DATA EXCLUSIVITY – A RECONCILIATION OF THE DEBATE FROM THE INDIAN PERSPECTIVE

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INTRODUCTION

It is but an inescapable part of human nature to expect returns for one's efforts. In fact, it is this expectation that forms the drive for further human achievement. However, the question is - Can one claim exclusive rights over the product of one's creation when the interest of the society at large is at stake? The answer to this question is rather complex because it involves a juxtaposition of the interests of the inventor and the society which then need to be carefully reconciled.

A need for similar deliberation arises in the context of test data submitted to Drug Regulatory Authorities for obtaining marketing approval of pharmaceutical drugs. The interest of the inventor is pitted against the interest of the society because while the former claims exclusive rights over the test data generated by him there is a fear that the grant of such 'data exclusivity' would affect public interest. The present paper attempts to examine this juxtaposition and provide reconciliation in the Indian context.

The block comprising certain developed nations and multinational pharmaceuticals are stressing on the need for exclusive rights over such data. The mantle is now upon the developing nations such as India to decide their stance on the issue.

The present paper only examines Article 39.3 and the concept of Data Exclusivity in the pharmaceutical sector. In Part One of the Research Paper an insight into the concept of data exclusivity is provided. As the controversy surrounding data exclusivity flows from Article 39.3 of the TRIPS Agreement, Part Two deconstructs and looks into the negotiating history of Article 39.3. From the on-going debate on the issue it is discernible that three major interpretations of Article 39.3 have emerged. In Part Three the researcher shall elaborate on each of these approaches. In Part Four the stance of India, as reflected in the Inter-Ministerial Report submitted in May 2007, will be discussed. In Conclusion, Part Five of the paper shall critically analyze the varied interpretations attributed to Article 39.3 and the Inter-Ministerial Report from the Indian standpoint to make a case for the model of data protection.

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UNDERSTANDING DATA EXCLUSIVITY

For a comprehensive understanding of the concept it is necessary to be aware of the associated terminology. The individual who invents the drug for the first time is the innovator and the person who subsequently manufactures an identical drug is termed the generic producer.

The generic drugs are identical to the brand name drug (innovator's drug) in terms of active ingredients, safety and efficacy and are comparable in dosage form, strength, route of administration, quality and performance characteristics, and intended use.[1]

Every drug that is manufactured cannot be marketed unless it is granted approval by the concerned Authority, the Drug Regulatory Authority in India. Under the current system in India an innovator can obtain marketing approval only after he establishes the safety and efficacy of his drug. In order to establish the same he needs to submit extensive pre-clinical and clinical test data pertaining to trials conducted on humans and animals.[2] However, a generic manufacturer has to only prove bio-equivalency, that is, chemical and biological equivalency, of his drug to that of the innovators'.[3] The Drug Regulatory Authority satisfies itself about the safety and efficacy of the generic drug by relying upon the test data submitted by the innovator.

This is in contrast to the system that will be followed under a Data Exclusivity Regime where the Drug Regulatory Authority is disallowed from relying on the innovators' test data to grant approval to generic manufacturers because the innovator has an exclusive right over the data generated by him.[4] Therefore, if the generic manufacturers wish to market the drug during the exclusivity period they will have to submit independent test data or they may simply wait for the expiry of the exclusivity period. The implementation of data exclusivity quite clearly then, impacts the entry of generic manufacturers.

The protection afforded under Data Exclusivity is distinct and independent to that obtained under a system of patents and hence, they must not be confused. This is

1. Molzon Justina A, "The Generic Drug Approval Process", (1996) 5 J. Pharmacy & L. 275, 275.
2. Under Rule 122-B(2) of The Drugs and Cosmetics Rules, 1945 for the marketing approval of a new drug results of pre-clinical and clinical trials as prescribed in Appendix I to Schedule Y must be submitted. Under Form 44 to the Drugs and Cosmetics Rules, 1945 the marketing approval for an already approved drug only requires a bio-equivalence test.
3. Dhar Biswajit and Gopakumar KM, "Data Exclusivity in Pharmaceuticals: Little Basis, False Claims", Economic and Political Weekly, (2006) 5073, 5073.
4. Report of the Commission on Intellectual Property Rights, Innovation and Public Health, (2006) http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf, last accessed on 6 March 2008.

reflected in the structure of the TRIPS Agreement, under which they have been discussed under separate Sections in Part II of the Agreement.[5]

LOCATING DATA EXCLUSIVITY UNDER THE LEGAL FRAMEWORK

The proponents of data exclusivity trace the concept to Article 39.3[6] of the Trade Related Intellectual Property Rights (TRIPS) Agreement. Article 39.3 comes under Part II, Section 7 of the TRIPS Agreement that discusses "*protection of undisclosed information*", a distinct category of intellectual property under Article 1.2.

There is no unanimity in the interpretation of Article 39.3. Presently, there are three emerging approaches to the interpretation of the provision- the first that advocates data exclusivity, the second that argues for data protection and the third that mandates a compensatory liability model.

In order to understand these diverse perspectives and decide their propriety, the researcher would first deconstruct and look into the negotiating history of Article 39.3. From the text it is apparent that the provision comes into play only when:

i. The specific member Nation requires the submission of undisclosed test or other data as a pre-condition for granting marketing approval of the pharmaceutical product,

ii. Such pharmaceutical product utilizes new chemical entities and

iii. The test or other data is the product of considerable effort.

On the fulfillment of the above criteria, it is incumbent upon the Member State to protect the data against *unfair commercial use* and disclosure. There is an exemption from the obligation to protect against disclosure only when it is necessary to protect the public or when steps have been taken to protect the data against unfair commercial use.

Article 39.3 can be invoked in India because the submission of test data is a pre-requisite for obtaining marketing approval under the law as has already been pointed out.

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5. Patents provide exclusive rights over an invention whereas Data Exclusivity purports to protect an innovator's test data. Also, the application for a patent is made at the stage of basic research itself unlike data exclusivity that comes into the picture only at the time of marketing approval. While a patent provides protection for 20 years, the period of protection in case of Data Exclusivity has been relatively more short-term and non-uniform. For example, Data Exclusivity conferred is 5 years in the United States and Australia, 10 years in the European Union, 8 years in Canada, 6 years in China and Japan. MSF Technical Brief, "Data exclusivity in International Trade Agreements: What consequences for access to medicines?", (2004) 3, http://www.citizen.org/documents/DataExclusivityMay04.pdf, last accessed on 7 March 2008.

6. "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."

Unfair commercial use is the most clinching phrase because it determines the extent of obligation of Member States such as India. As the Agreement does not elaborate on the meaning and scope of the phrase it forms the primary bone of contention giving rise to the three distinct interpretations. The phrase can be traced back to the concept of unfair competition envisaged under Article10*bis* of the Paris Convention, 1967 which was defined as any act contrary to honest practices of competition.

At this juncture, it would be of some help to look at the negotiating history of Article 39.3.

Originally, it was the United States of America that articulated its demand for test data protection in 1987. However, with the passage of time by 1990 she was joined by the European Community and Japan. The demand of the United States[7] in 1990 stated that Member States shall not use test data for the commercial benefit of any person except with the right holder's consent and on payment of reasonable value or on the conferment of exclusive rights for a reasonable period. The European Community's demand[8] was couched in terms that required protection against unfair exploitation by competitors for a reasonable period of time.[9]

Basing on these demands, a consolidated text[10] was framed for the forthcoming Brussels Ministerial Conference which used the term unfair commercial use and stated in clear terms that the data may not be relied upon for a reasonable time for the approval of competing products. No consensus having emerged at Brussels, Arthur Dunkel drafted the proposal for Article 39.3 which retained unfair commercial use but dropped the specific prohibition on reliance.[11] The same has been adopted

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7. "Contracting parties which require that trade secrets be submitted to carry out governmental functions, shall not use the trade secrets for the commercial or competitive benefit of the government or of any person other than the right holder except with the right holder's consent, on payment of the reasonable value of the use, or if a reasonable period of exclusive use is given to the right holder."
8. "Contracting parties, when requiring the publication or submission of test or other data, the origination of which involves a considerable effort, shall protect such efforts against unfair exploitation by competitors. The protection shall last for a reasonable time commensurate with such efforts, the nature of the data required, the expenditure involved in their preparation, and shall take account of the availability of other forms of protection"
9. Watal Jayashree, *Intellectual Property Rights in the WTO and Developing Countries*, (New Delhi: Oxford University Press, 2001), 198.
10. Parties, when requiring, as a condition of approving the marketing of new pharmaceutical products or of a new agricultural chemical product, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall [protect such data against unfair commercial use. **Unless the person submitting the information agrees**, the data may not be relied upon for the approval of competing products for a reasonable time, generally no less than five years, commensurate with the efforts involved in the origination of the data, their nature, and the expenditure involved in their preparation. In addition, Parties shall] protect such data against disclosure, except where necessary to protect the public.
11. Skillington Lee G. and Solovy Eric M., "The Protection of Test and Other Data Required by Article 39.3 of the Trips Agreement", (2003) 24 Nw. J. Int'l L. & Bus. 1, 9-11.

as Article 39.3 in the TRIPS Agreement. Hence, Article 39.3 does not contain an explicit prohibition on reliance of test data by subsequent generic manufacturers.

INTERPRETING ARTICLE 39.3 – A LOOK AT THE THREE DIVERSE APPROACHES

The debate surrounding data exclusivity hinges on Article 39.3 and more particularly, on the phrase 'unfair commercial use' which has not been defined in the TRIPS Agreement. The researcher will now elaborate on the three emerging perspectives on interpreting Article 39.3.

THE FIRST APPROACH - DATA EXCLUSIVITY

One of the approaches to the interpretation of Article 39.3 is the concept of Data Exclusivity. This has been floated by some developed nations such as the United States of America, the European Union, Canada, Japan and China and pharmaceutical multinationals such as the International Federation of Pharmaceutical Manufacturers Associations[12]. The United States of America was the first to provide for data exclusivity under The Hatch Waxman Act, 1984[13].

At the instance of the United States, nations such as Chile, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Mexico, Morocco, Nicaragua and Singapore have executed bilateral and multilateral trade agreements that incorporate data exclusivity.[14] For example, Article 1711(6) of the North American Free Trade Agreement required the signatories to provide a minimum five years exclusivity period.

United States of America has been mounting pressure on other nations including India to adopt data exclusivity by including them in the Priority Watch List in the Special 301 Report prepared by the United States Trade Representative (USTR). India has been enlisted in the 2007 Special 301 Report.[15] In 1996 USTR initiated action against Australia for not implementing data exclusivity. Succumbing to pressure from the United States, in 1998 Australia adopted a five-year period of

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12. Bale Harvey E., "Encouragement of New Clinical Drug Development: The Role of Data Exclusivity", International Federation of Pharmaceutical Manufacturers Associations. http://www.ifpma.org/documents/NR83/DataExclusivity.pdf, last accessed on 6 March 2008.
13. Under the U.S. Hatch-Waxman Act, 21 U.S.C. § 355(c)(3)(E)(ii) and (iii) a five year period of exclusivity has been conferred on an abbreviated new drug application whereas a three year period has been conferred on drugs having an active ingredient that has already been approved.
14. MSF Technical Brief, "Data exclusivity in International Trade Agreements: What consequences for access to medicines?", (2004) 4, http://www.citizen.org/documents/DataExclusivityMay04.pdf, last accessed on 7 March 2008.
15. 2007 Special 301 Report, http://www.ustr.gov/assets/Document_Library/Reports_Publications/2007/2007_Special_301_Review/asset_upload_file230_11122.pdf, last accessed on 7 March 2008.

exclusivity.[16] Interestingly, the United States also initiated action against Argentina. However, Argentina did not budge and continues to maintain its law without granting data exclusivity.[17]

It is the contention of those supporting exclusivity that the omission of the specific prohibition on reliance during the negotiations was only to avoid redundancy as the term unfair commercial use had already come to include a prohibition on reliance by regulatory authorities.[18] They affirm that the very fact that a competitor, the generic manufacturer, obtains a commercial benefit constitutes an unfair commercial use.[19]

It is their belief that the innovator must be provided an incentive for the considerable effort in terms of the time and resources invested in the course of generating test data. Estimates reveal that the development of a new drug costs $500 million and requires 15 years, on an average. In the absence of exclusive rights, generic companies would be able to free ride on the innovator's data reducing the cost incurred by them to around $1 million.[20] Also, where patents fail to provide protection (as in case of natural substances) data exclusivity would afford the necessary incentive.[21]

THE SECOND APPROACH - DATA PROTECTION

The second interpretation attributed to Article 39.3 is one that supports protection and not exclusivity.

This approach has been floated by the generic manufacturers and several developing nations. The Commission on Intellectual Property Rights, Innovation and Public Health[22] appointed by the World Health Organisation also subscribes to this view. Several arguments have been advanced to buttress this conclusion.

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16. Fellmeth, Aaron Xavier, "Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data under the Trips Agreement", (2004), 45 Harv. Int'l L.J. 443, 450.
17. Correa Carlos M., "Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines", (2004) 36 Case W.Res.J.Int'l.79, 82.
18. Dhar Biswajit and Gopakumar KM, "Data Exclusivity in Pharmaceuticals: Little Basis, False Claims", Economic and Political Weekly, (2006) 5073, 5075.
19. Correa Carlos M., "Unfair Competition under the Trips Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals", (2002) 3 Chi. J. Int'l L. 69, 78.
20. Bale Harvey E., "Encouragement of New Clinical Drug Development: The Role of Data Exclusivity", International Federation of Pharmaceutical Manufacturers Associations. http://www.ifpma.org/documents/NR83/DataExclusivity.pdf, last accessed on 6 March 2008.
21. Correa Carlos M., *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement* (Geneva: South Centre/WHO, 2002), 43, http://www.southcentre.org/publications/protection/protection.pdf , last accessed on 6 March 2008.
22. Report of the Commission on Intellectual Property Rights, Innovation and Public Health, (2006) http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf, last accessed on 6 March 2008.

During the negotiations of Article 39.3, the specific prohibition on reliance that had earlier been included was dropped which indicates that reliance by the regulatory authority upon the innovator's test data to approve subsequent applications of generic producers does not amount to unfair commercial use. This view is also supported by scholars such as Carlos Correa.[23]

The ordinary meaning conveyed by the phrase unfair commercial use is unjust application or conversion of data for the purpose of making a profit or other business benefit.[24] Reliance by the Government, that is, the Drug Regulatory Authority, does not amount to unfair commercial use because drug approval is a legitimate function of the State, a non-commercial entity.[25] This was re-affirmed in the Canadian case of *Bayer Inc. v. Attorney General*[26] wherein the Court held that when bioequivalence of the generic and innovator drug is proved, the Regulatory Authority does not rely upon any confidential information in granting approval. Hence, only when the competitor obtains the test data using fraudulent or dishonest means and uses it for his benefit it would comprise unfair commercial use.

Another argument forwarded is that the generation of test data does not involve any element of creativity or exercise of the intellect and thus, exclusive rights as are guaranteed to other intellectual property cannot be claimed in the instant case.[27]

The proponents argue that there is a significant public health angle to the debate as the conferment of exclusive rights would adversely affect access to drugs.[28] With the advent of data exclusivity, the entry of generic manufacturers is impeded[29] and the innovator is placed in a situation of monopoly which may result in a spiraling of prices and in turn affect access to drugs. The Supreme Court of India has read the fundamental right to health into Article 21[30] of the Constitution of India in *Consumer*

23. Correa Carlos M., "Unfair Competition under the Trips Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals", (2002) 3 Chi. J. Int'l L. 69,75.
24. Skillington Lee G. and Solovy Eric M., "The Protection of Test and Other Data Required by Article 39.3 of the Trips Agreement", (2003) 24 Nw. J. Int'l L. & Bus. 1, 16.
25. Correa Carlos M., "Unfair Competition under the Trips Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals", (2002) 3 Chi. J. Int'l L. 69, 76.
26. 87 C.P.R. (3d) 293, (Fed. Ct. of Appeal 1999).
27. Correa Carlos M., "Unfair Competition under the Trips Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals", (2002) 3 Chi. J. Int'l L. 69,71.
28. "Confronting the HIV/AIDS Crisis", Global Economic Justice (2004), 16 http://www.kairoscanada.org/e/economic/GEJRSummer2004.pdf, last accessed on 7 March 2008 where Medicines Sans Frontiers expresses its concern for the lives of persons living with HIV/AIDS in Central America due to the provision for data exclusivity in the Central American Free Trade Agreement.
29. Satyanarayana, K. et al., "Data Protection Issues in India", (2006) Indian J Med Res 723, 724.
30. "No person shall be deprived of his life or personal liberty except according to the procedure established by law".

Education and Research Centre v. *Union of India*[31]. This right cannot be effectively realized unless there is access to drugs.[32] The right has also been recognized at the international level.[33]

Paragraph 4 of the Doha Declaration adopted on 14 November, 2001 held that the TRIPS Agreement should be interpreted in a manner supportive of the Members' right to protect public health and promote access to medicines for all. Hence, the interpretation of data protection that promotes access to medicines should be adopted.

As a repercussion of data exclusivity, if the generic manufacturers wish to circumvent the exclusivity period they will have to replicate the trials to reaffirm the safety and efficacy of the drug. Such trials would be unethical in nature because the requirements of safety and efficacy have already been proved by the innovator.[34]

The other issue with the grating of data exclusivity is that in countries that have not provided for pharmaceutical patents, such a grant would guarantee a minimum monopoly to the innovator even in the absence of a patent protection.[35]

One of the means by which the exclusivity of a patent can be overcome is the issuance of compulsory licenses. Now, if in the case of a patented drug for which compulsory license has been issued, data exclusivity is also introduced, would data exclusivity pose a barrier to the use of compulsory license? If it does, then until the period of exclusivity expires, the license cannot be made use of. Therefore, countries will have to ensure that the use of compulsory licenses is not restricted by data exclusivity.[36]

THIRD APPROACH - COMPENSATORY LIABILITY

An alternative construction has been suggested in a 'compensatory liability' model, where the data is permitted to be relied upon in return of a 'fair' compensation being paid to the originator.[37] This approach takes a via media between the above two approaches.

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31. AIR 1995 SC 922, para 26.
32. Yamin Alicia Ely, "Not Just a Tragedy: Access to Medications as a Right under International Law", (2003) 21 B.U. Int'l L.J. 325, 330-331: Crook Jamie, "Balancing Intellectual Property Protection with the Human Right to Health", (2005) 23 Berkeley J. Int'l L. 524, 529.
33. Art.25(1) and Art.15 of The Universal Declaration of Human Rights, 1948; Art.12(1) and Art.12(2) of International Covenant on Economic Social and Cultural Rights, 1976; The Alma Ata Declaration, 1978; Art.7 of the TRIPS Agreement and Doha Declaration, 2001.
34. Junod Valerie, "Drug Marketing Exclusivity under United States and European Union Law", (2004) 59 Food & Drug L.J. 479, 482.
35. Satyanarayana, K. et al., "Data Protection issues In India", (2006) Indian J Med Res 723, 726.
36. MSF Technical Brief, "Data exclusivity in International Trade Agreements: What consequences for access to medicines?", (2004) 2, http://www.citizen.org/documents/DataExclusivityMay04.pdf, last accessed on 7 March 2008.
37. Basheer Shamnad, "Protection of Regulatory Data under Article 39.3 of Trips: A Compensatory Liability Model ?", http://papers.ssrn.com/sol3/papers.cfm?abstract_id=934269, last accessed on March 6, 2008.

The same model has been followed in the United States Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 1980. Under the Act any person seeking to use data must first attempt to obtain a voluntary license in exchange of some compensation. If the innovator and the subsequent applicant fail to reach a consensus within 90 days either of them resort to arbitration to adjudge upon the quantum of fee payable.[38]

INDIA'S STAND ON ARTICLE 39.3 – REPORT OF INTER-MINISTERIAL COMMITTEE

India amended its Patent Act, 1970 in January 2005 to make it compliant with TRIPS. However, it has not yet included any provision concerning data exclusivity. Due to the ongoing debate surrounding Article 39.3, an Inter-Ministerial Committee was constituted on February 10th, 2004 to assist the Department of Chemicals and Petro-Chemicals regarding the steps to be taken in the context of Article 39.3 of the TRIPS. Three years subsequently, on 31st May, 2007 the very date on which the Secretary Mrs. Satwant Reddy was stepping down from office, the much awaited Report was submitted. The Committee drew a distinction between the recommendations for the sectors of pharmaceuticals, agricultural chemicals and traditional medicines.

The Committee considered the varied interpretations and concluded that the models of exclusivity and compensatory liability ought to be rejected. The minimum requirements mandated by Article 39.3 are non-disclosure of test data and non-acceptance of fraudulently obtained data. For this, there is a need to strengthen the present legal and regulatory framework. The safeguard in the extant Drugs and Cosmetics Act, 1955 provides that an Inspector shall not, without the sanction in writing of his official superiors, disclose to any person any information acquired by him in the course of his official duties[39] was found to be inadequate. To ensure that undisclosed test data is not put to unfair commercial use thus, explicit provisions have to be included. The need to upgrade the physical infrastructure and technical skills was also recognized.

Though this would suffice for the present, it was opined that after the expiry of a transition period, higher standards of data protection *may* be adopted after a cautious study of its potential impact on the sector and the public. The duration of the transition period was to be deliberated upon. A model providing for a 5-year exclusivity period was formulated the implications of which was still to be analyzed. Hence, they thought that a calibrated approach with a transition period is best suited for India.

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38. Fellmeth, Aaron Xavier, "Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data under the Trips Agreement", (2004), 45 Harv. Int'l L.J. 443, 462.
39. Rule 53, Drugs and Cosmetics Rules, 1945.

ANALYZING THE THREE INTERPRETATIONS FROM THE INDIAN STANDPOINT

The interpretation of Article 39.3 has been mired in controversy and now it is time for developing nations like India to determine their standpoint on the issue. It is the submission of the researcher that the second approach is the most appropriate for India.

India is only obliged to fulfill the minimum requirements mandated by the TRIPS Agreement. The text of Article 39.3 does not mandate exclusivity and the negotiating history clearly rules out the adoption of a construction favouring either data exclusivity or compensatory liability. The adoption of either of these approaches would be indulging in the implementation of a TRIPS-Plus provision, that is, a provision going beyond the requirements of TRIPS to protect intellectual property[40]. Hence, the correct approach is to provide for data protection, that is, to punish a competitor for the fraudulent use of the test data submitted to the Regulatory Authority. To ensure observance of the same the legal and regulatory framework must be fortified as recommended by the Inter-Ministerial Committee.

The basic flaw in constructing Article 39.3 to mandate exclusive rights is that it is based on the underlying assumption that in the absence of exclusivity there is no incentive to undertake innovation. The very fact that innovation has occurred through these decades without exclusive rights bears out that such an incentive was never deemed necessary! Hence, it is simply greed that is prompting the developing nations to champion the cause of exclusive rights.

Aaron Fellmeth has discussed the viability of the compensatory liability model and he points to the weaknesses that it suffers from. Firstly, he says that there is no yardstick for arriving at the fair compensation. If the matter comes up before the arbitrator failing an agreement, he would be placed in a difficult situation because he would not be aware of the market value of the data. Further, what if the decided amount does not reflect the true balance between the interest of the innovator and the generic producer? If the provision of appeal is exercised by the aggrieved party, it would ultimately be a long drawn out process. In the light of these flaws he concludes that the approach would not be feasible.[41]

The researcher is in concurrence with the conclusion of Fellmeth and would like to highlight certain other additional arguments. If one were to look at the negotiating history of Article 39.3 such proposal had been floated by the United States of America in 1990 itself. However, it failed to garner the support of other Member nations and thus, such a construction ought to be avoided. The principle of *in dubio mitius* states

40. Carlos M Correa, "Bilateralism in Intellectual Property", 36 Case W. Res. J. Int'l L. 79, 79.
41. Fellmeth, Aaron Xavier, "Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data under the Trips Agreement", (2004), 45 Harv. Int'l L.J. 443, 463.

that merely because the language and intent of a treaty provision is ambiguous, it cannot be interpreted to impose onerous obligations. As the obligation of compensation has not been mentioned anywhere in Article.39.3, it is clearly an onerous construction and must be avoided.

Furthermore, the model envisaged by United States FIFRA would pit the generic manufacturer and the innovator against one another. There is bound to be a greater bargaining power in the hands of the innovator and thus the negotiation may not be fair and voluntary at all!

As has been highlighted by the second model of interpretation favouring data protection, the advent of exclusive rights forestalls a potential threat to the access of medicines.

The existing Indian system that does not provide exclusive rights to the innovator has contributed to the timely introduction of generic producers and access to drugs for many a poor patient.[42] When India had been considering amendments to the Patent Act, the United Nations Special Envoy for HIV/AIDS wrote a letter to the Prime Minister emphasizing that any decision concerning the Indian generic industry must be made bearing in mind the fact that the lives of nearly half the 7,00,000 persons infected with HIV/AIDS living in several developing nations depend upon it.[43] Hence, the life of many individuals would be affected by India's stance.

Moreover, for every generic equivalent that is manufactured during the period of exclusivity, separate clinical trials need to be conducted, which would lead to a spate of unwarranted and unethical trials.

Though the recommendation of the Inter-Ministerial Committee was published in May 2007, the government has not yet spelt out its policy decision. The researcher concurs with the Report to the extent that it recommends a data protection regime. However, the Committee went a step further to suggest that higher standards of data protection *may* be adopted after the expiry of an unstipulated transition period in the long-term interest. More than anything else, such an open-ended suggestion seems to have been included only to appease the block of developed nations!

The debate surrounding data exclusivity clearly juxtaposes the greed of a few individuals against the health and well-being of large sections of the population. As a closing observation, the researcher would like to submit that it is only wise to choose the interest of the latter over the former and can only hope that the Indian government also reconciles the above conflicting interests by adopting the approach of data protection.

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42. Satyanarayana, K. et al., "Data Protection Issues in India", (2006) Indian J Med Res 723, 725.
43. Stephen Lewis, "Letter from the UN Special Envoy to the Prime Minister", (2005), http://www.cptech.org/ip/health/c/india/unaids03112005.html, last accessed on 7 March 2008.