PATENT LINKAGE AND ITS ROLE IN PHARMACEUTICAL INNOVATION IN INDIA

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Abstract

India has signed the TRIPS agreement which has revolutionized its IP policy. The aim is to regulate and promote intellectual property rights globally. However, the developed countries are dominating developing countries like India to follow TRIPS plus which mandates to impose 'patent linkage' in one's country. India's existing laws are inconsistent with the objective of patent linkage, additionally, its innovations in the pharma industry are benefitting the public at large by providing generic drugs at affordable prices. The concept of patent linkage gives rise to conflict between private interest and public interest. India seems fair enough in its position of not allowing patent linkage in the country. The extent of the research rests on the Patent law in pharmaceutical innovations in India, and discourse around the notion of a patent linkage system, which is as of now, not implemented in India. The research paper has limited its scope and has excluded the role of patent linkage in pharmaceutical innovations globally. The patent linkage system, quite a controversial topic, especially in a country like India where priority is given to public benefit rather than private interest. It is important to understand, whether India is intended to instil patent linkage or not, due to increasing pharmaceutical innovations in India.

The expertise of Indian drug companies can be found in 'generics' and 'bio-similar drugs.' It is evident from the evolution of patent linkage in other countries that patent linkage crept into the system when a thriving generic industry existed. Thus, it is more likely that branded drug companies might dominate in implementing 'patent linkage' in India.

Keywords- TRIPS, Patent Linkage, Generics, Bio-Similar drugs.

INTRODUCTION

India too follows a similar approach when it comes to patents and innovations in the pharmaceutical industry. A general idea of this is well captured by Mr. Hendrith Vanlon Smith Jr., CEO of Mayflower-Plymouth, who notes:

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"When patents are granted, it creates opportunities for a few to profit in service of many. When patents expire, it creates opportunities for many to each profit in service of a few."

Patents are widely used in the pharmaceutical industry and are one of the most common types of intellectual property rights. A patent ensures that a new medicine is protected for a set period, typically 20 years[1] , and that only the inventor is permitted to bring it to market. As we might expect, if everyone keeps their ideas and results to themselves and works in secret, scientific progress would be much slower. Most importantly, a patent requires the inventor to publish their invention so that others can follow and benefit from their new ideas. Still, sharing significant details about innovation carries a high risk of being copied. That is why a patent guarantees that innovation is protected for at least a limited time.

A new drug, developed by a pharmaceutical company for curing a disease, is primarily sold under a brand name to aid clinicians in prescribing to patients. No other pharmaceutical company is permitted other than the pharma company that owns the drug to produce, sell, and finally earn profits through it as the drug is patent-protected. The term for the protection of a patent differs from country to country. The reason behind such variation is that a company applies for securing a patent even before the clinical trial is conducted. A clinical trial is necessary for assessing the drug's safety and efficacy. Then after, the effective patent period when the drug is finally approved is generally between 7-12 years. And, as soon as the patent expires, the same drug could be produced and sold by other companies. This is the point, where the drug is called a 'generic drug.'

'Patent linkage' can be referred to as one of the mechanisms to augment the monopoly of the patent. It includes "*linking generic drug marketing approval with the originator drug's patent status and refusing marketing approval until the relevant patent expires. The linkage system presupposes marketing approval as a violation of the patent*."[2]

Since 1970, granting patents to pharmaceutical inventions has been a controversial issue in India. Here, the 'patentability' of a drug has been comprehended and interpreted considering Section '2(1)(j), Section 2(1) (ja)' and Section 3 (specifically, Sections 3(d), 3(e) and 3(i)] of the Patents Act, 1970. Further, the 'Guidelines for Examination of Patent Application in the field of Pharmaceuticals,' published by the Office of the Controller General of Patents, Designs

[1] The Patents Act, 1970 (Act No. 39 of 1970).
[2] Ravikant Bharadwaj, K D Raju, and M Padmavati, "The Impact of Patent Linkage on Marketing of Generic Drugs," 18 *Journal of Intellectual Property Rights* 216 (2013).

and Trademarks assist the Examiners in the examination of pharmaceutical inventions. The research paper will deal with various intricacies related to the patent linkage involved in pharma innovations.

I. HISTORICAL DEVELOPMENT

During the period of 1970s, India immediately became a major supplier of low-cost drugs to several developing and underdeveloped countries. From 1970 to 1994, the Indian pharmaceutical industry became nearly self-sufficient and one of the largest exporters of generic medicines. Many developing countries relied on India for low-cost generic medicines. However, because Indian patent laws did not permit the patenting of pharmaceutical products at that time, innovation was hampered. The 'WTO agreement', to which India is a signatory, entered into force on January 1, 1995.[3] Article 27 of the TRIPs (Trade-Related Aspects of Intellectual Property) agreement (Annexure 1C of the WTO agreement) required the introduction of both product and process patenting in all fields of technology, including drugs, foods, chemical reaction products, and microorganisms.[4] To become TRIPS compliant, India needed to revise its patent laws to include product patent protection for pharmaceuticals.[5] While tracing the evolution of pharmaceutical legislation, the Honourable Supreme Court of India referred to a letter written by the WHO's HIV/AIDS Director on December 17, 2004, to the then-'Minister of Health and Family Welfare, Government of India.' It was quoted such as: "As India is the leader in the global supply of affordable antiretroviral drugs and other essential medicines, we hope that the Indian government will take the necessary steps to continue to account for the needs of the poorest nations that urgently need access to anti-retroviral, without adopting unnecessary restrictions that are not required under the TRIPS Agreement and that would impede access to medicines."

As a result, in 2005, the Indian Parliament amended 'section 3(d) of the Act' to maintain a balance between making Indian patent laws, TRIPS compliant and ensuring that such patentability has no negative impact on public health or interest.

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[3] Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, annex 1C, April 15, 1994, https://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm (accessed on March 1, 2024).

[4] 'Pharmaceutical Patents- Indian Scenario,' Chaba and Chaba IP, https://www.candcip.com/pharma-2 (accessed on March 3, 2024).

[5] Prabhu Ram, 'India's New "Trips-Compliant" Patent Regime Between Drug Patents and The Right to Health,' Chicago-Kent Journal of Intellectual Property, 2006, https://studentorgs.kentlaw.iit.edu/ckjip/wp-content/uploads/sites/4/2013/06/11_5JIntellProp1952005-2006.pdf (accessed on March 3, 2024).

The Annual Reports released by the Indian Patent Office provide data to display that the patentability of pharma inventions is augmented by an astonishing 60.17% between 2012 and 2017.

II. PATENT LAW IN INDIA

In 1856, for the first time in India, patent rights were introduced.[6] The Patent Act 1970 ("the Patents Act") repealed all previous legislation. India has signed both the 'Paris Convention for the Protection of Industrial Property' (1883) and 'the Patent Cooperation Treaty' (1970). According to the Patents Act, inventions that meet the criteria of 'newness, non-obviousness, and usefulness or industrial application' are eligible for patent protection.[7] The innovations to which a patent must be granted need to go under a rigorous process and if in between a third party raises an objection, it must prove that the innovation fits in the abovementioned criterion and thus, is eligible to get a patent.

Non-patentable inventions provided under the Patents Act cover procedures for agriculture or horticulture, processes for medicinal, surgical, curative, or prophylactic treatment of humans, animals, or plants, and substances obtained through admixture that only aggregates the properties of the components.[8]

Patents play a crucial role in innovations related to healthcare products, in nations where economic and tech capacities are proficient. However, in developing countries, where the purchasing power of the public is low and millions of poor people are affected by several diseases, in such circumstances instead of patented medicines, generic drugs would be of more importance and necessary.

Every year, pharmaceutical companies spend billions of dollars developing and researching new drugs. Out of a thousand drugs, only 3-5 are expected to make it to clinical trials, and only one is approved for marketing. Pharmaceutical companies patent the drugs they develop and gain exclusive marketing rights for 20 years.[9] The cost of the drug's development and research

[6] G. Krishna Tulasi and B. Subba Rao, 'A Detailed Study of Patent System for Protection of Inventions,' Indian Journal of Pharmaceutical Sciences, National Library of Medicine, National Centre for biotechnology Information, Pub Med Central, Sep-Oct 2008, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3038276/ (accessed on March 2, 2024).
[7] Supra note 1 at 2.
[8] V K Ahuja, *Intellectual Property Rights in India* (Lexis Nexis, 2nd ed. 2015).
[9] Chittaranjan Andrade, Nilesh Shah, and Sarvesh Chandra, 'The new patent regime: Implications for patients in India,' Indian Journal of Psychiatry, National Library of Medicine, National Centre for biotechnology Information, Pub Med Central, Jan-Mar 2007, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2900001/ (accessed on March 2, 2024).

is recovered through the pricing of the drug, which is sold to the public. Once a drug invented by a pharmaceutical company is registered under the Patent Act, the company gains a 20-year exclusive right to own the patent, as well as exclusive marketing rights for the drug during that time. No other pharmaceutical company is permitted to manufacture or produce the same drug. After 20 years, the patent expires. In such a case, other drug companies may manufacture and sell the same drug.

As per the 1970's Act, only process patents were recognized, not product patents. This enabled Indian drug companies to manufacture the same drug using another process known as reverse engineering. However, only after the 2005 amendment act, product patenting had been permitted in India for pharmaceutical inventions.[10]

A product patent grants the original inventor an exclusive right to a tangible product that one created.[11] Having these rights with the creator, no other manufacturer can produce the same product using the same or different method.

The primary advantage with respect to the product patent system is that it provides a higher level of protection to the inventor. However, one disadvantage is that there are fewer competitors in such a regime. This raises the possibility of monopoly, which can be a major issue in underdeveloped countries where a larger proportion of the population struggles for necessities.

Whereas, a process patent protects inventors for a specific process of creating or manufacturing a product. Most developing countries, such as India and Argentina, provide a process patent regime to their inventors and creators. In other words, a process patent regime protects a specific manufacturing process rather than the product itself. It is possible to produce the same product using other procedures or amending the parameters of the procedure.[12]

III. CONCEPT OF PATENT LINKAGE AND ITS APPLICATION

The situation in India is that a pharma medicine could be brought to the market either by the originator of the company or by any other generic company. However, for both companies, it is crucial to secure marketing approval from the Drug Controller of India. In one scenario,

[10] 'Everything to know about the patent of drugs,' Ipleaders, https://blog.ipleaders.in/everything-to-know-about-the-patent-of-drugs/ (accessed on March 2, 2024).
[11] 'IP Protection: Types of Pharmaceutical Patents,' Sagacious IP, https://sagaciousresearch.com/blog/types-of-pharmaceutical-patents-inventors-should-know (accessed on March 2, 2024).
[12] Ibid.

when a drug is invented by a pharma company, it immediately applies for a patent to establish a monopoly in the market. In contrast, accessibility and availability of drugs are the major purposes of public health policy. Thus, in India, the concept of evergreening does not exist. 'Evergreening' refers to the re-patent of a product by the inventor which allows him to maintain monopoly over the product. While, if therapeutic efficacy[13] has been seen in the product, then it is eligible for re-patent.

To promote the accessibility of drugs to everyone at cheaper prices, generic companies develop generic medicines. Generic medicines compared to the branded patented drug are not expensive and affordable to the public at large. A direct connection can be seen between the cost of drugs and the availability of generics. From the viewpoint of invention, generic drugs seem to be defeating the interest of inventors. However, at the same time, the interest of public good cannot be overlooked. Hence, it is of utmost importance to strike a balance between objectives of reasonable price and innovation.

Patent linkage refers to "the relationship between a generic drug's market approval and the patent status of its branded equivalent."[14] It states that "marketing approval for a generic cannot be granted before the patent term on the branded equivalent expires, or until the relevant authority determines that the branded drug's patent will not be infringed or is invalid unless the patent owner consents otherwise."[15]

The primary goals of 'patent linkage' are to resolve infringement and invalidity disputes as quickly as possible, as well as to prevent regulatory bodies from facilitating patent infringement through their administrative actions. In such a manner, patent linkage places a responsibility on the regulatory body to enforce patents. To achieve this, regulatory authorities probably ensure proper documentation as well as data transparency.

The Drugs and Cosmetics Act, of 1940 requires marketing approval from the Drug Controller General of India (DCGI) (hereinafter referred to as DC) before introducing a pharmaceutical drug into India. The Drugs Controller primarily determines whether a drug is appropriate for

[13] The Patent Act, 1970 (Act No. 39 of 1970).
[14] Patent linkage: Balancing patent protection and generic entry, DrugPatentWatch- Make Better Decisions. https://www.drugpatentwatch.com/blog/patent-linkage-resolving-infringement/ (March 2, 2024).
[15] *Id.*

market introduction. In most cases, before applying for marketing approval, the drug's inventor seeks patent protection under the Patents Act of 1970.[16]

The 'patent linkage' system essentially requires the generic manufacturer to demonstrate to the drug regulator that the drug for which he is seeking approval is not covered by a valid patent. This imposes a duty on the DC to ensure that generic manufacturers do not receive marketing approval for drugs that are already covered by an existing patent. Although this system of 'patent linkage' is recognized in the United States and some other countries, the Indian legislature has not expressly recognized it. The Delhi High Court[17] recently ruled that 'patent linkage' cannot be inferred from the provisions of the Drugs and Cosmetics Act of 1940. The applicable judicial decisions are discussed below.

The court in the case of, "Bristol-Myers Squibb Co. v. Hetero Drugs Ltd."[18] held that, the Drug Controller General of India is expected to perform his duties which the statute has bestowed and when performing its functions, parties are disallowed to violate any laws. It was also stated that if in case the drug for which defendants have sought approval, infringes the patent of the plaintiff, the approval shall not be granted to the defendant. This decision became a controversial issue among generic companies. It raised a genuine question; it is a judicial way of executing the 'patent-linkage' system which links the patent and the drug regulatory 'grant' procedure. The fascinating fact about the case was that the DC was not the party to the case and hence the order was not technically binding on him.

The decision of the above-mentioned case puts the responsibility of patent policing on the DC to make certain applications of generic drugs should not be submitted for approval which violates the patent rights of the innovator company. However, it seems undesirable as deciding the validity of a patent is an intricate process, thus, the duty of determining the validity is of the patent office or in certain circumstances of the court.[19]

In the case of 'Bayer Corporation & Ors vs. Cipla, Union of India & others[20],' Cipla, a pharma company applied to receive market approval on its drug called "Soranib," before the Drug Controller. Bayer Corporation who was the producer of its patented drug, aggrieved by the

[16] Ravikant Bharadwaj, K D Raju, and M Padmavati, "The Impact of Patent Linkage on Marketing of Generic Drugs," 18 *Journal of Intellectual Property Rights* 320-321 (2013).
[17] Bayer Corporation and Ors v. Union of India (UOI) and Ors, 2010 SCC OnLine Del 54.
[18] Delhi High Court *ex parte* order dated 19 December 2008.
[19] Anshul Mittal, "Patent Linkage in India: Current Scenario and Need for Deliberation," 15 *Journal of Intellectual Property Rights* 187-196 (2010).
[20] 2014 SCC OnLine SC 1709.

action of Cipla instituted a writ petition for seeking restraint on the grant of license to Cipla. The Supreme Court straightforwardly dismissed the application of patent linkage in India and held it inadmissible by citing several reasons such as: i. the powers and functions bestowed on Drug Controller are directed by the object of DCA 1940 instead of Patents Act. Moreover, DC has no expertise in tackling the issues about patent validity. India is a signatory to the TRIPS Agreement and hence, is not under obligation to implement the notion of a patent linkage system which was part of 'TRIPS Plus.'

Another case of **"**Bayer Corporation and Anr. v Union of India and Ors"[21]., the court observed that the object 'Section 156 of the Indian Patents Act 1970' has not been inflicting the duty to enforce and safeguard a patent on the government. Rather, the Government must adhere to the prohibition laid down by the Act, for not infringing the patent. It could not be understood that when DC approves a generic drug, he was violating or abetting the violation of an existing patented drug. The purpose of the DCA is restricted to the regulation of import, production, and distribution along with the sale of drugs as well as cosmetics. The scope is limited and it does provide for enforcing a patent granted under the Patents Act, which ultimately results in denial of marketing approval to 'a generic version of a patented drug.'

The primary aspect of securing market approval is satisfying the Drug Controller and it is the duty of a generic drug manufacturer. To stop the DC from bestowing the market approval on a 'generic version of the original patented drug' during the first three years has not been provided in the DCA 1940.

Thereafter, the Court penned down certain drawbacks that would arise if the patent linkage system were implemented in India. The drawbacks are as follows: The DC will be under obligation to reject every other application of generic medicine producer if the patented period of a patented product has not expired, which is in contravention to the provisions of DCA 1940 and the Patents Act.[22] Rather than testing the validity of the patent, the DC would make a presumption regarding it. Then, I might either fully reject the application of the applicant or put it on hold, until the Applicant receives the issue of validity regarding the patent settled in the proceedings. All these procedures are ultra vires to the functions of the DC. The patent holder could hinder all generic producers who might have made efforts to make it available in the market at a cheaper price. Thus, even if the patent holder does not go for securing market

[21] 2009 SCC OnLine Del 2469.
[22] *Id* at 8.

approval, the patented drug would be virtually unavailable in India at the discretion of the patent holder.

IV. MERITS AND DEMERITS OF PATENT LINKAGE

India knows the significance of innovation for the growth and development of the country. However, it weighs the notion of patent linkage relying on economic feasibility and 'access to medicines.' According to the developed nations, they find various benefits attached to the patent linkage, which are as follows:

1. Patent linkage aids in preventing generic drug manufacturers from entering the market with products that infringe upon patents held by brand-name drug companies. By requiring generic manufacturers to demonstrate that their products do not infringe on existing patents before marketing approval, patent linkage reduces the likelihood of patent infringement litigation, saving time and resources for both generic and brand-name companies.
2. Patent linkage strengthens the protection of patent rights by preventing generic competitors from entering the market until the relevant patents have expired or been invalidated. It ensures that patent holders have exclusive rights to their inventions during the patent term, allowing them to recoup their investments in research and development and incentivizing further innovation.
3. Patent linkage incentivizes pharmaceutical companies to invest in research and development by providing stronger protection for their intellectual property. By protecting patents and providing market exclusivity, patent linkage allows innovator companies to generate revenue from their investments in new drugs, which in turn funds further research and development efforts.[23]

To contradict, developing countries have certain contentions as follows-

- "Delayed arrival of affordable generic medicines in the market will also have adverse effects on the public health of the country.
- The Drugs Controller may not be well informed about the complex issues related to patent validity.

[23] 'Indian patent law on pharmaceuticals: challenges and opportunities,' Lexology., https://www.lexology.com/commentary/healthcare-life-sciences/india/ks-partners/indian-patent-law-on-pharmaceuticals-challenges-and-opportunities (accessed on March 2, 2024).

- The marketing approval only assesses whether the drug is safe to use and subsequently bestows upon it the right to carry on clinical trials so that it may enter the market as soon as the valid patent expires without any further delay.
- The generic drug manufacturers will be forced to focus more on research and development as they will also want to invent drugs rather than produce alternatives of the original drugs, which will lead to a surge in the prices of generic drugs."

Hence, an inference can be made that various pharma giants would be in favor of nations that accept and implement patent linkage systems in their laws. Such nations may become their major consumer base as these countries possess the capacity to provide a strong protective shield to their produced drugs. This would enable opportunities to commercial advantage their medicines even after the patent has expired before the generic drug is introduced in the market.

V. PATENT LINKAGE AND ITS RELEVANCE TO INDIA

There are various reasons behind not having a patent linkage system in India. Primarily, India is the second largest populated country in the world and has diverse healthcare and medical needs. Thus, accessible, and affordable medicines become the utmost priority. Further, the following analysis will unfold several elements of the reason for the non-implementation of patent linkage.

When a product is conferred with a patent, the three most essential conditions are required to be fulfilled, they are newness, non-obviousness, and industrial application. All three conditions are challenging as the patent seeker needs to prove the product's novelty, that the product contains some creativity, and lastly, the product must provide a technical solution to the technical problem. Indeed, it is a tough job!

After the patent is granted, the patent holder enjoys a monopoly over the product for twenty years. It means that no one can produce, sell, or use the product without the innovator's consent. However, several generic companies produce generic drugs during the twenty years of the patented drug and apply for securing market approval from the Drug Controller of India. As soon as the generic drug receives market approval and the patent period of the branded drug expires, the generic company is all set to launch its drugs in the market and sell its medicines at affordable prices.

Quickly referring biosimilars, these are the versions of branded drugs that provide more reasonable treatment to patients suffering from various diseases. There is a slight important

difference between generic medicine and biosimilar products. Simply put, a generic drug is generally synthesized from chemicals and its production takes place in an active ingredient that remains equal within each produced unit. Whereas, biosimilars from their meaning understand that it is produced from living organisms.

When a generic company applies to seek market approval from the DCGI, the authority does not go into the nitty-gritty of the patented product. DCGI which is an authority under the Drugs and Cosmetic Act 1940 and the Patents Act 1970 cannot be said that there exist connections just because drugs or medicines are patentable. DCGI has a statutory duty to bestow producing approval and marketing licenses. Whereas, the Patent authorities grant patents by examining the three essential factors and not indulging in the safety and security standards of patents. Thus, the Legislature does not have the intention to provide patent linkage in India.

Being a signatory to the TRIPS Agreement, India had a mandatory duty to grant patents to pharma innovations. Thus, in 2005 the patent law was amended and medicines were granted patents.[24] India's stand on IPRs and trade-related agreements harmonizes the invention and public health requirements, makes accessible affordable medicines, and promotes the growth of generic medicines.[25]

Global Trade Research Initiative stated that by raising objections to the demands of developed nations with regards to certain issues such as 'patent linkage,' in free trade agreements, India makes sure that generic medicine producers get exposed to bigger market access as well as the value of life-saving drugs decreases crucially.

The developed countries are always in the position of pressurizing developing countries like India to undertake certain commitments in free trade agreements on IPR cases which are agreed under TRIPs agreement of the WTO. Nowadays, in the realm of trade, such dominance of developed countries has resulted in creating 'TRIPs-plus.[26]

India is considered the 'pharmacy of the world' in both quality and quantity. There are many global healthcare professionals and funders, who regularly depend on quality-checked generic drugs produced by pharma companies of India. India is the source for many developing and

[24] Dr. Rajeshkumar Acharya, 'The Global Significance of India's Pharmaceutical Patent Laws,' Innovate Articles, American Intellectual Property Law Association, https://www.aipla.org/list/innovate-articles/the-global-significance-of-india-s-pharmaceutical-patent-laws (accessed on March 31, 2024).
[25] News, 'India's stand on IPRs, pharma help promote growth of generic industry: GTRI,' Business Standard, pub on. Feb 16 2024. https://www.business-standard.com/industry/news/india-s-stand-on-iprs-pharma-help-promote-growth-of-generic-industry-gtri-124021600267_1.html (accessed on March 31, 2024).
[26] *Id.* at 11.

underdeveloped nations for generic medicines. All these dependent countries are thankful to the existing Patent law of the country that allows the production and sale of generic medicines.[27] Such a humanitarian approach to protecting the interest of the public at large renders India a global leader in the pharma industry. Moreover, the Indian pharma industry is ranked in third position[28] internationally in pharma production in terms of volume and is especially known for its generic medicines and affordable vaccines.

Due to increased competition among generic companies, the cost of drugs to treat life-threatening diseases was lessened by more than 90%. As a result, India became a major source of necessary drugs at a reasonable price. About 96% of HIV medicine is purchased by developing country treatment programmes which is imported from India.

Due to such overdependence on other developing and underdeveloped countries and the notion of public good at large, the concept of 'evergreening' or re-patenting a product is prohibited in India. The priority is given to public health rather than the interest of the pharma industry.

Therefore, for the betterment of society, the Government of India initiated a program called, *'Jan Aushadhi'* which is translated as "medicine for people."[29] The initiative looked forward to rendering generic medicines i.e. unbranded quality medicines accessible at cheaper prices to indigent people in the country. Those medicines were accessible at retail outlets. There were also several *Jan Aushadh* stores, simply stating pharmacies that were selling only generic medicines as possible and giving priority to the public sector of the pharma sector.[30]

After analyzing the intricacies related to generic drugs and branded drugs, the non-existent interface between the Drug and Cosmetic law and the Patent law, the Indian approach towards generic drugs, the interest of the public at large as well as its initiatives, finally a question arises about quality and standard of generic drug. Because, ultimately, the medicine that doctors will prescribe, patients will blindly believe it.

Generic drugs are easily available at 30%-80% affordable price compared to branded equivalents. In May 2016, the 'Drugs Technical Advisory Board of India' amended Rule 65

[27] The Patent Act, 1970 (Act No. 39 of 1970) s. 107.
[28] Government of India, "Annual Report 2022-23" (Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals, 2022).
[29] Janodia M, 'Differences in price of medicines available from pharmaceutical companies and "*Jan Aushadhi*" stores,' 18 Value Health (2015).
https://www.valueinhealthjournal.com/article/S1098-3015(15)02504-8/fulltext (accessed on 01-04-24)
[30] SS Joshi, YC Shetty, and S Karande, 'Generic drugs- The Indian scenario,' National Library of Medicine, National Centre for Biotechnology Information, April-June, 2019. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6515776/ (accessed on April 4, 2024).

(11A) of the Drugs and Cosmetic Act, 1940, to enable pharmacists to dispense generic name medicines or branded drugs against prescription in brand names. It is important to note that the quality of generic drugs is based on standards of "purity, potency, stability, and drug release."[31]

It is expected from the Government that it should maintain uniform quality among all the generic medicines, then only, the doctors will prescribe the generic medicine with full confidence and willingness.[32]

Finally, the more the patents expire, the increase will be seen in the sale of generic versions of pharmaceutical medicines and drugs. Moreover, an increase in the usage of generic drugs will help to have a comparative analysis between the real-time effectiveness of generic medicines and branded medicines.

VI. CONCLUSION

To implement patent linkage in India for protecting patented drugs far way beyond. Although India is a developing country, it is referred to as the 'pharmacy of the world.' It has always given importance to benefitting the public at large and at the same time, and has not let the economy down. When a branded drug is granted a patent, for the next twenty years, nobody can sell or market it. However, seeking market approval from DCGI under the Central Drugs Standard Control Organization is allowed. It is because of the clear intent of the Legislature which is incorporated in the Patents Act, and DCA 1940. Therefore, India has never thought of this way that confers full monopoly over a drug to the producer company.

The concept of patent linkage has both advantages and disadvantages. Patent linkage benefits big pharma companies that invest heavily in the R&D of inventive medicines because it provides secondary protection for a patent monopoly. As stated earlier, India is currently the world's leading exporter of generic drugs. Thus, India should not tolerate payment of exorbitant prices for drugs that are available at a lower cost from generic companies. If patent linkage is brought to India, all the consumers would not be able to buy expensive drugs. Nevertheless, with remote possibility, if India introduces patent linkage in the country, then a robust equilibrium needs to be established between private and public interest.

[31] *Id.* at 12.
[32] Snehal Sengupta, "73 per cent cut at fair price medicine shop," The Telegraph online, 2015. https://www.telegraphindia.com/states/westbengal/73-per-cent-cut-at-fair-price-medicine-shop/cid/1468788 (accessed on April 4, 2024).

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