



EXPANDING FRONTIERS FOR COMPULSORY LICENSING

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Lessons learned from the COVID-19 Pandemic
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EU PROPOSAL FOR REGIONAL EMERGENCY CLS AND WAIVER OF DATA EXCLUSIVITY

- European Commission recently proposed streamlined, time-limited regional CLs and an exception to data/market exclusivity during declared emergencies where countries cannot act efficiently on their own; nat'l CL procedures are left untouched.
- EU-level regional CLs can allow the rapid manufacturing of products needed to tackle a crisis and free circulation within an aggregated EU market to reach all those in need.
- An emergency CL covers patents, published patent applications, supplementary protection certificates and utility models. EU CLs apply equally to a national and European patents. Companies will be pressured to provide access to trade secrets & tech know-how needed for manufacturing
- To expedite CLs, the CL can simply confer rights with respect to a product identified with its non-proprietary name, though this option is challenged by a proposed amendment to identify all relevant patents in the CL application. An Advisory Bd. issues non-binding recommendations.
- Patent owners would be able to share their views on granting a CL and the conditions surrounding it. Notice and participation rights allow the patent holder to propose a VL. Licensed products must be identifiable and differentiated from the originator product.
- An EU CL would also be available, in the context of Regulation (EC) No 816/2006, export to non-producing countries.
- Patent owners will receive fair compensation not to exceed 4% of gross revenue.
- Union pharmaceutical legislation (cf. Art. 80 para. 4 of Directive (EU) No COM(2023)192) provides for the suspension of data exclusivity and market protection when a CL is issued.

U.S. MARCH-IN PROPOSAL AND BROAD USE OF CONTRACTUAL GOVERNMENT-USE LICENSES & R&D CONDITIONALITIES

- President Biden has just announced a new effort to use federal “march-in” rights arising from taxpayer-funded inventions to allow alternative producers to manufacture and sell medical products when the needs of U.S. patients are not met because of inadequate supplies or unreasonably high prices.
- During the COVID-19 pandemic pursuant to 28 U.S.C. sec. 1498, the US introduces simple contractual language to immunize biopharmaceutical manufacturers from liability for patent infringement on dozens of occasions (KEI analysis).
- U.S. has recently imposed fairer pricing terms, including “most favored nations clauses” in pharmaceutical R&D funding agreements, including with Regeneron, and the Administration for Strategic Preparedness and Response is making fair pricing a standard part of its contract negotiations.

CL LAW REFORM IN BRAZIL (AND ARGENTINA)

- Brazilian legislators proposed a mandatory public-health-emergency CL mechanism that included access to trade secret protected know-how and biological resources held by the right holder and/or the national regulatory authority, some terms were vetoed by the President.
- The Bill provides for public participation in the selection of candidates for CLs, though issuance by the government is still discretionary. Remuneration is set at 1.5% and only on granted patents.
- A CL is not available if right holder reasonably make:
 - “objective commitments capable of ensuring that domestic demand is met in conditions of volume, price and term compatible with the needs of national or international emergency, public interest or state of public calamity nationwide, through one or more of the following alternatives:
 - I – direct exploration of the patent or patent application in the country;
 - II – voluntary licensing of the patent or patent application;
 - III - transparent contracts for the sale of products associated with the patent or the patent application.

PRESUMPTIVE OR MANDATORY CLS AND SIMPLIFIED PROCEDURES

- Although TRIPS Art. 27 seems to require that CLs be issued on their “individual merits,” it may nonetheless be permissible for CLs to be mandatory.
 - For example, India Patents Act, sec. 92A(2) requires that CLs for export to non-producing countries shall be granted; Canadian covid legislation also provided for mandatory CLs.
 - It also seems possible to provide for mandatory CLs in the case of an emergency or even for a class of pharmaceutical products.
- Countries might be hesitant to issue mandatory CLs, but there should be no hesitation in providing for presumptive CLs where the burden is on the patent holder to override the presumption.
- Simplified administrative procedures, administrative review, remuneration guidelines and other measures can simplify and expedite CL procedures.

CLS ON PENDING PATENTS, COMPONENT PATENTS, AND SUBSEQUENTLY FILED PATENTS

- The importance of being able to grant CLs on pending patent applications became much clearer during covid. Some have argued that premature CLs interfere with opposition procedures, but CLs can and have been issued on a much faster basis than oppositions and can be filed even with respect to “worthy” patents.
- Prospective or retroactive remuneration should not ordinarily be paid on patent applications subsequently granted or revived after suspension.
- To be able to fully work a product patent, it may be necessary to have involuntary access to patents on subsidiary product components as well.
- CLs should also be available for subsequently filed patents on particular pharmaceutical products to cover secondary product and process patents. If need be, as provided by the EC proposal, right holders can be notified of the CL and their right to remuneration once the government has notice of the new patent.

FAILED EXTENSION OF THE JUNE 2022 WTO DECISION ON EXPORT CLS TO COVER DIAGNOSTICS AND THERAPEUTICS

- Stalled because of USTR referral to the US International Trade Commission.
 - Cynical move by the US to delay, placate Pharma, and seek political cover
 - Nothing really to study – the decision obviously works better for therapeutics
 - Even if a study was needed, it should have been launched in May 2022
- EU originally supported a limited CL mechanism for diagnostics and medicines but never advocated for the TRIPS Decision extension.
- Switzerland, UK and other countries also opposed.
- Extension decision was mothballed in February at WTO 13th Ministerial Conf.
- Regrettably, global demand for covid antiviral and test-and-treat was suppressed by WTO inaction and Pfizer's delays and onerous tiered pricing.

ESTABLISHING A COMPULSORY LICENSING FACILITY

- To be maximally effective, to aggregate commercially attractive and more sustainable markets, and to promote generic competition at efficient economies of scale, countries should collaborate and coordinate for the issuance of CLs on key medical technologies.
- Advocates have been proposing this for a decade including to the UN High Level Panel on Access to Medicines
- Abbott and Reichman have also proposed regional CL/pooled procurement mechanisms, which would lead to more sustainability.
Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic, 23 J. Int'l Economic Law 1-27 (2020)
- A proposal to Unitaid for a funded CL coordination platform was rejected.

CLS ON TRADE SECRETS

- The problem of accessing trade secrets, confidential information, manufacturing know-how, and biological resources has become much more pronounced with respect to covid vaccines and biologics in general.
- There have been multiple recent proposals for CLs or public interest/health exceptions to trade secrets. See e.g. David S. Levine & Joshua Sarnoff, *Compelling Trade Secret Disclosure*, 74 *Hastings L. J.* 987 (2023).
- An alternative proposal from TWN focuses on allowing access to manufacturing know-how disclosed to national regulatory authorities.
 - This was included in the proposed Brazilian CL law reform.
 - This was also possibly indirectly referenced in the EC emergency CL proposals authorizing additional steps needed to effectuate an emergency CL and calling further for good faith between originator and emergency CL licensees.

CLS ON MPP LICENSED MEDICINES

- MPP licenses consistently contain clauses allowing MPP sublicensees to supply countries that have issued CLs.
- This can allow supply to countries that have MPP sublicensees but are not within the permitted territory of use and to countries that are patent blocked but want to import from an established MPP licensee.
- This may be the easiest way to facilitate expanded access to MPP licensed medicines, but it has never been used, though it may happen in Colombia.
- Note: other CL export/import options that could be expanded include:
 - Non-predominate quantities under an ordinary Art. 31 CL or Art. 44 judicial CL
 - Specified quantities pursuant to Art. 31bis
 - Unlimited quantities pursuant to an Art. 31(k) competition-based CL and pursuant to Art. 30 exception to Art. 31(f)

SOME RECENT CL CAMPAIGNS

- Colombia CL on dolutegravir is pending; AHF threat of CL on dolutegravir in Trinidad & Tobago; The Brazilian Interdisciplinary AIDS Association has also called on the Ministry of Health to issue a CL on dolutegravir.
- CL court case in South Africa on Vertex cystic fibrosis meds; threat of CL in Brazil forced Vertex to significantly lower prices. Vertex CL requests in Ukraine and India (revocation or CL) also.
- Knowledge Ecology International petitioned Canada to add risdiplam to Schedule 1 of the Canadian Patent Act
- Eli Lilly breast cancers CL litigation in India; CS request for CL on TB MDR drug, delamanid
- Unsuccessful efforts for CLs on covid antiviral nirmatrelvir/ritonavir in Dominican Republic, Colombia, Peru



USING COMPULSORY LICENSING TO SUPPORT THE MRNA TECHNOLOGY TRANSFER PROGRAMME

- CLs needed to create freedom to operate beyond the field of use and time restrictions of the largely illusory Moderna COVID-19 vaccine non-enforcement pledge. mRNA tech platform patents are very broad; already granted in S. Africa.
- Freedom to operate is blocked, even for COVID-19 mRNA vaccines, in some programme partner countries.
- In the absence of robust research exceptions (including commercial R&D), CLs may be needed for research on product optimization, new mRNA applications, and new manufacturing processes as well as for commercial production and sale
- Moderna, Pfizer, BioNTech, and others have large mRNA portfolio interests in treatments for many other diseases, including cancer, and are patenting accordingly.
- Regional coordination of CLs will be needed in export and import markets to aggregate viable and sustainable markets.