

INTERNATIONAL JOURNAL OF LEGAL SCIENCE AND INNOVATION

[ISSN 2581-9453]

Volume 3 | Issue 3

2020

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Compulsory Licensing vis-à-vis Covid-19

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ABSTRACT

In the wake of an ongoing pandemic, analyzing the contours of compulsory licensing is important. Compulsory licensing permits a person to reproduce a patented invention without obtaining authorization from the patent-holder. The Indian Patents Act, 1970 holds various provision in this regard which lays down the yardsticks for compulsory licensing. In case of an emergency the Central Government is empowered to grant compulsory licenses to tackle the issue. Covid-19 is one such emergency which require a grant of compulsory license on the vaccines. Article 3 of the TRIPS Agreement, which India is a signatory, recognizes the need for issuing compulsory license during emergencies. In this regard, compulsory licensing will pave way for affordable and universally accessible patented Covid-19 vaccines and other pharmaceutical inventions or processes, including the components and kits. Various countries such as Germany, Denmark, United Kingdom and Canada have incorporated the need for compulsory licensing in their legislations. In spite of several mechanisms in place to resolve this situation under the TRIPS Agreement, there are still major issues with respect to their effectiveness.

I. INTRODUCTION

Compulsory licensing essentially refers to the authorization of an individual (a third party) to make, use or sell a patented invention without obtaining permission from the owner of the particular patent. In the Indian paradigm, aspects of compulsory licensing are enumerated under Chapter XVI of the Indian Patent's Act. The concept of compulsory licensing is widely recognized in both international and national domains. Provisions of the Indian Patent Act, 1970 are in accordance with the TRIPS Agreement.

Irrespective of having the license for a particular patent, any individual may apply to the Controller after the expiry of three years, requesting for grant of compulsory license. In order to obtain the same, there are various yardsticks which are to be met—

- the instant patent has not met the reasonable demands of the public.
- Unaffordable price of the patented invention.

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- the patented invention is not yet been put to use in India.²

Furthermore, the Central Government may also grant compulsory licenses in situations of extreme emergencies or cases of non-commercial use by the public.³ In India, the first issue of a compulsory license was to Natco Pharma Ltd. for a particular compound initially owned by the Bayer Corporation.⁴

Once the Central Government gives the authorization to use a patented invention “for the purpose of the government,” such companies may commence manufacturing while bargaining the extent of the royalties with the owners of the patent.⁵ The government can refer to the High Court if there is no consensus concerning the royalties.

II. COMPULSORY LICENSING AND COVID-19

The pandemic has taken a massive toll on the healthcare sector and the economies of the world. Even prosperous countries have struggled to combat the coronavirus. Governments of the developing countries are to consider the population's vulnerability and make ways to grant compulsory licenses for any cure/vaccine that could possibly treat Covid-19. In addition, the TRIPS Agreement empowers the governments to provide their citizens with blanket versions of patented cure/treatments.

Under Clause 5 of the Doha Declarations, governments are empowered to grant compulsory licenses in the event of a national emergency without adhering to the protocol. Clause 5(c) sheds light on the fact that compulsory licenses can be granted in times of a ‘public health crisis.’ Therefore, Covid-19 can be brought within the ambit of the clause as mentioned above as it qualifies to be a public health crisis.

As per Article 31 of the TRIPS Agreement⁶, the member countries may issue compulsory licenses in certain circumstances. The Solidarity Call to Action (initiated by the WHO and Costa Rica) has encouraged patent owners to voluntarily surrender those patented products integral for Covid-19 at the UNITAID and Medicines Patent Pool (MPP) to be readily accessible for licensing in every country. Henceforth, compulsory licensing read with Paragraph 6 would assure affordable and universally accessible patented Covid-19 vaccines and other pharmaceutical inventions or processes, including the components and kits.

² The Indian Patents Act, 1970 § 84(1).

³ The Indian Patents Act, 1970 § 92(1)(4).

⁴ Bayer Corporation v. Union of India, 2014 SCC Online Bom. 963

⁵ The Indian Patents Act, 1970 § 100(5).

⁶ TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

Prior issuance of compulsory licenses for antiretroviral treatments was in response to the condition of citizens infected by HIV-AIDS as these drugs were unaffordable in the African countries. Ghana and Zimbabwe granted compulsory licenses for all antiretroviral drugs, while the other countries stuck to issuing licenses for specific patented drugs.⁷ A parallel can be drawn from the HIV-AIDS epidemic with Covid-19. The countries that had previously issued compulsory should ideally repeat the same to supply affordable antiretroviral drugs to its citizens.

III. STATE OF AFFAIRS IN THE INTERNATIONAL REGIME

In the wake of the Covid-19 pandemic, many countries have resorted to compulsory licensing to tackle the coronavirus. The Israeli Health Ministry issued a compulsory license for importing generic versions of lopinavir, which could treat Covid-19.⁸ This issue of compulsory license was not aimed at making the prices of these drugs affordable but due to the shortage of supply. By way of its amended Patent's Act, Canada formulated a speedier mechanism for issuance of a compulsory license as a response to Covid-19.⁹ Grant of compulsory license to technologies relating to Covid-19 was declared by a Resolution passed in Chile's lower house of the Parliament.¹⁰ Another Resolution was passed in Ecuador, mandating the President and the Health Ministry to provide free and affordable access to technologies and other aspects relating to Covid-19 by way of granting compulsory licenses.¹¹ There also have been reports that Germany and France are willing to issue a compulsory license if the situation calls for the same.

Additionally, Section 24 of the German Patent Act¹² and Section 5(2)(5) of the German Act on the Protection and Control of Infectious Diseases in Humans¹³ provides for the granting of compulsory licensing during a pandemic. In France, Article L. 613-16 of the Intellectual

⁷ Hilary Wong, *The Case for Compulsory Licensing during Covid-19*, 10 Journal of Global Health 1 (2020).

⁸ Kass D. *Israel Defies AbbVie IP To Import Generic Drugs For COVID-19* (May 16, 2014, 4:16 PM) <https://www.law360.com/articles/1255079?scroll=1&related=1>

⁹ COVID-19 Emergency Response Act, S.C. 2020, C-13 (Can.).

¹⁰ Proyecto de Resolución N° 896, Resolution for Involuntary Licensing of Patents Relating to Coronavirus, Cámara de Diputadas y Diputados [Chamber of Deputies], Mar. 17, 2020 (Chile).

¹¹ Resolution for Compulsory Licensing of Patents Relating to Coronavirus, Comisión Especializada Permanente de Educación, Cultura y Ciencia y Tecnología de la Asamblea Nacional [Education, Culture, Science and Technology Commission of the National Assembly], Mar 20, 2020 (Ecuador).

¹² Patentgesetz [PatG] [Patent Act], Dec. 16, 1980, BGBl. 1981 I at 1, § 24, last amended by Gesetz [G], Oct. 8, 2017, BGBl. I at 3546 (Ger.)

¹³ Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen [IfSG] [Act on the Protection and Control of Infectious Diseases in Humans], July 20, 2000, BGBl. I at 1045, §5(2)(5), last amended by Gesetz [G], June 19, 2020, BGBl. I at 1385, art. 5. (Ger.)

Property Code¹⁴, Article 57 of the Dutch Patent Act,¹⁵ and Section 53 Patents Act 1977 of the United Kingdom grants similar powers to the government in issuing compulsory licenses.¹⁶

Several leaders have vouched for the vaccine to be rendered as a ‘global public good,’ thereby negating the existence of monopoly rights. However, this idea was not detected in the Seventy-Third World Health Assembly’s Resolution— ‘Covid Response’ which aimed at providing a uniform response to the pandemic globally. Only a reference is made to the “flexibilities” enumerated in the Doha Declaration, which allows countries to grant compulsory licenses in circumstances of national emergency. Now that the vaccine trials are in their advanced stages, it is pertinent that the countries adopt measures to ensure monopoly rights conferred to private parties do not prevent the universal exchange of medical products.

IV. CONCLUSION

India is a member of the World Trade Organization member and a signatory to the TRIPS Agreement based on which the Indian Patents Act of 1970 was enacted. This has effectively set the seal on India as well as other members of the WTO to have a strong inter-dependable set-up to rely on in the event of a health crisis such as the current one. Although the importance of patent protection is duly acknowledged, certain security measures are in place to make sure that such protection can be infringed in unprecedented circumstances. These provisions enable a Member State to make public use of knowledge in its own territorial jurisdiction and the jurisdictions of other Member States.

In addition, the stakes of the private sector have not been completely disregarded, as there is an exhaustive structure for compensating them, which is subject to judicial review so as to protect private actors from abusive state actions. There still remains some form of ambiguity in ensuring worldwide production and availability of the Covid-19 vaccine at affordable prices. In spite of several mechanisms in place to resolve this situation under the TRIPS Agreement, there are still major issues with respect to their effectiveness. In the present scenario wherein even the strong nations have already been criticized for making efforts to monopolize prospective vaccines, the efficacy of the current mechanism is still debatable.

¹⁴ Code de la Propriété Intellectuelle [Intellectual Property Code], Art. L613-16.

¹⁵ Rijksoctrooiwet 1995 van 15 december 1994, Art. 57, Stb. 2010, 339. (Den.)

¹⁶ The Patents Act, (1977) § 53.