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Excellence with Morality

**OPTIMIZING INTELLECTUAL PROPERTY  
PRODUCTS FOR PUBLIC WELFARE;  
IS IT POSSIBLE?  
The Case of Pandemic Covid-19**

by

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Presented at Public Lecture,  
Faculty of Law, Universitas Pancasila,  
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# Opening remarks

**IP laws exist to improve the quality of people's by providing creations and innovations that make them better off.**

(Christopher Buccafusco & Jonathan Masur, 2017)





# What is the WTO?



- forum for negotiations
- agreed rules and commitments
- with basic principles for trade and dispute settlement
- member-driven
- supporting Secretariat



# Intellectual Property under WTO

Intellectual property rights are the rights given to persons over the creations of their minds. They usually give the creator an exclusive right over the use of his/her creation for a certain period of time

Linkage between Intellectual Property (IP) and trade: broadly through following two premises:

- (I) Widespread piracy, counterfeiting and infringements of intellectual property rights constituted a barrier to trade
- (II) IPRs transfer agreements



# Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

Annex 1C of WTO Agreement  
Coverage :

Most comprehensive multilateral agreement on intellectual property to date incorporating substantive provisions of:

1. Paris Convention (1967)
2. Berne Convention (1971)
3. Rome Convention (1961)
4. Treaty on IP in Respect of Integrated Circuits (1989)



# Objective

- To reduce distortions and impediments to international trade and take into account the need to promote competent as well as adequate protection of IPRs
- To ensure that measures and procedures to enforce IPRs do not themselves become barriers to legitimate trade
- To reduce tensions by reaching strengthened commitment to resolve disputes on trade-related IP issues through multilateral procedures
- To establish a mutually supportive relationship between the World Trade Organisation (WTO) and World Intellectual Property Organisation (WIPO)



## TRIPs: Areas of IP protected

- Copyright and related rights
- Trademarks including service marks;
- Geographical indications including appellations of origin;
- Industrial designs;
- Patents including the protection of new varieties of plants;
- The layout-designs of integrated circuits; and
- Undisclosed information, including trade secrets and test data.



## Intellectual Property & Public Interest

- IP systems should balance the protection and its enforcement with public interest consideration
- TRIPs Agreement balances the rights and obligation, transfer technology, for the progress and welfare of mankind







International intellectual Property Law, particularly TRIPs Agreement on patent leads to :



International law provides a just global solution, not only in times of pandemic, but also for other health emergencies



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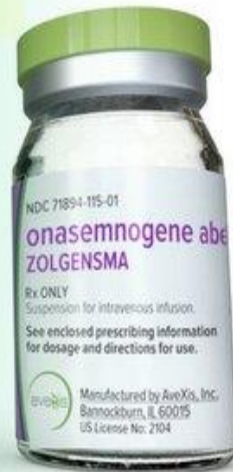
# zolgensma®

(onasemnogene  
abeparvovec-xioi)

suspension for intravenous infusion

**ZOLGENSMA**

(Onasemnogene  
abeparvovec)



**\$2.1**  
**Million**  
**Per injection**





# TRIPs Agreement

- “The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligation” (art. 7)
- Art 8 allows members to adopt measures necessary to promote the public interest, including to protect public health – so long as those measures are consistent with the TRIPs Agreement.



# Right to Health vs Intellectual Property

- International human right law establish a universal framework for promoting equitable global health, transforming moral obligations into legal rights for the good of human life





# Right to Health

Art 27 UDHR:

1. Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and **to share in scientific advancement and its benefits**
2. Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.





# Right to Health vs Intellectual Property

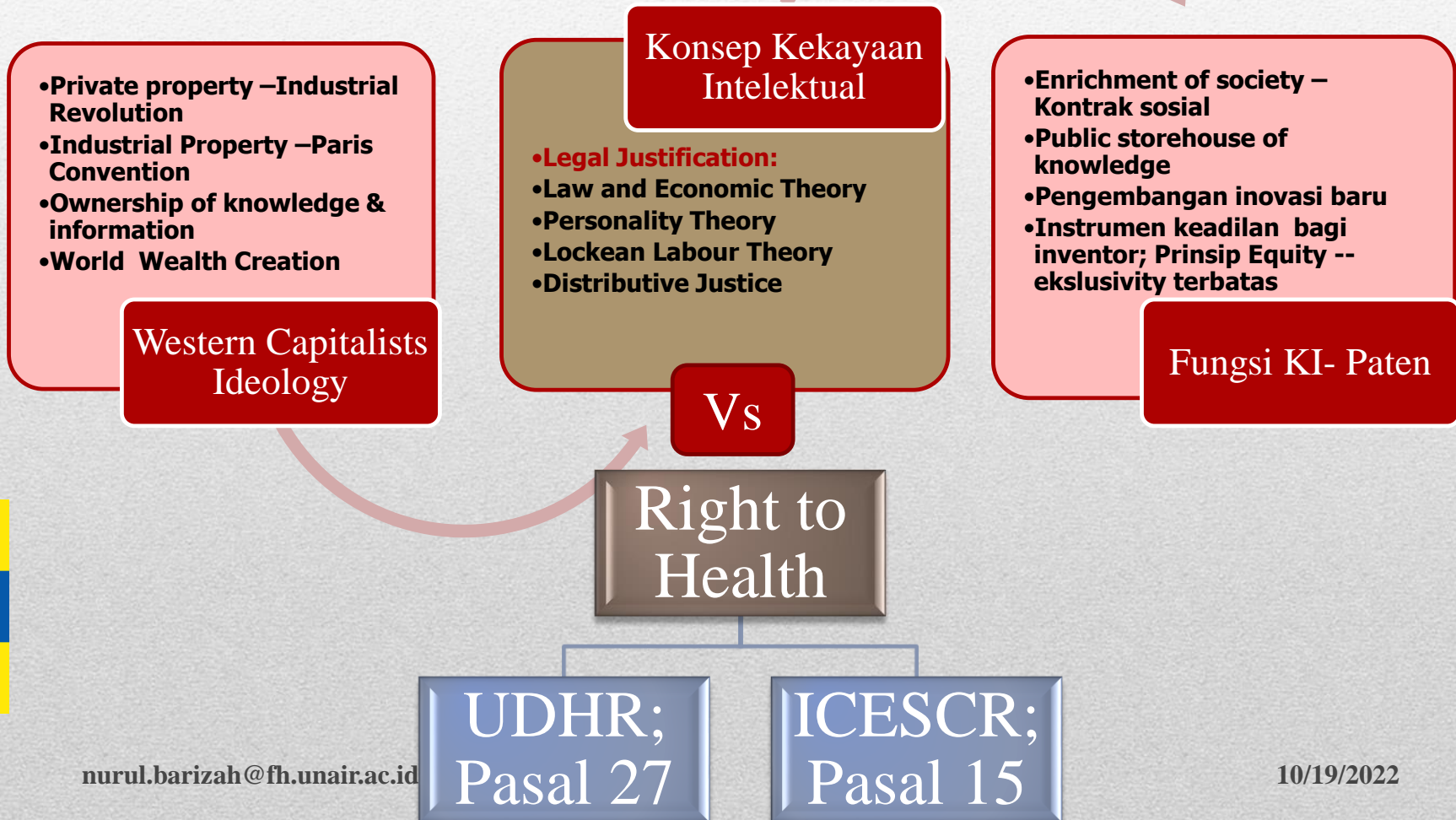
## Art 15 ICESCR

1. The States Parties to the present Covenant recognize the right of everyone:
  - a) To take part in cultural life;
  - b) To enjoy the benefits of scientific progress and its applications;
  - c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.



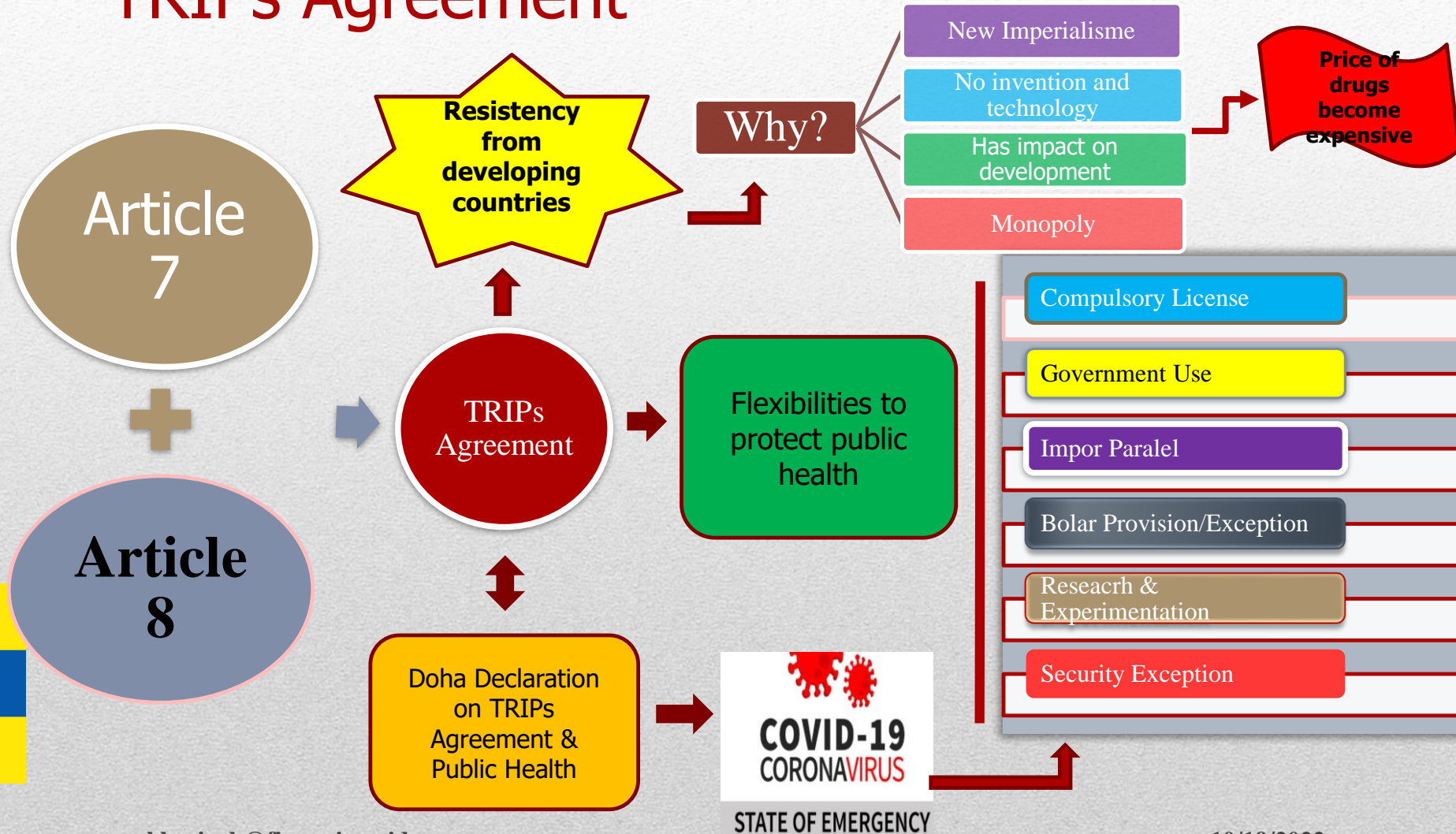


# Asal & Teori Perlindungan KI & Right to Health





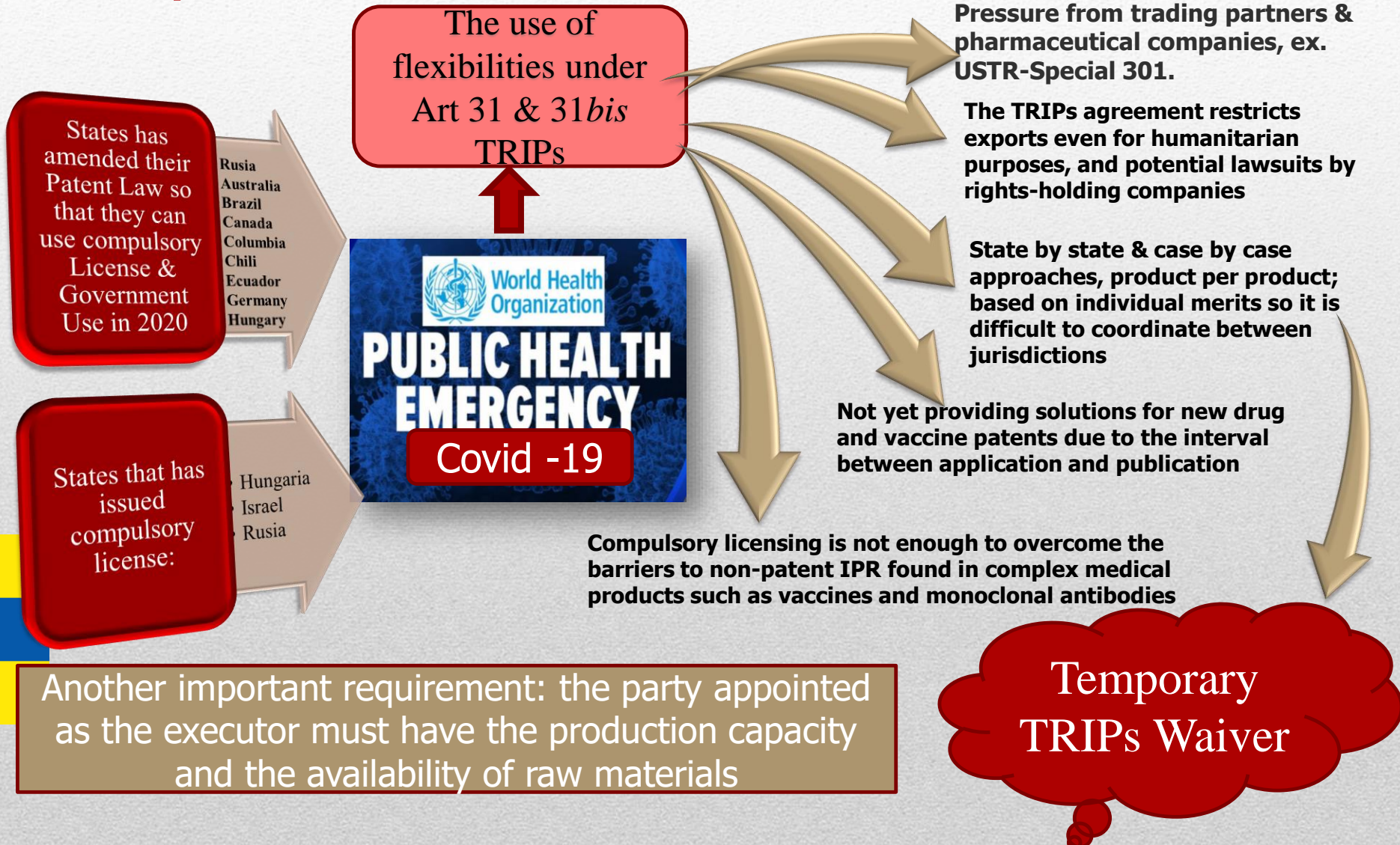
# TRIPs Agreement







## Implementation of TRIPs' Flexibilities





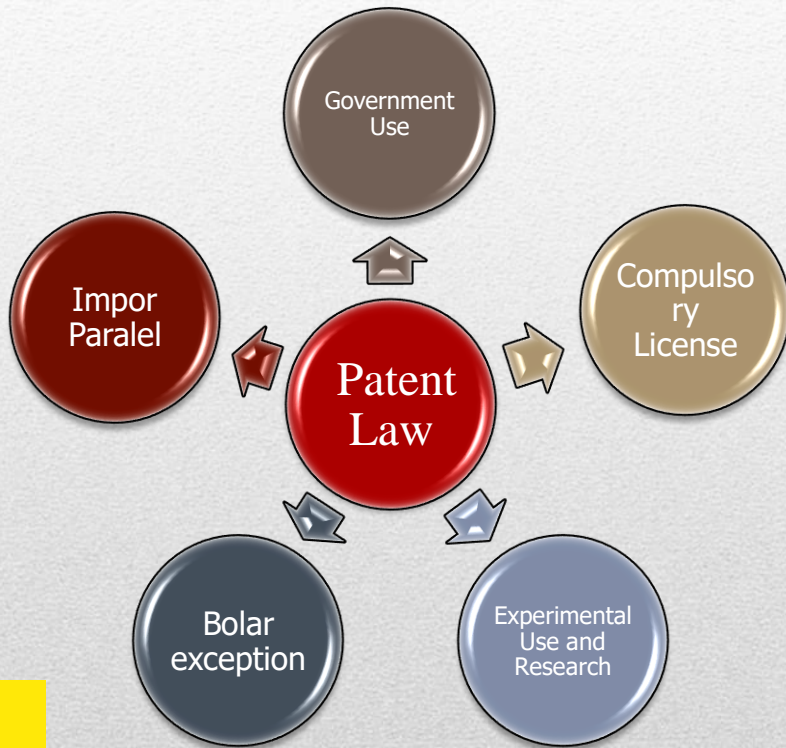
# Limitation of CL in Covid-19 pandemic

- The use of CL may invite unwarranted pressure
- CL require a case by case approach and are difficult to coordinate across jurisdictions
- CL does not provide an effective remedy for emerging and evolving barriers
- CL must be used primarily to supply a domestic market
- CL for export are logically and procedurally impractical
- CL cannot easily override non-patent IP barrier





# How about Indonesia?



Only Government Use of Patents is used; compulsory license – the terms are very naive; parallel import, bolar exception, and Experimental Use and Research can be used.



**HIV/AIDS  
Hepatitis B**

LAMPIRAN

PERATURAN PRESIDEN REPUBLIK INDONESIA  
NOMOR 76 TAHUN 2012  
TENTANG  
PELAKSANAAN PATEN OLEH PEMERINTAH TERHADAP  
OBAT ANTIVIRAL DAN ANTIRETROVIRAL

NAMA ZAT AKTIF, NAMA PEMEGANG PATEN, NOMOR PATEN, DAN  
JANGKA WAKTU PELAKSANAAN PATEN OBAT ANTIVIRAL DAN  
ANTIRETROVIRAL

| NO. | NAMA ZAT AKTIF  | NAMA PEMEGANG PATEN            | NOMOR PATEN  | JANGKA WAKTU PELAKSANAAN PATEN                         |
|-----|---|--------------------------------|--------------|--|
| 1.  | Efavirenz   | Merck & Co, INC                | ID 0 005 812 | Sampai berakhirnya jangka waktu Paten, 7 Agustus 2013  |
| 2.  | Abacavir  | Glaxo Group Limited            | ID 0 011 367 | Sampai berakhirnya jangka waktu Paten, 14 Mei 2018     |
| 3.  | Didanosin   | Bristol - Myers Squibb Company | ID 0 010 163 | Sampai berakhirnya jangka waktu Paten, 6 Agustus 2018  |
| 4.  | Kombinasi Lopinavir dan Ritonavir   | Abbot Laboratories             | ID P 0023461 | Sampai berakhirnya jangka waktu Paten, 23 Agustus 2018 |
| 5.  | Tenofovir   | Gilead Sciences, Inc           | ID 0 007 658 | Sampai berakhirnya jangka waktu Paten, 23 Juli 2018    |
| 6.  | - Kombinasi Tenofovir dan Emtrisitabin<br>- Kombinasi Tenofovir, Emtrisitabin dan Efavirenz | Gilead Sciences, Inc           | ID P0029476  | Sampai berakhirnya jangka waktu Paten, 3 November 2024 |



# Presidential Decree No 101/2021 (Nov) on Government use of Favipiravir drug

## Paten Obat Favipiravir dan Remdesivir Ada di Indonesia!

Pemerintah resmi mengeluarkan Perpres Nomor 101 Tahun 2021 tentang Pelaksanaan Paten oleh Pemerintah terhadap Obat Favipiravir dan Obat Remdesivir

### Pelaksanaan Paten Obat Covid-19



- Pemerintah melaksanakan paten terhadap obat Remdesivir dan Favipiravir



- Dilakukan untuk memenuhi ketersediaan dan kebutuhan yang sangat mendesak pengobatan COVID-19



- Dilaksanakan untuk jangka waktu tiga tahun. Apabila setelah jangka waktu pandemi belum berakhir, pelaksanaan paten diperpanjang sampai dengan pandemi COVID-19 ditetapkan berakhir



- Pelaksanaan paten memuat nama zat aktif, nama pemegang paten, nomor permohonan paten/nomor paten, dan judul invensi

Berikut nama zat aktif, nama pemegang paten, nomor permohonan paten/nomor paten, dan judul invensi tersebut:

| Nama Zat Aktif | Nama Pemegang Paten               | Nomor Permohonan Paten/Nomor Paten | Judul Invensi   |
|----------------|-----------------------------------|------------------------------------|---|
| Favipiravir    | Fujifilm Toyama Chemical Co., Ltd | W00201000982/IDP0032152            | Garam Amina Organik dari 6-Fluoro-3- Hidroksi-2- Pirazinkarbonitril dan Metode Pembuatannya             |
|                |                                   | W00201301813/IDP000045023          | Garam Natrium dari 6-Fluoro-3-Hidroksi-2- Pirazina Karboksamida   |
|                |                                   | W00201301812/IDP000040569          | Garam Meglumina dari 6-Fluoro-3-Hidroksi-2- Pirazin Karboksamida  |
|                |                                   | W00201103243/IDP000046140          | Tablet dan Serbuk Tergranulasi yang Mengandung 6-Fluoro- 3- Hidroksi-2- Pirazinakaroksamida             |
|                |                                   | W00200902268/IDP000034309          | Komposisi Farmasi yang Mengandung Turunan Pirazin, dan Metode Penggunaan Turunan Pirazin dalam Gabungan |

10/19/2022



# TRIPs Waiver; Proposal

- The origin TRIPs waiver proposal is to waive application of section 1,4,5 & 7 of part II and enforcement obligations part III related to health products and technologies.
- It includes vaccines, diagnostics, therapeutics, medical devices, personal protective equipment, their material and components, and their methods and means of manufacture





# The TRIPS waiver: Don't like it? Don't use it. **But don't block it.**





## TRIPs Waiver; Result & Decision

- A Ministerial Decision on TRIPs was adopted by MC12 (June 22), 20 months from the submission by request of India & South Africa, co-sponsored by 65 member, and supported by more than 100 member.
- Only waive certain provisions relating to the grant of CL under art 31 TRIPs, and some clarifications related to that art and art 39.3 (test data protection).
- It is limited patents on covid-19 vaccines, but not to therapeutics and diagnostics.
- It does not represent a genuine response to the TRIPs waiver request.





## National Innovation Development, Technology Transfer or Rely on Foreign Technology?



Sustainable  
INNOVATIONS®



Adequate & consistent regulations & policies are needed, that are supportive and conducive.

The Government regulation on technology transfer needs to be revised, emphasizing foreign technology licensing.

It requires commitment from the government for its implementation.

Stop Foreign Domination;  
Indonesia can be independent







# Vaccine –Merah Putih

- **Merah Putih Vaccine is developed by Universitas Airlangga under the guidance of the Indonesian Food and Drug Authority.**

**It is a successful collaboration between academics, university, business actors, and private sector.**

**The development involves several partners, such as PT Biotis Pharmaceuticals Indonesia, Ministry of Health, National Research and Innovation Agency, RSUD Dr. Soetomo, RS Universitas Airlangga, RS Paru Jember, RS Soebandi Jember, and RS Syaiful Anwar Malang**





# Information-Sharing Platform as Intellectual Responsibility & Corporate Social Responsibility

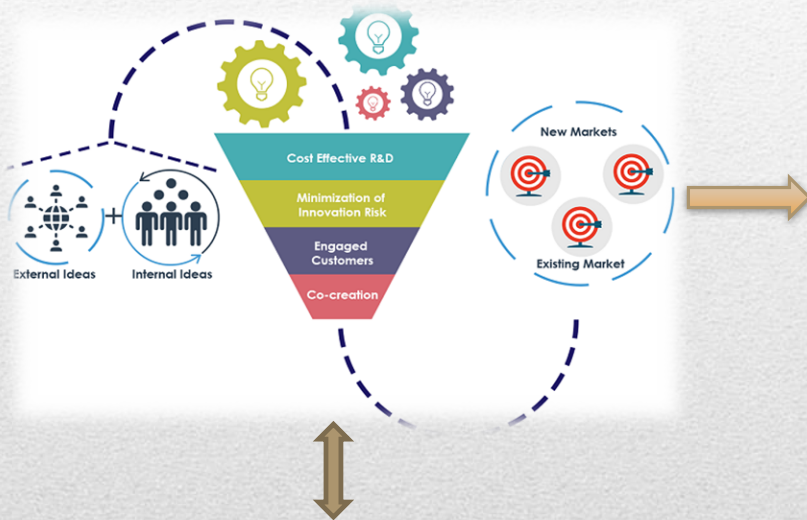


The cheapest vaccine circulating globally



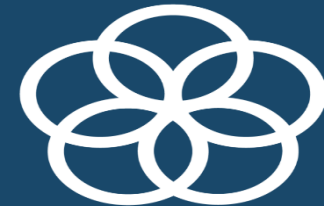


## Open Innovation (Medis): Fair Solution- Long Term



Sistem inovasi terbuka memungkinkan para ilmuwan di seluruh dunia berbagi, memanfaatkan data untuk kepentingan masyarakat, menghilangkan fragmentasi ilmu pengetahuan yang berbasis KI, arus informasi lebih bebas, penggunaan sumber daya lebih efisien, pengembangan obat-obatan dan vaksin lebih cepat guna menghadapi pandemi yang akan datang karena akses informasi penting tidak dibatasi oleh KI.

**17** PARTNERSHIPS  
FOR THE GOALS





# Conclusion and Suggestion

- Theoretically and normatively, IP protection can be optimized for public welfare, but in practice, it is uneasy and shall be fight for it.
- WTO member, can use available legal mechanisms to ensure quick and fair access to the future pandemic in accordance with the flexibility of the TRIPs Agreement - Articles 31, 31 *bis*, and 73 without any obstacles
- Information-sharing platforms need to be implemented as intellectual moral responsibility & corporate social responsibility to contribute solving global problems.
- The open medical innovation model offers a fair, long-term solution to improve medical research because access to critical information is not restricted by IP, enabling scientists to share and leverage data for the benefit of society.
- The Patent Law needs to be revised, especially the mandatory license, it also needs to be harmonized with the law or other related provisions including technology transfer



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Terima kasih