

Джерело - https://www.iam-media.com/coronavirus/the-key-covid-19-compulsory-licensing-developments-so-far

Canada: Act respecting certain measures in response to COVID-19, Part 12, passed by House of Commons of Canada on March 24, 2020 https://www.parl.ca/DocumentViewer/en/43-1/bill/C-13/third-reading#ID0ETAA

Canada vaccines production capacity

- Canada used to have a strong domestic vaccine industry. Federal records show in 1973, Canada relied on imports for only about one-fifth of its domestic pharmaceutical requirements including both vaccines and therapeutic drugs.
- But the industry began to dry up in the 1980s, with multiple firms closing their Canadian operations, including AstraZeneca, Bristol Myers and Johnson and Johnson.
- Today, Canada relies on imports for at least 85 per cent of the vaccines and other pharmaceuticals it uses.

https://pm.gc.ca/en/news/news-releases/2020/08/31/new-measures-ensure-supply-future-vaccines-and-therapies-against

Canada – investments in local manufacturing

The government has invested:

- more than $1 billion in vaccine procurement agreements to secure a domestic supply, of up to 429 million doses, of seven promising vaccines—representing more than 10 doses for every Canadian.
- $600 million will support private sector work to develop a vaccine, conduct therapeutic clinical trials, and pursue biomanufacturing opportunities in Canada.

  - The federal government also previously invested $46 million in a vaccine development facility at the University of Saskatchewan, which the prime minister said would be able to produce up to 40M doses annually. By end of 2021 to be completed.

  - Prime Minister Justin Trudeau announced Tuesday (Feb. 2) that Vancouver-based Precision NanoSystems Inc. (PNI) will be among those companies tapped to boost vaccine production (50M project by 2023) following a $25-million investment from Ottawa. 240M doses per year or 24M mRNA vaccines

https://www.canada.ca/en/innovation-science-economic-development/news/2021/02/backgrounder--government-of-canada-investments-in-covid-19-vaccines-and-biomanufacturing-capacity.html

https://pm.gc.ca/en/news/news-releases/2020/08/31/new-measures-ensure-supply-future-vaccines-and-therapies-against

National Research Council of Canada began construction of a center for the production of biological products based on cell biology (vector vaccines, protein, virus-like particles, recombinant proteins)

$126M investment and $20M annually on maintenance
2M doses monthly

In August 2020, construction was announced. Completion is scheduled for July 2021

https://nrc.canada.ca/en/research-development/nrc-facilities/biologics-manufacturing-centre

Canada - Statement at the TRIPS Council on 23 February 2021

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- The Government of Canada approached seven vaccine developers and discussed the possibility of producing them in Canada.
- Until very recently, the conclusion of these discussions was that production capacity in Canada was "too limited to justify the investment of capital and experience to start production in Canada."
- However, with further investment in manufacturing facilities, Canada has now been able to reach a memorandum of understanding with the US company Novavax to develop the production of its COVID-19 vaccine at the National Research Council of Canada's Biologics Manufacturing Center in Montreal.

«What we're very clear on is Canada will be developing domestic manufacturing, so regardless of what could happen in the future, we will have domestic production."» Трюдо

Джерело - https://www.iam-media.com/coronavirus/the-key-covid-19-compulsory-licensing-developments-so-far
Canada: Act respecting certain measures in response to COVID-19, Part 12, passed by House of Commons of Canada on March 24, 2020 https://www.parl.ca/DocumentViewer/en/43-1/bill/C-13/third-reading#ID0ETAA

France

- new law (No 2020-290) was enacted on 23rd March - introduced a new article - L.3131-15 – to the country's public health code,
- allowing the Prime Minister to order the seizure of all goods and services necessary to: fight against sanitary disaster; to temporarily control the prices of products; and to take any measures necessary to make relevant medicines available to patients.
- According to Clifford Chance, this goes well beyond the compulsory licensing measures adopted elsewhere: "From a practical standpoint, the Prime Minister would now be allowed (i) to permit the seizure of drugs and/or (ii) **to direct the launch of generic products on French territory before the expiry of patents/SPCs, if necessary**."

Джерело - https://www.iam-media.com/coronavirus/the-key-covid-19-compulsory-licensing-developments-so-far

Israel compulsory license (CL)

- The only country in which a Covid-19-related compulsory licence has been granted so far is Israel.
- On 18th March, the minister of health and attorney general issued a permit allowing the state to import a generic version of AbbVie's Kaletra from India for the treatment of coronavirus patients.
- The licence was issued under Section 104 of the patent statute, which allows the state to circumvent the law for national defence purposes.
- This requires no consultation with the patentee, which also has no right to judicial review.
- The decision is thought to have been triggered by concerns that AbbVie would not be able to supply Israel with sufficient quantities of the drug.
- The move is especially significant as it marks the first compulsory licence issued in the country under Section 104 since the provision's introduction in 1967.

Джерело - https://www.iam-media.com/coronavirus/the-key-covid-19-compulsory-licensing-developments-so-far

Israel: Patents Law 5727-1967 as consolidated 2014, Article 3, Sections 104-106 and 108-111A https://www.wipo.int/edocs/lexdocs/laws/en/il/il040en.pdf and unofficial English translation of the Israel's Permit, authorizing the importation of Kaletra for the sole purpose of treating patients with covid-19 can be found here: https://www.keionline.org/wp-content/uploads/A-Permit-to-the-State-to-Exploit-an-Invention-Pursuant-to-Chapter-Six-Article-Three-of-the-Patents-Law-5727-1967.pdf

Israel CL: patent law

Article Three: Use of Inventions in the Interest of the State

Right of State to exploit invention

104. The Minister may permit the exploitation of an invention **by Government departments or by an enterprise or agency of the State**, *whether a patent for it has or has not already been granted or has or has not already been applied for*, if he finds that that is necessary in the interests of the National security or of the maintenance of essential supplies and services.

Right of State to permit exploitation of invention

105. The Minister may, if he finds that that is necessary for the purposes enumerated in section 104, grant a permit under that section **to a person who operates under contract with the State, in order to ensure or facilitate the implementation of that contract** and for the requirements of the State only.

Джерело - https://www.iam-media.com/coronavirus/the-key-covid-19-compulsory-licensing-developments-so-far

Israel: Patents Law 5727-1967 as consolidated 2014, Article 3, Sections 104-106 and 108-111A https://www.wipo.int/edocs/lexdocs/laws/en/il/il040en.pdf and unofficial English translation of the Israel's Permit, authorizing the importation of Kaletra for the sole purpose of treating patients with covid-19 can be found here: https://www.keionline.org/wp-content/uploads/A-Permit-to-the-State-to-Exploit-an-Invention-Pursuant-to-Chapter-Six-Article-Three-of-the-Patents-Law-5727-1967.pdf

Israel CL: patent law

Article Four: Obligation of the State to Pay Compensation and Royalties

Royalties for use of patents by the State

108. If a permit was granted under sections 104 or 105, then the State Treasury shall pay to the owner of the invention, to the patent holder or to the holder of an exclusive license, as the case may be, **royalties set by agreement between the parties or – in the absence of agreement – set by the compensation and royalties committee.**

Джерело - https://www.iam-media.com/coronavirus/the-key-covid-19-compulsory-licensing-developments-so-far

Israel: Patents Law 5727-1967 as consolidated 2014, Article 3, Sections 104-106 and 108-111A https://www.wipo.int/edocs/lexdocs/laws/en/il/il040en.pdf and unofficial English translation of the Israel's Permit, authorizing the importation of Kaletra for the sole purpose of treating patients with covid-19 can be found here: https://www.keionline.org/wp-content/uploads/A-Permit-to-the-State-to-Exploit-an-Invention-Pursuant-to-Chapter-Six-Article-Three-of-the-Patents-Law-5727-1967.pdf

Wednesday, 22nd of Adar, 5780

March 18, 2020

To

The Emergency Department, Ministry of Health

K.S. Kim International Ltd., Company ID# 51-389054-1

A Permit to the State to Exploit an Invention Pursuant to Chapter Six, Article Three of the Patents Law 5727-1967

In accordance with the power vested in me under Cabinet Decision #4888 from March 13, 2020[1] pursuant to Section 112 of the Patents Law 5727-1967[2] (hereinafter – the Law), I hereby grant permission, in accordance with Sections 104 and 105 of the Law, to the Emergency Department at the Ministry of Health and to K.S. Kim International Ltd. to exploit the invention protected in patents numbers 173939, 207260, 185390 by way of importation of the lopinavir 200mg/ritonavir 50mg medication manufactured by Hetero, for the sole purpose of medicinal treatment of Corona patients (Novel Coronavirus 2019, pursuant to a Notice of a Dangerous Infectious Disease, under the Public Health Ordinance, 1940, dated 27.1.20). The permission to exploit is necessary in the interest of the maintenance of essential supplies and services.

[-]

MP Rabbi Yaacov Litzman

Minister of Health

Hungary: change in legislation on compulsory licensing

- Hungarian law contained only a provision for a compulsory license for export;
- Government Decree 212/2020 of 17 May 2020 included provisions on compulsory licenses for health emergencies.
- The CL is issued by the Hungarian IP Office (HIPO) on the basis of a submission from the Hungarian Pharmaceutical Regulator (OGYÉI) regarding national needs to address a critical health situation.
- The object of the CL can be any of the following:

a. Use of a medicinal product or API that is protected by a patent or supplementary protection certificate (SPC), or a medical device, or an investigational medicinal product protected by a patent; or

b. Use of a process, equipment or device necessary for the production of medical technology.

- For domestic needs only

Hungary: "secret" CL / government use of remdesivir

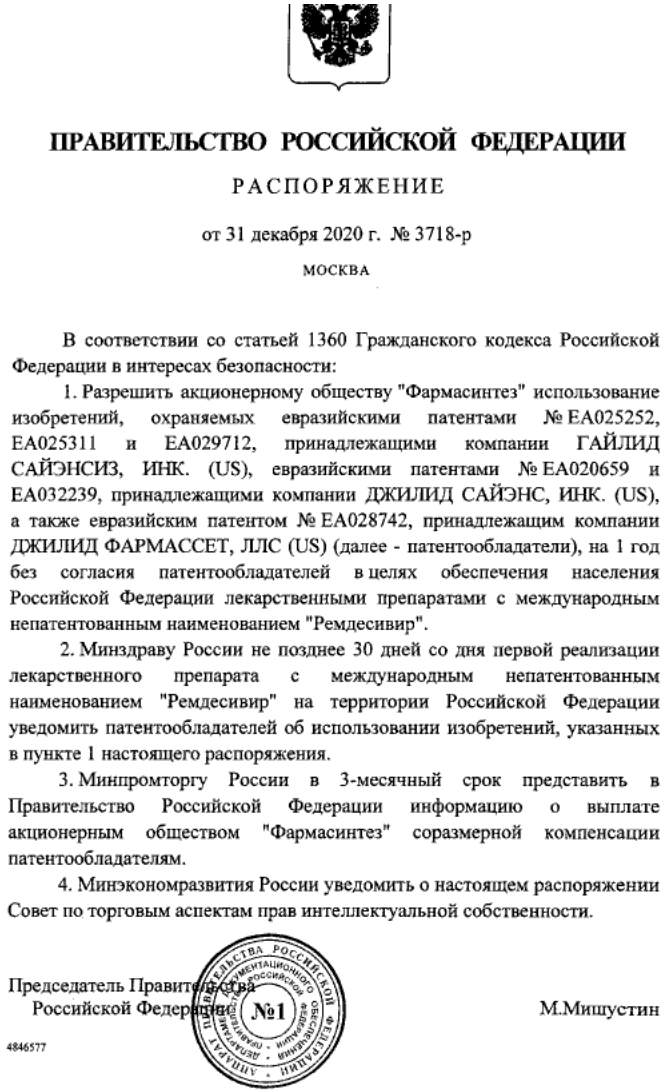
- On October 7, 2020, Reuters reported that Gideon Richter had produced 3,000 courses of remdesivir for Hungarians;
- The Hungarian government, which owns 5.25% of Richter's shares, approached the company during the first wave of the pandemic to investigate whether Remdesivir could be produced nationally.
- It took 5 months to solve the problem of synthesis
- The government funded the development
- US Chamber of Commerce Submission to USTR Special 301 Review 2021:

"This is despite the fact that Hungary has already purchased and used medicines through a Joint Procurement Agreement agreed between the European Union and the patent owner. The Hungarian government did not cooperate with the patent owner and did not indicate that the supply did not meet national needs. This is contrary to Hungary's commitment, as well as the European Commission's position on the use of compulsory licenses as a last resort and safety net, when all other attempts to make IP available fail."

Джерело - https://www.keionline.org/35558

Russia: "New Year's" CL / use by the government for remdesivir

- In November-December, the Duma considered amendments to the patent law to include the CL basis for health care needs. Stuck after the first reading;
- On December 31, 2020, by the order of the government in the interests of security, 5 Eurasian patents owned by three subsidiaries of Gilead allowed it use to JSC "Pharmasintez«
- Providing the population of the Russian Federation
- Notify the patent owner within 30 days from the date of first sale
- For a period of 1 year
- Gilead filed a lawsuit against Russian government



ПРАВИТЕЛЬСТВО РОССИЙСКОЙ ФЕДЕРАЦИИ

РАСПОРЯЖЕНИЕ

от 31 декабря 2020 г. № 3718-р

МОСКВА

В соответствии со статьей 1360 Гражданского кодекса Российской Федерации в интересах безопасности:

1. Разрешить акционерному обществу "Фармасинтез" использование изобретений, охраняемых евразийскими патентами № EA025252, EA025311 и EA029712, принадлежащими компании ГАЙЛИД САЙЭНСИЗ, ИНК. (US), евразийскими патентами № EA020659 и EA032239, принадлежащими компании ДЖИЛИД САЙЭНС, ИНК. (US), а также евразийским патентом № EA028742, принадлежащим компании ДЖИЛИД ФАРМАССЕТ, ЛЛС (US) (далее - патентообладатели), на 1 год без согласия патентообладателей в целях обеспечения населения Российской Федерации лекарственными препаратами с международным непатентованным наименованием "Ремдесивир".

2. Минздраву России не позднее 30 дней со дня первой реализации лекарственного препарата с международным непатентованным наименованием "Ремдесивир" на территории Российской Федерации уведомить патентообладателей об использовании изобретений, указанных в пункте 1 настоящего распоряжения.

3. Минпромторгу России в 3-месячный срок представить в Правительство Российской Федерации информацию о выплате акционерным обществом "Фармасинтез" соразмерной компенсации патентообладателям.

4. Минэкономразвития России уведомить о настоящем распоряжении Совет по торговым аспектам прав интеллектуальной собственности.

Председатель Правительства Российской Федерации М.Мишустин

4846577

Джерело - https://www.keionline.org/35558

Civil Society in middle income countries challenge Covid19 patents

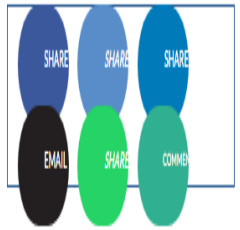
GSIPA2M
GLOBAL SUMMIT ON INTELLECTUAL PROPERTY & ACCESS TO MEDICINES: PATHWAYS TO ACCESS
15-17 January 2018 MARRAKECH - MOROCCO

News

Cancer patients' group calls for patent revocation on Remdesivir

PT Jyothi Datta | Mumbai | Updated on April 13, 2020 | Published on April 13, 2020

The Gilead drug is under trial to treat Covid-19



The Cancer Patients Aid Association (CPAA) has sounded a note of caution on the patent status of Remdesivir, an antiviral drug from Gilead Sciences Inc that is being tested for its effectiveness in treating patients with the

ARGENTINA: FUNDACIÓN GEP OPPOSES GILEAD'S PATENT APPLICATION ON REMDESIVIR

5 JUN 2020

CALL TO ACTION NEWS

Our partner, Fundación GEP, has filed a patent opposition against Gilead's patent application on remdesivir before the Argentinean Patent Office. The civil society organization has requested that the National Institute of Intellectual Property (INPI) rejects the patent application to prevent the company acquiring a monopoly on a drug which *could* be a breakthrough in the treatment of COVID-19.

Yesterday (4 June 2020), Fundación GEP filed a patent opposition against a patent application for remdesivir submitted by Gilead, the US multinational pharmaceutical company. Remdesivir is one of the drugs currently being studied in clinical trials for effectiveness in the treatment of COVID-19.

The corporation has filed numerous patent applications on remdesivir around the world, in February and April this year. As the pandemic grew, Gilead sought to protect its potential profits and block competition, which would be essential in order to upscale production and treat everyone in

THAI CIVIL SOCIETY OPPOSES PATENT ON AN INFLUENZA DRUG, NOW USED FOR COVID-19

30 JUL 2020

NEWS

- Favipiravir, originally approved as an influenza drug, is being used to treat COVID-19 patients with pneumonia, alongside anti-malarial and anti-retroviral medicines.
- During March and April 2020, Thailand imported over 150,000 tablets from Japan and China, brand name 'Avigan', priced at $4 (USD) per pill.
- The typical cost is $28-32 per person per day. The fair price has been estimated to be significantly less, at $1.45 per day.
- AIDS Access Foundation (AAF), our campaign partner in Thailand, has filed a third-party observation opposing FujiFilm Toyama Chemical's application, which AAF deems to be unmerited.

FujiFilm Toyama Chemical has filed for patents on favipiravir in numerous countries, including three in Thailand. If approved, this would continue to block generic competition until after 2031, as under Thai law, a patent's duration is 20 years from the date the patent application was filed.

Current treatment guidelines in Thailand for people with COVID-19 and pneumonia is to prescribe favipiravir for 5-10 days, requiring a total of 40-70 tablets. The price, for FujiFilm Toyama's branded medicine, equates to between $28-32 per person per day.

Proposal of South Africa and India for exemption from the use of TRIPS (TRIPS Waiver proposal)

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«1. Members' obligations to comply with or apply sections 1, 4, 5 (patents) and 7 (protection of undisclosed information) of Part II of the TRIPS Agreement or to enforce those sections in accordance with Part III of the TRIPS Agreement do not apply to the prevention, containment or treatment of COVID-19 within [X] years from the decision of the General Council [WTO].

4. This exemption shall be reviewed by the General Council not later than one year after its grant and then annually until such exemption is terminated, in accordance with the provisions of Article IX, paragraph 4, of the WTO Agreement.

5. Members may not challenge any action taken under the waiver provisions of this Decision under Article XXIII, paragraphs 1 (b) and 1 (c), of GATT 1994, or through the WTO Dispute Settlement Mechanism. "

Why is TRIPS Waver important?

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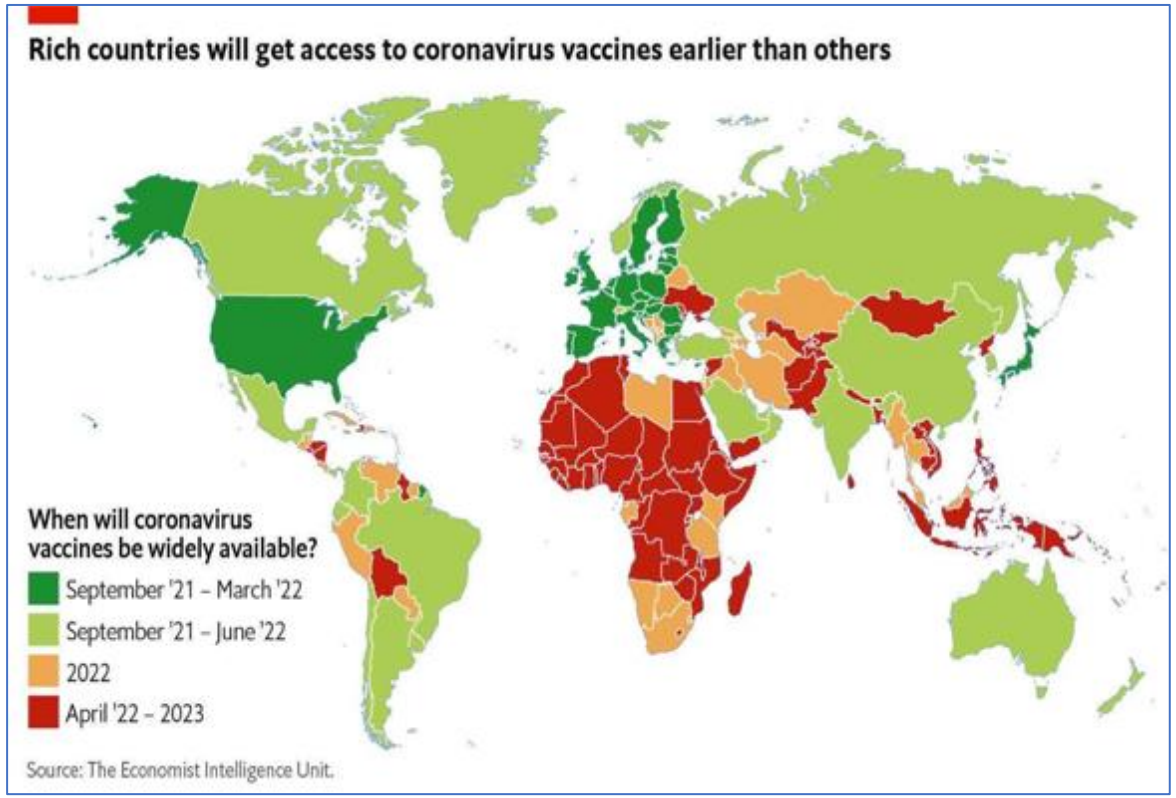
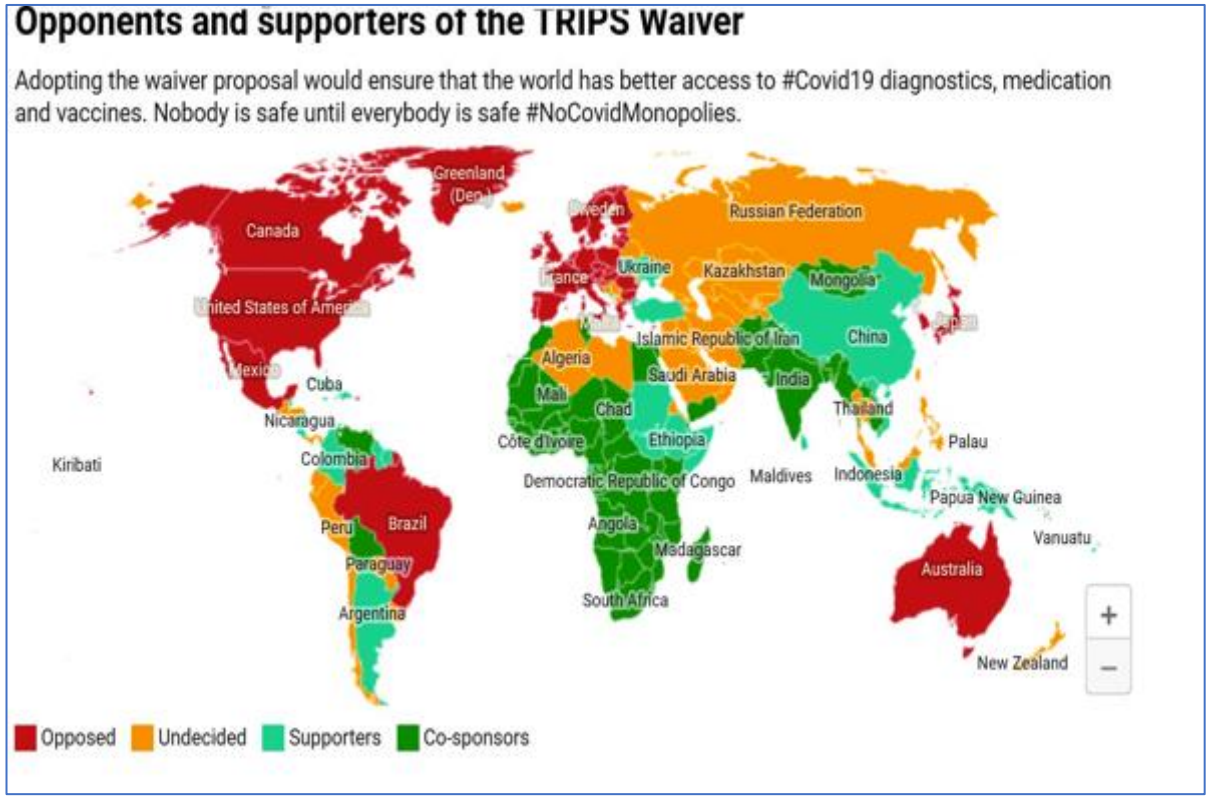
- Criticism and pressure from developed countries (EU, USA) even when using the permitted mechanisms of the TRIPS Agreement: compulsory licensing, exclusion of treatment methods, etc.
- Positive legal certainty, no need to conduct freedom-to-operate analysis
- This will provide countries with the political space needed to collaborate on R&D, manufacturing, scaling and supplying COVID-19 instruments.

*Countries will need to amend their legislation to take advantage of the opportunities offered by WTO TRIPS-Waver

Maps of inequity





EU IP Action Plan 2020: Need for Compulsory Licensing


EUROPEAN COMMISSION

COMMUNICATION FROM
PARLIAMENT, THE COUNCIL
COMMITTEE AND T

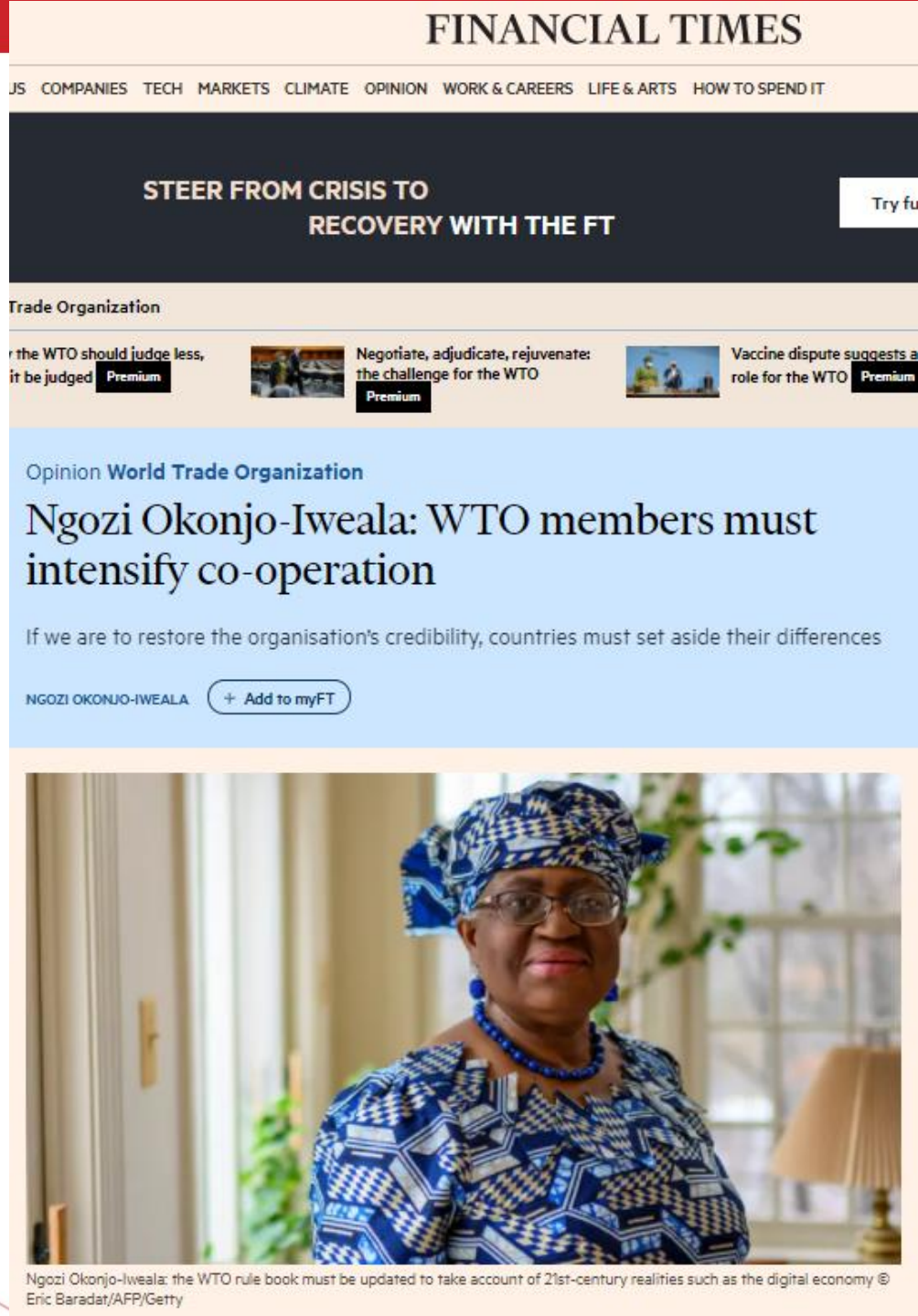
Making the most
An intellectual property action

"The Commission calls on Member States to ensure that the tools they have are as effective as possible, for instance, by putting in place fast-track procedures for issuing compulsory licenses in emergency situations."

- "Finally, the Commission sees the need to ensure that effective systems for issuing compulsory licenses are in place, to be used as a means of last resort and a safety net, when all other efforts to make IP available have
rade Related Aspects
RIPS) provides for a
sted, to issue
nent's authority to
grant permission to a party seeking use of a patented invention without the consent of the patent owner. The procedure can be fast-tracked in the case of national emergency. In combination with the Doha Declaration on the TRIPS Agreement and Public Health, it is clear that each WTO Member has not only the right to grant compulsory licences, but also the freedom to determine the grounds upon which such licences are granted."

3rd Way

- March 2, 2021 publication in the FT of the new Director General of the WTO
- A summit of COVID technology manufacturers organized by IFPMA, BIO took place on March 8-9
- New proposal from 7 countries (Ottawa Group), which aims to undermine the proposal for TRIPS waver (removal of export restrictions, exchange of experience on customs regulations, etc.)
- Ngozi: "We must find a "third way" on intellectual property that *preserves the multilateral rules that encourage research and innovation* while *promoting licensing agreements* to help scale-up manufacturing of medical products. Some pharmaceutical companies such as AstraZeneca, Johnson & Johnson and the Serum Institute of India are already doing this."



FINANCIAL TIMES

US COMPANIES TECH MARKETS CLIMATE OPINION WORK & CAREERS LIFE & ARTS HOW TO SPEND IT

STEER FROM CRISIS TO RECOVERY WITH THE FT

Try fu

Trade Organization

the WTO should judge less, it be judged Premium

Negotiate, adjudicate, rejuvenate: the challenge for the WTO Premium

Vaccine dispute suggests a role for the WTO Premium

Opinion World Trade Organization

Ngozi Okonjo-Iweala: WTO members must intensify co-operation

If we are to restore the organisation's credibility, countries must set aside their differences

NGOZI OKONJO-IWEALA + Add to myFT

Ngozi Okonjo-Iweala: the WTO rule book must be updated to take account of 21st-century realities such as the digital economy © Eric Baradat/AFP/Getty

Endorsements/support: reports

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- OECD Report: , “without the Waiver, while several developing countries have the capacity to manufacture vaccines, intellectual property (IP) rights and limited technology transfer remain barriers to build local production capacity, as stated in a recent OECD (Paris-based Organization for Economic Cooperation and Development) report,” he argued.
- The OECD report, according to Mr De Gama, “further states that R&D of vaccines, as well as production capacity, is concentrated in just a few countries in the world, thereby requiring most low- and middle-income countries to import vaccines.”
- Therefore, “sustainable policy options to respond to the virus should include encouraging the transfer of technical know-how to manufacturers in developing countries.”

- Boston University Policy Brief
- Endorsed by 175 former world leaders and Nobel Laureates
- CSO letter of support

Some counterarguments

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- There will be no incentive to R&D

- The policy brief said “with respect to the COVID-19 vaccines, governments around the world have invested an estimated $100 billion through different means in COVID-19 vaccine development so far. These vaccines would not exist without support from governments who have the resources available to contribute. Even where vaccine creators did not rely on public funds for the initial research and development stage, they had significant pre-orders and guaranteed global demand, ensuring massive profits”.

- Even the funds for the Oxford/AstraZeneca Covid-19 vaccine has been identified as coming from taxpayers or charitable trusts, of up to 98%, with less than 2% of the identified funding coming from private industry.

- “This confirms once again what the co-sponsors have said on pg 28 of IP/C/W/672 that AstraZeneca has gone so far as to state that the development of the vaccine will have no financial implications for the company since expenses to progress the vaccine are anticipated to be offset by funding by governments and international organizations,” the South African negotiator argued.

- According to a Guardian newspaper report of 6 March 2021, titled “From Pfizer to Moderna: who’s making billions from Covid-19 vaccines?”, expected sales for Pfizer in 2021 is between $15 billion to $30 billion; for Moderna, expected sales in 2021: $18-$20 billion; for Johnson & Johnson, expected sales in 2021: up to $10 billion; for AstraZeneca, expected sales in 2021: $2-$3 billion; with the remaining vaccines also likely to earn billions of dollars.

Some counterarguments

- VL and current collaborations will not be possible
- the legal nature of VLs (voluntary licenses), suggesting that “they are governed by contract law, and each agreement would contain clear clauses on the governing law, and how it may be terminated.”

- He said that “the majority of the current manufacturing agreements are contract manufacturing agreements, or fill- and-finish agreements,” suggesting that “even with the waiver technology, holding companies can continue to contractually engage contract manufacturers to manufacture on their behalf as well as companies only interested in fill-and-finish with the technology holding company supplying the bulk drug.”
- He explained that the “technology holding companies may also offer licensing deals in relation to their expertise and knowledge of the technology they hold.”

Some counterarguments

- VL and current collaborations will not be possible
- He said that for tens of billions of dollars of profits pocketed by Big Pharma, the world economy and countries are going to lose trillions of dollars due to the failure to accept the TRIPS waiver, he suggested.

Recent developments: 22 April informal TRIPS Council meeting

- At an informal TRIPS Council meeting held on a virtual platform on 22 April
- members had stuck to their positions in the small-group consultations he held on 12-13 April, and thereby made little progress, the chair maintained.
- According to the chair, the TRIPS Council will therefore continue its consideration of the waiver request.
- Ambassador Sorli said that he will report to the General Council at its meeting on 5-6 May, arguing that he had submitted a draft oral status report to the General Council which will be further discussed at a formal TRIPS Council meeting on 30 April.
- Switzerland, EU, UK are against
- Around 20 delegations took the floor at the meeting, with the majority of the members supporting the demand for text-based negotiations on the TRIPS waiver, said people familiar with the development.

When asked who owned the patent on his vaccine against poliovirus, its inventor Jonas Salk famously responded:

"The people, I would say. There is no patent. Could you patent the sun?"