THE DYNAMICS OF COMPULSORY LICENSING IN INDIAN PATENT LAW

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ABSTRACT

Patents are granted to inventors as a form of exclusive right, rewarding their ingenuity and investment while encouraging technological progress. However, this exclusivity is not without limitations, as it must coexist with the broader objective of ensuring that innovation ultimately serves public welfare. When patent monopolies restrict access to essential goods, medicines, or technologies, compulsory licensing provides a critical safeguard. It allows governments or authorized third parties to use a patented invention without the consent of the patent holder under defined circumstances, ensuring that the interests of society are not overshadowed by commercial considerations.

The basis of compulsory licensing is firmly rooted in international intellectual property law, particularly the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which recognizes the need for flexibility in situations such as national emergencies or public health crises. The Doha Declaration on TRIPS and Public Health reaffirmed this principle, emphasizing that the protection of public health and equitable access to medicines must take precedence over patent exclusivity.

In India, the Patents Act, 1970 incorporates these principles within its statutory framework, most notably through Sections 84 to 92. These provisions empower the government to issue compulsory licenses in cases where patented products are priced excessively, inadequately supplied, or withheld from the market in a manner detrimental to public interest. The Indian pharmaceutical industry has demonstrated the effective use of compulsory licensing, producing affordable generics for diseases such as cancer and HIV/AIDS, thereby cementing India's role as the "pharmacy of the developing world."

Although critics caution that frequent recourse to compulsory licensing may discourage investment in research and innovation, safeguards such as fair remuneration to patent holders mitigate this concern. Supporters argue that the mechanism promotes a healthier competitive environment and prevents patent abuse, thereby maintaining the delicate balance between protecting

intellectual property rights and ensuring accessibility.

Compulsory licensing thus emerges as a vital instrument that harmonizes innovation with social justice. By preventing intellectual property from becoming a barrier to essential goods and services, it reinforces the foundational principle that the rewards of innovation must extend beyond private profit and contribute meaningfully to the collective welfare of society.

Keywords: Patents, Compulsory Licensing, Intellectual Property Rights, TRIPS Agreement, Indian Patent Act

Introduction:

Patents grant inventors exclusive rights to produce, use, sell, and distribute their inventions for a defined period, encouraging innovation by protecting their efforts and investments. However, these exclusive rights are not absolute and are subject to safeguards that ensure public welfare is not compromised. In instances where a patent monopoly conflicts with public interest, such as when access to essential medicines or critical technologies is restricted, compulsory licensing emerges as a vital solution. This mechanism allows a government or authorized third party to utilize a patented product or process without the consent of the patent holder under specific circumstances. It ensures that while patents incentivize innovation, they do not become obstacles to addressing urgent issues like public health emergencies, safety concerns, or economic inequalities, reinforcing the broader goal of intellectual property law to benefit society as a whole.

Compulsory licensing is embedded in international frameworks such as the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights[1] (TRIPS). TRIPS recognizes the necessity of compulsory licensing, enabling member countries to incorporate provisions for its implementation into their domestic laws. This flexibility allows governments to issue compulsory licenses in conditions such as public health crises, anti-competitive practices, or situations where access to patented technologies is crucial for national or global welfare. The Doha Declaration[2] on TRIPS and Public Health further affirmed that public health should take precedence over patent rights, clarifying that countries are entitled to

[1] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31, Apr. 15, 1994, 1869 U.N.T.S. 299
[2] World Trade Org., Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 14, 2001)

use compulsory licensing to ensure the availability of essential medicines and technologies.

Examining the legal framework of compulsory licensing under patent laws is essential to understanding its role in balancing innovation with societal needs. This mechanism plays a critical role in bridging the gap between the rights of patent holders and the demands of public welfare, especially in critical sectors like healthcare and technology. While it challenges the exclusivity granted by patents, it emphasizes that innovation must ultimately serve humanity's broader interests. By adapting to evolving global challenges, compulsory licensing ensures that intellectual property laws remain tools for progress, equity, and the betterment of society.

Definition And Purpose:

Compulsory licensing is a critical mechanism designed to enhance public access to essential goods and technologies, but it remains a topic of debate due to concerns about its potential impact on innovation. Patent holders often argue that the possibility of compulsory licensing might discourage investments in research and development, especially in industries like pharmaceuticals where the cost of innovation is exceptionally high. They fear that the inability to fully capitalize on patent exclusivity could undermine their ability to recover significant investments, ultimately dissuading further innovation. This perspective highlights the need to carefully balance the rights of inventors with the broader societal need for affordable access to essential products.

On the other hand, supporters of compulsory licensing emphasize its role as a safeguard against patent abuse and monopolistic practices. They argue that it helps ensure that public welfare is not overshadowed by profit motives, especially in critical sectors such as healthcare. Additionally, the presence of a compulsory licensing framework often serves as a deterrent against exploitative pricing, prompting patent holders to voluntarily make their products more accessible and affordable to avoid the invocation of such measures. This creates a healthier competitive environment and fosters equitable access to innovation.

It is important to note that the process of issuing a compulsory license is governed by strict regulations and is not undertaken arbitrarily. Procedural safeguards ensure that patent holders receive fair compensation for their inventions, and licenses are granted only in exceptional circumstances, such as during public health crises or in cases of anti-competitive conduct. By prioritizing the public interest without undermining the rights of inventors, this balanced

approach facilitates coexistence between innovation and accessibility, creating a patent system that benefits both society and the innovators driving progress.

Compulsory licensing is a legal mechanism that allows a government or an authorized entity to produce a patented product or use a patented process without the consent of the patent holder, under specific circumstances. While patents provide inventors with exclusive rights to their creations, these rights are not absolute and must be balanced against societal needs. Compulsory licensing serves this purpose by ensuring that the monopolistic privileges of patent holders do not hinder access to essential goods or technologies. It is particularly significant in situations where public health, safety, or economic development is at stake. For example, during public health emergencies, such as pandemics or epidemics, compulsory licensing can facilitate the production of life-saving medicines or vaccines, ensuring their availability and affordability. Similarly, it can be invoked to address access to critical agricultural tools or technologies needed to safeguard food security or respond to environmental crises. By preventing intellectual property laws from becoming barriers to public welfare, compulsory licensing reinforces the principle that innovation should ultimately serve the greater good, fostering both equity and progress.

The Role of Compulsory Licensing:

Section 92A of the Indian Patent Act provides for compulsory licensing to manufacture and export patented pharmaceutical products to countries with insufficient or no manufacturing capacity in the pharmaceutical sector. Such licenses are granted to address public health issues, provided that the importing country has issued a compulsory license or authorized the import of the patented products from India. The Controller may issue such a license under specified terms, ensuring the product is solely used for public health purposes in the importing country. India's pharmaceutical sector has been one of the most prominent examples of the effective use of compulsory licensing, showcasing the country's commitment to public health and accessibility. Known as the “pharmacy of the developing world,” India has built a robust generic drug industry that supplies affordable medicines to millions, both domestically and globally. Compulsory licensing has played a vital role in this effort, particularly in cases where patent monopolies have resulted in exorbitant drug prices, making essential medicines unaffordable for a significant portion of the population. By leveraging compulsory licensing provisions under the Indian Patent Act, the government has enabled the production of

affordable generic versions of patented drugs without the consent of the patent holder, ensuring that critical treatments for diseases like cancer and HIV/AIDS are accessible to those in need. This mechanism has not only protected public health but also reinforced India's position as a global leader in generic drug production, demonstrating how intellectual property laws can be balanced with the imperatives of social justice and equity.

Intellectual Property Rights (IPR) aim to honour and motivate inventors by protecting their creations, fostering innovation that benefits humanity. However, these rights can sometimes restrict public access to critical inventions, prompting lawmakers to include safeguards that prevent misuse. Compulsory licensing was introduced to ensure that essential inventions are accessible and patent holders cannot exploit their rights for unreasonable gains. Under the Indian Patent Act, compulsory licenses may be granted when unreasonable terms restrict public access to a patented invention, with terms decided by the Controller to ensure fairness.

While some argue that compulsory licensing infringes on patent holders' rights, its primary purpose is to serve public welfare. Case law has consistently shown that such licenses are granted only in exceptional situations, such as public health emergencies. For instance, during the COVID-19 pandemic, there was a global shortage of vital drugs like remdesivir, with its cost significantly exceeding production expenses due to patent monopolies. This led to calls for compulsory licensing under Section 92 of the Patent Act to enable the production of affordable generic versions.

The Commerce Standing Committee of Parliament has emphasized the need for a comprehensive review of India's IPR policy to address emerging challenges and ensure a robust system that balances innovation with accessibility. Compulsory licensing, though sometimes viewed negatively by patent holders, prioritizes public welfare over profits, exemplifying how intellectual property laws can adapt to urgent societal needs, especially in times of crisis like a global pandemic.

Legal Framework:

In India, the legal framework for compulsory licensing is governed by the Patents Act, 1970, specifically under Sections 84 to 92. These provisions outline the circumstances under which compulsory licenses can be issued, as well as the procedures involved in granting them. The law ensures a balance between the rights of patent holders and the broader needs of society,

particularly in areas like public health where access to essential medicines is critical. This framework enables the government or authorized entities to utilize patented inventions without the patent holder's consent in specific situations, such as public health emergencies, unmet demand, or excessive pricing that limits accessibility.

India's approach to compulsory licensing aligns with international standards, particularly the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS provides member nations with the flexibility to incorporate provisions for compulsory licensing into their domestic laws, allowing them to address national emergencies, promote public health, and tackle anti-competitive practices. By adhering to these global guidelines, India has created a system that not only respects intellectual property rights but also prioritizes public welfare, ensuring that essential goods and technologies remain accessible to those in need. This balance reflects the adaptability of intellectual property law to serve both innovation and societal needs effectively.

Compulsory licensing allows a third party to produce a patented product without the patent owner's consent, ensuring public health interests are prioritized over monopolization.

- ***Key Points:***

- Purpose: Prevents patent holders from monopolizing goods, ensuring affordability and accessibility.

- Legal Basis: Rooted in the 2001 Doha Declaration on Public Health. Recognized under the TRIPS Agreement and incorporated into India's Patent Act of 1970.

- Controller's Discretion: Factors such as invention type, applicant capability, and public benefit are considered, with final decision-making by the Controller.

- Ownership Retention: The patent owner retains rights and receives compensation for production under the compulsory license.

Provisions and key sections related to Compulsory Licensing under the Indian Patent Act include:

1. *Section 84[3]:*

- A compulsory license can be granted three years after the grant of the patent if:
- The patented invention is not reasonably available to the public at affordable prices.
- The invention is not being worked in the territory of India.
- The reasonable requirements of the public concerning the patented invention are not being met. Allows compulsory licensing after three years of patent issuance if public needs are unmet, pricing is unreasonable, or the patent is unused in India.

2. *Section 92[4]:*

- Enables "suo motu" licenses during national emergencies, extreme urgency, or public non-commercial use, upon government notification.
- The government can issue compulsory licenses in cases of national emergency, extreme urgency, or for public non-commercial use.
- Examples include public health crises like pandemics or epidemics.

3. *Section 92A[5]:*

- This provision addresses the production of patented pharmaceutical products for export to countries with insufficient or no manufacturing capacity, fulfilling international obligations.

4. *Section 100[6]:*

- The government can authorize itself or a third party to use a patent for public purposes.

Significance:

Compulsory licensing serves multiple critical roles in ensuring that intellectual property rights

[3] The Patents Act, No. 39 of 1970, S. 84
[4] The Patents Act, No. 39 of 1970, S. 92
[5] The Patents Act, No. 39 of 1970, S. 92A
[6] The Patents Act, No. 39 of 1970, S. 100

align with societal needs:

1. *Improved Accessibility:*

Ensures the availability of essential medicines, technologies, and products at affordable prices, especially in low-income or developing countries.

2. *Public Health Impact:*

Facilitates access to life-saving drugs during pandemics or outbreaks, directly impacting millions of lives. Especially significant during pandemics, epidemics, or other public health crises, when the timely availability of critical medicines can save lives.

3. *Encourages Innovation:*

Promotes innovation by challenging patent holders to continually improve their offerings and optimize production costs to avoid compulsory licensing. Compels patent holders to focus on improving efficiency and affordability to avoid the risk of a compulsory license.

4. *Economic Development:*

Empowers domestic industries to produce critical goods, enhancing self-reliance and reducing dependence on monopolistic foreign entities.

5. *Facilitating Access To Essential Goods:*

Ensures that essential medicines, technologies, and innovations are available at affordable prices to the public.

6. *Enhancing Domestic Capabilities:*

Empowers domestic industries to manufacture critical products, reducing reliance on foreign imports and boosting self-sufficiency.

Conditions:

Compulsory licensing is not granted arbitrarily; it requires careful consideration to strict conditions to prevent misuse:

1. ***Reasonable Efforts To Negotiate:***

Typically, the applicant must demonstrate that reasonable attempts were made to obtain a voluntary license from the patent holder on fair terms, except in cases of national emergencies.

2. ***Public Welfare Prioritization:***

The license is issued only when it serves a larger societal benefit, such as addressing a public health crisis or ensuring access to affordable goods.

3. ***Royalty Payment:***

The patent holder is compensated through reasonable royalties determined by the government or a competent authority.

4. ***Non-Exclusive And Non-Transferable:***

The license is non-exclusive and cannot be transferred to another party.

5. ***Reasonable Royalty:***

While the license allows others to use the patented invention, the patent holder is still entitled to a "reasonable royalty" as compensation for their invention. The Controller determines the terms and conditions of the license, including the royalty payable to the patentee.

6. ***Revocation Of The License:***

If circumstances change and the conditions that led to the grant of the compulsory license are no longer valid, the license may be revoked by the Controller upon request from the patentee.

7. ***Compensation To Patent Holder:***

The patent holder must receive adequate compensation in the form of royalties, calculated based on the circumstances.

8. ***Public Welfare As The Primary Criterion:***

The grant of a compulsory license must address public interest, such as improving access to

essential goods or addressing unmet societal needs.

9. ***Efforts To Obtain Voluntary License:***

Applicants must demonstrate that they made reasonable attempts to secure a license from the patent holder on fair terms before applying for a compulsory license.

10. ***Application Process:***

Any interested party or licensee may file an application for a compulsory license. The applicant must demonstrate that the patent holder has failed to meet the public's needs or has priced the patented product excessively. The Controller of Patents, after hearing both parties, determines whether to grant the license.

Implications On Innovation And Public Welfare:

- ***Impact of compulsory licensing on innovation and patent holders:***

Compulsory licensing is a vital mechanism to ensure public access to essential technologies and goods, but it also sparks debate over its potential impact on innovation. Critics, particularly patent holders, argue that the possibility of compulsory licensing may deter investment in research and development, especially in high-cost sectors like pharmaceuticals. They contend that the ability to recoup substantial investments through patent exclusivity could be compromised if such licenses are granted too readily. This concern highlights the delicate balance between protecting inventors' rights and addressing societal needs.

Proponents, however, view compulsory licensing as a crucial safeguard against the misuse of patent monopolies, ensuring that public welfare is not sacrificed for private profit. They emphasize that the mere existence of this mechanism often motivates patent holders to offer their products at more affordable prices to avoid facing compulsory licensing interventions. By fostering competition and promoting accessibility, compulsory licensing helps prevent exploitative practices that could arise from unchecked monopolies.

Furthermore, compulsory licensing is not a measure taken lightly or arbitrarily. Strict procedural guidelines govern its issuance, ensuring that patent holders are adequately compensated for the use of their inventions. Licenses are only granted in exceptional

circumstances, such as public health emergencies or cases of anticompetitive behaviour, where the broader public interest outweighs the exclusivity of patent rights. This balanced approach ensures that innovation and public welfare can coexist, fostering a system that serves both inventors and society at large.

Positive Impacts:

1. ***Access To Essential Goods:***

Breaks monopolistic barriers, ensuring equitable distribution of resources critical to survival and growth.

2. ***Strengthens Local Capabilities:***

Encourages the development of domestic manufacturing and research industries, particularly in developing nations.

3. ***Enhanced Access:***

Directly impacts affordability and availability of critical goods, particularly in developing countries.

4. ***Public Health Benefits:***

Strengthens health systems by ensuring access to essential medicines and technologies during crises.

5. ***Economic Development:***

Boosts domestic industries by enabling them to manufacture patented products, fostering technological and industrial growth.

6. ***Checks On Monopoly Power:***

Reduces the potential for abuse by patent holders and promotes a more equitable market.

Challenges And Criticism:

Despite its public benefits, the system of compulsory licensing is not without challenges:

1. ***Complexity And Length Of Procedure:***

The process of obtaining a compulsory license can be lengthy, involving hearings, evidence, and appeals, which may delay access to the needed invention.

2. ***International Pressure:***

Countries that grant compulsory licenses, especially in the pharmaceutical sector, often face pressure from foreign governments and multinational corporations. For instance, after India granted a compulsory license to Natco for Nexavar, the country faced criticism from international pharmaceutical companies and trade groups.

3. ***Royalty Disputes:***

Determining a "reasonable royalty" is often a contentious issue, with patent holders seeking higher compensation and licensees arguing for lower payments. This can lead to protracted legal disputes.

4. ***Deterrent To Innovation:***

Patent holders may perceive compulsory licensing as a disincentive to innovate, especially in high-investment industries like pharmaceuticals. Patent holders might perceive compulsory licensing as undermining their incentives to invest in research and development.

5. ***Potential Misuse:***

Governments might misuse compulsory licensing provisions for political or economic motives, undermining the balance between patent rights and public welfare.

6. ***Trade Relations:***

Excessive use of compulsory licensing might strain international trade relations, especially with countries hosting major patent holders.

7. ***International Trade Tensions:***

Overuse of compulsory licensing might lead to trade disputes or strained relations with nations hosting large patent-holding corporations.

8. ***Administrative Complexities:***

Determining reasonable royalties and managing the licensing process can be challenging and resource-intensive.

Termination:

A compulsory license issued under Section 84 of the Indian Patent Act can be terminated if the conditions that justified its grant no longer persist and are unlikely to reappear. This ensures that the compulsory licensing mechanism is not misused and remains a temporary measure addressing specific issues. The patentee, or any individual or entity holding a vested interest in the patent, has the right to apply for termination of the compulsory license. However, the termination process is not automatic; the holder of the compulsory license has the right to oppose the application, ensuring a fair and balanced procedure. The decision to terminate is made by the Controller of Patents after carefully assessing the prevailing circumstances and considering the arguments from all parties involved. This provision ensures that while compulsory licenses address pressing public needs, they are revoked once the need is resolved, thereby restoring the full exclusivity of the patent holder.

Compulsory Licensing For Emergencies Or Public Use:

The Indian Patent Act provides for the issuance of compulsory licenses in exceptional circumstances, such as a national emergency, extreme urgency, or for public non-commercial purposes. In such cases, the Central Government has the authority to make a formal declaration in the Official Gazette, signaling the necessity for compulsory licensing to address the pressing situation. Following this notification, any interested party may apply to the Controller of Patents for a compulsory license. The Controller, after evaluating the application, is empowered to grant the license, ensuring that the terms and conditions of use are fair and reasonable. This provision aims to prioritize public interest by ensuring the availability of critical products or technologies, particularly during crises, without undermining the rights of patent holders. It strikes a balance between addressing urgent societal needs and maintaining the integrity of the patent system.

Patents And Public Welfare:

Patents are foundational elements of intellectual property law, providing inventors with

exclusive rights to their inventions for a specific period. These rights are intended to incentivize innovation by enabling inventors to profit from their creations without immediate competition. This exclusivity encourages investment in research and development, particularly in sectors like pharmaceuticals, technology, and engineering, where the costs of innovation are high. By ensuring a temporary monopoly, patents help inventors recover their investments and generate profits, fostering a cycle of innovation.

However, the patent system is not without its challenges. Its design is intended to balance the rights of inventors with the broader needs of society. While exclusive rights protect inventors, they can sometimes lead to adverse consequences, such as limited access to life-saving medicines, essential technologies, or agricultural innovations. When patent holders prioritize profits over accessibility, the public welfare can suffer, especially in cases of urgent societal need or economic disparity.

To address such conflicts, compulsory licensing serves as a vital legal mechanism. It allows governments to authorize the use of patented inventions without the consent of the patent holder, typically under specific conditions like public health emergencies or anti-competitive practices. For instance, in cases where critical medicines are prohibitively expensive or unavailable, compulsory licensing enables the production of generic versions, ensuring wider access. Similarly, it can be employed to prevent monopolistic control over essential technologies, fostering competition and innovation.

Compulsory licensing thus acts as a safeguard, ensuring that patents fulfil their dual purpose: incentivizing innovation while serving public welfare. By restoring balance when exclusive rights threaten societal interests, this mechanism exemplifies the adaptability of intellectual property law to address evolving challenges in a fair and equitable manner.

Global Perspectives:

India’s provisions for compulsory licensing are aligned with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, a global framework that sets minimum standards for intellectual property regulation among member countries. TRIPS acknowledges the need to balance patent rights with public interest, permitting countries to issue compulsory licenses under specific conditions such as national emergencies, anti-competitive practices, or

public health crises. India has effectively utilized this flexibility to ensure that patent laws serve societal needs, particularly when it comes to life-saving medicines.

The Doha Declaration on TRIPS and Public Health, adopted in 2001, further strengthened this framework by emphasizing that TRIPS provisions should not hinder member states from protecting public health. It clarified that countries have the right to issue compulsory licenses to address challenges like access to medicines for diseases such as HIV/AIDS, tuberculosis, and malaria. This declaration has provided a legal and moral basis for governments to prioritize public welfare over patent exclusivity in critical situations.

Many nations have followed a similar approach to compulsory licensing, particularly in the pharmaceutical sector. For example, Brazil and Thailand have issued licenses for HIV/AIDS drugs to lower costs and expand access for patients in need. South Africa, too, leveraged TRIPS flexibilities to improve access to affordable antiretroviral treatments during its HIV/AIDS crisis. More recently, the COVID-19 pandemic has highlighted the global importance of compulsory licensing, with countries considering or implementing it to ensure equitable access to vaccines and treatments.

These examples underscore the critical role of compulsory licensing in balancing the interests of patent holders with public health priorities. By utilizing the flexibilities offered under TRIPS and reinforced by the Doha Declaration, countries like India and others have demonstrated that intellectual property rights can coexist with public health imperatives, ensuring that innovation benefits society as a whole.

Landmark Case Laws:

1. Natco Pharma Ltd. v. Bayer Corporation (Sorafenib/Nexavar CL)[7]:

This was the first-ever case in India where a compulsory license was granted. Bayer held the patent for Sorafenib Tosylate (Nexavar), a drug used in the treatment of advanced kidney and liver cancer. The drug was sold at an exorbitant price, around ₹2.8 lakhs per month, making it unaffordable for most patients. Natco Pharma applied for a compulsory license, arguing that

[7] Controller of Patents, Natco Pharma Ltd. v. Bayer Corp., Compulsory License Application No. 1 of 2011 (Mar. 9, 2012) (India)
Bayer Corp. v. Natco Pharma Ltd., OA/35/2012/PT/MUM, Intellectual Prop. App. Bd. (Mar. 4, 2013) (India)
Bayer Corp. v. Union of India, 2014 (60) PTC 277 (Bom.) (India)

the reasonable requirements of the public were not being met, the patented invention was not available at a reasonably affordable price, and the invention was not being worked in India. The Controller of Patents granted the license in 2012, allowing Natco to sell the drug at a much lower cost with a royalty payment to Bayer. The decision was later upheld by the Intellectual Property Appellate Board (IPAB) and the Bombay High Court, solidifying the precedent that public health concerns can outweigh patent monopolies.

2. BDR Pharmaceuticals Pvt. Ltd. v. Bristol-Myers Squibb (Dasatinib/Sprycel CL)[8]:

BDR Pharma sought a compulsory license for Dasatinib, a cancer drug marketed as Sprycel by Bristol-Myers Squibb. The Controller General of Patents rejected the application in 2013. The rejection was primarily on the ground that BDR had not made adequate efforts to obtain a voluntary license from the patentee before applying for compulsory licensing. Furthermore, the Controller held that BDR had failed to establish a strong prima facie case under Section 84 of the Patents Act. This case emphasized the requirement that an applicant for a compulsory license must first genuinely attempt to negotiate with the patentee and provide sufficient justification before the Controller can consider granting a CL.

3. Lee Pharma Ltd. v. AstraZeneca AB (Saxagliptin CL Application)[9]:

In 2015, Lee Pharma filed an application for a compulsory license for Saxagliptin, a drug used for the treatment of type 2 diabetes and patented by AstraZeneca. The company argued that the drug was not available to the public at a reasonably affordable price and that public demand was not being adequately met. In 2016, the Controller of Patents rejected the application, holding that Lee Pharma had failed to establish any of the statutory grounds under Section 84(1). The Controller noted that there was insufficient evidence regarding unmet demand or unaffordability. This case reinforced the principle that compulsory licensing in India is not a casual remedy but requires strong and well-documented grounds to succeed.

Assessing The Need For Compulsory Licensing For Covid-19 Vaccines In India:

India has approved two vaccines for emergency use: COVAXIN, developed by Bharat Biotech

[8] Controller of Patents, BDR Pharm. Int'l Pvt. Ltd. v. Bristol-Myers Squibb Co., Compulsory License Application No. 1 of 2013 (Oct. 29, 2013) (India)
[9] Controller of Patents, Lee Pharma Ltd. v. AstraZeneca AB, Compulsory License Application No. 1 of 2015 (Jan. 19, 2016) (India)

in collaboration with the Indian Council of Medical Research, and COVISHIELD, manufactured by the Serum Institute of India under a license for AstraZeneca's vaccine. These vaccines are priced affordably; thus, production capacity remains the primary concern. With India's significant role in global vaccine manufacturing and its population exceeding 1.3 billion, there is immense pressure to meet both domestic and international vaccine demands.

The Serum Institute, as part of the WHO's COVAX alliance, must balance local and international supply obligations. Amid the rising cases and the second wave of COVID-19 in India, rapidly vaccinating a large population is critical to controlling the infection rate and reducing fatalities. While current supplies of COVAXIN and COVISHIELD are steady, the pandemic qualifies as a "national emergency" under Section 92 of the Indian Patent Act. If vaccine shortages arise, the government should be prepared to invoke compulsory licensing, enabling other pharmaceutical companies to produce vaccines. Such measures would ensure adequate supply to meet both national and international commitments, safeguarding public health during the ongoing crisis.

Conclusion:

Compulsory licensing serves as a critical mechanism for balancing the rights of patent holders with the needs of society, particularly in vital sectors like healthcare and technology. By challenging the monopolistic control of patent holders, it ensures that innovations, especially those with life-saving or transformative potential, are not limited to those who can afford exorbitant prices. Instead, it fosters an environment where public welfare is prioritized, aligning the patent system with broader societal goals. Policymakers play a crucial role in striking this delicate balance, fostering an equitable and just system that incentivizes innovation while addressing urgent societal needs.

Under the Patent Act, compulsory licensing functions as a legal tool to ensure that essential goods, such as critical medicines, remain accessible to the public. Although it limits the exclusivity of patents, it compensates patent holders appropriately, recognizing their contribution while addressing public health and welfare. This system reflects a commitment to fairness, aiming to reconcile the interests of inventors with the imperative to safeguard lives and well-being, particularly in the face of public health emergencies or market failures.

Globally, compulsory licensing is indispensable for addressing public health challenges

without being constrained by high prices or restrictive patent practices. Countries like India, Brazil, and Thailand have utilized this mechanism to secure access to life-saving treatments, demonstrating its value in overcoming barriers posed by exclusive patent rights. While there is ongoing debate about its potential impact on innovation, the broader objective remains to ensure that innovation serves the greater good, particularly in critical sectors like healthcare.

As a powerful tool, compulsory licensing emphasizes that patent rights should align with public welfare. By balancing the protection of inventors' rights with societal needs, it reinforces the principle that innovation should benefit humanity as a whole. Although it may pose challenges to patent holders and influence trade relations, careful implementation and adherence to international guidelines, such as the TRIPS Agreement and the Doha Declaration, can mitigate negative impacts while maximizing its benefits.

In a world increasingly dependent on innovation, mechanisms like compulsory licensing underscore the importance of equity and accessibility in intellectual property law. They ensure that the patent system is not just a driver of progress but also a pillar of justice, fostering a landscape where advancements contribute meaningfully to societal well-being.

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