Patent, tvångslicens och konkurrensrätt i pandemitider

AIPPI Seminarium 26 Maj 2021

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- **Bakgrund – Rätt till hälsa, patenträtt, konkurrensrätt och COVID-19**
- **Patenträtt v. Rätt till hälsa i enlighet med TRIPS-avtalet**
- **Doha Ministerial Declaration on Public Health & Paragraph 6 systemet**
- **Tvångslicensens olika legala grunder– Rätt till hälsa, konkurrensrätts, icke-utnyttjande etc.**
- **COVID-19, Tvångslicens & Patent Waiver-förslaget**
- **Analys och slutsatser**

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Rätten till hälsa i förhållande till immateriella rättigheter

Rätten till hälsa – grundläggande mänsklighet rättighet som står överordnad immateriella rättigheter?

Staten ska i praktiken verka för att erbjuda en adekvat levnadsstandard för dess invånare.

Art 25 UDHR – Universal Declaration of Human rights

“Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.”

Hamnar i viss konflikt med TRIPS-avtalet som ställer krav på signerande stater att etablera ett 20-årigt patentskydd för, bland annat, läkemedel. Detta patentskydd kan ställas i förhållande till rätten till hälsa – effekten som sådan har i viss mån uttryckt sig genom bristande tillgång till läkemedel.

The dilemma of unequal global access to COVID-19 vaccines

"The data show that 7.48 billion doses—enough to fully vaccinate about half the world's population with 2 shots—had been secured as of mid-November 2020. But so far, high-income countries have acquired 51% of the doses, leaving the remainder for low- and middle-income countries where 86% of the global population lives, according to the authors.

For example, the US is home to about 330 million people, or 4% of the world's population. But it has reserved 800 million doses, enough to vaccinate 400 million people…Japan, Canada, and Australia have a combined population of less than 200 million, but they've reserved a total of 1 billion doses despite accounting for only 1% of COVID-19 cases worldwide.

The COVAX facility, a global initiative led by the World Health Organization, has agreements with manufacturers to acquire 2 billion doses of COVID-19 vaccines, including 1.3 billion doses earmarked for 92 low- and middle-income countries. That's enough to vaccinate about 20% of their populations."

February 16, 2021
High-Income Countries Have Secured the Bulk of COVID-19 Vaccines
Bridget M. Kuehn, MSJ
JAMA. 2021;325(7):612. doi:10.1001/jama.2021.0189

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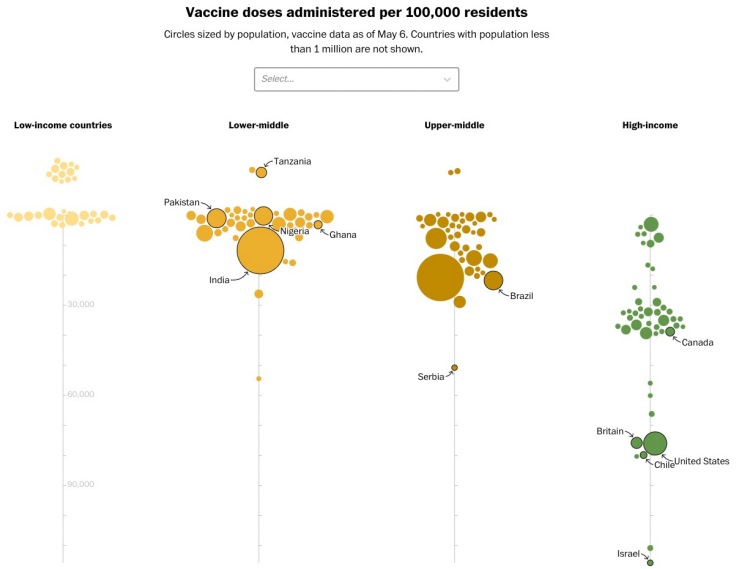

https://www.washingtonpost.com/world/interactive/2021/coronavirus-vaccine-inequality-global/

“Israel has the highest vaccination rate, having administered 57.65 doses per 100 people, followed by the United Arab Emirates (34.79 per 100 people), U.K. (14.42), Bahrain (10.16) and the U.S. (9.63).

The European Union’s vaccination rate is far behind the U.S. and U.K. at only 2.86 doses per 100 people.

Though China has the second highest number of administered doses, the country has only administered 1.67 doses per 100 people, and other heavily populated countries are also far behind the U.S.’s pace: Brazil has administered one dose per 100, Russia 0.69 doses (as of Jan. 13) and India 0.29 doses.”

Source: https://www.forbes.com/sites/alisondurkee/2021/02/02/here-are-the-countries-that-are-leading-in-vaccinating-their-citizens-against-covid-19/

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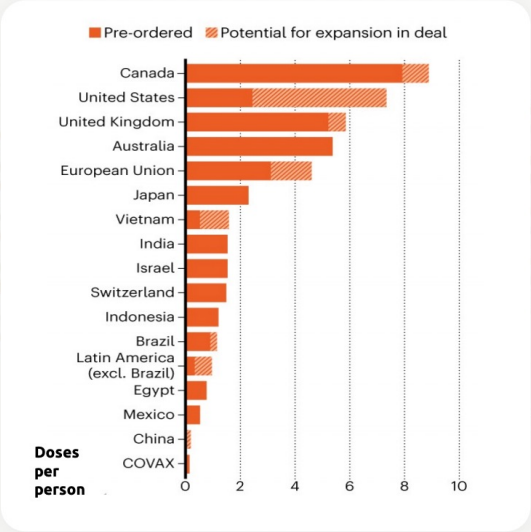
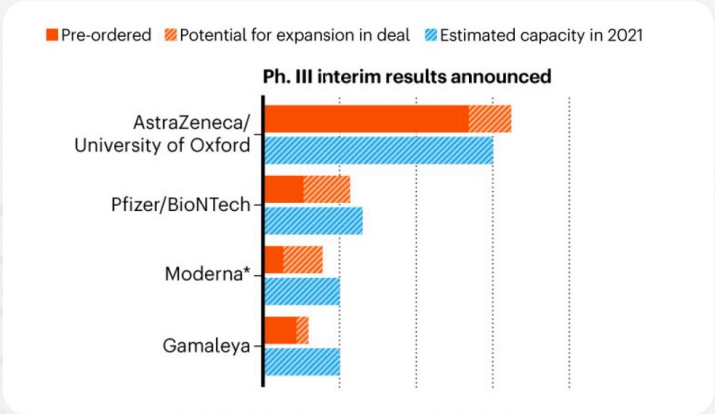
COVID-19 and the Move to Unilateralism

Best and worst supplied

Canada has pre-ordered almost 9 doses of COVID-19 vaccines per person





Through ***bilateral*** advance-purchase agreements, developed countries have ordered enormous amounts of vaccine leaving many other countries underserved.

Source: Nature

Source: Eleventh Meeting of the UNCTAD Research Partnerhsip Platform 17-18 December 2020 FROM COOPERATION TO UNILATERALISM: COMPULSORY LICENSING AND COMPETITION LAW AMIDST COVID-19 PANDEMIC Presentation by Mr. Alexey Ivanov, BRICS Competition Law and Policy Center

Why Did We Fail?

- Competition jumped from fairness to a war-like race aimed at value extraction, not sustainable cooperation
- As noted by Stiglitz, market alone is no longer enough to address the rising inequality. Transit to a fair, green economy calls for a global effort beyond just economy and just business
- As of now, there is no global legal order for fair competition, data sharing and pooling that could have enabled us to fight the crisis better
- The system came to be a vicious circle supported by power relations and private interests

"The pandemic is a clear test of international cooperation — a test we have essentially failed"

Antonio Guterres at the UNSC Meeting 24.09.20.

Source: Eleventh Meeting of the UNCTAD Research Partnerhsip Platform 17-18 December 2020 FROM COOPERATION TO UNILATERALISM: COMPULSORY LICENSING AND COMPETITION LAW AMIDST COVID-19 PANDEMIC Presentation by Mr. Alexey Ivanov, BRICS Competition Law and Policy Center

Access to affordable Essential Medicines – a basic Human Right

“The right to highest attainable health”
UDHR, ICESCR, European Social Charter etc.

Today, some two billion people lack access to essential medicines. Improving this access would save around 10 million lives each year. Of the approximately 35 million people infected with HIV/AIDS, some 27 million are living in the Sub Saharan Africa, which also accounts for 70% of the new infections globally.

Source: WHO, Fact sheet 360, 2014, http://www.who.int/mediacentre/factsheets/fs360/en

The COVID-19 pandemic has increased the unequal access and affordability gap further. Compulsory Licensing is a complex tool in the interface of right to health, intellectual property and competition law.

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Right to Health – International Legal Framework

Legal Basis for the Right to Health

The right to health is widely recognized in international human rights law. Below is a chart of the international and regional human rights instruments expressly recognizing the right to health:

Human Rights Instrument	Right to Health Provision
Universal Declaration of Human Rights	Article 25
International Covenant on Economic and Social Rights	Article 12
International Convention on the Elimination of All Forms of Racial Discrimination	Article 5 (d)(iv)
Convention on the Elimination of All Forms of Discrimination Against Women	Article 11.1(f) and 12
Convention on the Rights of the Child	Article 24
Convention on the Rights of Persons with Disabilities	Article 25
African Charter on Human and Peoples' Rights	Article 16
European Social Charter	Article 11
American Declaration of the Rights and Duties of Man	Article XI
Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights	Article 10

Source: https://www.hhrguide.org/2017/06/09/access-to-medicines-and-human-rights/

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Right to Health – European Legal Framework

Right to Health in European primary law = **Article 168(1) TFEU**

"A high level of human health protection shall be ensured in the definition and implementation of ***all*** Union policies and activities."

Consolidated Version of the Treaty on the Functioning of the European Union, OJ C 326, 26.10.2012, p. 47–390, Art. 168(1).

Also reflected in **Art 35 Charter of Fundamental Rights of the European Union**

"Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of ***all*** Union policies and activities."

Charter of Fundamental Rights of the European Union, (2012/C 326/02), Art. 35.

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Right to Health – European Legal Framework

European Social Charter, art. 11

The right to protection of health With a view to ensuring the effective exercise of the right to protection of health, the Parties undertake, either directly or in cooperation with public or private organisations, to take appropriate measures designed inter alia:

1. To remove as far as possible the causes of ill-health;

2. To provide advisory and educational facilities for the promotion of health and the encouragement of individual responsibility in matters of health;

3. **To prevent as far as possible epidemic, endemic and other diseases, as well as accidents**

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TRIPS and Public Health

Article 7

Objectives

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 obligations.

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TRIPS and Public Health

Article 8

Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

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Doha Ministerial Declaration on TRIPS & Public Health

“Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”

The Paragraph 6 system

1. What is the Paragraph 6 System?

As outlined in Chapter IV, Section C.3(a)(iii), the Doha Declaration on the TRIPS Agreement and Public Health (paragraph 6) recognized that WTO members with insufficient or no manufacturing capacity in their pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement, as the agreement then stood. To overcome those difficulties, WTO members adopted the Paragraph 6 System. It addresses a particular scenario for access to medicines:

- A country needs to import a medicine from a foreign supplier because it lacks sufficient manufacturing capacity in its pharmaceutical sector.
- The medicine can be produced under a compulsory licence in another country.
- Export of the non-predominant part of the production in that country does not satisfy the needs of the importing country.
- Therefore, the importing country has to use the Paragraph 6 System in order to import medicines produced under a compulsory licence from another country.

The System provides WTO members with an additional flexibility, which is a special type of compulsory licence permitting production of medicines exclusively for export. The System links demand in importing countries with supply from exporting countries. In addition, it waives the obligation on importing countries to pay adequate remuneration to the right holder following the grant of a compulsory licence (Article 31(h) of the TRIPS Agreement), if such remuneration is provided for in the exporting country.

Compulsory licensing & TRIPS

- License granted to other party without permission of the patent holder
- The rightsholder retains its IP right, as well as the right to license it further
- CL provisions were already included in the Paris Agreement, as well as in many national jurisdictions, long before TRIPS.
- National grounds to allow CL included non-working of the granted patent, FRAND, emergency / executive use, defense / military use etc.
- TRIPS allows compulsory licensing in the case of national emergency or extreme urgency, public non-commercial use, to remedy anti-competitive practices etc.
- TRIPS does in itself not limit the grounds for issuing a compulsory license.

Compulsory Licensing – Definition & Legal sources

Paris Convention art. 5.2
"Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work".

TRIPS Convention art. 31 + art 31bis as amended
"Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected"

TRIPS Convention art. 40(2)
"Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market".

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Compulsory Licensing in TRIPS Agreement

Article 31

Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use [7] of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

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Compulsory Licensing in TRIPS Agreement – Competition Law

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

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Compulsory Licensing in TRIPS Agreement

Article 40

1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.

2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.

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Amended the TRIPS agreement on 23rd January 2017

WTO: 2017 NEWS ITEMS

TRIPS

23 JANUARY 2017

WTO IP rules amended to ease poor countries' access to affordable medicines

An amendment to the agreement on intellectual property entered into force today (23 January) securing for developing countries a legal pathway to access affordable medicines under WTO rules.

MORE:

- Intellectual property
- TRIPS and public health
- #IntellectualProperty
- #publichealth

The amendment to the WTO Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement marks the first time since the organization opened its doors in 1995 that WTO accords have been amended.

The WTO Secretariat has received in recent days notifications from five members that they have ratified the protocol amending the WTO TRIPS Agreement. These notifications — from Burkina Faso, Nigeria, Liechtenstein, the United Arab Emirates and Viet Nam — brought to two-thirds the number of WTO members which have now ratified the amendment. The two-thirds threshold was needed to formally bring the amendment into the TRIPS Agreement.

https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm

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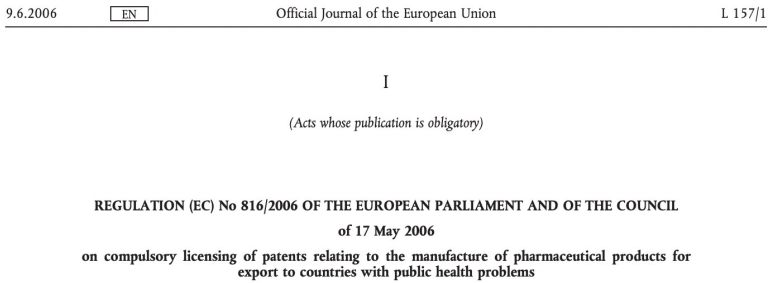
Article 31bis and EU – No right to import CL-medicines to EU



9.6.2006 EN Official Journal of the European Union L 157/1

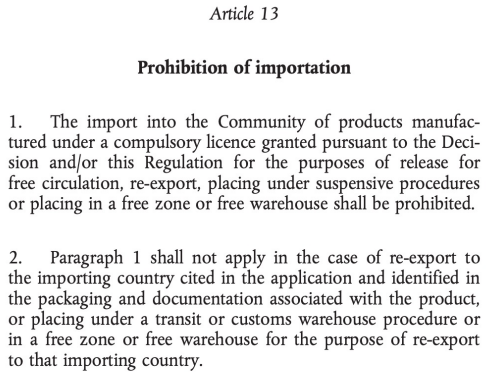
I

(Acts whose publication is obligatory)

REGULATION (EC) No 816/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 17 May 2006

on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems



Article 13

Prohibition of importation

1. The import into the Community of products manufactured under a compulsory licence granted pursuant to the Decision and/or this Regulation for the purposes of release for free circulation, re-export, placing under suspensive procedures or placing in a free zone or free warehouse shall be prohibited.

2. Paragraph 1 shall not apply in the case of re-export to the importing country cited in the application and identified in the packaging and documentation associated with the product, or placing under a transit or customs warehouse procedure or in a free zone or free warehouse for the purpose of re-export to that importing country.

The TRIPS amendment targets any least-developed country and those countries that have made a notification to the Council for TRIPS regarding their intent to make use of the system. EU opted out from this, and as a result, EU does not have right under TRIPS as of now to be eligible for import of CL medicines from other countries, but by way of the **Regulation 816/2006** EU member countries have the right to export to LDC´s.

Nor can an EU member state import CL medicines from another EU member state.

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Compulsory Licensing in TRIPS Agreement – In summary

•Case-to-case basis

• At times subject to lengthy notification and opposition procedure

• Prior negotiations (waived in case of national emergency, anti-competitive practices etc.)

•Scope and duration limited to the purpose

•Non-exclusive, non-assignable

•Predominantly for the domestic market, however Paragraph 6 and Article 31bis as amended allow foreign export

•To be terminated if the circumstances change

•Subject to judicial review regarding appeal and termination

•Adequate renumeration to be paid to the rightsholder

Compulsory licensing of Pharmaceuticals

Medicines Legend | FAQ | Other resources

Show or hide column(s)

☑ Country ☑ Date ☐ WTO Classification ☑ Type of Flexibility ☑ Products ☑ Patent filed/granted ☐ Originators ☐ Licensees ☑ Diseases ☐ Royalty rate ☑ Executed ☑ Reason if not executed

Showing 160 result(s)

Country	↓ Date	Type of Flexibility	Product	Patent filed/granted	Disease	Executed	Reason if not executed
filter		filter	filter	filter	filter	filter	filter
Russia	Feb 2021	Art 31	Remdesivir	Yes	Covid-19	Yes	
Israel	Mar 2020	Art 31	LPV/r	Yes	Covid-19	Yes	
United Kingdom	Jun 2019	Art 31	Lumacaftor-ivacaftor	Yes	Cystic fibrosis	Pending	Pending
Kazakhstan	Apr 2019	Art 31	Dolutegravir	Yes	HIV/AIDS	Pending	Pending
Switzerland	Jan 2019	Art 31	Pertuzumab	Yes	Cancer	Pending	
Russia	Jun 2018	Art 31	Lenalidomide	Yes	Leprosy, tuberculosis, AID...	Yes	
Norway	May 2018	Art 31	Nusinersen	Yes	Spinal muscular atrophy	No	Rejected
United States of America ...	May 2018	Art 31	HCV medicines	Yes	HCV	No	Subscription model for lowering price b...
United States of America	May 2018	Art 31	Naloxone	Yes	Opioid overdose	Pending	Pending
UK (Scotland)	Apr 2018	Art 31	Pertuzumab	Yes	Cancer	Pending	Pending
Chile	Mar 2018	Art 31	HCV medicines	Yes	HCV	Pending	
Colombia	Dec 2017	Art 31	DAAs	Yes	HCV	Pending	Pending
Malaysia	Sep 2017	Art 31	Sofosbuvir	Yes	HCV	Yes	
Germany	Aug 2016	Art 31	RAL	Yes	HIV/AIDS	Yes	
United Kingdom	Oct 2015	Art 31	Trastuzumab-Emtansine	Yes	Cancer	Pending	Pending
India	Jun 2015	Art 31	Saxagliptin	Yes	Type II Diabetes	No	Rejected

Source: Medicines Law & Policy Database, accessed 2021-05-25

Compulsory licensing of Pharmaceuticals

Colombia	Nov 2014	Art 31	Imatinib	Yes	Cancer	Pending	Pending
Peru	Nov 2014	Art 31	ATV	Yes	HIV/AIDS	Pending	pending
Ecuador	Jul 2014	Art 31	Sunitinib	Yes	Cancer	Yes	
Ecuador	Jul 2014	Art 31	Certolizumab	Yes	Rheumatoid Arthritis	Yes	
Ecuador	May 2014	Art 31	Mycophenolic acid	Yes	Kidney Transplants	Yes	
Congo	Apr 2014	Art 31	ARVs	Yes	HIV/AIDS	Yes	
Ecuador	Apr 2014	Art 31	Etoricoxib	Yes	Rheumatoid Arthritis	Yes	
Ecuador	Nov 2013	Art 31	RTV	Yes	HIV/AIDS	Yes	
Gabon	Jun 2013	Art 31	ARVs	Yes	HIV/AIDS	Yes	
India	Mar 2013	Art 31	Dasatinib	Yes	Cancer	No	Rejected
Ecuador	Jan 2013	Art 31	ABC/3TC	Yes	HIV/AIDS	Yes	
Ecuador	Jan 2013	Art 31	ABC/3TC	Yes	HIV/AIDS	Yes	
Ecuador	Jan 2013	Art 31	Gemcitabine	Yes	Cancer	Pending	Pending
Ecuador	Nov 2012	Art 31	ABC/3TC	Yes	HIV/AIDS	Yes	
Indonesia	Sep 2012	Art 31	ABC, DDI, EFV, EFV/FTC/...	Yes	HIV/AIDS, HBV	Yes	
Thailand	Aug 2012	Art 30	ARVs	Yes	HIV/AIDS	Yes	
Thailand	Jul 2012	Art 30	EFV/FTC/TDF, 3TC/AZT/...	Yes	HIV/AIDS	Yes	
Thailand	Jun 2012	Art 30	EFV/FTC/TDF, 3TC/AZT/...	Yes	HIV/AIDS	Yes	
India	Mar 2012	Art 31	Sorafenib Tosylate	Yes	Cancer	Yes	
Azerbaijan	May 2011	Art 31	ARVs	Yes	HIV/AIDS	Yes	
Ecuador	Apr 2010	Art 31	RTV	Yes	HIV/AIDS	Yes	
Sierra Leone	Dec 2009	Par7	DDI, IDV, LPV/r	No	HIV/AIDS	Yes	
Korea	Oct 2009	Art 31	Oseltamivir	Yes	H1N1 Influenza	No	Rejected

Source: Medicines Law & Policy Database, accessed 2021-05-25

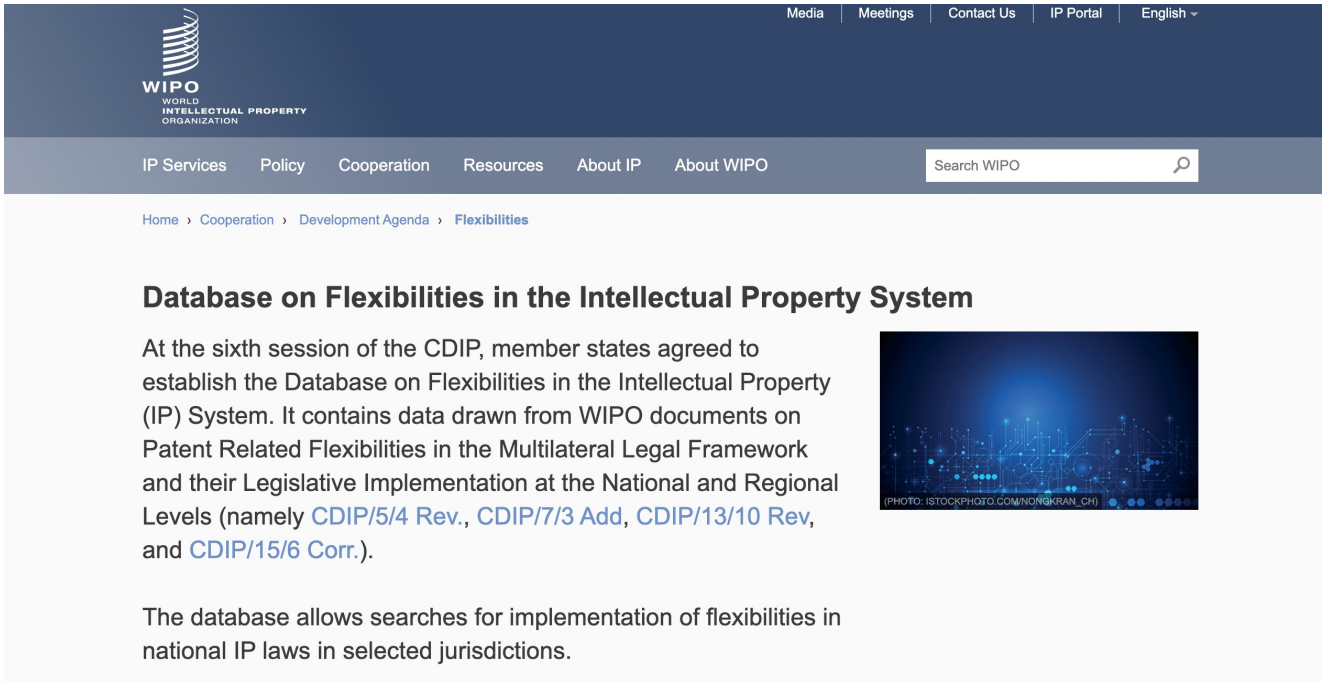
Compulsory licensing of Pharmaceuticals in the past – Growing trend, COVID-19 impact not counted

Table 2.1 CL Case Study Survey

Year(s)	Nation	GNI	# of Potential CLs	Disease	Disease Scenario Type	Outcome
2001	Canada	High	1	Anthrax	Type I	Discount
2001, 2007	Brazil	Middle	2	HIV/AIDS	Type II	Discount
2001	Brazil	Middle	1	HIV/AIDS	Type II	Discount
2005	Brazil	Middle	1	HIV/AIDS	Type II	Discount
2005	Brazil	Middle	1	HIV/AIDS	Type II	Discount
2010	Ecuador	Middle	1	HIV/AIDS	Type II	CL
2005	Eritrea	Low	1	HIV/AIDS	Type II	CL
2005	Ghana	Low	1	HIV/AIDS	Type II	CL
2006-2007	India	Middle	1	Cancer	Type III	None
2005	Indonesia	Middle	2	HIV/AIDS	Type II	CL
2005	Korea	High	1	Pandemic flu	Type I	VL
2001-2002	Korea	High	1	Cancer	Type III	None
2003-2004	Malaysia	Middle	3	HIV/AIDS	Type II	CL
2004	Mozambique	Low	3	HIV/AIDS	Type II	CL
2004	Philippines	Middle	1	Cardiovascular disease	Type III	None
2007	Rwanda	Low	1	HIV/AIDS	Type II	CL
2001-2003	South Africa	Middle	8	HIV/AIDS	Type II	CL/VL/ Discount/None
2005	Taiwan/China	Middle	1	Pandemic flu	Type I	Discount
2006, 2010	Thailand	Middle	1	HIV/AIDS	Type II	CL
2007, 2010	Thailand	Middle	2	HIV/AIDS, Cardiovascular disease	Type II, Type III	CL
2007-2008	Thailand	Middle	1	Cancer	Type III	Discount
2007-2008	Thailand	Middle	3	Cancer	Type III	CL
2001	United States	High	1	Anthrax	Type I	Discount
2004	Zambia	Low	3	HIV/AIDS	Type II	CL
2003-2004	Zimbabwe	Low	1	HIV/AIDS	Type II	CL

**Nations' incomes were classified using the World Bank's GNI listings for the year closest to that of the CL case study (data is available for 2000, 2005, 2007, and 2008). "Low" income is $975 or less per capita per year; "Middle" is above $975, but less than $11, 905 (for simplicity, this table combines the World Banks "lower middle income" and "upper middle income"); and "High" is more than $11,905* (World Bank 2010).

National Flexibilities database WIPO (+ ongoing work by AIPPI & WTO)



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Compulsory Licensing - Sweden

45 § En tvångslicens för att utöva en uppfinning i Sverige får meddelas om

1. det har gått tre år från det att patentet meddelades och fyra år från det att patentansökan gjordes,
2. uppfinningen inte utövas i skälig utsträckning i Sverige, samt
3. det saknas godtagbar anledning till att uppfinningen inte utövas.

Vid tillämpning av första stycket 2 jämställs med utövning av en uppfinning införsel av uppfinningen till Sverige från en stat inom Europeiska ekonomiska samarbetsområdet eller en stat som är ansluten till eller ett område som är anslutet till avtalet om upprättandet av Världshandelsorganisationen (WTO). *Lag (2004:159)*.

46 § En innehavare av ett patent på en uppfinning, vars utnyttjande är beroende av ett patent som tillhör någon annan, kan få en tvångslicens att utnyttja den uppfinning som skyddas av det andra patentet. En sådan licens meddelas endast om sökanden visar att den först nämnda uppfinningen utgör ett viktigt tekniskt framsteg av betydande ekonomiskt intresse i förhållande till den andra uppfinningen.

Om en tvångslicens meddelas enligt första stycket har innehavaren av det patent i vilket tvångslicens meddelas rätt att på skäliga villkor få en tvångslicens (motlicens) att utnyttja den andra uppfinningen. *Lag (2004:159)*.

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Compulsory Licensing - Sweden

47 § Om hänsyn till allmänt intresse av synnerlig vikt kräver det, äger den som vill yrkesmässigt utnyttja uppfinning, varå annan har patent, erhålla tvångslicens därtill.

48 § Den som utnyttjade patentsökt uppfinning yrkesmässigt här i riket när handlingarna i ansökningsärendet blevo tillgängliga enligt 22 § äger, om ansökningen leder till patent, erhålla tvångslicens till utnyttjandet, om synnerliga skäl föreligga samt han saknade kännedom om ansökningen och ej heller skäligen kunnat skaffa sig kännedom därom.
Sådan rätt tillkommer under motsvarande förutsättningar även den som vidtagit väsentliga åtgärder för att utnyttja uppfinningen yrkesmässigt här i riket.
Tvångslicens kan avse även tid innan patentet meddelades.

49 § En tvångslicens får endast beviljas den som kan antas ha förutsättningar att utnyttja uppfinningen på ett godtagbart sätt och i överensstämmelse med licensen. Sökanden måste också visa att han eller hon utan framgång har vänt sig till patenthavaren för att få ett licensavtal på skäliga villkor.

En tvångslicens hindrar inte patenthavaren från att själv utnyttja uppfinningen eller att upplåta licenser. En tvångslicens kan övergå till någon annan endast tillsammans med en rörelse där den utnyttjas eller var avsedd att utnyttjas.
För sådana tvångslicenser som avses i 46 § första stycket och 46 a § första stycket gäller dessutom att licensen endast får överlåtas tillsammans med det patent eller den växtförädlarrätt som licensen grundats på. *Lag (2004:159)*.

50 § Tvångslicens meddelas av rätten, som även bestämmer i vilken omfattning uppfinningen må utnyttjas samt fastställer vederlaget och övriga villkor för licensen. När väsentligt ändrade förhållanden påkalla det, äger rätten på yrkande upphäva licensen eller fastställa nya villkor för denna.

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Compulsory Licensing - Sweden

64 § */Upphör att gälla U:den dag regeringen bestämmer/* Den som vill väcka talan om patents ogiltighet, överföring av patent eller meddelande av tvångslicens skall anmäla detta till patentmyndigheten samt underrätta envar som enligt patentregistret innehar licens till eller panträtt i patentet. Vill en licenstagare väcka talan om intrång i patent eller om fastställelse enligt 63 § första stycket, skall han underrätta patenthavaren härom. Detsamma gäller, om en panthavare vill väcka talan med anledning av intrång i patent.

Underrättelseskyldighet enligt första stycket anses fullgjord, när underrättelse i betald rekommenderad försändelse sänts under den adress som antecknats i patentregistret.

Visas ej, när talan väckes, att anmälan eller underrättelse skett enligt föreskrifterna i första stycket, skall käranden givas tid därtill.
Försitter han denna tid, må hans talan icke upptagas till prövning. *Lag (1987:1330)*.

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REUTERS

World Business Markets Breakingviews Video More

COMPANY NEWS NOVEMBER 2, 2020 / 9:18 AM / UPDATED 7 MONTHS AGO

Russian firm seeks to produce COVID-19 drug without patent, Vedomosti reports

By Reuters Staff 2 MIN READ

MOSCOW, Nov 2 (Reuters) - Russian drugmaker Pharmasyntez has asked the Kremlin for permission to produce a generic version of U.S. firm Gilead Sciences's COVID-19 treatment remdesivir without a patent, the Vedomosti newspaper reported on Monday.

Siberia-based Pharmasyntez previously approached Gilead requesting a voluntary licence to produce and distribute the drug in Russia, the company's director, Vikram Punia, had told Reuters this year.

INSIDE DEVELOPMENT | COVID-19

COVID-19: Countries race to strengthen compulsory licensing legislation

By *Andrew Green* // 30 June 2020

Trade & Policy | Private Sector | Global Health | WTO

Our COVID-19 coverage is free. Please consider a Devex Pro subscription to support our journalism.

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TRENDING: CORONAVIRUS BIOTECH PHARMALOT FIRST OPINION

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Gilead sues Russia over a compulsory license issued to a company making remdesivir

By Ed Silverman May 4, 2021 Reprints

WORLD TRADE ORGANIZATION

IP/C/W/669

2 October 2020

(20-6725) Page: 1/4

Council for Trade-Related Aspects of Intellectual Property Rights Original: English

WAIVER FROM CERTAIN PROVISIONS OF THE TRIPS AGREEMENT FOR THE PREVENTION, CONTAINMENT AND TREATMENT OF COVID-19

COMMUNICATION FROM INDIA AND SOUTH AFRICA

1. On 11 March 2020, the World Health Organization (WHO) declared the coronavirus disease 2019 (COVID-19) to be a global pandemic, after having announced a related public health emergency of international concern (PHEIC) on 30 January 2020.

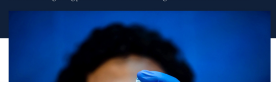
2. The World Trade Organization (WTO) has cautioned that the "Pandemic represents an unprecedented disruption to the global economy and world trade, as production and consumption are scaled back across the globe".[1] We have witnessed a break down in global supply chains coupled with growing supply-demand gaps.

3. Given this present context of global emergency, it is important for WTO Members to work together to ensure that intellectual property rights such as patents, industrial designs, copyright and protection of undisclosed information do not create barriers to the timely access to affordable medical products including vaccines and medicines or to scaling-up of research, development, manufacturing and supply of medical products essential to combat COVID-19.

NEWS

Biden administration supports waiving patent protections for Covid vaccines to raise global production

Biden has faced growing pressure to address Covid-19 surges in India and South America.



Pfizer, BioNTech pledge 2 billion COVID-19 vaccine doses to lower-income countries

Nathaniel Weixel · 2 days ago

American vaccine maker Pfizer and its German partner BioNTech pledged Friday to provide 1 billion doses of their COVID-19 vaccine to low-and-moderate income countries by the end of 2021.

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Some examples of IP Flexibilities during COVID-19

- Israel – Compulsory Licensing issued regarding lopinavir/ritonavir (brand name: Kaletra)
- Russia – Compulsory licensing issued regarding Remdivisir
- Bangladesh – Generic production and export of Remdivisir to 21 countries without license granted by Gilead (LDC-exemption). Compare with shortages in US.
- Updated national legislation regarding COVID-19 pandemic and executive powers related to IP Rights: Germany, France, Canada, Ecuador, Chile, etc…
- Voluntary licence waiver by pharmaceutical companies such as Abbvie regarding Medicine Patent Pool licenses for Kaletra

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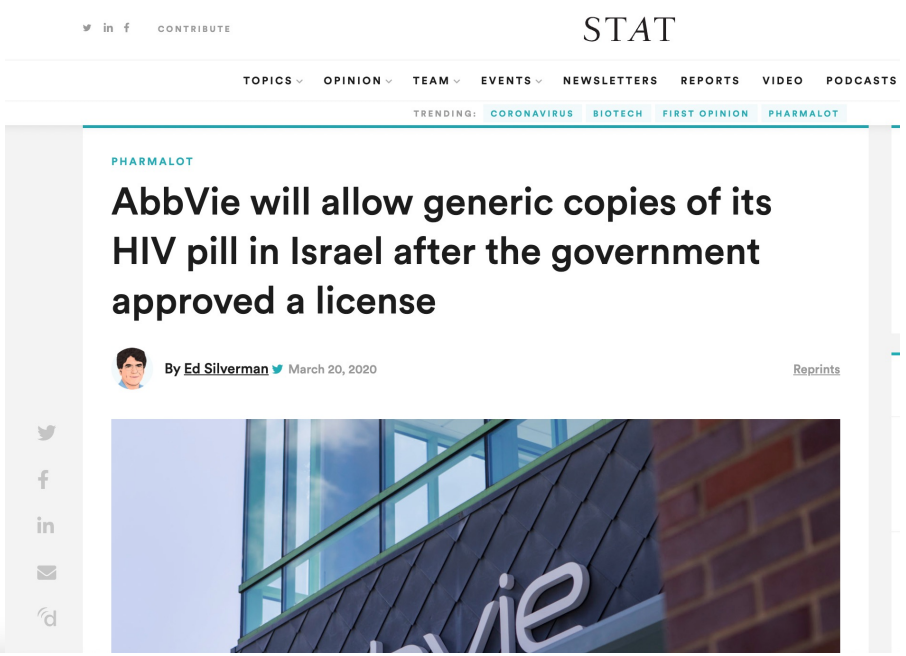
Compulsory Licensing - Israel

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.



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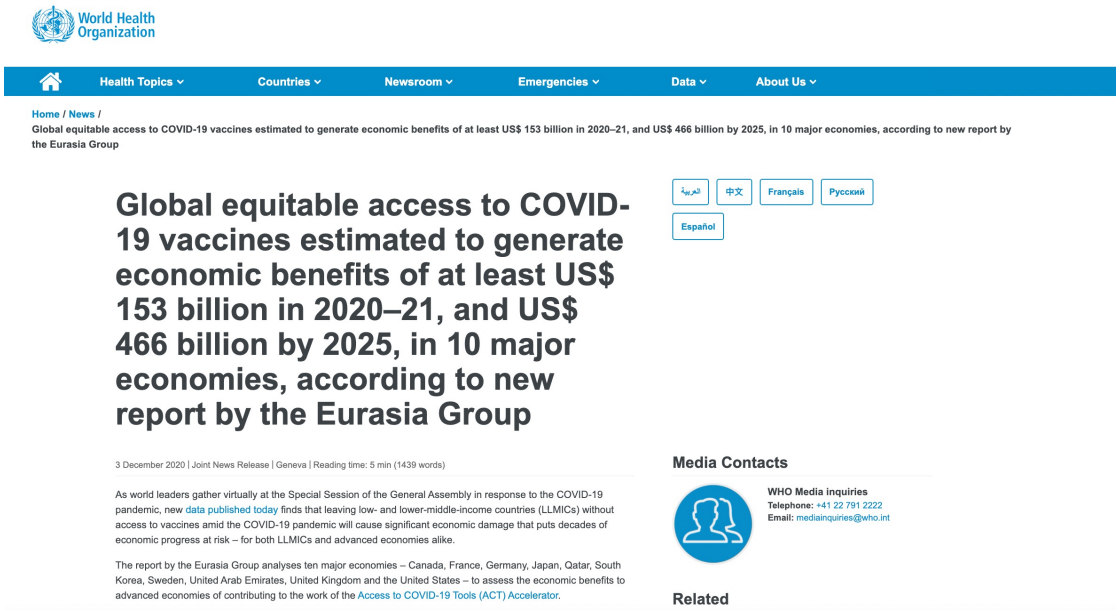
Equitable access and Economic Development – Win win?



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Global equitable access to COVID-19 vaccines estimated to generate economic benefits of at least US$ 153 billion in 2020–21, and US$ 466 billion by 2025, in 10 major economies, according to new report by the Eurasia Group

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Global equitable access to COVID-19 vaccines estimated to generate economic benefits of at least US$ 153 billion in 2020–21, and US$ 466 billion by 2025, in 10 major economies, according to new report by the Eurasia Group

3 December 2020 | Joint News Release | Geneva | Reading time: 5 min (1439 words)

As world leaders gather virtually at the Special Session of the General Assembly in response to the COVID-19 pandemic, new data published today finds that leaving low- and lower-middle-income countries (LLMICs) without access to vaccines amid the COVID-19 pandemic will cause significant economic damage that puts decades of economic progress at risk – for both LLMICs and advanced economies alike.

The report by the Eurasia Group analyses ten major economies – Canada, France, Germany, Japan, Qatar, South Korea, Sweden, United Arab Emirates, United Kingdom and the United States – to assess the economic benefits to advanced economies of contributing to the work of the Access to COVID-19 Tools (ACT) Accelerator.

Media Contacts

WHO Media inquiries
Telephone: +41 22 791 2222
Email: mediainquiries@who.int

Related

https://www.who.int/news/item/03-12-2020-global-access-to-covid-19-vaccines-estimated-to-generate-economic-benefits-of-at-least-153-billion-in-2020-21

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En kort bakgrund till fenomenet patent waivers

- I samband med pandemin har ett antal fenomen uppdagats, bland annat ***vaccine hoarding*** och ***scarcity mindset***
- **Vaccine hoarding**: stater bunkrar upp vaccin i större mängder än vad man nödvändigtvis behöver
- **Scarcity mindset**: stater begränsat sitt deltagande till internationella initiativ med utgångspunkten att resurser nödvändiga för behandling, prevention och begränsning av Covid-19 är kraftigt begränsade.
- Ett antal stater i utvecklingsländer upplevde stora svårigheter att bekämpa pandemins effekter på grund av detta.
- Immaterialrättigheternas styrka ställdes i förhållande till staternas (kanske främst utvecklingsländers) behov
- Indien och Sydafrika initierade ett förslag till WTO gällande ett system som i praktiken temporärt skulle begränsa immaterialrättigheter kopplade till Covid-19 pandemin. (Patent waiver)
- Syftet har varit att säkerställa tillgång till olika resurser relaterade till bekämpningen av Covid

Patent Waiver – Suggested by India & South Africa et alia.

WORLD TRADE ORGANIZATION

IP/C/W/669

2 October 2020

(20-6725) Page: 1/4

Council for Trade-Related Aspects of Intellectual Property Rights Original: English

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3. Given this present context of global emergency, it is important for WTO Members to work together to ensure that intellectual property rights such as patents, industrial designs, copyright and protection of undisclosed information do not create barriers to the timely access to affordable medical products including vaccines and medicines or to scaling-up of research, development, manufacturing and supply of medical products essential to combat COVID-19.

WORLD TRADE ORGANIZATION

IP/C/W/669/Rev.1

21 May 2021

(00-0000) Page: 1/4

Council for Trade-Related Aspects of Intellectual Property Rights Original: English

WAIVER FROM CERTAIN PROVISIONS OF THE TRIPS AGREEMENT FOR THE PREVENTION, CONTAINMENT AND TREATMENT OF COVID-19

REVISED DECISION TEXT

COMMUNICATION FROM THE AFRICAN GROUP, THE PLURINATIONAL STATE OF BOLIVIA, EGYPT, ESWATINI, FIJI, INDIA, INDONESIA, KENYA, THE LDC GROUP, MALDIVES, MOZAMBIQUE, MONGOLIA, NAMIBIA, PAKISTAN, SOUTH AFRICA, VANUATU, THE BOLIVARIAN REPUBLIC OF VENEZUELA AND ZIMBABWE

By means of a communication dated 21 May 2021, the following document is circulated at the request of the delegations of the African Group, the Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, the LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, the Bolivarian Republic of Venezuela and Zimbabwe.

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Arguments against Patent Waiver / CL

- COVID-19 vaccines not traditional vaccines - mRNA based, demands high technical know-how + raw material
- Manufacturing capacities already at maximum
- Patent Waiver / CL would weaken incentives and investments in pandemic research and development
- Infrastructure, technical know-how, personnel and other public health policies more important than IP rights

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Patentskyddet som en begränsning till fortsatt innovation?

I patent waiver förslaget tas följande upp kring synen på innovation i förhållande till rätten till hälsa:

- *Recognizing the importance of preserving incentives for research and innovation, and that these should be balanced with the public health interest;*

- Förslaget som sådant utmynnar i följande som staterna har att ta ställning till:

1. The obligations of Members to implement or apply Sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement or to enforce these Sections under Part III of the TRIPS Agreement, shall be waived in relation to health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19.

2. This waiver shall be in force for at least 3 years from the date of this decision. The General Council shall, thereafter, review the existence of the exceptional circumstances justifying the waiver, and if such circumstances cease to exist, the General Council shall determine the date of termination of the waiver.

- Viktigt att påpeka att det inte är patentskydd som hindrar innovation – det är vad patentinnehavaren väljer att göra med sitt patent, exempelvis ifråga om konkurrensrättsliga missbruk, som kan hindra innovation.

Patent Waiver – AIPPI Position Paper

WORLD TRADE ORGANISATION (WTO)
Council for Trade-Related Aspects of
Intellectual Property Rights (TRIPS Council)

AIPPI's position paper on the waiver for certain provisions of the TRIPS agreement for the prevention, containment and treatment of COVID-19 proposed by some countries within the WTO.

DD May 2021

AIPPI submits the following position relating to the above captioned topic, which is of paramount relevance to the matters our Association daily deals with:

A. INTRODUCTION TO AIPPI

AIPPI, the International Association for the Protection of Intellectual Property, was founded in 1897, and is dedicated to the development, improvement, and legal protection of intellectual property. The acronym of the organization was derived from its name in French: *Association Internationale pour la Protection de la Propriété Intellectuelle*. AIPPI is a non-affiliated, non-profit, politically neutral organization headquartered in Switzerland, having over 8,000 members representing over 130 countries. The members of AIPPI include lawyers, attorneys, and agents working across all fields of intellectual property in corporate and private practice throughout the world, as well as academics, judges, government officials and other persons interested in intellectual property. AIPPI is organized into 68 National and 2 Regional Groups.

The objective of AIPPI is to improve and promote the protection of intellectual property at both national and international levels. It does this by studying and comparing existing and proposed laws and policies relating to intellectual property and working with both government and non-government organizations for the development, expansion and improvement of international and regional treaties and agreements, and national laws.

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Patent Waiver – AIPPI Position Paper

- We assert that intellectual property rights should not be viewed *a priori* by any WTO member as a barrier to the development, manufacturing, distribution and provision of supplies and services of any kind. Contrary, according to Article 7 of the TRIPS Agreement (Objectives) , 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 obligations. The Doha Declaration on the TRIPS Agreement and Public Health indicates that the TRIPS Agreement is to be part of the wider national and international effort to address public health problems.

- AIPPI is not aware of evidence that intellectual property rights constitute a barrier for accessibility of COVID-19 related medicines and technologies. In the opinion of AIPPI, waiving TRIPS provisions would negatively impact the framework established to reach the objectives mentioned above in medium and long-term basis. AIPPI also urges WTO members to recognize how intellectual property rights have contributed to the advancement of science and to innovations in medicine and public health. The recently developed COVID 19 vaccines and therapeutics were discovered based on years or research supported by intellectual property rights.

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Patent Waiver – AIPPI Position Paper

- AIPPI supports the TRIPS Agreement and the flexibilities it provides to WTO members as well as the freedom to determine the appropriate method of implementing the provisions of the agreement within the members own legal systems (Article 1.1

- Coherent with our support to the flexibilities addressed above, our Association has passed resolutions in our annual congresses of years 1956, 1957, 1958, and 1960, on "*Restrictions of the rights of the patentee for reasons of public interest*", and in year 2008, a resolution entitled "*The impact of public health issues on exclusive patent rights*". We hereby reiterate our support to the WTO member's right to utilize the flexibilities already provided by the TRIPS agreement to protect public health under Article 8 of the Agreement and encourage them to implement functional domestic legal frameworks enabling them swiftly to do so.

Patent Waiver – AIPPI Position Paper

- To ensure legal predictability as well as the effectiveness of the requested legal changes, AIPPI believes that the execution, the implementation and then the effects of a waiver in various legal systems should be appropriately assessed beforehand.

- We trust that the discussions being held at the WTO TRIPS Council will find an appropriate global approach to contribute to the solutions to the problems imposed by the current pandemic while balancing the right of all to have access to health services and supplies with other stakeholder's rights and safeguarding, with a long-term vision, the system that has proven effective at reaching a technological stage advanced enough to develop and produce state-of-the-art responses to pushing global challenges in record times, as recently we all have witnessed.

Pro´s and Con´s of CL versus Patent Waiver

- Compulsory Licensing – Complex system, requires quite some time to pull-off in some cases, opposition by patent owner, need for decision on renumeration, paragraph 6 system not fully utilized due to procedural issues….

- On the positive side, a rather well-established legal route and due process, have de facto been utilized during COVID-19 (Russia, Israel…), paragraph 6 system underused…

  Patent Waiver – extremely complex to negotiate and draft with short notice, broad scope (substantive elements, time period, risk of trade diversion…), does not fully solve manufacturing, raw material and distribution issues, know-how and trade-secrets regarding mRNA vaccines do not follow automatically by way of waiver of IP rights…

  On the positive side, a “once-and-for-all” global solution to a global pandemic instead of nation-by-nation approach to CL, necessary to ensure economic recovery and sustainable development, re-connects with fairness and right-to-health paradigm and elevates the considerable public funding of vaccines etc.

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Some IPR-related anti-competitive practices and abuse of of dominant position under Article 101 and 102 TFEU

- Exclusivity vs. Freedom of Movement / Parallel Trade
- Refusal to deal / Refusal to supply / Refusal to license
- Pay for delay agreements
- Excessive Pricing / Margin Squeeze / Predatory Pricing
- Evergreening, sham litigation, abuse of regulatory system etc.

Art. 101 TFEU:

- (Certain) technology trasfer agreements
- Settlement agreements in pharmaceutical sector

Art. 102 TFEU:

- Refuse to license an IPR
- Abuse of IPRs or abuse of IPRs regulatory system

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Konkurrensrättsliga aspekter av tvångslicens inom pharma

- Tvångslicens-instrumentet, likt många andra juridiska verktyg, kan missbrukas
- Ett exempel är fallet **PMÖ 11561-20**, där det företag som hade stämts för intrång hävdade att patentet som intrånget gjordes gällande mot omfattades, eller borde omfattas, av tvångslicens. Rätten höll inte med eftersom den processuella gången för tvångslicens inte hade följts i det aktuella fallet.
- Fallet visar dock på möjligheten att motpart vid stämning rörande intrång kan söka freda sig genom tillgripande av tvångslicens-instrumentet.
- Å andra sidan så kan tvångslicens gynna konkurrensen, t. ex vid icke-utnyttjande av patent, oskälig licensvägran, samt missbruk av IP rättigheter som oskälig prissättning / FRAND etc.

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Analysis of COVID-19 Excessive Pricing cases

- Sharp price increases in price of essential items (masks, sanitizers, funeral services etc.) mostly in the beginning of the crisis March-April. Decreasing number of complaints post that period and prices slowly returning to normal, pre-crisis prices.

- Manifest difference in approach of EU, US and South Africa. EU treats the cases under “normal” excessive pricing regulation, US and South Africa target Price Gouging with benchmark of pre-crisis prices (US 10% increase, South Africa mixed approach).

- In their general responses, EU Competition authorities stressed their commitment to pursue excessive pricing cases as a matter of anti-competitive practices. Some authorities a mix of consumer protection / competition law approach.

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Analysis of COVID-19 Excessive Pricing cases and global responses

- Pricing regulations were introduced in some countries, but competition authorities did not rely on it per se as opposed to the South African cases. Futhermore, some countries pursues cases under "consumer protection law", "unfair pricing law" etc., where some countries combine competition and consumer protection agencies, where also more cases were noted in those countries (UK, Italy, Poland).

- Dominance & market share an issue in EU, not in US and South Africa. US and South Africa put emphasis on "***unconscionable***" and **"unfair"** aspect of the practices, regardless of the size of the undertaking and whether prices return to normal levels. Allow defense regarding increase in price.

- The courts in EU and the authorities did not show themselves particularly receptive to the rather blunt criticism of their judgements in some of the doctrine and economic debate in the pre-covid 19 excessive pharmaceutical cases. Difficult to asses how the pandemic would shape jurisprudence.

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Pharmaceutical Patents v Right to Health during COVID-19

- Strong legal basis in TRIPS providing for exceptions to protection of IPRs in regards to Public Health Policy and “emergencies”.
- Strong Legal basis in TRIPS for exceptions to protection of IPRs grounded on Anti-Competitive practices / Competition Law
- Need to revisit Ratio Legis as well as legal-economic rationales in regards to Patents / Competition Law / Right to Health
- Global trend towards protection of public procurement, public financing of research and demand-side solutions and fairness in pricing.
- European trend towards vigilant enforcement of competition law in the pharmaceutical sector **(Lundbeck, Generics UK, Astra Zeneca, Aspen (Italy and European Commission), Pfizer / Flynn (UK), CD Pharma (DK), Leadiant (Netherlands, Italy), Biogen (Belgium, Italy**)…

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Thank you for your attention!

Thoughts and comments?

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malki.afram@liu.se

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