**CMS Expert Guide to compulsory licensing**

**A legal roadmap of over 20 jurisdictions**

Intellectual property rights are critical for any economy that wants to foster a culture of innovation, risk taking, and entrepreneurship. Particularly in a medical context, pharmaceutical companies invest significant resources into researching, inventing, and gaining approval for new medicines to treat known and emerging diseases. Patents grant exclusive rights to the patent holders to exploit the patented product or process, enabling the pharmaceutical companies to recoup their investments and providing incentives for investing in new drugs.

However, such exclusive rights through patents can in some cases obstruct access to medicines, for example for low-income people in need of a medicine due to high prices. Particularly now, with potential COVID-19 vaccines racing through the development pipeline at dizzying speeds and some vaccines already being authorized for (emergency) use, pressure is mounting to ensure all countries have affordable access to any therapeutics or vaccines that emerge.

The COVID-19 outbreak has led to increased demand for several medicines around the world and many countries want to ensure that exclusive IP rights do not prevent them from producing enough medicine to combat COVID-19. Activists are calling for more attention to secure access to new medicines, putting pressure on lagging governments to act now so they will be able to immediately benefit from any advances in treating or preventing COVID-19. They refer to several mechanisms for guaranteeing affordable access to medicines, including issuing compulsory licenses, which allow parties to use an invention without the patent holder’s consent in extraordinary circumstances. The COVID-19 pandemic has therefore once again put compulsory licensing into the spotlight.

Compulsory licensing provides a specific mechanism to bypass a patent owner’s legal monopoly. However, compulsory licensing is a drastic measure, the last resort in extraordinary times or exceptional situations. So far, it has been put into practice only in rare individual cases. The analysis and implementation of "better tools to facilitate access to critical IP in times of crisis" is one goal of the EU Action Plan for IP (COM(2020), 760) and has put also compulsory licensing on the spot.

Even though compulsory licenses are only awarded under exceptional conditions, and where specific requirements are met, does the unprecedented scale and magnitude of the coronavirus crisis provide the right circumstances for applying this tool? Who can apply for such a compulsory license? Can the competent authority grant a compulsory licence without hearings under an urgent situation? And does the compulsory licensee have to pay a royalty to the right holder?

This guide provides a high-level overview of all such issues and requirements involving compulsory licensing over 20 jurisdictions.

We hope you find this edition of the CMS Compulsory Licensing Expert Guide an interesting read and if you would like any more detailed information and advice, please do not hesitate to get in touch with us.

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