Trends in Intellectual Property Research

Innovative

Article

Drugs, Public Health, and the Patent Linkage System in India and Japan

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Abstract: We may often come across mind boggling, incomprehensible doctor prescriptions quite difficult to decipher, with new drug names for the common flu and the usual 'paracetamols' found in other drugs under many different labels and names. This indicates nothing but the existence of a generic drug system. Generic drugs have same chemical formulas, properties and compositions as that of originator drugs or products. TRIPS plus concept of linking the drug regulatory authority and the patent authorities is prevalent in many states, emphasizing the prevention of generic drugs. This article will focus on patent linkage system of Japan and India and its functional details in these countries. The Japanese system is flexible, allowing the entry of generic drugs on certain conditions at the discretion of the Ministry of Health, Labor & Welfare and the results of the Japanese Patent Office. The uncertainties create a confusing view on the patent linkage system in Japan. The definition of original drugs and generic drugs are not clear in any of the provisions regulating the same, and permission or the prohibition of generic drugs or the determination of the status of a drug depends entirely on the ministries. Indian system, however, does not prohibit the entry of generics and promotes the usage of generics through various schemes, circulars and laws. It encourages doctors to prescribe the same for easy access to generic medicines. The article explores the contradicting provisions about generic drugs stipulated by the drugs & cosmetics act, 1940, expands on the bolar provisions in place and analyses the shortcomings of the system allowing generic drugs in India. The study highlights the need for a patent linkage system, supported by proper justifications and the concepts that could be implemented, for the effective functioning of both the drug regulatory authorities and the intellectual property authorities, protecting the interests of the patent owners as well as the common public, consequently.

Keywords: Patents; Patent Linkage; Generic Drugs; TRIPS; medicines

Citation: Medhiyaa Ramesh. 2024. Drugs, Public Health, and the Patent Linkage System in India and Japan. *Trends in Intellectual Property Research* 2(2), 11-16.
https://doi.org/10.69971/tipr.2.2.2024.29

1. Introduction

Health is wealth and it is not only the utmost priority or concern of any given individual, but also of any and every nation. Provision of adequate healthcare facilities and ensuring welfare of the citizens is one of the fundamental duties of a state, be it a common law state or a civil law state. While doing the same, countries should also ensure that the rights of other individuals and entities are not violated. Intellectual property rights (IPRs) are one such rights that could be infringed, in the process of ensuring easy access to healthcare and other medicinal facilities.

Patent linkage is one way to avoid the clash between patent rights and the fundamental human rights. It is the system where the marketing or licensing approval for a drug is contingent on its patent status or is based on the patent status of the product (Shin 2019). The name is derived from its literal sense meaning the linking of the patent regulatory authorities and the drug regulatory authorities to protect the patent holders. A patent linkage system protects the patent holders or patentees' rights over his or her product or drug. Patent owners of drugs support this concept, as it provides them an opportunity to restrict the entry of certain drugs into the market that resemble the patentee's drug or products. This system not only eradicates and reduces the patent infringement claims and suits considerably, as the generic companies cannot seek marketing approval while the patent is still valid but also motivates the generic drug companies to work on other forms of drugs through research and development. The patentees need not stress about other companies having to create versions of patented drugs before the expiration of their patent rights (LawTeacher 2013). US first introduced this system by an act to connect the both authorities, linking the marketing approval of drugs with the patent validity status, through the Hatch-Waxman Act. The Hatch-Waxman act or the Drug Price

Competition and Patent Restoration Act, 1984[1] was mainly designed to protect the patentees or patent owners' interests. The act ensured that patent information of the patented drug was disclosed, patent holder was aware of the generic company's intention and application for the marketing approval of its generic product and an opportunity was provided to both parties, i.e., the patent owner of the drug and the generic company to discuss the dispute resolutions for the alleged patent infringement (Lida 2022). The patent linking system of US is adopted by several countries while many countries follow their different patent linkage system.

The Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) [2] was enacted in 11 economies including, Japan, Mexico, and Brunei in 2018, to notify the patentee of an application for allowing the marketing approval of drugs without the due consent or permission of the patentee through the involvement of the appropriate authorities. The agreement also stipulates the need to provide adequate time and opportunity for resolving patent disputes pre-marketing and provisions for generic exclusivity (APEC 2023). The patent linkage system begins with patent listing, wherein the patentee lists the patents in a designated registry. The patent specifications must usually include the drug composition, specification and other important information pertaining to the drug and such a system is in place in the US, South Korea and Singapore (Yu 2024) However, the system in China, does not require the inclusion of drug specifications (Yao 2024).

A generic manufacturer usually applies for marketing approval, after listing the specifications and the applicant must mention if their product or patent infringes on existing patents. The system in the US and China does not give powers to the concerned regulators to check the patent infringement. The system in South Korea however includes the intervention of the regulators in verifying and checking patent infringements if any (Yao 2024). Once the applicant makes the declaration regarding infringement, the same must be communicated by the generic company or the applicant to the patent holder. The standard period stipulated for filing of a claim for infringement, for the patentees would be 45 days from the date of notification by the applicant and this is time frame stipulated by the US, was also adopted by China (Winninger et al.2021). Singapore slightly varies in this aspect, by providing 44 days to the patent owners to file claims, if any (Anonymous 2024). If an opposition is filed or an infringement claim is filed by the patentee, the approval of the generic drug will be put on hold. The time or the stay period for litigation introduced by the US, is thirty months,[3] and while Singapore also follows the same, China only has a 9-month period for litigation and resolution of disputes[4].

Exclusivity is a concept that can be found in most patent linkage systems across the globe. It is a concept that means a temporary marketing advantage or gain granted to the first generic drug manufacturer that challenges a drug owned by a particular brand name. Under the Hatch-Waxman Act, this has been defined in a way that provides a 180-day period of market exclusiveness. This prevents the authority from approving subsequent generic drugs produced by other manufacturers. China on the other hand provides 12 months, as exclusivity period for first generics also being the longest time frame provided for exclusivity by any state (Gao and Sherry 2024). The concept of patent linkage is not present in Europe, as the introduction of the patent linkage system would delay the entry of generic drugs. There are several conditions in place for the approval of generic drugs, patents not being one (Mishra 2023). Once marketing approval for generics are provided, such drugs are easily available for the common public to access.

2. Trips and the Patent Linkage System

The TRIPS agreement is the most common intellectual property (IP) agreement, ratified by 166 countries globally, including India and Japan.[5]While the agreement was comprehensive and elaborative regarding its provisions, it was contradictory, creating confusion for the validity and permissibility of the patent linkage system.

Article 28.1(a) of the agreement stipulates that "a patent shall confer on its owner the following exclusive rights: (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product".[6] This provision states that any product that has similar characteristics and features as that of the product of the patent owner or the patentee, cannot be made and sold without the approval of the patent owner. However, the TRIPS agreement mentioned that the TRIPS provisions supporting public health must be promoted and any provisions preventing member countries from taking steps to support public health and welfare must be condemned.[7]

Reading the above provisions, in the current case, the manufacture, sale and supply of generic medicines for public health or welfare falls well in line with the circular released by TRIPS but does not comply with article 28.1(a) banning the promotion of any products similar to the products produced or owned by the patentee, patent owner or the originator, thus including generic products in the current definition adopted by article 28.1(a). These rules and provisions contradicting each other do not determine the exact status of the patent linkage system and its legality. Prioritizing public health or the rights of the patentees is a burning question that needs to be clarified by TRIPS, and countries that have not yet taken a strong stance regarding the same, like Japan and India.

3. Japan

3.1 Patent Linkage System and Its Legality

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1 Available online: https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/hatch-waxman-letters (Accessed on 21 January 2025)

2 Available online: https://commonslibrary.parliament.uk/research-briefings/cbp-9121/ (Accessed on 21 January 2025)

3 Available online: https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/small-business-assistance-180-day-generic-drug-exclusivity (Accessed on 21 January 2025)

4 Available online: https://www.jonesday.com/en/insights/2021/09/patent-linkage-and-article-76-proceedings-in-china-a-litigators-perspective (Accessed on 21 January 2025)

5 Available online: https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (Accessed on 21 January 2025)

6 Available online: trips_art28_jur.pdf (Accessed on 21 January 2025)

7 Available online: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (Accessed on 21 January 2025)

Patent linkage system still falls under the TRIPS plus concept, regardless of the contradictions. TRIPs accord flexibilities where countries can increase the standard of protection for IP adopting measures accordingly including patent linking system. Since patent linking system adoption is optional, both India and Japan have chosen to adopt it in their own way.

Japan has not formally or fully adopted the patent linkage system owing to the complexities involved in the system but has devised a flexible patent linkage system that it follows (Hino et al. 2024). The patent linkage system in Japan does not completely bar the entry of generic drugs, but as a rule adopted and decided by the Ministry of Health and Labor (MHLW), marketing approval is not granted or provided to the drugs having ingredients, indications, dosages and administration of patented drugs whose patent is valid and existing at the time of application of the generic product (Hino et al. 2024). The system is flexible because, it is run based on the administrative decisions of MHLW rather than court decisions.[8] In the case of BMS vs Sawai, where BMS claimed that the compound 'Dasatinib' based on the marketing approval of Sprycel, was present in the drug manufactured by Sawai whose marketing approval was in process.[9] The active compound 'Dastanib hydrate, was found as 'Dastanib anyhydrate' in the drug manufactured by Sawai and the same was being contended. According to the rule adopted and practiced by MHLW, the drug cannot be approved for market supply due to the presence of a compound that the petitioner owns and has the patent rights for, the generic drug company was granted approval which was injuncted from producing and selling the drug later by the Tokyo District Court (Hino et al. 2024).

However, the green flag by MHLW indicates the approval possibility for generic drug companies and generic drugs, although the patents for the ingredients used are valid and owned by another company. If courts intervene and take over the process of the marketing approval for drugs from the MHLW, it means that the system needs more clarity and clear rules regarding the marketing of generic drugs. The patent owner of the active ingredient is notified for the marketing approval of the generic drug, and both parties discuss the resolutions of any disputes at any stage of the generic drug approval process. However, this does not mean that the generic drug marketing approval is in the hands of the original patent owner thus providing adequate flexibility and protection to both parties involved in the process.[10]

3.2 The Current Patent Linkage Process

Any generic drug manufacturer seeking marketing approval for the generic drug in question first applies to the MHLW for a pharmaceutical product according to the Pharmaceuticals and Medical Devices Act (PMDA).[11] The Pharmaceuticals and Medical Devices Agency[12], led by the health and welfare minister then examines and based on these results, minister determines whether to grant the approval or not.[13] The examination checks whether there are any cases of patent infringement with respect to the patented product and the generic product. The generic product should not contain any active ingredients of the originator's product, and should also be easy to produce, meaning that the materials or ingredients required for its production must be acquirable.[14]

The MHLW stated the conditions for approving generic products on handling patents pertaining to approval process and drug listing for generic products on June 5, 2009.The active ingredient should not be patented or fall within the patent of the original product owner or patentee, the generic product cannot be exactly same to the originator product or drug in terms of the efficacy, effects, dosage and number of dosages and whether the original drug owner still has the patent rights is determined based on the expected approval date of the generic drug (Lida 2022).

The drug patent information report form is used to collect information of the original patent owners and the specifications of the drug produced. Although not mandatory, most of the original patent producers submit the form, as the information in the form is not for the public. The generic drug information is then acquired from the generic drug manufacturer regarding the patents of any active ingredients used in the generic drug and the manufacture or viability of the acquisition of the generic product components. The MHLW does not examine its patentability, it simply follows the JPO examination results (Lida 2022). Once the JPO determines the same, the drug moves to the next stage of the National Health Institute (NHI) drug price listing. Listing is the process where the drug becomes eligible for reimbursement under Japan's National Health Insurance (NHI) system, allowing hospitals and pharmacies to dispense it at regulated prices. At this stage, both parties discuss the possible patent concerns for sale and supply of such drugs and of the listing. Now, even if the result of this resolution is not communicated to the MHLW, the MHLW approves the generic product for listing.

After approval of a generic drug and prior to its listing on the NHI Drug Price List, the original drug manufacturer and the generic drug manufacturer discuss whether there are any patent issues with the approved generic drug, and both parties report the results of their discussions to MHLW. This ensures that patents not subject to confirmation at the time of approval do not hinder the manufacture and sale of the generics.[15] It is almost impossible to sell a drug if the NHI price is not listed even if the parties agree or the MHLW gives the "go" for the drug (Shin 2019).

Problems may arise when the parties must decide the patent status and approval of a drug, because both parties have different interests in mind. This part of the system where the drug specifications and their patent status are discussed by the parties, if replaced by a court assisted mediation or arbitration or a court proceeding allowing the parties to resolve potential issues for the approval of the drug, can lead to complications delaying the process and an unsatisfactory decision. A landmark case is BMS v. Sawai pharmaceutical, 2023 where the plaintiffs challenged an injunction claimed by the defendants, EISAI R & D Management, the originator of the drug for the patent infringement of the drug. The defendants accused the generic drug manufacturer of infringing the patent of the originator

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8 Available online: https://cms-lawnow.com/en/media/law-now/files/87f58aa8e02b4adeb1c5c0b2c7ff9120 (Accessed on 21 January 2025)

9 Available online: https://www.bms.com/assets/bms/japan/pressrelease/20231129-pdf.pdf (Accessed on 21 January 2025)

10 Ibid,8

11 Available online: https://www.pmda.go.jp/english/ (Accessed on 21 January 2025)

12 Supra

13 Available online: https://www.pmda.go.jp/files/000152700.pdf (Accessed on 21 January 2025)

14 Ibid,8

15 Ibid,8

drug claiming damages accordingly.[16] The issue was whether the plaintiffs can claim a declaratory judgement or not. The plaintiffs also demanded a clarification regarding the patent linkage system from the MHLW to decide and determine cases for patent infringement cases stating that the current system where the patent infringement of drugs is being decided by the MHLW instead of courts is not according to the general doctrine of law. The court held that the authority determining the patent status and the issue with MHLW deciding such cases is a public issue between the plaintiff and the MHLW. The court directed the plaintiff to seek appropriate remedy by filing an action against the illegality of such an authority deciding cases or by filing an appeal against the government, but a declaratory judgement in the case was not recognized.[17]

3.3 Problems of The System

Japanese patent linkage system has been modified and adapted to suit its legal structure and concerns, but it still needs to be amended to address other issues arising from the system. Many experts claim that Japanese patent system is lacking transparency. It does not provide whether a generic drug falls under the ambit of an originators drug or not (Shin 2019). It also does not provide details regarding the patent data of the substances, ingredients and components and the combinations or formulae of the components used, unlike the system in some other countries thus leading to confusion and lack of clarity.

Another problem is that when the originator drug is invalidated during an examination trial or when the case is pending for the final verdict, marketing approval for the generic drugs is put on hold (Lida 2022). Although the drugs, and the drug manufacturers are different, the marketing approval for such generic drugs are not granted. The regulatory authorities may not approve such drugs, as the defective part of the drug can be the ingredients or ingredient combination used which could be the reason for the defect in the drug or the invalidation trial. However, if there is another body constituted exclusively for analyzing the components, ingredients and the drugs that goes for trial, parallelly working with the MHLW, like the Central Drugs Standard Control Organization (CDSCO) in India, supplying the necessary information, it would lead to smooth supply, manufacture and listing of the generic drug in the market (Lida 2022).

The current PMDA can be amended to include clear provisions for better understanding of the current patent linkage system and its functions. The provisions can include the intervention of courts to decide cases for patent infringement and the granting patents to generic drugs. The system overall, needs amendments for more clarity, accuracy and better functioning.

4. India

The patent linkage is not a common practise in India and is discouraged as India cannot afford the requisite resources to end the generic medicine market. India is the largest producer of vaccines and the largest manufacturer and exporter, by volume of generic drugs. Since patent linkage is a TRIPS plus concept, it's not mandatory to adopt it. The Central Drugs Standard Control Organization (CDSCO) under Ministry of Health and Family Welfare is the authority for regulating drugs and drug related disputes in India.[18]

4.1 Related Legal Provisions

India does not have any act or statute mentioning the patent linking system or its practice but has acts governing the manufacture and supply of generic drugs. The Drugs and Cosmetics act, 1940 regulates the manufacture, marketing approval, distribution and import of drugs or agricultural chemicals and cosmetics. 19 The Drugs and Cosmetics Rules, 1945 have provisions regarding the manufacture and supply of generic drugs. However, neither the act nor rules have a specified definition for generic drugs, just like the situation in Japan. The bolar provision expressly allows the production and sale of generics. Indian Patents Act, 1970 allows the generic manufacturers in India to work or experiment with any of the original or "new drugs" according to the definition adopted by the drugs and cosmetics act, 1940, and submit such data to the concerned regulatory authority, so that affordable medicines could reach the common people.[20]

Indian government promotes the usage and supply of generic medicines over branded ones. In 2008, the government of India introduced the "Jan Aushadhi" programme to manufacture and sell unbranded quality medicines to the poor people, at a reasonable price, with the help of the government. Many government retail outlets for the sale of such generic medicines as part of the scheme were established in different parts of the country.[21] The National Medical Commission (NMC) in August 2023, released a circular mandating doctors to prescribe generic version of the drugs, to ensure that the patients could afford the drugs.[22] However, the implementation of the same has paused, due to quality and efficacy reasons. In the future, the doctors are predicted to prescribe generic drugs only.

Some sections of Drugs and cosmetics act, 1940 and the drugs and cosmetics rules, 1945 are contradictory to each other, creating an unclear view on the legality and status of generic drugs. Section 16 of the Drugs and cosmetics of the act, 1940 prescribes rules for the quality of drugs implying that the generic drugs, just like branded drugs should comply with the quality standards and efficacy standards fixed by the authority.[23] However, section 107 of the same act prohibits the manufacture of spurious drugs meaning drugs

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16 BMS v. Sawai Pharmaceutical, Case No 2022 (Ne) 10093 (decision rendered on 10 May 2023)

17 Available online: https://practiceguides.chambers.com/practice-guides/patent-litigation-2024/japan/trends-and-developments (Accessed on 21 January 2025)

18 Available online: https://cdsco.gov.in/opencms/opencms/en/Home/ (Accessed on 21 January 2025)

19 Available online: https://www.indiacode.nic.in/bitstream/123456789/15278/1/drug_cosmeticsa1940-23.pdf (Accessed on 21 January 2025)

20 Available online: https://ipindia.gov.in/writereaddata/portal/ipoact/1_31_1_patent-act-1970-11march2015.pdf (Accessed on 21 January 2025)

21 Available online: http://janaushadhi.gov.in/mesgceo.aspx (Accessed on 21 January 2025)

22 https://www.nmc.org.in/autonomous-boards/ethics-medical-registration-board/

23 Ibid,21

that resemble another drug or drugs that are not original drugs.[24] Similarly schedule Y of the Drugs and Cosmetics rules, 1945 enlists a form for the sale and supply of the drugs already approved by the authority in India, allowing the generic manufacturers to register their generic drugs, promoting the patent linking system as a whole.[25]

4.2 The Generic Drug Approval Process

The safety and efficacy data of a previously approved drug is usually referred to while approving a generic drug. Besides this, additional clinical and non-clinical information is required to elucidate new claims for an approved drug and the data required for such tests may differ with the claims. The information required and the clinicals trials required will not be extensive if the drug is already approved by major agencies and is being sold in various markets or if the generic drug proves its efficacy and bioequivalence to the original drug. CDSCO will then review the applications and will consult with the expert committee, for deciding the grant of approval (Kumar and Chandra 2016). The production methods, specifications, fixed dose combinations if any, new dosage forms, number and date of approval already granted, reasoning for safety standards and such other data is to also be submitted.

4.3 Landmark Precedent on Patent Linkage

The case of Bayer Corporation & Anr v. union of India[26] re-affirmed the status of patent linkage system. The Indian patent office (IPO) in this case had provided the subject patent to Cipla for its drug 'Soranib' which the appellants claimed to be an imitation or a substitute of their patented drug. Bayer being aggrieved by this patent, filed a special leave petition, which was in favor of the IPO or Cipla, upholding the validity of the patent granted to Cipla.

The Delhi High court, which initially dealt with the case stated the following reasons for dismissing the petition by Bayer corporation.

1. Patent linkage system is not applicable in India, as it is not in line with the objectives of the Drugs and Competition act and Patents Act, 1970. If both these authorities and acts were to be linked, it would imply falling out of the context of both these acts. Drugs Control Authority is not violating any of the provisions of the Patents Act, by simply doing its duty properly.
2. The appellant Bayer contended that Form-44 which was filed in accordance with the Drugs and Cosmetics act,1970, for approval for manufacture and import of drugs, or for undertaking clinical trials of drugs was intended by the authority and act to show the patent status, thus implying patent linkage. However, the court asserted that the form is just to check the bio-equivalency and bioavailability of the generic drug to the patented drug. The column mentioning the patent status of the generic drug is just to verify the drug composition for determining the kind of clinical trial to be undertaken.[27]

The court did not accept the contention of the appellant which categorized the generic drug 'Soranib' in the current case as 'spurious drugs' according to the definition adopted by section 16 of the Drugs and Cosmetics Act,1970. The court opposed the contention by stating that all generic drugs would then be covered by the definition, if the generic drugs fall in the ambit of spurious drugs. The court recognized and stated that the patent linkage system is a TRIPS plus concept, and it re-confirms that such systems could be introduced as an addition to the mandatory required concepts, if the state feels the need and has the resources to fund the same, thus not supporting the possible introduction of the system to India.

4.4 Justification For Non-Adoption of Patent Linkage System

The Drugs Controller General of India had suggested to link the status of the patent of drugs while the drugs are being approved for marketing, but the same was strongly opposed by public health advocates and industry fashions. Because the time between expiration of the patent and the approval of the generic drugs will be too long, delaying the accessibility of affordable medicines to the commons. The lack of knowledge and qualifications by both the authorities, (drug controller and the patent officers) to adjudicate claims may revamp the entire system and drastic policy changes to include the same. It means if the drug regulatory authorities and the patent authorities are only knowledgeable in their respective fields and are not aware of the other, there would be changes in the laws of both drug related laws as well as the patent laws to include provisions to include patent linkage, while in contrary, the system as a whole could just be introduced, without causing further complications (LawTeacher 2013). India is a developing country not having adequate resources to produce non-generic, original products alone, can be a reason of encouraging manufacture and supply of generics.

These reasons, in the author opinion, are not sufficient for the non-introduction and non-implementation of the patent linkage system, especially functional compulsory licensing in India. Compulsory licensing under section 84 of the Patents Act, 1970, is the authorization provided by the government to make, sell or use a particular product or drug without the permission of the patentee or the patent owner.[28] These are usually granted when the government feels the dire need for a particular drug or product at an affordable price for the common people when the patent for the same is held by another, due to which its production and sale level is not adequate to meet the needs of the government or people. If there is a need for a particular drug for cure of a particular epidemic or disease, the same could be compulsorily licensed by the government, by providing the required compensation to the patent owners. This way, the patent owners and the common people benefit, instead of manufacturing and selling the generics of every drug, protecting the interests of the patent owners.

5. Conclusions

The current systems in both countries may be working just fine but increasing the standards and quality of research and development, by providing enough security to the rights and interests of the patent owner, can be initiated. While the partial adoption of the

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24 Supra

25 Supra

26 Bayer Corporation & Anr v. Union of India, AIR ONLINE 2019 DEL 1712(Delhi HC 2019)

27 Supra

28 Ibid,22

patent linkage system suits the Japanese industries, the system can be fully implemented by introducing few other factors and concepts. Compulsory licensing, to approve generics can be introduced. It will modify the current compulsory licensing structure wherein an individual or entity willing to create a generic version of a drug applies to the relevant authority, which then processes the application, provided four years have passed from the date of the grant of the patent. In the current structure, the government has no role to play, but the government authority intervention is essential for protection of rights of patentees and the welfare of the people. Similarly, Japan can constitute bodies such as the CDSCO and expert committees under the MHLW for delegation and faster disposal of claims, in contrast to the current structure where the MHLW without any designated committees handles all kinds of drugs and patents related disputes. To include the same, an exclusive act for regulating the patent linkage system mentioning the stage at which the linking will be made, the rules regarding the TRIPS compliant patent linkage system, the duties and roles of authority responsible, the kinds of products or drugs that would be covered under the act, the functioning of the patent linkage system, the disclosure of patent information, the period of such patent validity and the exceptions provided should be implemented. India, should implement the patent linkage system with special rules or provisions like the one proposed above and must prevent the production of spurious generics, benefitting the patentees, and people. Required reforms, policy changes and system overhaul will enable the smooth functioning of all sectors and industries.

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