International Journal of Research in Social Sciences
Vol. 6 Issue 11, November 2016,
ISSN: 2249-2496 Impact Factor: 6.278
Journal Homepage: http://www.ijmra.us, Email: editorijmie@gmail.com
Double-Blind Peer Reviewed Refereed Open Access International Journal - Included in the International Serial Directories Indexed & Listed at: Ulrich's Periodicals Directory ©, U.S.A., Open J-Gage as well as in Cabell's Directories of Publishing Opportunities, U.S.A

'DATA EXCLUSIVITY' AND IPR POLICY: INDIAN CONTEXT

Prof Vinod Sople[1]

Abstract

Data Exclusivity is about the test data that indicates safety and efficacy of a drug, which is required by regulatory authority for marketing approval. The data exclusivity matter is controversial and each side has their own valid points. However, we cannot ignore the major issue of the accessibility and affordability of the life saving drugs to millions of people in developing countries. The benefits of the new drugs are known to public only after trial data is generated which indicates drug's safety, quality and efficacy to the satisfaction of regulatory authorities. The process of generating test data is time consuming and costly. For example clinical trial process to test the efficacy, quality and safety of a new anti-cancer drug may take 6-7 years or in some cases exceed 10-12 years. Hence, protection of test data is key to company decisions on the locations of clinical trials. Patent protection and data exclusivity are two separate issues and to be viewed with separate perspectives of promoting innovation and accessibility to affordable generic drugs by common people.

Key words: Clinical Trials, Generic Drug, Evergreening, Efficacy,

1 **Prof Vinod Sople, Director, ITM-SIA Business School, Mumbna**

Introduction

Globally 'data exclusivity' is a topic of debate in pharmaceutical area due to tussle among MNCs in developed countries and domestics pharmaceutical businesses in developing countries. This tussle is for a test data that displays drug's safety and efficacy that is required by regulatory authority for marketing approval. Data exclusivity is also linked to the affordability of life saving drugs to the tens of millions of human beings in developing countries. Data exclusivity is the important thing to protection of public fitness and the pharmaceutical sector's work on generating test data after conducting field trials which are time consuming and involves huge expenses. In phama sector mere discovery of new drug is not sufficient enough to ensure the product safety and efficacy to the marketplace, but needs field trial data for consumption of new drug by human being. The new drug is recognised by public after trial data is generated, which indicates drug's safety, quality and efficacy standards set by regulatory government. The safety of test data is prime to enterprise decisions as the development and bringing to market a new drug requires the originator to conduct pharmacological and medical studies and producing test statistics for submission to the Drug Regulatory Authority for marketing approval of the new pharmaceutical product.

Data Exclusivity refers to a guideline that drug regulatory authorities do not permit to take a look at information of the innovator company for use to register a generic version of that medicine in the market. It is supported by the fact that MNCs in pharmaceutical sector spend huge money and time on field trials of drug to assess the efficacy, safety and quality of the new product. This test is known as clinical trial which is performed on animals and human beings for longer time. For example these tests of new anti-cancer drug might take 6-7 years or in a few instances even 15 years. These tests are done at multiple locations across the globe on the cross section of the human beings.

The clinical trial may be very complicated and takes longer time and incurs huge expenditure. Then the regulatory authority examines the records in an effort to make certain that drug treatments is having safety, efficacy before it enters the marketplace. The regulatory authority then asks the innovator or originator drug maker to submit drug test data and information to assess the safety, efficacy and quality of the new drug.

In pharmaceutical sector test data is very crucial and it carries all information of medical trials of drug. This data is result of long time effort and investment into clinical trials. The MNCs think that it is extremely unfair to permit a third party (generic drug makers) to make a commercial exploitation of such records. The originator drug maker, which might be MNC needs such data to be protected for a certain period of time so as to prevent generic drug producer from using the same.

As the test data from original drug manufacturer is available, generic manufacturer do not conduct fresh clinical trials on their own. They mention that their drug is 'bioequivalent' to the drug that has already been cleared by the regulator. As a result, the fresh trials are not necessary and they can use test data of original drug maker and thus foreclose generics with referencing. With this in mind, regulators in US and EU have brought 'data exclusivity' provisions that ban drug regulators from using originator's 'trial data' in subsequent drug clearance programs of generics. However, this restriction is for a certain time period. Hence data exclusivity law prevents entry of generic drug producer till the time data exclusivity period expires.

Literature overview

The development of a new pharmaceutical drug or agrochemical, (Charles Clif, 2007), usually requires enormous trying out, inside the laboratory or in the field, on animals, human beings, flowers, or the surroundings, relying on the character of the drug or chemical. The way in which these tests are undertaken are governed by way of policies (Pugatch Meir Perez, 2008) set by drug regulatory authority. The improvement of a new drug requires statutory clearances (Prabuddha Ganguli, 2003) from regulatory bodies before a pharmaceutical product can enter into the market. The clearance for marketplace authorization through countrywide regulatory frame is based totally on clinical test data. The purpose (Erika Fisher Lietzan, 2015) behind this authorisation is to ensure that drug's with safety, quality and efficacy get into the marketplace. Data exclusivity suggests that it has to be independent (Manthan D Janodia, 2008) of patents. Patent is for product or process of its manufacture, while data exclusivity is about the clinical trials carried out in the field on animals and humans for human safety and drug efficacy. Hence, it is important to note that patents and data exclusivity are different. Data exclusivity was first added (Animesh Sharma, 2007) in US in

1984 to guard efforts (money and time) of authentic drug manufacturer in view of the motivational factor for triggering the innovation. US enacted Hatch-Waxman Act, which gives 5 yr data exclusivity for drug with new Molecular Entities (NMEs). However, in European nations, (Katarzyna Zbierska, 2005) it varies from six to ten years. One of the benefits of data exclusivity regulation is the help in getting direct funding from the other countries for development of newer drugs. With data exclusivity law the pioneer company can invoke legal movement immediately against a firm coming in market with the similar product.

The authorities of India has constituted a high stage inter-ministerial committee to discuss and take steps in evolving regulations on provisions of TRIPS Article 39.3 for the safety of test records (Manisha Singh Nair, 2004). As consistent with latest countrywide IPR policy, (Draft Dec 19, 2014) India has no provision for facts exclusivity.

Patents vs. Data Exclusivity

Data exclusivity is an independent intellectual property right and should not be mixed with patents protection. Under Data exclusivity rights data generated by the original drug manufacturer may not be referred to or used by another person or company for a specific period of time. However, it does not prevent another company from generating the data on its own on the similar drug developed. This right has been considered to be of critical importance by countries to provide the necessary incentives for companies to generate the necessary data which is requited by the authorities along with patent application for new drug.

The patent gives the IP right holder the right to exclude others from making, using, selling, offering for sale, or importing the patented product. Patent protection does not exclude the copier from running its own tests and submitting the results to the regulatory authorities. In absence of any intervening patents, a generic alternative may still receive marketing approval, provided that the generic manufacturer conducts its own clinical trials and independently seeks marketing authorization.

If the patent period of the particular drug has expired, the data exclusivity will act independently to delay the entry of any generic companies wishing to enter the market until the period of data

exclusivity is over. However, in many cases the period of data exclusivity may have no material effect if it is within the patent period, because exclusivity is covered under patent life.

Data exclusivity right is a much stronger right than a patent because, unlike patent law, there are no exceptions or flexibilities that allow governments to change the law as per circumstances or national emergencies. For example, if governments wants to exercise compulsory license, then data exclusivity may act as a barrier to compulsory licensing of a patent on the same product by preventing marketing authorization for a compulsory licensee. Data exclusivity is attractive to originator companies because unlike a patent, data exclusivity is automatic (rather like copyright). There are no separate fees for Data Exclusivity application or maintenance of the right. As against this there a limited scope exists in patent law for legal challenges, which are expensive to handle and to defend. For these reasons pharmaceutical companies are strongly support data exclusivity regulation. Even data exclusivity is extending beyond the patent term, the costs to companies is negligible to have it.

The benefits of data exclusivity are the additional incentives for the companies in the long run to protect the heavy expenses of R&D and field clinical trials. Data exclusivity helps companies to extend the original use of the product, where no patent protection is available. Data exclusivity provides an additional opportunity for originator companies to recoup their investments, where marketing approval is given late in the patent life, so that the protection extends beyond patent expiry.

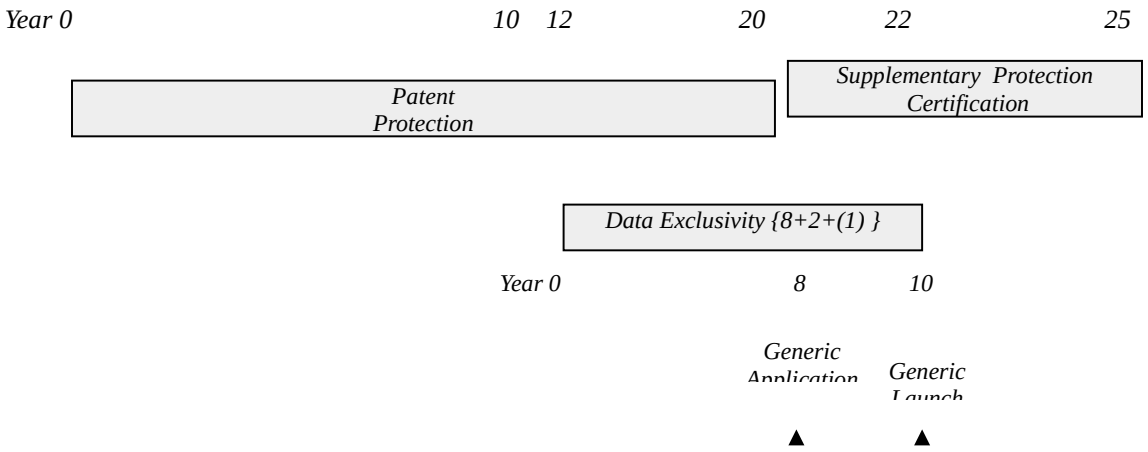

Figure 1: Patent and Data Exclusivity

In developing countries, where there is little or no innovative research capacity, the benefits of data exclusivity regulations are limited. In those cases, data exclusivity would not promote R&D and the benefits to the companies themselves. Here a potential addition to the R&D incentive, would be small because of the limited market potential in developing countries. However, data exclusivity would allow additional periods of exclusivity (Figure 1. http://gabionline.net/patents-and-exclusivity) for originator products, and it therefore would correspondingly delay the onset of generic competition. This results in keeping healthcare costs higher in developing countries in absence of generic drugs.

The protection of commercially valuable data held by governments is a duty of government. The guidelines are formalized in the TRIPS agreement, essentially to protect such data against unfair commercial use. However, Data exclusivity is a time-bound form of intellectual property protection. With data exclusivity provision by law the innovator companies authorized to recoup the cost of investment in producing data required by the regulatory authority. The effect of data exclusivity is to prevent the entry of generic competitors. It is independent of the patent life span of patented product. However, the costs and benefits of data exclusivity need to be considered in the context of bilateral trade agreements, particularly with the United States, where data exclusivity is likely to be part of the package of intellectual property measures governments are asked to accept.

Clinical Trial Data

Test data generation activity takes 8 to 10 years of hard efforts, before drug gets market authorisation as shown in Figure 2. The data generated in such work is proprietary to the originator and needs to be protected.

In Europe, under the 'old rules' data exclusivity lasted up to 10 years. However, the 'new rules' (From 2005) follows an '8 + 2 + 1' year approach (http://198.170.137/gen-dataex.htm) wherein from the grant of marketing authiorisation for the first 8 years data exclusivity is applicable. This means a generic company can make use of test data only after expiry of the 8 years and generic

company can market the generic formulation only after a period of 10 years, unless the innovator product qualifies for a further one year of exclusivity. In such a situation the generic company can only market their product after 11 years.

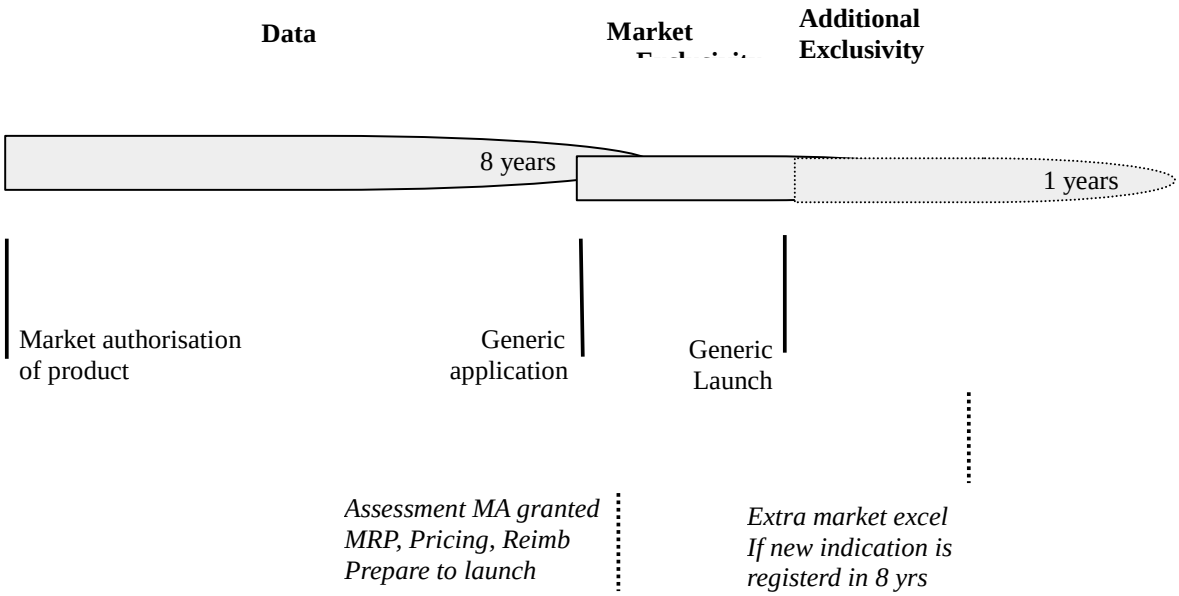

Figure 2: Data exclusivity formula(European Generic Medicine Association)

When the Indian government was in the process of introducing the 2nd Amendment to the Patents Act, 1970 in 2002, the MNCs had approached the government with the recommendation to introduce a data exclusivity provision in line with Article 39.3 of TRIPS. However, the government had refused to accept such request. The rationale behind this was to protect the common public so as to ensure affordability and accessibility of generic bio-eqavalants to them.

Implications - Data Exclusivity Law

The patent system is a good mechanism for stimulating and rewarding pharmaceutical innovations. Patents, as per law, last for 20 years, and the time taken for a new pharmaceutical product to go from patent application to regulatory approval is usually not less than 15 years. The patent systems, across many countries allow for the extension of the patent term for new drugs with delayed regulatory approval. A patent term extension extends the life of a patent by up to 5

years, so a five year data exclusivity period will usually expire before the patent monopoly.

According to a study on the effect of data exclusivity laws in the Europe, very few high-selling drugs gain further marketing monopoly from the provision of data exclusivity post approval. This was especially so where the patent term had been extended via an EU supplementary protection certificate (SPC). Drugs gaining significantly from data exclusivity were usually those which were unable to get an SPC or those which took an exceptionally long time to gain regulatory approval.

A patent on a new use or 'indication', formulation, salt or ester can block the registration or marketing of a generic medicine for treatments, where the original patent has already expired. This strategy is known as 'evergreening' aims to prevent or delay competition from generic medicines by extending market protection through patents on minor changes to the original product. However, India Patent law as per Sec 3(d) do not grant patents to new use or 'indication', formulation, salt or ester of the existing patented pharmaceutical formulation as these minor changes are termed as discoveries and not the inventions and are not eligible for grant of patent.

'TRIPS' on Data Exclusivity

WTO's (World Trade Organisation) agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) stipulated certain guidelines with regards to data exclusivity under Article 39.3. The guidelines are for countries to protect against 'unfair commercial use' of confidential data submitted by pharmaceutical/chemical companies to regulatory authorities on their new products to obtain marketing approval.

Article 39.3 is important because TRIPS guidelines are linked to the trade advantages for WTO members. However, all WTO members have not enacted data exclusivity laws as per guideline. This is because, Article 39.3 allows discretion to member on enactment. It does not specify a minimum term of protection. It is not clear in the guidelines that whether "unfair commercial use" includes use of the originator's data by the regulatory agency, while considering applications by 'generic' manufacturers. If original data is used by regulatory authority during evaluation of

application of the generic competitor and data is not disclosed to applicant then it does not comes under the purview of 'unfair commercial use'. Under this interpretation, Article 39.3 does not require data exclusivity. On the other hand, the research-based pharmaceutical industry, the United States Trade Representative and others have argued that Article 39.3 does require data exclusivity. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products, which utilise new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, members shall protect such data against disclosure, except where necessary to protect the public or otherwise steps are taken to ensure that the data is protected against unfair commercial use.

Data exclusivity is an administrative protection that can be implemented without any legislation. Requiring the government to treat test data as the exclusive property of the firm for a fixed period of time is an effective method of providing protection for the creative work of scientists. In practice, data exclusivity requires each company to fully test its products. Reverse engineered drugs are not always the same as the original, as different manufacturing processes can alter the drug in ways that could impact public health. Simply relying on another company's data is not only unfair business practice, but it also discourages R&D investments and is a potential public health danger.

Global Scenario

Nearly all advanced nations have 'data exclusivity' provisions for the chemical and pharmaceutical formulations. US is the first united states inside the world to offer legal sanctity to data exclusivity in 1984. It enacted Hatch-Waxman Act, which affords a 5 yr data exclusivity for brand new Molecular Entities (NMEs). In European, it varies from 6 to ten years in different countries.

The motives for having records exclusivity provisions in are:

- preserving balance between the pioneer customary drug industry.
- keep away repetition of costly clinical trials that have already established the drug safety and effectiveness.
- incentivising a new drug development in absence of patent protection

- avoid trial on animals because of duplication of tests will be avoided.
- obviate facet consequences to the human topics due to repetitive trials.

The countries across the globe comply with different data exclusivity intervals set by their respective regulatory authority (Refer Table 1).

Table 1: Data Exclusivity Period - Global Scenario

Country	**Data Exclusivity**
Australia	• 5 year data exclusivity period for new products containing pharmaceutical actives under Therapeutic Goods Amendment Act, 1998
China	• 6 years of data exclusivity as from the date of marketing approval, under Article 35 of the Implementing Regulations of the Drug Administration Law of 4 August 2002.
Europe	• 10 years to the corresponding European First Marketing Authorisation Date (Belgium, France, Germany, Italy, Luxembourg, Netherlands, Sweden, United Kingdom). EC directive 2001/83/EC prevents regulatory authorities from accepting applications for approval of generics that rely on this data until a data exclusivity period has expired.
Europe (Others)	• 6 years to First Marketing Authorisation Date (Austria, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland,Greece, Hungary, Iceland, Ireland, Latvia,, Lithuania, Malta, Norway,Poland, Portugal, Romania, Slovakia, Slovenia, Spain)
India	• No provision for data exclusivity
Japan	• 4 years (for medicinal products with new indications, formulations, dosages, or compositions with related prescriptions) to 6 years (for drugs containing a new chemical entity or medicinal composition, or requiring a new route of administration) to 10 years (for orphan drugs or new drugs requiring pharmaco-epidemiological study).
USA	• 5 years as established by Hatch-Waxman Act for new drug applications for products containing chemical entities never previously approved by FDA either alone or in combination with other chemical entities. The data exclusivity period begins on the

	date of marketing approval • In addition to the above exclusivity provisions, a 3 year data exclusivity period was also established by the Hatch-Waxman Act for supplementary applications in relation to a chemical entity that has been previously approved, where the application contains reports of new clinical investigations (excluding bioavailability studies). • In addition to the above exclusivity provisions, the Food and Drug Administration Modernization Act (FDAMA) was legislated on 21st November 1997, and introduced a 6 month period that can be added to any existing data exclusivity or patent protection on a drug for which FDA has requested paediatric studies and the manufacturer has conducted such studies in accordance with the requirements of the Act. • In addition to the above the Hatch-Waxman act provides an incentive of 180 days of market exclusivity to the "first" generic applicant to challenge an Orange Book listed patent by filing a substantially complete ANDA containing a paragraph IV certification and running the risk of having to defend a patent infringement suit.

(Source: https://www.genericsweb.com/How_to_Calculate_Standard_Patent_Expiry_Dates_and_Data_Exclusivity.pdf

In united kingdom, a common drug applicant can depend upon test facts submitted on new drug by the producer as soon as the data exclusivity duration referring to a selected drug has expired. The 2005 rules standardises the data exclusivity period across the EU community as 5 to 8 years from the date of initial authorisation inside the EU countries, for all the new drug products granted authorisation after October 30, 2005. Previously, durations of six and ten years (and in a few instances even zero years beyond patent expiration) have been in force throughout EU countries. Despite the fact that data exclusivity expires after 8 years, a generic product cannot be placed in the marketplace until 10 years after initial authorisation of the original drug. Data exclusivity is an administrative protection, which can be without difficulty implemented without the passage of law, requiring the government to treat test records as belongings of the firm that generated it, (for fixed period), is an effective method of offering protection.

As such, TRIPS Article 39(3) does not directly talk "data Exclusivity" but on "unfair industrial

use" and it is this word this is interpreted by way of MNCs as containing "data exclusivity" provision to include exclusivity in law.

Exclusive Marketing Rights

According to the TRIPS Agreement, developing nations were to extend patent protection to hitherto unprotected sectors at the end of a transitional period of 10 years (from 1995 to 2005). For this countries were required to take certain steps by 1995, including the granting of exclusive marketing rights (EMRs) to protect the intellectual property of inventors. In line with amendments to Indian Patents Act, 1970, the EMRs were granted to companies to meets certain conditions of this provision. This was more important for drugs and food products, where product patents had not yet been granted in India, and only process patents were in existence. The EMRs provide exclusive rights only to sell the product, unlike product patents, which give exclusive rights to manufacturers as well.

In US context data exclusivity means a period of exclusive marketing rights granted to a new drug application (NDA) upon obtaining marketing approval by the regulatory authority if certain statutory conditions are met.

The regulatory bodies require the pharmaceutical companies to submit extensive data establishing the safety and efficacy of a new drug before approving it for sale. This data arises out of many years of research and clinical trials and is the most expensive part of drug development. In EU & US 'data exclusivity' laws prevent the regulatory bodies from accessing the originators data, when considering an application for a generic competitor seeking approval to sell an equivalent competing product. Thus in the countries, where data exclusivity is granted and the regulatory authorities can take up the applications for generic versions only after the expiry of data exclusivity period. Alternatively, the competitor is required to generate his own marketing approval data. The period of data exclusivity is provided by the national legislation of a country and as such there is no uniform period.

Article 39.3 of TRIPS states that "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical

entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition members shall protect such data against disclosure, except, where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

Under 'unfair commercial use' the US and EU have clear understanding that the data exclusivity laws are required, however, the others have been of the view that regulators cannot disclose this data to generics and that use of this data by regulators as opposed to generics (in research) cannot be described as unfair commercial use. However, TRIPS provision in the Doha Declaration, allows considerable flexibility to countries to interpret its provisions in a manner that balances the interests of public health.

Indian law - Public Health and Data Exclusivity

The Indian Patent Act, 1970 does not include any data exclusivity rights. In line with TRIPS provision, which obligates the protection of 'undisclosed check facts', no provision of Indian law permits the drugs Controller of India (DCGI) to reveal this information to general producers. In addition WHO (world Health Organisation) on intellectual assets rights, innovation and public health, opposes the creation of data exclusivity in developing countries wherein markets have a limited capability to pay and little innovative potential to help their position. As per report of Satwant Reddy Committee, set up in 2007 to review India's compliance with TRIPS Article 39, 'data exclusivity' is not mandated and Indian laws have been enough to meet India's trips obligations.

It is genuine that data exclusivity measure is necessary to incentivize pharmaceutical innovation and provide returns to originator businesses for their investment in drug development and trials. However, in data exclusivity regulations there is a danger in delaying the entry of low priced generic drug into the market. For example one hundred forty medicines used in treating persistent sicknesses in Jordan, wherein 16 % them had no opposition from generics and that "originator drug makers have been relying specially on the usage of data exclusivity as opposed to patents to prevent conventional competition." This highlights the actual risk that data exclusivity poses and hence the country's patent system needs some provisions for balancing of

public interest with the profitability on invented products.

Drug Accessibility and Public health

In India generic drug manufacturers and public interest corporations are against data exclusivity regulation. It is because that with the data exclusivity regulation Drug Controller of India (DCI), which is regulatory authority, can be barred from to take a look at records, submitted by pharmaceutical giants, in granting marketing clinical trials on their own to assess the efficacy and safety of the generic version of the original drug. As such, field test is time consuming and requires huge investment, which the small businesses may not be able to do due their financial constraints. However, with working of innovator organization's test data, there could be sizable saving on cost and time and this help them in pricing their drug in inexpensive range to the common people for accessibility.

With data exclusivity law in force, smaller companies clinical trials will put off the process of arrival of life saving drugs at less price within the marketplace due to monopolization of the MNCs. Currently, Indian generic drug companies export large amount of life saving drugs to other developing countries at lower price. Any time delay in introducing new drug with affordable price could have an effect on the common people around the globe. In nutshell, data exclusivity law could have negative effect on public fitness. The absence of less expensive generics will place many existence saving capsules out of the reach of patients suffering with deadliest illnesses such as HIV/AIDS, diabetes, most cancers and Alzheimer sickness etc.

TRIPS Article 39(3) does not mention anything on data exclusivity. It talks on “unfair commercial use” of the drug test data. The pharmaceutical giants (MNCs) are misinterpreting Article 39(3) and construing “unfair industrial use” as “data exclusivity” with the only reason of monopolizing the drugs and maximizing their sales keeping aside accessibility of medicines for the poor.

In view of the forgoing arguments, the term “unfair business use” in Article 39(3) does not obligate implementation of data exclusivity law by WTO member. Hence, Indian authorities have also made clear that it has no obligation to put into effect data exclusivity law. This is in

view of the fact that, 6.5 million humans around the world urgently require HIV remedy and only one third of them are are receiving therapy. The data exclusivity law will significantly limit access to AIDS remedy globally. For example, in Guatemala, in 2004, Atazanvira drug utilized in HIV treatment, priced at USD 10,000 for consumption in steps with 12 months. It obtained data safety for five years under the regulation of the Guatemala authorities. Due to regulations Atazanavir drug (generic version) could not be put into the Guatemalan market until 2009. As a result accessibility to Atazanavir by affected patients was significantly constrained.

In fact, data exclusivity regulation might led to ever greening (Faunce TA, 2008)) of patent. The innovator agencies will make minor modification of their drugs and will get it blanketed underneath data exclusivity regulation. Data exclusivity will inspire funding in enhancing existing drugs in place of inventing new one. If data exclusivity is allowed, say for five years, and a patented drug is introduced within the seventeenth year of patent life, it will be able to increase the patent to seventeen plus 5 equaling 22 years and hence crossing the restriction of patent expiry of 20 years.

The data exclusivity will prevent the registration of well-known version of drug treatments even wherein innovator product lack patentability. For instance, whilst a pharmaceutical product does no longer meet the same old of patentability or whilst no patents are granted, the test data nevertheless comes under “data exclusivity” purview. For this reason, pharmaceutical giants will get protection of both patented in addition to non-patented products and it might amount to double safety. The data exclusivity regulation can stop the supply of drug under 'Compulsory Licensing' (CL) in Indian Patent Act. CL is enforced under positive conditions such as while patented drug is in insufficient quantity or when the price is out of reach of common person or when it is required for the treatment in extreme urgency or emergency. If data exclusivity is enforced, the 'Compulsory Licensing' cannot be implemented as data exclusivity law will act as a barrier to marketing approval for drug produced under CL. This will defeat the purpose behind the provision of 'compulsory licensing'.

Conclusions

The topic of data exclusivity is debatable as several different issues are connected to it.

The debate revolves around the interpretation of TRIPS Article 39.3 by developed and developing countries. The data exclusivity is controversial and each side has their very own legitimate factors. However, the major concern of the accessibility and affordability of the life saving drugs to millions of people in developing and under developed countries cannot be ignored. The rigid stand from both side will have an adverse effect on the common people.

The possible method to resolve the problem is to undertake the compensatory liability responsibility (Monirul Azam, 2016). Generic manufacturers should compensate the originator for the usage of the test data until the time the expenses on development on that drug is recovered. The compensatory liability model seems to be suitable as this would make data user to bring the new drug to the market at reasonable price without spending on field tests and the innovator will be able to earn on its investment. However, the amount of compensation should be affordable and have to be well inside the monetary limits of generic manufacturers.

The compensatory liability model (Jerome H. Reichman 2009) will fulfill both the requirement, however both the groups needs to reach an understanding. Compulsory Licensing ought to be supported by exclusivity regulation so that it should no longer be weighed on profit and should support hundreds of thousands people in developing countries for drug accessibility and affordability.

It would be wrong to ignore that intellectual assets protection and public fitness are inherently against each other, but, each can co-exist and support every other. Here needs flexibility approach to problem fixing.The fact to be kept in mind that 'The Indian Constitution' objectives are to create socialist welfare country. The fundamental rights and directive principles obligate government to deal with the difficulty in touchy manner. It should be kept in mind that proper health fitness is part of right to live healthy is guaranteed under Article 21 of the charter.

References

1. Animesh Sharma, (2007) Data Exclusivity with Regard to Clinical Data, The Indian Journal Of Law And Technology Volume 3, 2007

2. Clift C, (2007) Data Protection and Data Exclusivity in Pharmaceuticals and Agrochemicals, in Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices edited by A Krattiger, R T Mahoney, L Nelsen, et al. (MIHR: Oxford, UK and PIPRA, Davis, USA) p 434, www.ipHandbook.org.

3. Erika Fisher Lietzan, (2015) The Myths of Data Exclusivity, Lewis & Clark Law Review, Vol. 20.1, University of Missouri School of Law Legal Studies Research Paper No. 2015-22, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2653770.

4. Faunce TA, Vines T, Gibbons H. (2008) New Forms of Evergreening in Australia: Misleading Advertising, Enantiomers and Data Exclusivity, 16 Journal of Law and Medicine 220-232. http://law.anu.edu.au/StaffUploads/236-JLM%20evergreeningapotex09.pdf, also available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1405024

5. Jerome H. Reichman (2009) A Compensatory Liability Regime to Promote the Exchange of Microbial Genetic Resources for Research and Benefit Sharing, Designing the Microbial Research Commons: Proceedings of an International Symposium.

6. Katarzyna Zbierska, (2005) Distinctions between the European Union and the United States on Data Exclusivity, Abstract of LLM thesis - Munich Intellectual Property Law Centre.

7. Krishna Ravi Srinivas, (2008) Test data protection, data exclusivity and TRIPS: What Options for India? http://papers.ssrn.com/sol3/papers.cfm?abstract_id=935847

8. Manthan D Janodia, Ajay Chauhan, Shuaib M Hakak, D Sreedhar, V S Ligade and N Udup, Data Exclusivity Provisions in India: Impact on Public Health Journal of Intellectual Property Rights, Vol 13, September 2008, pp 442-446

9. Manisha Singh Nair, Data Exclusivity – The Indian Perspective, September 2004, http://www.mondaq.com/article.asp?articleid=28531.

10. Monirul Azam, (2016) Intellectual Property and Public Health in the Developing Country. Open Book Publisher

11. National IPR Policy, (Govt of India) http://dipp.nic.in/English/Schemes/Intellectual_Property_Rights/IPR_Policy_24December2014.p

df.

12. Prabuddha Ganguli, (2003) 'Complying with article 39 of TRIPS ... a myth or evolving reality?', World Patent Information 25 (2003) 329–333, www.elsevier.com/locate/worpatin

13. Pugatch Meir Perez, (2008) Intellectual property and pharmaceutical data exclusivity in the context of innovation and market access, http://www.iprsonline.org/unctadictsd/bellagio/docs/Pugatch_Bellagio3.pdf

14. Report on Steps to be taken by Government of India in the context of Data Protection Provisions of Article 39.3 of TRIPS Agreement, 31 May 2007, http://www.chemicals.nic. in/DPBooklet.

15. Satyanarayana K, S Srivastava and NK Ganguly. 2006. Data Protection Issues in India. Indian Journal of Medical Research 123:723–726. medind.nic.in/iby/t06/i6/ibyt06i6p723.pdf.

16. Vinod Sople, (2012) Managing Intellectual Property: The Strategic Imperative, PHI Learning, N Delhi