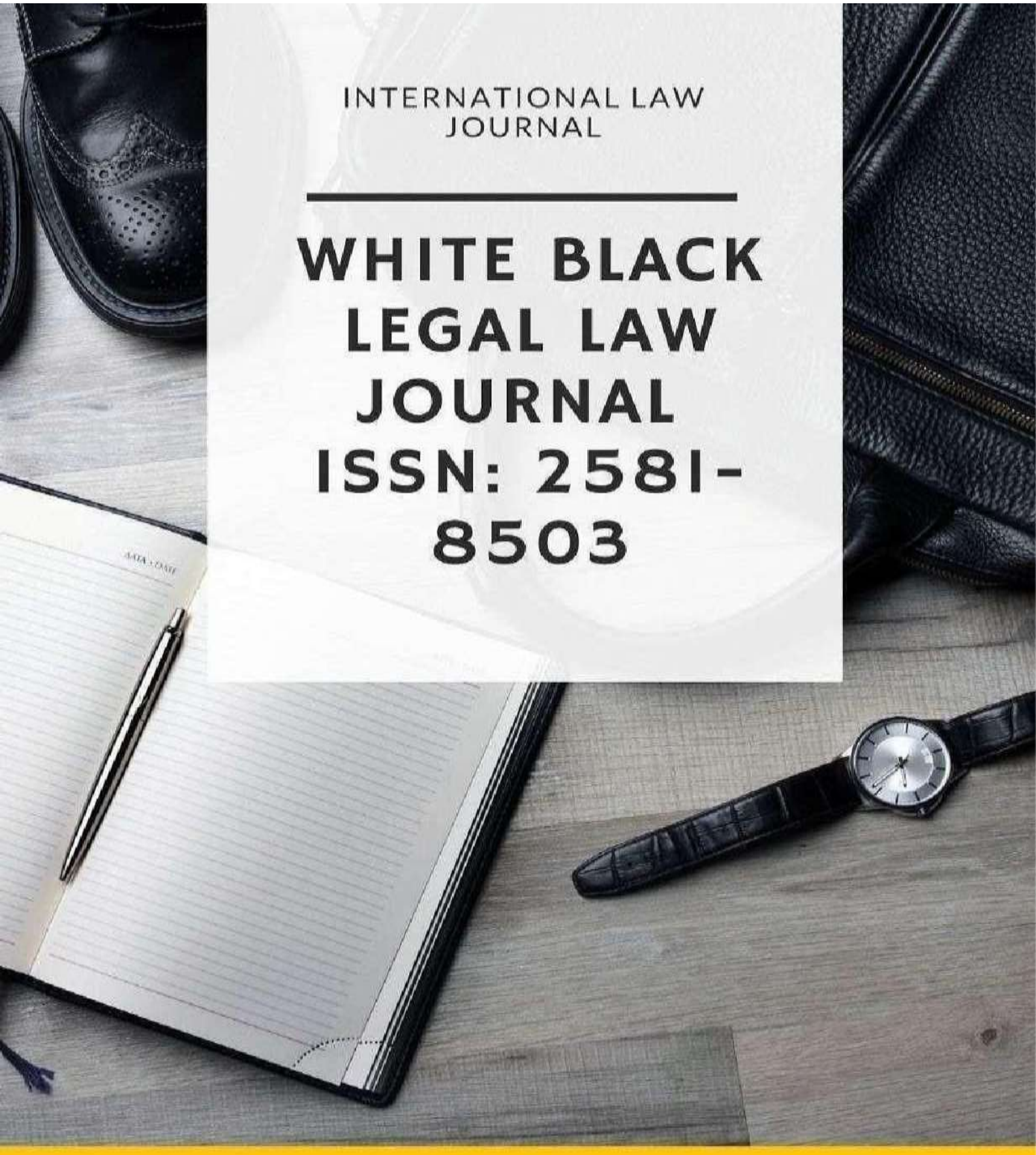

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ABOUT US

WHITE BLACK LEGAL is an open access, peer-reviewed and refereed journal providededicated to express views on topical legal issues, thereby generating a cross current of ideas on emerging matters. This platform shall also ignite the initiative and desire of young law students to contribute in the field of law. The erudite response of legal luminaries shall be solicited to enable readers to explore challenges that lie before law makers, lawyers and the society at large, in the event of the ever changing social, economic and technological scenario.

With this thought, we hereby present to you

SURGE IN FIXED-DOSE COMBINATION DRUGS: NEED FOR DATA EXCLUSIVITY PROTECTION IN INDIA

AUTHORED BY - ADVOCATE AVIRAL CHANDRAA

Recently, India rejected the European Free Trade Association (EFTA) nations' demand to keep the 'data exclusivity' provision in the free trade pact as it would be detrimental to its generic drug industry's interests. India, however, for over a decade, has been consistently against the inclusion of data exclusivity provision in FTAs.

The pharmaceutical industry of India is considered to be the most flourishing industry across the globe. The industry, particularly in India, is expected to reach $65 Bn by 2024 and $130 Bn by 2030. Indubitably, India has been conferred with the title of 'pharmacy of the world', being the largest provider of generic medicines globally. The conventional way of treating any disease is to provide a single pill tailored to cure that specific ailment; this method is known as Free-Equivalent-Combinations ("FEC"). In contrast to FECs, Fixed-Dose-Combinations ("FDC"), which are permutations and combinations of different pharmaceutical chemicals formulated into a single pill capable of treating multiple diseases simultaneously, have gained worldwide traction. Globally, more than one-third of all new drug products were FDC preparations and in the Indian pharmaceutical market too, FDCs have proven to be highly popular, particularly flourishing in the last few years.

However, Section 3(e) of the Patents Act, 1970 ("ACT") which describes what may not fall under the category of being a patentable invention, states that

"a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance."

Thus, considering the definition of FDCs, this provision renders them non-patentable. However, it is to be noted that not all FDCs are non-patentable. Those FDCs exhibiting a 'synergic effect' or 'surprising pharmaceutical reaction' do not fall within the purview of Section 3(e) of the Act. Effectively, FDCs can be patented if they primarily focus on drug efficiency, minimising dosage and optimising drug release formulations.

Challenges for FDCs' Development in India

FDCs play a significant role in public health as it can treat more than one disease concomitantly. It is invaluable for the patients who are being treated for complex and chronic diseases like tuberculosis and AIDS, which require a multi-drug treatment. Patients often forget to take different medication, thus causing impediment in their treatment and even harmful side-effects. Therefore, by reducing poly-pharmacy and pill burden, FDCs improve patient compliance. However, the challenge is that, if an incentive in the form of a monopoly does not seemingly exist, it is a curious question as to why pharmaceutical companies would be enthusiastic about treating chronic diseases through FDCs.

Furthermore, FDCs are also required to undergo clinical trials according to Rule 122E of the Drugs and Cosmetics Rules, 1945, which mandates clinical trials for 'new drugs.' As a result, the cost of FDCs increases without patent protection. This poses another hindrance for the pharmaceutical companies making FDCs. Essentially, this begs the question why companies would invest in clinical trials knowing that generic pharmaceutical companies may utilise their data to produce the same drug at a much lower price.

In order to remedy the reluctance of pharmaceutical companies to produce novel FDCs to avoid the free-rider problem the implementation of a data exclusivity regime is a pressing requirement. It confers monopoly for a certain period to the pharmaceutical company manufacturing novel FDCs and overpasses the requirement of Rule 122E of the Drugs and Cosmetic Rules, 1945 as well by establishing bioequivalence on expiration of exclusive period. By and large, this approach maintains the equilibrium between the economic rights of the pharmaceutical companies and the economic pricing of FDCs.

Incentivising FDCs' Innovation: The Role of Data Exclusivity

The lure of incentive serves as the primary motivation for the most of the pharmaceutical companies to develop life-saving drugs for chronic and imponderable diseases. Such incentives usually take various forms including patent protection and data exclusivity.

The notion of data exclusivity entails granting a period of exclusive marketing rights to the company that has produced a novel drug. Consequently, it carries two broad implications. Firstly, it offers the pharmaceuticals that have developed a novel drug with an exclusive period, thus preventing others

from manufacturing it. Hence, it effectively provides a first mover advantage to monopolise the production of that drug and recoup the costs associated with the clinical trial. Secondly, it eliminates the need for additional clinical trials to establish the bioequivalence of the drug, thus, profusely reducing the cost of the FDCs.

However, the data exclusivity regime is not applicable in India. Many Western countries assert that the data exclusivity regime is mandatory by virtue of Article 39.3 of the Trade Related Aspects of the Intellectual Property Rights Agreement ("TRIPS"), but developing and poor countries have rejected this assertion. For instance, in India, the Parliamentary Committee in its 88th Report on 'Patents and Trademarks System in India' stated that "*conceding to demand for data exclusivity would amount to agreeing to TRIPS-plus provisions." Consequently, adhering to the higher standards of intellectual property protection set by the developed nations.* It has also been argued that Article 39.3 of TRIPS mandates 'data protection' and not 'data exclusivity.' Pertinently, the Satwant Reddy Committee in its report on Steps to be taken by Government of India in the context of Data Protection Provisions of Article 39.3 of TRIPS Agreement rejected data exclusivity for pharmaceutical firms; while also acknowledging the necessity for India to gradually adopt higher standards of pharmaceutical data protection. Therefore, as things stand, the final recommendations of the committee on data exclusivity for 'pharmaceuticals' should be taken into account by the policy makers to fulfil the requirement of regulatory laws in India.

The Way Ahead

India's reluctance to adopt data exclusivity provisions in Free Trade Agreements is due to higher drug prices which ultimately affect drug accessibility. However, this can be mitigated by carefully designing the data exclusivity period to be sufficiently short to ensure early entry of generics while still providing adequate incentives for innovation. For instance, a data exclusivity period of 5-7 years could be adopted. This mechanism complies with the global standards on data exclusivity adopted by different countries and that protects public health interests as well.

India needs to revamp and overhaul its current Intellectual Property policy regarding FDCs. An incentive in the form of data exclusivity would be well-served as FDCs are not patentable under Indian law. However, the implementation of data exclusivity must be carefully balanced to ensure it does not stifle the availability of affordable medicines. Maintaining this balance will allow India to

uphold its reputation as the ‘pharmacy of the world’ as well as promote innovation in the pharmaceutical industry. In effect, a nuanced approach to Intellectual Property Rights that accommodates the need for innovation and public health can drive the growth of FDCs. This can ultimately enhance patient outcomes by providing more effective treatment options for complex diseases. The government, industry stakeholders, and policymakers must collaborate to create a robust framework that supports both innovation and accessibility in healthcare.