Non-disclosed information and trade secrets

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Article 7 & 8: Objectives and Principles

- Any review of the TRIPS Agreement should be carried out through the lens of the agreement's Objectives and Principles.
- The Objectives and Principles of the TRIPS Agreement often get lost in discussions about the purpose of intellectual property (IP) protection and the management of IP.
- Important to:
  - assess whether the implementation of TRIPS has contributed 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."
  - assess whether Members that adopt and take measures to protect public health and nutrition, promote the public interest, and prevent abuse of IPRs have been able to do this unhindered.

Article 39: Trade secrets and test data

- Covers both trade secrets and test data submitted to government agencies
- Not explicitly covered by pre-TRIPS international IP law
- Framed in terms of general concept of protection against unfair competition of 10bis Paris Convention:
    - which obliges members to ensure effective protection against acts of competition that are contrary to honest practices in industrial or commercial matters

Article 39.2: Trade secrets and know-how

- Requires undisclosed information (trade secrets or know-how) to benefit from protection.
- Undisclosed information
    - Is secret
    - Has commercial value because it is secret
    - Has been subject to reasonable steps to keep it secret
- TRIPS does **not require undisclosed information to be treated as a form of property**
- Person lawfully in control of such information must have the possibility of preventing it from being disclosed to, acquired by, or used by others without his or her consent in ***a manner contrary to honest commercial practices.***

Access to undisclosed information and know-how in a pandemic

- Access to undisclosed information became important during the Covid-19 pandemic
- Compulsory licensing may not be sufficient to assure access to know-how needed to manufacture more complex technologies such as vaccines
- In case of refusal to share such know-how, authorities should be able to compel access
- TRIPS Art 39 is not a barrier to CL of know-how. Art 39 protection from disclosure is limited to information acquired or used "a manner contrary to honest commercial practices"
- Still, this point has become contentious in the WHO Pandemic Agreement negotiations
- While parties recognise the need for regulation of undisclosed information /knowhow at the national level, they have refused a meaningful provision in the Pandemic Agreement to ensure cross border sharing of know-how

Proposal for access to know -how provision in the Pandemic Agreement

Article 11: Transfer of Technology:

In addition to the undertakings in paragraph 1 of this Article, where the urgent manufacture by qualified third parties of a pandemic countermeasure is necessary to respond to a pandemic or the threat of a pandemic but the manufacture is prevented or hindered through lack of access to undisclosed information possessed by one or more private rights holders located in one or more Parties, that or those Parties shall compel that or those rights holders to share the undisclosed information with the third parties.

Art 39.3: Undisclosed test data

- Scope
  - **Obligation to submit test data** for regulatory approval to market a pharmaceutical or agricultural product
  - Involving a **new chemical entity**
  - **Undisclosed** test or other data
  - Which involved **considerable effort**
- Members must:
  - Protect against unfair commercial use
  - Except when necessary to protect public health
- → 39.3 does **NOT** require establishing a data exclusivity regime

Use of compulsory licensing

Since 2001, ML&P has documented the use of TRIPS Flexibilities (Art 31, Art 31bis, Par 7) for health products:

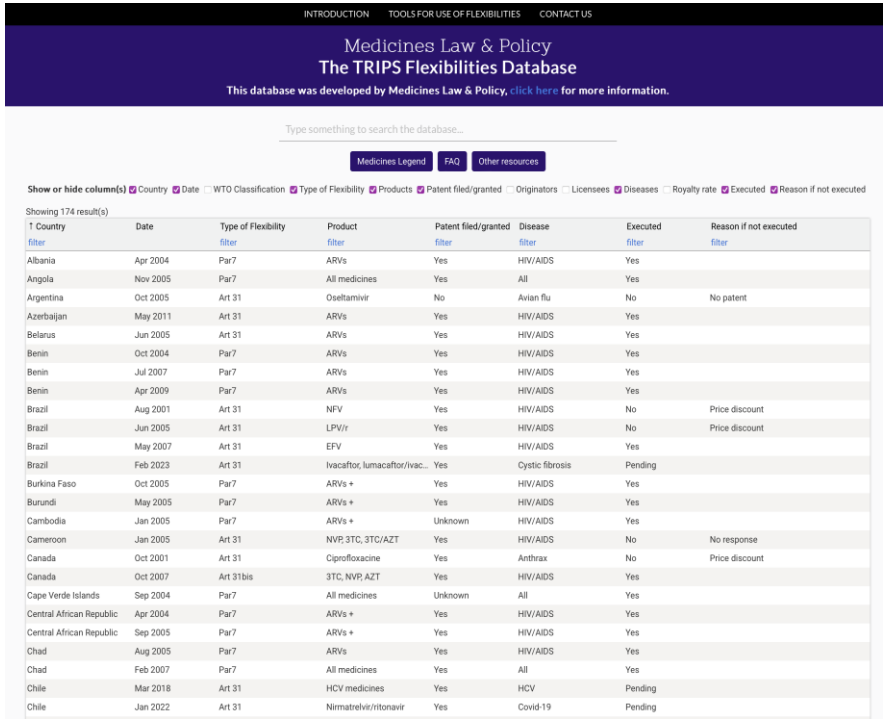
175 total number of entries

125 instances of compulsory licensing (CLs)

81 executed instances

30 non-executed instances:

- patent holder to offer VL/price discount/other access measure
- **Other barriers ->**



↑ Country	Date	Type of Flexibility	Product	Patent filed/granted	Disease	Executed	Reason if not executed
filter		filter	filter	filter	filter	filter	filter
Albania	Apr 2004	Par7	ARVs	Yes	HIV/AIDS	Yes	
Angola	Nov 2005	Par7	All medicines	Yes	All	Yes	
Argentina	Oct 2005	Art 31	Oseltamivir	No	Avian flu	No	No patent
Azerbaijan	May 2011	Art 31	ARVs	Yes	HIV/AIDS	Yes	
Belarus	Jun 2005	Art 31	ARVs	Yes	HIV/AIDS	Yes	
Benin	Oct 2004	Par7	ARVs	Yes	HIV/AIDS	Yes	
Benin	Jul 2007	Par7	ARVs	Yes	HIV/AIDS	Yes	
Benin	Apr 2009	Par7	ARVs	Yes	HIV/AIDS	Yes	
Brazil	Aug 2001	Art 31	NFV	Yes	HIV/AIDS	No	Price discount
Brazil	Jun 2005	Art 31	LPV/r	Yes	HIV/AIDS	No	Price discount
Brazil	May 2007	Art 31	EFV	Yes	HIV/AIDS	Yes	
Brazil	Feb 2023	Art 31	Ivacaftor, lumacaftor/ivac...	Yes	Cystic fibrosis	Pending	
Burkina Faso	Oct 2005	Par7	ARVs +	Yes	HIV/AIDS	Yes	
Burundi	May 2005	Par7	ARVs +	Yes	HIV/AIDS	Yes	
Cambodia	Jan 2005	Par7	ARVs +	Unknown	HIV/AIDS	Yes	
Cameroon	Jan 2005	Art 31	NVP, 3TC, 3TC/AZT	Yes	HIV/AIDS	No	No response
Canada	Oct 2001	Art 31	Ciprofloxacine	Yes	Anthrax	No	Price discount
Canada	Oct 2007	Art 31bis	3TC, NVP, AZT	Yes	HIV/AIDS	Yes	
Cape Verde Islands	Sep 2004	Par7	All medicines	Unknown	All	Yes	
Central African Republic	Apr 2004	Par7	ARVs +	Yes	HIV/AIDS	Yes	
Central African Republic	Sep 2005	Par7	ARVs +	Yes	HIV/AIDS	Yes	
Chad	Aug 2005	Par7	ARVs	Yes	HIV/AIDS	Yes	
Chad	Feb 2007	Par7	All medicines	Yes	All	Yes	
Chile	Mar 2018	Art 31	HCV medicines	Yes	HCV	Pending	
Chile	Jan 2022	Art 31	Nirmatrelvir/ritonavir	Yes	Covid-19	Pending	

https://medicineslawandpolicy.org/trips-flexibilities-database/

Data Exclusivity and effective use of CLs:

- There are various barriers (political and legal) to the effective use of CL
- Data exclusivity can be a barrier to effective use of CL if the law does not provide for a waiver of DE in case of CL
- (now recognised by the European Commission which has proposed such a waiver in the EU's medicines law).
- Countries that provide for DE waiver in case of CL include: Chile, Colombia and Malaysia

Thank you!

Further reading

Trade secrets/knowhow sharing
Levine, D.S. and Sarnoff, J.D., 2023. **Compelling Trade Secret Sharing: https://hastingslawjournal.org/wp-content/uploads/1-Levine-final.pdf**

https://medicineslawandpolicy.org/2023/10/sharing-know-how-trade-secrets-during-a-pandemic-we-must-be-planning-for-it-now/

TRIPS Flexibilities database: http://tripsflexibilities.medicineslawandpolicy.org

Pandemic Agreement:
https://medicineslawandpolicy.org/pandemic-accord/
https://gh.bmj.com/content/7/7/e009709

Data exclusivity:
https://medicineslawandpolicy.org/wp-content/uploads/2019/06/European-Union-Review-of-Pharma-Incentives-Data-Exclusivity.pdf
https://link.springer.com/chapter/10.1007/978-3-030-83114-1_7

EU wide compulsory licensing:
https://medicineslawandpolicy.org/2023/08/the-european-commissions-compulsory-licensing-proposals-are-sensible-but-do-not-go-far-enough/