

**A CRITIQUE OF  
“REPORT ON STEPS TO BE TAKEN BY GOVERNMENT OF INDIA IN THE CONTEXT OF DATA  
PROTECTION PROVISIONS OF ARTICLE 39.3 OF TRIPS AGREEMENT”**

**[SATWANT REDDY REPORT]**

**WITH A FOCUS ON AGROCHEMICALS**

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## I. INTRODUCTION

- 1.1 The Patents Act, 1970 was amended with effect from 1 January 2005 to comply with the obligations of the TRIPS Agreement.<sup>1</sup> The amendments have been seen by some as a creative use of the flexibilities available in the TRIPS Agreement,<sup>2</sup> though some of its provisions have not found favour with developed countries.
- 1.2 Article 39.3 of the TRIPS Agreement provides for protection of undisclosed test and other data required to be submitted for marketing approval of new chemical entities from unfair commercial use. This is an Intellectual Property right independent of patents. The interpretation of the scope of this Article has been very contentious. The view of the developed countries and the multinational pharmaceutical and agrochemical industry is that data submitted by innovators cannot be relied upon by the regulatory authorities for a specified term for approving the products of subsequent generic applicants as it would amount to unfair commercial use. On the other hand, the developing countries and the generic industry argue that Article 39.3 only requires the data of innovators to be protected from unauthorized disclosure and reliance on such data by regulatory authorities to approve the same products of subsequent applicants does not amount to unfair commercial use.
- 1.3 A bar on regulatory approval for a fixed period after the approval of the innovator non-patented products, delays the entry of affordable generic medicines and 'me too' agrochemicals. The resolution of this controversy is therefore important to industry and consumers not only in India but also globally, as India is a major producer, consumer and exporter of pharmaceuticals and agrochemicals.
- 1.4 The Department of Chemicals and Petrochemicals was entrusted with the task of recommending appropriate steps to be taken in the context of Article 39.3 of the TRIPS Agreement and the report was submitted on 31.5.2007<sup>3</sup> (hereinafter: the Committee report), recommending that applications for approval of 'me too' agrochemical products should not be granted for a period of 3 years after the approval of a new product for the first time in India thereby allowing the first registrant for an

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<sup>1</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, [hereinafter TRIPS Agreement], available at: [http://www.wto.org/english/tratop\\_e/trips\\_e/t\\_agm0\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm)

<sup>2</sup> See Amy Kapczynski, *Harmonization and its discontents: A case study of TRIPS implementation in India's pharmaceutical sector*, California Law Review, Vol. 97, No. 6, (2009).

<sup>3</sup> Satwant Reddy and Gurdial Singh Sandhu, *Report on Steps to be taken by Government of India in the context of Data Protection Provisions of Article 39.3 of TRIPS Agreement*, Ministry of Chemicals and Fertilizers, (2007), [hereinafter the Committee report], available at: <http://chemicals.nic.in/DPBooklet.pdf>

agrochemical to enjoy a period of monopoly. However a similar period of exclusivity was not recommended for pharmaceuticals.

- 1.5 The recommendations for the 3 year period of exclusivity have been incorporated in The Pesticides Management Bill (2008), which is currently pending consideration of Parliament. The EU, which is currently engaged in negotiating a Free Trade Agreement with India, is reportedly pressing the case for extending similar exclusivity for pharmaceuticals.
- 1.6 The deep and persistent divisions in Parliament and industry, among policy makers and international non-governmental organisations, as well as the inevitable trade off between the interests of promoting innovation and affordable access, warrant informed debate and decision making. This is particularly important in view of the ongoing negotiations of the EU-FTA and the imminent consideration of the Pesticides Management Bill by Parliament. However, no rigorous analysis of the Committee report has been reported till date.<sup>4</sup> It is in this context that a close study of the Committee report is particularly important as it probably the first (and only) detailed report that outlines government thinking, if not the government stand, post the TRIPS Agreement on the scope and interpretation of Article 39.3.
- 1.7 Mr D.G. Shah, Secretary General of the Indian Pharmaceutical Alliance (IPA) suggested that it would be appropriate to critically analyze the Committee report and its recommendations at this juncture where many legislative, judicial and diplomatic developments are taking place on almost a daily basis.
- 1.8 This critique is primarily an analysis of the reasoning in the Committee report from a legal perspective, particularly its interpretation of Article 39.3 of the TRIPS Agreement. As its recommendation of data exclusivity for agrochemicals has been acted upon through administrative instructions and is also pending consideration in a proposed legislation, this critique is largely restricted to this recommendation, and does not deal with pharmaceuticals, except in the passing.
- 1.9 I must acknowledge the insights and perspectives that Mr. D.G. Shah generously shared with me during the course of the study, as also the support of the IPA in undertaking it. Many thanks also to Mr. Pradip Dave and Mr. Samir Dave of PMFAI for sharing

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<sup>4</sup> Many articles and policy notes have focused largely on broad recommendations suggested by the Committee in the context of discussion of either the benefits or implications of data protection in its various forms. But these academic and policy notes have not analysed the Committee report in itself. See for example: Animesh Sharma, *Data Exclusivity with Regard to Clinical Data*, The Indian Journal on Law and Technology, Vol 3, 2007. p. 82. , available at: <http://www.nls.ac.in/ojs-2.2.3/index.php/IJLT/article/viewFile/20/18> ; Bala Anu, *Data Exclusivity: Pressing Issue*, August 22, 2010, available at: <http://ssrn.com/abstract=1676104>

important views and materials as well as Mr. Raghu Cidambi, Advisor, Intellectual Property and Regulatory affairs to the IPA for his comments on the draft of this manuscript. I wish to acknowledge the research assistance received from the student research team at Lexbiosis on some aspects of the study and special thanks to Shreya Munoth (IV Year Student, NLU, Jodhpur) for proofreading the manuscript. The views in this critique are however mine and not necessarily those of the IPA or the National Law University, Jodhpur.

## II. SUMMARY OF FINDINGS

### **Mandate of the Committee**

- 2.1 The Department of Chemicals and Petrochemicals was entrusted with the task of “suggesting measures that should be adopted in the context of data protection provisions as outlined in Article 39.3 of TRIPS” and recommending legislative changes if required. An inter-ministerial committee was also constituted to assist the Department in this task. Mrs. Satwant Reddy, the then Secretary and Mr G.S. Sandhu, the then Joint Secretary, authored the Committee report and submitted it on 31 May 2007.
- 2.2 The Committee came to conclusion that the obligation under the TRIPS Agreement would be met by the minimum standard of ‘non-disclosure’ of test and other data submitted to the regulatory authority for marketing approval for new chemical entities and that such a non-disclosure requirement would not preclude reliance on the data by the regulatory authorities for approval of the same products by subsequent applicants.
- 2.3 Having come to this conclusion, the Committee went on to recommend data exclusivity for traditional medicines and agrochemicals which is beyond the scope of the obligations under Article 39.3 and therefore clearly beyond the scope of the Committee’s mandate. Nothing in the Committee mandate required or authorized it to make TRIPS-plus policy recommendations.
- 2.4 It is significant that subsequent to the Committee report, the Parliamentary Standing Committee on Commerce in its *Eighty Eight Report on Patents and Trademarks Systems* had occasion to consider the issue of data exclusivity and has recommended that the Government should thwart attempts for data exclusivity for both pharmaceutical and agrochemical products.

### **Interpretation of Article 39.3**

- 2.5 In interpreting Article 39.3, the Committee states that “[t]he term data protection is generally interpreted to provide one or both” of “two types of protection” – namely ‘trade secret protection’ and ‘data exclusivity’. The Committee report understands ‘trade secret protection’ to be the protection of data submitted for registration against “unauthorized use or disclosure” but regulatory authorities “can rely upon this information to grant marketing approval to subsequent applicants for similar products without disclosing the confidential information to them.” On the other hand, data exclusivity “implies non-disclosure as well as non-reliance on the first applicant’s data by the Regulatory Authority at the time of granting marketing approval to the subsequent applicants.” The Committee is wholly in error in taking the position that these are the ‘two types’ of data protection envisaged by Article 39.3. The Committee has conflated the distinct concepts of data protection and data exclusivity and has unfortunately not engaged in any legal analysis to inform its interpretation.
- 2.6 The Committee report states that “most developed countries have adopted data exclusivity as the mode of protection complying with Article 39.3 obligation.” This is a fundamental and gross error. It is no doubt true that the developed countries *argue* that data exclusivity is a TRIPS obligation, but many did not legislate provisions concerning data exclusivity because of any requirement under TRIPS, but as a policy measure, or as a requirement under Free Trade Agreements.
- 2.7 Reading a mandate for data exclusivity within the Article 39.3 framework would, as rightly asserted by some commentators, “impose precisely the obligations that a large number of negotiators refused to countenance.” The imprecise interpretation in the Committee report may have some implications, should the issue be litigated in domestic or international fora, particularly as it is probably the first official interpretation of Article 39.3 provided by India, post the TRIPS Agreement.

### **Assertions supporting data exclusivity**

- 2.8 The Committee report makes two general assertions in support of data exclusivity (sometimes referred to as ‘data protection’ by the Committee). No reasoning is provided to justify these assertions and no data are provided to support them.

- 2.9 The first of these assertions is that there are a number of drugs - “mainly biotech drugs”– for which it “is difficult to make generics” and “[i]n case data protection is provided, such categories of drugs may become available early in India as the innovator companies would have greater confidence in entering the Indian market.” It is difficult to accept this assertion as it is unlikely that the difficulty in making generic versions would in any way impact the confidence of the innovator in introducing a product in the Indian market.
- 2.10 The second assertion is that data exclusivity would be helpful in checking the menace of spurious drugs and pesticides “and only those companies which have the resources to produce good quality products should be allowed to market them during the period of protection.” This is wholly untenable as manufacturers of spurious products operate entirely outside the legal realm and statutory provisions of registration and data exclusivity are of no consequence to them.
- 2.11 Conceptually, Intellectually Property (IP) issues concerning reliance on originator’s test and other data for the approval of generic products are entirely distinct from issues of quality and spurious products. This is the position taken by the Indian Government in the WHO. It is very surprising that the Committee has taken a stand contradicting the official position of India that IP issues should not be confused with the issue of spurious and sub-standard drugs.

### **Differential treatment of agrochemicals**

- 2.12 The Committee report did not recommend data exclusivity for pharmaceuticals. The recommendation in the Committee report for 3-year data exclusivity for agrochemicals is based in large part on the justification of differential treatment for agrochemicals as compared to pharmaceuticals. Regrettably, this justification is not based on any data or commonly accepted understanding of the situation.
- 2.13 The crux of the Committee’s justification is that innovators need to recoup the ‘huge costs’ of generating data required for registration as well as the costs of marketing and a limited period of monopoly where prices can be high would provide for this. On the other hand, without the period of exclusivity, there is an influx of ‘me too’ products which do not have any of this expenditure and are consequently priced much lower, eroding the ability of originators to maintain high prices and profits. This is precisely the same argument that has been used by the innovator pharmaceutical industry, but to no avail. Absent any reasoning based on factual data of comparative costs, it is quite

unclear how the Committee is justified in differentiating agrochemicals from pharmaceuticals. Further, without any data on costs, anticipated pricing during data exclusivity, the demand at these prices and the consequent estimated benefit to the originators, it is not possible to engage in any meaningful evaluation of the Committee's recommendation.

- 2.14 Quite extraordinarily, the Committee is of the view that the "responsibility" of the industry for the environmental impact of the toxicity of agrochemicals warrants data exclusivity. This possibly means that the agrochemical industry has an inherently higher risk of liability for environmental damage because of the toxicity of the chemicals they market as compared to pharmaceuticals. Apart from the fact that the pharmaceutical industry has the risk of significant liability to patients consuming drugs, it is wholly incomprehensible how data exclusivity is an appropriate policy measure for mitigating the risk to the agrochemical industry.
- 2.15 It is equally strange that the Committee is of the view that the costs of 'extension and development' (i.e. marketing the product "door to door to farmers in villages") warrants the grant of data exclusivity. It must be emphasised that conceptually, such costs have little to do with data submitted to a regulator for regulatory approval. It is significant that even the originators of both drugs and agrochemicals have never sought to justify their demands for data exclusivity on the basis of either their costs relatable to liability risks or marketing.
- 2.16 The Committee report speculates that harm is caused by some of the 'me too' product manufacturers because of the 'poor quality of the products', inadequate knowledge of the product leading to improper use and financial loss to farmers and lack of financial resources to incur the 'huge costs' of extension work and stewardship, and that this harm will be mitigated by data exclusivity as they will be kept out. This is wholly unacceptable.

### **Adequacy of existing legislation**

- 2.17 The Committee finds the provisions available in the Insecticides Act inadequate protection against disclosure by the regulatory authority of data submitted to it. The Committee has also noted that there is no prohibition on relying on such data for subsequent registrations. The Committee report therefore recommended that the Ministry of Agriculture take suitable steps to provide for the same.

- 2.18 Surprisingly, instead of amending the Insecticides Act to provide the statutory power to implement the data exclusivity provision, the Department of Agriculture issued administrative instructions to the Central Insecticides Board and Registration Committee on 30.10.2007, vide its letter No.17-2/2006-PP.I to implement data exclusivity of 3 years.
- 2.19 The Delhi High Court had occasion to consider this in the case of *Syngenta v. Union of India* and noted that:
- “There is no statutory guidance, either in the substantive portion of the enactment, or under the Rules, enabling even the rule making authority to prescribe a period of limitation for "data exclusivity".”

### **Committee recommendations and the Pesticides Management Bill (2008)**

- 2.20 The recommendations in the Committee report have been carried into the Pesticides Management Bill (2008), (hereinafter the Bill), with some changes, which is awaiting consideration of Parliament. The data exclusivity provisions are contained in Section 12 of the Bill. The recommendations of the Committee are discussed along with the corresponding provisions in the Bill in this critique.
- 2.21 The Committee report recommends ‘data protection’ for agrochemicals for 3 years from the date of registration in India, during which period the regulator would not be permitted to rely on the data submitted by the first applicant for approval of the same product of second or subsequent applicants in the ‘me too’ category. Clearly, what the Committee report meant by ‘data protection’ is data exclusivity. The Committee considered the alternative of a 5-year period of data exclusivity and the advantage of the longer period ‘to enable the long period of promotional work required for educating the farmers on the use of new chemicals’ but in view of the consensus of the industry, represented by Crop Life India, Crop Care Federation of India (CCFI) and Pesticides Manufacturers and Formulators Association of India (PMFAI), the Committee report recommended the 3-year period.
- 2.22 The Pesticides Management Bill, 2008 as introduced, provides for data exclusivity for pesticides not previously registered for 3 years. The Bill was referred to the Parliamentary Standing Committee on Agriculture. The Standing Committee noted that that the Committee had made recommendations in the context of the obligations under the TRIPS Agreement and was of the view that the period of data exclusivity should be increased to 5 years without any explanatory notes. Whether it was because of the ambiguity in the definition of new chemical entities in the Committee report or

otherwise, the legislation implementing this recommendation would appear to cover new formulations of old ingredients that have been previously approved. It is thus beyond the scope of the obligation under Article 39.3 of the TRIPS Agreement even in terms of coverage.

- 2.23 The Bill has departed from the recommendation in the Committee report in one very important aspect – the date from which the period of exclusivity is to be reckoned. The Committee report recommended that it should run from the date of registration *in India*. The Bill provides that it should run from first date of marketing approval *anywhere in the world*. Whether this is to incentivize the originator to promptly apply for, and obtain, marketing approval in India, thereby hastening availability (a justification advanced by the Committee for data exclusivity) or whether it was motivated by a concern to tightly limit the period of monopoly (and the consequent higher price, which was a concern of the Committee) is not known.
- 2.24 The recommendation in the Committee report to limit the period of data exclusivity to patent expiry, if the pesticide has been granted a patent in India, has been carried into the Bill. This is a problematic clause, both conceptually and practically. At the conceptual level, data exclusivity is a *sui generis* right intended to compensate the generator of data for his labour and is entirely different from, and independent of, patent rights that compensate the inventor for making the invention public and enabling others to practice it after the patent term. It is right that they should run concurrently but that is no basis to limit one right by the other. Practically, this provision is likely to lead to several anomalous consequences, which may not have been contemplated by the Committee. For example, if a patent term in India expires prior to 3 years from the date of first marketing authorisation anywhere in the world, data exclusivity would be limited to the shorter term and the originator would have been better off without a patent.
- 2.25 Another important aspect of the Bill is that data exclusivity can be granted for pesticides for name or label expansion through "new uses" that have not been previously registered. It is entirely unclear what 'name expansion' means. Neither name nor label expansion through new uses has been recommended by the Committee. It is entirely unclear from the Bill whether the exclusivity will be for the *use* or for the *product* itself. If it is the former, it will lead to problems of effective enforcement. While labels of 'me too' products will not be permitted with the new use, the 'me too' products will be available in the market and it is difficult to see how farmers can be

restrained from using such products for the new use. On the other hand, if the exclusivity is extended for the product itself, it can lead to ‘evergreening’ of data exclusivity by obtaining periodic approvals of new uses and new exclusivities. There is also considerable potential for anomalous situations to arise. For example, what is the position when a new use is approved after the expiry of the original exclusivity; or if ‘me too’ applicants generate data and obtain registration for a new use?

### **III. BACKGROUND**

- 3.1 The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) reflects the contentious nature of the negotiations and differences among WTO members on many issues pertaining to IP protection and enforcement standards. One such area of intense debate and discussion was in the context of Article 39.3 requiring protection of undisclosed test or other data submitted for marketing approval of pharmaceuticals and agrochemicals.
- 3.2 Three widely different positions have been taken on the issue. Developed countries supported by their pharmaceutical majors and crop protection (agrochemical) companies, have adopted an interpretation that would require a reasonable term of data exclusivity<sup>5</sup> during which period the regulatory authority is barred from relying on any data submitted by the originator for approval of subsequent applications of ‘me too’ products.
- 3.3 The other position, generally taken by developing countries, including India, is the one which interprets Article 39.3 to provide certain minimum standards concerning ‘non-disclosure’ obligations, usually termed ‘data protection’ as opposed to ‘data exclusivity’. This ‘non-disclosure’ obligation allows for a ‘permissive reliance’ standard, leaving it open to national regulators to rely on test and other data submitted to them by originators for marketing approval of subsequent applicants.<sup>6</sup>

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<sup>5</sup> European Union (EU), *Compulsory Licensing and Data Protection* (2001); *Encouragement of New Clinical Drug Development: The Role of Data Exclusivity* (IFPMA- 2000), available at: <http://www.ifpma.org/documents/NR83/DataExclusivity.pdf> It is also reported that Nicholas Piramal and OPPI in India have supported the stand taken by EU and US.

<sup>6</sup> See generally, UNCTAD-ICTSD, *Resource Book on TRIPS and Development*, Cambridge University Press (2004) [hereinafter UNCTAD-ICTSD Resource Book]; Carlos Maria Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement*, South Centre (2002) [hereinafter Correa- South Centre]; Commission on Intellectual Property Rights, *Innovation and Public Health [CIPRH], Public Health, Innovation and Intellectual Property Rights*, WHO (2006).

- 3.4 Some commentators have argued a third position - that Article 39.3 actually alludes to a middle-path requiring a compensatory liability regime.<sup>7</sup> Prof. Basheer, building on Fellmeth,<sup>8</sup> Dinca<sup>9</sup> and CPTech,<sup>10</sup> has argued that Article 39.3 would neither allow a ‘permissive reliance’ standard of data protection nor a ‘data exclusivity’ standard, but one that furthers a ‘compensatory liability regime’. Under this regime, any subsequent applicant for marketing approval may be allowed to rely on the originators’ data by providing ‘fair’ compensation.<sup>11</sup>
- 3.5 A decade and a half’s experience in implementing the TRIPS Agreement by different countries has proved utterly futile in generating any consensus.<sup>12</sup> This is also a reason why there are immense concerns in the post-TRIPS era where standards moving far beyond the TRIPS minimum standards are being negotiated under pressure from developed countries through regional or bilateral Free Trade or Investment Agreements.<sup>13</sup>
- 3.6 Moreover, data exclusivity poses fundamental concerns of access and affordability. This has been highlighted in the case of medicines, where generic entry is delayed due to monopolising clinical trial data.<sup>14</sup> In fact, an independent commission established by

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<sup>7</sup> Aaron Xavier Fellmeth, *Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data Under the TRIPS Agreement*, 45 Harvard International Law Journal. 443 (2004) [hereinafter Fellmeth]; Shammad Basheer, *Data Protection under Article 39.3 of TRIPS: A ‘Compensatory Liability’ Model?*, Oxford Intellectual Property Research Centre (2006) [hereinafter Basheer-Oxford]; Judit Rius Sanjuan et al., *A Cost Sharing Model to Protect Investments in Pharmaceutical Test Data*, CPTech Policy Brief No.1 (2006) [hereinafter CPTech].

<sup>8</sup> Fellmeth, p.464.

<sup>9</sup> Dinca Razvan, *The Bermuda Triangle of Pharmaceutical Law: Is Data Protection as Lost Ship?*, 8(4) Journal of World IP (2005).

<sup>10</sup> CPTech (2006).

<sup>11</sup> Jerome H. Reichman, *Undisclosed Clinical Trial Data under the TRIPS Agreement and its Progeny: A Broader Perspective*, UNCTAD-ICTSD Dialogue on Moving the Pro-Development IP Agenda Forward: Preserving Public Goods in Health, Education and Learning conference, Bellagio, 29 Nov.–3 Dec. 2004.

<sup>12</sup> In *Argentina — Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals*, (WT/DS171/3), US sued Argentina for not providing data exclusivity as a purported requirement under Article 39.3 of the TRIPS Agreement. Parties agreed to a mutually agreed solution and hence the WTO panel could not get a chance to deliberate on the correct standard required. Hence an authoritative and definitive interpretation of Article 39.3 has not yet been provided within the framework of WTO.

<sup>13</sup> Scafidi Susan, *The ‘good old days’ of TRIPS: the U.S. Trade Agenda and the Extension of Pharmaceutical Test Data Protection*, 4 Yale Journal of Health Policy, Law & Ethics 341 (2004), pp. 341-351; Carsten Fink and Patrick Reichenmiller, *Tightening TRIPS: Intellectual Property Provisions of U.S. Free Trade Agreements*, in Richard Newfarmer, *Trade, Doha and Development: A Window into Issues*, World Bank (2006), p. 285.

<sup>14</sup> Karin Timmermans, *Monopolising Clinical Trial Data*, PLoS Med. 2007 February; 4(2), available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1796904/>; Also see: M. Janodia, *Data Exclusivity Provisions in India: Its Impact on Public Health*, Journal of Intellectual Property Rights, Vol. 13, Sep. 2008.

the WHO in 2004 highlighted the need to tread a cautious path on issues concerning data protection and data exclusivity<sup>15</sup>:

“...[t]he TRIPS agreement does not refer to any period of data protection, nor does it refer to data exclusivity. ....If the patent period has expired, or there is no patent on the product, this *sui generis* data exclusivity may act independently of patent status to delay the entry of any generic companies wishing to enter the market. This is because the regulators cannot use the data in the period of protection to approve a product, even if the product is demonstrated to be bio-equivalent, where required. The only alternative for a generic company would be to repeat clinical trials, which would involve replicating tests in humans to demonstrate what is already known to be effective. These *sui generis* regimes, which provide for data *exclusivity*, need to be clearly differentiated from the TRIPS Agreement’s requirement for data protection”.

3.7 Similar logic would apply to agrochemicals and early entry of ‘me too’ products would make modern pesticides affordable and accessible to farmers. In the US, a pesticide which has borne the costs of regulatory tests to ensure environmental safety can be sold under a 10-year exclusive use provision under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Thereafter, ‘me too’ products are allowed registration by offering to share the regulatory test costs, which in the absence of agreement with the original registrant, is litigated and determined by the Courts. Quite apart from the problems of high prices during the period of the monopoly, even the higher prices of ‘me too’ or generic products resulting from a share of the costs of regulatory tests has been a matter of concern:<sup>16</sup>

“the share of regulatory test costs imposed on generic firms has major implications for post-patent competition because generic entrants typically capture a small share of the market and sell under competitive rather than monopolistic prices. Consumers and farmers are the main beneficiary of generic competition but their benefits are often delayed or never realized when the share of test costs borne by generic entrants is too large.”

3.8 Readers familiar with the ‘data exclusivity’ controversy will recognize that it is among the most fiercely argued issues in North-South IP debates. As Fellmeth puts it straight<sup>17</sup>:

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<sup>15</sup> WHO, *Public health, innovation and intellectual property rights, Report of the commission on Intellectual property rights, innovation and public health*, Geneva, 2006, p. 126, available at: <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf>

<sup>16</sup> Richard Just, *Anticompetitive Impacts of Laws that Regulate Commercial Use of Agricultural Biotechnologies in the United States*, 30 (II) *Natural Resource Management and Policy*, 2006, Section II.3, 353-396.

<sup>17</sup> Fellmeth, p. 448.

“The battle lines over data exclusivity are predictably drawn between net exporters and net importers of intellectual property. Many developing countries see little point in granting exclusive marketing privileges to wealthy foreign drug companies so that they may sell much-needed drugs at a premium price to an impecunious population”.

3.9 Reichman goes further in framing the debate on data exclusivity from a ‘public good’ perspective.<sup>18</sup> In the context of medicines (though it is equally applicable to regulatory tests for environmental safety of agrochemicals), he suggests:

“The conventional wisdom is that market and data exclusivity, and drug developers’ consequent ability to limit competition from generics above and beyond patent protection, are a necessary incentive for drug developers to fund ever more expensive clinical trials. Clinical trial data, however, are public goods that will be undersupplied and over protected so long as private actors provide them. Moreover, manufacturers have an incentive to present clinical trial data so that they support regulatory approval at the expense of public health. Although liability rules are better than the status quo, they would not resolve the problem of treating a public good as proprietary. Governments should thus oversee and fund clinical trials as the public good that they are.”

3.10 Proponents of data exclusivity have reasoned that the costs incurred in generating data for registration of agrochemicals are expensive<sup>19</sup> and the “rising economic significance of data exclusivity” in pharmaceuticals, was due to, *inter alia*, the “overwhelming financial resources and time” required for clinical trials.<sup>20</sup> Without sufficient global incentive, it is argued that companies may not invest in innovating new drugs or agrochemicals.

3.11 The debate, if anything, has been even more intense in India, at least as far as pharmaceuticals were concerned, typified by the highly vocal and diametrically opposite stands taken by the multinational companies in India, represented by the Organisation of Pharmaceutical Producers of India (OPPI) and the domestic industry represented by the Indian Pharmaceutical Alliance (IPA) and the Indian Drug Manufacturers Association (IDMA). The debate was most intense during the run up to

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<sup>18</sup> Jerome Reichman, “*Rethinking the Role of Clinical Trials Data in International Intellectual Property Law: The Case for a Public Goods Approach*”, *Marquette Intell. Prop Law Rev.*, 2009 Jan, 13(1), pp.1-68.

<sup>19</sup> See for e.g., Crop Life International (2004), *Position Paper on the protection of safety and efficacy data for existing and new crop protection chemicals*, Brussels, c.f. Correa, *Protecting Test Data for Pharmaceutical and Agrochemical Products in Free Trade Agreements*, Third UNCTAD-ICTSD Dialogue on Development and Intellectual Property, 12–16 October 2004, Bellagio, Italy, p. 2., available at: [http://www.iprsonline.org/unctadictsd/bellagio/docs/Correa\\_Bellagio4.pdf](http://www.iprsonline.org/unctadictsd/bellagio/docs/Correa_Bellagio4.pdf)

<sup>20</sup> Meir Perez Pugatch, “*Intellectual Property and Pharmaceutical Data Exclusivity in the Context of Innovation and Market Access*”, Third UNCTAD-ICTSD Dialogue on Development and Intellectual Property, 12–16 October 2004, Bellagio, Italy, pp.9-10. [hereinafter Pugatch], available at: [http://www.iprsonline.org/unctadictsd/bellagio/docs/Pugatch\\_Bellagio3.pdf](http://www.iprsonline.org/unctadictsd/bellagio/docs/Pugatch_Bellagio3.pdf)

the amendments to the Patents Act in 2005, to meet the deadline for bringing it in conformity with the TRIPS Agreement.

- 3.12 In the face of the mounting pressure to introduce data exclusivity provisions for pharmaceuticals and agrochemicals, the Department of Chemicals and Petrochemicals in the Ministry of Chemicals and Fertilizers of the Government of India, was entrusted with the task of recommending appropriate measures to be taken in the context of the data protection provisions in Article 39.3 of the TRIPS Agreement. An inter-ministerial committee (including external experts) was also constituted in February 2004 to assist the Department of Chemicals and Petrochemicals in this task.<sup>21</sup> The Committee report was submitted after extensive deliberations for over 3 years.
- 3.13 The Committee report recommended data exclusivity of 5 years for traditional medicines and 3 years for agrochemicals, during which period the regulator would be barred from relying on data submitted by the first applicant for approval of applications of subsequent applicants. For pharmaceuticals, the Committee recommended a ‘calibrated approach’ with the status quo continuing during an unspecified ‘transition period’ and data exclusivity to be considered thereafter.
- 3.14 The Committee report has not laid the controversies to rest as reflected by the deep divisions of opinion in Parliament. The Parliamentary Standing Committee on Commerce in its *Eighty Eight Report on Patents and Trademarks Systems* considered the issue of data exclusivity and has recommended as follows for both pharmaceuticals and agrochemicals<sup>22</sup>:

“5.47 As a condition for registering pharmaceutical and agro-chemical products, National authorities normally require the applicant to submit data relating to quality, safety and efficacy of the product. The Committee were informed that the MNCs are demanding ‘Data Exclusivity’ on their data, so that its use could be prevented for allowing generic manufacturers to take marketing approval. The Committee is aware of the fact that there is considerable pressure on the Government to accede to this demand. The Committee feel that conceding to demand for Data Exclusivity would amount to agreeing to TRIPS plus provisions. Once such a demand is agreed at bilateral forum, there will be additional demands, which may relate to higher level of intellectual property right, such as extension of patent period, restriction on compulsory licences,

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<sup>21</sup> Office Memorandum No.11025/7/2003-PI-II, Government of India, Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, New Delhi, dated 19th February, 2004.

<sup>22</sup> Parliamentary Standing Committee on Commerce, *Eighty Eighth Report on Patents and Trademarks Systems in India*, New Delhi, October 2008, Rajya Sabha Secretariat, available at: <http://164.100.47.5/newcommittee/reports/EnglishCommittees/Committee%20on%20Commerce/88th%20Report.htm>

restriction on parallel imports, and may be on R&D activity on patented subject matter. Data Exclusivity may result in delay in ensuring role of domestic enterprises through compulsory licensing system, and in preventing other parties from developing similar data.

**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. The Government must thwart such attempts, being made at the behest of certain vested interests. It should also guard against moves to enter into FTA with USA, as the developed countries, particularly the USA, are trying to bring in certain TRIPS Plus measures through Bilateral and Regional Agreements.”** (*emphasis in original*)

- 3.15 The Parliamentary Standing Committee on Commerce, under the Chairmanship of Dr. Murli Manohar Joshi does not seem to have taken note of the Committee report and even more surprisingly, does not seem to have been aware of the fact that the Department of Agriculture had already issued instructions to the Central Insecticides Board and Registration Committee on 30.10.2007, vide its letter No.17-2/2006-PP.I to implement the recommendation of the Committee report for data exclusivity of 3 years (see also 3.17 below) despite the fact that several sittings were held after the Committee report was submitted 31.5.2007. The report was adopted only on 26 September 2008 and submitted to Parliament in October 2008.
- 3.16 Within four days of the Parliamentary Standing Committee on Commerce adopting its report, the Minister of Agriculture, Shri Sharad Pawar finalised the Pesticides Management Bill (2008) which provided for 3-year data exclusivity for pesticides. The Bill was introduced in the Rajya Sabha on 21 October 2008 and referred to the Standing Committee on Agriculture on 31 October 2008. The Standing Committee on Agriculture submitted its report<sup>23</sup> to Parliament on 18 February 2009, but the Bill is still awaiting consideration. It duly took note of the Committee report but recommended that the 3-year data exclusivity proposed in the Bill be enhanced to 5 years, without any explanatory notes. It made no reference either to the fact that data exclusivity had already been administratively implemented or to the recommendation of the Parliamentary Standing Committee on Commerce warning against the implementation of data exclusivity. The only evidence from industry that appears to have been recorded

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<sup>23</sup> Standing Committee on Agriculture, *Forty sixth Report, The Pesticides Management Bill (2008)*, New Delhi, February 2009, Lok Sabha Secretariat, *available at*: [http://www.prsindia.org/uploads/media/1224668021/forty-Sixth%20Report-Standing%20Committee%20on%20Agriculture%20\(2008-2009\).pdf](http://www.prsindia.org/uploads/media/1224668021/forty-Sixth%20Report-Standing%20Committee%20on%20Agriculture%20(2008-2009).pdf)

was on 29 January 2009 from two witnesses, both from the Crop Care Federation of India. The record reads:

“The views/suggestions of the pesticide industry were then put forwarded (*sic*) by its representatives, Shri Salil Singhal & Shri R.G.Aggarwal. They drew attention to the need for ..... strict provisions of data protection, etc.”

3.17 In the meanwhile, Syngenta India Ltd., the Indian arm of a multinational manufacturer of pesticides moved the Delhi High Court by way of a writ petition.<sup>24</sup> A registration granted to a subsequent applicant for a pesticide was assailed on many grounds by Syngenta, which was the first applicant. In large part, this was an attempt to enlarge the departmental view of data exclusivity implemented through its administrative instructions on 30.7.2007 and 18.2.2008. The writ petition was dismissed as ‘speculative litigation’ and clearly an impermissible attempt “to invite the court to make a policy declaration” and heavy costs were imposed. The appeal filed by Syngenta was also dismissed. Though the administrative action in implementing data exclusivity was not challenged, the High Court thought it fit to observe as follows:

“39. Whilst there is no challenge to either of the circulars/ memoranda dated 30th October, 2007 and 18th February, 2008, the court cannot be unmindful of the fact that what is really being sought is a policy mandate. No doubt civil law assures a certain measure of protection to confidential data, and as between two parties, there may be situations where unlawful acquisition of such information by one of another's may be fraught with serious commercial consequences, necessitating equitable remedies, what the court is confronted here is a policy issue. **There is no statutory guidance, either in the substantive portion of the enactment, or under the Rules, enabling even the rule making authority to prescribe a period of limitation for "data exclusivity". It has been held [in] Bharat Barrel and Drum Mfg. Co. Ltd. v. ESI Corpn., (1971) 2 SCC 860 that the rule making authorities, in the absence of an enabling power, cannot prescribe periods of limitation. Thus, under our Constitutional framework, prescribing of periods of limitation to do something, or confer a positive right, is an essential legislative function, not exercisable by the courts (Ref. Common Cause vs. Union of India 2008 (5) SCC 511; P. Ramachandra Rao vs. State of Karnataka 2002 (4) SCC 578).**” (*emphasis added*)

3.18 Clearly, the Department of Agriculture would have been well advised to implement data exclusivity through an amendment to the Insecticides Act and their decision to do so through an administrative action appears to be illegal, enabling “back door’ entry of data exclusivity.

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<sup>24</sup> *Syngenta India Ltd v. Union of India*, W.P. (C) 8123/2008, High Court of Delhi

- 3.19 In the meanwhile, as has been widely reported in the press, the EU and India are in the final stages of negotiating a Free Trade Agreement and the EU is pushing the incorporation of data exclusivity provisions for pharmaceuticals. Predictably, the Indian pharmaceutical industry is firmly opposed to such a provision, arguing that it is not obligatory under the TRIPS Agreement. This is not a debate restricted to India alone and several international non-governmental organisations have urged that data exclusivity provisions are TRIPS-plus and should not find place in the Free Trade Agreement,<sup>25</sup> more so as India has emerged as the ‘pharmacy of the developing world’ and access to medicines would be affected globally.
- 3.20 In December 2010, the Prime Minister led an Indian delegation, which included Shri Anand Sharma, Minister of Commerce, to the EU-India Summit. Senior officials of the Government of India reportedly allayed apprehensions by categorically ruling out any ‘compromise on intellectual property rights’. They emphasised that ‘no TRIPS-plus commitments as initially mooted by the European Union’ would be accepted, nor would India ‘undertake any obligation which will require a change in domestic legislation.’<sup>26</sup> As a matter of fact, the Pesticides Management Bill (2008) was pending consideration in Parliament which included a provision on data exclusivity, a TRIPS-plus measure. However, the EU Ambassador, Ms. Daniele Smadja, reportedly said just a few weeks later that “provision of data exclusivity will also form part of the FTA”.<sup>27</sup>
- 3.21 The Prime Minister’s Office reportedly issued a statement that the Prime Minister had directed India’s negotiators not to accept any obligations ‘beyond domestic laws or as mandated in a WTO pact’<sup>28</sup> but the question that lingers is what the mandate in the WTO pact (i.e. TRIPS Agreement) is understood to be.
- 3.22 The present study is structured in a way similar to that of the Committee report. A summary of findings in chapter II precedes this background chapter. Central to the

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<sup>25</sup> See for example, *Open letter to EU Trade Commissioner, Universities Allied for Essential Medicines*, available at: [http://www.uclmedsin.org/resources/documents/UAEM\\_Letter\\_to\\_EU\\_Trade\\_Commissioner.pdf](http://www.uclmedsin.org/resources/documents/UAEM_Letter_to_EU_Trade_Commissioner.pdf); *MSF open letter to EU Trade Commissioner* dated 8 November 2010, available at: [http://www.msf.org/msf/fms/article-images/2010-00/MSF\\_open\\_letter\\_Commissioner\\_de\\_Gucht.pdf](http://www.msf.org/msf/fms/article-images/2010-00/MSF_open_letter_Commissioner_de_Gucht.pdf); *Health Action International and Oxfam (2010): Trading away access to medicines. How the European Union’s trade agenda has taken a wrong turn*, available at: [http://www.haiweb.org/ei\\_ip\\_updates/11%20Jan%202010%20Joint%20Declaration%20Trading%20Away%20Access%20to%20Medicines%20with%20endorsements.pdf](http://www.haiweb.org/ei_ip_updates/11%20Jan%202010%20Joint%20Declaration%20Trading%20Away%20Access%20to%20Medicines%20with%20endorsements.pdf)

<sup>26</sup> *No compromise on IPR in FTA with EU: Govt*, Indian Express, December 10, 2010, available at: <http://www.indianexpress.com/news/no-compromise-on-ipr-in-fta-with-eu-govt/722666/>

<sup>27</sup> *FTA with EU only by year-end*, Hindu, January 21, 2011, available at: <http://www.thehindu.com/business/Economy/article1108769.ece>

<sup>28</sup> *India not for IPR beyond domestic law in FTA with EU: PM*, Indian Express, April 30, 2011, available at: <http://www.indianexpress.com/news/india-not-for-ipr-beyond-domestic-law-in-fta-with-eu-pm/783896/>

current study, chapter IV is a critical analysis of the Committee report in five parts: Section I inquires into the Committee report and terms of reference to ascertain if the Committee analysis and recommendations were in accordance with its mandate. Section II examines the level of protection required by Article 39.3 of TRIPS Agreement. Section III briefly examines the view of the Committee on whether existing laws are TRIPS compliant. Section IV is a close look at the justification provided by the Committee for the differential treatment to agrochemicals. Finally, Section V examines the Committee's recommendation for data exclusivity for agrochemicals.

#### **IV. ANALYSIS OF THE COMMITTEE REPORT**

##### **SECTION-I**

##### **THE COMMITTEE REPORT AND ITS TERMS OF REFERENCE**

- 4.1 The Committee framed the following issues for consideration<sup>29</sup>:
- a) Steps to be taken in the context of Article 39.3 of TRIPS Agreement.
  - b) Whether data protection can be offered under the existing legal provisions or an appropriate new dispensation is required.
- 4.2 A plain reading of the Committee mandate suggests that what was expected of the Committee on issue (a) was to make recommendations of the measures, if any, which needed to be taken in fulfilment of the obligations of Article 39.3 of the TRIPS Agreement.
- 4.3 On issue (b), the mandate to the Committee was to examine the extent to which Indian laws were in compliance of TRIPS obligations and to recommend appropriate legislation if required.
- 4.4 The mandate to the Committee clearly did not require the Committee to go beyond the TRIPS requirement. The Committee came to conclusion that 'data exclusivity' is not mandated under the TRIPS Agreement and the obligation under the TRIPS Agreement would be met by the minimum standard of 'non-disclosure' of test and other data submitted to the regulatory authority for marketing approval for new chemical entities

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<sup>29</sup> As per the Office Memo No.11025/7/2003-PI-II dated 19<sup>th</sup> Feb, 2004, the Committee was established "to consider the steps to be taken by the Government in the context of the provisions of Article 39.3 of the TRIPS Agreement for the protection of undisclosed information..." and that the "Committee would, inter alia, look at whether *data protection* can be offered under the existing legal provisions or an appropriate new dispensation is required for this purpose." (*emphasis added*)

and that such a non-disclosure requirement would not preclude reliance on the data by the regulatory authorities for approval of the same products by subsequent applicants.

- 4.5 Having come to this conclusion on issue (a), the Committee went on to recommend data exclusivity for traditional medicines and agrochemicals which is beyond the scope of the obligations under Article 39.3 and therefore clearly beyond the scope of the Committee's mandate.

## **SECTION- II**

### **INTERPRETATION OF ARTICLE 39.3 OF THE TRIPS AGREEMENT**

- 4.6 Chapters 1 and 2 are the Committee's interpretation of Article 39.3 of the TRIPS Agreement. It should be noted that substantial literature is already available on the interpretation of Article 39.3<sup>30</sup> and it is not within the scope of this critique to exhaustively document this. Instead, the focus is on drawing attention to those parts of the Committee report that ignore, or are inconsistent with, authoritative interpretations and have a bearing on its conclusions and recommendations.

- 4.7 The Committee report rightly states that for "a full appreciation of the scope and spirit of Article 39.3, it should be read in conjunction with Article 39.1 and Article 39.2."<sup>31</sup>

- 4.8 Article 39.1 states:

"In the course of ensuring effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3".

- 4.9 The Committee report asserts that "Article 10*bis* of the Paris Convention was the first attempt to protect trade secret at the international level".<sup>32</sup> It should be noted that neither the TRIPS Agreement in its pertinent part (Article 39) nor the Paris Convention (Article 10*bis*)<sup>33</sup> refers to the 'trade secrets', although 'undisclosed information' has

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<sup>30</sup> For a detailed commentary, readers are requested to refer to the UNCTAD-ICTSD Resource Book, pp. 520-538

<sup>31</sup> Committee report, para 1.2, p. 1

<sup>32</sup> Committee report, para 1.2, p. 2

<sup>33</sup> Article 10*bis* of the Paris Convention (1967), has a mandate for Paris Union members to provide protection against "unfair competition" Article 10*bis* states:

(1) The countries of the Union are bound to assure to nationals of such countries effective protection against unfair competition.

(2) Any act of competition contrary to honest practices in industrial or commercial matters constitutes an act of unfair competition.

(3) The following in particular shall be prohibited: 1. all acts of such a nature as to create confusion by any means whatever with the establishment, the goods, or the industrial or commercial activities, of a competitor; 2. false allegations in the course of trade of such a nature as to discredit the establishment, the goods, or the

often been generally understood as ‘trade secrets’ or ‘know-how’. It was precisely because of the difference of opinion in finding a common and acceptable understanding as to what those terminologies could mean that led to the adoption of a more neutral terminology of ‘undisclosed information’ that does not characterise the contents of the information but is defined merely by the fact that it is undisclosed.<sup>34</sup> It may be noted that TRIPS was the first international agreement to expressly provide for a regime of *undisclosed information*.

4.10 Article 39.1 makes it clear that any obligation under Article 39 does not go beyond the confines of Article 10*bis* of Paris Convention or as specifically provided for under the TRIPS Agreement. It is important to note that Article 10*bis*, relates to unfair competition and does not resort to the treatment of undisclosed information as ‘property’. Hence Prof. Correa has argued that under Article 39, there is no general obligation to confer exclusive rights on undisclosed information - except only to protect it against unfair commercial practices.<sup>35</sup> Further, since Article 39 does not identify the natural and legal persons as ‘owners’ and instead refers only to the possibility of ‘preventing information lawfully within their control from being disclosed’ (as in Article 39.2), Correa also argues that Article 39 does not entail a property type of protection.<sup>36</sup> These observations are pertinent to understanding the “scope and spirit” of Article 39.3, but have not been taken into consideration by the Committee.

4.11 Article 39.2 lays down the general conditions for protection. It states:

“Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices<sup>37</sup> so long as such information:

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question; (b) has commercial value because it is secret; and (c) has been subject to reasonable steps under the

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industrial or commercial activities, of a competitor; 3. indications or allegations the use of which in the course of trade is liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purpose, or the quantity, of the goods.

<sup>34</sup> UNCTAD-ICTSD Resource Book, p. 521

<sup>35</sup> Correa C., *A Commentary on the TRIPS Agreement*, Oxford Commentaries on GATT/WTO Agreements, Oxford University Press (2007), pp. 367-368 [hereinafter Correa- Oxford Commentaries]

<sup>36</sup> *Id.*, p. 368.

<sup>37</sup> Annotated as *footnote 10 in the original text. The footnote reads: “For the purpose of this provision, “a manner contrary to honest commercial practices” shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.”*

circumstances, by the person lawfully in control of the information, to keep it secret.”

4.12 The Committee report does not make any observation concerning the interpretation of Article 39.2. It should be noted that Prof. Correa has argued that in interpreting Article 39.2 an appropriate balance should be sought among the interests of possessors of secret information and society’s interests in diffusion of technologies. Too stringent an interpretation may not be in the interest of many nations.<sup>38</sup>

4.13 The central debate surrounding data protection concerns the interpretation of Article 39.3 of the TRIPS Agreement. Article 39.3 states:

“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.”

4.14 It may be noted that the TRIPS Agreement for the first time clearly mandated protection of test data. Prior to the coming into force of the TRIPS Agreement, countries had considerable latitude as to whether or not to confer test data protection.<sup>39</sup> In interpreting Article 39.3, the Committee states that “[t]he term data protection is generally interpreted to provide one or both” of “two types of protection” – namely ‘trade secret protection’ and ‘data exclusivity’.<sup>40</sup> The Committee report understands trade secret protection (an unfortunate terminology as discussed in 4.9 above) to be the protection of data submitted for registration by regulatory authorities against “unauthorized use or disclosure” but “can rely upon this information to grant marketing approval to subsequent applicants for similar products without disclosing the confidential information to them.” On the other hand, data exclusivity “implies non-disclosure as well as non-reliance on the first applicant’s data by the Regulatory Authority at the time of granting marketing approval to the subsequent applicants.” The Committee is right in making this distinction between data protection and data exclusivity, but is wholly in error in taking the position that they are two types of data protection envisaged by Article 39.3. Although it is true that Article 39.3 does not

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<sup>38</sup> Correa- Oxford Commentaries, p. 373.

<sup>39</sup> Carlos Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement*, South Centre, Geneva (2002), available at: [http://www.southcentre.org/ARCHIVES/index.php?option=com\\_content&task=view&id=68&Itemid=67](http://www.southcentre.org/ARCHIVES/index.php?option=com_content&task=view&id=68&Itemid=67)

<sup>40</sup> Committee report, para 1.6, pp. 3-4.

prohibit 'data exclusivity' (as Article 1.1 allows Members to move beyond the common minimum standards of TRIPS), the minimum standard prescribed is only in relation to 'data protection' and 'data exclusivity' is a TRIPS-plus policy measure. The Committee has conflated these distinct concepts. Had it not done so, its recommendations may have been different.

- 4.15 The Committee report states that “most developed countries have adopted data exclusivity as the mode of protection complying with Article 39.3 obligation.”<sup>41</sup> This is a fundamental and gross error. It is no doubt true that the developed countries *argue* that data exclusivity is a TRIPS obligation, but many did not legislate provisions concerning data exclusivity because of any requirement under TRIPS. For example, the US introduced provisions on data exclusivity way back in 1984, long before the TRIPS agreement. Data exclusivity can be traced back to legislative amendments made in 1987 in the EU.<sup>42</sup> Canada also introduced data exclusivity not because approval of a generic product involved reliance on undisclosed information of the innovator but because it involved reliance on the innovator product, which is not an obligation under the TRIPS Agreement.<sup>43</sup> This proposition has been acknowledged even by commentators who subscribe to the notion that data exclusivity is a TRIPS obligation.<sup>44</sup>
- 4.16 The position that Article 39.3 does not prescribe a data exclusivity standard is also clear from the fact that in *Argentina — Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals*<sup>45</sup> the United States and Argentina, in June 2002, notified the DSB for a mutually agreed solution on the condition that should DSB clarify the standard of Article 39.3, Argentina would comply with it within a period of one year by bringing legislative changes for data exclusivity. To date there has been not a single case where the WTO-DSB has had an opportunity to clarify the standard. Thus, in no way does any authoritative and definitive interpretation of Article 39.3 require data exclusivity. Many commentators are of the opinion Article 39.3 does not prescribe

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<sup>41</sup> Committee report, para 1.5 p. 3

<sup>42</sup> Cook, TM, *The protection of regulatory data in the pharmaceutical and other sectors*, Sweet and Maxwell, (2000), p.15.

<sup>43</sup> Canada Gazette, Vol. 140, No. 21, October 18, 2006. Available at: <http://www.gazette.gc.ca/archives/p2/2006/2006-10-18/html/sor-dors241-eng.html>

<sup>44</sup> Pugatch, p.7, “Data exclusivity, on the other hand, is an expression of trade secrets. It is aimed at protecting and safeguarding the proprietary know-how and information included in the registration filed against any type of unfair commercial use of pharmaceutical products”; Further in p.9: “Interestingly, both the US and European models do not fall under the category of trade secrets. Rather they are an inseparable part of the regulations concerning the approval of pharmaceutical products”; and p. 18: “...., it is this author's view that the ambiguity of TRIPs Art. 39.3, drove the US, and to a lesser extent the EU, to actively seek the establishment and implementation of data exclusivity legislation of a US standard in many developing countries.”

<sup>45</sup> WT/DS171/3

a data exclusivity standard.<sup>46</sup> Even the EU, which is a strong proponent of data exclusivity, appears to recognise that it is not obvious that Article 39.3 imposes the obligation of data exclusivity<sup>47</sup>:

“It must be admitted that the wording of Article 39.3 does not, from a *prima facie* reading, appear to impose data exclusivity during a certain period of time. This lack of clarity is the obvious result of a difficult negotiation process where divergences of views arose between developing and industrialised countries as to the necessity of EC/US like type of data protection as well as among industrialised countries on the length of the data exclusivity period”.

4.17 The Committee report notes that there were divergent views on whether Article 39.3 is a mandate for data exclusivity.<sup>48</sup> Unfortunately, there is no detailed discussion by the Committee of these views, beyond a mere listing. It is therefore unclear whether any weight was attached to any of these views or not and if so, why.

4.18 The Committee report makes two assertions in support of ‘data protection’. Unfortunately, the Committee does not clarify which ‘type’ of data protection it is referring to. If it is the data protection mandated under the TRIPS Agreement (i.e. protection of undisclosed test or other data for new chemical entities), these assertions are of no consequence. If on the other hand, it is data exclusivity, then one has to examine the assertions. The first of these assertions is that there are a number of drugs - “mainly biotech drugs” – for which it is “is difficult to make generics” and “[i]n case data protection is provided, such categories of drugs may become available early in India as the innovator companies would have greater confidence in entering the Indian market.”<sup>49</sup> No reasoning is provided. It is difficult to accept this assertion as it is unlikely that the difficulty in making generic versions would in any way impact the confidence of the innovator in introducing a product in the Indian market.

4.19 The second assertion is that data protection would be helpful in checking the menace of spurious drugs and pesticides<sup>50</sup> “and only those companies which have the resources to produce good quality products should be allowed to market them during the period of protection.” No reasoning is provided to justify this assertion and no data is provided to support it. Whatever data is available, in the context of drugs, suggests that the extent

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<sup>46</sup> Basheer- IPI Report, p. 18.

<sup>47</sup> European Union, *Questions on TRIPs and data exclusivity, An EU contribution*, Brussels, 2001, p. 19, available at: [http://trade.ec.europa.eu/doclib/docs/2006/may/tradoc\\_122031.pdf](http://trade.ec.europa.eu/doclib/docs/2006/may/tradoc_122031.pdf)

<sup>48</sup> Committee report, paras 1.7-1.9, pp. 4-5

<sup>49</sup> Committee report, para 1.10, p. 5.

<sup>50</sup> Committee report, para 1.11, pp. 5-6.

of the menace is exaggerated. The most authoritative report, one issued by the Drugs Controller General (India) along with the Indian Statistical Institute pegged counterfeit drugs in Indian markets at 0.3% against the oft alleged 25-30%.<sup>51</sup> On the other hand, a recent report by Agrochemical Policy Group - a New Delhi based organisation, has pegged the loss due to spurious pesticides at Rs. 7000 crores.<sup>52</sup> In any event, there is nothing to suggest that data exclusivity can solve the problem of spurious drugs/pesticides. Businesses that supply spurious products do not run through the cumbersome procedures of getting marketing approvals and will continue to do so whether or not there is data exclusivity.

4.20 In fact, the very notion of conflating IP issues with those of 'spurious' drugs has been hotly contested by the Indian Government in the WHO.<sup>53</sup> If the official position of the Indian Ministry of Health is that IP issues should not be connected to the issue of spurious drugs, which is factually and conceptually correct,<sup>54</sup> it is very surprising that the Committee has taken a contradictory stand. Conceptually, IP issues concerning reliance on originator's test and other data for the approval of generic products are entirely distinct from issues of quality and spurious products.

4.21 The Committee then proceeds to examine the two obligations imposed by Article 39.3 – "protection against disclosure and protection against unfair commercial use"<sup>55</sup> and discusses three issues in this context:

- '*Data*' entitled for protection, and notes that undisclosed test and other data submitted for registration developed with considerable effort and expense is entitled to 'some' protection'.<sup>56</sup>

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<sup>51</sup> CDSCO, '*Report of Country Wide Survey of Spurious Drugs*', (2009), available at: [http://cdsco.nic.in/REPORT\\_BOOK\\_13-7-10.pdf](http://cdsco.nic.in/REPORT_BOOK_13-7-10.pdf) Also see: Radika Pandey, '*Supply of Fake Drugs Grossly Overstated*', Mint Report, , available at: <http://www.livemint.com/2009/11/27010916/Supply-of-fake-drugs-grossly-o.html>

<sup>52</sup> Jha, '*Spurious Pesticides Cost Country Rs. 7000 crore- study*', Business Standard, available at: <http://www.business-standard.com/india/news/spurious-pesticides-cost-farmers-rs-7000-cr-study/383278/>

<sup>53</sup> Lynne Taylor, '*India Chides WHO Over Counterfeit Drugs*', Pharmatimes (March, 2010) , available at: [http://www.pharmatimes.com/article/10-03-31/India\\_chides\\_WHO\\_over\\_counterfeit\\_drugs.aspx](http://www.pharmatimes.com/article/10-03-31/India_chides_WHO_over_counterfeit_drugs.aspx); Also see: Katlin Mara, '*Debate Erupts over WHO Police Work Against "Counterfeit" Drug Trade*', IP Watch (May 2010), available at: <http://www.ip-watch.org/weblog/2010/05/20/debate-erupts-over-who-police-work-against-counterfeit-drugs-trade/>

<sup>54</sup> Brant J and Malpani R, '*Eye on the Ball: Medicine Regulation- Not IP Enforcement- Can Best Deliver Quality Medicines*', Great Britain: Oxfam International, (February 2011), available at: <http://www.oxfam.org/sites/www.oxfam.org/files/eye-on-the-ball-medicine-regulation-020211-en.pdf>

<sup>55</sup> Committee report, para 2.1, p. 7.

<sup>56</sup> Committee report, para 2.2, pp. 7-8.

- *Unfair commercial use*, and notes the divergence of opinion on whether reliance on regulatory data amounts to unfair commercial use without setting out its own reasoning or opinion.<sup>57</sup>
- *Meaning of ‘new chemical entity’ (NCE)*, and after noting the various view points and practices, recommends that a definition of NCE is needed.<sup>58</sup>

4.22 Prof. Correa has articulated a premise of permissive reliance (on data submitted for registration) for approval of generic equivalents based on the inherent flexibility involved in the word ‘unfair’.<sup>59</sup> Other commentators disagree with the standard of permissive reliance, arguing that the term ‘*unfair*’ will be completely redundant, even accepting that there is high degree of interpretative flexibility in the term.<sup>60</sup> However, the negotiating history does reveal that the US proposal to structure Article 39.3 on any practice based on the effects that may arise was defeated and a more balanced structure was accepted where certain types of practice - to mean those that are commercially unfair - was accepted.<sup>61</sup> What amounts to ‘unfair’ has also been applied in a diverse manner within the mandate of Article 10*bis* of the Paris Convention.<sup>62</sup> On what amounts to ‘commercial use’, again, Correa’s position in support of permissive reliance is based on the argument that the commercial use standard would apply only to private parties (to obtain by fraud etc..) and not to governments - “notably by the national health authorities to assess the efficacy and toxicity of a pharmaceutical or agrochemical product”. Relying on Ladas, Prof. Correa adds that though use by governments will have commercial consequences due to early entry of a generic competitor, it may not amount to a commercial activity but a legitimate state practice since the information is not used by someone who is actually in that commerce.<sup>63</sup> The Committee has unfortunately not engaged in any legal analysis to inform its recommendation.

4.23 There are several important aspects of the interpretation of Article 39.3 that have been ignored by the Committee. The Committee report could have made clear that the TRIPS minimum standards mandate is restricted to NCEs that clearly does not include

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<sup>57</sup> Committee report, para 2.3, p. 8.

<sup>58</sup> Committee report, para 2.4, pp. 8-10.

<sup>59</sup> *Id.*, p. 381.

<sup>60</sup> Basheer- IPI report, p. 19

<sup>61</sup> Correa- Oxford Commentaries, p. 382

<sup>62</sup> *Id.*, p. 381.

<sup>63</sup> *Id.*, p. 381.

new dosage forms and new uses, and also that its newness could be local or universal.<sup>64</sup> Further, the Committee has not gone into interpretative questions of what amounts to ‘considerable effort’. Some commentators suggest that it can be interpreted to cover data where certain ‘investment’- whether technical or economic- is made by the originator of the data. But protection is not based on the creative quality of the data in itself.<sup>65</sup> The non-disclosure obligation crafted in Article 39.3 makes it possible for a member to specify a particular time period even when test data is protected under principles of trade secret protection, which allows for permissive reliance.<sup>66</sup>

4.24 Again, Article 39.3 does not mandate any test data protection (under the standards prescribed therein) when the national regulatory authority of a WTO member country relies on submissions made by originators in foreign jurisdictions since Article 39.3 starts with “Members, when requiring”.<sup>67</sup> So any obligation under Article 39.3 kicks in only when WTO members do indeed require the submission of data. However, usual conditions of protecting undisclosed information under Article 39.2 may apply. In fact, Prof. Gopalakrishnan has suggested limiting the data requirement to new drugs that are introduced for the first time in India and not available in the market anywhere in the world.<sup>68</sup>

4.25 The arguments against data exclusivity have not been dealt with by the Committee, except briefly in noting the possible interpretations of the term ‘unfair commercial use’. Prof. Correa has rightly argued why Paris Convention principles of unfair competition – on which the Article 39.3 framework is based – does not demand treatment of the term ‘unfair’ to any particular standard.<sup>69</sup> It is further submitted that even the negotiation history of the TRIPS Agreement does not favour an interpretation of a data exclusivity type of protection.<sup>70</sup> Prof. Reichman has argued that the Appellate Body jurisprudence in *India - Pharmaceutical Mailbox* case may not allow an interpretation that moves beyond the TRIPS requirement and hence 39.3 should not be tweaked in favour of a

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<sup>64</sup> *Id.*, p. 379, citing, T. Cook, *Special Report: The Protection of Regulatory Data in the Pharmaceutical and Other Sectors*, Sweet and Maxwell (2000).

<sup>65</sup> *Id.*, p. 379-380

<sup>66</sup> *Id.*, p. 380.

<sup>67</sup> Basheer- IPI Report, p. 35

<sup>68</sup> *See*: Gopalakrishnan N S. and Kadavan, *Study on Test data Protection in India*, Eastern Book Company (2005). *Also see*: Prof. Gopalakrishnan’s submissions made to the committee- Committee report, p. 55.

<sup>69</sup> Carlos Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement*, South Centre, Geneva (2001).

<sup>70</sup> Jerome Reichman, *Undisclosed Clinical Trial Data and Its Progeny*, UNCTAD-ICTSD Dialogue on Moving the pro-development IP agenda forward: Preserving Public Goods in health, education and learning, Bellagio, 29 Nov.- 3 Dec. 2004, available at: [http://www.iprsonline.org/unctadictsd/bellagio/docs/Reichman\\_Bellagio4.pdf](http://www.iprsonline.org/unctadictsd/bellagio/docs/Reichman_Bellagio4.pdf)

data exclusivity regime.<sup>71</sup> Prof. Basheer has also highlighted why data exclusivity is not the standard required by Article 39.3 - specifically in the context of definitional ambiguity surrounding the term ‘unfair’, and how regimes of data exclusivity have been crafted in NAFTA in contrast to that of the TRIPS requirement.<sup>72</sup>

- 4.26 In conclusion, one may state with reasonable certainty that the minimum requirement under Article 39.3 is of data protection allowing a standard of ‘permissive reliance’. Reading a mandate for data exclusivity within the Article 39.3 framework would, as rightly asserted by some commentators, “impose precisely the obligations that a large number of negotiators refused to countenance.”<sup>73</sup> It is unfortunate that the Committee report does not clearly bring out the conclusive and accurate positions with certainty concerning the minimum requirement of TRIPS.

### **SECTION-III**

#### **IS THE INDIAN LAW TRIPS COMPLIANT?**

- 4.27 The second task entrusted to the Committee (the first being the steps to be taken in the context of Article 39.3 of the TRIPS Agreement) was to examine whether “data protection can be offered under the existing legal provisions or an appropriate new dispensation is required”.<sup>74</sup> In this context, the Committee discusses the existing law in India in Chapter 3. The Committee report notes that both the Drugs and Cosmetics Act and the Insecticides Act require the submission of “valuable test data” for marketing approval of drugs and agrochemicals, the implication being that the precondition for the applicability of Article 39.3 is satisfied and therefore there is obligation to protect such data from disclosure and unfair commercial use.<sup>75</sup>
- 4.28 The Committee report notes that India does not have separate legislation to protect against unauthorized use or disclosure of confidential information but relevant legal mechanisms that exist include the common law, principles of equity, law of breach of confidence, law of torts and the Indian Contract Act where the remedies are compensation and injunction. In addition, Section 5 of the Official Acts provides that unauthorised disclosure of official secrets is an offence.<sup>76</sup> Unfortunately, there is no

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<sup>71</sup> *Ibid.*

<sup>72</sup> Basheer-IPI Report pp. 23-25

<sup>73</sup> Fellmeth, p. 436

<sup>74</sup> Committee report, p. iii.

<sup>75</sup> Committee report, para 3.0, p.13

<sup>76</sup> *Ibid.*

further discussion on whether these provisions are adequate in the context of Article 39.3 of the TRIPS Agreement and what the specific shortcomings are, if any.

4.29 For example, the Committee does not take into account the scope and adequacy of the common law position in India. Although the common law of trade secret protection is not fully developed within India, the courts have generally relied on common law positions in the United Kingdom.<sup>77</sup> It should be noted that there is no direct Indian authority that has specifically extended common law principles of trade secret protection to information submitted to governmental agencies. However, the position in the common law countries is that reliance by governments on regulatory data does not amount to violation of trade secret protection.<sup>78</sup> In *R v. Licensing Authority ex p Smith Kline & French Laboratories*,<sup>79</sup> the House of Lords (UK) held that under the Medicines Act of 1968 “it was the right and duty of the licensing authority to make use of all the information supplied by any applicant for a product license which assists the licensing authority in considering whether to grant or reject any other application.....The use of such information should not harm the appellants and even if it were to do so, this is the price which the appellants must pay for cooperating in the regime designed by Parliament for the protection of the public and for the protection of the appellants and all manufacturers of medicinal products from the dangers inherent in the introduction and reproduction of modern drugs.” There is also no discussion on whether the codification of the common law position is desirable.

4.30 Prof. Goplakrishnan has, in his submissions, suggested that there must be provisions concerning “[l]iability of persons in the office of DCGI under the Official Secrets Act, 1923 in case of **unauthorized disclosure of the secret information**”, which he argues should also be extended to Insecticides Act.<sup>80</sup> (*emphasis added*)

4.31 The Committee reviews the statutes requiring the submission of data for registration and marketing approval for both drugs and insecticides.<sup>81</sup> As far as is relevant to agrochemicals, the Committee report concludes that:<sup>82</sup>

“The Insecticides Act does not provide for any kind of protection to the data submitted for registration. Though Rule 29 creates an obligation on Insecticides Inspector to maintain confidentiality of information acquired

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<sup>77</sup> *John Richard v. Chemical Process Equipment (P) Ltd.* AIR 1987 Del. 372

<sup>78</sup> UK, Canada, Australia and New Zealand follow such a standard. *See generally*: IMAK-Report, p. 20.

<sup>79</sup> (H.L.) [1990] 1 A.C. 64; (1989) 1 All ER 578.

<sup>80</sup> Committee report, p. 55.

<sup>81</sup> For an excellent background of the historical evolution of both the laws, *see generally*: Gopalakrishnan: Test data study, pp. 39-56.

<sup>82</sup> Committee report, para 3.3, p. 20.

by him in the performance of his office duties, this does not extend to the Registration Committee. Section 9(4) clearly empowers the Registration Committee to allow subsequent registration based on data submitted for original registration.”

4.32 The implication of the above seems to be that the Committee finds the provisions available in the Insecticides Act inadequate protection against disclosure by the regulatory authority of data submitted to it and no prohibition on relying on such data for subsequent registrations.

#### **SECTION-IV**

##### **DIFFERENTIAL TREATMENT OF AGROCHEMICALS**

4.33 Chapter 5 of the Committee report is devoted to justifying differential treatment for agrochemicals as compared to pharmaceuticals, leading to a recommendation for conferring 3-year data exclusivity for agrochemicals. At the outset, it must be recognized that neither differential treatment to agrochemicals nor data exclusivity is a TRIPS obligation under Article 39.3. However, as mentioned earlier, the Committee has thought it fit to make what is essentially a policy recommendation beyond its mandate. Chapter 5 of the Committee report provides the basis for this recommendation and therefore warrants close scrutiny.

4.34 The differential treatment is sought to be justified on the basis of the following six general assertions:<sup>83</sup>

- a. 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.
- b. Because of the toxic nature of the substances involved, the crop protection industry must face a responsibility for environmental impact to which the pharmaceutical industry is not exposed.
- c. Further in case of agricultural chemicals, the process of data generation continues even after the product registration has been done due to the requirements of periodic review, data call in by the authorities, adaptation to the advanced standards of science and technical knowledge, product stewardship etc. Failure to meet these requirements may lead to revocation of product registration.

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<sup>83</sup> Committee report, para 5.1, pp. 23-24.

- d. The costs involved in conducting the above registration related studies for agricultural chemicals are huge. Product registration is only the first part of the cost. The originator incurs substantial subsequent costs on extension and development work involving door to door contact with the farmers in villages to ensure better use to obtain the optimum results, without compromising safety.
  - e. While in the case of pharmaceuticals one in every 10,000 molecules investigated is approved by the FDA for marketing, in the case of agrochemicals only one of 20,000 molecules makes it from the laboratory to the fields.
  - f. Because of its chemical nature and the wide range of organisms potentially affected by their use, agrochemical products have to undergo more than 40 safety tests.
- 4.35 The position in India is then outlined<sup>84</sup> to further buttress the desirability of differential treatment to agrochemicals and justify data exclusivity. The main arguments are:
- a. Substantial data on bio-efficacy, toxicology, process of manufacture, effect on environment, safety of spray operators, compatibility with containers and also transportation and stability has to be submitted for registration of agrochemicals. The Committee has relied on the estimates of 'industry sources' that these studies are spread over 3 to 4 years. The Committee points out that in contrast to these extensive requirements for agrochemicals, the requirement for approval of drugs is only a confirmatory study in a small number of volunteers and bioequivalence with the originator product.
  - b. Once the original registration is obtained by the originator/ first applicant u/s 9(3) of the Insecticides Act(1968), a large number of 'me too' registrations are obtained immediately, u/s 9(4) of the Act – virtually without any test data.
  - c. All the 'me too' registrants may not have complete knowledge of the compound. Consequently there is no transfer of knowledge/technology to the users of new but 'me too' products, sometimes leading to improper use with adverse consequences on health and the environment, development of resistance and uneconomic returns to farmers.
  - d. Innovators are reluctant to bring the latest discoveries to India as the 'me-too' registrant is at an unfair advantage. This deprives the country and the farmers of

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<sup>84</sup> Committee report, para 5.2, pp. 24-25.

- access to insecticides which are more effective, environment friendly and have lower dosage.
- e. It is noticed that there were only about 200 insecticides registered in India at that time with another 30 in the process of being registered. As compared to this the number of insecticides registered in some other countries is considerably higher e.g. 750 in USA, 550 in China, 600 in Europe, 480 in Pakistan, 450 in Vietnam, 450 in UK, 300 in Thailand.
  - f. There is an increasing tendency on the part of multinational companies to not manufacture pesticides in the country but to import formulations from abroad as ‘me too’ registration under section 9(4) is not permitted for such products.
  - g. In the case of pharmaceuticals, information regarding the correct drug and its dosage form for a particular disease is conveyed to the consumer through the doctors. In agrochemicals this role is discharged by the companies after introducing the chemical in the market through extension services and stewardship for 3 to 4 years. ‘Me-too’ registrants do not undertake this supervision as it involves huge cost and often because of lack of adequate knowledge of the compound.
  - h. This deficiency on the part of ‘me-too’ registrants and poor quality of the products has in some cases resulted in application of the wrong agrochemicals or its excessive use causing financial loss to the farmers, sometimes laying waste precious agricultural land.
- 4.36 The third leg of the justification<sup>85</sup> is that the protection allowed for agrochemicals is generally higher than that for pharmaceuticals. Examples of the USA, Europe, Canada and Japan are cited. It is also noted that Brazil has differential treatment for agrochemicals – data exclusivity of 10 years with 5 years for additional data is allowed, whereas no data exclusivity is available for pharmaceuticals.
- 4.37 Three aspects stand out in the Committee’s justification for differential treatment to agrochemicals:
- a. First, the Committee has travelled into territory far beyond the bounds of the task entrusted to it – to review the steps to be taken in the context of Article 39.3 - and has sought to justify data exclusivity which is TRIPS-plus.

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<sup>85</sup> Committee report, para 5.3, p. 26.

- b. Second, even the recommendation for data exclusivity for agrochemicals is substantially based on assertions unrelated to Article 39.3 of the TRIPS Agreement, such as liability risks and marketing costs of agrochemicals, taking the recommendations even farther away from the scope of the original mandate.
  - c. Third, there is near-total lack of any factual basis for the justification offered by the Committee including that for differential treatment of agrochemicals as compared to pharmaceuticals. No data are provided to support these assertions, nor are they in the nature of obvious and well accepted truths.
- 4.38 It is not within the scope of this critique to furnish the factual data – one would imagine that the onus of providing factual justification would be on those proposing the policy and a government Committee with its vast resources and access to data would be better positioned to do it on this vital issue, particularly when it has laboured for three years to make its recommendations. However, even a cursory examination of the main arguments suggests that neither the differential treatment to agrochemicals propounded by the Committee nor the reasoning supporting data exclusivity for agrochemicals are acceptable without further data and analysis:
- a. The thrust of the Committee’s justification of differential treatment of agrochemicals is founded on the expenses and effort involved in establishing efficacy in each country and the agro-climatic regions. No data whatsoever is furnished estimating these costs and what period of data exclusivity would be justified in relation to these costs, except to assert that “registration related studies for agricultural chemicals are huge”. It must be noted that these assertions are in comparison with pharmaceuticals. The Pharmaceutical Manufacturers and Researchers of America (PhRMA) claim (based on studies of the Tufts Center for the Study of Drug Development) that the average cost of the development of a drug in 2001 was USD 802 million and this increased to USD 1.3 billion in 2005. The R&D expenditure of the PhRMA members is consistently about 17% of sales, most of which is directly attributable to generation of data required by regulatory authorities to establish safety and efficacy and post marketing surveillance.<sup>86</sup>
  - b. The Committee’s justification of differential treatment for agrochemicals based on the higher costs of generating data in India as compared to the ‘small confirmatory

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<sup>86</sup> Pharmaceutical Research and Manufacturers of America, Pharmaceutical Industry Profile 2011 (Washington, DC: PhRMA, April 2011), *available at*: [http://www.phrma.org/sites/default/files/159/phrma\\_profile\\_2011\\_final.pdf](http://www.phrma.org/sites/default/files/159/phrma_profile_2011_final.pdf)

studies' and bioequivalence studies for pharmaceuticals appears to be factually inaccurate. The Committee report notes that “[a]s per industry sources duration of data generation is about three years and approximate cost of data generation is Rs.30-35 lacs for each applicant for India.”<sup>87</sup> While no data is given of the costs of ‘small confirmatory studies and bioequivalence studies, it is most unlikely that they are any less, quite apart from the fact that Rs. 30-35 lakhs is not a huge expenditure. Significantly, an industry representative is sceptical about the extent of additional costs incurred for registration in India, pointing out that “these tests do not involve high additional costs since the originator is already having data generated from the first set of trials conducted in other countries and many times it will be a mere repetition. *The costliest data like neurotoxicity, carcinogenicity and mutagenicity are never repeated and the old original studies are accepted.*”<sup>88</sup> It is clear that for many tests, the Registration Committee does rely on data generated elsewhere to be submitted in India.<sup>89</sup>

- c. Quite extraordinarily, the Committee is of the view that the “responsibility” of the industry for the environmental impact of the toxicity of agrochemicals warrants data exclusivity. This possibly means that the agrochemical industry has an inherently higher risk of liability for environmental damage because of the toxicity of the chemicals they market as compared to pharmaceuticals. Apart from the fact that the pharmaceutical industry has the risk of significant liability to patients consuming drugs, it is wholly incomprehensible how data exclusivity is an appropriate policy measure for mitigating the risk to the agrochemical industry! And more so, selectively to the originators of the toxic chemical, as presumably even ‘me too’ manufacturers would be similarly liable for environmental damage.
- d. It is equally strange that the Committee is of the view that the costs of ‘extension and development’ (i.e. marketing the product “door to door to farmers in villages”) warrants the grant of data exclusivity. It must be emphasised that conceptually, such costs have little to do with data submitted to a regulator for regulatory approval. It is significant that even the originators of both drugs and agrochemicals have never sought to justify their demands for data exclusivity on the basis of either their costs relatable to liability risks or marketing.

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<sup>87</sup> Committee report, footnote 10, p. 20.

<sup>88</sup> Interview with Samir Dave, PMFAI (28<sup>th</sup> Feb 2011). (*emphasis added*)

<sup>89</sup> See, *Guidelines for data requirement under section 9(3) and 9(4)*, available at: <http://cibrc.nic.in/guidelines.htm>

- e. The further justification is data generation continues even after registration and there is also a requirement of product stewardship, supervised applications etc. Again, no estimates of these costs are available and it is not clear whether such costs are incurred only by originator companies or by 'me too' product manufacturers also. No note is taken of the fact that pharmaceutical marketing authorizations are also subject to surveillance requirements.
- f. The crux of the Committee's justification is that innovators need to recoup the 'huge costs' of generating data required for registration as well as the costs of marketing and a limited period of monopoly where prices can be high would provide for this. On the other hand, without the period of exclusivity, there is an influx of 'me too' products which do not have any of this expenditure and are consequently priced much lower, eroding the ability of originators to maintain high prices and profits. This is precisely the same argument that has been used by the innovator pharmaceutical industry, but to no avail. Absent any reasoning based on factual data of comparative costs, it is quite unclear how the Committee is justified in differentiating agrochemicals from pharmaceuticals. Further, without any data on costs, anticipated monopoly pricing during data exclusivity, the demand at these prices and the consequent estimated benefit to the originators, it is not possible to engage in any meaningful evaluation of the Committee's recommendation.
- g. The Committee further argues, pointing to the limited availability of about 200 pesticides in the country (with 30 more under registration) as against the much larger number available elsewhere, that the uncertainty of returns in a competitive market as opposed to a monopoly is a disincentive for originators to manufacture the products in India, thereby delaying the availability of useful agrochemicals to the detriment of farmers and the country. Again, this is exactly the same argument advanced by the innovator pharmaceutical industry, with the detriment said to be to patients and the country. Such an argument therefore does not serve to justify differential treatment. It must also be mentioned that commercial decisions to manufacture the technical in India or making available particular formulations are influenced by a number of factors and availability alone is insufficient to assure demand. The Committee has not ventured into any analysis of the reasons for the situation in India and the extent to which the absence of data exclusivity has been a contributory factor.

h. The Committee report speculates that harm is caused by the ‘poor quality of the products’, inadequate knowledge of the product leading to improper use and financial loss to farmers and lack of financial resources to incur the ‘huge costs’ of extension work and stewardship, of some of the ‘me too’ product manufacturers and that this harm will be mitigated by data exclusivity as they will be kept out. Needless to say, the Committee report does not provide any data. On the face of it, this speculation appears wholly misconceived. Poor quality of products is a regulatory issue and data exclusivity cannot make a dent on it. It is implausible that the originators engage in such large scale extension that the problem of improper use is mitigated to an appreciable extent. ‘Me too’ manufacturers appear to have contributed to extension and Government agencies have made significant efforts in this area.

## **SECTION-V**

### **COMMITTEE RECOMMENDATIONS**

- 4.39 Chapter 6 of the Committee report sets out the proposed provision for data exclusivity for agrochemicals and discusses the pros and cons. Chapter 7 contains the final recommendations. The contents of these two chapters are discussed together below for convenience. The two chapters also cover the conclusions and reasons for the recommendation of data exclusivity for traditional medicines and data protection for pharmaceuticals during a transition period and data exclusivity thereafter, but these are not discussed in this critique.
- 4.40 The Committee report recommends ‘data protection’ for agrochemicals for 3 years from the date of registration in India, during which period the regulator would not be permitted to rely on the data submitted by the first applicant for approval of the same product of second or subsequent applicants in the ‘me too’ category.<sup>90</sup> Clearly, what the Committee report meant by ‘data protection’ is data exclusivity. The Committee considered the alternative of a 5-year period of data exclusivity and the advantage of the longer period ‘to enable the long period of promotional work required for educating the farmers on the use of new chemicals’ but in view of the consensus of the industry, represented by Crop Life India, Crop Care Federation of India (CCFI) and Pesticides

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<sup>90</sup> Committee report, paras 6.1 (pp 27-30) and 7.4.1 (pp 39-42).

Manufacturers and Formulators Association of India (PMFAI), the Committee report recommended the 3 year period. Other salient features and “safeguards” include:

- a. Very importantly, it is noted that “data protection will be limited to New Chemical entities (NCE), as required under article 39.3 of the TRIPS agreement” (by ‘data protection’, the Committee means data exclusivity) but the Committee report defines a NCE as “[a]n agrochemical product which contains an active ingredient or formulation of such an ingredient that has not been previously approved in India irrespective of whether the product is patentable or not.”<sup>91</sup> Clearly, data exclusivity is recommended for an active ingredient or a formulation containing it that has not been previously approved in India. What is however ambiguous is whether the recommendation also extends to a new formulation that has not been previously approved in India, even if it is one of previously approved actives. (See also 4.43 below). Further, ‘data protection’ is recommended to “only post-1995 molecules which have not yet been introduced in India.” It is unclear whether this applies only to active ingredients or also to formulations; and whether the 1995 cut-off applies to discovery of the active ingredient (as for example, the date of application of a patent) or the date of first approval anywhere in the world of the active ingredient, or the formulation.
- b. For “pesticides” patented in India, ‘data protection’ shall not exceed the term of patent.
- c. ‘Data protection’ can be waived or relaxed by government in cases of “national emergency”, “extreme urgency”, “public health or environment related crisis” and “public interest” to allow ‘me too’ registrations. The public interest ground can be invoked when the product is not available 6 months after registration in India, the “reasonable” requirements of the public are not met, or the product is not available at “reasonable” prices. What is ‘reasonable’ can be determined by government.
- d. ‘Me too’ applications can be filed during the period of ‘data protection’ and can be tentatively approved and become operational immediately on expiry of the ‘data protection’ period, so that availability of generic products is not delayed.
- e. There are also other provisions recommended, including waiver for the limited purpose of government use for academic and research purposes. Significantly, a mechanism of “price negotiation” has also been recommended to be put in place to

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<sup>91</sup> Committee report, para 7.4.1, p. 41.

ensure that the prices of the new agrochemicals “remain reasonable”. This is implicit recognition of the likelihood of high prices prevailing during the term of data exclusivity.

4.41 At the outset, it must be pointed out that the use of terminology of ‘data protection’, when ‘data exclusivity’ is actually intended is indeed unfortunate. They are two different concepts and should not be confused. The incorrect understanding of the Committee of these two concepts<sup>92</sup> may have contributed to this confusion and could have implications should it become a matter of dispute in international or domestic fora, particularly because it is terminology used by an officially constituted Government committee.

4.42 The Committee report recommended that the Ministry of Agriculture suitably amend the Insecticides Act to implement the above. The Ministry of Agriculture has however decided to replace the Insecticides Act in toto and has proposed a new legislation – The Pesticides Management Bill in 2008. This is pending consideration of Parliament. Interestingly, the Bill does not resort to the use of contentious terminology such as data protection or exclusivity and NCE. Instead, it directly provides for non-reliance on data submitted by first applicants of any new pesticide (whether containing a NCE or not) for approval of subsequent ‘me too’ applicants. The relevant provisions are in sub-sections (6) – (8) of Section 12 the Bill. Section 12 (6) and (7) read as follows:

(6) The data submitted for the purpose of registration in respect of a pesticide under this section which has not been previously registered shall not be relied upon for grant of registration of the same pesticide in respect of any other person for a period of three years.

(7) Subject to sub-section (6), where a pesticide has been granted a patent, the period of non-reliance on data shall be limited to the period of the patent.

*Explanation.*- The words "not been previously registered" in respect of a pesticide shall include its name or label expansion through "new uses":

Provided that the provisions of non-reliance on data submitted for registration of a pesticide by the first registrant shall be available for the period with effect from the date of the first marketing approval granted anywhere in the world and this shall not apply to the data relating to bio-efficacy and shelf-life part of pesticides where data is to be generated for use under Indian conditions.”

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<sup>92</sup> See 4.14-4.16 above for a detailed discussion.

- 4.43 As mentioned earlier, the Standing Committee on Agriculture has recommended increasing the term of data exclusivity to 5 years, without any explanatory notes. Whether it was because of the ambiguity in the definition of NCE in the Committee report or otherwise, the legislation implementing this recommendation would appear to cover both active ingredients and formulations.<sup>93</sup> It is thus beyond the scope of the obligation under Article 39.3 of the TRIPS Agreement even in terms of coverage – new formulations of old ingredients that have been previously approved could also apparently be covered if some data in addition to that generated for use under Indian conditions is required to be submitted for its approval. The proposed legislation also does not distinguish between “post 1995” molecules and others.
- 4.44 The Bill has departed from the recommendation in the Committee report in one very important aspect – the date from which the period of exclusivity is to be reckoned. The Committee report recommended that it should run from the date of registration *in India*. The Pesticides Management Bill provides that it should run from first date of marketing approval *anywhere in the world*. Whether this is to incentivize the originator to promptly apply for, and obtain, marketing approval in India, thereby hastening availability (a justification advanced by the Committee for data exclusivity) or whether it was motivated by a concern to tightly limit the period of monopoly (and the consequent higher price, which was a concern of the Committee) is not known. The impact of this provision in the Bill cannot be deduced, as there is no data in the Committee report that would aid such analysis.
- 4.45 The Bill has carried out the Committee’s recommendation to limit the period of data exclusivity to patent expiry, if the pesticide has been granted a patent in India. This is a problematic clause, both conceptually and practically. At the conceptual level, data exclusivity is a *sui generis*<sup>94</sup> right intended to compensate the generator of data for his labours and is entirely different from, and independent of, patent rights that compensate the inventor for making the invention public and enabling others to practice it after the

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<sup>93</sup> The definition of a pesticide in Sec 3(s) would seem to include both the active ingredient and its formulation: "pesticide" means any substance or mixture of substances of chemical or biological origin intended for preventing, destroying, attracting, repelling, mitigating or controlling any pest including unwanted species of plants or animals during the production, storage, transport and distribution of agricultural commodities or animal feeds including substances intended for use as plant growth regulator, defoliant, desiccant, fruit thinning agents, or sprouting inhibitor and substances applied to crops either before or after harvest to protect them from deterioration during storage and transport and Sec 3(a) reads: "active ingredient" means the technical grade pesticide present in a formulation. 'Formulation' is defined not in terms of a product, but in terms of its manufacture in Sec 3(i) : "formulation" means manufacture of a preparation containing one or more technical grade pesticide in a definite proportion along with other specified ingredients.

<sup>94</sup> See 3.6 above.

patent term. It is right that they should run concurrently but that is no basis to limit one right by the other. Practically, this provision is likely to lead to several anomalous consequences, which may not have been contemplated by the Committee. For example, if a patent term in India expires prior to 3 years from the date of first marketing authorisation anywhere in the world, data exclusivity would be limited to the shorter term and the originator would have been better off without a patent. A further uncertainty in such a situation is if the patent is revoked. Having limited data exclusivity to the term of a patent, would it be open to the originator to claim the full term of the data exclusivity on revocation?

4.46 Another important aspect is in the explanation to Section 12(7). This sub-section enables the grant of data exclusivity to pesticides ‘not having been previously registered’. The explanation provides that “[t]he words “not been previously registered” in respect of a pesticide shall include its name or label expansion through “new uses”.” It is entirely unclear what ‘name expansion’ means. Neither name or label expansion through new uses have been recommended by the Committee, though it has generally been noted as an issue and differing views have been recorded.<sup>95</sup> Alternatives have been outlined in the context of drugs,<sup>96</sup> but not for pesticides. It is entirely unclear from the Bill whether the exclusivity will be for the use or for the product itself. If it is the former, it will lead to problems of effective enforcement. While labels of ‘me too’ products will not be permitted with the new use, ‘me too’ products will be available and it is difficult to see how farmers can be restrained from using ‘me too’ products for the new use. On the other hand, if the exclusivity is extended for the product itself, it can lead to ‘evergreening’ of data exclusivity by obtaining periodic approvals of new uses and new exclusivities. There is also considerable potential for anomalous situations to arise. For example, what is the position when a new use is approved after the expiry of the original exclusivity; or if ‘me too’ registrants or applicants generate data and obtain registration for a new use?

4.47 The Bill has substantially incorporated the recommendations in the Committee report for arming the government with powers to relax or exempt the operation of data exclusivity in cases of “national exigency”, “urgency”, “public interest” or for use by the government for academic and research purposes.<sup>97</sup> The intention of the Committee

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<sup>95</sup> Committee report, p.9

<sup>96</sup> Committee report, p.49

<sup>97</sup> Sec. 12(8), The Pesticides Management Bill, 2008.

was obviously to have a provision that parallels the compulsory licencing provisions in the Patents Act to achieve the same ends.<sup>98</sup> Unlike in Sec. 92 of the Patents Act however, there is no need for notification by the Central Government of national exigency or extreme urgency and unlike in Sec 84. (or the recommendation in the Committee report) no guidance is available on what constitutes public interest. While the Patents Act grants the power to issue compulsory licence to the Controller, the Bill does not specify the authority to relax or exempt the operation of data exclusivity, nor does it specify on whose application it may be done or the procedure to be followed. Unless these and related issues are addressed satisfactorily, the constitutional validity of the provision may be challenged on the ground that it confers unbridled discretionary power to the government, in violation of Article 14 of the Constitution. Even so, there could be a piquant situation if the authorities under the patents Act and the Pesticides Management Act differ in their conclusions on the same set of grounds for the same product.

4.48 Very clearly, the provision of data exclusivity proposed in the Committee report and carried into the Bill is not in the context of fulfilment of the TRIPS obligation under Article 39.3. It is a TRIPS-plus policy measure sought to be justified on policy grounds unrelated to Article 39.3. The Committee report mainly reiterates the justification of differential treatment for agrochemicals provided in Chapter 5 of its report in Chapters 6 and 7. The inadequacies and inconsistencies of this justification have already been commented upon earlier in this critique and do not require repetition.

4.49 The Committee report also recommends that the Ministry of Agriculture incorporate provisions to ensure that:<sup>99</sup>

“Data of the Originator must be kept secure and not be accessed by any unauthorized person, nor be accessible to such person. All technical and organizational safeguards as are possible must be implemented.”

It is not clear whether this is through any legislative measures though it seems to be implied in the recommendation of the Committee under the heading “Need to Strengthen Legal Provisions on Data Protection” which reads:<sup>100</sup>

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<sup>98</sup> Compulsory licences can be issued under Sec. 84 of the Patent Act on application to any person interested, on any of three grounds: (i) the “reasonable requirements of the public with respect to the patented invention have not been satisfied”; or (ii) “the patented invention is not available to the public at a reasonably affordable price”; or “the patented invention is not worked in India”; or under Sec. 92, on notification in respect of a patent by the Central Government in circumstances of national emergency or extreme urgency or public non-commercial use.

<sup>99</sup> Committee report, para 7.4.1, p. 40.

“The present legal provisions on data protection in India do not adequately meet the spirit of Article 39.3 of TRIPS even in terms of the minimum requirements.”

4.50 In conclusion, it may be noted that while there are proposed legislative measures that clearly implement a data exclusivity regime for agrochemicals, at the same time the judiciary has been quite sensible in not allowing policy based assertions concerning ‘data exclusivity’ in the Courts. This has substantially reduced the possibility of judicial approval of data exclusivity through the back door. However interestingly, and rather unfortunately, it has not discouraged the government from adopting TRIPS-plus measures in the form of data exclusivity for agrochemical products. This is being achieved through the Pesticides Management Bill, 2008 by relying on the erroneous policy considerations asserted in Committee report and the approval that was blindly subscribed to and endorsed by the Standing Committee on Agriculture. Definitely, the Committee report has utterly failed to provide any rational and legal basis for recommending data exclusivity for agrochemicals. Since the approach of the Committee is fundamentally flawed and that the Standing Committee on Agriculture did no better by endorsing such a flawed approach, there can be nothing more to point to the damning indictment of the Bill in including provisions on data exclusivity for agrochemicals.

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<sup>100</sup> Committee report, para 7.1, p. 38.