

DATA EXCLUSIVITY WITH REGARD TO CLINICAL DATA

Animesh Sharma*

ABSTRACT

Intellectual property rights have evolved over the years with the intention of protecting novelty and innovation of ideas while creating a competitive market, at both a local and global level. The strongest tools to achieve this end have arguably been patents – protecting inventions that are novel, non-obvious and demonstrate utility. Most countries give a protection term of twenty years from the date of filing a valid submission. In the field of pharmaceuticals, foods and agrochemicals, marketing of products requires statutory clearances from the appropriate national regulatory bodies, in order to ensure that the products satisfy certain minimum criteria of quality and safety. Generating such data generally involves elaborate experimentation, trials in various phases, chemical analysis, and an estimation of the impact on the environment, all of which are time-consuming and expensive processes. Thus the intellectual property right of data exclusivity becomes important, as it involves the question of whether these processes, once completed, can be taken advantage of by other applicants. This paper analyses the concept of data exclusivity, studying article 39 of TRIPS, and addresses the question of whether data exclusivity laws should be introduced in India.

TABLE OF CONTENTS

I.	INTRODUCTION	83
	A. Data Exclusivity as a Separate Intellectual Property Right	84
	B. The Advantages of Data Exclusivity	85
II.	DATA EXCLUSIVITY UNDER TRIPS	86

* 5th Year Student, National Law School of India University.

A. An Analysis of Article 39(3)	88
B. Summary	91
III. DATA EXCLUSIVITY LAWS IN NORTH AMERICA AND THE EU	92
IV. DATA EXCLUSIVITY: AN INDIAN PERSPECTIVE	96
A. The Current Legal Regime	96
B. Arguments in Favour of Data Exclusivity in India	98
C. Why Say No to Data Exclusivity?	98
V. CONCLUSION	102

I. INTRODUCTION

The pharmaceutical industry can be said to comprise of pioneer and generic companies: the former develop and market new drugs and the latter copy some or all aspects of those drugs and sell them.¹ Data exclusivity, also known as marketing exclusivity, refers to a practice whereby, for a fixed period of time, drug regulatory authorities do not allow the registration files of a pioneer company to be used to register a therapeutically equivalent generic version of that medicine.² In other words, during a set period of time, data exclusivity would prevent a pharmaceutical applicant from obtaining a marketing authorisation for its drug through a facilitated procedure entailing reliance on preclinical and clinical data generated by a previous applicant to support a successful application for its own drug, where the drugs manufactured by both applicants are effectively the same and thus can be approved or rejected by taking the same data into account.³ Thus, data exclusivity guarantees additional market protection for originator pharmaceutical companies⁴ by preventing health authorities from accepting applications for generic medicines during the period of exclusivity.

¹ Valerie Junod, *Drug Marketing Exclusivity under United States and European Union Law*, 59 *FOOD & DRUG L.J.* 479, 479 (2004).

² Praveen Dalal, *Data Exclusivity: An Indian Perspective*, at <http://www.ipfrontline.com/depts/article.asp?id=12300>.

³ *Id.*

⁴ An 'originator pharmaceutical', as opposed to a generic pharmaceutical company, is one which produces a new, original drug, rather than producing a generic equivalent of an already produced drug.

During the limited period of exclusivity, the second entrant can obtain marketing approval only if it generates its own data supporting the safety and efficacy of its drug. The practical consequence is that generic competition is delayed for the duration of marketing exclusivity.⁵ Protection of registration data, through the data exclusivity that results from non-reliance on the data, is a governmental function. The registration data is provided to the authorities in confidence and is not meant to be referred to by third parties. Further, governments should be required to protect the data that they receive in a manner that will enable the originators to enforce their rights.⁶ It is thus the government, through its regulatory agencies, and not the originator of the data, that is responsible for preventing copiers from taking advantage of proprietary data during the period of data exclusivity.

A. Data Exclusivity as a Separate Intellectual Property Right

Data exclusivity is often considered to be an extension of the rights under a patent. However, it is important to note the distinction between the two rights, as data exclusivity qualifies as an independent intellectual property right. Patents and data exclusivities are awarded independently. Unlike a patent, which gives the holder the right to exclude others from making, using, selling, offering for sale, or importing the patented product, the protection that governments must accord proprietary test data does not prevent any manufacturer from running its own tests and submitting the results to the regulatory authorities. Assuming the absence of any intervening patents, a generic alternative may still receive marketing approval, provided that the generic manufacturer conducts its own preclinical and clinical trials and independently seeks marketing authorisation by the regulatory bodies.⁷ For instance, the drug's patent may expire or be ruled invalid before marketing approval and marketing exclusivity are granted. Similarly, if a valid patent covers the pioneer drug, it effectively prevents generic entry, whether or not a marketing exclusivity period is running.⁸ Data exclusivity also differs from a patent in that

⁵ Dalal, *supra* note 2.

⁶ INT'L FED'N OF PHARM. MFRS. ASS'NS, ENCOURAGEMENT OF NEW CLINICAL DRUG DEVELOPMENT: THE ROLE OF DATA EXCLUSIVITY 15 (2000), <http://www.ifpma.org/documents/NR83/DataExclusivity.pdf>.

⁷ *Id.* at 3.

⁸ *Id.*

it is not a right that the pioneer firm can invoke directly against a generic firm.⁹ In particular, the pioneer firm cannot directly challenge the second entrant to whom the agency would have mistakenly granted marketing approval, despite an ongoing marketing exclusivity, as data exclusivity merely protects the data given to the agency in order to approve the product, unlike a patent, which protects the product itself.¹⁰ Thus, data exclusivity and patents are distinct forms of protection – the protection of one right is neither dependent nor linked to the other in any intrinsic way.¹¹

B. The Advantages of Data Exclusivity

The purpose of data exclusivity is to ensure that the initial registrant of a new drug can recover the costs of testing the drug for efficacy and safety. Extensive testing directly translates into considerable costs for generating the data necessary to obtain approval of each new active ingredient. Drug developers contend that they cannot afford to bring drugs to market without data exclusivity because later registrants, who did not have to invest in the high cost of obtaining marketing approval, can free-ride on the initial registrant's approval and sell the same or similar drug at a lower price.¹²

One argument for data exclusivity laws is that pharmaceutical manufacturers will have a greater incentive to develop drugs for diseases that are considerably more prevalent in developing countries, as incentives based solely on sales in developed countries will not encourage the creation and testing of these products if the market for them in the developed countries is limited. This is premised on the assumption that a lack of data exclusivity in a certain country would make

⁹ See Junod, *supra* note 1, at 493.

¹⁰ *Id.*

¹¹ See, e.g., *Organon v. Teva*, 244 F. Supp. 2d 370, 373 (D.N.J. 2002); see also *id.*, at 482 (noting that a drug's patent may expire or be ruled invalid before marketing approval and marketing exclusivity are granted, or, similarly, that a valid patent covering a pioneer drug effectively prevents generic entry, whether or not a marketing exclusivity period is running); INT'L FED'N OF PHARM. MFRS. ASS'NS, *supra* note 6, at 15 ("Data exclusivity is an independent intellectual property right and should not be confused with the protection provided by other rights, especially patents.").

¹² G. Lee Skillington, *The Protection of Test and Other Data Required by Article 39(3) of TRIPS*, 24 Nw. J. INT'L L. & BUS. 1, 8 (2003) ("Estimates of costs vary widely, but studies by the Tufts Center for the Study of Drug Development indicate that the costs of developing a new drug [were] \$54 million in 1976 (in 1976 U.S. dollars), \$231 million in 1991 (in 1991 U.S. dollars), and \$802 million in 2002 (in 2002 U.S. dollars)." (footnote omitted)).

it very difficult for the pioneer manufacturer to recover the expenses associated with research and testing in that country, as subsequent generic manufacturers would be able to undercut its prices by copying the pioneer's drug after the patent expires and reusing the pioneer's data in order to obtain approval, thus reducing costs significantly.¹³

II. DATA EXCLUSIVITY UNDER TRIPS

Proponents of data exclusivity argue that it is mandated in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).¹⁴ The controversy surrounding data exclusivity has in large measure been related to the different interpretations given to the relevant provisions of TRIPS.

Section 7 of TRIPS is entitled Protection of Undisclosed Information, and article 39 therein talks about data exclusivity.¹⁵ TRIPS introduced the first international standard on the subject. Article 39(1) talks about protecting member states against unfair competition¹⁶ and article 39(2) states that natural and legal persons have the possibility of preventing information lawfully within their control from being disclosed to others without their consent in a manner

¹³ *Id.* at 13-14.

¹⁴ Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 1 (1994), 33 I.L.M. 1125 (1994); Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31 (1994), 33 I.L.M. 81 (1994) [hereinafter TRIPS].

¹⁵ TRIPS, *supra* note 14, at art. 39.

¹⁶ Article 39(1) reads: "In the course of ensuring effective protection against unfair competition as provided in article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 below and data submitted to governments or governmental agencies in accordance with paragraph 3 below". *Id.* at art. 39(1). Article 10bis of the Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 828 U.N.T.S. 107, as last revised at the Stockholm Revision Conference, July 14, 1967, 828 U.N.T.S. 303 [hereinafter Paris Convention], requires all countries of the Paris Union to provide all nationals of the Union with effective protection against unfair competition, and this protection must be provided on a 'national treatment' basis pursuant to article 2.

contrary to honest commercial practices.¹⁷ Article 39(3) is the provision directly concerning data exclusivity and reads as follows:¹⁸

Members, when requiring, as a condition of approving the marketing of a pharmaceutical or of agricultural or 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 when necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

On the face of it, it seems that this provision mandates data exclusivity. The structure of article 39 suggests that the negotiating parties conceived of the regime for test data as a particular case in the framework of the protection of undisclosed information.¹⁹ However, the article must be carefully scrutinized keeping in mind its legislative history and intention. TRIPS is not a uniform law and it only establishes broad parameters for national rules for different members. The inclusion of test data in TRIPS as a category of intellectual property does not permit one to draw any conclusion about the nature of the protection conferred.²⁰ The question that then arises is how much freedom TRIPS allows WTO members to apply different approaches for test data protection, and to what extent a competitive model without exclusivity would

¹⁷ Article 39(2) states that “natural and legal persons” should be able to prevent “information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices” as long as the information in question is a “secret” under sub-clause (a), “has commercial value because it is secret”, and “has been subject to reasonable steps under circumstances, by the person lawfully in control of the information, to keep it secret”. TRIPS, *supra* note 14, at art. 39(2).

¹⁸ *Id.* at art. 39(3). The proviso to the article states:

For the purpose of this provision, “a manner contrary to honest commercial practices” shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

¹⁹ Carlos M. Correa, *Unfair Competition under TRIPS: Protection of Data Submitted for Registration of Pharmaceuticals*, 3 CHI. J. INT’L L. 69, 72 (2002).

²⁰ *Id.* at 70.

be compatible with the minimum standards set out by article 39(3).²¹ This calls for an analysis of article 39(3) and its possible interpretations.

A. An Analysis of Article 39(3)

1. Data Necessary for Marketing Approval

Article 39(3) makes it clear that the first condition for its application is that a member state stipulates data submission as a condition for obtaining marketing approval for pharmaceuticals or agrochemical products. Thus, the obligation to protect test data only arises in the member states where national regulations require the submission of such data. If a member state opts not to require this data, article 39(3) will naturally not apply.²²

2. Undisclosed Data

To qualify for protection under article 39(3), the pertinent information must be undisclosed. This means that information that is already public (due to publication in a scientific journal or magazine, for example) does not fall within its scope. Any requirement for the submission of published or otherwise disclosed information to national regulators shall not generate any private right limiting the use of such information by the government or third parties, since the information is already available to the public.²³

3. New Chemical Entities

Another important condition for the application of article 39(3) is that the data must refer to a 'new chemical entity'. TRIPS, however, does not define the term 'new'.²⁴ Proponents of data exclusivity argue that article 39(3) protects data and products involved in the marketing approval systems. The word "new" thus refers to the status of a chemical entity within the marketing approval system, not with respect to the state of the art or novelty in the patent sense.²⁵

²¹ *Id.*

²² *Id.* at 73.

²³ *Id.* at 73.

²⁴ *Id.* at 74.

²⁵ *See id.*

A chemical entity may be deemed new in the absence of any prior application for approval of the same drug, or if the same drug has not previously used in commerce.²⁶ However, one could also argue that article 39(3) refers to a chemical entity that was not found within the marketing system at the time of submission. Therefore, only data related to products with chemical entities that were not publicly known before the submission of the data would be eligible for protection.²⁷

Since TRIPS avoids defining the term ‘new chemical entity’, there is no way of declaring one interpretation as superior to the others, and thus member countries have a certain degree of leeway in their implementation concerning this area. Thus, to argue that the definition of a ‘new chemical entity’ would include a new therapeutic use of an old drug, an argument that holds sway in developed countries like the USA, would amount to giving a strained meaning to a provision that allows for flexibility. In fact, article 39(3) would not apply in cases where approval is sought for new indications, dosage forms, combinations, new forms of administration, crystalline forms, isomers, etc. of existing drugs, since there would be no novel chemical entity involved.²⁸ This is because the new product will be intrinsically similar to the previous product and will not require data exclusivity protection.²⁹

4. Considerable Effort

Article 39(3) mandates protection when the process of obtaining the data involved a “considerable effort”. However, the article is vague about the type of effort (technical or economic) involved or the magnitude of it that would be deemed considerable. The term may be interpreted to mean the concentrated

²⁶ *Id.*

²⁷ *See id.*

²⁸ *Id.* at 75.

²⁹ *See* Case C-368/96, *The Queen v. Licensing Auth. established by the Medicines Act 1968, ex parte Generics (U.K.) Ltd*, 1998 E.C.R. I-7967, [1999] 2 C.M.L.R. 181, 220 (1998). The Court held that a second product is essentially similar to an earlier approved product if the second product has the same qualitative and quantitative composition in terms of active principles, the same pharmaceutical form and is bio-equivalent to the first product, unless it is apparent in the light of scientific knowledge that it differs significantly from the original product as regards safety or efficacy. In these cases, the original applicant does not receive new periods of so-called “marketing exclusivity” for each new indication, dosage form, or dosage schedule.

or special activities, physical or mental, that are extensive in scope or duration.³⁰ Inclusion of this standard also suggests that national regulatory authorities may call for the applicant to prove that the information for which protection is sought is the outcome of considerable effort.

5. Unfair Commercial Use

The interpretation of this phrase has by far given rise to the maximum debate concerning data exclusivity. The non-disclosure obligation under article 39 requires that the test data not be disclosed unless steps are taken to ensure that the data is protected against “unfair commercial use”. Here, the key questions are: what constitutes unfair commercial use, and how can that protection be guaranteed? If the government authority relies on the dossier of the pioneer manufacturer in order to grant permission to a generic manufacturer, does this amount to unfair commercial use?

Developed nations argue that a member state’s reliance, at or without the request of a competitor of the originator of data, on data submitted by the originator in a manner that benefits the competitor, would constitute unfair commercial use of the data.³¹ Their argument states that any reliance on the data by a competitor before the originator has had the opportunity to recoup the costs associated with the considerable efforts to develop the data would be unfair, as it would give the competitor a free ride on the investment made by the originator. However, since there is no absolute or universal rule to determine when certain practices should be deemed unfair, it is likely that different countries will judge the fairness of certain situations differently, depending on their values and competitive advantages.³² If the drafters of TRIPS had intended the obligation to be fulfilled by the creation of such a private right, they would have expressly required the member states to give submitters a private right of action.³³ Article 39(3) could have certainly adopted a stance proscribing reliance

³⁰ Skillington, *supra* note 12, at 28.

³¹ *Id.* at 29.

³² *Id.* (“Some countries may consider it an unfair practice for a follower company to commercially benefit from the data produced by the originator via a marketing approval system based on similarity . . . In others, it may be regarded as the legitimate exploitation of an externality created during legitimate competition in the market.”).

³³ *Id.* at 22.

on clinical data and specifying a time period for protection. The U.S. had in fact made such a proposal in the TRIPS negotiations, but the proposal was not incorporated into the final text of TRIPS.³⁴ Article 39(3) can be clearly distinguished from the more explicit provision in the earlier NAFTA agreement, in which disclosure and reliance of clinical data is specifically proscribed, and a minimum exclusivity period of five years is stated.³⁵

One of the most important rules of statutory interpretation is that what is not explicitly included is thereby excluded (*expressio unis est exclusio alterius*).³⁶ Keeping this rule in mind, the drafters of TRIPS certainly had the opportunity to impose more specific requirements of data exclusivity, but chose not to do so. Thus, contrary to those who argue that article 39(3) mandates data exclusivity, it is entirely consistent with the language of the article to simply require that data submitted for drug approval be kept confidential by the government authority while allowing the authority to rely on this data to approve subsequent generic applications.

B. Summary

In sum, article 39(3) clearly requires some form of protection for test data, but does not require member states to grant exclusive rights. Its main purpose is not to prevent the use of such data by governments, but to prevent unfair use by competitors. The language, context, principles of statutory interpretation and purpose of the article do not support an interpretation that the required protection can be implemented only on the basis of exclusivity rights. This interpretation is confirmed by the history of the negotiation of TRIPS. The United Nations Conference on Trade and Development (UNCTAD) has also stated that “authorities are not prevented [under article 39(3)]... from using

³⁴ Correa, *supra* note 19, at 77.

³⁵ North American Free Trade Agreement, Dec. 17, 1992, Can.-Mex.- U.S., art. 1711, 32 I.L.M. 605, 675 [hereinafter NAFTA].

³⁶ 82 C.J.S. § 323; *ABC Laminart v. AP Agencies Salem*, (1989) 2 S.C.C. 163 (applying the maxim in India); *Gilmore (Valuation Officer) v. Baker-Carr*, [1962] 1 W.L.R. 1165 (CA) (applying the maxim in the U.K.); *West Virginia University Hospitals v. Casey*, 499 U.S. 83 (1991) (applying the maxim in the U.S.).

knowledge and data, for instance, to assess subsequent applications by third parties for the registration of similar products.³⁷

The correct interpretation that must be given to article 39 is quite clear and unambiguous at this point. TRIPS does not make granting of data exclusivity rights mandatory, but gives the member states the freedom to choose the nature and extent of protection they want to offer.

However, the question of whether India should grant data exclusivity is quite separate from what the interpretation of article 39 is. TRIPS gives a country the option to choose whether or not to grant data exclusivity rights. The question as to whether or not a country should actually grant this right to pharmaceutical companies is a totally separate one, and that answer must be arrived at on its own merits and is not linked to the interpretation of article 39 of TRIPS.³⁸

III. DATA EXCLUSIVITY LAWS IN NORTH AMERICA AND THE EU

Although courts across jurisdictions have not dealt with data exclusivity rights extensively, two relevant cases throw some light on the nature and extent of data protection rights. In *Ruckelshaus v. Monsanto Co.*,³⁹ the U.S. Supreme Court described the extensive practice of relying on data submitted by the first applicant in the U.S. and recognised that the relevant authority could use the data submitted by the originator to assess second-entrant applications. According to the law applicable at the time of the complaint, the applicant was entitled to compensation, but not to exclusive use of the data. On the other

³⁷ UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT, TRIPS AGREEMENT AND DEVELOPING COUNTRIES (UNCTAD/ITE/1) 48 (1996).

³⁸ It is crucial to understand this distinction as it negates the claims that as signatory to TRIPS, India is obligated to grant data exclusivity rights.

³⁹ 467 U.S. 986 (1984). The *Ruckelshaus* case relates to the protection of data submitted for the registration of an agro-chemical product. Though a subsequent applicant was obliged to compensate for the use of Monsanto's original data, Monsanto argued that such use undermined its reasonable investment-backed expectations and was unconstitutional. The basic argument of the plaintiff was that the possibility given to a competitor by US law of using the data submitted for the registration of a product without compensation nullified the data originator's "reasonable investment-backed expectation", which the court upheld.

hand, in *Bayer, Inc. v. Canada (Attorney General)*,⁴⁰ the General Court of Appeal of Canada decided, despite the fact that NAFTA provides for a minimum term of exclusivity, that the approval of a subsequent application on the basis of a prior registration was legitimate.⁴¹ The Court observed that the health authority neither requested undisclosed information a second time nor examined it; the authority just checked whether the original and subsequent products were indeed the same.⁴² The issue was decided under Canadian law and NAFTA article 1711.⁴³ The Court held that if the authority does not actually examine and rely on that confidential or trade secret information on behalf of the generic manufacturer, there is no use of data, and hence the exclusivity provision is not applicable.⁴⁴

The popular argument in the USA and the EU nations is that data exclusivity is a mandatory right that must be granted by member states under TRIPS, since the manufacturer that developed the test data has invested heavily and deserves a fair return on investment. Where patent law fails to provide

⁴⁰ *Bayer, Inc. v. Canada (Attorney Gen.)*, [1999] 243 N.R. 170 (Fed. Ct.) (Can.).

⁴¹ Correa, *supra* note 19, at 80.

⁴² *Id.*

⁴³ The relevant portion of article 1711 reads:

(5) *If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such data involves considerable effort, the Party shall protect against disclosure of the data of persons making such submission, where the origination of such data involve considerable efforts, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use.*

(6) *Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for the product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.*

(7) *Where a Party relies on a marketing approval granted by another Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on.*

NAFTA, *supra* note 35, art. 1711.

⁴⁴ Correa, *supra* note 19, at 80.

protection unless data exclusivity is granted, proponents of data exclusivity argue that competitors would face no barrier to producing and registering an exact copy of the product.⁴⁵ In the EU, Council Directive 65/65⁴⁶ provides a period of data protection of either six or ten years, depending on the member state concerned: the larger member states provide ten years, while the smaller provide only six years. However, for products that are approved through the centralised procedure, Regulation 2309/93⁴⁷ provides a ten-year period of data protection. During this period of time, the regulatory authorities cannot approve any applications that seek to rely on the originator's data.⁴⁸ The U.S. law has changed since *Ruckelshaus*, with the passing of the Drug Price Competition and Patent Term Restoration Act of 1984,⁴⁹ otherwise known as the Hatch-Waxman Act, and in such a scenario the authorities now would be unable to rely on the plaintiff's data. U.S. law now specifically provides that a subsequent applicant cannot use the initial applicant's safety and efficacy data that the Food and Drug Administration (FDA) relies upon for approval for five years after the initial date of approval.⁵⁰ Furthermore, there is no requirement that the pharmaceutical product be patented, have current patent protection, or even be patentable.⁵¹ Thus, the law protects non-patentable products or products whose patent protection will terminate before the five-year exclusivity period

⁴⁵ Carlos María Correa, *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines*, 36 CASE W. RES. J. INT'L L. 79, 83 (2004).

⁴⁶ Council Directive 65/65/EEC, 1965 O.J. (No. 22) 368, reprinted in 1965-1966 O.J. SPEC. ED. 20 (1972).

⁴⁷ Council Regulation 2309/93 of 22 July 1993, 1993 O.J. (L 214) 1 (laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products).

⁴⁸ INT'L FED'N OF PHARM. MFRS. ASS'NS, *supra* note 6, at 3-4. The new system adopted by the European Parliament in December 2003 employs an "8+2+1" period of data protection for all member states, granting an initial eight years of data protection for the dossier of an innovative pharmaceutical product. Subsequent to this, a generic company may manufacture and register an analogous drug, but cannot commercialize it until the end of the tenth year. This may be extended by one year if any new indications are discovered for the innovative drug. David Childs, *The World Health Organization's Prequalification Program and its Potential Effect on Data Exclusivity Laws*, 60 FOOD & DRUG L.J. 79, 81 (2005).

⁴⁹ 35 U.S.C. § 156 (1988). The Act prohibits competitors from relying on the data submitted by the originator for a five-year period after approval of the product associated with the data, if the product contains an active ingredient that had not been previously approved by the U.S. Food and Drug Administration.

⁵⁰ 21 U.S.C. § 355(c)(3)(D)(ii).

⁵¹ See *id.*

expires.⁵² However, an initial applicant may set up financial arrangements with subsequent applicants to use the dossier in attempts to secure marketing approval.⁵³ Applicants can obtain a 'right of reference' from the initial applicant, as per which permission is given by the initial applicant to rely on its data, after which the beneficiary of this right can submit its application regardless of marketing exclusivity.⁵⁴ Further, as a balance of incentives to first entrants in the markets, the Hatch-Waxman Act provides an extension of patent term for first products. Where a drug is approved by the FDA and a patent exists covering the drug, its use, or manufacture, an extension of the patent term can be granted, proportional to the period needed for regulatory approval of the product.⁵⁵

However, infectious diseases kill over ten million people each year, more than ninety per cent of whom are in the developing world.⁵⁶ The magnitude of this crisis has drawn attention to the fact that millions of people in the developing world do not have access to the medicines that are needed to treat disease or alleviate suffering.⁵⁷ The reasons for the lack of access to essential medicines are manifold, but in many cases the high prices of drugs are a barrier to needed treatments.⁵⁸ The Doha Declaration on TRIPS and Public Health, 2001, emphasised that TRIPS should be interpreted and implemented in a manner that supports WTO members' right to protect public health and, in particular, to promote access to medicines for all.⁵⁹ For these reasons, various developing

⁵² John A. Tessensohn, *Reversal of Fortune—Pharmaceutical Experimental Use and Patent Infringement in Japan*, 4 J. INT'L LEGAL STUD. 1, 60 (1998)

⁵³ Childs, *supra* note 48, at 80.

⁵⁴ Junod, *supra* note 1, at 492.

⁵⁵ Erica J. Pascal, *The Billion-Dollar Naming Game: How Ambiguities in Patent Term Extension Provisions Allow Companies to Add Billions of Dollars to the Bottom Line*, 24 BIOTECHNOLOGY L. REP. 547, 548 (2005).

⁵⁶ Ellen 't Hoen, *TRIPS, Pharmaceuticals Patents and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT'L L. 27, 27 (2002).

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/Dec/2 (Nov. 14, 2001), ¶ 4, available at http://www.wto.org/english/thewto_e/minist_e/mindecl_trips_e.pdf; see also The Separate Doha Declaration Explained, at http://www.wto.org/English/tratop_e/trips_e/healthdecl_expln_e.htm. The Doha Declaration was designed to respond to concerns that TRIPS would make access to medicines difficult for patients in developing nations, and was the result of considerable discussion among developing and developed nations on the correct interpretation and role of TRIPS in this context. See generally Daya Shanker, *Access to Medicines, Paragraph 6 of the Doha Declaration on Public Health, and Developing Countries in International Treaty Negotiations*, 2 INDIAN J. L. & TECH. 8 (2006).

nations as well as human rights groups and NGOs argue that TRIPS does not mandate granting of data exclusivity rights. These polarising viewpoints have given rise to extensive debate about data exclusivity in various jurisdictions, including India.

IV. DATA EXCLUSIVITY: AN INDIAN PERSPECTIVE

A. The Current Legal Regime

The Drugs and Cosmetics Act, 1940 (DCA) regulates the import, manufacture, distribution and sale of drugs in India. The right of a manufacturer to market a drug arises upon the grant of a licence under the DCA and the Drugs & Cosmetics Rules, 1945. In 1988, major changes were introduced in the DCA to regulate the granting of approval of new drugs for manufacture or import.⁶⁰ Part X-A was added for the regulation of import of manufacture of new drugs including biological and special products. Rule 122-E gave a new and much wider definition of the term 'new drug'.⁶¹ Irrespective of the fact that the safety and efficacy of a drug is established in another country, fresh data as to its safety must be submitted in India, but the level of clinical trials depends on the status of the drug in other countries.⁶² Further amendments were made in 2001 to deal with requirements of subsequent approval, and Appendix 1-A was added to Schedule Y⁶³ as per which the entry of generic drugs is made relatively easy and expeditious under DCA. Generic manufacturers are only

⁶⁰ N.S. GOPALAKRISHNAN & BENOY KADAVAN, *STUDY ON TEST DATA PROTECTION IN INDIA* 28 (2005).

⁶¹ The new definition includes three categories of drugs where it is obligatory to provide data for approval. The first category is a new substance of chemical which is not used in the country for a long period and which has not been recognized as effective and safe in the country. The second category is an approved drug with new indication, dosage or dosage form. The third category is a new combination of two or more already approved drugs or an existing combination with new indications, dosage or dosage form.

⁶² See 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 ARTICLE 39.3 OF TRIPS* 11, 42 (2007), <http://chemicals.nic.in/DPBooklet.pdf>. If the drug is already approved in another country, Phase I and Phase II trials are not to be conducted again in India. Only Phase III or confirmatory trials are required to be conducted. See *id.* at 47.

⁶³ Schedule Y talks about the "requirement and guidelines on clinical trials for import and manufacture of new drugs". Drugs and Cosmetics Act, 1940, sch. Y.

required to prove that the generic version is bio-equivalent to the original drug.⁶⁴ They are not bound to provide any other data mentioned in Schedule Y. This in turn allows them to enter the market quickly with cheaper generic alternatives. Thus, data with considerable effort is only insisted in case of new drugs introduced in the market for the first time.⁶⁵ This position is evidently in contradiction with the objective of data exclusivity. Under the Insecticides Act, 1968, any subsequent applicant for registration of the same insecticide has to be granted registration on the same conditions as imposed for the original registration. In other words, the subsequent applicant need not give data proving the efficacy and safety of the insecticide. He has to submit only the chemical composition and leaflets that were approved for the original registrant.⁶⁶

Under pressure from various interest groups, the government has recently been considering proposals to amend the DCA in favour of data exclusivity. It is proposed to add a new section 18A for prohibition and liability for disclosure of information and to amend the Rules.⁶⁷ For approval under subsection (1) of the new section, the licensing authorities may ask for submission of undisclosed information by the applicant. Under sub-clause (2), the licensing authority will have to keep undisclosed information submitted for new drugs, unless the government by notification seeks disclosure of such information in public interest.⁶⁸ In addition, the Organization of Pharmaceutical Producers of India has requested the Government to amend Schedule Y of the DCA to include a provision for data exclusivity for a period of six years from the date of marketing approval.⁶⁹

⁶⁴ Letter from Anand Grover, Lawyers Collective HIV/AIDS Unit, to Prabhunath Singh, Chairperson, Petition Committee, Parliament House (Jul. 7, 2006), http://www.lawyerscollective.org/%5Eamtc/data_exclusivity/LCHAU_submissions.doc.

⁶⁵ GOPALAKRISHNAN & KADAVAN, *supra* note 60, at 34.

⁶⁶ *Id.* at 38.

⁶⁷ Alfred Adebare, *Data Exclusivity: The Implications for India*, at http://www.articlealley.com/article_16562_18.html n.3 (noting that the introduction of § 18A will ensure that no person is entitled to the licence under § 10(c) or under § 18(c) for a drug unless approved by the licensing authorities in accordance with the rules prescribed under the DCA).

⁶⁸ *Id.*

⁶⁹ *Id.*

B. Arguments in Favour of Data Exclusivity in India

As mentioned earlier, drug developers contend that they cannot introduce new drugs in the market without data exclusivity laws to protect their interests. Proponents of data exclusivity refer to the success of the Hatch-Waxman Act in the USA, which has so far resulted in dramatic benefits for consumers. Within three years of its enactment, fifty-four more new drugs were under development and testing – far more than the total number of orphan drugs in the market on the date of enactment.⁷⁰ As of January 2001, a total of 212 orphan drugs had been approved, with another 855 drugs as candidates for development.⁷¹ Hence, introduction of data exclusivity would end up benefiting the consumers in a big way. Furthermore, one of the most significant problems for developing countries like India is the formulation of products directed at diseases or conditions that are not normally found in developed countries. Drugs catering to the needs in India will only be developed if data exclusivity laws exist in India. It is only when sufficient protection is accorded to drug manufacturers that they will come to India and spend their resources and time on developing drugs for diseases endemic to India. Another argument is that granting a reasonable data exclusivity period will make India an attractive destination for research and development work.⁷² Given these reasons, and international pressure as well as demands from the pioneer pharmaceutical industries, should India make way for a data exclusivity regime? To answer this question, let us examine the demerits of introducing data exclusivity in India.

C. Why Say No to Data Exclusivity?

Most drug manufacturers in India work only on generic drugs.⁷³ If data exclusivity is approved, domestic enterprises would be prevented from obtaining marketing approvals on the basis of the data submitted by the first enterprise that had generated and submitted the data. There are various reasons why data exclusivity rights should not be granted in India.

⁷⁰ Skillington, *supra* note 12, at 12-13.

⁷¹ *Id.*

⁷² GOPALAKRISHNAN & KADAVAN, *supra* note 60, at 41.

⁷³ *Id.* at 40.

Firstly, there seems to be no clear economic justification as to why data exclusivity should be granted to firms that already avail a patent protection term of twenty years globally for their products. The Patents Act, 1970, was recently amended by the Patents (Amendment) Act, 2005, introducing many changes favourable to the pharmaceutical industry, including re-introduction of product patents for drugs, medicines, and foods, including products of chemical reactions.⁷⁴ The patent term has been made twenty years from the date of submission of the complete specification. New and wider definitions of terms relevant to the pharmaceutical industry have been given under the amended Act. Indian companies such as Dr. Reddy's, Sunpharma and Cipla are also of the view that data exclusivity will prolong the monopoly already given by product patents.⁷⁵

If the generic industry in India is curbed further, a large amount of cheap supply of medicines at very competitive prices will be seriously affected. In practice, data exclusivity terms, since they are granted from the date of introduction of a particular product in a given market, may have the effect of extending the monopoly term of the patent holder beyond the term of the patent and delaying the entry of generics.⁷⁶ A hypothetical situation could help in explaining this argument. Assuming Indian law granted data exclusivity for five years, this would mean that a patent granted for a product in 1995 would be valid until 2015 under the amended Patents Act. However, if this product were introduced in the Indian market only in 2011, then data exclusivity in Indian law would protect the regulatory data submitted by the company until 2016 thus delaying the entry of generics, and extending the product monopoly for another year beyond the patent period.⁷⁷

Secondly, India is a major supplier of the world's generic medicines and exports two-thirds of its generic drugs to developing countries. The excellent capability of Indian pharmaceutical industry to produce generic drugs at

⁷⁴ See generally Shamnad Basheer, *India's Tryst with TRIPS: The Patents (Amendment Act), 2005*, 1 INDIAN J. L. & TECH. 15 (2005).

⁷⁵ GOPALAKRISHNAN & KADAVAN, *supra* note 60, at 42.

⁷⁶ Padmashree Gehl Sampath, *Economic Aspects of Access to Medicines after 2005: Product Patent Protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry*, at <https://www.who.int/entity/intellectualproperty/studies/PadmashreeSampathFinal.pdf>.

⁷⁷ *Id.*

affordable cost is a well-established fact.⁷⁸ These exports are critical for addressing and treating a great number of public health illnesses and in the global fight against AIDS.⁷⁹ India has been largely responsible for reducing the prices of antiretroviral drugs by as much as 98%.⁸⁰ Thus, Indian generic manufacturing clearly plays a vital role in the global fight against diseases.⁸¹ If data exclusivity rights are granted, this respectable status that India enjoys in the eyes of the developing world would certainly be lost and new data exclusivity provisions may have a disastrous affect on health conditions worldwide.

Thirdly, the research-based pharmaceutical industry claims that data exclusivity provides incentives for companies to generate the necessary data, since without marketing exclusivity, brand-name companies would not want to conduct expensive preclinical tests and clinical trials.⁸² This argument is flawed because pharmaceutical companies do not need incentives to produce preclinical and clinical test data because they have no choice in that matter: they must supply this information if they want to sell their drugs.⁸³ Preclinical testing and clinical trials are a requisite for any new drug marketing application.⁸⁴ In India, the tests have to be supplied to the Drug Controller General of India (DCGI), whether or not marketing exclusivity is granted.

Fourthly, one of the perceived gains of data exclusivity is an increase in foreign direct investment in the pharmaceutical sector and the arrival of newer medicines for Indian patients. The argument that data exclusivity laws will encourage the introduction of new medicines into the Indian market betrays a misunderstanding of their implications. In fact, there is a possibility that data exclusivity would actually provide incentives to delay the entry of new products

⁷⁸ GOPALAKRISHNAN & KADAVAN, *supra* note 60, at 40.

⁷⁹ See *AIDS Drugs Threatened*, N.Y. TIMES, Mar. 5, 2005, at A12, <http://www.nytimes.com/2005/03/05/opinion/05sat3.html>.

⁸⁰ Health Global Access Project, *India Could Cut-off Africa's Access to Affordable AIDS Drugs; Indian Parliament May Begin Considering the Issue*, at http://www.healthgap.org/press_releases/05/030104_HGAP_AA_INDIA_IPR.html.

⁸¹ Jeremy Clark Ogusky, *Data Exclusivity Regulations in India*, at http://www.bilaterals.org/article-print.php?id_article=5425.

⁸² See INT'L FED'N OF PHARM. MFRS. ASS'NS, *supra* note 6, at 1.

⁸³ Junod, *supra* note 1, at 485.

⁸⁴ *Id.*

for MNCs would prefer to keep prices high in developed markets by delaying their entry into the developing world at lower prices.⁸⁵ This is because introducing the drugs in developing countries at lower prices will invariably lead to a fall in their price globally also. To preserve that high price, new drugs would only be introduced after a delay in developing countries.

Fifthly, data exclusivity would render redundant the use of a compulsory licence, a market exclusivity waiver on patents provided by TRIPS in the event of a health emergency. A compulsory licence is the instrument available in India to curb the abuse of monopoly by multinational companies. The government can issue such a licence after three years of the grant of the patent, if it is found that the patented drug is not available, or it is too expensive, or the development of domestic industry or an export market is hampered. However, if data exclusivity laws are introduced, they may act at cross purposes with compulsory licences, because the DGCI may have to ask Indian companies to conduct fresh clinical trials before getting marketing approval.⁸⁶ There is a possibility that the domestic sector may not be able to duplicate even its own data for getting marketing approval even when the companies may be granted a compulsory licence for meeting the demands for some patented products.⁸⁷

Sixthly, in order to enter even small and marginally profitable markets, generic competitors would be required to duplicate expensive and time-consuming clinical trials in order to establish safety, quality, and efficacy. Another concern is that animals and other research subjects are dangerously exploited if the second applicant has to replicate studies already performed by the pioneer company.⁸⁸ If the same agency has approved a drug based on clinical data provided by one company, there is no logical reason why the same drug should be refused marketing approval if another company produces it.

Finally, currently, the DCA defines 'new drug' requiring regulatory approval as something much wider in scope than 'new chemical entity', including drugs

⁸⁵ Grover, *supra* note 64, at 4.

⁸⁶ Dalal, *supra* note 2.

⁸⁷ Adebare, *supra* note 67.

⁸⁸ Junod, *supra* note 1, at 486.

“proposed to be marketed with modified or new claims, namely, indications, dosage, dosage form . . . route of administration.”⁸⁹ If the data exclusivity law is enacted as mandatory for all ‘new drugs’ as presently defined under the DCA, drug companies will be able to enjoy *de facto* monopoly rights over trivial changes that may not even be patentable under patent laws for lack of inventiveness, but still qualify as new drug under the DCA. This can arguably constitute protection to an unreasonable extent for pioneer pharmaceutical companies. The extension of intellectual property beyond its boundaries, so as to protect investment and not intellectual contributions, disrupts the essence of a system conceived to reward the creators of original ideas and new inventions.

V. CONCLUSION

Considering the fact that various interest groups are seeking amendments in Indian law to introduce data exclusivity provisions, the issue is a crucial one. As noted above, there are several reasons why data exclusivity laws should not be brought into India at this stage. An analysis of article 39 of TRIPS and its legislative history indicates that TRIPS speaks of data protection in a flexible manner, and does not mandate data protection to be implemented by bringing in a data exclusivity regime. Thus, the argument that data exclusivity must be provided for in Indian law for India to be in compliance with TRIPS is fallacious. Protection against “unfair commercial use” under TRIPS must be interpreted to mean protection through non-disclosure and prohibiting others from accessing test data for unfair commercial use. TRIPS gives member states the freedom to choose the nature and extent of protection they want to offer. This interpretation of TRIPS finds support from most Indian pharmaceutical companies.⁹⁰

Most Indian companies recognise the government’s use of data as an exception and support allowing authorities enough discretion to use research data for comparison with a subsequent product’s data.⁹¹ Use of pioneer data by the authorities for granting approval to a subsequent product is not an unfair

⁸⁹ Dalal, *supra* note 2.

⁹⁰ GOPALAKRISHNAN & KADAVAN, *supra* note 60, at 42-43.

⁹¹ *Id.* at 43.

commercial use, but is a harmonious balance between public and private interests, and is also the exercise of a sovereign function of the licensing authority. The introduction of product patents in India has provided further protection to pioneer manufacturing companies, and the generic industry in India as well as the general health of ordinary citizens seems likely to suffer if data exclusivity were brought into effect in India. Thus, it does not seem advisable to enact data exclusivity laws in India or to amend the DCA or the Insecticides Act to accommodate data exclusivity.

This, however, does not mean that no change at all is required in data protection laws in India. While, a specific clause should be introduced that allows the DCGI to demand undisclosed information for drug approval for manufacture of generic drugs,⁹² at the same time, provisions creating obligations on the part of the DCGI to keep the undisclosed information submitted to them secret should be introduced so that information is not leaked to other competing companies. While the Indian pharmaceutical sector is largely against data exclusivity, it does support a stronger system of data protection in India.⁹³ There is no express provision in the DCA or the Rules obligating the Drugs Controller General of India to keep the data submitted to him under these laws in confidence. Although Rule 53 creates an obligation on part of the Drugs Inspector to keep the information supplied to him secret, this has not been extended to the office of the DCGI.⁹⁴ In the absence of such a provision, the DCGI may not be covered by the Official Secrets Act, 1923 either. The common law protection of trade secrets submitted to the authorities has not extended to India through case law as of now.⁹⁵ Thus, there seems to be a lacuna in the law for ensuring protection of undisclosed information submitted to the DCGI for approval. Strong trade secret protection laws are thus required to fill this void and to satisfy the demands of the Indian pharmaceutical sector. Thus, the DCA should be amended not to focus on data exclusivity but to introduce mandatory provisions for ensuring the safety and quality of drugs.

⁹² *Id.* at 46.

⁹³ *Id.* at 44.

⁹⁴ *Id.* at 35.

⁹⁵ *Id.* at 36.

Until the Indian market reaches a stage at which data exclusivity laws will be useful or conducive to the Indian pharmaceutical sector, the move to amend the DCA and other laws to accommodate data exclusivity should therefore be opposed, subject to the introduction of the changes recommended in this article.