

**PARAGRAPH 8 OF THE MINISTERIAL DECISION ON THE TRIPS
AGREEMENT**

**COUNCIL FOR TRIPS INFORMAL THEMATIC SESSION
FOR EXTERNAL STAKEHOLDER INPUT**

James Love
Knowledge Ecology International
Geneva, 28 September 2023

The June 17, 2023 decision on TRIPS and COVID 19 Vaccines was very narrow

It was a temporary, conditional waiver of Article 31.f of the TRIPS, to provide some additional but limited flexibility on exports under a non-voluntary authorization.

The decision only applied to one virus, and only to vaccines, and attached several conditions upon its use.

Limiting the ability of vaccine manufacturers to benefit from economies of scale and trade, the WTO limited eligibility for both importing and exporting, to developing countries, subject to further opt-outs.

There were some clarifications on the decision, but in the nature of restating existing flexibilities in TRIPS.

Did not address IP or investment provisions in bilateral or plurilateral agreements

The decision has not been used by WTO members.

Compare to what high income countries did during the COVID pandemic

Canada

COVID-19 Emergency Response Act, S.C. 2020, c. 5, Assented to March 25, 2020.

Part 12 amended the Patent Act to, among other things, provide that the Minister of Health could authorize the Government of Canada and any person specified in the application to make, construct, use and sell any patented invention to the extent necessary to respond to a public health emergency that is a matter of national concern.

Germany

The Protection of the Population in Case of an Epidemic Situation of National Significance (Gesetz zum Schutz der Bevölkerung bei einer epidemischen Lage von nationaler Tragweite) of 27 March 2020.

Confers upon the Federal Ministry of Health additional powers to control the epidemic situation, or order or instruct a subordinate authority to order patents used to manufacture and sell COVID 19 counter measures be used in the interest of public welfare.

The German act applied to a wide set of countermeasures, including:

Medicines, the active ingredients, starting materials and auxiliary materials for them, with medical devices, laboratory diagnostics, aids, as well as personal protective equipment and disinfection products.

United States

Very aggressive use of 28 USC 1498(a) / FAR 52.227-1

FAR 52.227-1 Authorization and Consent.

(a) The Government authorizes and consents to all use and manufacture, in performing this contract or any subcontract at any tier, of any invention described in and covered by a United States patent-

Some COVID 19 ([link](#)) or other examples ([link](#))

Google search terms

Site:hhs.gov 52.227-1

Site:sec.gov 52.227-1

etc

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		RATING	PAGE OF PAGES	
				1	36
2. CONTRACT (Proc. Inst. Ident.) NO. W911QY21C0016	3. EFFECTIVE DATE 27 Oct 2020		4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 0011565573		
5. ISSUED BY W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	CODE W911QY	6. ADMINISTERED BY (If other than Item 5)		CODE	
		See Item 5			
7. NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, state and zip code) EJ L LLY AND COMPANY (b) (6) 1 LILLY CORPORATE CTR INDIANAPOLIS IN 46285			8. DELIVERY [] FOB ORIGIN [X] OTHER (See below)		
			9 DISCOUNT FOR PROMPT PAYMENT		

Section I - Contract Clauses

CLAUSES INCORPORATED BY REFERENCE

52.227-1	Authorization and Consent	JUN 2020
52.227-2	Notice And Assistance Regarding Patent And Copyright Infringement	JUN 2020
52.227-3	Patent Indemnity	APR 1984

7. NAME AND ADDRESS OF CONTRACTOR (No., street, country, State and ZIP Code)

PHILIPS NORTH AMERICA LLC 113528

Attn: JAMES

PHILIPS NORTH AMERICA LLC 2 CA
2 CANAL PARK 3RD FL
CAMBRIDGE MA 021412232

8. DELIVERY

 FOB ORIGIN OTHER (See below)

9. DISCOUNT FOR PROMPT PAYMENT

10. SUBMIT INVOICES

ITEM

PART II SECTION I CONTRACT CLAUSES**I.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)**

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The full text of a clause may be accessed electronically at: <http://www.acquisition.gov/far>. HHSAR clauses at <http://www.hhs.gov/policies/hhsar/subpart352.html>

52.227-1	Dec 2007	Authorization and Consent, Alternate 1 (APR 1984)
52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
52.227-3	Apr 1984	Patent Indemnity
52.227-11	May 2014	Patent Rights – Ownership by the Contractor

European Union

COM(2023)224 - Proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006

Publication date, 27 April 2023

Use of TRIPS exceptions in developing countries was limited

Bolivia (Canada did not respond to 31bis request)

Chile, Colombia, Peru, Dominican Republic

What was needed

Mandates to use flexibilities

Measures on access to know-how and biologic resources

Commitment or opt-in pool to share government rights in publicly funded R&D

Note on TRIPS Article 44.2

Applies to all IP in the TRIPS.

No limits on technologies or purposes. Not limited to emergencies.

Does not require prior negotiation or even notification of rights holders

Does not restrict exports

Does require compensation/remuneration

By far, the least restrictive measure for non-voluntary uses. In medical area, only the US has aggressively embraced.