



Generic Drugs: An Analysis In The Light Of The Concept, History & Status

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Abstract

The attitude of the developed economies towards the health care is very much imperative in nature. Also the developed worlds are to a certain extent showing favourable gesture towards generic forms of drugs. The curious reason behind such a perspective might be the understanding that the generic drugs possess true potential to overcome the challenges that the health sector is facing in terms of accessibility of drugs to the people. This paper gives an insight towards the notion of generic drugs and its potential to overcome some of the setbacks faced in the health care sector. Also this paper has given weightage towards the growth of Indian Pharmaceutical sector in the market domain, especially in the crucial case of generic drug manufacturing. The author touches various aspects regarding the development of Indian generic drug industry and its historical elements. The author concludes his work with the thought that the generic drugs and the generic Drugs industry is a real boon to the health care as well as the economic sector of the nation. Even though it is an accepted fact, there are certain shortfalls which are very much visible in every corner. An effective plan to overcome these negativities is the need of the hour.

Key words: generic drugs, patent, health sector, pharmaceutical etc.

1.1 Introduction

On a foundational explanation, a drug means a scientifically originated compound for a specified purpose of handling a disease or a medical condition. The discovery of drugs is absolutely an inventive process of discovering new remedy for a specific diseased situation.¹ A Generic Drug can be defined as a type of pharmaceutical drug that is comprised of the equivalent or identical chemical substance that was in the first place protected through patents. The applicability of Generic medicines in day to day life of human beings is enormous. Generic Medicines can enable huge cost- savings as they create competition, driving down prices.² The usage of generic equivalents will substantially bring down the cost of medicines to both the state as well as the citizens.

Every prescription drugs holds two forms of names. The one is its generic name and the other one is its brand name.³ The names actually indicate contrastive peculiarities of common therapeutic objects. The Generic name indicates active chemical agent and some of the impressive attributes of the Generic drug as a chemical formulation are efficacy, safety, pharmacokinetics, and pharmacodynamics. The major focal point of the marketed drugs are market orientation and they possesses features like advertising budgets, high market shares, number of prescriptions sold, and investment return etc. The generic drugs are showcasing a model for amplifying rational therapeutics, while at the very same time the branded drugs are

¹ Bhupesh Taneja, Jyoti Yadav, Tushar K.Chakraborty and Samir K.Brahmachari, *An Indian effort towards affordable drugs: "Generic to designer drugs"*, BIOTECHNOL.J.2009,4,348-360 The Drug Discovery process can be broadly classified into two major categories : non-target -based empirical drug discovery and target -based rational drug discovery. The empirical or classical drug discovery approach has largely been dependent on serendipity and relies on physiological readouts of phenotypes and amelioration of disease in a particular assay system, e.g., the historical discovery of penicillin and the discovery of modern day viagra have been the result of good fortune. A rational target- based drug discovery approach, on the other hand , begins with identification of a possible target with a putative role in a medical condition of a possible target with a putative role in a medical condition. Technological advances in the field of genomics, proteomics and computational tools have been the main drivers of target -based drug discovery over the last few decades.

² Generic Medicines, *Interchangeability of WHO-Prequalified generics*, (April 03,2020, 11.05 A.M), https://www.who.int/medicines/publications/druginformation/WHO_DI_30-3_GenericMedicines.pdf?ua=1

³ Lloyd miller, *"Doctors, Drugs, and Names"*, JOURNAL OF AMERICAN MEDICAL ASSOCIATION (April 04, 2020, 11:30 A.M) <https://www.jstor.org/stable/24672098?seq=1>

often ridiculed as a tool of irrational prescriptions and deceptive promotions.⁴ The aspect of drug name and brand is considered as a weighting yardstick in maintaining the levels of therapeutic standards.⁵ The inquisitive question asked by Donovan Ward, former American Medical Association president through Medical World News shows the brand consciousness that then and now prevails. He asked his readers that, “do drug names concern the doctor?”⁶. As per his own words: “Of course, a physician may prescribe generically if he wishes, and I do, in cases compatible with the patient’s needs. But, to take a random example, when I prescribe digitalis, I must know who makes the medicine. The range between therapeutic dose and a toxic dose that too narrow for me to be able to sleep nights if I thought my prescription was being from a bottle simply bearing the generic label of an unknown manufacturer or marketing firm.”⁷

1.2 Generic Drugs and Brand domination: An analysis based on the Indian scenario

The curious case of India in the generic drug scenario is quite engrossing and an unavoidable subject of consideration. Indian drug development domain always eyed in the evolution and development of a much cost effective medicinal alternative.⁸ The rate and expense of drugs in India are appreciably subservient in terms of price compared to other countries like United States, United Kingdom, Indonesia, Pakistan etc.⁹. India exclusively holds a massive number of FDA approved manufacturing potential in any country outside the United States. Also she had spearheaded and succeeded in the development of commercially feasible technologies capable of producing a broad range of essential drugs such as anticancer, antiviral, anti-bacterial, anti- glaucoma, anti-inflammatory, analgesics and cardiovascular drugs.¹⁰ The growth of generics Industry in India is deeply beholden to numerous research institutes that contributed in the build out of the state -of- the- art technologies and process formulations for the making of the generic drugs. The springing up of these modern technologies catapulted the growth of the Indian Drug Industry to achieve the milestone of being the largest manufactures of generic drugs in the world. Relying upon one of the earliest account released by the Department of Chemicals and Petrochemicals through its annual Report during the year 2007-2008, India has a rough estimate of about 24,000 drug manufactures.¹¹ And the latest figure portrays a much significant increase. The status of the Indian Pharma Industry is topnotch around the world and conducting a twofold service to the world. I.e India is exporting a considerable quantity of Pharmaceutical products to the developed nations like U.S.A, U.K, Germany, Russia and Japan. Equally India is also competitively on a low cost supplying Generic Drugs to diverse less- developed countries like Nigeria, Vietnam, Sri Lanka, Pakistan, Bangladesh and Nepal.¹²

The legal scenario related to the Invention of Drugs and the allied aspects were also a little befuddled. One among the proper and long stood law related to the ambit of Patents were the Patents and the Designs Act of 1911 and later it was replaced by The Indian Patent Act of 1970 and the same brought in cardinal changes.¹³ As per the Patent Act of 1970 the ambit of product

⁴ S.H.Knutti, “How to Promote and Assure Rational Drug Therapy,” Mod. Hosp., 1959, 93, pp 86-89.

⁵ Jeremy A.Greene, *What’s in a Name? Generics and the Persistence of the Pharmaceutical Brand in American Medicine*, JOURNAL OF THE HISTORY OF MEDICINE AND ALLIED SCIENCES, (April 03,2020, 11:50 AM) <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.996.7745&rep=rep1&type=pdf>

⁶ Donovan Ward, “Why do Drug Names Concern the Doctor?” MED WORLD NEWS, pp 40-42 (March 1967)

⁷id.

⁸ Bhupesh Taneja, Jyoti Yadav, Tushar K.Chakraborty and Samir K.Brahmachari, *An Indian effort towards affordable drugs: “Generic to designer drugs”*, BIOTECHNOL. J. 348-360 (2009) , “Domestic pharmaceutical companies have traditionally thrived on innovating process patents and by utilising low labor and research costs to export generic drugs to markets in developed countries, including the United States.

⁹ Agarwal, S.P.Gupta. A.Ashwani, Dayal, R., *Technology transfer perspectives in globalising India (drugs and Pharmaceuticals and bio technology)*. J. TECHNO’S TRANSFER 32, 397-423 (2007)

¹⁰For example : Sultamicilin, azithromycin, norfloxacin and ciprofloxacin. “ Domestic pharmaceutical companies have traditionally thrived on innovating process patents and by utilising low labor and research costs to export generic drugs to markets in developed countries, including the United States. One of the land mark contribution made by the Indian Genetic Industry is that, It revolutionarily reduced the cost of antiretroviral therapy for HIV/AIDS treatment by the manual collaboration of institutions like the Indian Institute of Chemical Technology (IICT), Council of Scientific and Industrial Research (CSIR) and Indian Pharmaceutical companies like CIPLA. The combined effort of the institution aided the lives of many poor patients and more than 250000 HIV patents got access towards their essential drugs at a very affordable price. India became a nation who exports cheap active pharmaceutical Ingredients (API’S) and pharmaceutical formulations of numerous medicines, to motion vaccines and antiretrovirals (ARV’s).

¹¹ Annual Report , DEPARTMENT OF CHEMICALS AND PETROCHEMICALS 2007-2008, (April 23,2020, 08:15 P.M), <https://chemicals.nic.in/sites/default/files/annual%20report%20English%202018.pdf>.

¹² Even in the middle of all these scientific and market advantages in the Pharma sector, the part and portion of India in the World Market related to the Pharmaceutical Industry is less than 1.5% of a global sale of nearly US \$ 875 Billion. The presence and role of tire I leading international figures of the Industry and their confidence driven investments can act as a cure to the ironical setback that the Indian Pharmaceutical Industry is facing right now.

¹³ The ancient roots of the Patent can be unearthed along with the ancient Greek Civilisation. It is believed that the Ancient Greece is the place where the idea of patent earlier originated. In the Venetian Patent Statute of 1450 the earlier protection was granted were 10 years. It cannot be avoided that the principal contribution and the development of Patent law was happened in the Industrial Era. The unfolding of the Indian Patent regime happened through eventful and multiple stages and the Indian Patent law is highly indebted to the colonial roots. The first ever legal document that addressed the aspect of Patent in India was Act VI of 1856, which licensed exclusive privileges to the inventors in India. Later the Act of 1856 was revamped by the Act of 1859, which gave room for the British Patent holders to easily enjoy their exclusive privileges in India. Then emerged Patent and Designs Protection Act of 1872 which gave way to Protection of Invention Act of 1883, which further gave for a consolidation act of 1888. Aftermath of the 1883 legislation one of the longest standing statute law on the Patent came into force called the The Indian Patents and Designs Act of 1911, it further remained in force until independence. The still

patent on foods, pharmaceuticals and chemicals were not permitted, but only favoured process patents in these respective categories. The 1911 act owned a history of patenting pharmaceutical products that resulting in high price of medicines as controlled by a large group of multinational companies.¹⁴ The reshaping of the 1970 patent law gave boost to the development of the new process technologies and reverse engineering methods for the production of different essential medicines and the same ensured that this would bring affordable medicines in the market.¹⁵ One among the most mentionable changes happened as part of the revamp is the introduction of a Drug Price Control (1970). The purpose of such a control is to monitor the maximum price that could be charged for any drug. The establishment of drug manufacturing companies like Hindustan Antibiotics Ltd (HAL) and Indian Drugs and Pharmaceuticals Ltd (IDPL) in the Public sector reveals the attitude and support of the Government in the health care Sector. India's engagement with the production of modern medicines is also associated with the names Bengal Immunity Ltd (BIL), 1919, Smith Sain Street Pharmaceuticals Ltd (SSPL). The government had nationalised many of these Pharmaceutical companies. And the presence of state run pharmaceutical companies are also worth mentioning and they are Goa Antibiotics Ltd, Karnataka Antibiotics and Pharmaceuticals Ltd, Rajasthan Drugs and Pharmaceuticals Ltd.¹⁶ The National R & D institution by the CSIR, National Chemical Laboratory Pune in 1950, Central Drug Research Institute in Lucknow in 1951 and Indian Institute of Chemical Technology (IICT) in Hyderabad are good examples of government institutions with superior resources and quality enabled human resource for the production of Pharmaceutical drugs.¹⁷

1.3 Some ground breaking Achievements ¹⁸

As mentioned earlier, the role of National Chemical Laboratory (NCL), Central Drug Research Institute (CDRI) and Indian Institute of Chemical Technology (IICT) are cardinal in drawing a fabulous account in the global pharmaceutical market-front rejuvenating the Indian position in the development and sales of Pharmaceutical products.

The NCL has been instrumental in the expansion of numerous prominent technologies and methods that aids the manufacturing of drugs. Some of the prominent developments of NCL are that the Organic synthesis group of the NCL had formulated an economical and cost effective processes for anti HIV-agents (i.e., AZT, stavudine, lamivudine, cardiac and antimalarial drugs, etc.). The triumph of the NCL continued in the manufacture of epibatidine, a painkiller with a potential of 200 times effective than morphine, and a novel process using a zeolite catalyst for the manufacture of ranitidine, an anti-ulcerate and one of the leading drug in terms of sale. An alternative and much more economical technologies have also been introduced in the case of etoposide, atorvastatin, irinotecan, nevirapine, ziprasidone, cisapride, celirolol and multiple other major drugs.¹⁹

Like NCL the CDRI also successfully wrote some colourful history in the pages of Indian Pharmaceutical sector. The CDRI developed more than 100 solid and successful technologies for the bulk production of drugs, drug intermediates and biological/fermentation products. Parallel to the successful development of drugs and technology the CDRI has also been involved in the development of Generic equivalent of the Drugs.²⁰ Also the CDRI has partnered with so many celebrated names in the industry in the development of Drugs and the list includes CIPLA, Dabur, Hindustan Latex, Lupin, Nicholas Piramal, Torrent, Unichem and many others.

The role of IICT in spreading the share of Indian Involvement in the Global Market scenario was very crucial. The IICT contributed a major role in drug development and brought innovative and cost effective approach for AZT production and subsequently to other HIV inhibitors such as betzalladines, calanolides, miscalamines and HIV protease inhibitors. It has also contributed in the development of technologies for multiple drugs like diazepam, salbutamol, anti cancer drugs²¹, anti-diabetic drugs, anti-inflammatory drugs (enfenamic acid flurbiprofen), enalapril for high blood pressure and anti-bacterial agents²². Added to these achievements, IICT had successfully developed the process for pentamidine for the cure of Kala Azar (Visceral Leishmaniasis) and transferred the process to CIPLA.²³

prevailing law on Patent was emerged in the year of 1970 called The Patent Act of 1970 (that came into force in the year of 1972)

¹⁴ THOMAS J, INNOVATION IN INDIAN AND CHINA CHALLENGES AND PROSPECTS IN PHARMACEUTICALS AND BIOTECHNOLOGY : (D'Costa A.P. eds, Palgrave Macmillan London; 2009),pp,110-137

¹⁵ *Id*

¹⁶ Maggon, K., *New drug discovery and development in India*, *Drug News Prospects* (April 18, 2020, 10:28 A.M), <https://europepmc.org/article/med/23573553>

¹⁷ Over a long period of years the involvement of NCL, CDRI and IICT in the development of Quality Pharmaceutical drugs are really appreciable. The process technology for the production of drugs developed by these institutions re been followed and used by many top notch and small scale pharmaceutical companies

¹⁸ Bhupesh Taneja, Jyoti Yadav, Tushar K.Chakraborty and Samir K.Brahmachari, *An Indian effort towards affordable drugs: "Generic to designer drugs"*, *BIOTECHNOL.J.*2009,4,348-360

¹⁹ Some of the other major development that contributed by the NCL is the new and advanced process for biotin, one of the B- complex group of vitamins, NCL also exploring synthesis and purification methodologies for chiral molecules as drugs. NCL is also exploring synthesis and purification methodologies for chiral molecule as drugs. Some important industrial partners to whom technologies have been transferred for manufacture and marketing include Alembic, Cadilla, CIPLA, Dabur, Emcure, Glenmark, Godrej Agrovet, Lupin, Orchid Chemicals, Ranbaxy and PFG Life Sciences.

²⁰ Acyclovir (Ranbaxy), ephedrine hydrochloride (Malladi Drugs & Pharmaceuticals), dextropropoxyphene hydrochloride (Wockhardt), Pyriithoxin (Themis Chemicals), Clofazimine (Astra- IDL), 5,6 - dimethyl - benzimidazole (K. Methaqualone & Chemicals), and N- methyl piperazine, artemether (IPCA Labs)

²¹ For example : Vinblastine, vincristine, etoposide

²² For example : Sultamicilin, azithromycin, norfloxacin and ciprofloxacin.

²³ IICT has acted instrumental in the development of docetaxel, Taxol C-13 side chain (API intermediate) and several new anti cancer agents, Among various other technological advancement and achievements, IICT is also making efforts towards the

1.4 Towards the road to Innovation : A radical shift.

India is today a leading contender in the generic drug market around the world, a big thanks to the indigenously developed reverse engineering methods. More than 100 major drugs and 300 bulk drugs are being produced in India by making use of the cost effective technologies. The prior approach of patents facilitates the procurement of Indian generics industry by enhancing reengineering of existing high priced drugs by alternate processes. The involvement of national R& D institutions and their ground breaking technologies boosted the scope of large scale production of drugs through reverse engineering methods. The emergence of changes in the Patent law of India paved a way for a radical change. India obliged towards WTO norms has renamed its Patent regime and hence allowed patenting rights to both products as well as process. This created a situation where the Indian drug companies were prevented from selling drugs patented by other firms unless they are licensed to do so. This very factor sowed the seed of innovative thinking in the discipline. The Indian Pharmaceutical domain, which once developed cost effective drug alternatives solely through the process of reverse engineering changed its phase by stepping in to the development of innovative technologies for the production of Drugs.

1.5 Drug Discovery in India.

One of the predominant success stories that decorated the history of Indian drug discovery is through the discovery of urea stibamine and its effective application for the treatment of *kala-Azar* in the year of 1920 by Prof. U.N. Brahmachari. The drug discovery experience of India had witnessed the emergence of several group of scientists in national R&D institutions and in academia who wrote success stories in the development of cost-effective drugs and technologies for purpose of treatment. Indian scenario of Research and Development was very much vibrant and potential in nature. The Drug and Pharma Research Program (DPRP) of the Department of Science and Technology (DST) have been very much instrumental in developing innovative research in the domain of drug discovery.²⁴ Another initiative is the Millennium Indian Technology Leadership Initiative (NMITLI) program of the CSIR, which also aimed to revamp the partnerships between the public and privately funded R&D institutions. One of the most acclaimed achievements of the NMITLI program was the global win in developing a nova; therapeutic molecule for TB and that was a breakthrough achievement after a long waiting of more than 40 years.²⁵ The advancement and furtherance of lysostaphin as a biotherapeutic under the cooperative efforts with Institute of Genomic and Integrative Biology (IGIB), CDRI and Bharath Biotech is also considered to be one among the commendable achievement of NMITLI scheme. In the earlier times the development of lysostaphin as a therapeutic agent faced a major roadblock over the period of time due to potential immunogenicity of a parenterally administered protein and the disablement of lysostaphin preparations.²⁶ This problem was later tackled by the NMITLI program, the IGIB had developed a progressive technology for recombinant mature lysostaphin and later licensed to the Bharath Biotech to obtain lysostaphin that is considerably pure, free from pre-pro and pro-lysostaphin and the same can be produced in large quantities from *E. Coli*. The scientific studies had proved that the respective drugs are efficacious and successful in restraining topical infections created by the drug resistant strains of *Staphylococcus aureus*. This formulation is considered to be the first ever biotech molecule to clear Investigational Drug Application in India. The NMITLI program founded on the traditional medicinal system had developed poly herbal formulations, for ailments like diabetes, arthritis and hepatocellular protection.

1.6 The therapeutical use of protein: An Indian Contribution

India took a remarkable step in the utilisation of protein as a therapeutics and successful development and prompt marketing of clot-dissolving agents.²⁷ The expansion of an economically effective technology aimed at the development of therapeutic grade streptokinase by the IMTECH, Chandigarh is a big step in the drug development domain. The IMTECH, had transferred the respective technology to Cadilla for the purpose of development and marketing in Indian under the name 'STPase'. The IMTECH had also taken further successful steps in the creation of an engineered clot-specific streptokinase that becomes active when it encounters the blood clot. This respective technology for the purpose of global clinical development and commerce later transferred to Nostrum Pharmaceuticals. Along with all these developments, Bharat Biotech and Shantha Biotech have also pioneered separately in the development of the recombinant streptokinase for the therapeutic usage.²⁸

creation and development of technology for cost effective synthesis of pure chiral compounds. Timolol maleate, an anti glaucoma agent was the first chiral drug successfully developed at IICT in the year of 1989 and transferred to FDC Ltd. IICT has a mentionable list of collaborations and technology partners that includes Armour Chemicals, Bombay Drug House, Cadilla, Cheminor Drugs, CIPLA Coromandal Pharma, Dabur, IDPL, Indus Pharma, Lupin, Nicholas Piramal, Ranbaxy, Reddy's Laboratories, Sun Pharmaceuticals, Torrent Pharmaceuticals, Unichem, Zydus and many others.

²⁴ One of the potential service and aspiration of the DPRP to the industry and the academia is nothing short of development of new drug formulations and creation of infrastructure to facilitate drug discovery. The DPRP has a vivid collaboration with so many prestigious research institutions and numerous industry stakeholders. And the combined effort of all these collaborations had successfully resulted in the development of various diseases like malaria, TB, cardiovascular diseases, hepatitis B, dengue, etc.

²⁵ NMITLI program during the time of its formation and development, it joined hand in hand with more than 12 international knowledge partners and Lupin Laboratories as the industry partner and they were very much ambitious for the formation of new targets, drug delivery systems, bio enhancers and therapeutics. They have successfully developed a new chemical molecule called Sudoterb (LL-3858), the main function of the said molecule is for the treatment of TB and the molecule was impressively successful enough to work as a successful alternative by replacing some other existing medicines. The toxic rate of the medicine was also less in nature compared to its counterparts.

²⁶ To define Lysostaphin is a 27-kDa glycyglycine endopeptidase created by *Staphylococcus simulans* that destroys all the strains of *staphylococcus* by splitting the pinta-glycine bridges that joint the peptidoglycan in their cell walls. Due its natural peculiarities especially its rapid and distinctive mechanism, the lysostaphin has the potential capacity to be used as a first-line substitute for the treatment of *S. Aureus* infections.

²⁷ one of the prominent example for the use of protein is streptokinase.

²⁸ The respective medicines are marketed under the trade name Indikinase and Shankinase.

REGEN - D is another prominent Indian name developed by the IGIB by drawing protein component as a therapeutic agent. The significance of the said medicinal compound is for the treatment of diabetic foot ulcers, burns and skin grafts. The marketing of REGEN -D was by the Bharat Biotech.

Along with the synthesis of protein components, India had tremendously thrived in the utilisation and experimentation of natural products. The IICB had ascertained certain natural components like dihydrobetulinic acid, luteolin, diospyrin and indoxyl quinolines as inhibitors of leishmania topoisomerase. The brilliant researchers at the IICB had invested their expertise and deduced some herbal formulations obtained from *M. koenigii* and *Tribulus terrestris* and the same is proved very much practical in the treatment of prostate cancer. The brand name of the said medicine is 'Prostalyne'. Another development of the IICB is a molecule isolated from the flowers of *Woodfordia fruticosa*. The use of the molecule is mostly in the treatment of peptic ulcers. The development of two antimalarial compounds from mussels, 'NIO-1' and 'NIO-2' through the collaborative efforts of scientists at National Centre for Cell Sciences (NCCS), National Institute of Oceanography (NIO) AND international Centre for Genetic Engineering and Biotechnology (ICGEB) have been recognised as very-much applicable against the *Plasmodium falciparum*.

1.7 The status of Generic Drugs

In America, prescribing generic drugs by the medical practitioners over the costly branded drugs are a federal concern. During the period of 1960's, the United States senators Russell Long (D-LA) and Joseph Monroney (D-NM) had introduced a bill for the utilisation of federal programs to implement prescribing by generic drug name and to endorse the switching of generic alternatives in the place of branded drugs at the pharmacy. Also Senator Gaylord Nelson (D-WI) had condemned the tendencies of the American physicians to commonly prescribe expensive brand name drugs when cheaper equivalent generic drug are available.²⁹ The Pharmaceutical Manufacturers Association (PMA) and the National Pharmaceutical Council (NPC) had criticised this move of generics and rebutted that the generic drugs cannot be equated with the branded drugs. William C. Cray the then chief of public relations for the PMA had even commented that, "there is really no such thing as a 'generic' drug; all drugs were made by a manufacturer and therefore carried the reputation of that firm"³⁰

Scientifically speaking Generic Drugs are pharmaceutical commodities/goods/inventions that contain the similar chemical compositions of a drug that are protected through patents. The industry in the Pharmaceutical segment is considered to be one among the largest in terms of revenue and profit making. Man's unparalleled need for medicines for his living purposes are the real fuel for the Pharmaceutical industry in its aggressive pursuit for growth. The Generic Drug industry is as competitive as its counterparts. The entry of Generic Drugs to the Indian pharmaceutical eco system had already marked multiple anniversaries. Now India is a key player in the international market regarding Generic Drugs.

1.8 Conclusion:

The growth statistics of the Generic Industry never means that the field is away from issues and challenges. The scheme and intention of a generic drug industry is more on accessibility and affordability than commercial. It is more of a social cause than trade and business, but the rudimentary reason upon which the concept build still stays in darkness or not is a matter to be pondered with. It cannot be conclusively affirm the fact that the Generic Drugs are for charity, it also pursue a commercial value. U.S pharmaceutical market is a predominant example for the exploitation of the said commercial value of the Generic Drugs. In India also the Generic Drugs are considered as a hot pie that expands its scope to the global market. But acknowledging the existing situations and the climate of the industry, how far the generic drugs satisfy the needs of the millions in achieving the much essential goal of "access to medicines."

In the social front, the Generic Medicines and its allied aspects are circulated with some predicaments needs to be subscribed for identifying the solutions. The impact extended by the issue and accessibility of Generic Drugs are not uniform as per the social conditions of our country. So what kind of an impact does the circulation of Generic Drugs in the social stream has achieved? Whether it is a positive impact or a negative impact? It is the undeniable duty of the governments to ensure proper measures to defend the health needs of its people. Considering Generic Drugs as a measure to tackle the issues surfacing in the access to medicine regime, how far the central and the state governments guarantee the fluidic working of the concept? Lack of awareness about generic drugs is a mammoth social problem that needs to be encountered and in achieving the same, to what extent the respective governments took measures? Considering Indian economy as a specimen, the very concept of Generic Medicine widely opens several issues to be addressed and demands certain pragmatic solutions. After the Novartis³¹

²⁹ Gaylord Nelson, Opening Statement to the United States Senate, Select Committee on Small Business on Monopoly", Competitive Problems in the Drug Industry, 1967

³⁰ Jeremy A. Greene, *What's in a Name? Generics and the Persistence of the Pharmaceutical Brand in American Medicine*, JOURNAL OF THE HISTORY OF MEDICINE AND ALLIED SCIENCES, (April 03, 2020, 11:50 AM) <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.996.7745&rep=rep1&type=pdf>, During the period of 1970's multiple refutations and counter statements were released against the Generic Drugs. Some of the notable comments that substantiate the respective arguments are, "Strictly speaking, there is no such thing as a 'Generic Drug'", quoted by Harry Wiener of the Pfizer's, Benjamin Wells who belongs to the NPC had commended that, "every drug product, regardless of the name we give it, has been made by someone".

³¹ Novartis A.G.v. Union of India (2013) 6 SCC 1, The judgement rendered by the apex court in the Novartis case was celebrated across India as a revolutionary one in assuring the reach of life saving medicines to the hands of poor and the needy. The decision of the court acted as a bolt from the blue for the pharmaceutical companies against their aggressive and vested "Patent Ever greening" measures to win a market domain and excessive profit. The court critically examined the scope of Section 3(d) of the Indian Patent (Amendment) Act of 2005 and decided against the Petitioner by denying the patent application filed by the Novartis A.G by examining that the concerned case is ceased of an invention, so the question of patentability is out of concern and cannot permit any patent.

case the Indian legal scenario had changed considerably. India reached to an unprecedented low score in the global IP climate charts and the front runners who own the top markets started condemning our IP credibility. It affected the economic scenario and whether the existing trend will disturb the notion of access to medicine to the unprivileged mass of this country is also a prime question to be answered.

Legal scenario regarding the Generic Drug deserves a revisit. It is to be identified that the policies and the global commitments shaped in the pharmaceutical industry will distraught the constitutional rights and directives. And if any valid reasons that destroys the spirit of growth in the generic drug industry is identified then an appropriate action is very much in need. The state along with its stake holders must act before it is too late.

