

DATA EXCLUSIVITY IN INDIA: A SAGA OF IGNORANCE AND ILLOGICALITY

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Abstract

The central point of conflict between innovator and generic pharmaceutical companies is how generic companies circumvent drug authorization procedures for manufacturing products already invented by innovator companies. Governments rely on the post-screening data submitted by innovators to check the similarity of the generic's product with the innovator's product. Generics are able to reduce costs because of low trial and testing costs. This helps them market cheap and similar medicines but according to the innovators, there must be intellectual property protection given on the data that they have already submitted given its newness and expensive generation. Governments should not rely on them at least for a few years. The TRIPS Agreement is ambiguous on this issue leading to different interpretations. India interprets

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against such protection on the misplaced belief that imposing it would finally lead to delay and increase in medicine costs. This paper brings out the fallacy in the above line of thought by interpreting the TRIPS in a manner which clearly indicates towards a regime of data exclusivity as a means of intellectual property protection. Analysis of data from countries shows the benefits of such interpretation- encouraging critical research and development of cheaper and more effective medicines. It allows for foreign investment and collaboration opportunities. India's position on data exclusivity is incorrect and dangerous making the country lose out on crucial benefits. Concerns such as high prices of medicines can be remedied utilizing the provisions already there in Indian law. This plan of action will protect intellectual property towards better public healthcare conditions.

I. INTRODUCTION

The Indian pharmaceutical industry has high output and growth rates and is one of the top five in the world.¹ It is widely credited to have

¹The industry was estimated to be US\$ 10.76 billion in 2008 and grew at a high compound annual growth rate (CAGR) of 9.9 per cent till 2010 and has been estimated to grow at a CAGR of 9.5 per cent till 2015. It ranks 4th in volume terms and 13th in value terms. *Drugs and Pharmaceuticals*, CONFEDERATION OF INDIAN

helped in controlling diseases, especially in poor countries, by marketing cheap drugs through its domestic generic industry.² The generic industry, unlike its counterpart innovators, is able to produce and market drugs already discovered and patented, at cheaper costs because it is allowed to circumvent all clinical trial processes for their medicines by submitting bioequivalence reports, without conducting full clinical trials of their medicines, to the designated government authority and the authority relies on the data submitted by the innovator to check the bioequivalence of the generic's product. This process deserves criticism because the generics are able to produce the same medicines without investing as much time and money.

In this context, this paper intends to look at the Agreement on Trade Related Aspects of Intellectual Property Rights and examines the kind of protection and incentives it envisages and whether and how the Indian legal system complies with its obligations.

The existing body of literature in the Indian context has interpreted the TRIPS to mean that it does not refer to a regime of data exclusivity and having it would be against India's interests. It develops on the premise that protecting intellectual property rights in India would necessarily be against India's interest. This paper brings out the fallacy in this argument and presents an alternative argument that not only does TRIPS refer to a data exclusivity regime but with a whole basket of legal reform, such a regime can act in India's interests to promote public healthcare. It proposes that the existing *status quo* of not recognizing data exclusivity has only harmed India's

INDUSTRY,

<http://www.cii.in/Sectors.aspx?enc=prvePUj2bdMtgTmvPwvisYH+5EnGjyGXO9hLECvTuNtw8YL926EJfiCmU3ofN0YX>

²*India is fittingly known as pharmacy of the developing world*, 14 MSF UNTANGLING THE WEB OF ANTIRETROVIRAL PRICE REDUCTIONS 6-7 (July 2011).

interests and hence there is an urgent need to look at our legal structure

Part I of the paper is opened to the reader to describe the philosophical base and how the paper seeks to take the reader through the complex arguments to be put forth. Part II deals with the various entities, operations and universal issues in relation to data exclusivity. Part III discusses the various provisions of the TRIPS Agreement while the next part interprets them. The subsequent part discusses the Indian position and proposes changes in its legal regime. Part VI deals with miscellaneous concerns and benefits stemming from this discussion. The paper ends with a conclusion summarizing the various issues raised in the paper.

II. TYPICAL PHARMACEUTICAL INDUSTRY

A. *Entities Operating*

The general norms of how pharmaceutical industries operate in the world are consistent across countries.³ A pharmaceutical product that is first authorized for marketing based on data submitted for proving its efficacy, safety and so on is called the innovator pharmaceutical product.⁴ A lot of research, time and money is generally invested while conducting research on the product especially in clinical trials.

³*Infra* note 5, 43, 46 and 56.

⁴*Glossary*, WORLD PHARMACEUTICAL FRONTIERS, <http://www.worldpharmaceuticals.net/glossary.htm>. These definitions have been taken because the drug approval procedures in different countries are fundamentally and normatively same. Mayu Hirako provides an excellent comparison of the procedures in Mayu Hirako, *A Comparison of the Drug Review Process at Five International Regulatory Agencies*, 41 *DRUGINFORMATIONJOURNAL*291–308 (May 2007).

The research and trials' data have to be submitted to the stipulated statutory authority for getting marketing approval.

Upon evaluation, if the authority deems it appropriate and if the test results and the medicine satisfy the authority, it will give permission to the innovator company for marketing the product.

Any company that also wants to market the product that the innovator company produces can do so by first manufacturing a product that is similar to the innovator's product and selling it subsequently but without putting its brand name on the package and only the generic name of the drug which basically means the chemical composition. The generic company need not make its product undergo clinical trials. It only has to show that its product is 'bioequivalent' to the innovator product of which it wants to produce a generic version. The government authority utilizes the innovator's clinical trial data produced to see whether or not a generic's product is bioequivalent to the innovator's product. The most obvious benefit that the generic company gets in this scenario is the fact that it does not have to pay the high costs nor spend the time that clinical trials would usually take. If the government authority gives its approval, the generic can sell the medicines at low prices albeit without its brand name and by including only the generic name of the medicine.

B. Common Concerns

Several concerns are raised when an industry operates as described above. Innovators object to how generic companies are able to avoid clinical trials and still manufacture and market the innovator drugs.

It is trite to mention that clinical trials are very expensive and the costs of such data have exploded over time and even rough estimates are testament to their high costs. While launching a drug, the money spent on research constitutes a major portion of the total costs

involved.⁵ This percentage has only grown through the years.⁶ This paragraph can be clubbed into one single line.

With the costs involved, the time taken to get the regulatory approval by the governmental authority to grant permission to the innovator to manufacture the medicine, is also a cause for concern. It takes a long

⁵According to objective estimates, the average cost has risen to almost 60% of the total development costs and that of pediatric trials has increased nearly eight fold from 2000 to 2006. Clinical Trial Facts and Figures, CENTRE FOR INFORMATION AND STUDY ON CLINICAL RESEARCH PARTICIPATION, http://www.ciscrp.org/professional/facts_pat.html. The total cost can reach \$300–\$600 million to implement, conduct, and monitor a large, multicenter trial to completion. INSTITUTE OF MEDICINE (US) FORUM ON DRUG DISCOVERY, DEVELOPMENT, AND TRANSLATION, TRANSFORMING CLINICAL RESEARCH IN THE UNITED STATES, CHALLENGES AND OPPORTUNITIES, WORKSHOP SUMMARY 26 (2010).

⁶Apart from the high cost of research, there is also the problem of drugs not succeeding even after research has been done. Matthew Herper, *The Truly Staggering Cost Of Inventing New Drugs*, FORBES, <http://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/2/>. Worldwide, research and clinical testing costs have risen to hundreds of millions of dollars per approved new molecule according to all kinds of estimates. Clinical success may be achieved at substantially lower cost with alternative models of pharmaceutical development and testing, but embracing those alternatives requires streamlined regulatory and organizational approaches and sacrifices in the richness of the evidence on the basis of which physicians must make subsequent prescription choices. F.M. Scherer, *R&D Costs and Productivity in Biopharmaceuticals*, HKS FACULTY RESEARCH WORKING PAPER SERIES RWP11-046, JOHN F. KENNEDY SCHOOL OF GOVERNMENT, HARVARD UNIVERSITY (December, 2011), http://dash.harvard.edu/bitstream/handle/1/5688848/RWP11-046_Scherer.pdf?sequence=1. Even when countries tried to reduce money spent on research, there was a drop seen in the effectiveness of drugs. According to studies conducted by a major Indian company, Wipro, in 2008-2010, there were fifty-five drug terminations in phase III which was much more than the number of terminations during the previous three year period. The number of drugs entering phase III clinical trials last year fell by a staggering 55 percent. Jennifer Zaino, *The State of Global Clinical Research Trials*, WIPRO AND UBM TECH WEB., http://www.wipro.com/Documents/TW_1108035_StofClinTrials_REV_v1.pdf

time to conduct research and get approval for pharmaceuticals.⁷ According to Professor Carlos Correa,⁸ it is the regulatory approval aspect of test data that makes them commercially important. In view of these cost and time concerns, innovators argue that it is unfair that generic companies are able to circumvent the clinical trial process. Supplying the same product at a cheaper price eats into the innovators' products. This acts as a disincentive to innovators and discourages them from investing in research and developing new medicines.⁹

Arguments in favour of such an industrial structure recognize the important of the very fundamental distinction between innovators and generics i.e. cheap medicines. Cheaper medicines allow more people to buy them, by and large improving the healthcare conditions of the country.¹⁰ Governments are usually in a fix because while there are cheap medicines on the one hand, on the other, there always is scope for research developing more effective medicines. The generic industry is also hit by massive quality concerns.¹¹

A *via media* to this conundrum is protecting the data that the innovator submits to the authority and a restriction on government

⁷For a comprehensive study of time and costs pattern in research and development, see Henry Grabowski, *Follow-on biologics: data exclusivity and the balance between innovation and competition*, 7 NAT. REV. DRUG DISCOV. 479-488 (2008).

⁸Carlos M. Correa, *Protecting Test Data for Pharmaceutical and Agrochemical Products Under Free Trade Agreements*, UNCTAD-ICTSD, http://www.iprsonline.org/unctadictsd/bellagio/docs/Correa_Bellagio4.pdf

⁹Development Studies, *Medicine & Intellectual Property*, UNIVERSITY OF DUBLIN, TRINITY COLLEGE, http://www.tcd.ie/Economics/Development_Studies/link.php?id=87. See Harris G and Slater J., *Bitter pill: "Branded generics" eat into drug makers' profits*, WSJ, April 17, 2003, at A1.

¹⁰See for example the India government's attempts at increasing use of generic drugs at *infra* 94.

¹¹For a totality of the issues explained through the Indian context, see ¶ 5.4 of this paper.

authorities relying on them. The restriction generally extends to a few years from the time the innovator company has received marketing approval. This system of protection is known as data exclusivity.¹²

Even with this solution, generics argue that a system of data exclusivity increases their costs because they have to conduct the trials again and high research costs increase cost of medicines. Developing countries like India do not want to take any chances of increase in medicine costs because of the battle against widespread, deadly diseases.

The above debate has found itself a place in international debates on the protection of intellectual property. In the following sections, the researcher intends to highlight how there indeed is a solution within the confines of international intellectual property instruments. The researcher further intend to show how India needs to reformulate its laws on the basis of its international intellectual property obligations if it has to even dream of guaranteeing the human right to healthcare.

¹²For a bird's eye view of the underlying notions and benefits of data exclusivity, see Henry Grabowski & Joseph Di Masi, *Biosimilars, Data Exclusivity, and the Incentives for Innovation: A Critique of Kotlikoff's White Paper*, DUKE UNIVERSITY DEPARTMENT OF ECONOMICS WORKING PAPER (February, 2009), <http://www.cbpp.org/9-8-08sfp.pdf>.

III. OBLIGATIONS UNDER THE AGREEMENT ON TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

The globalizing economy has brought with itself issues of competitiveness which can be achieved only by innovation and product differentiation. This domain has high costs and high risks and must attract equally high rewards. Protection of intellectual property in this context is critical. It helps not only the developed countries but also developing countries in their transition to industrialization.¹³

The Agreement on Trade Related Aspects of Intellectual Property Rights¹⁴ was framed in the year 1994 at the end of the Uruguay Round of the World Trade Organization.¹⁵ The TRIPS was a major multilateral trade-intellectual property instrument in the series of multilateral trade agreements recognizing the importance of intellectual property in trade issues, signed in the late twentieth century.¹⁶

India has been a signatory to the TRIPS and Indian intellectual property laws have been known to be largely TRIPS compliant.¹⁷ As

¹³L. Peter Farkas, *Trade-Related Aspects of Intellectual Property, What Problem with transition Rules What Changes to U.S. Law, How has Congress Salvaged 377?*, in THE WORLD TRADE ORGANIZATION, MULTILATERAL TRADE FRAMEWORK FOR THE 21ST CENTURY AND U.S. IMPLEMENTING LEGISLATION 463, (T. Stewart ed., 1996).

¹⁴Hereinafter, 'TRIPS' or 'the TRIPS Agreement'.

¹⁵Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, April 15, 1994, http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm.

¹⁶GRAEME B. DINWOODIE AND ORS., LEADING INTERNATIONAL INSTITUTIONS AND ACTORS, INTERNATIONAL INTELLECTUAL PROPERTY LAW AND POLICY, 46 (2001).

¹⁷Jeffrey Colin, *Coming into Compliance with TRIPS: A Discussion of India's New Patent Laws*, 25 Cardozo Arts & Ent. L.J. 877 (2007).

a developing country,¹⁸ India had been given time till 2005 for aligning its laws with the TRIPS.¹⁹

IV. TRIPS' PROVISIONS

Article 39 is found in Section 7, Protection of Undisclosed Information, and is relevant to our discussion. According to Article 39.3

“3. 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 (Emphasis supplied). In addition, Members shall protect such data against disclosure, except

¹⁸Members of developing countries announce on their own whether they are “developing” or “developed”. A “developing country” status invites a number of advantages including longer transition periods under WTO Agreements. *Who are the Developing Countries in the WTO?*, WTO, http://www.wto.org/english/tratop_e/devel_e/d1who_e.htm. The TRIPS as such provided a one-year transition period to all countries. [Art. 65(1): Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement.] Developing countries were provided a further period of four years. [Art. 65(2): A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5.] India has been a developing country since the time of the General Agreement on Tariffs and Trade, the predecessor of the WTO.

¹⁹Atsuko Kamiike and Takahiro Sato, *The TRIPs Agreement and the Pharmaceutical Industry: The Indian Experience*, CONFERENCE ON COMPARATIVE ASPECTS ON CULTURE AND RELIGION: INDIA, RUSSIA, CHINA”, http://srch.slav.hokudai.ac.jp/rp/group_06/activities/files/20110915_16/20110916_KamiikeSato.pdf.

where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use.”

A. *Interpreting the TRIPS*

For the purposes of our discussion, the words ‘shall protect such data against unfair commercial use’ must be taken into consideration.

The TRIPS can be interpreted using principles under the Vienna Convention on Law of Treaties, 1969. Under the general rule, any interpretation under this treaty starts with:-

- (a) The ordinary meaning of the terms of the treaty
- (b) In the context of such terms
- (c) In light of the treaty’s object and purpose.²⁰

Hence, the starting point of interpretation is the elucidation of the meaning of the text and all the principles must be taken together and

²⁰Article 31(1) VCLT. It is important to note that the rules have to be taken together and not individually or in bits. The WTO Appellate Body (AB) has laid down more specific principles for the interpretation of the TRIPS Agreement in the India-Patented Pharmaceuticals (Mailbox) Case. WTO Appellate Body Report on India-Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS50/AB/R (Dec 19, 1997), [http://www.wto.org/english/tratop_e/dispu_e/79r.pdf](http://www.wto.org/english/tratop_e/dispu_e/dispu_e/79r.pdf). Ironically, this was the first case to be filed and fought under the TRIPS and utilizing the Dispute Settlement mechanism. The United States was successfully able to argue that India had not yet set up the Patent Mailbox Mechanism for registering patent applications and had hence, violated the TRIPS. In the case, the Court held that for interpreting TRIPS, The rules of Article 31 of the Vienna Convention on the Law of Treaties apply. The panel and the AB began by examining the express terms of the TRIPS Agreement, giving them their ordinary meaning in their context, and light of the object and purpose of the agreement. The performance of the parties would be evidence of its intended meaning. Extracted version of these rules can be found at, FREDERICK M. ABBOTT, THE TRIPS-LEGALITY OF MEASURES TAKEN TO ADDRESS PUBLIC HEALTH CRISES, 73 (1998).

not individually.²¹ Further, the performance of the parties would be evidence of the intended meaning of the terms in the TRIPS.

B. Ordinary Meaning of the Terms

A dictionary and other sources of definitions help to ascertain the ordinary meaning of the terms.²²

‘*Shall*’ is generally interpreted to mean a command or instruction.²³ ‘*Protect*’ refers to defend, protect or guard against.²⁴ ‘*Such*’ can refer to something that has already been said.²⁵ “*Unfair*” means to deprive of fairness while commercial refers to some activity engaged into for profit and use means²⁶ to put something to work. Such use can be both direct and indirect.²⁷

In the construction of the sentence, when the words are taken together, it is evident that the words cast a duty on the government to protect the data that innovators submit against direct or indirect unfair commercial use.

However, because of the vagueness and subjectivity surrounding unfair commercial use, the treaty interpretation is not complete.

²¹Commentary to Article 27, VCLOT, paragraph 11, Yearbook of the International Law Commission, 1966, Vol. II, p. 220.

²²RICHARD GARDINER, TREATY INTERPRETATION, 166 (2008).

²³Oxford English Dictionary, <http://www.oed.com/view/Entry/177350?rskey=J0wBOH&result=2#eid>.

²⁴*Id.*, <http://www.oed.com/view/Entry/153127?redirectedFrom=protect#eid>.

²⁵*Id.*, http://www.oed.com/search?searchType=dictionary&q=such&_searchBtn=Search.

²⁶*Id.*, <http://www.oed.com/view/Entry/37081?redirectedFrom=commercial#eid>.

²⁷CHRISTIAN LENK, NILS HOPPE AND ROBERTO ANDORNO, ETHICS AND LAW OF INTELLECTUAL PROPERTY, CURRENT PROBLEMS IN POLITICS, SCIENCE AND TECHNOLOGY 188 (2007).

C. 'Context'

The context of the words occurring can be determined from the grammar and the syntax of the provision or phrase within which a word in issue is located.²⁸ Applying this rule, it can be seen that 'against unfair commercial use' actually describes the extent to which duty to protect such data exists. It is important to note that words occurring before or after clauses have been used as the immediate context to interpret the meaning of phrases in treaties.²⁹ Just before the clause being analyzed, there is a comma and before the comma, the undisclosed test or other data described to mean any information that has been generated after investing a lot of time and money. Now, the context of the words can be understood also by the structure or scheme underlying a provision or the treaty *as a whole*.³⁰ Looking at this provision as a whole, the exact nature of "unfair commercial use" can be interpreted to mean use of the data that has been generated,

²⁸*Id.* at 178. *Supra* note 24.

²⁹*Id.* at 183. Joost Pauwelyn, *The Role Of Public International Law In The WTO: How Far Can We Go?*, 53 *J I L* (2001). The author analyzed Article 3.2 of the World Trade Organization, Understanding on Rules and Procedures Governing the Settlement of Disputes, which reads "The dispute settlement system of the WTO is a central element in providing security and predictability to the multilateral trading system. The Members recognize that it serves to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law. Recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements." The author said that in exercising this judicial function of interpretation, WTO panels may clarify the meaning of WTO covered agreements, but they may not "add to or diminish the rights and obligations provided in the covered agreements. The immediate context of the relevant passage in Article 3.2 confirms this reading. The sentence directly follows the instruction for panels to clarify WTO covered agreements "in accordance with customary rules of interpretation of public international law." This is a clear indication that the last sentence of Article 3.2 also deals with the interpretive function of panels.

³⁰*Id.* at 182. Also see, *Dispute Concerning Filleting within the Gulf of St. Lawrence "La Bretagne"* (Canada/France) (1986) 82 *ILR* 591, 620-21.

without putting in the effort as described in the first clause, by any person, at a profit. This logical interpretation seems to clearly fit in the present context where a party i.e. the innovator, generates data i.e. clinical trial data, with a lot effort i.e. time and cost,³¹ submits it to the regulatory authority for approval of its product i.e. medicine and another party i.e. the generic, makes use of such data for profit use (i.e. the generic selling the medicines at reduced prices and making profits).

In summation, the above two sections intend to show that the TRIPS requires protection of expensive test data submitted by innovators from direct or indirect use by generics because if the generics were allowed to make use of such data without spending any costs or time, it would be very unfair for the innovators.

D. Objects and Purposes of the TRIPS and performance of parties

This section intends to substantiate upon the logical conclusion in the above paragraph by discussing whether or not, in light of the objects and purposes of the TRIPS, a system of data exclusivity is required. Because this discussion naturally intends to look at how generic industries and restrictions upon them, function across the world, by extension, this discussion would also satisfy a further tool of interpretation, specifically for the TRIPS that what the parties had intended to be included under the TRIPS can be deduced from the acts of parties itself.³²

The object and purpose of the TRIPS Agreement is to fulfil the public health obligations and strike a balance with the intellectual property

³¹*Id.* at 6, 7, 8, 9 and 10.

³²*Supra* at 21.

necessities.³³The TRIPS built on the Paris Convention³⁴ but goes beyond it in terms of prescribing higher obligations and minimum standards on state parties.³⁵

Ultimately, it is the defense of the common interests of mankind operates when it comes to multilateral treaties covering issues such as

³³The Preamble of the TRIPS Agreement has been interpreted to highlight protection of intellectual property that needs to be undertaken keeping in view the social and economic necessities of the country. This view has been carried forward in Articles 7 and 8 that aim at prescribing a balance between protecting intellectual property and promoting the social, economic conditions of the country. See Peter K. Yu, *The Objectives and Principles of the TRIPS Agreement*, <http://www.peteryu.com/correa.pdf>. Even in India, the Madras High Court accepted this understanding and held that TRIPS gave enough flexibility to the government while adopting TRIPS in its provisions and highlighted the need to ensure access to health to all citizens including that of providing access to healthcare. See Linda L. Lee, *Trials and Trips-Ulations: Indian Patent Law And Novartis Ag V. Union Of India*, 23-1 BTLJ 281. Article 31, 3(a) of the Vienna Convention reads "Any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions" shall be considered together with its context in the interpretation of a treaty. Only after the processes of negotiation and agreement were followed, was the Doha Declaration framed. Hence, it may be termed to be a 'subsequent agreement' to the Agreement on TRIPS. James Thuo Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health under the Vienna Convention on the Law of Treaties*, 15-2 HJLT 291 (2002).

³⁴Paris Convention for the Protection of Industrial Property of March 20, 1883, http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html.

³⁵"Although it built on the Paris and Berne conventions of 1883 and 1886, respectively, TRIPS went well beyond the original anti-copying objectives of the drafters." J.H. Reichman, *The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries?*,³² Case W. Res. J. Int'l L. 441 (2000). "The international intellectual property system was recently strengthened and broadened by the Uruguay Round of multilateral trade negotiations whose intellectual property component, known as the "TRIPS Agreement," builds on the Paris and Berne Conventions. See Final Act Embodying the Results of the Uruguay Round of the Multilateral Negotiations, Marrakesh Agreement Establishing the World Trade Organization, signed at Marrakesh, Morocco, Apr. 15, 1994, Annex 1C, Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement"), in Results of the Uruguay Round 6-19, 365-403 (GATT Secretariat ed., 1994). Cited in J.H. Reichman & Anr., *Intellectual Property Rights in Data?* 50 Vand. L. Rev. 51.

health and artistic and scientific property.³⁶ In this backdrop, ‘unfair commercial use’ must be interpreted to mean any use that ultimately does not fulfill the public health objectives of enacting the Agreement on TRIPS.

E. ‘Performance of the Parties’:

In 1987, the United States proposed that that data exclusivity could be introduced under the concept of trade secrets. Business entities from the developed countries of the U.S., Japan and the E.U. jointly submitted that the Clinical Trial data generated took a lot of time and resources to generate.³⁷ After the TRIPS was enacted, developed countries like the United States and the European Union have interpreted Article 39.3 to be in favor of a regime of data exclusivity.³⁸ Even a developing country Argentina has been convinced about this interpretation.³⁹

F. Furthering the American Dream

In the United States of America, a company that wants to manufacture an innovator drug has to file an application called a New Drug Application. Before 1984, a company that wanted manufacture

³⁶2 PAUL REUTER, INTRODUCTION TO THE LAW OF TREATIES 2 (1989).

³⁷*Position Paper on Data Exclusivity*, THE INDIAN PHARMACEUTICAL ASSOCIATION, <http://www.spicyip.com/ip-resources.html>.

³⁸Charles Clift, *Data Protection and Data Exclusivity in Pharmaceuticals and Agrochemicals*, HANDBOOK OF BEST PRACTICES, DATA PROTECTION AND DATA EXCLUSIVITY IN PHARMACEUTICALS AND AGROCHEMICALS 431-436 (Krattiger, RT Mahoney, L Nelsen, et al., 2007).

³⁹This convincing was not without problems and the US invoked the WTO Dispute Settlement Mechanism against Argentina. The countries entered into an understanding via *Notification of Mutually Agreed Solution According to the Conditions Set Forth in the Agreement* (IP/D/18/Add.1, IP/D/22/Add.1) and Argentina finally passed laws requiring Data Exclusivity in 1996, <http://www.eldis.org/assets/Docs/29224.html>.

generic drugs of a product already approved by the FDA had to file another New Drug Application (hereinafter referred to as “NDA”)⁴⁰ effectively duplicating the investments made in the first NDA and taking more time.⁴¹

The Drug Price Competition and Patent Term Restoration Act, 1984, commonly known as the Hatch-Waxman Act, amended the Federal Food, Drug, and Cosmetic Act, 1938.⁴² The purpose of this Act was to facilitate the introduction of generic drugs without undermining incentives for innovation.⁴³ It was designed to benefit makers of generic drugs, research-based pharmaceutical companies and the public.⁴⁴

In the present regime, the generic drug manufacturer can submit an Abridged New Drug Application (hereinafter referred to as “ANDA”) if the generic drug manufacturer’s active ingredient is the “bioequivalent” of the listed drug. Regulatory authorities cannot rely on the originator’s test data to approve subsequent applications for five years from the date of the FDA approval to the originator.⁴⁵

⁴⁰The Court upheld this rule in the case of Roche Prods. v. Bolar Pharm. 733 F.2d 858 (Fed. Cir. 1984).

⁴¹Mylan Pharm. Inc. v. Henney, 94 F.Supp.2d 36, 39 (D.D.C.2000). In this case, the Court had granted Mylan’s and Pharmachemies’ claims for declaratory relief based on their dispute with the FDA regarding Barr’s entitlement to the 180-day period of market exclusivity.

⁴²For the process in the United States, THOMAS M. JACOBSEN, MODERN PHARMACEUTICAL INDUSTRY: A PRIMER 273 (2010).

⁴³Bayer AG v. Elan Pharmaceutical Research Corp., 212 F.3d 1241 (Fed.Cir.2000).

⁴⁴Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1568 (Fed. Cir.1997). The Court had relied on the cases of Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 669-74; Telectronics Pacing Sys., Inc. v. Ventritex, Inc., 982 F.2d 1520, 1524-25, (Fed.Cir.1992).

⁴⁵Judit Rius Sanjuan, *U.S and E.U Protection of Pharmaceutical Test Data*, CONSUMER PROJECT ON TECHNOLOGY, <http://www.cptech.org/publications/CPTechDPNo1TestData.pdf>. The main condition is that the approved new drug application must contain a new active

There is also a 3-year period of marketing exclusivity granted which means that for the three year period, the FDA will not accept any application for the same drug and indication.⁴⁶ Under the recently passed Patient Protection and Affordable Care Act⁴⁷, data exclusivity for biologics has been extended to four years from the date of product approval of the innovator product.

When data exclusivity was first introduced, some originator brands lost half their market share in a year after generic medicine entry.⁴⁸ The regime evidently has not affected the spread of generic drugs market- generic drugs comprised 66% of the American market in 2009⁴⁹ and 80% in 2011.⁵⁰ The market is one of those that show the maximum potential for growth and have become increasingly competitive. The generic industry is growing at more than 7.8%, a pace that is faster than the world pharmaceutical market.⁵¹

ingredient that is a New Chemical Entity or new active moiety, never previously approved by the FDA alone or in combination.

⁴⁶Steven, *It's 12 Years of Data Exclusivity*, THE GROSSMAN FDA REPORT, <http://www.fdamatters.com/?p=883>.

⁴⁷The United States Supreme Court upheld the constitutionality of most of the PPACA in the case *National Federation of Independent Business v. Sebelius* 567 U.S. (2012), Case No: 11-393.

⁴⁸Grabowski H and Vernon J. Brand, *Loyalty, Entry and Price Competition in Pharmaceutical after the 1984 Drug Act*, 35-2 JLE 331-350 (1992).

⁴⁹Shrank WH, Cox ER, Fisher MA, Mehta J, Choudhry NK, *Patients' Perceptions of Generic Medications*, 28 *Health Aff*(Millwood) 546-556 (2009).

⁵⁰*Generics grab 80% share of US market and fill 78% of prescriptions*, GENERICS AND BIOSIMILARS INITIATIVE ONLINE, <http://www.gabionline.net/Reports/Generics-grab-80-share-of-US-market-and-fill-78-of-prescriptions> .

⁵¹*The Pharmaceutical Industry in the United States*, SELECT USA, <http://selectusa.commerce.gov/industry-snapshots/pharmaceutical-industry-united-states>. *Facts at a Glance*, GENERIC PHARMACEUTICAL ASSOCIATION, <http://www.gphaonline.org/about-gpha/about-generics/facts>.

G. The EU Aspects

Data Exclusivity entered the European Union in 1987 through the 87/21/EEC Directive.⁵² Applicants for medicinal products that showed that their product was “essentially similar” to a product already authorized could rely on the test data submitted by the first applicant for the product. Different exclusivity periods were specified for different categories of products. The new 2001/83/EC Directive amended in 2004, introduces a harmonized “8+2+1” formula for new drugs approved either through the centralized procedure or the mutual recognition procedure. It refers to an eight-year Data Exclusivity, starting with the initial approval of the “European reference medicinal product” and a two year Market Exclusivity while the total period of 10 years can be extended by an additional one year maximum if, during the first eight years of those ten years, the data originator obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.⁵³ Statistics have proven that the European Union had the

⁵²Council Directive 87/21/ECC of 22 December 1986, amending Council Directive 65/65/EEC on the approximation of provisions laid down by law, regulations or administrative action relating to proprietary medicinal products. The process in the European Union can be understood from <http://www.ema.europa.eu/ema/>.

The European Agency for the Evaluation of Medicinal Products regulates procedures throughout the European Economic Community. Since 2004, it has been known as the European Medicines Agency (“EMA”). See b Adam R. Young, *Generic Pharmaceutical Regulation in the United States with Comparison to Europe: Innovation and Competition* 8 WASH. U. GLOBAL STUD. L. REV. 165 (2009). In the same paper, the authors provide an interesting comparison of the American and the EU regimes. The understanding of generic medicines is similar in the EU as it is in the USA. See European Generic Medicines Association, *FAQ on Generic Medicines*, <http://www.egagenerics.com/index.php/generic-medicines/faq-on-generic-medicines>.

⁵³Judit Ruis Sanjuan, *U.S and E.U Protection of Pharmaceutical Test Data*, Judit Rius Sanjuan, CPTech Discussion Paper - No. 1 First Published: 3 April 2006 Revised: 12 April 2006.

highest generic penetration rates in 1994-2004.⁵⁴ Interestingly, the European Union comprises of countries with both market regulation as well as stricter control of prices and generic industries have grown across the board.

H. Chinese Perspectives

Adhering to the provisions of the TRIPS was one of the conditions laid down on China for accession to the WTO in 2001.⁵⁵ China introduced data exclusivity in its law through the enactment of the Regulations for Implementation of the Drug Administration Law.⁵⁶ In 2007, Amended Regulation on the Administration of Drug Registration (Amended Regulation) were promulgated. The Regulation uses the concepts of 'new' drug and 'generic' drug. A new drug is one that has not been previously marketed in China, whereas a generic drug is one that has an existing national drug standard, and was previously approved to be marketed by SFDA.⁵⁷ Data submitted to the SFDA⁵⁸ for the approval of a drug containing a new chemical entity is protected against improper commercial use for six years from the date of marketing approval.⁵⁹ Interestingly, this protection is enjoyed not only by new drugs but also generics that imitate products

⁵⁴*Id.* at 37.

⁵⁵ACCESSION OF THE PEOPLE'S REPUBLIC OF CHINA, Decision of 10 November 2001, World Trade Organisation, WT/L/432, 23 November 2001.

⁵⁶Article 35. Enacted on August 4, 2002. With effect from September 15, 2002.

⁵⁷Steven Rizzi and Max Lin, *Generic Drug Approval Process in China*, FOLEY, July 2011, http://m.foley.com/files/Publication/e29262fa-55dc-4d12-9c90-d2bb07794ba7/Presentation/PublicationAttachment/4f0dcc1f-bd20-4ee2-a9c6-d36f62a9adcc/RizziLin_DrugApproval.pdf

⁵⁸The State Food and Drug Administration, P.R. China

⁵⁹Cheri Grace, *The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China Considerations for Access to Medicines*, June 2004, <http://www.who.int/hiv/amds/Grace2China.pdf>

sold abroad.⁶⁰ Even with such a data exclusivity provision, pharmaceutical manufacturing is dominated by generics. Compared with patented prescription drugs, the generic industry has grown more in both absolute terms and as a percentage and this trend is expected to continue.⁶¹ The industry is scheduled to grow at a CAGR of 12.9 percent to a value of USD 57.1 billion by 2014.⁶² The government nurtures the emergence of large scale generic drug companies, partnerships with multinational corporations to enable investment in R&D and encourages the overall use of generic drugs among the population.⁶³

V. TRANSNATIONAL LESSONS LEARNT FROM DATA EXCLUSIVITY REGIMES

From the above study, it is clear that generic industries are flourishing and growing even in countries that have a Data Exclusivity regime. Most times, innovator companies get patent protection for their drugs even before they get marketing approval. Data Exclusivity in such a situation helps in recouping costs. The benefits of data exclusivity are not restricted only to developed countries and their entities but even to domestic research companies. It provides incentives for research to identify new uses for existing unpatented products and for originator

⁶⁰<http://www.biolaawgics.com/India/Guise%20Biogeneric%20regulatory.pdf>

⁶¹*China's pharmaceutical industry- Poised for the Giant Leap*, KPMG (2011).

⁶² BioJobBlogger, Why Generic Drug Companies Will Dominate Future Pharmaceutical Markets, BioJOBLOG, Feb. 2010, <http://www.biojobblog.com/2010/02/articles/biobusiness/why-generic-drug-companies-will-dominate-future-pharmaceutical-markets/>.

⁶³Franck Le Deu, Rajesh Parekh et. al, *Health care in China: Entering 'uncharted waters'*, MCKINSEY & COMPANY, Nov. 2012, <http://www.mckinseychina.com/2012/09/03/healthcare-in-china-entering-uncharted-waters-2/>

companies to introduce products into developing countries, since, in effect, exclusivity would protect the companies from generic competition.⁶⁴

Even though many developing countries do not accept that the TRIPS mandates a Data Exclusivity regime, a number of them have entered into Free Trade Agreements (hereinafter referred to as “FTAs”) which require them to have Data Exclusivity in their law.⁶⁵

Data Exclusivity is necessary to provide a measure of certainty to the innovator that they will be provided with a period of protection for their efforts of testing a drug and ensuring its safety and effectiveness for patients no matter when, where or how long it takes to bring a drug to market. Patents are an important form of intellectual property, but are not themselves necessarily sufficient to create the favorable environment needed to support the development of medical advances.⁶⁶ Thus, by providing incentives for innovation through the system of data exclusivity, pharmaceutical industries have been able to flourish ensuring the good and satisfaction of all.

Concerns have been raised with regard to the system of compulsory licensing and that a regime of Data Exclusivity will go against it by delaying entry of generic medicines.⁶⁷ However, this concern is misplaced because the system of compulsory licenses works

⁶⁴CHARLES CLIFT, HANDBOOK OF BEST PRACTICES, DATA PROTECTION AND DATA EXCLUSIVITY IN PHARMACEUTICALS AND AGROCHEMICALS 434.

⁶⁵The FTA’s do not necessarily refer to the TRIPS but have a minimum period of five years of Data Exclusivity. Carlos M. CORREA, University of Buenos Aires UNCTAD-ICTSD Dialogue on Moving the pro-development IP agenda forward: Preserving Public Goods in health, education and learning.

⁶⁶Data Exclusivity Periods and Next Generation Improvements to Innovator Biologics: Key Issues Duke University Department of Economics Working Paper, No. 2009-05, Apr. 29, 2009, <http://www.ifpma.org/innovation/ip-rights/data-exclusivity.html>

⁶⁷WHO Drug Information Vol 19, No. 3, 2005, p. 239.

independent of the working of a generic industry. Further, experts have argued that given the few instances when compulsory licenses have been granted all over the world, it is unlikely the issue is of any major importance.⁶⁸

The fact that the TRIPS does not lay down specific aspects about length of data exclusivity, nature of it and so on enables countries to introduce them using different mechanisms. Generic Industries are able to capture their market share and ensure more citizens are able to access medicine through smart marketing initiatives including strategic tie-ups, high quality products and synched supply chain management⁶⁹ with different policy initiatives⁷⁰.

It has also been proposed that such a regime would hugely be in favor of small biotech firms and a data protection regime would be built into it. Hence, it must be seen that not only have a variety of countries recognized Article 39.3 referring to a Data Exclusivity regime but also in view of their public health status, the objectives of entering into intellectual property instruments have been largely fulfilled.

⁶⁸Clifford Chance, Newsletter, May 2012, Patent Law Series- Compulsory License- A growing threat to patent holders?, http://www.cliffordchance.com/publicationviews/publications/2012/05/client_briefing_patentlawseriescompulsor.html.

⁶⁹SOHM, Inc., *Entering the Huge USA Generic Pharmaceutical Market*, Mar., 2012, <http://www.sohm.com/2012/03/16/sohm-inc-entering-the-huge-usa-generic-pharmaceutical-market/>.

⁷⁰*Strategies to Increase Generic Drug Utilization and Associated Savings*, AARP PUBLIC POLICY INSTITUTE, http://assets.aarp.org/rgcenter/health/i16_generics.pdf. A White Paper release by Thomson Reuters in December 2010 provided interesting insights into transnational deals that led to generic countries expanding their markets. See David Harding, *Gaining Market Share in the Generic Drug Industry through Acquisitions and Partnerships*, THOMSON REUTERS, <http://thomsonreuters.com/content/science/pdf/lis/newport-deals.pdf>.

VI. THE INDIAN SCENARIO

A. *Generic Manufacturers and the Patent Regime*

India restricted product patents in pharmaceuticals through its principal patent legislation, the India Patents Act, 1970⁷¹ and allowed only for process patents to encourage generic pharmaceutical industries. The absence of product patents allowed generic industries to flourish because they were able to ‘reverse engineer’ the medicine and manufacture the same using their own process.⁷² After India became a signatory to the TRIPS in 2005, it has introduced product patents,⁷³ which allows generic versions to be introduced after the patent period is over.⁷⁴

B. *Pharmaceutical Industry in India- The Legislative Framework:*

⁷¹India Patents Act, 1970, Act 39 of 1970.

⁷²Ajay D’souza, *Future Of Indian Pharma Lies Beyond Generics*, THE HINDU, April 22, 2012, <http://www.thehindu.com/business/future-of-indian-pharma-lies-beyond-generics/article3339963.ece>.

⁷³For an understanding of industry response to this move, see Lorandos Joshi, *Changes in India’s Patent Law and its Repercussions on the Global Drug Industry*, <http://www.lorandoslaw.com/Publications/Changes-in-Indias-Patent-Law.shtml>.

“As a result, many MNCs exited India in the 1970s. They began to come back after 2005, launching their drugs, filing for patents, and filing lawsuits against infringement.” E. KUMAR SHARMA, *Pill Talk*, Pharma companies need to do more to cure the country of its health care ills, April 15, 2012, *Business Today*. The parent legislation, amendment act and the amended version of the parent legislation can be found at <http://www.wipo.int/wipolex/en/details.jsp?id=2407>.

⁷⁴Waning et al. *Journal of the International AIDS Society* 2010, A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries.

The principal legislation that regulates the pharmaceutical industry in India is the Drugs and Cosmetics Act, 1940.⁷⁵ It was enacted to regulate the import, manufacture, sale and distribution of drugs.⁷⁶ The Drugs and Cosmetics Rules were made in the year 1945.⁷⁷ The importer who wants to import a new drug⁷⁸ or manufacture it in India must be approved by the Licensing Authority⁷⁹ under the prescribed procedure.⁸⁰ When applying for permission, all entities have to submit data including the results of local clinical trials.⁸¹ The norms for conducting clinical trials and the format and nature of the data submitted can be found in Schedule Y to the Rules.⁸²

⁷⁵Drugs and Cosmetics Act, 1940, Act 23 of 1940.

⁷⁶Cadila Pharmaceuticals Ltd. Vs. State of Kerala and Ors., A.I.R. 2002Ker 357. For Statement of Object and Reasons, see Gazette of India, 1940, Pt. V, p. 34; for the Report of the Select Committee, see *id.* at 143. It was later extended to cosmetics too via Act 21 of 1962. According to the Madhya Pradesh High Court, "...the Legislatures of all the Provinces passed resolutions in terms of Section 103 of the Government of India Act, 1935, authorizing the Central Legislature to legislate for regulating the import, manufacture, distribution and sale of drugs and cosmetics to the extent the above matters fell within List II of the Seventh Schedule to the Government of India Act." See Dr. Prakash Chandra Tiwari v. The State of Madhya Pradesh and Ors., I.L.R. [1980]MP628.

⁷⁷Via notification No. F. 28-10/45-H(1). The notification came out in exercise of the powers conferred by sections 6(2), 12, 33 and 33N of the Drugs and Cosmetics Act.

⁷⁸Defined in Rule 122 E.

⁷⁹Defined in Rule 21(b). The Drugs Controller General of India is the nodal authority for licensing of certain drugs including blood, blood products, I.V. Fluids, Vaccine and Sera. See <http://cdsco.nic.in/html/CDSO%20Contact%2025-9-08.htm>. Different state-level authorities regulate different aspects of drug control. For details about the Drug Control Administration working in the State of Andhra Pradesh, see <http://www.apdca.net/>.

⁸⁰Rule 122-A describes the procedure for importing while Rule 122-B describes the procedure for manufacture.

⁸¹Rule 122-A (2) and Rule 122-B(2).

⁸²Reports of such clinical trials have to be submitted in the same format as given in Appendix II to the Schedule.

The clinical trials are conducted in the following phases: Human Pharmacology Phase, Therapeutic Exploratory Phase, Therapeutic Confirmatory Phase and Post Marketing Surveillance.⁸³

Schedule Y supports the growth of the generic Indian pharmaceutical industry⁸⁴ especially with the inclusion of Appendix 1-A which governs application for grant of permission to import or manufacture an already approved new drug having much lesser requirements than those for new drugs manufactured.⁸⁵ With this schedule, generic drug manufacturers usually adhere to the Guidelines for Bioavailability and Bioequivalence Studies framed in March 2005 by the Central Drugs Standard Control Organization.⁸⁶ However, by and large, there is little clarity on what kind of laws apply and companies usually go by past experience while requesting registration of their medicine.⁸⁷ India does not have a system of data exclusivity⁸⁸ and clearly, it is hence, violating the TRIPS Agreement.

⁸³Section 122-DA of the Act. Read Y. Madhavi's short but comprehensive piece on the dimensions of regulatory issues around clinical trials. http://www.nistads.res.in/indiasnt2010-11/T3_Industry/Regulation%20of%20Vaccine%20Clinical%20Trials%20in%20India.pdf. Dr. Sundeep Mishra presents other regulatory problems in his piece. He also talks about the advantages of conducting clinical trials in India and the concerns. See <http://www.usibc.com/sites/default/files/members/files/ficcidrsmishraaiims.pdf>.

⁸⁴Perspect Clin Res. 2010 Jan-Mar; 1(1): 6–10. PMCID: PMC3149409, Evolution of Clinical Research: A History Before and Beyond James Lind, Dr Arun Bhatt .

⁸⁵Animesh Sharma, *Data Exclusivity with Regard to Clinical Data*, 3 IJLT 82-104 (2007).

⁸⁶<http://cdsco.nic.in/html/be%20guidelines%20draft%20ver10%20march%2016,%2005.pdf>. For a technical, comparative understanding of regulatory standards around the world, see The basic regulatory considerations and prospects for conducting bioavailability/ bioequivalence (BA/BE) studies – an overview, Comparative Effectiveness Research, Mar., 2011.

⁸⁷<http://www.biologics.com/India/Guise%20Biogeneric%20regulatory.pdf>

⁸⁸*Supra* note 2 and 77.

C. Studies and Changes Made by the Government

The Government of India in February, 2004 constituted a Committee known as the Satwant Reddy Committee with the task of interpreting Article 39.3. The Committee interpreted Article 39.3 to require data exclusivity for insecticides but not in the case of pharmaceuticals.⁸⁹ The Government introduced the Pesticide Management Bill, 2008 to make the required amendments however, the bill has not been brought up for consideration even till this date.⁹⁰ The changes have been introduced through government notifications under the Insecticides Act, 1968.⁹¹

There has been no judicial interpretation of Article 39.3 *per se*. The High Court of Delhi had been moved to enforce the above notifications in *Syngenta India Ltd. v. Union of India* but there was no interpretation of TRIPS.⁹²

D. State of Indian Industry and the Need for Data Exclusivity

India's success story as a growing world superpower and its pharmaceutical success is marred by its pathetic healthcare conditions.⁹³

⁸⁹The whole report can be accessed at <http://chemicals.nic.in/DPBooklet.pdf>.

⁹⁰It is still pending discussion in the Rajya Sabha i.e. the Upper House of the Parliament. See <http://mpa.nic.in/preb12.pdf>. Also see the Ministry of Parliamentary Affairs' circular including it in the list of bills to be considered <http://mpa.nic.in/preb12.pdf>.

⁹¹No.17-2/2006-PP.I dated October 30, 2007 and F.No.17-2/2006-PP.I dated, February 18, 2008.

⁹²W.P. (C) 8123/2008, Delhi High Court. The Court in ¶ 39 did refer to the fact that the statute does not prescribe this kind of exclusivity but since neither of the notifications were in questions, it did not go further.

⁹³There is wide urban-rural disparity from childhood to about 5 years. Beyond that age, the disparity is compounded by social ills such as female foeticide and discrimination against women. Accessibility to cheap and effective healthcare

India is at a stage of crossing over from being a pirating nation to one strongly protecting intellectual property rights through a TRIPS compliant regime.⁹⁴ Lack of a Data Exclusivity has made India lose out on gains on other trade agreements which would have helped it offset the rising prices of drugs, if any.⁹⁵

There are real quality concerns with the generic medicines today in the drug approval process.⁹⁶ The regulations governing generic drugs

remains a distant dream. See PLANNING COMMISSION OF INDIA: Health Care in India- Vision 2020, R. Srinivasan. http://planningcommission.nic.in/reports/genrep/bkcap2020/26_bg2020.pdf

⁹⁴http://www.wipo.int/about-wipo/en/wipo_journal/pdf/wipo_journal_1_1.pdf, [http://www.ey.com/Publication/vwLUAssets/Doing_business_in_India_2011/\\$FILE/Doing_business_in_India_2011.pdf](http://www.ey.com/Publication/vwLUAssets/Doing_business_in_India_2011/$FILE/Doing_business_in_India_2011.pdf). There are major concerns about enforcement as well. See <http://www.ipo.gov.uk/ipr-guide-india.pdf>

⁹⁵Upon demands from countries like Switzerland for data exclusivity in the India-EU Free Trade Agreement, India vociferously voiced concerns against it and refused to include it. *India fights back over its generics*, ALLIANCE SUD NEWS, April 1 2012. The issue of data exclusivity in the India-EU FTA was still in consideration in the year 2012. EU-India FTA: Ska Keller, April 30, 2012, <http://www.theparliament.com/latest-news/article/newsarticle/eu-india-fta-ska-keller/>. This is particularly unfortunate because it has been recognized that the agreement is for mutual benefit. For India, what is in the reckoning is the free flow of much needed capital, technology and personnel from countries such as Luxembourg. Luxembourg for early conclusion of India-EUFTA, Oct, 16,2012, *The Economic Times*, http://articles.economictimes.indiatimes.com/2012-10-16/news/34498965_1_india-gaston-strocnck-luxembourg-ambassador-luxembourg-stock-exchange.

⁹⁶Doctors are concerned about the poorly staffed drug regulatory authority that checks generic drug quality, *What ails the generic drug?*, *Times of India*, July 29, 2012,

http://articles.timesofindia.indiatimes.com/2012-07-29/special-report/32923254_1_generic-drugs-quality-and-efficacy-pioneer-drug .See Chaudhuri, Sudip and others; Mackintosh, Maureen and Mujinja, Phares G M (2010). Indian generics producers, access to essential medicines and local production in Africa: an argument with reference to Tanzania. *European Journal of Development Research* 22(4), 451–468. Foot note The author has argued that branded drug manufacturers have withdrawn from Tanzania making way for generic drugs which are decisively lower in quality or not much concerned about it. See Heather Timmons, *India Expands Role As Drug Producer*, *The New*

themselves have been attacked on the ground that they are insufficient.⁹⁷

The government has given several advantages to the generic industry. There are several initiatives aimed at boosting their sale. The government gives them preference while prescribing medicines in government hospitals.⁹⁸

The ready market has ensured a sense of security to the generic industry. There is hardly any concern about research and development further. Most Indian companies do not have enough resources or the incentive to invent better quality drugs.⁹⁹

YorkTimes, July 6, 2010. The US FDA had directed action against an Indian generic drug manufacturer citing quality issues.

⁹⁷The author argues that quality issues in Indian drugs arise because the Bioequivalence regulations do not require showing toxicity of the drug. Mercurio, Brya, *Northwestern University Journal of International Human Rights*, Vol. 5, Issue 1 (Fall 2006), 1-40 Mercurio, Bryan 5 Nw. Univ. J. Int'l Hum. Rts. 1 (2006-2007).

⁹⁸Not only do more doctors in government hospitals prescribe them than in private ones. See Nirmalya Dutta, *Generic drugs- What You Need To Know*, Sept 26, 2012, <http://health.india.com/diseases-conditions/generic-drugs-what-you-need-to-know/>, but the Government has also setup special stores outside government hospitals that dispense generic medicines. The stores are called 'Jan Ausadhi'. See Jan Ausadhi, Department of Pharmaceuticals, Government of India, <http://janaushadhi.gov.in/foradescriptionoftheirstyleoffunctioningandideologicalbasis>.

⁹⁹Research and development have traditionally been major investments undertaken by governments as opposed to the private sector putting huge costs on the public exchequer. See the Government of India report, *Research and Development in industry: An Overview*, November, 2007 <http://www.dsir.gov.in/tpdup/irdpp/07rndoverview.pdf>. In July 2012, the Government agreed to set up a 20 billion rupees venture capital fund for pharmaceuticals. See <http://www.thehindu.com/business/Industry/govt-to-set-up-rs2000crore-venture-fund-for-rd-in-pharma/article3599041.ece>.

It is high time these hand outs by the government were stopped and an economically sensible interpretation of TRIPS was carried out.

E. Package of Reforms Required:

A system of Data Exclusivity can also be introduced with exception such as protection only to undisclosed data and not to data that has already been published and protection only for the data relied upon.¹⁰⁰

F. Price Controls

Concerns about costs of the medicines are very valid but the same can be remedied through India's home grown model of drug price regulation. The Drug Price Control Order, 1995 (hereinafter referred to as "**DPCO**")¹⁰¹ was formulated under section 3 of the Essential Commodities Act, 1995¹⁰² And fixes prices of drugs in the market. The Government while fixing prices is only guided by the Drug Price Control Order and is given enough flexibility to undertake whatever kinds of investigations it deems fit while fixing the prices.¹⁰³

Under the DPCO price control is to be based on sales turnover, market monopoly and market competition. The current tally of number of drugs subject to this regulation is 74.¹⁰⁴ The Indian Government has been fairly active in favor of controlling prices. It

¹⁰⁰*Supra* note 31.

¹⁰¹Standing Order 18(E) looks incomplete.

¹⁰²Drug Price Control Order, 1995 Act 10 of 1995.

¹⁰³Drug Price Control Order, 1995, §3(1), Act 10 of 1995.

¹⁰⁴*India Looks to Expand Drug-Price Control*, THE WALL STREET JOURNAL, <http://online.wsj.com/article/SB10000872396390443819404577633070809995582.html> .

has recently allowed price control even in the case of patented medicines.¹⁰⁵

Today, only one-tenth of the drug market is price controlled as against nearly 90 percent during the late 1970's.¹⁰⁶ Even with this extensive protection, the Price Control mechanism seems to have been a failure. It must be urgently strengthened because it will be a crucial component while fulfilling India's needs.¹⁰⁷

The government can look at¹⁰⁸ having a more participatory model of price regulation where industry concerns are brought on board while

¹⁰⁵Narayan Kulkarni, *Side effects of the New Drug-Pricing Policy*, Oct. 5, 2012, <http://biospectrumindia.ciol.com/content/newsAnalysis/11210053.asp>.

¹⁰⁶Govt. of India (2005b), Report of the Task Force to Explore Options Other Than Price Control for Achieving the Objective of Making Available Life-Saving Drugs at Reasonable Prices", September, 20, pp.17.

¹⁰⁷In spite of the very powerful drug price control mechanism we have, from 1994 through 2004, price has increased enormously across therapeutic groups. Between 1981 and 2001, drug companies in India registered super-normal profits consistently as compared to other commodity sectors. *Id.* The Supreme Court has been very concerned with rising drug prices. In response to a petition brought in by All India Drug Action Network, on Oct. 11, 2011, the Supreme Court directed the secretaries of ministry of health and ministry of chemical and fertilizer to file affidavits in four weeks stating whether the Union government wanted to bring the essential medicines under the ambit of price control. There are concerns such as those around the absence of controls for substitute medicines. Nidhi Chauhan, COMPETITION ASSESSMENT OF PHARMACEUTICAL SECTOR IN INDIA, COMPETITION COMMISSION OF INDIA, NEW DELHI, <http://cci.gov.in/images/media/ResearchReports/nidhifeb12.pdf>.

¹⁰⁸It is interesting that while the researcher had started working on this paper, there were indications that the National Pharmaceutical Policy would include a weighted average method of determining drug prices i.e. by taking into account what the average market prices of drugs in the segment being considered are but while concluding the research, a news item has reported that at the last moment, the Finance Ministry placed objections over the drug price determination mechanism. See Pharma GoM finalises pricing policy, to cover 348 drugs, Press Trust of India, September 28, 2012, <http://profit.ndtv.com/news/economy/article-pharma-gom-finalises-pricing-policy-to-cover-348-drugs-311396> and <http://www.business-standard.com/india/news/decisionpharma-policy-deferred/492163/>.

discussing prices. The government can also try looking at a more systematic mechanism of periodical drug price control like the mechanism present for regulating electricity tariff.¹⁰⁹

VII. MISCELLANEOUS CONCERNS AND BENEFITS

With more research and development, there will be more opportunities, more employment and people would be able to afford more and better medicines. This growth can be capitalized upon by the government to enhance the healthcare standards among the poorest of the poor. There will be more clinical trials where people will be able to earn more. India is already growing as a destination for conducting clinical trials. Any form of data exclusivity will increase research and development sectors leading to more trials and more economic benefits.¹¹⁰

Article IV.5 of the WTO Agreement establishes a Council for Trade-Related Aspects of Intellectual Property (TRIPS Council). The Council meets in regular session to oversee the implementation of the TRIPS Agreement and conduct other business, including negotiation further to an agenda “built in” to the TRIPS Agreement, and on

¹⁰⁹The Electricity Policy is far more commercially relevant than the Pharmaceutical Policy. For instance, under the Tariff Policy, tariff for electricity is to be fixed keeping in mind the financial viability of the sector and the ability to attract investments and promoting competition. There is an extensive system of electricity regulatory commissions that look into tariff control among other issues. For an overview of Indian electricity laws see Regulatory and Policy Environment, India’s Energy Sector, Dun & Bradstreet India, http://www.dnb.co.in/IndiasEnergySector/Regu_Power.asp.

¹¹⁰Clinical trials can be conducted in India at a fraction of the costs involved in other countries which attracts many pharmaceutical companies. Antal K. Hajos, Conducting Clinical Trials in India- A Case Study, SIBF Symposium- Re-shaping the Pharmaceutical Industry.

proposals put forward by the Members. The TRIPS Council according to its rules of procedure acts only by consensus which makes it very difficult for it to reach decisions.¹¹¹ Hence, witnessing a successful resolution of conflicting interpretations and demands around Article 39.3 might be difficult.

Under Article 64 of the TRIPS, disputes about respect to the Agreement's obligations respect have been made subject to the WTO's dispute settlement procedure. Ironically, India's track record in this respect has been particularly bad. This mechanism in the TRIPS' context was first used against India by the USA for failure of India's obligations to set up the patent mailbox system.¹¹² Because absence of a data exclusivity regime violates the TRIPS, we can expect a complaint being filed with the WTO. In view of India's track record thus far, any negative decision by the WTO will only add to a negative image of India in terms of protecting Intellectual Property.

It may always be argued that the WTO can be moved against domestic price controls imposed by India on pharmaceuticals. However, the fact that India has had a robust price control mechanism functioning till now and that price controls are in place even in developed countries, trumps any such claim.

VIII. CONCLUSION

In this paper, the authors have tried to show that interpreting the TRIPS Agreement requires introducing data exclusivity which would

¹¹¹World Trade Organization, *Whose WTO is it anyway?*, "Reaching decisions by consensus among some 150members can be difficult." http://www.wto.org/english/thewto_e/whatis_e/tif_e/org1_e.htm.

¹¹²*Supra* note 18.

help research, development and an overall improvement in the quality of medicines and thus, fulfil the public health objectives for which the TRIPS has been enacted. It looked at systems around the world to show how the system had worked which allowed for data exclusivity in a manner that achieved better access to health care. India requires a serious relook at its pharmaceutical laws to ensure that the rhetoric flow medicines does not wrongly take policy measures away from the ideal track. Different ways of introducing amendments were also discussed.

The Indian status quo of refusing to acknowledge its obligation of data exclusivity, in the long run, will not only lead to a prolonged TRIPS' violation, but a plain derogatory effect on the Indian healthcare system. The only solution is to interpret TRIPS in a manner that aims at the common interests of mankind: protect intellectual property to achieve better public health.