



2014

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Recommended Citation

Reddy T., Prashant (2014) "The Data Exclusivity Debate In India: Time For A Rethink?," *Indian Journal of Law and Technology*. Vol. 10: Iss. 1, Article 1.

DOI: 10.55496/ROGS5690

Available at: <https://repository.nls.ac.in/ijlt/vol10/iss1/1>

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THE DATA EXCLUSIVITY DEBATE IN INDIA: TIME FOR A RETHINK?

Prashant Reddy T.*

Data exclusivity or regulatory marketing exclusivity is a concept that has been subject to much debate in the Indian context – with specific reference to the Indian pharmaceutical and agro-chemical industries. This debate has been carried on in the backdrop of obligations under the TRIPS as well as the Indo-EU Free Trade Agreement.

In this paper, the author discusses the concept of data exclusivity in the light of the existing regulatory regime for pharmaceuticals and agro-chemicals in India. He also examines various Committee reports to glean the Indian stance on data exclusivity for agro-chemicals as well as pharmaceuticals and the contradictions therein. The paper proposes data exclusivity as an incentive for drug companies to conduct clinical trials, particularly local clinical trials in India rather than free-riding on foreign trials. Although such local clinical trials are in the interest of public health, they remain almost prohibitively expensive. Therefore, it is necessary that the conduct of such trials is incentivised. As the high threshold for patentability in India deters patents from being employed as such incentive, this paper nominates data exclusivity as a possible solution.[§]

INTRODUCTION

For the last few years India has been witness to several debates on the suitability of a data exclusivity regime for the country, initially in the context of TRIPs and later in the context of the proposed Indo-EU FTA.¹

By way of a brief introduction, ‘data exclusivity’, which is also known as ‘regulatory data protection’, aims to provide a period of marketing exclusivity for those manufacturing pharmaceuticals or agro-chemicals. Such marketing exclusivity is granted only for those pharmaceuticals and agrochemicals

[§] Supplied by Editorial Board.

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¹K.G. Narendranath, *IPA takes on global pharma majors rejects data exclusivity obligation*, ECON. TIMES (Oct. 25, 2002) available at: http://articles.economictimes.indiatimes.com/2002-10-25/news/27354556_1_data-exclusivity-ipa-undisclosed-test; Susan Finston, *Data exclusivity law brooks no delay*, HIN. BUS. LINE., (Jul. 18, 2006) available at: <http://www.thehindubusinessline.in/2006/07/18/stories/2006071800221100.htm>; PTI, *India against inclusion of data exclusivity in any FTA*, ECON. TIMES (Apr. 6, 2011) available at: http://articles.economictimes.indiatimes.com/2011-04-06/news/29388653_1_data-exclusivity-drug-seizure-issue-data-protection

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which are required by the law to go through rigorous clinical trials or field trials, in order to validate safety and efficacy of the product.² The limited period of exclusivity allows the first mover, who has conducted the extensive testing, to recover the costs of the clinical or field trials, failing which there would be no incentive for any of the other firms to conduct extensive testing for any of their products.³

The Indian stand on 'data exclusivity', be it the reports of Government of India (GoI) or Parliamentary Standing Committees, has been quite perplexing and marked by several contradictions and oversights not to mention the occasional gaffe. For instance, in a press release put out by the GoI during the Indo-E.U. FTA negotiations, the Minister for Industry & Commerce was quoted as stating that data exclusivity is well beyond the provisions of Article 39.3 of TRIPs and that India does not provide data exclusivity for pharmaceuticals and agro-chemicals.⁴ The statement was factually incorrect because unlike the pharmaceutical industry, the agro-chemical industry in India has had a data exclusivity regime since 2007, albeit through delegated legislation and not parliamentary legislation.⁵

In fact, at the time of the press release, the very same Government was actively trying to push for the Pesticide Management Bill, 2008 in Parliament; which bill would not only strengthen but also lengthen the existing data exclusivity regime for the agro-chemical industry.⁶ For the GoI to make such a gaffe during sensitive trade negotiations is probably without precedent. More interestingly however this statement also exposes the contradiction of denying data exclusivity for the

²See generally Aaron Xavier Fellmeth, *Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data under the TRIPs Agreement*, 45 HARV. INTL. L.J. 443 (2004)

³*Id.*

⁴ Article 39.3: 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. BS Reporter, *India will not provide data exclusivity: Anand Sharma*, BUS. STAN. (Mar. 30, 2011) available at: <http://www.business-standard.com/india/news/india-will-not-provide-data-exclusivity-anand-sharma/430285/>; PRESS INFORMATION BUREAU: *Anand Sharma Chairs Consultative Committee of Parliament on Challenges in IPR-International and Domestic*(Mar. 29th, 2011) available at: <http://pib.nic.in/newsite/erelease.aspx?relid=71341> (For text of the press release)

⁵*Infra* n. 64.

⁶*Infra* n. 62.

pharmaceutical sector on the grounds that it is 'TRIPS-plus' but actively pushing for a 'data exclusivity' regime for the agro-chemical sector.

Gaffes aside, there is a need to understand the policy debates that preceded the GoI's decision to proceed with data exclusivity for agro-chemicals in order to explain the contradiction in not extending similar protection to the pharmaceutical sector. Why is it that the GoI applies the TRIPS yardstick to deny data exclusivity for the pharmaceutical sector, while applying a different yardstick for approving a 'data exclusivity' regime for the agrochemical industry? Working towards this end, this article aims to examine key policy documents which influenced the GoI's decision on data exclusivity and explain the oversights and shortcomings with the arguments against a data exclusivity regime for the pharmaceutical industry in India.

The essay hopes to force a rethink of the present GoI position on a 'data exclusivity' regime for pharmaceuticals and at the very least stir the pot with some new arguments

The basic structure of this essay will be as follows:

- (i) Part I seeks to introduce the concept of data exclusivity followed by a discussion of the regulatory regime for Indian pharmaceuticals;
- (ii) Part II seeks to examine the Indian policy debates on data exclusivity and the contradictions therein, with specific reference to reports on the subject commissioned by the GoI or the Parliament.
- (iii) Part III seeks to question the assumption that it is acceptable for India to free-ride off foreign clinical trial data instead of conducting its own clinical trials on the Indian population in order to validate drugs on the Indian people who often are of a different genetic disposition from the population in the more developed countries and who also live in a different socio-economic context from people in the more developed countries. This part of the essay seeks to establish a direct link between the regulatory requirement for local clinical trials in India and a data exclusivity regime to incentivise such clinical trials in India. If it can be argued that India should conduct more rigorous clinical trials on Indians, it necessarily follows that India can no longer free-ride off clinical trial data in foreign countries to grant its regulatory approvals. Once it is established that India cannot free-ride off foreign clinical trial data, it follows that India will have to put in place measures to incentivise clinical trials

on Indians, especially since the threshold for patent protection in India has been placed so high. In the circumstances, data exclusivity could effectively prove to be just the incentive required to encourage more companies to conduct local clinical trials.

(iv) Part IV, seeks to examine the possibility of spurring innovation in the pharmaceutical industry, especially in the areas of Fixed-Drug-Combination (FDC) and traditional knowledge (TK) medicine. Incentives for innovation in both of these areas are poorly served by Indian patent law and a data exclusivity regime may serve as a better incentive.

PART I – PHARMACEUTICAL INNOVATION, DRUG REGULATION & CLINICAL TRIALS IN INDIA

Pharmaceutical innovation is, by any measure, one of the most complicated ventures faced by mankind and according to widely accepted estimates it can easily take up to almost a decade and close to a billion U.S. dollars to deliver a new drug from the laboratory to the market.⁷ Most pharmaceutical innovation begins in the laboratory with the screening of thousands of chemicals to either identify or synthesis a suitable drug candidate for the disease in question.⁸ Once a suitable drug candidate is identified, it is required to undergo rigorous clinical trials on animals, initially and later on human beings in order to establish both safety and efficacy of the drug.⁹

The history of rigorous clinical trials can be traced to the tragic ‘thalidomide tragedy’ in Europe. The U.S. was saved from this tragedy due to the vigilance of its drug regulator, the USFDA. The ‘thalidomide tragedy’ however led to a fundamental restructuring of the manner in which pharmaceutical drugs would be tested for safety and efficacy.¹⁰

⁷See generally Di Masi et. al., *The Price of Innovation: new estimates of drug development costs*, 22 J. HEALTH ECON. 151 (2003).

⁸See also Di Masi et. al., *Cost of innovation in the pharmaceutical industry*, 10 J. HEALTH ECON. 107(1991).

⁹*Id.*

¹⁰See generally Food & Drug Administration (FDA) – *Legislation* – available at <http://www.fda.gov/RegulatoryInformation/Legislation/default.htm>; See also Food & Drug Administration (FDA) – *Thisweek in FDA History – July 15, 1962* – available at <http://www.fda.gov/AboutFDA/WhatWeDo/History/ThisWeek/ucm117836.htm>.

It is likely that several drugs will fail to cross this barrier i.e. they may be efficacious but unsafe in the long run or they may not demonstrate the same level of efficacy as predicted during laboratory tests. If a drug clears this final threshold it will enter the market and may proceed to become a blockbuster drug which earns billions. However if the drug fails to clear the threshold of regulatory approval it will result in the sinking of the entire investment into the development of the new drug. Given the claimed investments and the risk in the innovation process it is hardly a surprise then that firms involved in the innovation process seek significant protection in the form of 'data exclusivity' and patent protection.

At this stage it is necessary to highlight the conceptual difference between patenting and data exclusivity since both concepts are often confused in the Indian context. The intellectual property in the invention or discovery of a new drug is usually protected by filing a patent application. Usually a patent application is filed at the very initial stages, almost as soon as the drug candidate demonstrates some efficacious properties during in-vitro testing. Not every patented drug will necessarily make it to the market since the patenting process is absolutely distinct from the regulatory process which certifies the safety and efficacy of the drug for the patient market. Therefore while patenting is based on whether the drug in question is novel and inventive when compared to prior art, regulatory approval for marketing of the drug is based on how safe and efficacious the drug is on both animals and human beings. 'Data exclusivity' is linked to the regulatory process i.e. the clinical data submitted by the innovator to the regulatory cannot be used by the regulator to grant generic pharmaceutical companies approval to manufacture generic versions of the same drugs.¹¹

Traditionally, innovator firms in the U.S. had complete and perpetual control of 'clinical trial' data i.e. life-long exclusivity over their clinical data. In principle, any generic firm could enter the market, subject to the patent status of the drug, provided that such a firm could carry out its own clinical trials and submit its own data to the regulator.¹² However, there was enough empirical evidence to demonstrate that generic firms were reluctant to carry out their own clinical trials due to the costs

¹¹See generally Uttam Gupta, *Data-Exclusivity vs patent: The myths and the realities*, HIN. BUS. LINE., (May. 16, 2006).

¹²See generally, Ashlee B. Mehl, *The Hatch Waxman Act and Marketing Exclusivity for generic drug manufacturers: An entitlement or an incentive?*, 81CHI.-KENT L. REV. 649 (2006).

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involved and also because of ethical issues of replicating clinical trials.¹³ All of this changed when the U.S. Congress enacted the Drug Price Competition and Patent Term Restoration Act (also known as the 'Hatch-Waxman Act') in the year 1984.¹⁴

The aim of this legislation was to increase competition amongst generic pharmaceuticals with an intention to lower the overall prices of drugs for the patient. The legislation sought to achieve this objective of lowering its drug prices by simplifying the process for granting regulatory approval to generic drugs. Pertinently, the legislation waived the requirement for generic firms to duplicate expensive and ethically problematic clinical trials which had already been conducted by the innovator firm.¹⁵ Instead, generic firms were granted marketing approvals for their drugs, on the basis of clinical data generated by the innovator, provided that the generic firm was able to establish that its drugs were bioequivalent to the innovator drugs.¹⁶ Bioequivalence tests establish that both drugs are chemically equivalent therefore confirming that the generic drug will act in a manner similar to the innovator drug.¹⁷ Given that bioequivalence tests were relatively inexpensive when compared to duplicating entire clinical trials it was no surprise that these amendments spurred the development of a whole new generic pharmaceutical business in the U.S.A.¹⁸

However in order to maintain some incentive for innovator firms to continue conducting clinical trials, especially in cases where the innovator firm would not enjoy patent protection, the U.S. Congress continued to give innovator firms a 5 year period of data exclusivity during which no other firm could enter the market through mere bioequivalence trials.¹⁹

¹³*Id.*

¹⁴*Id.*

¹⁵*Id.*

¹⁶*Id.*

¹⁷*Id.*

¹⁸*Id.*

¹⁹*Id.*

The above is the brief history of 'data exclusivity' in the U.S.A. Eventually the concept of data exclusivity as a sui generis mode of protection spread to other jurisdictions across the globe.²⁰ Before going any further on the 'Data Exclusivity' question it is first necessary to discuss in some detail the drug regulation scheme under the Drugs and Cosmetics Act, 1940 which is the legislation that governs the pharmaceutical regulatory sphere in India.

THE REGULATORY REQUIREMENTS UNDER INDIAN LAW FOR NEW DRUG APPROVALS

The Drugs & Cosmetics Act, 1940 ("DCA") is the primary legislation covering the sphere of drug regulation in India. This legislation which was enacted in 1940, even before India declared its independence from the British has remained in place with a few minor amendments. The DCA is quite a skeletal legislation which only lays down a legal framework for the institutions which are required to carry out regulatory functions along with definitional clauses on sub-standard or spurious or misbranded drugs. The primary regulatory requirements, including the clinical trial protocols, are delegated by the DCA to the GoI which for its part has enacted the Drugs and Cosmetics Rules, 1945 ("DCR").²¹ These rules can be amended by the GoI without prior approval from Parliament and as such these rules or any amendments to them are rarely ever debated in Parliament. Discussed below are the key provisions which lay down the requirements for clinical trials for new drugs in India.

(i) Rule 122E – Definition of 'New Drug': Contrary to the normal scheme of Indian legislations, the definition of 'New Drug' is found in the DCR, 1945 and not the DCA, 1940. The relevant rule is Rule 122E.²² This provision classifies a new drug into the three following categories:

(a) Any drug, "*including bulk drug substances, which has not been used in the country to any significant extent under the conditions prescribed, recommended or suggested in the labelling thereof and has not been recognized as effective and safe by the licensing authority*";

(b) A new drug already approved by the licensing authority for "*certain claims, which is now proposed to be marketed with modified or new claims, namely indications, dosage, dosage form (including*

²⁰See generally Valerie Junod, *Drug Marketing Exclusivity under United States and European Union Law*, 59 FOOD DRUG L.J. 479.

²¹S. 33 of the Drugs & Cosmetics Act, 1940.

²²Part XA of the Drugs & Cosmetics Rule, 1945.

sustained release dosage form) and route of administration". It should be noted at this stage, that new uses or incremental innovations not resulting in increasing therapeutic efficacy are not patentable under Section 3 of the Indian Patents Act, 1970.

(c) "*A fixed dose combination of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims, viz. indications, dosage form and route of administration*". This component of Rule 122E, pertaining to 'fixed dose combinations' ("FDC") will have to be read along with Appendix VI to the DCR, 1945. The Appendix specifies in some detail the various clinical trial requirements for FDCs of different permutations and combinations. For instance, if one or more of the active ingredients are new, the resulting FDC will necessarily have to undergo clinical trials. If both active ingredients constituting the FDC have been individually approved, the resulting FDC may still be required to undergo clinical trials. Similarly if the ratio of active ingredients in an already approved FDC is sought to be changed, there may be a need to carry out clinical trials depending on certain parameters.

(ii) The clinical trials requirements – Rule 122A, Rule 122B & Schedule Y to the Drugs & Cosmetics Rules, 1945: Rules 122A & 122B lay down the regulatory requirements to either import into India or manufacture in India a *new drug* as defined in Rule 122E. Both Rules 122A (Import) & Rule 122B (Manufacture) require that new drugs meet the regulatory requirements laid down in Schedule Y to the DCR, 1945.²³

'Schedule Y', which is titled 'Requirement and Guidelines on Clinical Trials for Import and Manufacture of New Drug', lays down the requirements for the three phases of clinical trials. According to Schedule Y, the three phases of a clinical trial are as follows:

Phase I: The main objective of Phase I of clinical trials is to determine the maximum tolerated dose in humans; pharmacodynamic effects; adverse reactions, if any, with their nature and intensity; and pharmacokinetic behaviour of the drug as far as possible.

²³The relevant portion of the provision reads as follows "(2) *The importer of a new drug when applying for permission under sub-rule (1), shall submit data as given in Appendix I to Schedule Y including the results of local clinical trials carried out in accordance with the guidelines specified in that Schedule*";

Phase II: The main objective of Phase II of clinical trials is to evaluate the effectiveness of a drug for a particular indication or indications in patients with the condition under study and to determine the common short-term side-effects and risks associated with the drug. While Phase I trials are carried out on a small group of healthy volunteers, Phase II trials are required to be carried out on a small group of patients.

Phase III: Also known as “therapeutic confirmatory trials”, these are the most rigorous and extensive phase of trials and are designed to “*to confirm the preliminary evidence accumulated in Phase II that a drug is safe and effective for use in the intended indication and recipient population.*” This phase tests the dosage related effects, usage in different population groups, in different stages of disease and the safety/efficacy of the drug in combination with other drugs. Phase-III trials are typically the most extensive and by implication the most expensive.²⁴

(iii) Waiver of Clinical Trials: While the clinical trial requirements themselves seem to be rather rigorous, Schedule Y actually begins by providing an exemption from conducting Phase I, Phase II & Phase III clinical trials in those cases where the drug has already received foreign regulatory approval. Given that most new drugs are introduced in the market after they have received foreign regulatory approval, the Indian drug regulator, routinely, exempts manufacturer or importers, of the new drug, from carrying out any clinical trials and approval is instead granted on the basis of bio-equivalence tests.²⁵ However even if all three phases of clinical trials are waived, Schedule Y, still requires local clinical trials on 100 Indian patients.²⁶ The logic behind local clinical trials is to confirm the safety and efficacy of the drug on Indian patients since it is presumed that clinical trials carried out predominantly in Western countries, on Western populations need to be re-confirmed on Indian people who maybe genetically different from western population and also live in a different socio-economic context.²⁷

²⁴DiMasi; *supra* note 7.

²⁵*Infra* n. 77.

²⁶The relevant part of the definition reads: *If the drug is already approved/ marketed in other countries, phase III data should generally obtained on at least 100 patients distributed over 3-4 centres primarily to confirm the efficacy and safety of the drug, in Indian patients when used as recommended in the product monograph for the claims made.*

²⁷*Infra* n. 69.

Predictably, a proviso in Rule 122 A (Import) or Rule 122B (Manufacture) allows for the Indian drug regulator to waive even local clinical trials on Indian patients on the grounds of ‘public interest’. The proviso reads as follows: “*Provided that the requirement of submitting the results of local clinical trials may not be necessary if the drug is of such a nature that the Licensing Authority may, in public interest decide to grant such permission on the basis of data available from other countries.*” The grounds of ‘public interest’ are not explained and as will be explained in a later Section of this essay, this provision has come under withering criticism from a Parliamentary Standing Committee.²⁸

PART II – THE ‘GREAT INDIAN DEBATE’ ON THE REQUIREMENT OF A DATA EXCLUSIVITY REGIME FOR PHARMACEUTICALS AND AGRO-CHEMICALS

The ‘data exclusivity’ debate in India essentially began with the negotiation and eventually the signing of TRIPs. In fact, the focus of the debate continues to be Article 39.3 of TRIPs. The provision reads as follows:

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. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

As evident from a reading of the text, Art. 39.3 required member-countries to protect test-data related to trials of pharmaceutical or agricultural chemical products to be protected against “unfair commercial use”. Since TRIPs never defined the meaning of “unfair commercial use”, the entire debate surrounding Art. 39.3 is centred on this one phrase.²⁹

While the innovator’s lobby in the US and Europe interpreted that particular phrase as requiring India to put in place a ‘data exclusivity’ regime, the lobby of generic companies, left-leaning academics and generic pharmaceutical companies interpreted the phrase as requiring at the most a ‘data protection’ regime wherein the drug regulator would be mandated to ensure the confidentiality of the submitted information, while continuing to grant approvals to generics on the basis of such

²⁸*Infra* n. 78.

²⁹See generally Watal, Jayashree, *Intellectual Property Rights in the WTO and Developing Countries* (2001) pp. 201-204.

confidential information.³⁰ In order to resolve the conflict on the interpretation of Article 39.3 the GoI commissioned at least one study and carried out yet another study by itself.

This Section of the paper will briefly summarize the above studies along with some other reports, such as reports by Parliamentary Standing Committees which although not binding on the GoI, have great persuasive value on the policy making apparatus of the GoI.

(i) The CUSAT study: The first comprehensive study on ‘test-data protection’ was conducted by the School of Legal Studies at the Cochin University of Science & Technology (CUSAT) in January, 2004, with funding from the Department of Commerce, Ministry of Commerce & Industry, Government of India.³¹

This study, titled ‘Study on Testdata Protection in India’ was reportedly “*undertaken to identify the suitable mode of protection of test data in India considering the interest of the Indian industry, while complying with the TRIPS obligations.*”³² Towards this end the CUSAT study focussed on three objectives: (a) The TRIPs requirements under Article 39.3; (b) The existing safeguards for ‘protection of test-data’ in India & (c) The perspective of the Indian Pharmaceutical Industry on the topic.

After examining the history of TRIPs and the negotiating history of Article 39.3 TRIPs the CUSAT study concluded by stating: “*the argument that data exclusivity is the only mode to protect test-data against unfair commercial use is not correct.*”³³ Further the report also stated that “*data exclusivity will only be a TRIPS plus approach and not bound by member countries.*”³⁴ Instead, the study suggested that the bar against “unfair commercial use” in Article 39.3 could be restricted to “*protection through non-disclosure*” which prohibited others “from accessing this test data for unfair commercial use” i.e. giving ‘test data’ the

³⁰See generally: Carlos María Correa, *Protection of data submitted for the registration of pharmaceuticals: Implementing the standards of the TRIPs agreement*, SOUTH CENTRE (2002); Position Paper – *Data Exclusivity: A Major Obstacle to Innovation and Competition in the E.U. Pharmaceutical Sector*, European Generic Association (EGA) (2000); Position Paper – *Regulatory Data Protection – A building block for pharmaceutical R&D*, Organization of Pharmaceutical Producers of India (2008).

³¹Prof.N.S.Gopalakrishanan et. al., *Study on Test-data Protection in India*, CUSAT (2005) at (This study was later published as a book by the Eastern Book Company).

³²*Ibid* at p [v];

³³*Ibid* at p. 45;

³⁴*Id.*

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status of confidential or trade secret information.³⁵ This mode of protection would still allow the introduction of generics on the basis of bio-equivalence data and would have little effect on keeping generics from the market.

With regard to the requirements of the domestic Indian pharmaceutical industry, the study, after extensive consultations with the domestic generic pharmaceutical industry, concluded that the Indian industry “was demanding strong protection of confidentiality” for test-data but not a data exclusivity regime.³⁶ As a result, the CUSAT study limited its recommendations to the introduction of new laws pertaining to the non-disclosure of test-data submitted to the pharmaceutical and agro-chemical regulatory authorities.³⁷ The demand for data exclusivity or ‘non-reliance’ on the test-data of innovator companies by follow on generics was clearly rejected by the study. It must be noted, that ‘data-protection’ per se, i.e. a mere confidentiality of clinical trial data is no longer the most pressing demand of the innovator pharmaceutical lobby in 2013 because companies like GSK and Roche have announced their intention to make available all clinical trial data publicly available, in order to ensure that the medical community has access to complete information.³⁸

The CUSAT study did not include within its purview any of the possible beneficial effects of a data exclusivity regime on public health, especially the utility of the data generated from local clinical trials on Indian citizens. Furthermore, the CUSAT study despite raising a warning flag with regard to drug regulatory mechanism in India and calling for “putting effective systems” in place, omits to critically examine the manner in which local clinical trials were being supervised by the DCGI.³⁹ As will be explained later in this article, the requirements of local clinical trials have a direct bearing on the need for data exclusivity and it is absolutely crucial to study the manner in which these studies are being administered.⁴⁰

³⁵*Ibid* at p. 45-46.

³⁶*Ibid* at p. 46.

³⁷*Ibid* at p. 46-48.

³⁸ Rupert Neate, *GlaxoSmithKline to publish clinical trial data*, GUARDIAN (Feb 5, 2013) available at:<http://www.guardian.co.uk/business/2013/feb/05/glaxo-smith-kline-publish-clinical-trial-data> (last visited on 4th March, 2013)

³⁹*Supra* note 32 at p.45.

⁴⁰*See generally* Part III.

(ii) Report of the Inter-Ministerial Committee setup by the Government of India: Towards the end of the 10 years period provided to India to make its laws TRIPs compliant, the Government of India constituted a special inter-ministerial committee to examine the data exclusivity issue.

This committee constituted on the 10th of February, 2004 was headed by Mrs. Satwant Reddy, Secretary and Mr. Gurdial Singh Sandhu, Joint Secretary, to the Department of Chemicals & Petrochemicals, Govt. of India. The Committee also had as its members, representatives from other relevant Ministries of the Government of India.⁴¹ The final report submitted by the Committee was officially titled “Report on steps to be taken by Government of India in the context of Data Protection Provisions of Article 39.3 of TRIPs Agreement”⁴² (Hereinafter ‘Reddy Committee Report’).

The ‘office memorandum’ constituting the Committee required it to examine and consider the steps to be taken by the Government of India in the context of the provisions of Article 39.3 of the TRIPs Agreement, for the protection of undisclosed regulatory information.⁴³ The Committee was also required to look at whether data protection can be offered under the existing legal provisions or whether the Government was required to create a new mechanism.⁴⁴

In its final report submitted on the 31st of May, 2007 the Committee examined separately the requirements of the agro-chemical industry, the pharmaceutical industry & the traditional medicine sector. Surprisingly, the Committee made different recommendations for each sector i.e. it recommended a ‘data exclusivity’ regime for agro-chemicals but only a ‘non-disclosure’ or confidentiality regime for the information submitted by the pharmaceutical sector and the sector of traditional knowledge medicines industry i.e. the test data would be considered confidential but a regulator could still depend on this information to grant approvals to generics. The detailed reasoning of the committee for each sector is explained below:

⁴¹The committee had a total of 15 members, most of whom were bureaucrats from various Ministries also had as its members academics, lawyers and the Drug Controller General of India.

⁴²Mrs. Reddy et. al., *Report on steps to be taken by Government of India in the context of Data Protection Provisions of Article 39.3 of TRIPs Agreement*, GOVT. OF INDIA (2007).

⁴³Notification No.11025/7/2003-PI-II, Department of Chemicals and Fertilizers, Ministry of Chemicals and Fertilizers, Government of India, 19th February, 2004.

⁴⁴*Id.*

(a) The Agro-chemical industry: The Committee assessed the suitability of a ‘data exclusivity’ regime for the agro-chemical industry without any discussion on the minimum international obligations that India was required to fulfil under Article 39.3 of TRIPs.

Instead, the Committee adopted a more ‘nationalistic approach’ i.e. it decided to approach the issue of ‘data exclusivity’ not from the perspective of TRIPs but instead on the overall effect of such a policy on India and its farmers. The Committee very pertinently notes that India cannot depend on foreign data while approving the safety and efficacy of agro-chemicals since “*efficacy tests for agro-chemicals must be repeated in every country, even in several regions in a country due to differences in crops, pests, agronomical practices, climate conditions and terrains.*”⁴⁵

The committee also noted that as a result of India not providing ‘data exclusivity’ protection to agro-chemicals, the Indian farmers were being deprived of the latest agro-chemicals since there was no way for originator companies to protect their test-data from being exploited by free-riders.⁴⁶

As a result the Committee recommended that test data generated by originator agro-chemicals be given a three year ‘data exclusivity’ term during which the regulatory authority could not rely on the data of the originator to grant approvals to generics.⁴⁷

(b) The Traditional Medicines industry: While assessing the requirement of a ‘data exclusivity’ regime for the traditional Indian medicines, a category of medicines that is formally recognized under Indian law, the Committee once again stayed away from any TRIPs analysis, focussing instead on the existing incentives under the law for innovation of traditional knowledge. The Committee notes that in the absence of patent protection for traditional knowledge under the Patents Act, 1970, there are few incentives for the traditional medicine industry to continue innovation.⁴⁸ The committee also notes that the Government was in the process of establishing a regulatory mechanism for traditional medicines and that the sector would have to conduct rigorous trials to validate the safety and efficacy of these medicines.⁴⁹ Given the increasing regulatory demands of the

⁴⁵*Supra* n. 43 at p. 23-26.

⁴⁶*Id.*

⁴⁷*Ibid* at p. 39 (para 7.4).

⁴⁸*Ibid* at p. 36-37; Section 3(p) expressly prohibits the patenting of traditional knowledge.

⁴⁹*Id.*

sector and the lack of any other incentives for the sector, since patent protection is banned for traditional medicines, the Committee recommended a five year ‘data exclusivity’ regime be granted for traditional medicines for the following purposes⁵⁰:

“i) Data in support of new use or new dosage forms for traditionally used medication.

ii) Data generated in respect of standardization of products.

iii) Data generated for safety / efficacy / stability / quality / process standardization of an existing or a new product.”

(c) The Pharmaceutical industry: With regard to the pharmaceutical industry, the Committee was of the opinion that India’s minimum requirements under Article 39.3 of TRIPs would be fulfilled by strengthening the ‘data-protection’ laws to ensure that the drug regulators maintained the confidentiality of the ‘test data’ submitted to it.⁵¹ It however recommended, that in the long run, India should move towards a ‘data exclusivity’ regime for even pharmaceuticals and went ahead to suggest a possible model for the same.⁵²

Interestingly, the Committee distinguishes its recommendations for the agro-chemical industry and the pharmaceutical industry on the grounds that while the former could not depend on ‘foreign data’ for regulatory approval in India, the latter industry was allowed to depend on ‘foreign data’ for regulatory approval within India. In pertinent part the report states: “Unlike pharmaceuticals, efficacy tests for agro-chemicals must be repeated in every country, even in several regions in a country due to differences in crops, pests, agronomical practices, climate conditions and terrains.”⁵³

As noted elsewhere in the Committee’s report, the law in India allows companies to secure approvals on the basis of ‘foreign test-data’ and data from local clinical trials on a small number of Indian patients along with bio-equivalence tests. According to the report, the cost of local clinical

⁵⁰*Ibid* at p. 42-43.

⁵¹*Ibid* at p.44.

⁵²*Ibid* at p. 46-53.

⁵³*Ibid* at p.23.

trials and bio-equivalence tests is a “far simpler exercise requiring much less time, effort and money than conducting the full set of clinical trials”.⁵⁴

The Committee therefore links its final recommendations on data exclusivity for ‘pharmaceuticals’ to the requirements of regulatory laws in India. However, if the regulatory requirements of the law itself are questioned, the conclusions of the Committee will have to be re-examined.

The question therefore that will be examined at a later stage in this essay is the paradox of India prescribing rigorous local trials for agro-chemicals but exempting pharmaceuticals from the same. This is important because as explained earlier the requirement for ‘data exclusivity’ is intrinsically linked to the regulatory requirements of Indian laws.

(iii) Report of the Parliamentary Standing Committee on the ‘Patents & Trademarks System in India’: This Parliamentary Committee, consisting of 30 odd Members of the Indian Parliament, across party lines, was conducting a general study on the ‘Patents & Trademarks System in India’ and it tabled its final report before Parliament on October 24th, 2008.⁵⁵

Since major pharmaceutical organizations for both innovator and generic companies along with ‘access to medicine’ NGOs had deposed before the Committee, the issue of ‘data exclusivity’ was also examined by this Committee.⁵⁶ In pertinent part the Committee notes:

“The Committee feel that conceding to demand for Data Exclusivity would amount to agreeing to TRIPS plus provisions.”⁵⁷

“5.48 Since the consequences of Data Exclusivity are quite serious, the Committee strongly recommend that the Government should not fall prey to such demands of MNCs.”⁵⁸

⁵⁴ *Ibid* at p.15.

⁵⁵ 88th Report on Patents & Trade Marks System in India, Department Related Parliamentary Standing Committee on Commerce, RajyaSabha, Parliament of India (2008).

⁵⁶ *Ibid* at para 5.47-5.48.

⁵⁷ *Ibid* at para 5.47.

⁵⁸ *Id.*

For reasons best known to the Committee it did not make any reference to the Reddy Committee report despite the same being brought to its notice by one of the organizations which deposed before the Committee.⁵⁹

The Committee also completely failed to acknowledge the fact that the Government of India had already implemented a ‘data-exclusivity’ regime for the ‘agro-chemical’ industry through a notification of the Central Government.⁶⁰ If the Committee had taken note of this particular fact, it would have been hard-pressed to state that India should not adopt a ‘data-exclusivity’ regime merely because it is a ‘TRIPs-plus’ regime.

(iv) Report of the Parliamentary Standing Committee on the ‘Pesticide Management Bill, 2008’: In 2008 the Central Government, acting on the recommendations of the Reddy Committee Report, incorporated a ‘data exclusivity’ clause into the Pesticide Management Bill, 2008 which was subsequently introduced into Parliament on the 30th of September, 2008 by the Ministry of Agriculture, Government of India.⁶¹ Clause 12(6) of this Bill, which is the ‘data exclusivity’ clause, prohibited the Indian regulators from relying on the data submitted by an originator for granting approval for a period of 3 years. As is the usual practice the Bill was referred to a Parliamentary Standing Committee for examination and public consultations. Not only did the Standing Committee approve of the ‘data exclusivity’ clause, it recommended that the period of ‘data exclusivity’ be extended from 3 years to 5 years.

In pertinent part the report states *“In order to encourage the introduction of newer pesticide molecules in the country, the Committee recommend that the data protection period should be increased to five years. Applicants may be asked to declare in their applications the ‘Trade Secret Data’ that require protection. However, Central Government should have the power to disclose the ‘Trade Secret Data’ information when it is absolutely essential in public interest.”*⁶²

⁵⁹*Ibid* at Annexure IX.

⁶⁰*Infra* n. 63.

⁶¹46th Report on the ‘Pesticide Management Bill, 2008’, Department Related Parliamentary Standing Committee on Agriculture (2008).

⁶²*Ibid* at para 33.

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Unlike the other Parliamentary Standing Committee referred to earlier, this particular committee made no reference to TRIPs at all. The Pesticide Management Bill, 2008 has been pending before the Parliament of India for the last four years.

It may also be pertinent to mention that the Government of India was so keen to enforce a 'data exclusivity' regime in India that instead of waiting for Parliament to pass the aforementioned Bill, it issued two notifications creating a 'data-exclusivity' regime for the agro-chemical industry.⁶³

PART III: THE IMPORTANCE OF LOCAL CLINICAL TRIALS TO INDIAN PUBLIC HEALTH – THE MISSING LINK IN THE DATA EXCLUSIVITY DEBATE

A. THE LINK BETWEEN LOCAL CLINICAL TRIALS AND DATA EXCLUSIVITY

By implication, most of the Indian arguments against data exclusivity for pharmaceuticals presume that India does not need to provide an incentive for clinical trials in India since it can effectively 'free-ride' off the regulatory data that pharmaceutical companies are bound to generate for the prosperous markets of North America & Europe. Such a negotiating strategy bears close resemblance to India's historic decision in 1970 to do away with pharmaceutical patents.⁶⁴

The assumption in that case was that regardless of the legal position in the Indian market, pharmaceutical companies would continue with innovation for foreign markets.⁶⁵ It is however doubtful whether such logic can be replicated in the context of local clinical trials which are carried out to validate drugs in the socio-economic-genetic context of the Indian sub-continent. In other

⁶³ No.17-2/2006-PP.I dated 30th October, 2007, Department of Agriculture & Co-operation, Ministry of Agriculture, Government of India, F.No.17-2/2006-PP.I dated 18th February, 2008, Department of Agriculture & Co-operation, Ministry of Agriculture, Government of India;

⁶⁴ See generally Shamnad Basheer, *India's Tryst with TRIPS: The Patents (Amendment) Act, 2005*, 1 IND. J. L. & TECH. 15 (2005). One of the main reasons given by the Government of India to justify the decision to bring back pharmaceutical patents in 2005, apart from its TRIPs obligation, was the hope that Indian companies were capable of carrying out pharmaceutical innovation for neglected diseases i.e. diseases afflicting developing countries like India and which were ignored by western pharmaceutical companies who were more concentrated on drugs for diseases affecting the more prosperous markets of the West. This dream of Indian scientists focussing on Indian diseases was partly realized when Indian scientists at Ranbaxy successfully concluded clinical trials of the first low-cost Indian drug against malaria. See generally Mansi Mithel, *Ranbaxy launches home-grown malaria drug*, BUS. WORLD, Apr. 30, 2012. Available at: <http://businesstoday.intoday.in/story/ranbaxy--malaria-drug-synriam/1/24381.html>

⁶⁵ See generally N.R. AYYANGAR, REPORT ON THE REVISION OF THE PATENTS LAW (1959).

words, the innovator firm has to carry out such trials exclusively for the Indian market and it is only incentives in the Indian market that are going to influence the decision of the innovator firm.

If there is a consensus on the fact that such local clinical trials are vital to meet the public health requirements of Indian patients, it follows that Parliament must provide innovators an incentive to carry out local clinical trials in India. In normal circumstances if a pharmaceutical drug already had patent protection, there would be no need to grant an added incentive to carry out local clinical trials. Instead, the drug regulator could withhold regulatory approval until such tests are carried out.

However as we have witnessed in India, a large number of drugs on the market do not have patent protection due to a high threshold under the Indian Patent Act, 1970 and if India were to mandate local clinical trials without any added incentive, it is possible that most pharmaceutical companies would have little or no incentive to carry out such trials without added incentives since the law does not prevent their competitors from 'free-riding' on the original clinical trial data.

Data exclusivity could be one such incentive for pharmaceutical companies to carry out local clinical trials. As explained earlier, the requirement of local field trials for testing pesticides in local Indian conditions was one of the main reasons that the Indian Government is pushing for a data-exclusivity regime for agro-chemicals. The issue thus that we are required to examine in this context, is whether the Indian govt. has factored in the importance of 'local clinical trials', while arguing against a data exclusivity regime for pharmaceutical companies.

B. THE REPORT OF THE PARLIAMENTARY STANDING COMMITTEE ON HEALTH & ITS IMPLICATIONS FOR LOCAL CLINICAL TRIALS

In the budget session of the Indian Parliament in 2012, the Parliamentary Standing Committee on Health & Family Welfare, which has as its members 30 MPs, from across the political spectrum, had tabled a damning report on the state of drug regulation in India.⁶⁶ The report, which is probably the first ever comprehensive study of the Indian drug regulatory framework focussed on the functioning of the Indian drug regulator and also the manner in which local clinical trials were being routinely waived by the drug regulator without any cogent reasoning.

⁶⁶59th Report, *The functioning of the Central Drug Standard Control Organization (CDSCO)*, Department Related Parliamentary Standing Committee on Health, Rajya Sabha, Parliament of India (2012).

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In a scathing indictment of the drug regulator - the CDSCO – the report stated the following “*The Committee is of the firm opinion that most of the ills besetting the system of drugs regulation in India are mainly due to the skewed priorities and perceptions of CDSCO. For decades together it has been according primacy to the propagation and facilitation of the drugs industry, due to which, unfortunately, the interest of the biggest stakeholder i.e. the consumer has never been ensured.*”⁶⁷

On the point of local clinical trials, the parliamentary panel examined three specific points: (i) The importance of local clinical trials for India; (ii) the regulatory requirements for local clinical trials in the DCR, 1945 & (iii) the manner in which local clinical trials were being waived.

Given the scathing and eloquent critique by the Panel report, the writer has extracted in whole, the relevant statements made by the Panel:

(i)The importance of local clinical trials for India: The committee had the following to state on the issue of local clinical trial in India: “*The basic purpose of Phase III trials is to determine if there are any ethnic differences that can alter the metabolism, efficacy and safety of the drug when administered to patients of different ethnicities living in India (such as Indo-Aryans, Dravidians, Mongoloids, Tribals etc.). There is evidence that the effect of some drugs can vary among various ethnic groups. For example, the blood levels reached after intake of lipid lowering agent rosuvastatin are far higher in Asians, compared to Europeans and North American Caucasians, Hispanics and Blacks needing lowering of dosage. Failure to lower dose in Indians can result in severe toxicity, including life-threatening muscle injury leading to fatalities. Hence, testing drugs in the Indian ethnic groups is of paramount importance before approving any drug of foreign origin.*”⁶⁸

This issue raised by the Committee is of utmost interest in the Indian context since it questions a longstanding assumption that India could free-ride on foreign regulatory approvals, especially approvals granted by the United States Federal Drug Regulatory Authority (USFDA). It should also be noted that the rationale provided by the Committee in order to push for more local clinical trials on Indians, has also been used in the West to

⁶⁷*Ibid* at para 2.2.

⁶⁸*Ibid* at para 7.10;

question the practice of outsourcing clinical trials to countries like India which differ in their genetic makeup from countries in the West.⁶⁹

Although the Committee does not exactly examine the manner in which USFDA approvals are granted, the writer has sought to fill in this minor oversight, by explaining the ethnicity and race requirements for clinical trials in the USA.

Traditionally, USFDA 'Guidance for the Industry' on 'Collection of Race and Ethnicity Data in Clinical Trials'⁷⁰, have recommended that data be collected in the following format for different races: (a) American Indian or Alaska Native (b) Asian (c) Black or African American (c) Native Hawaiian or other Pacific Islander (d) White.⁷¹ Although there is no separate category for Indians, the definition of 'Asian' stretches from persons having origins in the Far East to persons from the sub-continent i.e. from Japan to Pakistan.⁷² Prima facie, this classification seems to be suspect since a majority of Indians are not of the Mongoloid race as is the case with most people who have their origins from countries like China or Japan. In fact, India is one of the most genetically diverse populations. It must be remembered that the USFDA guidance is not binding and recent studies have concluded that an overwhelming majority of patients enrolled in clinical trials in the US are 'white'.⁷³ It is worrying to note such statistics because the USFDA is often considered to be the gold-standard when it comes to the issue of regulatory approval for pharmaceutical products.

It should also be noted that the lack of local clinical trials is a global problem not limited to India. While studying the AIDs situation in Africa, the All Party Parliamentary Group (APPG) of the United Kingdom has complained of 'missing information' for the African patients infected with the HIV+ve virus since most clinical trials were designed for the

⁶⁹Seth Glickman etc. *Ethical & Scientific Implications of the Globalization of Clinical Research*, N. ENG J. MED 816-823 (2009).

⁷⁰*Guidance for Industry: Collection of Race & Ethnicity Data in Clinical Trials*, USFDA (2005) available at: <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm126396.pdf>

⁷¹*Ibid* at p. 5.

⁷²*Id.*

⁷³Evelyn et. al., *Participation of Racial/Ethnic Groups in Clinical Trials and Race Related Labelling: A Review of New Molecular Entities approved 1995-1998*. 93 Journal of the National Medical Association (2001).

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markets of developed countries. In pertinent part the report stated “*As well as missing medicines and diagnostics there is missing data about the suitability of some of the existing medicines for a developing country context. Clinical trials are often designed with a view to registration in the developed world, to capture maximum commercial benefits.*”⁷⁴

It may help to mention, that there has been a long-standing demand even within the U.S., for making available clinical trial information as per various subsets including sex, race and ethnicity. In response, the U.S. enacted, in July 2012, the Food and Drug Administration (FDA) Safety and Innovation Act (FDASIA) which “*makes available information about differences in safety and effectiveness of medical products according to demographic subgroups, such as sex, age, racial, and ethnic subgroups, to health care providers, researchers, and patients.*”⁷⁵ This new requirement however extends to only reporting requirements and does not extend to mandatory clinical trials on a more diverse range of patient groups.

Given the above circumstances, the GoI probably needs to re-examine the kind of clinical data that is being submitted to the USFDA and take steps to incentivise the collection of more data on the native Indian population, from different parts of the country to ensure that the medical community has more accurate information on the effects of pharmaceutical drugs on different groups. In order to incentivise such trials, the GoI will have to provide some kind of incentive such as a ‘data exclusivity’ regime.

(ii) The regulatory requirements for local clinical trials in the DCR, 1945: On the point of re-examining Indian regulatory requirements, the Committee had this to say: “*The Committee is of the view that taking into account the size of our population and the enormous diversity of ethnic groups there is an urgent need to increase the minimum number of subjects that ought to be included in Phase III pre-approval clinical trials to determine safety and efficacy of New Drugs before marketing permission is granted. In most western countries the required numbers run into thousands. However since the major objective in India is to determine the applicability or otherwise of the data generated overseas to Indian*

⁷⁴ The Treatment Time Bomb: Report of the Enquiry of the All Party Parliamentary Group on AIDS into Long-Term Access to HIV Medicines in the Developing World (2009) (U.K) at p. 26.

⁷⁵S. 907, Food and Drug Administration Safety and Innovation Act (FDASIA); See also Press Release, *Clinical trials reporting by sex, race and ethnicity signed into law*, The Society for Woman’s Health Research, (July 2012) available at <http://www.womenshealthresearch.org/site/News2?page=NewsArticle&id=13470>

*population, the requirement should be re-assessed and revised as per principles of medical statistics so that major ethnic groups are covered. A corresponding increase in the number of sites so as to ensure a truly representative sample spread should also be laid down in black and white. Furthermore, it should be ensured that sites selected for clinical trials are able to enrol diverse ethnic groups. For domestically discovered drugs, the number of subjects should be revised as well. This can be easily achieved by changes in the Good Clinical Practice (GCP) guidelines.*⁷⁶

If the above recommendation of the Committee is accepted by the GoI, and it is hard to see as to how the Govt. is going to ignore such a recommendation, the regulatory authorities will have to re-examine why and how innovator firms will carry out local clinical trials when they have no way to prevent free-riders from entering the markets on the basis of such data thereby corroding the competitive advantage of the innovator firms. As explained earlier, this question is all the more pertinent given the high threshold for pharmaceutical patent protection in India.

(iii) The manner in which local clinical trials were being waived: While studying the manner in which the Indian drug regulator was conducting local clinical trials on the Indian population, the committee noted, and shockingly so, that a total of 31 new drugs were approved for the Indian market in the period of 30 months without any local clinical trials being conducted in India.⁷⁷ The local clinical trials were reportedly waived on the basis of the ‘public interest’ provision in Rule 122A & B. When the Regulator was asked for the basis of determining ‘public interest’ to waiver local clinical trials, it was not given a satisfactory answer. In pertinent part, the report states “*The Ministry explained that under the rules, DCGI has the power to approve drugs without clinical trials in “Public Interest.” No explanation is available as to what constitutes Public Interest. How can approvals given to foreign drugs without testing on Indians be in Public Interest?*”⁷⁸

When the regulator attempted to defend its actions on the basis that these drugs had been tested rigorously in foreign countries, the Committee countered this by stating that the

⁷⁶*Supra* n. 68 at para 7. 29.

⁷⁷*Ibid* at para 7.16.

⁷⁸*Ibid* at para 7.17.

regulator was waiving local clinical trials on mere presumptions that the drugs would work similarly on Indians and that the committee had not been offered any evidence to prove this presumption.⁷⁹ Commenting on how most of foreign clinical trials were being conducted on ethnicities not found in India, the Committee reminded the regulator that “*The interest is in those ethnicities that live in India, not Slavs, Caucasians, Hispanics and Negroes.*”⁸⁰

(iv) Incentivizing local clinical trials through a data exclusivity regime: It follows from the report of the Parliamentary Committee, that the GoI should seriously consider revising the clinical trial rules to ensure that larger Phase III, clinical trials are conducted on various sub-groups of the Indian population. The obvious issue that presents itself at the juncture, is whether innovator pharmaceutical companies or for that matter, even generic pharmaceutical companies will invest in such clinical trials without the added incentives. Normally a patent regime would have provided such an incentive but as we have seen in India, the threshold for patentability is extremely high and the Indian patent office has been liberal in turning down patent applications filed by innovator pharmaceutical companies. Would these companies invest in clinical trials, knowing fully well that generic pharmaceutical companies could free-ride of their data and enter the market at a much lower price? Or would generic pharmaceutical companies invest in clinical trials knowing well that their competitors would free-ride off their data? The answer is likely in the negative in both cases.

If pharmaceutical companies are expected to invest in local clinical trials, it follows that the State will have to give them some kind of incentive and as things stand now, a data-exclusivity regime appears to be the best model to incentivise such trials.

PART IV: INCENTIVIZING PHARMACEUTICAL INNOVATION THROUGH A DATA EXCLUSIVITY REGIME

Conventionally, pharmaceutical innovation has always been viewed through the prism of patent law. However there are circumstances in which patent law cannot incentivise innovation. Two such

⁷⁹*Ibid* at para 7.19

⁸⁰*Id.*

examples are pharmaceuticals based on traditional knowledge and fixed-dose combinations of either new or existing pharmaceuticals. For reasons, explained below, although both classes of pharmaceuticals are not patentable, they still have to go through a rigorous clinical trials process before being approved for sale to the public.

(A) CREATING INCENTIVES FOR INNOVATION IN THE TRADITIONAL KNOWLEDGE BASED PHARMACEUTICAL INDUSTRY:

The provision barring the patenting of traditional knowledge in the Patent Act, 1970 reads as follows:

Section 3 (What are not inventions) (p) – an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.

The above provision is a sub-provision of Section 3 of the Patent Act, which describes all that subject matter which is not patentable in India. Section 3(p) was inserted into the Act through the Patent (Amendment) Act, 2002. This provision was introduced in the backdrop of several much publicized cases in the U.S. and Europe where attempts were made to patent properties of neem, turmeric and basmati despite the fact that these properties had been known in India for several hundred years.⁸¹

While the overall intention behind Section 3(p) is laudable, it does point to the need of providing other incentives to stir innovation in the traditional knowledge sector, especially since India enjoys a comparative advantage in this sector because of its long history in traditional knowledge related medicines.⁸²

The three broad categories of traditional medicines dealt with under the Drugs and Cosmetics Act, 1940 are as follows: Ayurvedic, Siddha and Unani drugs.⁸³ These traditional medicines are considered to have several advantages over the allopathic medicines and have been providing

⁸¹Soutvik Biswas, *India hits back in 'bio-piracy' battle*, BBC (Dec. 7, 2005) available at http://news.bbc.co.uk/2/hi/south_asia/4506382.stm (last visited March 1, 2013).

⁸²See generally Priyanka Pulla, *Ayurveda: Hoax or Science?*, OPEN (Feb. 1, 2013) available at <http://www.openthemagazine.com/article/living/ayurveda-hoax-or-science> (last visited March 1, 2013).

⁸³See generally Chapter IVA, Drugs & Cosmetics Act, 1940.

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increasingly stiff competition to allopathic industry. The greatest selling point of these traditional medicines is that they are natural in the sense that they are usually not chemically synthesized.⁸⁴

However as noted by a report of the World Health Organization (WHO) just because a medicine is 'natural' it does not automatically follow that the medicine is 'safe'.⁸⁵ The same WHO Report states that there is a common belief that long use of a medicine, based on tradition, assures both safety and efficacy. Most importantly the WHO Report notes that several of these medicines are being used outside of their traditional cultural and social context and that some of these medicines are used in combination with heavy metals and chemicals.⁸⁶ Given these concerns the WHO Report recommended that such traditional medicines be brought within the ambit of national drug regulatory systems.⁸⁷ This demand for more clinical trials has also been backed by a Section of the medical community which has been demanding concrete scientific evidence of the validity of these traditional knowledge based drugs.⁸⁸

In India the Drugs and Cosmetics Act regulates and monitors only the manufacturing of Ayurvedic, Siddha and Unani medicines. There is no mechanism for requiring these drugs to go through clinical trials and there have been few trials involving Ayurvedic drugs.⁸⁹ The logic for this conclusion seems to be that traditional medicines which have worked for centuries do not require fresh validation.

⁸⁴See generally Birgit Heyn, *Ayurveda: The Indian Art of Natural Medicine and Life Extension* (1990) & Chopra A, Doiphode VV. *Ayurvedic medicine-core concept, therapeutic principles, and current relevance*, Medical Clinics of North America. 2002; 86(1):75–88.

⁸⁵THE IMPORTANCE OF PHARMACO-VIGILANCE: SAFETY MONITORING OF MEDICINAL PRODUCTS, World Health Organization (2002) at p.21.

⁸⁶*Id.*

⁸⁷*Ibid* at p. 23.

⁸⁸Rakesh Kalshian, *Old Drugs, New Bottles*, OUTLOOK, (June 07, 1999) available at <http://outlookindia.com/article.aspx?207589> (last visited March 1, 2013).

⁸⁹See generally Lodha R. Bagga A, *Traditional Indian systems of medicines*, Annals of the Academy of Medicine, 2000 Jan-29(1):37-41.

In response to the above mentioned concerns, the GoI had announced that it would make it mandatory to conduct pre-clinical and clinical trials for new Ayurvedic formulations.⁹⁰ It was hoped that the validation of these new Ayurvedic formulations through clinical trials would not only help in establishing the safety and efficacy of these drugs but also boost international regulatory and consumer confidence in these drugs.⁹¹ The government is yet to put in place any regulations requiring mandatory clinical trials.

This proposal of the Government however has come under fire from the manufacturers of Ayurvedic medicines, their main objection being that the cost of clinical trials would drive up the costs of the drugs.⁹² Although none of these industries have articulated their concerns in terms of the ‘free-rider’ problem, this does seem to be one of the reasons for opposition to a stronger regulatory regime. If the entire industry is allowed to free-ride off the clinical results that were generated by one company, through considerable investment, then in that case it is unlikely that any company would have an incentive to generate clinical data. Therefore in order to incentivise the generation of clinical data it is absolutely necessary to provide some kind of exclusivity to the company generating such clinical data, through considerable investment.

A ‘data exclusivity’ incentive is completely in sync with the Central Government’s recent move to enforce higher regulatory standards for the industry. This recommendation is also keeping in line with the Reddy Committee Report which in pertinent part stated the following:

“As per WHO study, traditional medicines are popular with almost 70% of the Indian Population. Since most of these medicines are already in the public domain, there is no patent protection for these under the Indian Patent Act. There is, however, a need to develop proprietary medicines based on the raw materials described in the classical texts by promoting greater research and development, improving their efficacy and to find new uses for these. Data protection can play an important role in this regard. It was discussed that a

⁹⁰C.H.Unnikrishnan, *Ayurvedic drugs too will need to be clinically tested, say govt.*, MINT (Jul. 7, 2010) available at <http://www.livemint.com/Home-Page/fcpNVX6GXqmJCnQ4TWkNuj/Ayurvedic-drugs-too-will-need-to-be-clinically-tested-says.html>(last visited March 1, 2013).

⁹¹*Id.*

⁹² P. K. Krishnakumar, *Clinical trials for new Ayurvedic formulations find few takers*, ECON. TIMES (Feb 18, 2009) available at http://articles.economicstimes.indiatimes.com/2009-02-18/news/27639980_1_ayurvedic-drugs-clinical-trials-new-ayurvedic(last visited March 1, 2013).

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fixed period of data protection for five years with non-reliance by the Drug Regulator on the data submitted by the first applicant while approving second and subsequent applicants, should be appropriate.”⁹³

It is time for the Government to seriously consider implementing the above recommendations of the Reddy Committee Report.

(B) CREATING INCENTIVES FOR INNOVATION IN THE FIXED-DOSE-COMBINATION (FDC)

CLASS OF PHARMACEUTICAL INNOVATION:

FDCs deserve a special mention in this article because for better or for worse, the Indian pharmaceutical industry is churning out these FDCs at a prodigious rate.⁹⁴ As was the case with traditional knowledge, FDCs are not patentable in most cases, in large part, due to Section 3(e) of the Patent Act, 1970 discussed below:

Section 3 (e): *A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance:*

This provision of the Patents Act renders un-patentable ‘a mere admixture resulting only in the aggregation of the properties of the components thereof’. This provision specifically affects FDCs because this class of drugs consists of formulations of two or more active ingredients combined in a single dosage form and where one or both of the active ingredients may have already received regulatory approval.

However not all FDCs are un-patentable. Those FDCs showing a ‘synergistic effect’ are patentable under Section 3(e). A FDC is considered to demonstrate a synergistic effect, when the FDC results in a magnification, and not a mere aggregation of properties of the individual drugs. Only FDCs showing a mere aggregation of properties of the individual drugs are considered to be not patentable under Section 3(e).

FDCs have a significant role to play in public health because a single FDC can treat more than one disease at the same time. From the perspective of doctors operating in a challenging environment, FDCs are invaluable to patient care because these drugs increase patient compliance substantially.

⁹³*supra note 43* at 6.4.3.

⁹⁴*See generally* Chandler Gautam & Lekha Saha, *Fixed Dose Combinations (FDCs): Rational or Irrational – A viewpoint*, BR J CLINPHARMACOL. 2008 MAY; 65(5): 795–796.

The reason for this is the fact that the patient will now have to take only one drug instead of two or three or more drugs. This can be a boon for patients who are being treated for complex diseases like AIDS and tuberculosis, both of which require a multi-drug treatment and the WHO has been extremely appreciative of the role played by FDCs in the treatment of the aforementioned diseases.⁹⁵ In the absence of a FDC, patients may often forget to consume the different medication, leading to complication in their treatment regimens and even dangerous side-effects such as resistance to future treatment. Easy and increased compliance of patients makes the overall treatment safer, more effective and substantially cheaper.⁹⁶

Although FDCs are un-patentable per se, these drugs may still be subject to the requirement of clinical trials. As per Rule 122E of the Drugs and Cosmetics Rules, 1945, a Fixed Dose Combination is a 'new drug' thereby necessitating clinical trials. For certain categories of FDCs especially those involving a new active ingredient it is mandatory to carry out clinical trials.

Such clinical trials require investment and the pharmaceutical company planning to introduce a novel FDC into the market will be required to invest substantial resources in order to establish the safety and efficacy of the FDC. The question therefore is whether or not a pharmaceutical company will have an incentive to create a novel FDC even though it will not be provided with any form of monopoly marketing or manufacturing rights, either under patent law or data exclusivity legislation?

The answer to this question is both a yes and a no.

As noted by one Report by the U.K. Parliament on the treatment of AIDS in Africa, Cipla, a leading Indian pharmaceutical company was one of the first players in the market to create a novel FDC by combining three known active ingredients which had already been invented by three different companies.⁹⁷ The Report commended Cipla for creating this novel FDC because not only did the FDC greatly simplify the treatment of HIV/AIDS in Africa, but also because the drug was attractively priced.⁹⁸ The Report also very pertinently pointed out that Cipla created this FDC in

⁹⁵*Fixed Dose Combinations for HIV/AIDS, Tuberculosis and Malaria*, World Health Organization, (2003) available at <http://apps.who.int/medicinedocs/en/d/Js6172e/> (last visited March 1, 2013).

⁹⁶*Ibid* at p. 30.

⁹⁷*Supra note* 75 at p. 26.

⁹⁸*Id.*

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reaction to the market demand and had done so despite no patent (or data exclusivity) incentives for the same.⁹⁹

At first glance the above observation seems to change the rules of the game of pharmaceutical innovation especially because substantial amounts had to be sunk into clinical trials that were carried to validate the safety and efficacy of the drugs for not only the WHO pre-qualification program but also US FDA approval.

The counter-point to this debate that is often missed is the unique set of conditions that were usually attached to the sale of some of these novel FDCs at a truly attractive price. The conditions as noted in a new report by the New York Times noted that: “each country must submit large, irrevocable purchase orders and pay cash. Someone other than the drug company must bear the costs of registering each drug in each country, which might include lobbying Parliament or fighting patent lawsuits. There also must be a guaranteed supply of the raw active ingredients at fixed prices.”¹⁰⁰

Such conditions basically assured companies like Cipla with economies of scale, a constant cash flow, an uninterrupted supply chain and a possible waiver of the cost for expensive clinical trials (which is usually the only substantial investment in developing a new FDC). Pharmaceutical companies were able to negotiate such conditions and achieve economies of scale because of the fact that the campaign against AIDS in Africa was being spearheaded by a handful of international organizations, which collectively represented millions of patients thereby lowering transactions costs for negotiations as also facilitating bulk orders at a low cost.

Moreover some of the expensive clinical trials carried out to validate the FDCs created by Indian Pharmaceutical Companies were funded by Institutions such as The European and Developing Countries Clinical Trials Partnerships (EDCTP).¹⁰¹ The EDCTP was instrumental in funding the

⁹⁹*Id.*

¹⁰⁰ Donald G. McNeil, *Plan to bring generic AIDS drugs to poor nations*, N.Y.TIMES, (Apr. 6, 2004) available at <http://www.nytimes.com/2004/04/06/health/plan-to-bring-generic-aids-drugs-to-poor-nations.html>(last visited March 1, 2013)

¹⁰¹Press Release, *HIV/AIDS infected children can now benefit from a European and Developing Countries Clinical Trials Partnership-funded trial*, European and Developing Countries Clinical Trials Partnerships, IP/07/1336 (Sept. 14, 2007) available at

clinical trials of a crucial FDC for children affected with HIV/AIDS.¹⁰² This drug was the first paediatric FDC approved by the USFDA for the treatment of AIDS.¹⁰³ The main intention behind explaining in such great detail the causes for such low-priced FDCs is not to belittle the achievements of Cipla. The reason instead for going into such details is to point out the unique conditions behind these novel attractively priced FDCs. It is unlikely that such conditions will replicate themselves in other markets for diseases other than AIDS because there is no other disease against which has managed to capture the political activism that has fuelled the sustained campaign against AIDS.

How then does one provide an incentive to pharmaceutical companies to develop new FDCs for diseases other than AIDS? This question is of special significance for the Indian Pharmaceutical Industry which has created a massive market for such drugs in India by flooding the market with FDCs of nearly every permutation and combination. Ordinarily, if new FDCs were being constantly introduced into the market there would be no need to provide any additional incentive. The truth however is that several of the hundreds of FDCs marketed in India were objected to by the Indian drug regulator on the grounds that there were either 'irrational' or that their safety and efficacy had not been validated through clinical trials.¹⁰⁴ The drug regulator has faced a stiff fight from the industry which has fought tooth and nail against the ban.

The most recent concern has been expressed by the Parliamentary Standing Committee which expressed extreme distress at the state of affairs regarding regulation of the FDCs and it urged the government to ban and prohibit several FDCs. In pertinent part the report states "*There is a need to make the process of approving and banning FDCs more transparent and fair. In general, if an FDC is not approved anywhere in the world, it may not be cleared for use in India unless there is a specific disease or disorder prevalent in India, or a very specific reason backed by scientific evidence and irrefutable data applicable specifically to India that*

<http://europa.eu/rapid/pressReleasesAction.do?aged=0&format=HTML&guiLanguage=en&language=EN&reference=IP/07/1336>(last visited March 1, 2013).

¹⁰²*Id.*

¹⁰³*Id.*

¹⁰⁴DCGI lifts ban on certain FDCs, INDIAN. EXP. (Jul. 16, 2013) *available at* <http://www.indianexpress.com/news/dcgi-lifts-ban-on-certain-fdcs/336641> (last visited March 1, 2013).

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*justifies the approval of a particular FDC. The Committee strongly recommends that a clear, transparent policy may be framed for approving FDCs based on scientific principles.*¹⁰⁵

The solution is not to impose a blanket ban on FDCs. The solution lies in better regulation and incentives to validate innovative FDCs through clinical trials. The DCGI is now attempting for better regulation but since there is no patent protection for a good portion of new FDCs it is also necessary to discuss the issue of a complete lack of incentive for private firms to invest in clinical trials in the absence of a data exclusivity regime.¹⁰⁶ The reason for this reluctance is that such innovators of novel FDCs have no means to avoid the very same ‘free-rider’ problem that we discussed in the context of the traditional knowledge medicine sector.

If clinical trials are conducted for a new FDC, the resulting product will necessarily have to be priced higher in order to recover the costs of the trials. Competitors however will be able to skip potentially expensive clinical trials by getting approval for their FDCs by establishing the bio-equivalence of their product with the first FDCs that has gone through the clinical trials. The competitors will be able to sell their FDCs minus the cost of clinical trials therefore ensuring that their product is cheaper than the company which has carried out the clinical trial. As a result the innovator of the FDC will have to incur losses and will be dissuaded from developing new FDCs which require clinical trials. As a result there will be no FDCs left to copy. This is a classic case of the tragedy of the commons. There is thus a need for some kind of exclusive monopolistic rights in order to stimulate research and development of those novel FDCs that cannot be protected under patent law.

In the opinion of this author a period of data exclusivity for FDCs which have been validated through clinical trials, conducted through considerable investment, will provide an adequate incentive for the development of new FDCs. A period of data exclusivity will ensure that for a limited period of time no other manufacturer will be allowed regulatory approval on the basis of the clinical data generated by the originator FDC. The period of monopoly will allow the originator FDC to recover the costs of the clinical trials plus profits.

¹⁰⁵*Supra note 67* at para 9.8.

¹⁰⁶*See* Letter from DCGI to all State Drug Regulators regarding approval of safety and efficacy of FDCs, Jan 15, 2013 *available at* http://cdsco.nic.in/Approval_of_the_safety_and_efficiency_of_FDC.pdf (last visited March 1, 2013).

CONCLUSION: THE WAY AHEAD FOR THE INDIAN DEBATE ON 'DATA EXCLUSIVITY'

Like most IP-related debates in India, the data exclusivity debate has often been overtaken by concerns regarding its effects on pricing and access to medicine. While these concerns are legitimate, it is also necessary for Indian policymakers to understand that quality of clinical trial data available to the medical community is as important as pricing. Pricing issues need to be dealt with frameworks other than the IP frameworks. The most efficient way to deal with the issue of pricing is through 'price-control' legislation.

As demonstrated in this paper, the rationale behind the GoI applying the TRIPS yardstick of 'data exclusivity' differently to the pharmaceutical and agrochemical industry is unclear. If the GoI were to accept the Parliamentary Standing Committee's recommendation to conduct more local clinical trials in India there is little doubt that the GoI will have to introduce some kind of incentive to induce innovator firms to carry out such trials on Indian citizens.

Such an incentive could be in the form of data exclusivity or government funding of clinical trials. Similarly, the incentive requirements for innovation in the field of traditional knowledge medicine and fixed-dose-combination, both of which are not patentable under Indian law, will be well-served by data exclusivity incentives.

To this end, the GoI must review the need for a data exclusivity regime along with a substantial review of India's drug regulatory framework.
