OLARTEMOURE Compulsory Licenses

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IP exploitation and Compulsory Licenses during COVID-19 in Colombia

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Context and Law and Regulations

- Decision 486 Art. 65: grant a Compulsory License based on "… public Interest, emergency or national security" declaration. These article is based on Articles 30 and 31 of TRIPS Agreement.
- Issue: has Colombia ever issued a Compulsory License for patents based on said article of D. 486?
- Response: No. But...



Previous attempts for a CL in CO

- Governmet of Colombia had at east 2 previous <u>non-successful</u> requests where Compulsory Licenses (CL) were considered:
 - LOPINAVIR and RITONAVIR-KALETRA® (antiretroviral medication for the treatment and prevention of HIV/AIDS) and
 - IMATINIB-GLEEVEC® (treatment of Philadelphia chromosome positive chronic myeloid leukemia- a blood type of cancer).
- Declaration of public interest for both medicines issued in both cases based on Colombia's public health interest. Request by NGOs and local pharma companies to grant CL based on said Decalaration.
- No Compulsory License proceeding initiated at the Colombia IPO. Instead, the Declaration was used to issue a Price Control Decree by Minstry of Health for said medicines.
- Based on said cases and experiences, a detailed regulation was requested and issued to establish a detailed procedure for granting a CL based on a Public Interest declaration: Decree N° 4302 of 2008.



The Andean Tribunal of Justice provided a guidance for a CL in the Andean Community countries (CO, PE, EC, and BO)

Andean Tribunal of Justice (Andean Community court for IP) issued a judicial decisión on 2019 ("Interpretación Prejudicial 144-IP-2019") saying any public health emergency, such as a pandemic, is a valid reason to grant CL only if it is a reasonble, necessary, and a valid measure to:

(i) effectively control the health emergency;

(ii) there is no other alternative less restrictive or burdensome to the IP owners, <u>and</u>

(iii) the benefits outweights the negative effects.



¿Needed CO a CL based on a Health Public Interest Declaration to control the COVID-19 pandemic?

- Issue: May the access, importation, use, and/or availability of COVID-19 related medicines, treatments, and/or medical devices be blocked, become more expensive, or affect the effectiveness of the government to control the public health crisis created by the pandemic because of the patents granted to the above?
- Colombian Congress requested publicly to the President to declare a CL on patents and trademarks related to COVID-19
- The President of Colombia declared the "State of Emergency" in Colombia which allows him to legislate instead of Congress.
- He issued Decree 476 de 2020 (Article 1.7): Ministry of Health was given authorization to issue a Declaration of Public Interest for the protection of the publich health and take measures to secure the access and use of "medicines, medical devices, vaccines and any other health related technology for diagnostic, prevention and treatment of COVID-19".

¿Is necessary a CL based on the Decalaration of Public Interest due to COVID-19?

- Issue: Does this declaration meant Compulsory Licenses (CL) would be granted by the Colombian IPO on patents granted over "medicines, medical devices, vaccines and any other health related technology for diagnostic, prevention and treatment of COVID19"?
- No CL has been issued or initiated until today.
- Instead:
 - Between March 17 to June 15, 2020 exempt of annuity payment for patents or renovation oficial fees for trademarks for any Colombian patents or trademarks related to COVID-19
 - PROSUR (BR, AR, CO, EC, PE, and UR) published a report with the list of patents amd technology publicly available in each country(See: <u>https://prosur.org/wp-</u> <u>content/uploads/2020/04/Boletin-PROSUR-COVID19-1.pdf</u>)
 - Declaration and Decree 476 was used to ease regulatory market and importation authorzation by INVIMA (Colombian PMDA or FDA) for importation and commercialization of medicines, treatments, technologies, medical devices, etc.
 - Ministry of Science and Technology created a public program to finance (USD 10.5M in 2020/21 and USD 3M aid for patent protection) and promote R&D in medicines, treatments, medical devices, epidemiology studies and software, AI, IoT and Big Data to fight, control, or treat COVID-19 and support Start Ups that bring to market resulting medicines, treatments or medical devices based on local R&D.

THANK YOU MUCHAS GRACIAS どうもありがとうございました。 OLARTEMOURE

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