VOLUME 2 | ISSUE 3

INTERNATIONAL JOURNAL OF ADVANCED LEGAL RESEARCH

NEED FOR DATA EXCLUSIVITY LAW IN INDIA – A STUDY

- Rachna R Kurup[1]

ABSTRACT

In the present day, the process of protecting data that has high commercial value or may have one in the future has acquired significant importance, but the concept ofdata exclusivity continues to be a topic for debate all over the world and a reason for a tussle between developing and developed countries. Data exclusivity mainly tries to support the non-disclosure of clinical test data of pharmaceutical and Agro products which have for a certain period to give exclusivity to the originator thereby recognising his effort and time. However, data exclusivity is capable of exploiting the common people by charging a high price for the products. Therefore, concerns related to data exclusivity should be decided by considering and weighing their pros and cons. It is very much important to fathom the controversy behind data exclusivity since it has a close link with the accessibility as well as affordability of drugs to a giant population living in third world countries.The scope of the paper is to understand the concept of data exclusivity in India and the pros and cons associated with the granting of data exclusivity in the country.

INTRODUCTION

Intellectual property law aims to encourage innovation and novelty along with creating a competitive market. It ensures that the originator of an innovative product gets protection and recognition for his effort. For the past few years, there have been a lot of ongoing debates on granting data exclusivity to Pharmaceutical and Agro companies in our country. Though the concept is not properly defined anywhere, it can be understood as the protection of commercially valuable data from commercial exploitation for a certain period[2].Data exclusivity gained global recognition when the TRIPS agreement laid down a provision under

[1] Student at Symbiosis Law School, Hyderabad

[2] Manthan D Janodia , Ajay Chauhan, Shuaib M Hakak, D Sreedhar, V S Ligade and N Udupa, Data Exclusivity and technology, 2014Provisions in India: Impact on Public Health",13, Journal of Intellectual Property Rights, 442, 2008.

Article 39.3which ensures protection to the originator test data from a third party to prevent any kind of commercial exploitation.This is mainly because behind every invention, the originator has to invest a lot of time, hard work and money especially in the case of pharmaceuticals as the research and clinical test for medicines are even more tedious and expensive and therefore originator has the right to be recognized and to prevent generic companies to exploit them commercially it is crucial to protect the important test data temporarily from the third party[3]. Test data contains all the crucial information about the product which is submitted to the approving authorities to get permission to release in the market. It has also details about the efficacy quality and safety of the drug and therefore it should be protected from third parties so that the immense amount of effort and hard work of the inventor of the product is not misused by a competitor. However, there are lots of disadvantages associated with data exclusivity. If data exclusivity is granted, there is a high chance of economical exploitation as the originator company will have a monopoly in the market which will provide them with the freedom to decide the price of the product[4]. Though India is a signatory of the TRIPS agreement, it does not comply with any provisions that accept data exclusivity due to fear of exploitation mainly because there is a high probability that the provisions of data exclusivity can endanger the rights of the economically backward segment of the country.

WHAT IS DATA EXCLUSIVITY?

In the present day, the process of protecting datathat has high commercial value or may have one in the future has acquired significant importance. There are a lot of arguments as to protecting such data according to Article39.3 of the TRIPS agreement as exclusive data. Data exclusivity refers to the right which is given to the innovator company whereby, the drug approval authorities keep the test data of the innovator company undisclosed and prevent it from being used by other companies to register generic versions of the drug[5]. In simple words, we can say that data exclusivity is an advantage given to the originator of a drug or any other chemical entity to not disclose their clinical trial data that possess commercial value

[3] Adebare Alfred, Data Exclusivity: The implications for India, November 2005, available at www.articlealley.com/ article_16562_18.html, (visited on 7th March 2021)
[4] Nair Manisha Singh, Data Exclusivity – The Indian Perspective, available at http://www.mondaq.com/ article.asp?articleid=28531, (visited on 16th March 2021)
[5] Supra 1

for a specific period. This right or benefit is completely different from other intellectual property rights and should not be confused with a patent[6].

Every innovator company invest lots of money, risk, energy and time to check the safety, efficiency and quality of the drug and this process is called a clinical trial[7].The test data will contain all the information about the clinical trial and therefore holds commercial value. This is a very time consuming and crucial process behind the production of a drug. For instance, a clinical trial to test the safety and efficiency of a drug will take about 6- 7 years or even more than that. The newly processed drug is first tested on animals and later tried on human beings. The authorities will then check the data and ensure that the drugs are safe to use and have quality and efficacy. This data is used by many companies for registering their generic version which is the exploitation of the hard work of the originator company[8]. Usage of the clinical data of the originator company is considered an unfair commercial practice as other companies are taking advantage of the fruit of the originator company and by giving the data exclusivity, it protects third parties from using the test data to get marketing approval[9].

ADVANTAGES OF DATA EXCLUSIVITY

- Firstly, before releasing a product into the market, there goes a lot of hard work, risks, huge investment and energy of the inventor company and therefore it is very important to give concrete recognition to the inventor company and also protect it from getting exploited. Such recognition can be only provided through the protection of trial data[10]
- Secondly, the patent right is not sufficient to protect the data of the inventor as the concept of the patent is very limited. It applies only to certain patentable products[11]. If data exclusivity laws are implemented, then the protection will apply to non-patentable products as well and no third party will be allowed to take advantage of it[12]

[6] Archita Srivastav, Demand for Data Exclusivity in India and its Implications, International Journal of Law Management & Humanities, 4,2020,847
[7] Supra 7
[8] Ragavan, S, Data exclusivity: a tool to sustain market monopoly, Jindal Global Law Review **8,** 241–260 (2017)
[9] Uttam Gupta, Data-Exclusivity vs patent: The myths and the realities, HIN. BUS. LINE.,4,2006
[10] Gargi Chakrabarti, Need for Data Exclusivity: Impact on Access to Medicine available at http://nopr.niscair.res.in/bitstream/123456789/2030/1/JIPR%2013(5)%20442-446.pdf
[11] Id.
[12] Ragavan, Srividhya, The Significance of the Data Exclusivity and Its Impact on Generic Drugs, Texas A&M University School of Law Legal Studies Research Paper, 17, 2017.

- Thirdly, more development and research will take place in the country as more foreign pharmaceuticals will reach India. In the absence of data exclusivity law, foreign pharmaceuticals are not interested in coming to India[13]
- Fourthly, products cannot be commercialized as soon as receiving patent protection and therefore clinical trial is done after filing for patent protection in almost all cases as it is an extremely tedious and time-consuming process.
- Finally, the demand for better and more effective drugs is extremely important in the present time as the world is facing a health crisis right now. Giving protection to data will encourage companies to come up with innovative inventions.

DISADVANTAGES OF DATA EXCLUSIVITY

The process of granting data exclusivity to pharmaceutical companies is criticized by many countries due to the high chance of exploitation

- Many of them opine that there is no use in giving data exclusivity right as a patent can be availed by such companies for protecting their data. The patent right will provide 20 years of protection of the chemical trial data. Also, a proper economic justification is absent for granting data exclusivity[14]
- The innovators of the drugs can exploit the common man by charging high price on their products as they enjoy monopoly status over them and has the freedom to price their product. In developing countries where people are struggling to make the ends meet, charging high prices for medicine will put the state in a tough and helpless position
- Another argument is that the addition of the word "chemical entity" will include non-patentable products as well which will in turn the chance and scope of exploitation by the originator company[15]
- Furthermore, giving data exclusivity rights will delay the entry of a generic version of the drug into the pharmaceutical market and the originator of the drug will get extended benefits out of it.

[13]Kristina Lybecker, When Patents aren't Enough: The Case for Data Exclusivity for Biologic Medicines, IP WATCHDOG, available at http://www.ipwatchdog.com/2014/07/09/patents-arent-enough-data-exclusivity-for-biologic-medicines/id=50318/, (Last visited on 10-May-2021)
[14] Supra 4
[15]Id.

- Finally, data exclusivity will make compulsory licensing under patent law ineffective because even if compulsory licensing is granted to a third party, he will not be able to make use of the license because the data exclusivity will prevent the entry of competitors

INTERNATIONAL OBLIGATIONS AND GLOBAL SCENARIO

The concept of data protection received attention for the first time when the Paris Convention made the restriction of unfair competition practices. This resulted in the protection of undisclosed information as an obligation[16]. Later, the concept once again gained importance when the TRIPS agreement in the year 1994 mandated the protection of such data and incorporated Article 39(3)for the purpose[17]. As per the article, the member countries, when granting the marketing of drugs or Agrochemical which uses 'new chemical entities' the clinical trial data which contains important information, involves considerable effort and therefore such data should be protected from disclosure. Furthermore, the usage of these data without the permission of the originator before a stipulated period will be an unfair trade practice.

Also, as per Article 39(3) of the TRIPS agreement to get protection under the article, 7 main essentials are required to be fulfilled and they are[18]:

1. **Data submitted for market approval:** The data exclusivity or protection under article 39(3) is available to the clinical trial data which is submitted for market approval before the concerned national authorities and protection will be provided for voluntary submission or accessory basis[19]
2. **Scientific data:** the data should contain crucial information about the drug such as the details regarding the safety, quality and efficacy of the chemical drug
3. **Undisclosed:** The data should not be published in any public domain and if it is, then the data will be not exclusive and no protection will also be given
4. **New Chemical entities:** the meaning of the term "new chemical entities" is very vagueas the article doesnot give a proper definition for it. Also, the term has a

[16]Supra 2
[17] Encouragement of New Clinical Drug Development: The Role of Data Exclusivity, International Federation of Pharmaceutical Manufacturers Association, 2000, 3, available at http://www.ifpma.org/documents/NR83/DataExclusivity.pdf(Visited on 27th April 2021)
[18]G. Lee Skillington & Eric M. Solovy, The Protection of Test and Other Data Required by Article 39.3 of the TRIPs Agreement, 24 NW. J. INT'L L. & BUS,1, (2003)
[19]Supra 2

different meaning in different countries. So, there isa lot of discussion going on to confirm whether the term means novelty as mentioned under patent law but the general understanding is that while considering the term new chemical entities it should associate with safety and efficacy[20].

5. **Considerable effort:** The article does not give a proper meaning of considerable effort, but it means that the data should contain information that is the result of hard work, money investment, energy, time and risk which makes it commerciallyvaluable. protection cannot be given to data that is not an outcome of considerable effort[21].
6. **Unfair commercial use:** The article says that the originator need not disclose the data unless proper steps are taken to make sure that the data will be protected from exploitation. This obligation under the agreement has attracted so many debates regarding data exclusivity. Furthermore, the term unfair practice is different in different countries and therefore a uniform meaning cannot be used. However, in practice whenever a second entrant misuses the data of the originator without his prior approval, it is considered an unfair commercial practice.
7. **Duration:** duration for the protection of the exclusive data is not prescribed and the countries can grant any reasonable period for data exclusivity.

There are a lot of cases in which drugs were not granted data protection as they were not fulfilling all the criteria properly

In the case of *Epicept Corporation v. Canada (Health)*[22], the pharmaceutical company was prohibited from granting data exclusivity on an oncological drug. The main contention was that though the drug was innovative, the prime ingredient used in the drug was an already approved ingredient called "histamine dihydrochloride" for various other diseases. The court held that the previously approved ingredient is present in the drug and therefore the new cannot be considered to be innovative and data exclusivity cannot be granted.

[20] Kiruthika D, Data Exclusivity and Indian Law available at http://journal.lawmantra.co.in/wpcontent/uploads/2015/09/5.pdf (Visited on 28th April 2021)
[21] Jaya Bhatnagar and Vidisha Garg, India: Data Exclusivity, available at http://www.mondaq.com/india/x/79418/Information+Security+Risk+Management/Data+Exclusivity(Visited on 28th April 2021)
[22] 2010 F.C. 956

The same opinion was reiterated in the case of *Celgene Inc. v. Canada*[23], in which the drug called Thalidomide was rejected from granting data protection as the active ingredient present in the new drug called thalidomide was previously approved.

In the case of Takeda Canada Inc. v. Canada[24]it was held by the court that the drug, Dexilant was a mere variation of another drug that has been previously approved. Variation of a previously approved drug cannot be considered an innovative drug and therefore data protection was not granted to the drug.

In the case of Photocure ASA v. Canada (Health)[25], FCC refused to grant data protection to a new drug called Cysview. The rejection was on the ground that the active ingredient which was used in the new drug HAL HCL was just a varied form of an already approved ALA HCL. FCC relied upon the Takeda judgement and pointed out that a mere variation will not be considered an innovative drug.

Almost all of the developed countries like the USA, Australia, New Zealand, European Union have supported data exclusivity and have implemented laws for the protection of undisclosed data. However, the laws in every country are different and there is no uniform standard for them. The general period for the protection of undisclosed data in such countries is seen between 5 to 10 years[26].In 1984, the United States of America was the first country to implement a data exclusivity law. The drugsprice competition and patent restoration act were called as Hatch-Waxman act. Under this act, the new drug will get a 5-year data exclusivity protection while an improved version of the already existing drug will get 3 years.Also, some countries provide a maximum of 5 years of data exclusivity if by any chance the authority is taking more time than required for approval. China and Taiwan give 6 years, while countries like the Philippines and Korea give 8 years.

INDIAN SCENARIO

Today, there is no legislation enacted in India to protect undisclosed data that is submitted to the concerned authority for marketing approval. Being a signatory ofthe TRIPS agreement, India is expected to comply with the laws of the TRIPS agreement but has failed in doing

[23]2012 F.C. 154
[24]2013 F.C.A. 13
[25]2015 F.C. 959
[26] Valerie Junod, Drug Marketing Exclusivity under the United States and European Union Law, Food & Drug L.J. 479, 2004.

so[27]. The existing legislation is not adequate. However, some of the relevant laws related to data exclusivity are:

Trade secret:trade secret protection will give prevent the disclosure of data. However, even if this legal remedy can be used to prevent exploitation of the data it doesnot prohibit the authorities from depending on the data themselves to grant marketing approvals for the competition. In the case of *Anil Gupta and Anr v. Kunal Dasgupta and Ors*[28]. The court held that what makes that data confidential is the effort the plaintiff had applied for the invention which resulted in a unique product.

TheOfficial Secrets Act, 1923: according to this law, public servants are prohibited from disclosing confidential information without authorization which will affect the sovereignty, integrity and security of the country. However, this legislation is not wide enough as it only protects confidential information from misuse and does not ensure the protection of data. Though as per this legislation, disclosure of data will attract damages but does not mention anything about ensuring the protection of such data and therefore cannot be considered according to article 39(3) of the TRIPS agreement

Indian Patents Act, 1970: Patent law protects product and process for the originator, however, the scope of the patent is very limited as it only gives protection to patentable inventions. Also, the law specifically protects only products and processes and not the data associated with them. Therefore, the patent will not be adequate to protect undisclosed data[29].

Insecticide Act,1965: As per section 5 of this act, it is mandatory for the inventor of an agricultural chemical to provide all the data regarding the security and efficacy of the product on human beings and plants to the registration committee. After examining the data, the committee can approve marketing the product in the market.

NECESSITY FOR DATA EXCLUSIVITY IN INDIA

The contention for bringing data exclusivity for the protection of clinical trial data is that this data is used by the authorities o check the safety, quality and efficacy of the drugs which is

[27] Animesh Sharma, Data exclusivity with regard to Clinical Data, available at http://ijlt.in/wpcontent/uploads/2015/08/Sharma-Data-Exclusivity-with-regard-to-Clinical-Data-3-Indian-J.-L.-Tech.-82.pdf (Visited on 29th March 2021)

[28]AIR 2002 Delhi 379

[29] Bharti Jain, Impact of Granting Data Exclusivity in Agro-Chemcial Sector available at http://nopr.niscair.res.in/bitstream/123456789/34015/1/JIPR%2021(1)%2038-41.pdf (Visited on 29th April 2021)

the by-product of immense hard work, time, energy, huge investments that are made by the originator company. The clinical trials and research take several years to release a new drug into the pharmaceutical market. By disclosing these extremely valuable data, the hard work and research of the inventor are unprotected[30]. The M.D of Novartis, which is one of the largest and most successful pharmaceutical companies in the world opined that formulating a drug is an extremely risky task that has considerable effort behind it. Therefore, it is very important to protect it from getting exploited by generic companies. As per article 39(3) of the TRIPS agreement the usage of test data of the innovator company by the generic company without prior approval from the innovator companies is an unfair commercial practice. If such unfair commercial practice of generic companies is not kept under check, then it would amount to a failure to comply with the provisions of the TRIPS agreement.

Another significant point to be considered is that when clinical trial data is protected from disclosure, it will give rise to better and innovative drugs and act at a quicker pace. As India doesnot have laws that protect clinical data, foreign pharmaceuticals companies are not interested to reach the country for their research and development purposes. If laws regulating data exclusivityare implemented in the country, then it would attack more giant foreign pharmaceuticals which will give rise to better technology, research and development. Also, many organizations in our country such as the confederation of Indian Industry, the department of scientific and industrial research support data exclusivity. A committee which was constituted under MrSatwant Reddy has also suggested implementing data exclusivity for 5 years, the committee recommended it to be brought under the trade secret with no change in the registration process[31]. Furthermore, when we consider the utilitarian theory, the protection of innovative products will give rise to better and more innovative at an increasing rate. Therefore, if no protection is given to the originator, there will be fewer innovations in the industry[32].

CONCLUSION

[30] Biswajit Dhar and K. M. Gopakumar, Data Exclusivity in Pharmaceuticals: Little Basis, False Claims available at http://www.jstor.org/stable/4419006, (Visted on 29th April 2021)
[31] Satwant Reddy & Gurdial Singh Sandhu, Ministry Of Chemicals & Fertilizers, Report On Steps To Be Taken By Government Of India In The Context Of Data Protection Provisions Of Art. 39.3 Of Trips 11, 42 (2007)
[32] Satwant Reddy, Report on Steps to be taken by Government of India in the context of Data Protection Provisions of Article 39.3 of TRIPS Agreement ,available at http://chemicals.nic.in/sites/default/files/DPBooklet.pdf (Visited on 30th April 2021)

To sum up, everything stated so far, the concept of data exclusivity is something that should be implemented in India as well. Since a lot are issues attached to data exclusivity, a lot of debates are happening to decide whether it should be implemented in India. However, protecting the data will act as a catalyst for innovative inventions, recognizes the effort of the originator and increase the development in the drugs and Agrochemical industry. When it comes to a developing country like India, Data exclusivity will no doubt bring prosperity to the drugs and chemical industry but it should be implemented in such a way that it does not affect the health sector of the country. Just like the two sides of a coin, the concept has its advantages and disadvantages as well. There is an increased risk of exploitation by the originator by keeping the price of the drugs towards the higher end as they enjoy a monopoly status after receiving protection under data exclusivity. Also, the accessibility of the generic version of the drugs will be put under question. However, just like these issues are of legitimate concern, the need to bring more development in the quality and efficacy of the drugs are of equal importance too. Article 39(3) of the TRIPS agreement is drafted in a very flexible way that the member states can make necessary according to their conditions. Therefore, we can say that data exclusivity is in no way an evil concept but while bringing such legislation to India a middle path formula should be followed so that the social and legal conditions of the country will not be affected.

RECOMMENDATION

- To protect the work of the originator from misuse by third parties, data exclusivity laws should be implemented in India so that along with protecting the efforts of the originator, it will also motivate and encourage novelty and innovations in this field.
- While implementing laws on data exclusivity in India, the lawmakers should keep in mind the health sector of the country and therefore should take a liberal approach by making use of the flexibilities of Article 39(3).