HURDLES IN COMPULSORY LICENSING OF PHARMACEUTICAL PRODUCTS IN INDIA: A CRITICAL ANALYSIS

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ABSTRACT

Compulsory licensing is an useful legal mechanism that allows a government to permit a third party to use or manufacture a patented product without the permission of the patentee. In the pharmaceutical sector, compulsory licensing can help in reducing the price of life-saving medicines and improve their availability to patients. The TRIPS Agreement recognizes Compulsory licensing as a legal flexibility, Doha Declaration on TRIPS and Public Health confirmed that WTO Members can use this flexibility to protect public health.[1]

India has incorporated compulsory licensing provisions mainly under Sections 84 to 92A of the Patents Act, 1970. Section 84 allows interested person to apply for a compulsory license when the reasonable requirements of the public are not satisfied, the patented product is not available at a reasonably affordable price or the invention is not worked in India.[2] But the practical use of Compulsory licensing faces many difficulties. These include procedural requirements, the three year waiting period, negotiations with patent holders, lengthy litigation, financial and technical limitations, uncertainty about reasonable prices, international pressure and concerns about pharmaceutical innovation. This paper examines these hurdles and suggests measures to make Compulsory licensing more effective in ensuring access to life-saving medicines in India.

Keywords: Compulsory Licensing, Pharmaceutical Patents, Access to Medicines, Public Health, TRIPS Agreement, Patents Act 1970, India.

[1] World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 20 November 2001.
[2] The Patents Act, 1970, No. 39 of 1970, Sec. 84 (India).

1. INTRODUCTION

For protecting human health and saving lives of people medicines are essential. Pharmaceutical companies invest considerable amounts of money and time in research and development of new medicines. Patent protection gives these companies exclusive rights over their inventions for a limited period. This protection is intended to encourage innovation and recover research costs.

However, patent protection, when a patented medicine is sold at a very high price or is not sufficiently available to patients create problem. In such condition, compulsory licensing becomes important. It allows a government to authorize another manufacturer to produce or use a patented medicine without the consent of the patent owner, subject to certain legal conditions.[3]

Compulsory licensing is important for developing countries like India, where a large number of people may not be able to afford costly patented medicines. India has therefore provided detailed provisions for compulsory licensing in the Patents Act, 1970.

Although the Indian legal framework provides an important public-health safeguard, the actual use of compulsory licensing is not easy. Various legal, economic, administrative and political difficulties may prevent or delay its use. Therefore, it is important to understand these hurdles and determine how the system can be improved.

2.MEANING AND IMPORTANCE OF COMPULSORY LICENSE

Compulsory licensing means that a government permits a person or company to use a patented invention without obtaining the voluntary permission of the patent holder. The patent itself is not cancelled. The patent holder continues to own the patent and receives remuneration for the authorized use.[4]

In the pharmaceutical sector, compulsory licensing can serve several important purposes:

[3] Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, art. 31, 1869 U.N.T.S. 401.
[4] World Trade Organization, TRIPS and Public Health: Compulsory Licensing of Pharmaceuticals and TRIPS, WTO.

- Making life-saving medicines more affordable;
- Increasing the supply of patented medicines;
- Preventing the misuse of patent rights;
- Addressing public health emergencies;
- Encouraging competition from generic manufacturers and
- Protecting the public interest.

Therefore, compulsory licensing should not be understood as an attack on the patent system. It is better understood as a balance between the rights of patent owners and the public's right to access medicines.

3. INTERNATIONAL LEGAL FRAMEWORK

3.1 TRIPS AGREEMENT

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) provides international standards for intellectual property protection. Article 31 permits WTO Members to authorize the use of a patented invention without the permission of the patent holder, subject to certain conditions.[5]

Normally, the person seeking a compulsory license must first try to obtain a voluntary license from the patent holder on reasonable commercial terms. However, this requirement may be relaxed in certain situations such as national emergency, extreme urgency, public non-commercial use and certain cases of anti-competitive behaviour.[6]

The TRIPS framework also requires payment of adequate remuneration to the patent owner.

Thus, although TRIPS recognizes compulsory licensing, it also imposes certain procedural requirements. These requirements can sometimes make the process complicated and time-

[5] Agreement on Trade-Related Aspects of Intellectual Property Rights, supra note 3, art. 31.
[6] Ibid

consuming.

3.2 DOHA DECLARATION, 2001 Meaning and Importance of Compulsory Licensing

The Doha Declaration on the TRIPS Agreement and Public Health was adopted in 2001. It was an amazing achievement for developing countries because it confirmed that TRIPS should not prevent WTO Members from taking measures to protect public health.

The Declaration recognized the right of each WTO Member to determine the grounds upon which compulsory licenses may be granted.[7]

The Doha Declaration therefore strengthened the legal position of countries such as India to use compulsory licensing when necessary for public health purposes.

3.3 ARTICLE 31BIS AND EXPORT OF MEDICINES

Another important issue was the supply of medicines to countries those did not have sufficient pharmaceutical manufacturing capacity. Article 31(f) of TRIPS generally required production under a compulsory license to be mainly for the domestic market.

To address this problem, the WTO created the Article 31bis system. It permits certain pharmaceutical products manufactured under compulsory license to be exported to eligible countries that lack sufficient manufacturing capacity.[8]

Although this system provides an important solution, its procedural requirements can still make the process difficult for developing countries.

4. COMPULSORY LICENSING UNDER INDIAN LAW

India has included compulsory licensing provisions in Chapter XVI of the Patents Act, 1970.

SECTION 84

Section 84 provides that an interested person can apply for a compulsory license after three

[7] World Trade Organization, Declaration on the TRIPS Agreement and Public Health, supra note 1.
[8] Agreement on Trade-Related Aspects of Intellectual Property Rights, supra note 3, art. 31bis.

years from the grant of a patent if:

- The reasonable requirements of the public have not been satisfied;
- The patented invention is not available at a reasonably affordable price or
- The patented invention is not worked in the territory of India.[9]

These grounds make Section 84 an important public health provision.

SECTION 92

Section 92 provides a special mechanism for compulsory licensing with out time limit in cases involving national emergency, extreme urgency or public non-commercial use.[10]

SECTION 92A

Section 92A deals with compulsory licensing for the export of pharmaceutical products to countries that have insufficient or no manufacturing capacity.[11]

Therefore, Indian law provides several routes through which compulsory licensing can be used. However, the existence of these provisions does not automatically make the system easy to use.

5. MAJOR HURDLES IN COMPULSORY LICENSING

5.1 REQUIREMENT OF PRIOR NEGOTIATION

One of the main difficulties under Section 84 is the requirement to make reasonable efforts to obtain a voluntary license from the patent owner.

The applicant generally has to show that it approached the patent holder and tried to obtain a license on reasonable terms. The law generally considers six months to be a reasonable period for such negotiations.[12]

[9] The Patents Act, 1970, supra note 2,sec.84(1).
[10] Ibid., sec. 92.
[11] Ibid., sec. 92A.
[12] Ibid., sec.84(6)(iv).

This requirement is intended to protect patent owners from unnecessary compulsory licensing. But it can create delays when patients urgently need a medicine.

For life-saving medicines, even a few months of delay can have serious consequences. Therefore, the law already provides exceptions for situations such as national emergency and extreme urgency, but greater clarity in their practical application would be useful.

5.2 THREE YEAR WAITING PERIOD

Section 84 generally allows a compulsory license application only after three years from the date on which the patent was granted.[13]

This may become a problem when a newly patented medicine becomes essential soon after the patent is granted. Patients may face high prices or shortages of medicines during this period.

Although Section 92 provides an alternative in cases of emergency, the three-year requirement is still be a significant hurdle in ordinary circumstances.

5.3 COMPLICATED LEGAL PROCEDURE

The process of obtaining a compulsory license involves several legal and factual requirements. The applicant may have to provide evidence concerning:

- The availability of the medicine;
- Its price;
- Public demand;
- Manufacturing capacity;
- The ability of the applicant to produce the medicine;
- The terms offered to the patent holder.

[13] Ibid., sec.84(1).

This requires legal, technical and economic expertise.

Large pharmaceutical companies may have sufficient resources to deal with these requirements, but smaller companies may find the process expensive and difficult. Consequently, a legally available remedy may not always be practically accessible.

5.4 LENGTHY LITIGATION

A patent owner has the right to challenge the grant of a compulsory license. Litigation can therefore significantly increase the time required for a license to become practically effective.

The Indian case of Natco Pharma Ltd. V. Bayer Corporation is an important example. Natco was granted a Compulsory license for Bayer's cancer medicine Nexavar in 2012. Bayer challenged the decision and the matter continued through judicial proceedings.[14]

Judicial review is necessary to protect legal rights but prolonged litigation can delay access to affordable medicines.

5.5 FINANCIAL AND TECHNICAL PROBLEMS

Granting a compulsory license does not mean that affordable medicines will immediately become available.

The licensee must have:

- Sufficient financial resources;
- Manufacturing facilities;
- Technical knowledge;
- Access to raw materials;
- Regulatory approvals;
- Quality-control facilities and

[14] Natco Pharma Ltd. V. Bayer Corporation, W.P. No. 1323 of 2013, Bombay High Court, decided on 15 July 2014.

- An effective distribution system.

Are major difficulties for small scale manufacturers.

For complex medicines, particularly biological products and advanced therapies, manufacturing may require highly specialized technology. Therefore, compulsory licensing must be supported by adequate domestic manufacturing capacity.

5.6 Difficulty in Determining a "Reasonably Affordable Price"

One of the grounds for compulsory licensing under Section 84 is that the patented product is not available at a reasonably affordable price.[15]

However, the meaning of affordability is not the same for everyone. A medicine that is affordable for a high-income consumer may be extremely expensive for a low-income patient.

The assessment should consider factors :

- Average income;
- Treatment cost;
- Duration of treatment;
- Number of patients requiring the medicine;
- Government healthcare expenditure and
- Prices of comparable medicines.

A clear and objective method for assessing affordability could reduce uncertainty in compulsory licensing proceedings.

5.7 DETERMINING REASONABLE REMUNERATION

Compulsory licensing does not mean that the patent owner receives nothing. The patent owner must generally receive appropriate remuneration for the authorized use of the patent.[16]

[15] The Patents Act, 1970, supra note 2, sec. 84(1)(b)
[16] Ibid., sec.90.

The difficulty is determining the correct amount.

If the royalty paid to the patent holder is too high, the price reduction achieved through compulsory licensing may become small. On the other hand, if the royalty is too low, the patent owner may argue that its rights are being unfairly affected.

A transparent system for determining royalties would help in reducing disputes.

5.8 International Trade and Political Pressure

Another important hurdle is international, political and commercial pressure.

Although the WTO recognizes compulsory licensing, countries may be concerned about possible reactions from major trading partners or multinational pharmaceutical companies. Developing countries become feared that extensive use of compulsory licensing could affect foreign investment, trade relationships or future negotiations.

The Doha Declaration was particularly important because it confirmed that WTO Members have the right to use TRIPS flexibilities to protect public health.[17]

Nevertheless, legal rights may not always remove the practical fear of international pressure.

5.9 CONCERN ABOUT PHARMACEUTICAL INNOVATION

Pharmaceutical companies argue that patent protection provides an incentive for investment in research and development. For developing a new medicine large number of financial resources and long time period for research is required.

If compulsory licensing is used too frequently or without clear standards, companies may fear that they will not be able to recover their investment.

At the same time, excessive patent protection can result in medicines becoming unaffordable.

Therefore, the real challenge is to maintain a reasonable balance between innovation and access to medicines. Compulsory licensing should be used where there is a genuine public health need

[17] World Trade Organization, Declaration on the TRIPS Agreement and Public Health, supra note 1.

rather than as a routine method of reducing medicine prices.

5.10 PATENT THICKETS AND MULTIPLE PATENTS

Modern pharmaceutical products may be protected by several patents. Different patents may cover the active ingredient, formulation, manufacturing process, dosage or method of delivery.

This situation is sometimes described as a patent thicket.

In such circumstances, obtaining a compulsory license over one patent may not always be enough to allow effective production of the medicine. The manufacturer may face other patent barriers.

Therefore, examination of pharmaceutical patents and prevention of unnecessary secondary patents are also important for improving access to medicines.

5.11 LACK OF GOVERNMENTAL WILL

A further hurdle is the willingness of governments to actually use compulsory licensing.

The existence of legal provisions is not sufficient if authorities are unwilling to exercise them. Governments may hesitate because of:

- International pressure;
- Fear of litigation;
- Concerns regarding investment;
- Uncertainty regarding legal consequences;
- Administrative difficulties and
- Relations with pharmaceutical companies.

Therefore, strong institutional guidance and clear government policies are required.

6. NATCO PHARMA LTD. V. BAYER CORPORATION

The Natco Pharma Ltd. V. Bayer Corporation case is the most important Indian example of

pharmaceutical compulsory licensing.

The case concerned Bayer's patented cancer medicine Nexavar (sorafenib tosylate). Natco applied for a compulsory license under Section 84 of the Patents Act, 1970.

The Controller granted the compulsory license in March 2012 after finding that the statutory requirements were satisfied. The decision was challenged by Bayer, but the compulsory license was subsequently upheld by the Bombay High Court.[18]

The case demonstrated that compulsory licensing can help address problems of affordability and availability of important medicines. However, it also demonstrated that the process may involve extensive legal proceedings and therefore take considerable time.

The case remains an important example of how Indian patent law balance the interests of pharmaceutical innovators with public health requirements.

7. EFFECT OF HURDLES ON ACCESS TO LIFE-SAVING MEDICINES

The difficulties associated with compulsory licensing can directly affect patients.

If the process is too complicated or takes too long:

- Generic competition may be delayed;
- Medicine prices may remain high;
- Patients may not receive timely treatment;
- Government healthcare expenditure may increase;
- Pharmaceutical manufacturers may hesitate to enter the market and
- The public health objective of compulsory licensing may be weakened.

These problems are particularly serious in treatment of Cancer, HIV/AIDS, tuberculosis and

[18] Natco Pharma Ltd. V. Bayer Corporation, supra note 14.

other serious diseases where treatment may be expensive and continuous.

Therefore, compulsory licensing should be supported by a system that is efficient, transparent and capable of responding quickly to genuine public health needs.

8. SUGGESTIONS FOR IMPROVING THE COMPULSORY LICENSING SYSTEM

8.1 SIMPLIFICATION OF PROCEDURE

The procedure for compulsory licensing should be made easier and faster, particularly for life-saving medicines.

8.2 CLEAR GUIDELINES ON AFFORDABILITY

The government should establish clearer criteria for determining whether the price of a patented medicine is reasonably affordable.

8.3 TRANSPARENT ROYALTY SYSTEM

Clear guidelines should be developed for determining remuneration to patent holders. This would reduce uncertainty and litigation.

8.4 STRENGTHENING DOMESTIC MANUFACTURING

India should continue to develop domestic pharmaceutical and biotechnology manufacturing capacity so that compulsory license can be effectively implemented.

8.5 ENCOURAGING VOLUNTARY LICENSING

Voluntary licensing should be encouraged where it can quickly increase supply and reduce prices. Compulsory licensing should remain available when voluntary arrangements fail to meet public needs.

8.6 BETTER USE OF TRIPS FLEXIBILITIES

India should continue to make full use of the flexibilities available under TRIPS and the Doha Declaration while ensuring compliance with international obligations.

8.7 **STRONGER PATENT EXAMINATION**

The patent system should carefully examine secondary pharmaceutical patents to prevent unnecessary extension of patent protection.

8.8 **GREATER GOVERNMENT PREPAREDNESS**

The government should develop clear guidelines for responding to public health emergencies so that compulsory licensing can be used quickly when required.

9. **CONCLUSION**

Compulsory licensing is an effective tool for improving access to affordable medicines. Both international law and Indian laws recognize its importance in protecting public health. The TRIPS Agreement, the Doha Declaration and Article 31bis provide an international framework, while Sections 84–92A of the Indian Patents Act provide domestic legal mechanisms.[19]

However, several hurdles reduce the practical effectiveness of compulsory licensing. These include the requirement of prior negotiation, the three-year waiting period, complicated procedures, litigation, financial and technical limitations, uncertainty about affordability and remuneration, international pressure, patent thickets and concerns regarding pharmaceutical innovation.

The answer is not to remove patent protection or to use compulsory licensing in every case. Instead, India should develop a balanced and predictable system in which patent rights are protected while public health interests are given adequate importance.

Compulsory licensing should therefore remain an exceptional but effective public health safeguard. Its ultimate purpose should be to ensure that patent protection does not prevent people from obtaining medicines that are necessary to save or improve their lives.

[19] The Patents Act, 1970, supra note 2, sec. 84–92A; Agreement on Trade-Related Aspects of Intellectual Property Rights, supra note 3, arts. 31 and 31bis.

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