

Compulsory Licences are Back!

How the Covid-19 Pandemic has Revamped the Debate over a Controversial TRIPS Flexibility

Enrico Bonadio (Reader in IP Law - City, University of London) & **Magali Contardi** (Research Fellow at Sant'Anna School of Advanced Studies, Italy, and Phd Candidate at the University of Alicante, Spain)

For two years the world has been battling the coronavirus (Covid-19) pandemic. Within this context, intellectual property (IP) rights, especially patents, have proven to be both the good and evil for an effective Covid-19 response. The unprecedented rapid development and availability of Covid vaccines, and related medical technologies, have certainly showed the importance of a robust IP environment. On the other hand, many commentators have highlighted the need to strike a fair balance between the interests of the research-based pharmaceutical industry and the public interest to access Covid-19 related technologies. Also, many developing and least-developed countries, led by South Africa and India, have backed an IP waiver for Covid-19 technologies at the World Trade Organisation.

Against this background, the talk will highlight recent cases where compulsory licences have been granted or applied for in relation to Covid-19 medicines and vaccines in several countries, including Bolivia (under Article 31-bis TRIPS), Israel and India (with an application filed by generics' manufacturer Natco). It will moreover review the recent legislative amendments adopted by some WTO States (e.g., France) aimed to facilitate the (compulsory) transfer of vaccine's technologies.

While compulsory licences are praised by several commentators and NGOs, the point is also made that such flexibility may prove insufficient to transfer the underlying technology. Even where such licences are granted, confidential information around the licenced inventions can be kept by pharmaceutical companies and are not easily retrievable. In other words, such companies could lawfully engage in being obstructive by refusing to disclose their know-how. It would be difficult, if not impossible, to require pharmaceutical companies to reveal that secret, also because even if such companies were dragged into courts judges would not know which information should be disclosed.

Despite the above drawbacks, the presentation will make the point that the availability of compulsory licences may still have some merit. By keeping the pressure on pharmaceutical companies, maintaining such an option on the table may convince recalcitrant patent owners to lower prices or grant generics' producers' voluntary licences. For example, the recent Natco application for a compulsory licence over Baricitinib has prompted Eli Lilly, the patent holder, to grant royalty-free and non-exclusive voluntary licences to Indian generic manufacturers Sun, Pharma Cipla and Lupin.