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## Compulsory Licensing under Indian Patent Law

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*Intellectual Property Rights offer protection to the creator of a particular work from the misuse and/or copying of their work. The basis for the protection so granted is to allow the creator to gain commercial benefit through their work which they have invested considerable time, money, effort, creativity, etc. in creating. This is done to compensate creators for their creative work and to incentivise people to create intellectual property. The intellectual property though leads to commercial gain for the creator, its ultimate benefit is reaped by the society. Intellectual property aids in the advancement of society and as such certain limitations are imposed on the protection offered to Intellectual Property. One such limitation concerning patents is referred to as "compulsory licensing". Under this regime the Controller General of Patents can under various grounds, the primary one being the benefit of society can license a patented invention to a third party so that it may work upon and produce the invention within the country. The compulsory licensing regime under Indian Patent Law has been analysed in the present article.*

**Keywords:** *licensing, patent, WIPO.*

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### INTRODUCTION

The World Intellectual Property Organisation defines a Patent as an exclusive right granted to an inventor for their invention which is either a product or a process that introduces and establishes a novel manner of performing a particular task or provides a novel technical solution to an existing problem. A patent gives to the inventor an exclusive right to

commercialise their invention. This means that no one can commercialise an invention unless the patent owner consents to the same. The patent owner has the sole right to commercialise their invention and has the right to choose the specific details of how their invention shall be commercialised and/or released to the public. This may be done either via licensing or by the transfer of patent rights wholly via assignment through which the exclusive rights associated with a patent are transferred to another entity.

## PATENT LAW REGIME IN INDIA

The Indian Patents Act of 1970<sup>1</sup> deals with all subjects related to patents in India. Patent protection in India lasts for a period of 20 years from the date on which the patent was filed.

### *What is Compulsory Licensing?*

A compulsory license refers to the special dispensation given by the Controller General of Patents to a third party to manufacture, utilise, or retail patented inventions and/or processes without prior authorisation of the patent owner<sup>2</sup>. This concept intends to act as a balance between the rights of a patent holder and the interests of the nation and its populace and is recognised by the international TRIPS (Trade-Related Aspects of Intellectual Property Law) Agreement as well as under Indian law i.e., Chapter XVI of the Indian Patent Act, 1970 (Sections 82 - 94)<sup>3</sup> which provides for Compulsory Licensing. One may apply for a compulsory license after 3 years have elapsed since the date from which the patent application was filed. A combined reading of sections 89(2)<sup>4</sup>, 83(b)(3)<sup>5</sup>, and 83(f)(4)<sup>6</sup> of the Act reveal the objective of compulsory licensing. The practice is intended to prevent monopolistic control over the importation and exploitation of patent rights. The controller grants such a license to make way for proper commercial exploitation of the invention and/or in the interest of the people of the

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<sup>1</sup> Indian Patent Act, 1970

<sup>2</sup> Hana Onderkova, 'Compulsory Licensing in India and changes brought to it by the TRIPS Agreement' (*European Commission*, 12 October 2021) <[https://intellectual-property-helpdesk.ec.europa.eu/news-events/news/compulsory-licensing-india-and-changes-brought-it-trips-agreement-2021-10-12\\_en](https://intellectual-property-helpdesk.ec.europa.eu/news-events/news/compulsory-licensing-india-and-changes-brought-it-trips-agreement-2021-10-12_en)> accessed 12 February 2022

<sup>3</sup> Indian Patent Act, 1970, s 82-94

<sup>4</sup> Indian Patent Act, 1970, s 89(2)

<sup>5</sup> Indian Patent Act, 1970, s 83(b) (3)

<sup>6</sup> Indian Patent Act, 1970, s 83(f) (4)

Nation. In recent judgments, Indian courts have held that the competition act's ban against anti-competitive acts and the patent act's provision of compulsory licensing are not mutually exclusive; rather, they must be construed in accordance with one another. The Controller also may look into whether a patentee had engaged in anti-competitive conduct.<sup>7</sup>

### **GROUND FOR THE GRANT OF A COMPULSORY LICENSE?**

The grounds for the grant of a compulsory license are given under S. 84(1)<sup>8</sup> of the Patents Act and are as follows:

- The public's reasonable requirements concerning the patented innovation have not been met.
- The patented innovation is not readily available to the general public at a reasonable cost.
- The patented invention is not utilised in India.

The controller considers the per capita income and purchasing power of the Indian people/or the user, the cost of production, the availability and affordability of any alternative for the product, and so on in order to establish a reasonable price.<sup>9</sup> Section 83<sup>10</sup> of the Act must be examined in order to establish the feasibility of the invention. In order to be worked in India, innovation should be used to its greatest commercial potential and technological innovation should be encouraged. The owner of a patent does not have a monopolistic right over the patented technology. This is especially true in the case of medical innovations; patent rights should not jeopardize public health or prevent the government from encouraging it. Medical inventions should support not just the patentee's financial gain, but also the health of the citizens of the country. The innovation's price point should be such that it is affordable to people from all socioeconomic backgrounds.

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<sup>7</sup> *Koninklijke Philips Electronics v Rajesh Bansal, Sole Proprietor* (2018)

<sup>8</sup> Indian Patent Act, 1970, s 84(1)

<sup>9</sup> 'Commentary On Compulsory Licensing Under The Patents Act, 1970' (IIPRD, 22 August 2020) <[https://www.iiprd.com/commentary-on-compulsory-licensing-under-the-patents-act-1970/#\\_ftnref7](https://www.iiprd.com/commentary-on-compulsory-licensing-under-the-patents-act-1970/#_ftnref7)> accessed 13 February 2022

<sup>10</sup> Indian Patent Act, 1970, s 83

*The public's aforementioned "reasonable requirements" as specified under the act are not fulfilled (as per Section 84(7)<sup>11</sup> when:*

I. The patentee refuses to provide a fair license or licenses, and as a result:

- An industry suffers.
- The demand for the patented item cannot be adequately addressed.
- There is no supply or development of a market for the patented goods made in India.
- In India, the formation or development of commercial operations is hindered.

II. A condition is imposed on the patent license by the patentee:

- That leads to problems arising concerning goods that are not protected under the patent.
- Industrial and commercial activities suffer in the country.

III. The patent is not being utilised in India in a commercial manner to a satisfactory level or is not being utilised to its fullest reasonable extent.

IV. Importation from overseas prevents the patented innovation from being used on a commercial basis in India.

## **FACTORS FOR DETERMINING THE MATTER OF GRANTING A COMPULSORY LICENSE**

The controller when analysing a case regarding the grant of a compulsory license shall take into account the following factors:<sup>12</sup>

- The nature of the innovation, the amount of time since the patent was sealed, and any steps taken by the patentee or any licensee to fully exploit the invention.
- The applicant's capacity to put the innovation to good use for the general public.

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<sup>11</sup> Indian Patent Act, 1970, s 84(7)

<sup>12</sup> Indian Patent Act, 1970, s 84(6)

- The applicant's willingness to take on the risk of investing funds and putting the innovation into production if the application is approved.
- Whether the applicant has attempted to secure a license from the patentee on acceptable terms and circumstances and failed to do so within a reasonable period as determined by the Controller.

However, in cases of an extreme emergency, anti-competitive practices by the patentee, or public wide non – commercial use, the aforementioned shall not be applicable.

### **REVOCAION OF A COMPULSORY LICENSE**

After two years have passed since the issue of a compulsory license, the Central Government or any interested party can petition the Controller for an order to cancel the patent. The following are grounds for revocation of a compulsory license:<sup>13</sup>

- That the patented invention has never been used on Indian soil.
- That the public's reasonable requirements regarding the patented innovation have not been met.
- The patented innovation is not accessible to the general public at a reasonable cost.

*The Controller has the authority to defer petitions for compulsory licensing:* When an application is made under sections 84 or 85 on the grounds that the invention has not been utilised commercially to a reasonable extent in India or has not been worked on in India, and the controller is satisfied that the time period between the patent's sealing and the time of application is insufficient for achieving the aforementioned conditions, he may postpone the application for a maximum of twelve months.<sup>14</sup>

*Licensing of related patents (S. 91)*<sup>15</sup>: Following the award of the first patent, any person with the right to work on the second invention, whether as a patentee or a licensee, may apply to the controller for the issuance of the first patent's license. To get the license, the applicant must

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<sup>13</sup> Indian Patent Act, 1970, s 85

<sup>14</sup> Indian Patent Act, 1970, s 86

<sup>15</sup> Indian Patent Act, 1970, s 91

prove that the first and second patents are connected; and that the first patent is required to fully commercialize the first patent. The patent should have had a large commercial impact. Additionally, the applicant should be willing to license his patent to third parties. This is done in order to stimulate commercial growth and maximize the use of inventions.

*Grant of Compulsory License upon Central Government Notification (S. 92)<sup>16</sup>*: The government may issue a notification on compulsory licensing of a patented medicine in the event of a national emergency, severe urgency, or for non-commercial public health purposes. Any individual interested in obtaining a license upon notice may submit an application to the controller. If satisfied, the controller may award the licensee and set the terms and conditions. The controller shall determine the lowest selling price after deducting the patentee's royalty.

*Issue of Compulsory License for export of patented medicinal products due to grave problems in a foreign country (S. 92A)<sup>17</sup>*: It is a clause that permits an applicant to produce and export patented pharmaceutical items to a nation that lacks manufacturing capabilities and is experiencing a public health crisis. Such an application may be made only after the nation has granted a compulsory license for the commodity or has authorized its import from India by notice. Pharmaceutical products are defined as any product or proprietary method that is required to manufacture the necessary medications and diagnostic kits to address a public health issue.

#### **SETTING THE TERMS AND CONDITIONS OF COMPULSORY LICENSE SO GRANTED (S. 88)<sup>18</sup>**

While setting the terms and conditions of each compulsory license, the controller must take into consideration the following conditions:

- The controller must make efforts to obtain an amount of royalty and other monetary benefits which are to be accorded to the patent holder and/or other beneficiaries which is reasonable, having taken into consideration while setting the amount the nature of

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<sup>16</sup> Indian Patent Act, 1970, s 92

<sup>17</sup> Indian Patent Act, 1970, s 92A

<sup>18</sup> Indian Patent Act, 1970, s 88

the technology patented, the investment made by the patent holder in creating the patented technology and obtaining a patent, and other allied relevant factors.

- The patented technology should be used to the maximum by the person who has been issued a license while the person also makes a reasonable profit.
- The patented technology must be available to the general public at a reasonable price.
- The license must be a non-exclusive license.
- The rights so accorded by the compulsory license must not be assignable.
- The license is issued for the remaining time period of the period (unless public interest dictates that a shorter period would be better).
- The license should prioritise the supply of the patented technology first to the Indian market and provisions for export may also be appended.
- If the patented technology pertains to semiconductors, then the license issued shall allow the patented technology to be worked for public non - commercial use.
- In case the license is granted to fix a situation that has been ruled as being anti-competitive, then the licensee shall be allowed to if needed export the patented technology.

Additionally, the Central Government in the public interest may instruct the Controller to authorize any licensee in respect of a patent to import the patented object or a substance or article created by a patented method from outside. The Controller may set limits on the royalty and payment payable to the patentee, the number of imported goods, the sale price of the imported goods, and the duration of importation.

#### **POWERS OF THE CONTROLLER REGARDING GRANT OF A COMPULSORY LICENSE**

When the manufacture, use, or sale of materials not covered by the patent is harmed as a result of the patentee's restrictions on the grant of licenses under the patent, or on the purchase, hire, or use of the patented article or process, the Controller, if satisfied, may order the grant of licenses under the patent the applicant or to the applicant's customers. When an application is filed under Section 84 by a person who is the holder of a license under the patent, the

controller may terminate an existing license or, instead of granting a license to the applicant, he may order the alteration of the existing license.

When the same patentee owns two or more patents and an applicant for a compulsory license establishes that the reasonable requirements of the public have not been met with respect to some of the patents, if the Controller determines that the applicant is unable to work the license granted under the patents efficiently or satisfactorily without infringing the patentee's other patents, and if the patents involve technological advancement or are of an economic nature. When the Controller settles the terms and conditions of a license, the licensee may apply to the Controller for a revision of the terms and conditions after working the invention on a commercial scale for a period of at least 12 months on the grounds that the settled terms and conditions have proven to be unnecessarily prohibitive preventing the licensee from working the invention and incurring losses.

## CONCLUSION

The provisions regarding compulsory licensing are recognised worldwide and are contained in both the TRIPS agreement and under Indian Law. Compulsory licensing is a crucial part of the patent law regime of a country. While an inventor must be given incentive for their innovation, the interests of society and humanity must also be considered alongside the interests of the patent holder. Compulsory licensing is essential because it caters to the needs and aspirations of the public by allowing them to obtain modern technology at affordable rates, incentivizes the utilisation of inventions in the country, thus boosting indigenous technology and industry, and helps strengthen the economy. The issue of public interest is most profoundly present in cases regarding pharmaceutical products wherein it is the duty of the state to see to it that lifesaving drugs are available to all people from different economic backgrounds and that new inventions remain available for all rather than a few rich people. Compulsory licensing allows patent holders to benefit but at the same time stands against monopolistic and anti-competitive practices. Inventors cannot gatekeep their inventions solely for their own benefit. As such compulsory licensing is an essential concept that allows for the

advancement of society while also protecting the reasonable interests of inventors and has established itself as an inalienable part of patent law.