TEST DATA PROTECTION AND TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

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Master of Philosophy

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CERTIFICATE

This is to certify that the dissertation entitled **TEST DATA PROTECTION AND TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS** submitted by me in partial fulfillment of the requirements for the award of the degree of **MASTER OF PHILOSOPHY** is my own work and has not been previously submitted for the award of any other degree of this or any other university.

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TABLE OF CONTENTS

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ABBREVIATIONS

ANDS	:	Abbreviated New Drug Submission
CIPR	:	Commission of Intellectual Property Rights
DSU	:	Dispute Settlement Body
EC	:	European Community
EEA	:	European Economic Area
EFPIA	:	European Federation of Industrial and Pharmaceutical Association
EGA	:	European Generic Association
EMEA	:	European Medicines Evaluation Agency
FDA	:	Food and Drug Authority
FIFRA	:	Federal Insecticide, Fungicide and Rodenticide Act
FTA	:	Free Trade Agreement
GATT	:	General Agreement on Tariff and Trade
IDMA	:	Indian Drug Manufacturers Association
IFPMA	:	International Federation of Pharmaceutical Manufacturers Association
ILO	:	International Labour Organisation
IMO	:	International Maritime Organisation
IPA	:	Indian Pharmaceutical Alliance
IPCC	:	International Publishers Copyright Council
MNC	:	Multinational Companies
NAFTA	:	North American Free Trade Agreement
NCE	:	New Chemical Entity
NDS	:	New Drug Submission
OPPI	:	Organisation of Pharmaceutical Producers of India
PhRMA	:	Pharmaceutical Manufacturers and Research Association of America
RTA	:	Regional Trade Agreement
TRIPS	:	Trade Related Aspects of Intellectual Property Rights
UNCED	:	United Nations Conference on Environment and Development
UNCTAD	:	United Nations Conference on Trade and Development
UNEP	:	United Nations Environment Programme
UNESCO	:	United Nations Educational Scientific and Cultural Organisation
UNFCC	:	United Nations Frame Work Convention on Climatic Change
USTR	:	United States Trade Representative

WCT	:	World Copyright Treaty
WHO	:	World Health Organisation
WIPO	:	World Intellectual Property Organisation
WMO	:	World Meteorological Organisation
WTO	:	World Trade Organisation

CHAPTER I

DATA PROTECTION-AN OVERVIEW

I.1. Introduction

Data collection, compilation and its protection is an inevitable component of knowledge-based society. Different kinds of data are produced in various sectors every day which have their own commercial value. The mode of protection of these data has been posing considerable difficulties. The absence of original expression and creativity makes data or its compilations difficult to protect under copyright. Copyright protects expression of the work or creativity and that protection is not extended to ideas, methods or information.

Article 2(5) of the Berne convention[1] recognizes the protection of collection of literary and artistic works. It does not use the word 'database', but instead uses 'collections of literary and artistic works' which by reason of the selection and arrangement of their contents constitute intellectual creations and shall be protected as such[2]. The level of creativity required for the collection of works for enjoying copyright protection is not defined at international level, different interpretations apply. In some countries so called 'Sweat of the Brow' databases, which are not creative but are based on a certain level of effort or investment, are protected under copyright. Article 10.2 of the Trade Related Aspects of Intellectual Property Agreement (TRIPS Agreement) broadens the protection to database by expressly including protection to the compilations of data or other material[3].For the first time it uses 'compilations of data or other material', which by reason of the selection or arrangement of their constitute intellectual creations shall be protected. Consequently, under the TRIPS Agreement, compilations of copyrightable and non-copyrightable

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[1] Berne Convention for the protection of Literary and Artistic works Article 2(5) ,provides as follows: "Collections of literary and artistic works such as encyclopedias and anthologies which, by reason of the selection and arrangements of their contents, constitute intellectual creations shall be protected as such, without prejudice to the copyright in each of the works forming part of such collections.", Paris, July 1971, Available at www.wipo.org.

[2] According to the World Intellectual Property Organisation (WIPO) Guide to the Berne Convention, the creator of such a collection is required to 'bring to bear an element of creativity' to such a work.

[3] An explicit provision on the protection of databases was included in Article 10(2) of the Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) which was concluded in Marrakesh, on April 15, 1994. That provision states as follows: "Compilations of data or other material, whether in machine readable or other form, which by reason of the selection or arrangement of their contents constitute intellectual creations shall be protected as such. Such protection, which shall not extend to the data or material itself, shall be without prejudice to any copyright subsisting in the data or material itself."

material should be protected so long as requisite level of originality in the selection or arrangement is satisfied[4]. Article 5 of the 'WIPO Copyright Treaty' extends protection to data broadly defined to include both copyrightable and non copyrightable material. It also relaxes the Berne conditionality in line with TRIPS Agreement Article 10.2.[5]

Most of the countries, which are members of either of these agreements, included protection for compilation of data or material, which by its arrangement or selection constitutes intellectual creations in their national copyright legislations. So copyright protection is extended to database, provided the database is made of creative input in selection or arrangement of pre-existing data. All databases are not protected under the copyright regimes mentioned above. So how to protect database (compilations of data) which will not qualify otherwise for copyright protection because of the absence of creative input, but which involves investment and labour in its development. The courts in United States and other countries use a concept "Sweat of the Brow" which means protection for labour and investment in providing protection for these databases under the copyright regime. The courts in India also used the concept of sweat of the brow doctrine until 1995 for giving remedy to database owners. The decisions of protecting compilation on a 'Sweat of the Brow' rationale, however violate a basic premise of copyright paradigm, which claims to protect only the original expression that authors embody in information products.[6]

In 1991 United States Supreme Court in a landmark decision, *Feist Publication inc v Rural Tel. Service Company,*[7] ruled that a compilation work such as

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[4] TRIPS Agreement relaxes the criteria for protection of compilations of data from Berne convention. Under Berne convention for receiving protection originality in selection *and* arrangement is needed whereas originality in selection *or* arrangement is needed under TRIPS Agreement.

[5] , The *WIPO Copyright Treaty (WCT)* which was adopted in Geneva on December 20, 1996, contains in its Article 5 a provision on copyright protection of databases, which, under the title "Compilations of Data (Databases)" provides as follows: "Compilations of data or other material, in any form, which by reason of the selection or arrangement of their contents constitute intellectual creations, are protected as such. This protection does not extend to the data or the material itself and is without prejudice to any copyright subsisting in the data or material contained in the compilation." The Diplomatic Conference also adopted, by consensus, the following agreed statement: "The scope of protection for compilations of data (databases) under Article 5 of this Treaty, read with Article 2, is consistent with Article 2 of the Berne Convention and on a par with the relevant provisions of the TRIPS Agreement." Article 2 of the WCT, to which the agreed statement refers, states, under the heading "Scope of Copyright Protection," as follows: "Copyright protection extends to expressions and not to ideas, procedures, and methods of operation or mathematical concepts as such."

[6] J.H. Reichman and Pamela Samuelson, "Intellectual Property Rights in Data", *Vanderbilt Law Review,* vol. 51 , 1997, p. 52-163.

[7] 499 U.S. 340,1991.

a database must contain a minimum level of creativity in order to be protectable under the copyright law. This decision overruled many of the earlier decisions of lower courts which accepted "Sweat of the Brow" as a test of copyrightability. Under this test, if a compilation was created as a result of a great deal of effort, copyright protection would extend to the compilation regardless of the creativity or originality in the selection, coordination or arrangement of the facts. The US Supreme Court expressly states that this 'sweat of the brow' analysis was faulty, and that copyright extended only to the original selection, coordination and arranging of data, and not to any unprotected facts contained with in the compilations.

I.2. European Union

European Union adopted 'Database directive' in March 11, 1996.[8] It was created to harmonize the intellectual property laws regarding databases of 18 countries of European Economic Area (EEA) by supplementing copyright to protect databases produced by sweat of the brow. Directive create a *sui generis* intellectual property protection which explicitly protects compilation or collections of facts regardless of any creativity. It also confirms that if there is creativity involved in creation, it should be protected under copyright.[9] The term of protection is for 15 years, but if database is updated significantly, entire database receives another 15 years of protection. So if the owner of the database makes some updates from time to time the protection can extend to perpetuity (never ending). A lawful user of the database cannot extract or re-use even insubstantial part of its contents in repeated and systematic ways. Member states can provide exceptions to exclusive right, for the purposes of illustration for teaching or scientific research, as long as the source is indicated and to the extent justified by the non-commercial purpose. So when compared with the 'fair use' exceptions of the copyright law, the exceptions provided in the database directive is narrow[10].

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[8] See Directive 96/9/EC of the European parliament and of the council of 11 March 1996 on legal protection of databases, 1996 O.J (L.77)20.

[9] Article 1(2) of European Union Database directive defines database as a collection of independent works, data or other materials arranged in a systematic or methodical way and individually accessible by electronic or other means.

[10] Article 1705(1) of the NAFTA Agreement obliges the parties to protect the works covered by Article 2 of the Berne Convention, "including any other works that embody original expression within the meaning of that Convention." The provision adds that this includes *inter alia*, "compilations of data or other material, whether in machine readable or other forms, which by reason of the selection or arrangement of their contents constitute intellectual creations, shall be protected as such."

I.3. WIPO Draft Database Treaty

The European Union and United States submitted proposals to World Intellectual Property Organisation (WIPO) for the adoption of an International database treaty under its digital agenda. The developing countries questioned the need for a new form of intellectual property protection for database. They argued that databases are protected effectively under the existing framework of copyright law and under the contract law and unfair competition law. They opposed this TRIPS-PLUS agenda of the developed countries. The proposed database treaty is on the agenda of the WIPO, but till now it is not adopted because of the objections from the International organizations, researchers and scientific community[11]. They argue that this proposed draft treaty will establish a new legal regime that could impose serious constraints on science and education, undermining the ability of researchers and educators to access and use scientific data.

The WIPO proposed draft treaty called for protection of databases created as a result of substantial investment by database producers in the collection, assembly, verification, organization or presentation of information. The draft treaty permitted database compilers and publishers to restrict anything in their database. It prohibited unauthorized use of any substantial portion of a database, as defined by database owner. It provides 25 year protection for databases, but it can extend to perpetuity if some changes or additions are made. The exceptions to the exclusive right of database owners is narrow when compared with that of the WIPO copyright treaty.

I.4. National Legislations

Database in the United States are not protected except to the extent that an original selection or arrangement may be subject of copyright. An uncreative database such as white pages in the telephone directory is thus unprotected there, but yellow pages business directory may have the creative selection or arrangement of entries

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[11] Many specialized agencies of the United Nations like World Meteorological Organization (WMO), International Maritime Organization (IMO), United Nations Educational, Scientific and Cultural organization (UNESCO) and many national scientific organizations opposes the adoption of database treaty.. In addition to the concerns raised by the international scientific community, some developing countries, which use significantly more data from other countries than they produce themselves, are concerned that they will not be able to obtain the data they need. As a result of these concerns, WIPO is moving slowly on a database treaty. Member countries have been asked to submit new treaty language to WIPO, and a series of regional meetings were held to define the possible content of a new treaty.

protected. So for extending protection to the unoriginal databases, in the recent past, many Bills[12] were introduced in the United States congress to expand copyright protection to compilation of facts. All efforts in this direction were unsuccessful. These bills attempted to provide broader protection to database than that of European Union directive. The bills even included non copyrightable components of computer programs for protection under database. United States legislation recognizes an exclusive right to control the uses of database contents. It even forbids the extraction, use or reuse of even insubstantial parts by or for multiple persons within an organization or entity. The period of protection is for 25 years, but it can be renewed, if any change of commercial significance is made and not solely on additional substantial investment. The scientific community in the United States reacted with alarm to the proposed Database legislation, arguing that it would stifle research. The scientific agencies within the United States government (Environment Protection Agency and National Oceanographic and Atmospheric Administration) took the lead in persuading the National Economic Council within White House to oppose the adoption of a Database Treaty in WIPO.

The United Kingdom also enacted a new regulation for the protection of unoriginal databases. This regulation will protect databases which are created as a result of substantial investment in obtaining, verifying or presenting their contents, but not requiring any personal intellectual creations. The only case came before the UK court is the *British Horse Racing Ltd* v *William Hill Organisation Ltd*[13], gave right holders very broad protection, but the case is currently before the European Court of Justice to elucidate the meaning of extraction, re-utilisation and part of the contents of the database[14].

According to some scholars the initiatives by European Union and United States would confer a far broader and strong monopoly on database developers than is needed to avert market failure. It would create an exclusive property rights regime of virtually unlimited duration that would be subject to few, if any public policy limitations. It would jeopardize basic scientific research, elimination competition in

[12] HR 3531 in 1996, HR 2652 in 1997, HR 354, HR 1858, HR 2291 in 1999.
[13] (2001) High Court of Justice, Ch Div, 9 February 2001, case no HC 2000, 1335.
[14] Apart from these countries, only Mexico provides five-year protection to non-original databases.

the markets for value added services and products.[15] That is the reason why whole scientific group opposes the adoption of the bill. They convinced the US administration to oppose the adoption of Database Treaty in WIPO.

These bills provide compilers and database owners with absolute and virtually perpetual protection which would violate both the limited times proviso of the enabling clause of the constitution and its express justification for granting intellectual property rights in terms of the advancement of scientific and technical progress.

I.5. Database Protection: Implications

There are various arguments raised in favour and against database protection. Most important argument put forward favour strong protection for non-original databases. This view is based on guaranteeing an appropriate return on the often substantial investment needed to create, maintain and update its contents. These initiatives aim to rescue database producers from the threat of market-destructive appropriations by free-riding competitors who contributes nothing to the costs of collecting or distributing the relevant data.[16] This protection would be all the more necessary in a situation where digital and information technology makes it easy to copy and distribute the contents of databases without the permission of owners.

According to International Publishers Copyright Council (IPCC), main justification for an international treaty on the *sui generis* system of protection for databases is that databases are central to establishing the 'Global Information Society'. Large investment and labour is involved in compiling and maintaining a database. So a *sui generis* exclusive protection is needed for the databases.

International Council for Science (ICSU) opposes the database protection and rejects all the above contentions. They argues that free flow of information is the backbone for the development of science and technology. But the existing proposal for the protection of database confers broader and stronger exclusive right protection for the owner of database which will prevent the free flow of information. These groups argue that adequate protection exists within the existing intellectual property framework. The sweeping definition given to what constitutes databases and counter

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[15] , J.H. Reichman and Pamela Samuelson, "Intellectual Property Rights in Data", *Vanderbilt Law Review,* vol.51,1997, p. 52-163.
[16] Ibid.

productive perpetual monopolies by allowing owners of database to extend the period of protection indefinitely create concerns.

The specialized agencies of the United Nations like World Meteorological Organization (WMO), United Nations Environment Programme (UNEP), International Labour Organization (ILO), International Maritime Organization (IMO), United Nations Educational, Scientific and Cultural organization (UNESCO) and World Health Organization (WHO) all objected the adoption of Database Treaty.

UNESCO observed in its submissions that "it should first be made clear whether the protection of the legitimate interests of database producers could not be effectively ensured under existing legislation, in particular, the rules applicable to unfair competition. If, however, it should prove necessary to resort to the *sui generis* approach, the protection to be provided would have to strike a balance between the need to ensure the security of the database producers legitimate investment against unfair competition and the need to ensure the free circulation of data in the interest of scientific research and the satisfaction of the pressing requirements of social life. Scientists, Educational, Cultural and information circles should be allowed to make free and fair use of databases.[17]

WMO observed that basic requirement and fundamental feature of international cooperation in meteorology coordinated by WMO is the free and unrestricted exchange of meteorological data. If the free and unrestricted exchange of meteorological data is not assured, the provisions of services such as weather forecast and warnings to the public and various sectors like shipping and aviation will be affected.[18]

An area in which data are more crucial is the environmental protection. Some of the environmental agreements like United Nations frame Work Convention on Climate Change (UNFCC)[19], International Convention to Combat Desertification[20],

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[17] Submission by UNESCO to WIPO relates to draft database protection treaty on Geneva, September.17-19, 1997. Available at www.wipo.org, last visited , 27 Oct, 2005.

[18] Observation submitted by WMO to WIPO relates to draft database treaty in , Geneva, September 17-19, 1997. Available at www.wipo.org observations, DB/IM: information meeting on intellectual property on databases.

[19] Article 4 (commitment) and Article 5 (research and systematic observation) refer to the promotion of and cooperation in the understanding climate change, through free and prompt exchange of relevant information.

[20] Article 16 deals about information collection, analysis and exchange.

and Vienna Convention for the protection of Ozone layer.[21] Agenda 21, the blue print for action which came out from the United Nations Conference on Environment and Development (UNCED) also carries the message of the importance of free exchange of data and information.

UNEP plays a vital role in the collection and dissemination of larger quantity of data. Through a worldwide network of collaborating and resource centres, including the Global and Regional Integrated Data (GRID) network and the World Conservation and Monitoring Centre, UNEP facilitates and coordinates the collection and dissemination of the best possible scientific data and information at the global and regional levels. Decision makers, scientists and members of civil society also getting online access to targeted regional and sectoral environmental data from UNEP. So any database protection mechanism should take into account the essence of these commitments and the work of international organization in the free flow of information and knowledge[22].

Some of the scientific agencies are also opposing the adoption of database treaty. They argue that scientific advantages rely on full and open access to data. Both science and the public are well served by a system of scholarly research and communication that moves rapidly and openly with minimal constraints on the availability of data for further analysis. The tradition of full and open access to data that led to breakthrough in scientific understanding, as well as to downstream economic and public benefit. Publication of data is essential for the scientific research and the dissemination of knowledge.

The 'Commission on Intellectual Property Rights'(CIPR) in its report mentions that "our central concern here is that strengthening of intellectual property protection for databases at the international level, whilst encouraging more investment in new commercial database products and services, may at the same time greatly reduce the access of scientists and researchers in developing countries to the data they contain because they will often lack the financial means to pay for necessary subscriptions." Developing countries, CIPR argues, should not follow the lead of the

[21] Article 3 deals with the research and systematic observation.
[22] Information available at www.unep.org.

United States and the European Union by implementing legislation like *sui generis* protection to databases.[23]

Recently the 'Royal Society' submitted its observations on the European Union Database Directive to European Commission. It states that "the *sui generis* database right, which prevents extraction and use of the data themselves, is inappropriate for scientific data and we recommend that it be repealed or substantially amended following commission's review of the database directive". Failing repeal, we recommend that scientists and learned society gather information on the impact of the database directive on the conduct of science. So that they can give sound guidance to their governments at the European Commission next review of the directive, likely to be in 2006.[24]

So protection of database should take care of concerns of relevant parties. The existing database protection largely supports the interest of right holders and not the users. Data protection as argued by many scholars harms science and ultimately the science based industry, including those of developed countries. The best possible solution for the protection of databases appears to be the protection against unfair competition as included in Article 10 *bis* of Paris Convention[25] for the Protection of Industrial Property than providing an exclusive property right.

Among various data or database, protection of data relating to pharmaceutical and agrochemical products has been a matter of contention in recent times. This entire contention arises from Article 39.3 of the TRIPS Agreement.

I.6. Test Data Protection

As a condition for registration of new Pharmaceutical and Agrochemical products, national authorities normally require the submission of data relating to efficacy and toxicity. The legal protection of such data, particularly in respect of the use there of for subsequent marketing approval for similar medicines, has raised different approaches and considerable controversy. Unlike, other forms of undisclosed

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[23] Commission on Intellectual Property Rights , *"Integrating Intellectual Property Rights and Development Policy"*, London ,September, 2002, p 119-121.

[24] Royal Society, "Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science, Prepared by Royal Society Working Group on Intellectual Property, Available at www. Royalsoc.ac.uk , last visited Dec 4, 2005.

[25] Article 10 *bis* of the Paris Convention, The countries of the Union are bound to assure to nationals of such countries effective protection against unfair competition.

information which are primarily private rights, in the case of test data protection, data has been passed from private to public authority and they have a responsibility to ensure that such information is not accessible to third parties or unauthorised persons. Developed countries provide protection to test data in the name of data exclusivity, whereas developing countries protect test data against unfair commercial use. Data exclusivity gives the originator absolute right, whereas the protection against unfair commercial use provides minimum right.

Compared to more traditional Intellectual Property Rights such as patents or copyrights, test data protection is very unusual since it does not require any inventive activity for it to be granted. Patent protection is sought, *inter alia*, as away to compensate the inventor for in research and development efforts. However the object of data exclusivity is to compensate the manufacturer of a new product for time and money invested in running approval test. It is only based on the fact that an investment has been made by the originator in carrying out the necessary tests to demonstrate the safety and efficacy of their new medicine.

Many countries including India do not have any legislation on protection of test data. So in the absence of protection for voluminous data those originators are statutorily obliged to submit to the regulatory authorities for the marketing approval of pharmaceuticals and pesticides, helps other companies to access this information and come out with the same or similar molecule.

I.7. Legal Regime for Test Data Protection

The TRIPS Agreement provisions on the protection of Trade Secrets are found in Article 39, and refer to "Undisclosed information" on the one hand and "Data submitted to governments or governmental agencies" on the other. In both cases, protection is understood to mean, "Ensuring effective protection against unfair competition" as provided in Article10 bis of the Paris Convention (1967) Although the protection of Undisclosed Information is included in Paris Convention, but there was no effective method within the Paris Convention for adjudicating the meaning of the provision and enforcing the results of adjudication in the event of any infringement. Consequently there was no effective multilateral standard for protecting undisclosed information, including undisclosed test and other data provided to regulatory authorities as a condition for obtaining marketing approval.

TRIPS Article 39.1 requires members to protect certain undisclosed data in accordance with TRIPS Article 39.3 in the course of ensuring effective protection against unfair competition as provided in Art 10bis of the Paris convention. For WTO members this provision essentially adds 'unfair commercial use' and disclosure of test and other data to the list of examples of prohibited acts of unfair competition in Paris 10bis. Consequently this brings TRIPS Article 39.3 in the Paris acquis.

I.8. Relationship between Patent and Test Data Protection

With respect to the relationship between test and other data related to chemical entities and possible patent protection for those same chemical entities, there is nothing either explicit or implicit in TRIPS Agreement that requires or allows for any linkage between the term of data protection and the term of related patent. These are two distinct types of intellectual property, covered by distinct section of TRIPS Agreement. Patent covered by Section 5 part II of TRIPS Agreement, while Undisclosed information including test data in Section 7 part II .In case, where there is any relationship between different Intellectual Property Rights in TRIPS Agreement, this relationship explicitly stated. For example the relationship between Trade Mark and Geographical Indications in Article 22, Article 24 of the TRIPS Agreement.

The terms used in Article 39.3 of TRIPS Agreement are not defined. The TRIPS text only obliges protection of test data for 'new chemical entities' against 'unfair commercial use'. But EU and US read into this language an obligation to grant at least five years of data exclusivity for pharmaceuticals and ten years data exclusivity for agrochemical products. They argue that such exclusivity is particularly important for pharmaceutical products that have to invest considerable time and money to obtain regulatory approvals.

According to, US Trade Representative (USTR) General Counsel Article 39.3 requires that Marketing approval data "not be used to support, clear or otherwise review other applications for marketing approval for a set amount of time unless authorized by the original submitter of the data. Any other definition of this term would be inconsistent with the logic and with the negotiating history of the provision."

The term unfair commercial use is not defined in the TRIPS. Application or conversion of this data by some one other than the originator is unfair or unjust at a time before the originator has been able to at least recoup the investment made to produce the data.

Data exclusivity can interfere with the actual use of a compulsory licence. For example, after the originator has submitted relevant data and obtained registration of a 'new chemical entity', what would happen to a company who got compulsory license to market same product. Data exclusivity may affect the application of paragraph 6 of Doha Declaration of Public Health and its subsequent implementing decision on 30 August 2003, which makes compulsory license procedure more flexible. So if compulsory license is granted, but test data is protected under Article 39.3 then how the generic make medicines. It is not practical for the generic manufacturers to do all test and develop its own test data because it will take many years and huge expenditure which makes the granting futile. Data exclusivity could thus pose an obstacle to effective use of compulsory licences, as the entry of the generic product would be delayed for the duration of the exclusivity period or for the time it takes to undertake a new compilation of test data. If a compulsory license for patent is granted, license for accompanying data should also be granted. In an earlier July 1990 draft TRIPS Agreement it was stated that 'there shall be no compulsory licensing of proprietary information', however it was not included in the final TRIPS Agreement. European Community (EC) and some other countries recently indicated that they would regard it as reasonable to make both the relevant patent and the relevant data the subject of compulsory licence, when it is granted otherwise the whole system will be meaningless. EC consider, that Article 39.3 of the TRIPS Agreement should certainly not be interpreted in such a way as to weaken or nullify members right under other provisions of the agreement, such as fast track procedure in case of emergency foreseen under Article 31(b), which is recognition of the need in certain circumstances, for compulsory licences to be given immediate effect. It is important that national legislations should provide provisions for the inclusion of proprietary data with the issuance of compulsory licence for medicines.

The Drugs and Cosmetic Act, 1940 and The Insecticide Act, 1968 deals with the marketing approval of Pharmaceutical and Agrochemical products in India.

Government of India recently constituted a committee to study test data protection for pharmaceuticals and pesticides. The committee is planning to take advantage of flexibility afforded by TRIPS Agreement at the same time meeting its obligations. They are planning to define 'new chemical entity' mentioned in international agreements in a narrow fashion to exclude large number of products, which are new only because of their administration method, formulations and indications.

I.9. Scope and Objective of Study

The proposed study will first explain what data is and how it is protected. Secondly it explains what is test data, its importance and the negotiating history of Article 39.3 of TRIPS Agreement including the stand taken by various countries. Thirdly, it attempts to analyse the interpretation given by various judicial bodies. Fourthly it deals about why developed countries especially US and EU pressuring for the inclusion of data exclusivity, and why developing countries oppose it. Then it analyses the data exclusivity provisions in NAFTA and other Bilateral Intellectual Property Agreements entered by USA with different countries. It also analyses the various model of protection provided for clinical test data by different countries. In the last part it deals with India and clinical data protection. In this part it analyses the existing legislations relating to test data protection in India and the options before India to comply with its TRIPS obligations. This study will focus only on data relating to pharmaceutical and agrochemical products.

The objective of the study is to identify the types of protection for test data existing in different countries, the kind of protection that the TRIPS Agreement envisages and the sort of protection suitable for developing countries, especially for India. It also looks into the current ongoing debate within India in this issue. The purview of this study proposes to limit the scope of the examination of the data protection in relation to test data as contained in Article 39.3 of the TRIPS Agreement.

I.10. Methodology

The study will be based on both Primary and Secondary sources. Primary sources include documents relating to Intellectual Property Agreements particularly provisions related to Test data protection. Further it will cover the secondary sources such as books, articles and comments of various experts on the subject related to the study.

Present work is divided into six chapters. Second chapter explains what test data is, how it is produced and whether it needs protection. It also looks into the national legislations relating to test data protection and national court decision. Third chapter analyses negotiating history of Article 39.3, it will interpret the terms used in the provision. Fourth chapter analyses the test data protection in FTA and RTA. It also deals with United States bilateral pressure for inclusion of data exclusivity in developing countries legislations. Fifth chapter deals with the kind of protection currently existing in India for test data and the kind of protection suitable for India? Final chapter consolidates conclusions and suggestions.

CHAPTER II

TEST DATA PROTECTION- EMERGING LEGAL REGIME

II.1. Introduction

A new medicine has to undergo lengthy, expensive and complex processes for approval before its marketing. New medicines will be constantly examined and evaluated during its development, to maximize its effectiveness and minimize side effects.[1] These safety and efficacy studies are broadly classified into preclinical and clinical studies. This is the most cumbersome procedure in the drug research.

II.1.1. Pre Clinical Trials

The first step is the synthesis and extraction, which consists of identification, production and multiplication of new chemical molecules which has the potential to produce desired effects in the human body, considering the mechanisms of disease or biological process.[2] The new medicine is tested in animals to asses its pharmacodynamic[3], pharmacokinetic[4] and toxicological effect. The results of these tests are carefully examined and only after the due verification of this chemical molecule to be safe, it is then tested on human beings.

II.1.2. Clinical Trials

Clinical studies in human beings are designed to evaluate the safety, effectiveness or usefulness of an invention includes research on therapeutics, diagnostic procedures and preventive measures including vaccines.

The objective of phase I of clinical trial is to determine the safety of the maximum tolerated dose in healthy adults of both sexes. It also looks for evidence of

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[1] Meir Perez Pugatch , *"Intellectual Property and Pharmaceutical Data Exclusivity in the context of Innovation and Market Access"* ICTSD-UNCTAD Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines,Bellagio,12-16 October 2004, available at www.iprsonline, last visited September 24, 2005.

[2] Razvan Dinca, "The Bermuda Triangle of Pharmaceutical Law is Data Protection a Lost Ship?" *Journal of World Intellectual Property,* Vol. 8, no.4, July 2005 p 518.

[3] It is the study of the biochemical and physiological effects of drugs and the mechanisms of drug action and the relationship between drug concentration and effect. It is the study of what a drug does to the body.

[4] Branch of Pharmacology dedicated to the study of the time course of substances and their relationship with an organism or system. It explores what the body does to the drug.

toxicity or unexpected undesirable reactions and to study the bioavailability[5] and pharmacokinetics of the new chemical entity[6].There are two specific kinds of tests in Phase I.[7] Phase II of the clinical testing is conducted in a limited number of patients of both sexes to determine therapeutic uses, effective dose range and further evaluation of safety and pharmacokinetics if necessary. Normally 20-25 patients should be studied for assessment of each dosage[8]. Phase III of clinical trials are conducted on a large number of patients. They often involve several hundred human subjects and are conducted for substantial periods. These tests are designed to determine the efficacy of the investigational drug and to uncover any unanticipated side effects that the drug may have, considering age and gender, drug interactions and specific dosage for different indications.[9] While the phase III trials are underway, longstanding animal toxicity studies are undertaken to determine the effects of prolonged exposure and effects on subsequent generations.[10] The duration of the studies vary widely among therapeutic classes. For drugs that affect the reproductive system or that will be used over long periods of time, animal toxicity studies are typically expensive and lengthy.[11]

If the results are satisfactory in terms of efficacy and safety, they are presented to the authorities for evaluation. If the new chemical entity is relate to agrochemicals, not only is an evaluation of its efficacy and toxicity are required, but also the

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[5] It is a measurement of the rate and extent of therapeutically active drug that reaches the systematic circulation and is available at the site of action.

[6] Carlos Correa *"Protection of data submitted for the registration of pharmaceuticals: Implementing Standards of TRIPS Agreement"* (Geneva: south centre publication),2002, p.9.

[7] Single Ascending Dose studies are those in which groups of 3 or 6 patients are given a small dose of the drug and observed for a specific period of time. If they do not exhibit any adverse side effects, a new group of patients is then given a higher dose. This is continued until intolerable side effects start showing up, at which point the drug is said to have reached the maximum tolerated dose. Multiple Ascending Dose studies are conducted to better understand the pharmacokinetic/pharmacodynamic of the drug. In these studies, a group of patients receives a low dose of the drug and the dose is subsequently escalated upto predetermined level.

[8] Indian Council of Medical Research "Ethical Guidelines for Biomedical Research", New Delhi, 2000, p.29.

[9] See Carlos, no ,3.

[10] Ibid.

[11] A post- approval research is also conducted to remove any doubts that might subsists on the adverse effects not included in the initial clinical trials by experimental studies and surveillance activities on populations that are not involved in the pre-marketing trials, such as children, pregnant women and elderly subjects. These post-approval studies are useful also in knowing the drug's long term morbidity and mortality profile, which cannot be obtained through the initial clinical trials.

assessment about the product in a particular environment or with regard to crops are also required.[12]

The results of all these preclinical and clinical trials are compiled together and submits to the regulatory approval authority for getting marketing approval. These data are commonly known as test data. Test data is important for health and environmental purposes. They allow the national authorities and users to evaluate the merits and demerits of new pharmaceuticals and agrochemicals. They are also important for commercial purposes, as the availability of data is a condition for obtaining marketing approval of new products, modification of products or new uses of existing products[13]. To protect this voluminous data the originators are statutorily obliged to submit it to the regulatory authorities and the concept of test data protection arises.

In developed countries, the submitted test data should not rely by regulatory authorities when examining subsequent applications relates to same chemical molecule. The regulatory authorities in the developing countries normally rely on the submitted test data in its own jurisdiction or in other jurisdiction, if the subsequent applicants show confirmatory trial data.

II.2. Arguments for Protection

According to groups arguing for data exclusivity, the test data is generated after substantial investment of time, expertise, resources and money. Normally it takes 8-11 years to complete this test. Development of these test data represents about 60% of research and development cost of new drugs[14]. So protection in the form of data exclusivity is needs.

According to International Federation of Pharmaceutical Manufacturers Association (IFPMA)[15] "The development and bringing to market of a new drug

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[12] Carlos. M. Correa "Protecting Test Data for Pharmaceutical and Agrochemical Products under Free Trade Agreements" ,UNCTAD-ICTSD Dialogue on Moving the Pro-development IP Agenda Forward: Preserving Public Goods in Health, Education and Learning,Bellagio,29Nov-3Dec2004, Available at www.iprsonline ,last visited, September. 3,2005.

[13] Ibid.

[14] For example, research based pharmaceutical companies in the united states invested $21.8 billion for research and development in 1998,a 10% increase over 1997.with 40 % of these R&D expenditures are going for pre-clinical functions and 30% going towards completing the phase I,II,III clinical trials required by the food and drug administration. Thus 70% of all R&D expenditures in the US spend for getting marketing approval.

[15] IFPMA represents Multinational Drug Companies concentrated in Europe.

requires the originator to conduct extensive chemical, pharmacological, toxicological and chemical research and training at an average cost of $800 Million US dollars and takes 10-15 years. The data generated by such work, while proprietary to originator must be submitted to regulatory authorities of countries around the world in order to obtain approval to market the drug".[16] Crop life international which represents multinational agrochemical companies argues that 'While in the pharmaceutical sector one of every 5000 molecules investigated is approved by Food and drug Authority(FDA) for marketing, in the agrochemical sector, only one in approximately 140,000 studied molecules makes it from laboratory to the field. Because of their chemical nature and the wide range of organisms potentially affected by their use, agrochemical products must pass more than 120 different safety tests. Additionally efficacy test must be repeated in each country even in several regions of one country, due to differences in crops, pests, agrochemical practices, climate conditions and terrains'. The average development costs for a new agrochemical in year 2000 was 200 Million Euros and the average development time is over 9 years from discovery of a new chemical entity.[17]

General argument is that, the development of new drugs and agrochemicals incur huge expenses. The companies are interested in a legal mechanism that allows them to recoup it in the marketing stage by escaping for a determined period of free competition. Considering that only a few of the medicines enter into the market after all these processes finally obtain marketing approval. The research-based industry argues that this protection should be reinforce, to provide an incentive for the originators to take the risk on this kind of enterprise.[18] The subject of protection is test data: the data of clinical trials carried out by the originator company in order to prove safety and efficacy. This information is not created or invented. It is obtained by applying standard protocols on a new chemical substance. The test data is outside the purview of patent protection, even if the new chemical entity is protected under

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[16] See Carlos , no.8.

[17] Ibid.

[18] See for example, European Federation of Pharmaceutical Industries and Associations (EFPIA),position paper: TRIPS Article 39.3 (protection of undisclosed data), a critical issue for the development of safe and innovative medicines for patients, November 2000,at 4;available at www,efpia.com.org/4_pos/legal/trips-39.3.pdf(last visited 21 July 2005); International Federation of Pharmaceutical Manufacturers Associations(IFPMA),Encouragement of new clinical drug development: The Role of Data Exclusivity, Geneva, Switzerland, 2000; available at www.ifpma.org/documents/nr643/DataExclusivity.2000.PDF (last visited 4 August 2005).

patent. The concept is not the protection of creation, but investment made in conducting test and development of data.

Research based pharmaceutical trade association[19] points out that, of every 5000 new chemical entities (NCE'S) screened, on an average, only five are tested in clinical trials and only one of those is approved for patient use.[20] The drastic increase in R&D expenditure, especially in clinical trials declined the number of new drugs approved for market use. So there is an argument for protection of submitted test data. The argument got prominence after 1980's when more and more generic pharmaceutical companies started production. They used the submitted test data of originator for getting marketing approval. The regulatory authorities should not be allow to rely on the submitted test data, when they examine the subsequent applications, which relates to the marketing approval of similar medicines.

II.3. Arguments against Protection

The group[21] which opposes data exclusivity argues that, it is a mere extension of monopoly right. The originator is getting 20 years of patent protection and it is sufficient to recoup the investment involved in the development of the product. The projected period and expenses for conducting clinical trials is wrong. Most of these tests are conducted in government laboratories or are highly funded by government. If the subsequent manufacturers also wants to conduct the same tests for getting marketing approval , it is wasteful of money, time and repeated tests in animals and human begins are ethically questionable. In the name of data protection, the originators are aiming to get market exclusivity by preventing market entry of generic manufacturers. Data exclusivity will also act as monopoly right in the absence of patent protection.

Instead of providing data exclusivity countries should follow the practice of providing marketing approval for subsequent manufacturers by showing bioequivalence[22] to the original product. This is the practice followed in majority of

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[19] European Federation of Pharmaceutical Industries and Associations (EFPIA).

[20] Association of the British pharmaceutical industry, The development of medicines (London: ABPI),2002.

[21] European Generic Association (EGA) and other generic manufacturers in different countries.

[22] Once test data was submitted by the originator company, the regulatory authorities could rely on the data to approve subsequent applications on similar product, or to rely on proof of prior approval of a similar product in another country. Generic manufacturers need only to prove that their product is chemically or therapeutically identical to the original product. This is the bioequivalency test. This approach enabled fast introduction of generics into the market without data related cost. Or, a scientific basis on which generic and brand name drugs are compared with one another. Drugs are bioequivalent if they enter circulation at the same rate when given in similar doses under similar conditions

the developing countries including India. This practice helped the generic medicinal companies to flourish and market the medicines in less price compared to price of original products. To destroy the generic manufacturer companies, which is the lifeline of millions of poor people, the developed countries armed by multinational drug companies are trying to impose data exclusivity through backdoor.

II.4. National Legal Regimes for Test Data

II.4.1 United States

Test data was protected under trade secret regime in US before 1980. The originators can keep this data secret without sharing others. The high cost of obtaining the necessary test data caused serious problems for developers and consumers. To regulate the availability of test data for developers and consumers, test data protection was introduced for the first time in United States Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) in 1980, which introduced a hybrid regime combining a period of exclusive rights and a period of compensation. The object was that "the health and safety data would be immediately available to the public, but the competitors could not use the data to register competing products for a fixed period of time". In 1982 a report by a committee of the US congress found that there were only 34 drugs, often called "orphan" drugs (Drugs for rare diseases). The report found that patent protection was often not available to provide a means of recouping the costs associated with testing of these drugs. The US congress enacted legislation entitled "The Orphan Drug Act"[23] . One of the most important measures in the Act was the provision of a seven year period of exclusive marketing rights for those companies that provide the extensive test and other data necessary to obtain marketing approval for an orphan drug. After two years 'Drug Price Competition and Patent Term Restoration Act' (1984) (Hatch-Waxman Act) which prohibited competitors from relying on the data submitted by the originator for a five year period after the approval of the product associated with the data, if the product contained an active ingredient that had not been previously approved by the US Food and Drug Administration. After the expiration of this period, competitors are permitted to rely on the showings and data submitted by the originator of the product, if these competitors can show that

[23] G. Lee Skillington & Eric.M.Solovy: "The protection of Test and other data required by Article 39.3 of the TRIPS Agreement": *North Western Journal of International law & Business*, 2003, V. 24, p. 9-10.

their products are bioequivalent to the approved product.[24] Now data exclusivity in the United States is provided in Section 505 (355) (D) of The Federal Food, Drug and Cosmetic Act of 1997.[25] The US model provides five-year period of data exclusivity to new drugs and three years of data exclusivity to new indications of existing drug.

II.4.2. European Union

European community also adopted a measure in 1986 similar to the Hatch-Waxman Act. It prohibited reliance on the data submitted by the originator for 6 years and 10 years for 'high technology medicinal product'. These measures have been referred collectively as data protection laws, given that they were intended to a large degree to promote the generation of test data. From these instances, we can assume that they are not considered as intellectual property rights but only as a regulatory mechanism for the generation and protection of test data.[26] In the European Union (EU), since 1987, the Member States have provided exclusivity protection for the data filed in support of marketing authorizations for pharmaceuticals. During the exclusivity period, the health authorities shall rely on an originators test data to approve other applications without the originators consent. The minimum period of such protection is six years, but ten years is obligatory for "high technology products", and also for new chemical entity authorizations granted by the European Medicines Evaluation Agency (EMEA)[27]. Article 4.8 of Directive 65/65 as amended by Directive 87/21/EEC provide protection for pharmaceutical test data. Similar provisions for the veterinary products are contained in Directive 81/851/EEC, as amended by Directive 90/676/EEC.[28] Till recently, for the purpose of obtaining the authorization for market use, a generic drug does not require the submission of a registration file if it can be demonstrated that it is essentially similar to a medical product which has been authorized within the community for a period of not less than six years. The directive also stated that the period of exclusivity shall be extended to ten years in the case of high-technology medicinal products and that member states can extend the period of exclusivity to ten years for all medicinal products .In

[24] Ibid.
[25] Available at 25 USC 305 (C) (D) (ii &iii)- Federal Food, Drug and Cosmetic Act of 1997,chapter 5-Drugs and Devices, Section 355, (Washington :FDA) http:// www.fda.gov /opa com /laws /fd act/.5 htm .
[26] Ibid.
[27] Ibid.
[28] UNCTAD-ICTSD project on *"Intellectual Property Rights and Sustainable development"*, Cambridge university press, New York , 2005, p. 535.

December 2003 a new level of data exclusivity in EU according to the 8+2+1 formula was adopted. According to the provision, eight years of data exclusivity, two years of marketing exclusivity and an additional year of protection of new indication of existing product.[29] The rationale is after completion of first 8 years the generic manufacturers can use data for preparing their products but they can market only after completion of 10 years of marketing approval.

II.4.3. Other National Laws

The National laws reviewed reveals that a large number of countries do not have specific data protection provisions for pharmaceutical products. Many countries in the Asian region specifically provide for protection of test data from unfair commercial use, using a language similar to that in Article 39.3 of TRIPS Agreement[30]. In Thailand, the Trade Secrets Act protects undisclosed test data from being disclosed, taken away or unfairly used for commercial purposes[31]. China and Vietnam provide data exclusivity for six and five years respectively. China provides data exclusivity as early as in 1992[32]. In the case of Egypt, Patent law provides for the protection of test data from disclosure and unfair commercial use for a period until it is no longer confidential, or for a period not exceeding 5 years, which ever comes first.

Argentina provides the non-exclusivity model[33]. According to the law, test data should only be submitted for registration of new chemical entities. However when a pharmaceutical product is already marketed in Argentina or in any other countries that comply with certain standards defined by the law, the national health authority may rely on the prior registration. There is no need in those cases for applicant to submit test data.[34]

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[29] Meir Perez Pugatch , *"Intellectual Property and Pharmaceutical Data Exclusivity in the Context of Innovation and Market Access"* ICTSD-UNCTAD Dialogue on Ensuring Policy options for Affordable Access to Essential Medicines,Bellagio,12-16 October 2004, Available at www.iprsonline, last visited September 24, 2005.

[30] See Annex-II

[31] Ibid.

[32] Ibid.

[33] It provides limited protection to submitted test data. Subsequent applicants should provide only data of bio equivalency test to regulatory authorities for getting marketing approval. Other words the regulatory authorities can rely the test data of the first applicants when they examine the application of second comer.

[34] UNCTAD-ICTSD Project on *"Intellectual Property Rights and Sustainable Development"*, Cambridge University Press, New York, 2005, p-533.

Switzerland provides 10 year data exclusivity for pharmaceuticals and agrochemicals. However there are exceptions in the case of animal testing. To avoid unnecessary duplication of animal testing, subsequent applicants are allowed to refer to the previously submitted data after a shorter period of time, but must share the costs of these tests with the originator.[35] In the case of Israel huge clash of interest between the multinational researches – based pharmaceutical industry, backed by USTR Trade representative and generic industry in Israel, supported by 'TEVA', the largest generic pharmaceutical company in the world.[36] An inter-ministerial Committee was appointed and they gave recommendation for the enactment of data exclusivity legislation. According to this legislation five year market exclusivity will give to the originator of submitted test data. In these five years the generic can use this submitted test data for manufacturing their product and export it to other countries. The USTR argued that it does not meet minimum TRIPS standard. Still that stand off is going on and USTR in its 2005 Report includes Israel in the Priority Watch List.[37]

New Zealand interpreted 'unfair commercial use' to include the use which regulatory authorities can make of original data for the approval of subsequent applications of generic medicines, animal remedies or pesticides as this would give a commercial advantage to the second or subsequent applicant. Further, although TRIPS is silent on the period of such protection, going by the equivalent provision in NAFTA, New Zealand felt it was clear that such a period was meant to be restricted to five years. Thus as part of the implementing legislation for TRIPS in 1994, New Zealand amended its Medicines Act 1981, the Pesticides Act 1979, and the Animal Remedies Act 1987 to give a Five year market exclusivity, to new pharmaceutical and agricultural chemical products.[38]

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[35] Ingo, Meitinger: "Implementation of Test Data Protection, According to Article 39.3 TRIPS "The Search For a fair interpretation of the Term "unfair commercial use" *Journal of world intellectual property*, V 8, No 2, March 2005, p. 129.

[36] See : Gabizon , "*Teva opposes Data protection Law for several Billion Reasons*", in Haaretz (4th Jan, 2004).

[37] The protection period in Israel would begin on the date of marketing approval in the first developed country recognized by Israel .This means that in practice Israel will have a period of marketing exclusivity. that is always less than 5 years. The protection period is terminated automatically once there is generic substitute to the original drug in one of the recognized countries regardless of time of registration in Isreal.

[38] Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (Oxford University Press, New york) 2001, p.201-202.

In the case of Singapore it curtailed the five-year period of data exclusivity by starting protection from the date of filing of the originator's pharmaceutical product, rather than from the date of its marketing authorization, which is the standard practice in the United States and European Union. Beginning the count from the date of filing is illogical, since the originator does not reap any commercial benefit from the data exclusivity when its product is awaiting marketing approval and, thus is not on the market. The effective period of data exclusivity provided in Singapore is thus curtailed by nine to fifteen months.[39]

In Spain the 'second applicant for approval of a medicament essentially similar to another already approved medicament may, with the express consent of the holder of the approval, refer certain parts of his application to the original file. So with the authorization second applicant can use the test data.[40] Italy also prohibits the disclosure of confidential data submitted to the competent authorities to obtain approval for marketing pharmaceutical or agricultural chemical products and forbids third parties from acquisition direct use or disclosure of such data.[41]

Some countries like Poland, Greece, Germany, and Portugal link data exclusivity to the life of the underlying patent for the product for which marketing approval is being sought.. In France confidential use of data in pharmaceutical product marketing approval files, filed pursuant to the French procedure cannot be disclosed to the public in accordance with paragraph 5 of Article 1 of the order of 13 March 1986. The Drug law of the Federal Republic of Germany protects parties in Germany who have provided confidential test or other data concerning a finished medical product in order to obtain a marketing authorization from the national competent authority. In Norway undisclosed test and other data are protected from unfair commercial use by an administrative practice that prevents an applicant from relying on data provided by another applicant without the latter's consent. For Medical products, this protection expires when the other applicant himself had a marketing approval for six years.[42] In the case of Brazil Article 195 of the Protection against Unfair Competition Act provides: A crime of unfair competition is committed

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[39] Jacques Gorlin, "*Encouragement of New Clinical Drug Development: The Role of Data Exclusivity*", IFPMA, 2000, page 8

[40] Ibid.

[41] Ibid.

[42] IIFT, *Article 39.3 of the TRIPS Agreement:Its Genesis and the Present Context*, (Indian Institute of foreign trade, New Delhi, 2003), p.29-30.

by he/she who divulges, exploits or uses without authorization, the results of test or other undisclosed data the elaboration of which involved considerable effort and which has been presented to government entities as a condition for approving the commercialization of product[43]. Colombia also protects test data by data protection decree, where the commercialization of a new chemical entity is approved; the related undisclosed information may not be used directly or indirectly as supporting information for the approval of a separate application relating to the same new chemical entity[44].

Japan provides market exclusivity for six years where no second comers will be given regulatory approval. The Japanese Health ministry will publish proprietary data at the time of marketing approval. While it has no data exclusivity as such, Japan has a re-examination provision that precludes the issuance of any second approval for six years after the approval[45].

II.5. National Decisions

Many national courts have pronounced decisions relating to the reliance by regulatory authority on originators submitted test data when examining the subsequent applications. In most of the cases Multinational Drug Companies (MNC) approached the court against the abbreviated procedure[46] or the bioequivalency method in giving marketing approval for the generic manufacturers.

One of the earlier decisions relating to the alleged 'unfair commercial use' of governmental agency was in 1984 in *Ruckelshaus v Monsanto co*[47]. The case relates

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[43] See Annex II.

[44] Ibid.

[45] A Review of Existing Data Exclusivity Legislation in Selected Countries, International Federation of Pharmaceutical Manufacturers Associations, Revised version,2005 available at http://www.ifpma.org. Last visited August 23, 2005. Bulgaria, Canada, China, Costa Rica, Egypt, Guatemala, Hungary, Iceland, Jordan, Mexico, Norway, Slovak republic, Singapore, Switzerland, Ecuador, Venezuela, Peru and other countries how data exclusivity legislation. Guatemala provides data exclusivity for 16 years under pressure from USA in 2000. In 2002 because of the pressure from civil society they deleted data exclusivity. But US Ambassador to Guatemala threatened to withdraw GSP. Guatemala was force to adopt a new data exclusivity legislation, which provides 5 years in 2003. The incident shows how US is using various tactics or developing countries for imposing their trade agenda. See Annex II.

[46] In some countries, the procedure of giving marketing approval on the basis of bioequalency test is called abbreviated procedure.

[47] 467 US 986,104 s.ct.2862,June 26, 1984 as quoted in Jerome.H.Reichman "undisclosed clinical Trial data under the TRIPS Agreement and its progeny: A Broader perspective, available at http:www.iprsonline.org / unctad ictsd / bellagio/ docs/Reichman-Bellagio 4 .pdf. last visited September 13,2005 .

to the protection of data submitted for the registration of an agrochemical product. Though a subsequent applicant was obliged to compensate for the use of monsanto's original data, Monsanto argued that such use undermined its reasonable "investment backed expectations" and was unconstitutional. A basic argument of the plaintiff was that the possibility given to a competitor of using the data against payment of compensation nullified its "reasonable investment-backed expectation". However, the Supreme Court described the extensive practice of relying on the data submitted by the first applicant in the US, and rejected Monsanto's complaint The United States supreme court observed that the filing of a confidential data prior to congressional decision to confer special protection upon such data could not be construed as conferring any assurance against internal agency use during the consideration of application of a subsequent firm for registration. The reluctance of the US Supreme Court in this case to impose an unqualified restriction on the use of data filed with regulatory authorities was expressly conditioned on the need to sustain competition in unpatented products.

The second decision was given by Canadian Federal Court, which mainly interpreted the data exclusivity provisions of North American Free Trade Agreement (NAFTA) to which Canada is a party. In Canada, the manufacturers must file a "new drug submissions" (NDS) that includes data from pre-clinical and clinical test to show that the product is safe and effective. If a generic manufacturer wants to market its product in Canada, the requirement to submit an 'NDS' is waived, and the manufacturer of the subsequent 'new drug' is required to file only an 'abbreviated new drug submission' (ANDS),that proves that the subsequent product is bioequivalent to the first approved product.

Paragraph 5 of Article 1711 of NAFTA requires protection of certain test and other data against disclosure in the manner as required by TRIPS Agreement Article 39.3.But paragraph 6 of NAFTA Article 1711 requires parties to prohibit, for a specified period, a person from relying on test and other data submitted by another without authorization of the person who submits the data originally. To implement

paragraph 5 and 6 of NAFTA Article 1711, the Canadian government, in 1995, promulgated chapter 870, section c.08.004.1 (1) of Food and Drug Regulation.[48]

The Federal court effectively ruled this provision effect less by ruling that it does not apply in most cases since the usual approval process of a generic drug does not entail actual examination and direct reliance on the originators data. The existing regulation does not apply to "indirect" reliance on the originators data. Court further held that, if a generic manufacturer is able to establish the safety and effectiveness of its product on the basis of bioequivalence or bioavailability studies without the minister having to examine and rely upon confidential data filed by innovator, there is no reason or justification for the minimum five year protection from competition[49]. This interpretation of subsection C.08.004.01 (1) is consonant with section 5 and 6 of Article 1711 of the NAFTA.

So even express provision of exclusivity is mentioned in the NAFTA, the mere reliance on a prior registration without the use of the data does not allow claiming exclusivity. The reliance by the national regulatory authorities is not a prohibited act. Most of the national laws reviewed and the decisions given by courts even in developed countries show that it is better to follow the bioequivalency test for giving marketing approval to generic products than asking for expensive tests. This is in consonance with the solving of public health problems and the development of generic manufacturers in developing countries.

An elaborated interpretation of Article 39.3 of the TRIPS Agreement is examined in the next chapter, which is a bone contention between developed and developing countries.

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[48] (1) Where a manufacturer files a new drug submission, an abbreviated new drug submission, a supplement to a new drug submission or a supplement to an abbreviated new drugs submission for the purpose of establishing the safety and effectiveness of new drug for which the submission or supplement is filed., and the minister examines any information or material filed with the minister ,in anew drug submission, by the innovator of a drug that contains a chemical or biological substance not previously approved for sale in Canada as a drug, and the minister, in support of the manufacturer's submission or supplement, relies on data contained in the information or material filed by the innovator, the minister shall not issue a notice of compliance in respect of that submission or supplement earlier than five years after the data of issuance to the innovator of the notice of compliance or approval to market that drug, as the case may be, issued on the basis of the information or material filed by the innovator for that drug, C.R.C .1978.ch.870,section c.08,004.

[49] Carlos Maria Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement*, (South Centre publication, Switzerland). P 25.

CHAPTER III

TEST DATA PROTECTION IN TRIPS

TRIPS is the first International Agreement specifically imposing obligations for the protection of test data. Article 39.1 of TRIPS Agreement refers to "Undisclosed information" on the one hand and "Data submitted to governments or governmental agencies" on the other.

Article 39.3 of the Trade Related Aspects of Intellectual Property Rights (TRIPS) provides:

> Members, when requiring, as a condition of approving the marketing of pharmaceuticals 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.

This chapter examines the nature of the TRIPS obligation. The first part will examine the negotiating history; and the second part will examine the criteria for the protection of test data under Article 39.3.

III.1. Negotiating History of Article 39.3

United States introduced a proposal for the regulation of trade secret during TRIPS negotiations in 1987. The proposal demanded, "Trade secret should be broadly defined to include undisclosed valuable business, commercial, technical or other proprietary data as well as technical information, misappropriation including the unauthorized acquisition, use of disclosure of a trade secret, must be prevented". In addition the proposal demanded strict limits on the disclosure of "trade secret submitted to governments as a requirement to do business except in extreme circumstances involving national emergencies, or in cases of public health and safety, if such disclosure did not impair actual or potential markets of the submitter or the value of the submitted trade secrets."[1]

The European Community (EC) insisted that the protection of trade secret be subject to unfair competition rules as provided under the Paris Convention. This conception finally prevailed over the consideration of undisclosed information as a

[1] F.K.Beier & G.Schricker (eds), *"GATT or WIPO? New Ways in the Intellectual Protection of Intellectual Property"*, (IIC Studies, Weinheim), 1989, vol.2, p 181,186.

form of property as suggested in the informal submission of the US.[2] The United States put forth the view that the issue underlying the protection of trade secrets was the same as that underlying the protection of intellectual property rights generally, namely that of not benefiting from the fruits and labours of others improperly.[3] It was suggested that that a two-pronged approach should be taken to the protection of trade secrets. First, in regard to the transfer of know-how between private parties, the confidentiality of information given given to employees and restrictions on its divulgation should be protectable through the courts. Secondly, there should be restrictions on the use and disclosure of information available to governments. Most of the submissions of US were based on 'Uniform Trade Secrets act'[4]. However, the decisions given by the US courts also influenced their proposals.

Canada proposed that TRIPS Agreement should contain a general obligation that would prevent anyone other than the owner from using trade secrets, contrary to honest commercial practices. Such protection of trade secrets would be covered by the concept of "repression of unfair competition" in the Paris Convention.[5]

III.2. Position of Developed Countries

Developed countries due to the influence of big pharmaceutical and agrochemical companies wanted to include test data protection in the form of data exclusivity in the TRIPS Agreement. A proposal by the business communities from Europe, Japan and USA clearly specified the obligation to establish a data exclusivity period.[6] In comparison with later proposal, the first proposal relates to test data protection by US to the negotiating committee was milder. Because it allows the use

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[2] Resource book on TRIPS and Development, "*UNCTAD-ICTSD Project on Intellectual Property Rights and Sustainable Development*", (Cambridge university press, New York), 2005 p 523.

[3] IIFT, "*Article 39.3 of the TRIPS Agreement: Its genesis and the present context*",(Indian Institute of Foreign Trade, New Delhi) 2003, p.14.

[4] Uniform Trade Secret Act is a model statute governing trade secret rights in USA. This Act has been adopted in large part by different states in United States. Uniform Trade Secrets Act (1, 14 ULA 438 (1985).

[5] Documents MTN. GNG/ NG 11/ W/47 of October 25, 1989, at 10, H, and 16, H; MTN. GNG/ NG11/16 of December 4, 1989, at 14 /15.

[6] Business community Proposal reads as:

(1) "Information required by a government to be disclosed by any party shall not be used commercially or further disclosed with out the consent of the owner.

(2) Information disclosed to a government as a condition for registration of a Product shall be reserved for the exclusive use of the registrant for a reasonable period from the day when government approved based on the information was given. The reasonable period shall be adequate to protect the commercial interest of registrant".

of submitted test data with right holder's consent, on payment of reasonable compensation[7].

Whereas European community proposed that,

(a) In the course of ensuring effective protection against unfair competition as provided for in Article 10 bis of the Paris Convention:

(b) 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[8].

In comparison with the proposal put forward by the United States, the proposal of the European communities tried to connect test data protection with Article 10 bis of Paris convention which relates to protection against unfair competition. This proposal extends not only to test data but also to other data. The protection should also take into account the availability of other forms of protection, for example patent protection[9]. Though exclusive use is not mentioned expressly, EC favoured such exclusivity for a reasonable period in proportionate with the expenditure involved.

Switzerland proposed that "proprietary information submitted to a government agency for purposes of regulatory approval procedures such as clinical or safety tests shall not be disclosed without the consent of the proprietor, except to other government agencies if necessary to protect human, plant or animal life, health or the environment. Governmental agencies shall not be entitled to use the information for commercial purposes. They may disclose it only with the consent of the proprietor or to the extent indispensable to inform the general public about the actual or potential danger of a product"[10].

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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 then 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". Proprietary information submitted to a government agency for the purposes of regulatory approval procedure such as clinical or safety tests shall not be disclosed.

[8] MTN.GNG/NG 11/W/68.

[9] But this part is not clear, what was their intention, if there is patent protection no need of separate protection to test data? Or test data protection will run parallel with patent protection?

[10] G.Lee Skillington and Eric M.Solovy. " The protection of test and other data required by Article 39.3 of the TRIPS Agreement". *North Western Journal of international law and Business,* vol 24.1, 2003, P.16.

III.3. Position of Developing Countries

The delegations from developing countries rejected any form of protection for trade secrets under TRIPS. They viewed that trade secrets did not constitute a form of intellectual property and therefore fall outside the scope of the work of the negotiating group. They argue that trade secrets could not be regarded as a form of intellectual property, since the requirement of disclosure, which was an essential form of intellectual property rights, could not be enforced in this case. In 1989 India, Peru and Brazil argued, that trade secrets were not a form of intellectual property rights and held that the protection against unfair competition under Article 10 *bis* of the Paris Convention on Industrial property, 1967, would suffice, and that protection by contract and under civil law was to be preferred to intellectual property rules.[11] The proposals from the developing countries and Japan did not contain provisions related to test data protection[12]

The Chairman of the TRIPS negotiating group provided the initial formulation for including undisclosed information in the proposed Agreement, which reads as,

> Parties which require that trade secrets be submitted to carry out governmental functions shall not use the trade secrets for the commercialization or competitive benefit of the government or of any person other than the right holder except with the right holder's consent. Proprietary information submitted to a government agency for the purposes of regulatory approval procedures such as clinical or safety tests shall not be disclosed[13].

Negotiations were held with the aim of finalizing text in as many areas as possible before the ministerial conference of Brussels in December 1990. Developing countries led by India, Argentina, Brazil, Chile, Columbia, Egypt and Nigeria objected to the inclusion of test data protection.

Regarding test data protection, the following text was prepared for the ministerial conference in Brussels:

> PARTIES, when requiring, as a condition of a approving the marketing of new pharmaceutical products or of a new agricultural chemical product, the submission 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 of the approval of competing products for

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[11] Document MTN.GNG/NG 11 / W/ 37 of July 10, 1989, at note 46, Document MTN.GNG/ NG 11/ W/ 45 of October 27, 1989, at 5 note.

[12] C. Correa and A. Yusuf " *Intellectual Property and International Trade*," (Kluwer law international, London), 1998. p. 238.

[13] See note, 3.

> 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[14].

Thus the Brussels draft unambiguously provided a period of five year exclusivity and non reliance. This permits a period of five years to originators of test data, for products utilizing new chemical entities even where these were not eligible for patent protection[15]. In the Brussels, drafters used protection against unfair commercial use of submitted test data. It appears that the drafters chose the term "unfair commercial use" in order to integrate the concepts of proposals by USA, EC and Switzerland.

Once this proposal was incorporated into the consolidated proposal, the developing countries, which had never included an equivalent text in their proposals, strongly opposed it[16], thus advocating in favour of the interests of their domestic industries, which are strong producers of generic medicines. As a result of this opposition, the Ministerial Conference of Brussels finally failed to reach an agreement regarding the content of test data protection[17].

A year later the then Director General of the GATT, Arthur Dunkel, tabled a text which eliminated the references both to exclusive rights and to a certain period of protection and restricted to protection of data relating to pharmaceutical or agricultural chemical products which utilized new chemical entities[18]. It was incorporated as Article 39.3 of TRIPS Agreement. It reads as:

> 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.

The final text of the Agreement of TRIPS adopted in 1994 made no mention about the period for which undisclosed information was to be granted protection. But

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[14] GATT Secretariat, Draft Final Act Embodying the results of the Uruguay round of Multilateral negotiations, MTN.TNC/W/35 Rev.1 (3rd December 1990).

[15] Jayashree Watal: "*Intellectual Property Rights in the WTO and Developing Countries*", (Oxford University Press, New York), 2001. p. 199.

[16] Communication form Argentina, Brazil, Chile, China, Columbia, Cuba, Egypt, India, Nigeria, Peru, Tanzania and Uruguay, WTO. DOC. MTN.GNG/NG 11/W/71, 14th May 1990.

[17] Razvon Dinca, "The "Bermuda Triangle" of Pharmaceutical Law, Is Data Protection a Lost Ship?" *Journal of World Intellectual Property*, Vol.8, No.4, July 2005. p.524.

[18] Ibid.

it retained the concept that a form of protection in addition to protection from disclosure must be provided by members and retained the phrase "unfair commercial use" that was created to encompass the concepts in the proposals of the EC, Switzerland and USA[19]. Though it failed to specify the term of protection, it included limitation to products which utilize 'new chemical entities'. The ambit of disclosure has been broadened to include not only cases where it is 'necessary to protect the public' but also where data are protected against unfair commercial use. So members are not obligated to provide the originator of the data with exclusive property rights. The intention of this provision is not to give exclusive or monopoly rights, but to provide protection against unfair competition and against dishonest commercial practices by third parties.

III.4. Balancing Unfair Commercial Use and Disclosure

According to Article 39.3 of the TRIPS Agreement, there are two obligations arising out (1) protection against unfair commercial use (2) protection from disclosure.

Article 39.3 should be read in the light of Article 39.1 of the TRIPS Agreement. Article 39 provides that, in the course of ensuring effective protection against unfair competition as provided in article 10 *bis* of the Paris convention[20], members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3". Article 10 *bis* of the Paris Convention requires that all countries of the Paris Union should provide all Nationals of the union with effective protection against unfair competition, and this protection is based on national treatment principle pursuant to Article 2 of the Paris Convention.[21]

The term 'unfair competition' is defined in Article 10 *bis* (2) of Paris convention as "any act of competition contrary to honest practices in industry or

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[19] See Lee Skillington ,no. 10.

[20] The countries of the Paris Union are bound to assure to nationals of such countries effective protection against unfair competition.

[21] G.Lee Skillington& Eric.M.Solovy: "The Protection of Test and other Data require by Article39.3 of the TRIPS Agreement", *North Western Journal of International law& Business*, vol . 24,no.1, 2003, p.2.

commercial matters", and mentions the three acts listed in Paris Convention Art10bis (3)[22]. Professor Bodenhausen clarifies that in his commentary[23].

> "What is to be understood by 'competition' will be determined in each country according to its own concepts; countries may extend the notion of acts of unfair competition to acts which are not competitive in a narrow sense. Any act of competition will have to be considered unfair if it is contrary to honest practices in industrial or commercial matters". This criterion is not limited to honest practices existing in the country where protection against unfair competition is sought. The judicial or administrative authorities of such country will therefore have to take into account the honest practices established in international trade. If a judicial or administrative authority of the country where protection is sought finds that an act complained of is contrary to honest practices in industrial or commercial matters, it will be obliged to hold such act to be an act of unfair competition and to apply the sanctions and remedies provided by its national law. A wide variety of acts may correspond to the above criteria.[24]

The principal aim of the negotiators of Article 39 is to prevent unfair competition, but protection against unfair competition does not entail the granting of exclusive rights. Unfair competition as defined by World intellectual Property Organization (WIPO) is as follows;

> An act that a competitor or another market participant undertakes with the intention of directly exploiting another persons industrial or commercial achievement for his own business purposes without substantially departing from the original achievement.[25]

By virtue of TRIPS Article 39, the WTO members agree that unfair commercial use and disclosure of certain test and other data constitute unfair competition within the meaning of the Paris Article 10 *bis*. Hence there is an obligation for providing protection against unfair commercial use and not data exclusivity.

III.5. Conditions for Protection under Article 39.3

According to Article 39.3 of TRIPS Agreement, each member country should provide minimum protection to data that meet all the following criteria:

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[22] (a) all acts of such nature as to create confusion by any means whatever with the establishment, the goods, or the industrial or commercial activities, of a competitor;
(b) False allegations in the course of trade of such a nature as to discredit the establishment, The goods, or the industrial or commercial activities of a competitor.
(c) 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.

[23] G.H.C. BODENHAUSEN, *Guide To the Application of the Paris Convention for the Protection of Industrial Property*, as Revised at Stockholm in 1967.

[24] Ibid.

[25] WIPO,Protection against Unfair Competition Geneva ,1994, p.55 as quoted in UNCTAD-ICTSD project on Intellectual Property Rights and Sustainable Development Resource Book on TRIPS and Development, (Cambridge university press: New York), 2005, p.521.

- The data was submitted as a condition for obtaining marketing approval for a product in that member.
- The product for which marketing approval was sought was a pharmaceutical or agricultural chemical product.

III. 5.1. Criteria for protection

- The product for which marketing approval was sought contained a new chemical entity.
- The data were undisclosed at the time of submission.
- Generation of data involves considerable effort.

Members of the WTO agree with these criteria, prescribed under Article 39.3 of TRIPS Agreement. The point of difference exists in the definition of (1) New chemical entity and (2) unfair commercial use and, the nature of protection as to whether limited or exclusive protection be given.[26]

III.6.1 Interpretation of Article 39.3

A basic condition for the application of Article 39.3 of the TRIPS Agreement is when a member imposes an obligation to submit data as a condition to obtain the marketing approval of pharmaceutical or agrochemical products. Article 39.3 does not apply when it is necessary to submit such data, for instance, when marketing approval is granted by national authority relying on the existence of a prior registration else where.[27] So one of the easiest methods to comply with TRIPS is not to insist for test data in cases where the drug or agricultural chemical product is approved in the market in any part of the world or there is published literature regarding its safety and efficacy.[28]

Second condition is the subject matter of protection under this Article is 'undisclosed information' contained in a written material which details the results of

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[26] The terms used in Article 39.3 are not defined in the TRIPS Agreement. So normally International Judicial Bodies use Article 31 of the Vienna convention of Law of Treaties in interpreting International agreements. If the interpretation of agreement is not clear with Article 31, the international judicial bodies used Article 32 of the Vienna conventions, which allows the use of supplementary means of interpretation.

[27] UNCTAD-ICTSD project on *Intellectual Property Rights and Sustainable development*, (Cambridge University press, New York), 2005, p. 530.

[28] N.S Gopalakrishnan &Benoy.k.kadavan , *"Study on Test Data Protection in India"*,(Eastern Book Company Luknow), 2005.

scientific health and safety testing of pharmaceuticals and agrochemicals, in relation to human, animal and plant health and impact on environment and efficacy of use. The protected data also include manufacturing, conservation and packaging methods and conditions to the extent that their submission is needed to obtain marketing approval.[29]

III. 6.1. New Chemical Entity

Another controversial element of Article 39.3 is the protection of drugs or agrochemicals that "utilize new chemical entities". Whether the chemical entities must be "new" in the sense of having never before received marketing approval in the country at issue is not clear from the text.[30] Countries which oppose data exclusivity argue that WTO member countries have sufficient latitude to define what constitute 'new chemical entity'. In the context of drug development one interpretation of the term 'new chemical entity' is to include any drug with any modification in its use, dosage or combination. The narrow interpretation of the term is to limit only to give protection to drug which do not previously exist in the world.[31]

But some commentators argued that the term 'new' imposes 'novelty' standard in patent. TRIPS Article 39.3 protects data and products involved in the marketing approval systems, rather than such data that are related to patent. Consequently, the word "new" in this context refers to the status of a chemical entity within the marketing approval system, not with respect to the state of art or 'novelty' in the patent sense.[32] The US Food and Drug Administration define a "new chemical entity" as a drug that contains no active molecule that has been approved by FDA in any other application submitted under the Federal Food, Drug and Cosmetics Act.[33]

The justification for a broad interpretation of the term 'new chemical entity' is that approval is required even in the case of drugs with modification in its use, dosage

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[29] See UNCTAD-ICTSD note .27.

[30] Aaron Xavier Fellmeth, "Secrecy ,Monopoly ,and Access to pharmaceuticals in International trade law: protection of marketing approval data under the TRIPS Agreement", *Harvard international law Journal*, vol.45, Summer 2004, p.465.

[31] The TRIPS Agreement requires members to grant this protection only in respect of new chemical entities. There is no need to provide it for a new dosage form , new formulation, new indication, new use of a known product .The united states has attempted to implement its preferred interpretation of new chemical entity in its domestic jurisdiction.

[32] See,Lee, Skillington supra foot note 10 [TRIPS Article 25 requires members to protect "new and original designs". In Article 39.3, it appears that "new" is also used in the sense of "novel".

[33] Ibid.

or combination before marketing. Even in these cases, the authorities insist on data regarding safety and efficiency for marketing approval. The expenditure incurred in these cases is high irrespective of whether the drug is new or not.[34] It is further argues that in case, interpretation is limited to drugs that are entitled to patent, test data protection become meaningless. This interpretation will exclude a large number of drugs that may not qualify patent protection. [35] There is an argument that a new chemical entity should interpret to include new uses, formulations or dosage forms.

There are also different interpretations that relates to the newness of the medicine and its character of being is universal or local; universal means first application in the world whereas local means in the particular country. The justification of narrow interpretation is favoured to protect the poor people in the developing and least developed countries. Unless data exclusivity is limited, the MNC drug company's monopoly the drug market which they have used for 'ever greening of patent'[36] and makes drugs unaffordable to poor people. The 'new chemical entity' which develops out of intellectual creativity is only eligible to get protection. So to prevent this unjust monopoly the 'new' in Article 39.3 should be interpreted in strict standard in par with the 'novelty' in patent. An interpretation which is in consonance with the interest of developing countries and also reasonable is 'new chemical entity' does not constitute new indications, dosage forms, combinations, new forms of administration, crystalline forms, isomers and the second use of known substance.

The question of whether or not new indications, formulation and dosages should benefit from their own new periods of data exclusivity was raised in United Kingdom. In the Generic case[37], UK High court referred a number of questions relating to the proper interpretation of Article 4 of Directive 65/65/EEC up to the European courts. Following an initial marketing authorization, subsequent data relating to new indications, routes of administration and dosages was generated and

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[34] Normally in the case of modification of use, dosage or combination developers produce results of truncated trials and not whole. The argument raised for broad interpretation is wrong.

[35] A large number of drugs are not qualified for patent protection, especially after the development of biotechnology because it contains naturally occurring substances. In some jurisdiction no protection of patent is provided if substance contains naturally occurring substances or some times new drugs may fail in one or two patentability criteria.

[36] Extension of Patent period beyond the normal period of protection by making small changes.

[37] *R. v The Licensing Authority established by the medicines Act* 1968, exp. *Generics (UK.) limited , R.v The Licensing Authority established by the medicines Act* 1968,exp.*The welcome foundation Limited, R.v The Licensing Authority established by the medicines Act* 1968,exp Glaxo operations UK Limited and others,(Generics),case c-368196[1999]2c.M.L.R.181.

submitted to the medicines control agency by these firms, leading to new or varied marketing authorizations. So, the question that was raised was; whether these new indications, routes of administration and dosages be protected with their own new period of data exclusivity, as a reflection of the investment made by the firms generating that data. The originator firms argue that these new indications at least ought to benefit from a new period of data exclusivity. The generic firms were of the opinion that they ought to be able to be register according to abridged procedure provided for under article 4.8(a) (iii) of Directive 65/65/EEC as amended, and that new indications should not receive a separate period of data protection. The Medicines Control Agency (MCA) marketing authorization for the generic medicinal product will extend to all therapeutic indications except where those modifications constitute an innovation of considerable therapeutic importance. The European Court of Justice (ECJ) in its judgment held that only products in the light of scientific knowledge that it differs significantly from the original product as regards safety or efficacy could claim further protection.

So it is clear that the term 'new chemical entity' in Article 39.3 of the TRIPS Agreement is interpreted in different ways in different jurisdictions. TRIPS Agreement provides individual countries sufficient freedom to adopt suitable definition to provisions for safeguarding their public health and growth of domestic industry. By interpreting the term "new chemical entity" in the light of object and principles of TRIPS Agreement and also according to Para 4[38] and 5 (a)[39] of Doha Declaration of Public Health[40], is in the interest of developing countries.

Member countries are thus under no obligation to provide protection when approval is sought for new indications, dosage forms, combinations, new forms of

[38] Paragraph 4 of Doha Declaration reads, "We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members right to protect public health and in particular, to promote access to medicines to all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for the purposes".

[39] Paragraph 5(a) of Doha Declaration of Public health reads, "In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles".

[40] Adopted in November 14,2001,full text available in http/www.wto.org, last visited in 27 Nov, 2005.

administration, crystalline forms, isomers etc, of existing drugs since there would be no novel chemical entity involved.[41]

III.6.2. Considerable Effort: What It Means

Article 39.3 calls for protection of data "the origination of which involves considerable effort". If the term 'considerable effort' interpreted in the ordinary meaning, it means "the concentrated or special activities, physical or mental, that are extensive in scope or duration. The wording used in Article 39.3 is broader than that has been employed in Article 70.4, where for example reference to "significant investment" is made.[42] Because here effort involved should not only be significant in economic terms, but also from a technical and scientific point of view including experimental activities.[43]

By including the term 'considerable effort' as a condition in TRIPS Agreement Article 39.3 once again extends intellectual property protection to investment and labour which might disrupt the essence of a system conceived to reward the creators of original ideas and new inventions.[44] The concept of considerable effort which includes economic, technical, intellectual and labour is difficult to ascertain, unless the originator companies themselves reveal or any independent committee finds it. According to one view, a viable solution will be to give protection to data generated for new drugs with new molecules as it can easily be said to be result of considerable effort.[45]

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[41] See N.S Gopalakrishnan , no.28.

[42] Article 70.4 of TRIPS Agreement read as "in respect of any acts in respect of specific objects embodying protected subject matter which become infringing under the terms of legislation in conformity with this agreement, and which are commenced, or in respect of which significant investment was made, before the date of acceptance of the WTO Agreement by that member, any member may provide for a limitation of remedies available to the right holder as to the continued performance of such acts after the date of application of this agreement for that member. In such cases that member shall, however, at least provide for the payment of equitable remuneration".

[43] UNCTAD-ICTSD project on *Intellectual Property Rights and Sustainable Development, Resource Book on TRIPS and Development* (Cambridge university press, New York), 2005, p. 531.

[44] According to Trans Atlantic Consumer Dialogue (TACD), "data exclusivity provisions are part of a growing class of suigeneris forms of protection that are designed to protect investment, rather than innovation. Because data exclusivity is not a reward for invention (which is already rewarded by patents) but rather a protection of investment, there should be greater transparency of the basis for the protection and a reasonable relationship between the investment and protection", available at http//www.tacd.org, last visited 26,May,2005.

[45] N.S Gopalakrishnan and Benoy .K. Kadavan *Study on Test Data protection in India,* (Eastern Book Company ,Lucknow),2005.

III.6.3. Unfair Commercial Use

TRIPS Agreement Article 39.3 provides that submitted Test Data should be protected against unfair commercial use. Unfair commercial use in Article 39.3 should be interpreted in the light of Article 10 *bis* of Paris Convention. The concept of unfair competition is different in various countries according to the extent of competition in the market, however, interpretation of unfair commercial use by developed and developing countries are different. According to EU and US any use of data submitted by the originator, for granting approval to a subsequent applicant without the authorization of the originator of the data must be treated as an unfair commercial use. This include, disclosing the undisclosed data, exempting the second applicant from producing data based on publication, granting market approval for the subsequent applicant with out insisting for the data since the product is already approved and use of the originators data for comparing the data submitted by subsequent applicants. The only way, to effectively achieve this is to provide an exclusive period of protection for the data, so that the data of the originator could not be used by anyone without permission.[46]

The rationale for this argument is that the originators invested millions of money for the compilation of data. Pharmaceutical companies understandably argue that it is unfair, if the product of possibly millions of dollars of clinical trials and other investigations were made available to competitors who thereby avoid the need for comparable expenditure in order to obtain marketing approval.[47]The developed countries argue that "The Agreement does thus contain an obligation to protect test data against unfair commercial use and that the most effective method of doing so is to deny the regulatory authorities the possibility of relying on such data for a reasonable period of time. Further more, data protection should be available, whether or not the product is subjected to regulatory approval and is protected by patent or not, since data protection is quite a different issue from patent protection".[48]

The office of the General Counsel of USTR defines 'unfair commercial use' in the following manner,

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[46] Ibid.

[47] Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy*, London.

[48] Quoted from paper submitted by the EU to TRIPS council for special discussion on intellectual property and access to medicines,20 June 2001,available at http// www.wto.org, last visited 16 June ,2005.

> TRIPS Agreement understood it to mean that the submitted data will not be used to support, clear or otherwise review other applications for marketing approval for a set amount of time unless authorized by the original submitter of data. Any other definition of this term would be inconsistent with the logic and negotiating history of the provision.[49]

Government of New Zealand stated that

> Defining unfair commercial use can only properly be done by reference to the context of the complete provision, the purpose behind the provision. In the light of this we interpreted Article 39.3 that there is a restriction on the use of which regulatory authorities can make of original data which they hold in order to approve subsequent applications for approval of generic medicines, animal remedies or pesticides.

In other words where undisclosed information is provided to a regulatory authority by an applicant so that the authority can approve the applicant's product, if this information is then used by the authority to approve the product of a second applicant, this is, in New Zealand's view "unfair commercial use". In effect, the regulatory authority is giving a commercial advantage to the second applicant in that the applicant does not have to generate the data, which was required of the first applicant. This can be a significant economic saving.[50]

The EU addresses the unfair commercial use in Article 39.3 in the following manner,

> The main question of interpretation is what is meant by unfair commercial use. Clearly this concept is different from the concept of unfair competition, as used in Article 39.1 of the TRIPS Agreement with reference to Article 10 *bis* of the Paris convention on the protection of industrial property, and which relate to behavior among competitors. Protection of registration data is a government function. Article 39.3 does not indicate, whether the notion of 'unfair commercial use' refers to unfair commercial use by generic manufactures, to those who have submitted the data, or the use by regulatory authorities of these data for the benefit of competitors.[51]

As per the interpretation given by the developed countries not only is the second applicant, but even the regulatory authorities are prevented from using the

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[49] The Protection of Undisclosed Test data in accordance with TRIPS Article 39.3 (May1995),Cited in PHRMA,PHRMA SPECIAL 301 SUBMISSION:PRIORITY WATCH LIST COUNTRIES,at45(2002),available at http:// www.phrma.org/international/resources/2002-02.22.45, pdf, (Last Visited March 6, 2005).

[50] Government of New Zealand, Presentation at the APEC seminar on the TRIPS Agreement on protection of Undisclosed information and control of Anti-competitive practices,(May 17-19,1995).

[51] Lucas R. Arrivillaga "An International Standard of Protection for Test Data Submitted to Authorities to obtain marketing authorization for drugs, TRIPS Article 39.3", *Journal of World Intellectual Property*, Vol.6, .Jan 2002, p.151.

originator's submitted test data, when they examine subsequent applications of same drug for marketing approval.[52]

The interpretation given by these countries are against the 'Right to Health' enshrined in the International Human Right Covenants. If this interpretation is accepted, which is on the behest of multinational drug companies, it will result in the death knell of the health sector, and will damage the generic sector pharmaceuticals. The interpretation given by the developed countries, which they claim comply with the TRIPS Agreement is against not only the objects and principles of TRIPS Agreement but also against Doha Declaration of public health, 2001.

On the contrary, developing countries argues that Article 39.3 does not require the recognition of exclusive rights, but protection in the framework of unfair competition rules. By linking test data protection with unfair competition under Article 10 *bis* of Paris convention, there is no scope for exclusive right. By Article 39.3 of the TRIPS Agreement there is an obligation on the part of all WTO member countries to Provide protection to test data. The obligation is only to prevent the dishonest use of submitted test data by third parties. However, under the TRIPS Agreement governmental authority would not be prevented from relying on the data presented by one company to assess the submissions by other companies relating to similar products. If the regulatory body were not free, when examining a file, to use all of the knowledge available to it including data from other files, a great deal of repetitive toxicological and clinical investigation will be required which will be wasteful and ethically questionable[53].

Developing countries in a paper submitted to the TRIPS Council, argue that "the unfair commercial use" of confidential data, means that a third party could be prevented from using the results of the test undertaken by another company as background for an independent submission for marketing approval, if the data had been acquired through dishonest commercial practices. However, Article 39.3 does

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[52] The reason behind this position is that "equity demands that protection be provided for data, which can cost the original submitter several million dollars to produce. Disclosing this data to the public or allowing its use by another applicant unfairly denies the compiler of the data the value of its efforts and grants an economic advantage to later applicants for marketing approval enabling them to avoid the cost of developing test data for their own products. Countries that allow such unfair advantages to later applicants discourage developers of new pharmaceuticals and agricultural chemicals from seeking to introduce their state-of-the-art products in the countries market. so not only is such protection required by the TRIPS Agreement ,it is both equitable and wise from a public health policy standpoint.

[53] See UNCTAD-ICTSD, no.43.

permit a national regulating authority to rely on data in its possession to assess second and further applications, relating to the same drug, since this would not imply any "unfair commercial use"[54].

The most liberal interpretation in respect of protection against unfair commercial use was proposed by one scholar, the expression 'unfair commercial use', reasonably interpreted, does not sustain a reading that Article 39.3 requires provision of exclusivity or of compensation. It has left wide room for manoeuvre for member countries to determine,

(a) when such use exists, and

(b) the means of protection.

An unfair commercial use may be determined to exist, for instance, in situations in which a competitor obtains through fraud, breach of confidence or other 'dishonest' practices, the results of testing data and uses them to submit an application for marketing approval in its own benefit. It would also apply in cases where the government provides access to undisclosed testing data in order to provide an advantage to a firm, which did not produce them or share their costs[55]. But the use of submitted test data by the governmental authorities for conducting its statutory functions constitute fair use.

This opinion represents substantially the view of the developing countries in respect of the minimum standard of protection imposed by TRIPS Article 39.3, as expressed in the position stated by the United Nations Conference on Trade and Development (UNCTAD) in 1996[56]. Even the generic industries in Europe represented by European Generic Association (EGA) have the same opinion[57].

The effect of data exclusivity affects the generic companies which lack the resources for doing clinical trials. These companies consider data exclusivity as a model of extending monopoly or ever greening of patent by the originator companies.

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[54] Paper submitted by Africa Group, Barbados, Bolivia, Brazil, Dominical Republic, Ecqador, Honduras, India, Indonesia, Pakistan, Jamaica, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela available at www.commin.nic.in/doc.wtotrips3.htm, last visited Feb 27, 2005.

[55] Razvan Dinga " The Bermuda Triangle of Pharmaceutical law is data protection a lost ship"?, *Journal of World Intellectual Property*, Vol. 8, No. 4, July 2005. P.526.

[56] UNCTAD, The TRIPS Agreement and Developing countries, UNCTAD/ITE/1, New York and Geneva, 1996 at 48.

[57] See European Generic Medicines Association, TRIPS Article 39.3 does not require Data Exclusivity Provisions – A critical issue for access to medicines, Position Paper, July 2000, available at www.egagenerics.com/doc/ega_trips39.3, 2000.pdf, last visited 19 March 2005.

The European Generic Association (EGA) argues "data exclusivity merely extends the originator companies market monopoly over a product by not allowing the authorities to process an application for marketing authorizations.[58]

Some developing countries provide a strict obligation of the competent authorities to keep submitted test data undisclosed. However, they do not preclude, but rather foresee, that applicants for generic products, instead of submitting their own set of test data to the authority, would prove the identity of their product with an already registered (Bioequivalency testing). If this identity is established the authority will then not require any additional test results regarding safety and effectiveness of the product[59].

The practice of a regulatory authority using the data submitted by a first applicant in order to make the assessment necessary to grant marketing authorization to a subsequent applicant is perfectly consistent with the requirement prohibiting "unfair commercial use". This is the argument raised by most of the developing countries. They argue that states have freedom to determine how to implement provisions within their own legal system and practice.

Thus Article 39.3 should be interpret in the light of the object and principles of TRIPS Agreement and subsequent developments in the area of right to public health.. Thus, a third party should be prevented from using the results of the test undertaken by another company as a background, for an independent submission for marketing approval. If the respective data had been acquired through dishonest commercial practices[60]. Dishonest commercial practice is expressly prohibited under protection against unfair competition enshrined in Article 10 *bis* of Paris Convention and Article 39 of TRIPS Agreement. The role of regulatory authority in assessing the application is a statutory function. Hence, the government authority would have to rely on the

[58] European Generic Association-"Data Exclusivity: A Major obstacle to innovation and competition in the EU pharmaceutical sector ",http;//www.egagenerics.com/gen-dataex-htm, last visited, 9 July, 2005.
[59] Ingo, Mertinger, "Implementation of test data protection according to Article 39.3 TRIPS 'The search for a fair interpretation of the term 'unfair commercial use'" *Journal of World Intellectual Property Right*, Vol.8, No.2, March 2005. P.130.
[60] Article 39.2 reads "Natural and legal persons shall have the possibility of preventing information lawfully with in their control from being disclosed to acquired by, or used by others without their consent in a manner contrary to honest commercial practices". "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 practice were involved in the acquisition.

data presented by one company to assess submissions by other companies related to the similar product.

According to one scholar, 'commerciality' in Article 39.3 "clearly excludes use by the government, notably by the national health authority to assess the efficacy and toxicity of a pharmaceutical or agrochemical product. The examination of the data submitted by applicants with a view towards granting marketing authorization represents and administrative use for the purposes of protecting public health by an assessment of the efficacy and toxicity of the pharmaceutical products prior to their marketing from this perspective, this is used for public interest and not for commercial use[61].

A legitimate non commercial use would presumably encompass use by various government departments to avoid any health or safety risk revealed by the data in local environment. Similarly, "the promotion of research and science in public interest would presumably allow some uses of the data that would be both non-commercial and consistent with any research exemption embodied in domestic patent laws".[62]

According to another scholar, The WTO members have considerable discretion to define 'unfair commercial use' in the context of national laws. So the argument is that the use of the data by drug regulatory authorities to assess the efficacy and toxicity of pharmaceutical and agrochemical product is not a commercial use. Hence the obligation to protect test data is met where the national law prohibits the use of data through 'misappropriation': getting commercial advantage by use of the data through fraud, breach of confidence or other dishonest practices or uses. In this context countries need not protect test data through the grant of exclusive rights and the need for adoption of data exclusivity does not arise.[63]

After examining the arguments raised by both sides it is clear that Article 39.3 provided enough flexibility for countries to enact test data protection provisions in their national jurisdiction considering the interest of the public and the survival of both pharmaceutical and agricultural industries. There is no obligation on the part of countries to include data exclusivity in their domestic law. Article 39.3, mandates the

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[61] Razvan Dinga, "The Bermuda Triangle of Pharmaceutical Law is data protection a lost ship"? *Journal of World Intellectual property*, Vol.8, No. 4, July. 2005. P.525.
[62] Ibid.

protection of submitted test data in line with the protection given to the undisclosed information. The provision provides disclosure of test data in the public interest, but steps are necessary to avoid unfair commercial use. Some countries like India do not have provisions to keep submitted test data secret. So there is obligation for these countries to protect submitted test data form unfair commercial use by amending the respective legislations. And the regulatory authorities are free to rely on the originators submitted test data when they deal with the marketing approval of subsequent manufacturers.

III.7. Consultation at WTO

There is no conclusive WTO Jurisprudence on this subject. However, at the request of United States, US and the Republic of Argentina have undergone a process of consultation about the Argentine law of test data protection.[64] The main point of contention of the US was that, while prior to August 1998, the Government of Argentina provided a ten year term of protection against unfair commercial use for undisclosed test or other data submitted to Argentinean regulatory authorities in support of applications for marketing approval for agricultural chemical products, it had stopped that practice thereafter.

Regulation 440/98 of the Argentinean law concerned the approval or authorization for commercialization of a pharmaceutical product. The authorization requires that certain information pertaining to the efficacy of the product be made available to the local health authority. This law protects the information from dishonest commercial use and shall not be disclosed. However, under Article 5, "similar products" can be approved or authorized by the "local sanitary authority", once the original product has been registered in Argentina. [65]

On 20th June 2002 the United States and Argentina notified the WTO Dispute Settlement Body of a mutually agreed solution[66] in which, *inter alia*, they stated that;

> The Governments of the US and Argentina have expressed their respective points of view on the provisions of Article 39.3 of their TRIPS Agreement, and they have agreed that the differences in interpretations shall be solved under the DSU

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[63] Sisule.F.Musungu, "Use of Flexibilities in TRIPS by Developing Countries. Can They Promote Access to Medicine", Commission of Intellectual Property Rights, Innovation and Public Health, London, Available at www.cipr.uk, last visited July 14,2005.
[64] See WT/DS 171/3; WT/DS 196/1.
[65] IIFT, "*Article 39.3 of the TRIPS Agreement:Its Genesis and the Present Context*": Indian Institute of Foreign Trade, New Delhi:2003 ,p 41.
[66] See WT/DS 171/3.

> rules. The parties will continue consultation to assess the progress of the legislative process, and in the light of their assessment, the US may decide to continue consultations or request the establishment of a panel related to Article 39.3 of the TRIPS Agreement.
>
> In addition, the parties agree that should the DSB adopt recommendations and rulings clarifying the content of the rights related to undisclosed test data submitted for marketing approval according to Article 39.3 of The TRIPS Agreement, and should Argentinean law be inconsistent with Article 39.3 as clarified by the above-mentioned recommendations and rulings, Argentina agrees to submit to the national congress within one year an amendment to Argentinean law as necessary, to put its legislation in conformity with its obligations under Article 39.3 as clarified in such recommendations and rulings.[67]

Apart from TRIPS Agreement, World Intellectual Property Organisation (WIPO) also attempted to evolve a model provision on protection against unfair competition, with particular reference to test data protection. Article 6 (4) of the model provision deals with test data protection.

Article 6(4) provides that

> (a) use or disclosure of secret information submitted for procedure for approval of market, any act or practice, in course of industrial or commercial activities shall be considered an act of unfair competition. If it consist or results in (1) unfair commercial use of secret test or other data, the origination of which involves considerable effort and which have been submitted to a competent authority for the purpose of obtaining approval of marketing of pharmaceutical or agricultural chemical entities (2) disclosure of such data, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use (This provision shall not apply to secret information containing Pharmaceutical products until January.1, 2016).

It tries to promote a high standard of fairness in this field. But the provision almost like TRIPS Agreement Article 39.3 and gives no supplementary indication in this respect. The official commentary of the drafters mentioned that,

"Protection is given only to pharmaceutical and agrochemical products which utilizes new chemical entities. The manner in which the information is obtained is immaterial to the act or practice being considered an act of unfair competition. It may be obtained from the authority either directly or indirectly. The unfairness of the act arises from the fact that the enterprise has not developed the test or other data itself and thus avoided the expense of producing them".[68] In order to get protection against unauthorized use or disclosure, the test or other data must be result of considerable effort in relation to test or other data, already available in the pharmaceutical and

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[67] See .ibid, para (9) "Protection of Test Data against Unfair Commercial Use".

[68], WIPO, *Model Provisions on Protection against Unfair Competition, Articles and Notes*, WIPO, Geneva, Switzerland, 1996, p.58.

agricultural chemical field. 'Unfair Commercial use' means, the use of data in question to produce the same or similar products. Such use would not normally be made by the authority in question but by third parties, it could so take the form of sale of data to others. The act of disclosure of test data is considered as an act of unfair competition. The unauthorized disclosure may consist in publishing the information or passing it to others, for example research purposes. Such disclosure should be considered as act of unfair competition regardless of whether the person who has disclosed the information receives any financial remuneration for disclosure. Article 6(4) provides two exceptions where disclosure of test or other data is not considered as an act of unfair competition. The exception would apply to disclosure by a public authority. The first exception applies where the disclosure is necessary to protect the public, notably for the purposes of health protection. The second applies where steps have already taken to ensure that the data are protected against unfair commercial use".[69]

To ignore the negotiating history of Article 39.3 in favour of exclusive right of data is against the legal principles and fair trade. The discredition of 'rule of law' by the developed countries is against the treaty interpretation of international law. With the deletion of bracketed version of Brussels draft of 1990 from the Dunkel draft of 1991 and the final Agreement of 1994, there is no room for any interpretation that would grant a defacto exclusive property rights on the scheme of protection for regulatory data that Article 39.3 actually mandates.Article 39.3 provide exceptions from protection when actions are necessary to take in public interest. Thus states have the freedom to use the exceptions for taking actions in public interest. The reliance of originators submitted test data by regulatory authorities when examining the subsequent applications is not a proscribed use or unfair commercial use under Article 39.3 of the TRIPS Agreement.

[69] Ibid.

CHAPTER IV

BILATERAL AND OTHER MULTILATERAL APPROACHES

IV.1. TEST DATA PROTECTION IN FTAs AND RTAs

The inclusion of intellectual property provisions in Free Trade Agreements (FTA) and Regional Trade Agreements (RTA) are part of a coordinated process to make intellectual property norms globalize at an increasing rate. The two actors responsible for this process are the US and the EU. All of these FTA and RTA contain provisions to the effect that a party to such an agreement may implement more extensive protection than required under the TRIPS Agreement, or that agreement does not derogate from the other agreements providing even more favourable treatment.[1] . Through these agreements, developing countries are obliged to comply with multilateral standards in conventions to which they are not party. For example, the Jordan FTA requires Jordan to give effect to Articles 1- 14 of World Intellectual Property Organization (WIPO) Copyright treaty and to ratify the International Convention for the Protection of New Varieties of Plants (UPOV).[2]

The bilateral and regional trade agreements are used to curtail developing countries interest by adhering to 'TRIPS –PLUS' standards,[3] which will further restrict their options for enhancing access to medicines. In the case of test data protection, which is already present in the early US bilateral agreements like, the one concluded in 2000 with Vietnam, are more stringent in later agreements, such as those with Chile, Morocco and notably, the Central American Free Trade Agreement (CAFTA).[4] Even the word used by developed countries in these FTA's and RTA's for test data protection is 'Data Exclusivity', which means providing exclusive property rights to submitted test data. A study conducted by Organization of Economic Cooperation and Development in 2002 finds that most "RTA's dealing with intellectual property rights have far-reaching provisions than those found in the TRIPS Agreement".[5] In the case of test data protection, the US is the "demandeur", in the sense that FTA's and RTA's between the US and developing countries are based

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[1] See for example, Article 1702 of NAFTA, Article 4.1 of the Jordan FTA and Article 11 of the Nicaraguan bilateral investment treaty.

[2] Peter DRAHOS "BITS and BIPS", Bilateralism in Intellectual Property", *Journal of world intellectual property*, Vol. 7. 2004. p.799.

[3] Ibid.

[4] Karin Timmermans "Interwining Regimes: Trade, Intellectual Property and Regulatory Requirements for Pharmaceuticals", *Journal of World Intellectual Property*, vol.8, 2005, p.71.

[5] OECD-Trade Directorate, *"Regional Trade Agreements and the Multilateral Trading system"*, (Paris :20 November 2002).TD/TC (2002) 8/final .

on the data exclusivity standards of the former. In other words, it would seem that the regional and bilateral negotiating tracks lead developing countries to agree to commit to a level of test data legislation that is substantially higher than the level of TRIPS Agreement.[6]

IV.I.I. North American Free Trade Agreement (NAFTA)[7]

NAFTA was adopted with United States, Canada and Mexico as parties. It is the first bilateral agreement which expressly includes test data protection. In Article 1711 (5), (6) and (7) NAFTA require a party that mandates the disclosure of trade secret information for marketing approval of pharmaceutical or agricultural chemical products to protect against the disclosure of data. However, this disclosure protection is only required where the origination of the data involved considerable efforts, but there is exception from disclosure of protection, if the use of data is necessary to protect the public. In addition, data submitted to the government by a party for approval of pharmaceutical or agricultural chemical products may not be used by any person, other than the person that submitted the data in support of an application for product approval, during a reasonable period and it is normally not less than five years from the date on which the party granted approval to the person that produced the data for approval to market its products. The concept of "considerable effort" in the TRIPS Agreement is also included in NAFTA, subject to above conditions. The parties are not restricted from implementing abbreviated approval procedures for pharmaceutical and agricultural chemical products on the basis of bioequivalent and bioavailability studies.[8]

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[6] Meir perez PUGATCH, "*Intellectual property and pharmaceutical data exclusivity in the context of innovator and market access*" .ICTSD UNCTAD Dialogue on Ensuring policy options for affordable Access to Essential medicines, Bellagio, 12-16 Oct, 2004, p.18.

[7] North American Free Trade Agreement. US-Can-Mex, 107 stat 2057, 32 ILM 605 (1993).

[8] Article 1711(5) of NAFTA states- If a party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the party shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use.

Article 1711(6) of NAFTA states-Each party shall provide that for data subject to paragraph 5 that are submitted to the party after the date of entry into force of this agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during the reasonable period of time after the submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the persons effort and expenditures in producing them. Subject to this provision, there shall be no limitation on any party implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.

In comparison with the test data protection provision in the TRIPS Agreement, the provisions relating to the protection of test data in NAFTA is more extensive. It expressly prohibits the reliance of the data for a reasonable period of time which was there in the Brussels draft of TRIPS Agreement, but was however excluded from the final TRIPS Agreement.

IV.1.2. Central American Free Trade Agreement(CAFTA)

Central American Free Trade Agreement (CAFTA)[9] considerably modifies the TRIPS approach towards protecting undisclosed information. By Articles 15.10(1) (a).&(b), it mandates a five year data exclusivity period for pharmaceutical products and ten year data exclusivity period for agrochemical products from the date of approval was granted by party to the person received authorization in other territory[10]. So waiting period fully utilized, it may enjoy at least 10 year data exclusivity for pharmaceuticals and 15 years data exclusivity for agrochemical products, during which no other party could be able to use the relevant test data or rely on a foreign marketing approval. In CAFTA the concept of 'new chemical entity' is limited to entities not previously approved by the same parties.[11] CAFTA also includes a provision which will extend data exclusivity to the full term of patent[12], which might affect the governmental use of compulsory license.

Another FTA involving United States but still in the negotiating process is Free Trade Area of Americas [FTTA], which consists of 38 members. A draft agreement which was finalized provides for a TRIPS –PLUS regime of intellectual

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[9] Text available at http://www.ustr.gov/new/fta/cafta/final/index.htm>, USA, Costa Rica, Elsavador, Guatemala, Honduras and Nicaragua signed this agreement on 28 may 2004.

[10] For example, an originator got marketing approval in Nicaragua on 12-5-2005 for a pharmaceutical product. That person wants to submit only before 12-5-2010 in USA to data exclusivity. That is effectively 10 year data exclusivity in USA. He can prevent 10 year a generic manufacturer from getting marketing approval in USA. Other side is that, originator can keep the US market with out supply of the product eligible for data protection for at least 5 years.

[11] Carlos. M. Correa "*Protecting Test Data for Pharmaceutical and Agrochemical Products under Free Trade Agreements*, "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. Last visited 24 August, 2005.

[12]Article 15.10 (3) (a) of CAFTA provides –"where a party permits, as a condition of approving the marketing of a pharmaceutical product, persons other than the person originally submitting safety or efficacy information, to rely on evidence product that was previously approved, such as evidence of prior marketing approval in the party or in another territory, that party shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claming the product or its approved use during the term of that patent, unless, by consent or acquiescence of the patent owner.

property protection. Section 10 of the proposed draft FTAA intellectual property defines a frame work for the protection of undisclosed information. This frame work provides protection for a period of at least 5 years from the date of approval granted to the party submitting such information. The proposed protection does not mention the confidential character of the information, and it refers to data on the safety and efficacy of the product whether it is confidential or not. This would basically mean that the prohibition to access information would apply not only to confidential information, but also include information that is available in the public today. In addition unlike TRIPS Agreement, it would apply to new products or mere variants on already known products. This would limit the use of important information for timely compulsory licensing and would imply the erection of artificial barriers to the entrance of competitive products, which do not appear to be required for the protection of intellectual assets.[13] Additionally, if data pertaining to a patented product were protected the term of data protection would not be altered even if the patent term expires earlier. In other words, the patent holder would be able to get extended term of protection on the data pertaining to the product in question.[14]

In a submission given by United States Trade Representative (USTR), to the WHO Commission on IPR, Innovation and Health Care. It was argued that the intellectual property provisions included in FTA and regional agreements negotiated by US and its trading partners, have been referred as TRIPS –PLUS, because it is alleged by some, they impose obligation that extend beyond those expressly set forth in TRIPS Agreement and thus they violate the Agreement. Characterizing these provisions as TRIPS –PLUS is misleading, however because this provisions are fully comply with the frame work established by TRIPS Agreement. While it is true that these provisions often are more specific and provide greater intellectual property protection than provided by TRIPS Agreement. In the case of data exclusivity, the submission stated that "Data exclusivity" protection provide important and necessary incentive for research and innovation. The process of developing and testing a new pharmaceutical product requires a huge commitment of resources. The Data protection provisions contained in bilateral and regional FTA's thus benefit

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[13] David Vivas. Eugui, "*Regional and Bilateral Agreements and a TRIPS –PLUS World; The Free Trade Area of the Americas (FTAA)*" published by Quaker United Nations Office, Geneva, p 18.
[14] IIFT, "*Article 39.3 of the TRIPS Agreement :Its Genesis and the present context*": Indian institute of Foreign Trade, New Delhi,2003, p.45 .

developing countries by providing incentives to innovators to launch and register their products there after receiving the necessary approvals and in many cases the protection reflect already international practice.[15]

IV.I.3. Andean Community

The protection of test data is included in the common regime on industrial property of the Andean community. Article 266 provides an exclusivity period to submitted data. But Decision 486 introduced an important amendment to pre-existing regulation in relation to protection of test data. It eliminated the exclusivity period for the use of submitted test data.[16]

IV.2. Bilateral FTAs

Even in the bilateral level, also the United States is imposing TRIPS-PLUS obligation on developing countries. Under most of the recent FTAs entered between US and developing countries, test data protection falls under provisions relating to 'measures related to certain regulated products'. The bilateral agreements in this respect contain TRIPS – PLUS provisions, such as the prohibition of reliance on prior test data of both patented and off-patent products by marketing approval authorities; the requirement of local/national novelty of 'new chemical entities'(as opposed to universal novelty); the requirement to extend exclusive protection for five years to data that has been disclosed through the grant of marketing approval (as opposed to the limitation of protection to undisclosed data under TRIPS Agreement); and the extension of test data protection beyond the expiry of the corresponding patent.[17]

The US-Morocoo Free Trade Agreement imposes an obligation for 'non-reliance' on either the pioneer approval or the pioneer data package itself for a period of at least 5 years from the date of approval for a pharmaceutical product and 10 year from date of approval, for agricultural chemical product. It provides at least 3 years of non-reliance for new clinical information.[18]

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[15] Available at http//www.ustr.org (last visited Oct. 25,2005).

[16] See UNCTAD- ICTSD, foot note No. 11.

[17] Final Report *"Moving the Pro-development Intellectual Property Agenda Forward: Preserving Public Goods in Health, Education and Learning"*, The Fourth Bellagio Series of Dialogues on Development and Intellectual Property, UNCTAD-ICTSD Dialogues, Bellagio, Italy, 29 November- 3 December 2004.

[18] Draft Free Trade Agreement, US-Morocco, Article 15.10; Available at http// www.ustr.gov/new/FTA/Morocco/text/index.htm Last visited, May, 27 2005.

Article 17.10 of the US-CHILE FTA[19] places 5-years non-reliance, non-disclosure for pharmaceutical products and 10-years non-reliance, non-disclosure for agrochemical products. Article 17.10.2 (C) of the same agreement provides that national drug regulatory authorities shall not grant marketing approval for patented drug to a third party without the consent or acquiescence by the patent owner. Article 16.8 of the US-Singapore FTA, provides five years of data exclusivity from the date of the originator's approval mandated for pharmaceutical products (10 years for agricultural products). In cases where a generic supplier seeks regulatory approval based on data submitted in another country, the period begins on the date of approval in whichever country is later. If the patent expires before the term of data exclusivity, the data will still be kept confidential for the rest of the period.

US-Australia FTA provides five years of data exclusivity from the date of the originator's approval mandated for pharmaceutical products (10 years for agricultural products). If data is used to gain approval in another territory that provides up to five years of data exclusivity for drugs, the data exclusivity in that territory must be honoured in each party. Article 17.10(1). If a drug's patent expires before the period of data exclusivity, the data exclusivity remains in tact. Article 17.10(3)[20]. The US FTA with Singapore obliges the parties to apply a much broader concept of 'pharmaceutical and agricultural product' without specific reference to 'new chemical entities'.

The US bilateral agreement with Sri Lanka provides data exclusivity for a reasonable period of time. According to the agreement, 'Unless the person submitting the information agrees, the data may not be relied upon for the approval of competing products for a reasonable period of time, taking into account the efforts involved in the origination of the data, their nature, and the expenditure involved in their preparation, and such period of time shall generally be not less than five years from the date of marketing approval. However Sri Lanka did not implement it till 2000.[21] The US trade agreements with, Ecuador, Laos, Cambodia, Vietnam, Bahrain, Thailand and others includes data exclusivity provisions. In comparison with the US,

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[19] US-Chile Free Trade Agreement, chapter 17-intellectual property, http;//www.ustr.gov/assets/Trade-Agreements/Bilateral/Chile-FTA/ final text/PDF, last visited , June 19, 2005.

[20] US-Australia Free Trade Agreement, chapter 17-intellectual property, http//www. ustr. gov/ assets /Trade Agreements/Bilateral/ Australia. FTA/ Final-text/. Last visited- July 11,2005.

[21] K M Gopakumar, "*TRIPS Agreement Implementation and Public Health Safeguards*", (South Asian Year Book of Trade and Development, ,Centad, New Delhi), 2005, p.258.

the Intellectual Property provisions of new generation FTA's between EU and developing countries are not strict. The EU trade agreements with Chile, (Article169) of the agreement requires protection, including "protection of undisclosed information and protection against unfair competition as referred to in Article 10 bis of the Paris Convention for the protection of industrial property.

IV.3. Bilateral Trade Retaliation

United States is also using threat of trade retaliation against developing countries by including in priority watch list under Special 301 under Omnibus Trade and Competitiveness Act of 1988.[22] In 1996, the United States Trade Representative (USTR) initiated a special 301 investigation against Australia, claiming that Australia's drug marketing approval regime provided inadequate protection to drug approval data. It allowed subsequent registrants to rely on a prior marketing approval by showing bioequivalence. After two years of US pressure, Australia finally adopted a five year data exclusivity standard in 1998.[23] The USTR similarly sanctioned other countries that do not share its view of Article 39.3. In 1997, for example, the US administration withdrew Argentina's preferential tariff rates granted under the generalized system of Preferences reducing Argentinean imports into the United States by an estimated $ 260 million. The primary reason for withdrawal of benefits was that, although Argentina observed the drug data non disclosure requirement under Article 39.3, it allowed subsequent applicants to rely upon an initial registrant's marketing approval.[24]Thailand also does not guarantee data exclusivity, but has been similarly exposed to US pressure. Taiwan has also been pressured by the United States, which complains that Taiwanese legislation on data exclusivity does not meet WTO requirements.[25] In response to pressure from the U.S. government, Taiwan decided to take measures to regulate and protect the data of pharmaceutical

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[22] The key mechanism to combat the infringement of US IPR is established under a special provision of the 'Omnibus Trade and Competitiveness Act of 1988 called "special 301".Since the 1998 Trade act become law, United States Trade Representatives (USTR) has created three list for those foreign countries which fail to meet US standards on intellectual property protection. These lists are (1) Priority foreign countries (2) priority watch list (3) watch lists. The 1988 Trade Act allows the USTR to identify those countries whose practices are deemed to constitute barriers to US commerce as well as to conduct an investigation concerning their practices .The USTR also enjoys full authority to take away action it deems appropriate to retaliate against the foreign country concerned.

[23] Therapeutic Goods Legislation Amendment Act,1998,No.34 (Australia).

[24] Aaron Xavier Fellmeth, "Secrecy, Monopoly, and Access to Pharmaceuticals in international trade law: Protection of marketing approval data under the TRIPS Agreement". *Harvard International Law Journal.* vol. 45 Number 2, summer 2004 ,p.457.

[25] Ibid.

companies. On September 22, 2004, Taiwan's government approved draft amendments to their Pharmaceutical Affairs Law. Under these new amendments, foreign pharmaceutical companies will be given a five-year period for the protection of pharmaceutical tests and studies on new products, as well as a three-year protection period for improvements on existing products.

In its recent "Special 301" submission, the (Pharmaceutical Manufacturing and Research Association of America) PhRMA[26] has commented that 'time has come for the US Government to consider the launch of a WTO dispute settlement case on data exclusivity'. According to PhRMA, 'the simplest and straight forward case might be against a WTO member that does not provide any data exclusivity at all'.[27]

Another example is the launch of an investigation by the European commission against Turkey in December 2003, following a complaint by European Federation of Industrial and Pharmaceutical Association (EFPIA).The investigation concerns obstacles to trade allegedly caused by Turkish practices and measures involving lack of Transparency, discriminatory application of the pharmaceutical import, sales and marketing system, including a "lack of protection of commercially sensitive data submitted as part of marketing approval procedure".[28]

In the USTR 2002, Special 301 Report, which indicated that the "United States is actively considering the initiation of new WTO cases, for later this year or early next year against certain WTO members that appear not in compliance with their TRIPS obligations". The USTR Special 301 Report of 2005 also states that "one of the key implementation priorities that we have focused on this year's review is implementation of Article 39.3 of TRIPS Agreement, which requires WTO members to protect test data submitted by companies to health authorities against 'unfair commercial use' for pharmaceuticals and agricultural products."[29] Due to the

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[26] PhRMA, which represents and lobbies for the powerful US Pharmaceutical and Biotechnological industry, claims that exclusivity should be granted for no fewer than ten years. They play vital role in the inclusion of strict provisions of intellectual property in the Uruguay round negotiations.

[27] PhRMA, submission of PhRMA for the "SPECIAL 301" Report on INTELLECTUAL PROPERTY BARRIERS, available at http://www.cptech.org/ip/health/phrma/301-99/301.htm last visited August 17,2005.

[28] European commission, Notice of intimation of an examination procedure concerning obstacles to trade within the meaning of council regulation (EC), No 3286/94, consisting of measures imposed and practices followed by the Republic of Turkey affecting Trade in Pharmaceutical product, 2003 , *Official journal of the European Union.*

[29] Available at http//www.ustr.org (last visited ,Sep. 5,2005).

considerable efforts involved in producing the safety and efficacy data needed to obtain marketing approval, the TRIPS Agreement requires that the original applicant must receive protection for that data against unfair commercial practices. Accordingly the US and other countries provide a period of protection during which second-comers may not rely on the data submitted by the innovative company to obtain marketing approval for their copies of the product. This means that, during the period of exclusivity, the data provided by the originator cannot be relied upon by regulatory approval of similar product.[30]

This year's priority watch list includes Argentina, India, Israel, Pakistan, Turkey and others for the lack of test data protection (Data exclusivity). In the case of Argentina even after May 2002 US-Argentina agreement on partial settlement of WTO dispute settlement initiated by US, still Argentina does not provide protection from unfair commercial use for confidential data submitted by research-based pharmaceutical companies. In the case of India, the report says that, India has yet to implement a TRIPS compliant regulation to protect confidential test and other data submitted by innovative pharmaceutical and agricultural chemical companies seeking marketing approval for their products against unfair commercial use[31]. There is tremendous pressure from the United States on India and Pakistan to implement data exclusivity; the former put both countries on priority watch list for this reason[32]. United States includes Vietnam in this year watch list, because US pharmaceutical industry is concerned that there are no provisions in Vietnamese law to protect test data against unfair commercial use, which is a requirement under TRIPS Agreement and Bilateral Trade Agreement.

So the US Omnibus Trade and Competitiveness Act of 1988 is designed as a powerful tool to enable the US administration to enforce US rights and scale down foreign trade barrier. However, it is doubtful, whether the imposition of trade leverage is compatible with WTO substantial provisions for Dispute Settlement[33], which

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[30] Ibid.
[31] Ibid.
[32] See Gopakumar, no.24
[33] Article 23.1 of the WTO Dispute Settlement Understanding states, "When Members seek the redress of a violation of obligations or other nullification or impairment of benefits under the covered agreement or an impediment to the attainment of any objective of the covered agreement, they shall have recourse to, and abide by, the rules and procedures of this Understanding.

requires a member to request consultations with other party concerned to resolve the dispute before trade concession can be suspended.[34]

Although USA failed to make its case for data exclusivity in WTO, it is successful in incorporating TRIPS –PLUS standards like data exclusivity and patent term restoration[35] in the fora, such as FTA's and RTA's. The changing of the fora is basically part of the US agenda in the case of intellectual property. After finding WIPO hard to crack, they shifted IPR into WTO negotiations. Then in WTO, when developing countries becoming stronger they shifted to RTA's and FTA's.[36]USA and EU tried to scuttle the efforts of the developing countries to prevent TRIPS-PLUS agenda fruitless. They broke the alliance of the developing countries in the area of IPR like they are trying to break G-20 and G-33 in Agriculture negotiations by giving some favours to individual countries.

The TRIPS -PLUS agenda like data exclusivity, patent term restoration, reducing flexibility of invoking compulsory licence, patenting of life form, business method patents or software patents will clearly affect the interest of developing countries. The recent case of the introduction, removal and re-introduction of data exclusivity in Guatemala is also a crystal clear demonstration of the way in which the

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[34] The consistency of the authorization given to the US government to retaliate under several sections of the US Omnibus Trade Act was examined by a WTO panel in the case initiated by the EU. However on the basis of a commitment by the US government not to unilaterally apply sanction panel cannot find any WTO violation. This interpretative principle invoked by WTO dispute settlement body in USA-US-301 case. The EU complained about the application of several section of US law authorizing the US executive to retaliate countries which *interalia* did not provide adequate level of Intellectual Property Rights. But the panel did not find USA in violation of WTO rules based on the assurance given by US government that the relevant provision of S.301 would be administered consistently with WTO DSU. This commitment was considered by panel sufficient to held non- violation of WTO rules.

[35] This is a TRIPS-PLUS agenda of US where the extension of the term of patent protection beyond 20 years to compensate for delays in patent examination and in marketing approval of protected products, as well as to link drug registration to status of patent protection. Art 1709(12) of NAFTA which says, a party may extend term of patent protection, in appropriate cases to compensate for delays caused by regulatory process. CAFTA-Article 15.9.6(a) also states about patent term restoration, which extends a up to 5 years. In US the 1984, Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) increased effective patent term protection by an additional maximum period of 5 years. In the EU, regulation EC 1768/92 allows a pharmaceutical company to extend the term of its patent by an additional period of up to 5 years, as long as effective patent life does not exceed fifteen years from the data of marketing authorization. This mechanism is called supplementary protection certificate. In the Canada patent protection case DSB rejected in the EU claim of patent term extension. If it includes the patent laws of developing countries, MNC Drug Companies will use it for ever greening of patent which will be harmful.

[36] In the case of Protection of Tradition Knowledge now developed countries shifted forum TRIPS to WIPO again that is the reason for establishment of inter-governmental committee on protection of tradition knowledge, folk lore.

United States is applying pressure on developing countries in this respect. Australia enacted the data exclusivity in 1998 after the United States government launched a Special 301 investigation against Australia in 1996. Developing countries already entered into 'Free Trade Agreement' with United States which contain data exclusivity should seek to amend and clarify those provisions to ensure that such protection does not prevent timely entry of generic medicines. Developing countries that are currently negotiating 'FTA' should ensure that all flexibilities in the TRIPS Agreement with respect to protection of test data are preserved.

CHAPTER V

INDIA AND TEST DATA PROTECTION

V.1. Introduction

Indian pharmaceutical industry is the most advanced among developing countries. It is in the front rank of India's science based industries with wide ranging capabilities in the complex field of drug manufacture and technology. Playing a key role in promoting and sustaining development in the vital field of medicines, India pharmaceutical industry boasts of quality producers and many units approved by regulatory authorities in United States and United Kingdom. It holds a leadership position among developing countries, in terms of technology, quality and range of medicines manufactured. It ranks fourth in the world and thirteenth in terms of value. It also witnessed consistent growth over the past three decades after the adoption of Indian Patent Act, 1970. In 2005, Indian Parliament amended the existing Patent Act, for the inclusion of Product Patent regime in pharmaceutical and agrochemical sector in order to comply with the TRIPS Agreement. Now the developed countries and multinational pharmaceutical and agrochemical companies are arguing for the inclusion of data exclusivity in the Indian domestic legislations.

India opposed to the protection of undisclosed tests and other data for marketing approvals during TRIPS negotiations. As the negotiation progressed, a consensus formed on a text that was less strict than the text favoured by those pushing for the inclusion of this matter in TRIPS agreement. The Government of India constitute a committee to find out what changes should made to the Indian legislation to make it TRIPS compliance. The Drugs and Cosmetics Act, 1940 along with the Insecticide Act, 1968 deals with the marketing approval of pharmaceutical and agrochemical products in India.

V.1.1. Drugs and Cosmetics Act

Drugs and Cosmetics Act, 1940 along with Drugs and Cosmetics Rules, 1945 contains provisions to regulate the clinical trials, manufacture, sale of drugs and cosmetics in India. In 1988 amendments were made to regulate the provisions relating to approval of the new drugs for manufacture or import. By this amendment, obtaining license for conducting clinical trials in India was added. It was made mandatory that clinical test data was to be submitted for marketing approval for new

medicines under schedule Y of the Act. The data includes a brief description of the drug and its therapeutic class, chemical and pharmaceutical information, Animal pharmacology, Animal toxicology, details of Phase I, II and III clinical trials, regulatory status in other countries and marketing information.[1]

In 2001 Drug and Cosmetics rule was amended by incorporating the conditions for conducting clinical trial.[2] The procedure for applying the marketing approval depends on the status of the new drug, which can be broadly classified into three categories: new drug substances discovered that are already approved/marketed in other countries; new drug substances discovered that are not approved/marketed in other countries; and new drug substances discovered in India.

In case of the first category, it is sufficient if confirmatory trials (phase III) are conducted to obtain data about the efficacy and safety of the drug in a large number of patients (minimum 100, in 3-4 centers), generally in comparison with a standard drug or a placebo, to confirm efficacy and safety claims made in the product monograph.

For the second category, permission for clinical trials is given with a "phase lag". Phase I of a new drug substance, for example, is allowed only if the drug has completed phase I and moved to phase II in other countries; similarly phase II is allowed in India only after completion of phase II in other countries and phase III has commenced. Phase I trials cannot be initiated in India for new drug substances discovered in other countries unless phase I data from other countries is available. In the case of new drug substances discovered in India, clinical trials have to be carried out as human/clinical pharmacology trials (phase I).

The phase I trials are carried out on healthy human volunteers (minimum two at each dose level) to determine the maximum tolerated dose in humans, adverse reactions etc .Exploratory trials, or phase II trials, are carried out on limited number of patients (normally 10-12 at each dose level) to determine therapeutic uses, effective dose range and further evaluation. Confirmatory trials, or phase III trials, are

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[1] N.S Gopalakrishnan and Benoy.K.Kadavan, "*Study on Test Data Protection in India*": (Eastern Book Company), Lucknow 2005.

[2] Rule 122 DA was added for governing application for permission to conduct clinical trials for new drug or investigational new drug. An application for grant of permission to conduct phase I human trials must be accompanied by such data and other information required under schedule Y. Applications for phase II and phase III clinical trials must be accompanied by data emerging from the respective earlier stages of clinical trials. Investigational New drug is defined as "a new chemical entity as a product having indications but which have never been earlier tested on human being", Quoted from ibid.

conducted to obtain sufficient data about the efficacy and safety of the drug in a larger number of patients (minimum 100 in 3-4 centers), again in comparison with a standard drug or a placebo, to confirm efficacy and safety claims made in the product monograph. If the new drug substance is not marketed in any other country, phase III trials should be conducted on a minimum of 500 patients spread across 10-15 centers.

In the case of new drug substances discovered that are not approved or marketed in other countries, Schedule Y would previously put India back by a step as compared to other countries due to the phase lag that needed to be adhered to. In January 2005, government enacted a new rule that allows foreign pharmaceutical companies and other interested parties to conduct trials of new drugs in India at the same time that trials of same phase are being conducted in other countries. This new rule supersedes a directive of India's Drugs and Cosmetic rules that required a 'phase lag' between India and rest of the world. According to the old rule, if a phase III study had been completed elsewhere, only a phase II study was permitted in India. Even under the new rule, phase I trials will not be normally permitted in India. The Drug Controller has discretion to relax the submission of certain data specified in the Schedule Y, if the new drug is approved or marketed in other countries.

The generation of these data involves investment of millions of rupees and many years. After the introduction of product patent for pharmaceutical products in 2005 the number drugs of registered first time in India will increase because compare with the expense in developing new medicines is less in India than in western countries. Recently Indian pharmaceutical companies are giving more importance to research and development and also many companies are in collaboration with foreign companies for the joint development of new medicines. The clinical trial industry is a fast growing area where Multinational drug manufacturing companies outsource clinical trials to India.

There is no express provision in Drugs and Cosmetic act or in the rules relating to the protection of clinical trial results submitted, to regulating authority. Rule 53 of The Drugs and Cosmetic rules, 1945 provides that an inspector of (Drug Controller General of India) DCGI, shall not with the sanction in writing of his official superiors disclose to any person any information acquired by him in the course of his official duties. But this rule only deals with the Drug inspector and not all staffs in the office. There is no case that relates to the protection of submitted test

data in India. It would be better if an express provision in the Act is included to comply with minimum TRIPS obligations.

V.1.2. Insecticides Act

The Preamble of The Insecticides Act, 1968 says, that the Act is to regulate the import, manufacture, sale, transport, distribution and use of insecticides with a view to prevent the risk to human beings or animals. By section 5 of the Act, central government shall constitute a registration committee to register insecticides in India after scrutinizing their formulae and verifying claims made by the importer or the manufacturer, as regards their efficacy and safety to human beings and animals. Section 9 (1) of the Act provides that any person desiring to import or manufacture any insecticide apply to the registration committee for the registration of insecticide with sufficient data of test related to efficacy and safety of pesticide. These test data running to 20,000 or more pages pertains to chemistry, toxicology, bioefficacy and maximum residue limits of the proposed molecule. The Committee will conduct necessary enquiry regarding the claims made by the manufacturer. If the committee is satisfied with the efficacy and safety of the insecticide the committee allots a registration number and a certificate is issued. If the use of insecticide involves severe risk, the registration committee may refuse to register the insecticide.[3]

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3. Registration of insecticides. 9 (1) Any person desiring to import or manufacture any insecticide may apply to the Registration Committee for the registration of such insecticide and there shall be a separate application for each such insecticide: Provided that any person engaged in the business of import or manufacture of any insecticide immediately before the commencement of this section shall make an application to the Registration Committee within a period of 1*[Seventeen months] from the date of such commencement for the registration of any insecticide which he has been importing or manufacturing before that date:

1*["Provided further that where any person referred to in the preceding proviso fails to make an application under that proviso within the period specified therein, he may make such application at any time thereafter on payment of a penalty of one hundred rupees for every month or part thereof after the expiry of such period for the registration of each such insecticide."]

(2) Every application under sub-section (1) shall be made in such form and contain such particulars as may be prescribed.

(3) On receipt of any such application for the registration of an insecticide, the Committee may, after such enquiry at it deems fit and after satisfying itself that the insecticide to which the application relates conforms to the claims made by the importer or by the manufacturer, as the case may be, as regards the efficacy of the 1*[on such conditions as may be specified by it"] and on payment of such fee as may be prescribed, the insecticide, allot a registration number thereto and issue a certificate of registration in token thereof within a period of twelve months from the date of receipt of the application: Provided that the Committee may, if it is unable within the said period to arrive at a decision on the basis of the materials placed before it, extend the period by a further period not exceeding six months: Provided further that if the Committee is of opinion that the precautions claimed by the applicant as being sufficient to ensure safety to human beings or animals are not such as can be easily observed or that notwithstanding the observance of such precautions the use of the insecticide involves serious risk to human beings or animals, it may refuse to register the insecticide.

If the Insecticide is introduced for first time in India, the committee will grant two years provisional registration to enable the applicant to generate data for obtaining original registration. The originator should submit data on the suitability of a product in a particular geographic region for getting approval. Subsequent application for registration of the same insecticide has to be granted registration on the same condition, but there is no need to give data proving the efficacy and safety of the insecticide.[4] The Act however does not talk about the confidentiality of the submitted test data for registration to committee. Like Rule 53 of the Drugs and Cosmetic Act, Rule 29 of the Insecticide Act also talks about the obligation of the Insecticide Inspector to maintain confidentiality. There is TRIPS Agreement obligation to comply for keeping submitted test data secret. The expense of generating test data for insecticides is more than the expense for generating test data for pharmaceuticals.

Both Drugs and Cosmetic Act of 1940 and Insecticides Act of 1968 seek submission of clinical test data for marketing approval of pharmaceuticals and agrochemical products, but there is no provision in both this Act to keep submitted test data secret. Only a vague provision is in Section 5 of the official secret Act, provides that unauthorized disclosure of official secrets is punishable offence, which deal with official secrets, and whether test data comes under official secrets is not clear.

In the draft pharmaceutical policy, the chemicals ministry has said it was examining various options for protecting the undisclosed test data submitted by inventors. One option it is weighing is to waive such protection during a national

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(3B) Where the Registration Committee is of opinion that the insecticide is being introduced for the first time in India, it may, pending any enquiry, register it provisionally for a period of two years on such conditions as may be specified by it.

(3C) The Registration Committee may, having regard to the efficacy of the insecticide and its safety to human beings and animals, vary the conditions subject to which a certificate of registration has been granted and may for that purpose require the certificate-holder by notice in writing to deliver up the certificate to it within such time as may be specified in the notice."]

(4) Notwithstanding anything contained in this section, where an insecticide has been registered on the application of any person, any other person desiring to import or manufacture the insecticide or engaged in the business of, import or manufacture thereof shall on application and on payment of prescribed fee be allotted a registration number and granted a certificate of registration in respect thereof on the same conditions on which the insecticide was originally registered.

[4] N.S Gopalakrishnan and Benoy. K .Kadavan, *"Study on Test Data Protection in India"*: (Eastern Book Company,Lucknow), 2005.

emergency, as in the case of compulsory licensing. At present, the drug controller does not require elaborate data to approve a drug if the applicant can prove that it is available in the blood stream in equal measure as the original drug approved in any other country.

V.2. India's Position in WTO

During the TRIPS Agreement negotiations, India asserted that trade secrets cannot be regarded as intellectual property and should be dealt with contract and civil law. The main reason for this view was that in the case of trade secrets there is no disclosure such as is required for the subject matter of intellectual property rights.[5] India also opposed protection of undisclosed tests and other data for marketing approvals during TRIPS Agreement negotiations. As the negotiations progressed, a consensus was formed on a text that was less strict than the text favoured by those pushing for the inclusion of this subject matter in TRIPS Agreement. Ultimately the consensus prevailed for a some what diluted level of discipline in this area but left the text ambiguous on duration of such protection. [6]

Even after the coming into force of this TRIPS obligation there is no consensus in India, as to how it should be implemented. As an active voice of developing countries, India always objected to give exclusive rights to submitted test data in various foras. India is of the view that the negotiating history of TRIPS Agreement Article 39.3 itself rejected the argument for exclusive rights to test data. The text for the Brussels ministerial conference on Uruguay Round Agreements contained an explicit provision for preventing use of data for subsequent marketing approval. The Brussels text reads that, "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". This provision is not included in the final text. So there is no intention on the TRIPS Agreement negotiators to provide data exclusivity to prevent government and its agencies from using the data for subsequent market approval.[7] The reliance by the regulatory authority on originators test data when examining the

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[5] Documents. MTN.GNG/NG 11/16,at 32 note 63 and MTN.GNG/ NG 11/20, at 17 note 24.

[6] Jagadish Bhagwati, Mat Hlas Hirsch editors "*Uruguay Round and Beyond*". (Springer-Verlay Berlin-Heidelberg), 1998 p.48.

[7] K.M Gopakumar "Submission before the Committee for the Protection of Undisclosed Information under Article 39.3 of the TRIPS Agreement (Affordable Medicines and Treatment Campaign) India.

generic medicines is not unfair commercial use. It is a statutory function on the part of the government to examine all data available, before giving marketing approval to any medicines.

India's submission to the World Trade Organization relates to Test Data protection states,

> Article 39.3 of the TRIPS Agreement leaves considerable room for member countries to implement the obligation to protect test data against unfair competition practices. The TRIPS Agreement provides that 'undisclosed information' is regulated under the discipline of unfair competition, as contained in Article 10bis of the Paris Convention for the protection of industrial property. With the inclusion of this provision in the Agreement, TRIPS Agreement clearly avoids the treatment of undisclosed information as a property and does not require granting 'exclusive rights to the owner of the data.[8]
>
> More extensive protection in national legislation than is required by the TRIPS Agreement may result in limitations for the implementation of health policies. We consider that members should be free to implement the TRIPS Agreement in ways that best accommodate the protection of health policies in national legislation. It continued that, any interpretation of the provisions of the TRIPS Agreement should take into account the principles set forth in Article 8. The reading of such provision should confirm that nothing in the TRIPS Agreement will prevent members from adopting measures to protect public health, as well as from pursuing the overarching policies defined in Article 8.[9]

India opposed granting of any data exclusivity. She argued (a) TRIPS requires only member countries need to protect test data against unfair commercial use. (b) Under Article 39.3 there is nothing that we should provide regarding marketing exclusivity. (c) TRIPS agreement should be interpreted according to ordinary meaning of the words used and taking into account object and purpose of agreement as expressed in Articles 7[10], 8[11], 66.2 and also according to the paragraph 4 and 5(a) of the Doha Declaration of Public Health 2001.

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[8] India's Submission to TRIPS Council on 29 June 2001 (IP/C/W/296).

[9] Ibid.

[10] The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

[11] 1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

V.3. Views of Industry

V.3.1. Organisation of Pharmaceutical Producers of India

Research based and generic based pharmaceutical companies have different views relating to test data protection. Organization of Pharmaceutical Producers of India (OPPI) [12] made a strong plea for five-year data exclusivity in line with their counterparts like IFPMA and PhRMA in Europe and US respectively. Their argument is based on the role of data exclusivity in bringing more consumer safety and investment for R&D.[13] The discovery, development and bringing to market a new drug requires the originator to conduct extensive clinical trials, pharmaceutical research and testing to generate data for submission to Drug Regulatory Authorities for marketing approvals of anew drug. This activity takes 10-12 years of painstaking efforts. The data generated in such work is proprietary to the originator and needs to be protected from unfair commercial use. OPPI has recommended that data protection should be for at least five years after the marketing approval. Data protection is required to ensure confidentiality of data needs to obtain marketing approval of the product. Data protection does not debar the entry of another manufacture on the patent expiry of a product, as far as such manufacturers can generate their own data, and hence will not delay the generic entry.[14] OPPI concludes that, data exclusivity will bring more product introductions, research and development and clinical trial business to India, otherwise India will be losing out to china and Brazil which have taken strong position on data exclusivity. According to Pfizer, India possesses significant potential to become a preferred location for research and development for the global biotechnology and pharmaceutical sector. Recent studies have estimated that India can become the most preferred destination for global pharmaceutical and biotech companies looking for partnerships and setting up of new operations. In 2002, clinical trial industry in India was $70 Million. Market is growing at a rate of 20% per annum.

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[12] OPPI is an organization of MNC Pharmaceutical Companies in India.

[13] They suggest changes in Drugs and Cosmetic rules so as to grant data exclusivity to the test data owner. They argue that all kinds of undisclosed information given to the Drug controller irrespective of the nature of the drug and cost involved require exclusive protection for a minimum period of six years. They rejected the application of 'The Official Secrets Act', which generally propagated as an adequate safeguard for data protection, deals with the protection of data available with regulatory authorities and does not check reliance of such undisclosed data while granting marketing approvals to other entrants. It is feared that the lack of data exclusivity will affect contract research and manufacture.

[14] Available at www.indiaoppi.com/pharmind india.htm, last visited, Dec.21, 2005.

The outsourced clinical research market in India will increase between $500 to $1.5 Billion by 2010.[15]

V.3.2. Indian Pharmaceutical Alliance

However, Indian Pharmaceutical Alliance (IPA) is against government conceding any demand for data exclusivity including market exclusivity. They argue that TRIPS Agreement does not call for market exclusivity as understood in the US and the EU. Regulatory authorities are not prohibited from relying upon such data for determining the safety and efficacy of a previously approved product, when marketing approval is sought by generic manufacturers who do not infringe patents. This is particularly necessary to obviate the social and economic costs of repetitive animal and human testing.[16]

V.3.3. Indian Drug Manufacturers Association

The Indian Drug Manufacturers Association (IDMA) openly opposed the demand for data exclusivity of multinational pharmaceuticals. It asserted that the demand was "in violation of the spirit of Doha declaration, which reaffirmed the right of WTO members to use all flexibilities to meet health emergencies and urgencies. It further contended that "The phrase data exclusivity does not figure in TRIPS Agreement, this is TRIPS Agreement-PLUS demands which appear in US Food and Drug Administration regulations.[17]

Pharmaceutical Research and Manufacturers of America (PhRMA) associate vice president states that "both the logic and negotiating history of Article 39.3 of TRIPS Agreement leave no doubt that providing data exclusivity for a certain period of time was the envisaged way to protect data against unfair use as prescribed by Article 39.3.Whether any system other than data exclusivity over a reasonable period of time would meet requirements of Article 39.3 of the TRIPS Agreement is to be assessed on a case-to-case basis, but examples of actual application by WTO members of alternative and TRIPS complaint- systems to non-reliance over a reasonable period do not appear to exist".

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[15] Pfizer Clinical Research in India, Available at www.pfizer india .com, last visited 6, November 2005.

[16] Ajay Jain, *"Pharma cos in Grip of feverish Debate on Data Exclusivity,"*. The Financial Express, May.27, 2003.

[17] Assafa ENDESHAW "Asian perspectives on Post –TRIPS issues in Intellectual property", *Journal of World Intellectual Property*, 2003, p.222.

Pfizer blamed a few domestic pharmaceutical companies for their short term advantages, as these are preventing government from implementing data exclusivity, which is a major impediment for engaging in greater clinical research and in registering new products.[18] According to Aventis India , patents are social contract between innovator and society. They provide incentives for discovery and development of innovative drugs. But Data exclusivity is about limiting a government's abilities to use individuals proprietary data, derived from considerable effort, this data is needed to demonstrate safety, quality and efficacy of innovative drugs to regulatory authorities, hence both forms of protection are independent and both are needed[19].

A Ranbaxy laboratory supports data exclusivity in India for a period not beyond when data exclusivity is over in any other part of the world.[20] Nicholas Piramal has the view that it is very important for India to provide at least five year test data protection as is done by all countries. It will help research in India and increase substantial investment in clinical research.

According to one expert, India has some interest and natural advantages in clinical research. India's highly skilled medical fraternity, many world class medical institutions and large treatment naïve population has given a hope that Indian potential as a global hub for clinical research can be reached sooner rather than later[21]. Clinical trials need to be conducted on patients who have not been previously treated by other drugs. Such patients are becoming rare in the United States and other western countries. Cost competitiveness will enable Indian industries and research institutions to contribute to global drug development in a significant way since the technology infrastructure required to support clinical trials will surely give India a definite advantage over other countries[22].

In the area of Pesticides also MNC crop protection majors are lobbying hard for 5- 10 year exclusive protection on test data relating to new pesticides molecules which they are now obliged to submit to the government to obtain authorization for

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[18] ,Sanjay Sardana "*Ptizer Pitches for a Quick Work of Data Exclusivity*", available at http// www. F.e.com/ fe-full-story php content-id-43939, last visited may 2- 2005.
[19] Jain see, no .16.
[20] Ibid.
[21] Ramesh Mashelkar, "*Report of the Expert Committee on a Comprehensive Examination of Drug Regulatory Issues Including the Problem of Spurious Drug*", Ministry of Health and Family Welfare, Government of India, Nov, 2003, p.66.
[22] Ibid.

marketing in the country.[23] Demand aimed at tackling unfair competition from domestic me-too generic agro-chemical manufacturers. Their argument is broadly in line with their counter parts in the pharmaceutical industry have been seeking. MNC companies contend that the absence of protection for voluminous test data they are statutorily obliged to submit to registration authorities under "The Insecticide Act" for marketing approval of pesticides allows other companies to access the information and come out with the same or similar molecules.[24]

There is an obligation on the part of the countries to protect the submitted test data from 'unfair commercial use' under TRIPS Agreement. Only new chemical entity is eligible to get protection. No protection for new indications, new dosage forms, new formulations or the second use of known substance. The regulatory authorities can rely on the submitted test data when they decide on subsequent approval of generic application for marketing approval.

The Committee constituted by the government is studying all aspects. Most of the MNC Pharma majors and pesticides majors had given submission for 5- 10 years of data exclusivity, in which they wants to prevent the relying of originator's submitted test data by regulatory authorities when they examine subsequent generic application. But majority of Indian companies argues for only trade secret form of protection to test data, some companies especially purely generic companies are opposing any form of protection.

Committee in its earlier draft planned to give trade secret form of protection to submitted test data, according to the norms followed by countries that have manufacturing capabilities but weak drug development capabilities. The developed countries with large pharmaceutical companies involved in advanced research and superior manufacturing capabilities for introducing new drugs; provide protection of data submitted for approval for a fixed period of time (Data exclusivity).

The chairman of the committee said in March 2005 that, "We will meet our obligations but will not concede more protection to data submitted for regulatory purposes, while amending the Drugs and Cosmetic Act and the Insecticide Act". We should take advantage of the flexibility afforded by the TRIPS Agreement .They are

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[23] Harish Damodaran "*Pesticide Multi National Companies seek 5-10 year Data Exclusivity*", Business line –Monday March 8, 2004.
[24] Ibid.

thinking of restricting the protection to a pioneer drug's data from 'unfair commercial use' by second applicant only if it is genuinely new molecule and not when it is 'old medicine in new bottle'. They are thinking of defining a 'new chemical entity' mentioned in international agreement in a narrow fashion to exclude a large number of products which are new only because of their administration method and form. They are also looking at protecting the regulatory authority from liability against theft or unintentional leaks of confidential data submitted by drug inventors[25].

But there are press reports in October 2005 that the committee took an opposing view than earlier. They are planning to recommend 3-5 year data exclusivity and relying on the judgment of sophisticated drug regulator in another country, where the inventor has submitted the costly safety and efficacy data, is indirect reliance on the inventor's property to give commercial advantage to another company. The idea is to give incentive for the development of products which are required badly and need huge investments, but may not get any patent protection. It will also recommend the level of protection to be given against such use of innovator's data.[26]

If this suggestion is accepted, the regulatory authorities will not accept bioavailability or confirmatory trials. The MNC pesticide makers like Bayer, DuPont and Syngenta informed the Chemical ministry that they would wait for amendment to the Insecticide Act before launching their products in India.[27]

If data exclusivity accepts it will be end of generic pharmaceutical industries which is the life line of poor peoples in the world. After the adoption of product patent to pharmaceutical products there are signs that the access of pharmaceuticals in affordable price is difficult. So if data exclusivity also adopted then not only the poor peoples in India but also peoples in other developing and least developed countries especially in Africa will suffer. The Committee appointed by the government of India is going to submit its report shortly. Even if committee submits its recommendation, the Government has no obligation to accept their recommendations. So as one of the largest producers of generic medicines India should provide a minimum protection to submitted test data consistent with reasonable interpretation of TRIPS Agreement and in the interest of developing world.

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[25] Drugs Cos may Sell Copies of New Generic. Economic Times , March 17, 2005 .p.4.
[26] Gireesh Chandra Prasad "*Pesticide MNCs Likely to get Data Protection Soon*", The Economic Times- Tuesday ,January 3, 2006.
[27] Copying Patented Drugs may Become Difficult, Economic Times 26. Oct, 2005 p.10.

This study proposes the following suggestions to Government of India while implementing Test data protection in National legislations.

- Protection should be given only to 'new chemical entities' and not to new indications, formulations, routes of administration, second use of same compound.
- Protection should be against 'unfair commercial use' of data and not data exclusivity.
- Protection period in India should begin on the date of marketing approval in the first country recognized by India.
- Protection of test data should not affect the use of 'Bolar exception' and compulsory licensing under Patent.
- Protection should end with the expiry of patent period.
- Regulatory authorities should allow to rely on the originators test data when examining subsequent applications.

CHAPTER VI

CONCLUSIONS

Test data protection and patents are the most critical and relevant forms of intellectual property for pharmaceutical and agrochemical sector. Both accordingly constitute an important element in TRIPS regime. Patents, it may be noted, are included in the part II of the section 5 and the Test data protection are included in the section 7 of the TRIPS Agreement. Although both patents and Test data create two distinct legal regimes of protection, their concerns as mentioned above, are directed towards pharmaceutical and agrochemical sector. Patent normally grants to the innovator a reward for the creation and innovation. The object of test data protection is the protection for the investment made in the development of test data rather than any innovation. This, accordingly, raises the question-whether the intellectual property right protection should at all extend to Test Data. The extension of intellectual property beyond its boundaries so as to protect investment and not intellectual contribution, no doubt, disrupts the essence of a system conceived to reward the creators of original ideas and new inventions.

Test data protection which is included in Article 39.3 of the TRIPS Agreement creates two different interpretations. Developed countries led by United States, European Union argue that the nature of obligation under Article 39.3 is the implementation of 'Data Exclusivity' regime in the national legislations of WTO Member Countries. Whereas developing countries argue that nature of obligation under Article 39.3 is to provide protection against 'unfair commercial use' for submitted test data and not the data exclusivity.

During the Uruguay Round, negotiations of the TRIPS Agreement, United States and other developed countries argued for the inclusion of data exclusivity as a component of intellectual property rights. The developing countries led by India opposed even the inclusion of 'Trade Secret' in the regime of intellectual property. Trade secrets are protected according to the national legislations before their inclusion in the TRIPS Agreement. The test data protection was merely a regulatory mechanism in EU and US and was accordingly not included in intellectual property legislations.

The test data protection was separately included in the Hatch-Waxman Act and European Council Directive 65/65/EEC respectively. The multinational pharmaceutical alliances like PhRMA, IFPMA and multinational pesticide manufacturers led by Crop Life International played a vital role in the inclusion of test data protection under the TRIPS Agreement. Final TRIPS text provides only minimum protection to submitted test data than exclusive property right argued by the developed countries. It even removed the prohibition of reliance by the regulatory approval body when the regulatory body deals with the marketing approval of competing products.

The developed countries argue that Article 39.3 of the TRIPS Agreement stipulates data exclusivity in respect of pharmaceutical and agrochemical data. The agreement does contain an obligation to protect test data against 'unfair commercial use' and the most effective method of doing so is to deny regulatory authorities the possibility of relying on such data for a reasonable period of time. Furthermore data protection should be available whether or not the product subject to regulatory approval is protected by patent or not, since data protection is quite a different issue from patent protection. They further argue that since drug companies spend huge money for generating the data and information and it is not fair that other companies should be allowed to use that data, without going through the painful process of generating that information.

The developing countries on the other hand, argue that the TRIPS Agreement does not require the imposition of data exclusivity for submitted test data, but only protection against unfair commercial use. By linking the protection of test data with the protection against unfair competition under Article 10bis of the Paris Convention for the protection of industrial property, the negotiators clear aim was the protection from dishonest use of data. The TRIPS Agreement does not create property protection for test data, but just refers to its possession. So, there is no requirement for granting exclusive rights to the owner of the data. The obligation binds states to protect marketing approval data under the regime of trade secrets. The Member States are free to decide in respect of the system of protection to implement it in the domestic

sphere depending on the access to drugs and public health needs of individual countries.

The regulatory authorities are free to use the data for non-commercial purposes. A legitimate non commercial use would presumably encompass use by various government departments to avoid any health or safety risk revealed by the data in local environment similarly "the promotion of research and science in the public interest would presumably allow some uses of the data that would be both non-commercial and fair consistent with any research exemption embodied in the domestic patent laws"[1].

Article 39.3 of the TRIPS Agreement appear to provide sufficient flexibility for countries to adopt a TRIPS consistent measure for the protection of submitted test data in a way which takes national policies and priorities into account. Article 1.1 of the TRIPS Agreement states "members shall be free to determine the appropriate method of implementing the provision of this agreement within their own national legal system and practice". The WTO Appellate Body[2] interpreted this provision in India Patent Dispute (US) case. It held 'Members, therefore are free to determine how best to meet their obligations under the TRIPS Agreement with in the context of their own legal systems'. Countries shall determine how to implement the different requirements through their own domestic laws; this means that countries cannot be required to follow exactly the example of other countries, even though there is pressure to do so. The WTO member countries should implement only minimum protection to submitted test data in their national legislations under protection against 'unfair commercial use'. TRIPS Agreement expressly included protection for test data against unfair commercial use and not exclusivity protection. The developed countries argument for a data exclusivity regime, which prevents the reliance by the regulatory authorities of originators on the first submitted test data, when regulatory authorities evaluate the safety and efficacy of the subsequent bioequivalency data submitted by the generic manufacturers, is without any substance.

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[1] 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 , Bellagio, 29 Nov- 3 Dec, 2004, available at www.iprsonline.org/unctad ictsd/bellagio/docs/Reichman. Bellagio4.pdf, Last visited Sep 16, 2005.

[2] Appellate Body Report on India- Patents (US), para.59, WTO Document, WT/DS 50/R.

The TRIPS Agreement sets no clear requirement to avoid relying on prior test data for subsequent applications, nor does it mandate a fixed period of market exclusivity. The TRIPS Agreement only prohibits the unfair commercial use of the submitted test data. Requiring generic producers to conduct their own tests on same chemical compounds is socially wasteful and ethically incorrect. Patent holders are already getting a monopoly period of 20 years. Extension of this period whatever in the name of data exclusivity or patent term restoration is against the public interest.

Article 39.3 of the TRIPS Agreement cannot be interpreted in such a way as to mean that members are required to establish a special legal regime for the protection of undisclosed test or other data submitted for regulatory approval of pharmaceutical and agrochemicals. The implementation of Article 39.3 in the form of data exclusivity compromises the access to medicines by reducing the competitive edge of generic pharmaceutical industry on which most developing and least developed countries depend. The United Nations Human Rights Commission Resolution (April 2001) called on "all states to ensure that application of international agreements is supportive of public health policies which promote broad access to safe, effective and affordable, preventive, curative or palliative pharmaceutical and mechanical technologies. So, Article 39.3 of the TRIPS Agreement should be interpreted according to ordinary meaning of words used and taking into account objects and purposes of agreement as expressed in Article 7, 8, 66.2 and paragraph 4 and 5(a) of the Doha Declaration of Public Health. In cases of ambiguity or where more than one interpretation is possible, the interpretation should be supportive of WTO members 'Right to protect Public Health'.

The data exclusivity allows monopoly rights to the manufacturing company even after the expiration of patent. It can charge higher price and earn more than would have been possible in case of free competition. A study conducted by the 'United States Office of Technology Assessment' shows that profits in the pharmaceutical industry are considerably higher than in other industries and that the rate of return is much higher than what is needed to cover the cost.[3] The originators

[3] Office of Technology Assessment, Pharmaceutical R&D: Costs, Risks and Rewards, 1993.

argument is that they are spending millions of money for the generation of the data and patent alone could help in recouping the invested money is false. The figures for the cost and duration of testing activities are highly contentious.

Data exclusivity might affect the use of 'Bolar exception' and the compulsory licencing under the Patent regime. A Bolar provision allows interested (generic) manufacturers to start producing test batches of a product before the patent expires. If the data is protected exclusively, then how can a generic manufacturer use the originators submitted test data to show bioequivalency? The data exclusivity might affect the smooth working of the compulsory licence of patent. If the originator is not ready to provide test data for the manufacturing of medicine to the compulsory licence holder, how is it possible to manufacture medicine? In general it neutralizes the flexibilities in the TRIPS Agreement.

United States is concluding Regional Trade Agreements(RTAs) and Free trade agreements(FTAs) with many developing countries with TRIPS-PLUS provisions. All these agreements contain strict data exclusivity provisions which expressly prohibit the reliance of regulatory authority of originators submitted test data when dealing with the marketing approval of subsequent applications for same chemical compounds. The United States inclusion of data exclusivity in FTAs and RTAs, it could be argued, are against the spirit of TRIPS Agreement. The United Nations Human Development Report (UNDP) 2005 raises concerns with respect to the effects of TRIPS Agreement and other intellectual property obligations contained in regional and bilateral FTAs.[4] The inclusion of data exclusivity as a marketing approval method in many FTAs is affecting access to medicines in developing countries. Some FTAs even provides waiting period, in that period other manufactures can't even apply for regulatory approval. It is a very dangerous situation which might wipe out the entire generic medicines from the world. So, developing countries should exercise caution while entering into FTAs and RTAs which have provisions relating to data exclusivity.

[4] See UNDP Human Development Report 2005, "International cooperation at crossroads, Aid, Trade and security in an unequal world", Available at http// hdr.undp.org, last visited in Dec 7, 2005.

There are other bilateral approaches which need consideration.United States Trade Representative (USTR), for instance includes many developing countries in its priority watch list and regular watch list for the non implementation of data exclusivity in their domestic sphere under Special 301 provision of 'Omnibus Trade and Competitiveness Act'. The use of Special 301 provision which allows trade retaliation against developing countries for the implementation of TRIPS provisions is against the free and fair trade principles of the WTO and also against the principles of the WTO Dispute Settlement Understanding.

It may be noted that the courts in the developed countries have also been taking position against providing data exclusivity. The decision given by the Canadian court in interpreting data exclusivity provisions of the NAFTA and the Canadian domestic law on regulatory approval is worth quoting. The decision given by a United Kingdom court in the *Smith Kline* case reiterated the right and duty of the licensing authority to make all information supplied by applicants, when it deals with other applicants. These decisions reject the argument of the developed countries for the data exclusivity or the prohibition of reliance by the regulatory authority during the examination of subsequent applications.

Multinational drugs and insecticide companies in India, are also arguing for the implementation of data exclusivity. By TRIPS Agreement there is no obligation on the part of India to provide data exclusivity. But there is an obligation on the part of India to provide protection against 'unfair commercial use' of submitted test data. The two legislations which are dealing with the issue are Drugs and Cosmetics Act and Insecticide Act. There is no provision in both of these legislations to keep the submitted test data secret. It is better for India to amend these two legislations and add express provisions to make it obligatory the secrecy of submitted test data.

India should, therefore amend its 'Drugs and Cosmetics Act' and the 'Insecticide Act' to include specific provision for the protection of submitted test data from 'unfair commercial use'. It can also add this obligation in the Drugs and Cosmetics Rules and Insecticide Rules. It should allow the regulatory authorities to rely the submitted test data of originators when examining bioequivalency test of

generic manufacturers. It should prevent third parties from using the originators submitted test data for commercial purposes. The use of test data by the regulatory authorities is a non commercial use and not prohibited under Article 39.3 of the TRIPS Agreement.

There is an argument that it is not proper to keep the whole submitted test data secret. The disclosure of marketing approval data honors the public interest in being informed about the safety and effectiveness of an approved drug and allows researchers and scientific group to conduct further testing and to verify or dispute the accuracy and impartiality of data submitted by the registrant. The lack of access to data contradicts the right of public to be informed about the safety and efficacy of the approved products. The concept of data exclusivity and database protection is against the free flow of data which is one of the pillars for the development of knowledge based society.

Article 39.3 of the TRIPS Agreement provides sufficient flexibilities to WTO member countries for implementing minimum protection to submitted test data in accordance with their socio- economic and development aspects. The public interest in limiting data protection is to promote competition and ensure that data protection does not become the means to block timely entrance of affordable generic medicines of public health importance. The developing countries should prevent the legitimization of data exclusivity and patent term restoration by the developed countries through FTAs and RTAs.

In conclusion, the study proposes the following considered suggestions while implementing the Article 39.3 requirements of the TRIPS Agreement. These are:

- WTO member countries should provide protection against 'Unfair Commercial Use' of submitted test data and not the data exclusivity.
- Regulatory authorities should be allowed to rely on the originators submitted test data when examining generic applications of same compound.

- Protection should be given only to 'new chemical entities' and not for new formulation, new indication, new therapeutic use and second use of same compound.
- If drug is marketed any where in the world, bioequivalency test should be accepted for giving marketing approval in another country for same drug.
- Test data protection should not affect the use of 'Bolar' exception and compulsory licencing under Patent.

Annex I

Free Trade and Regional Trade Agreement

	Free Trade and Regional Trade Agreement	Test Data Provision
1	NAFTA	**Protection of Disclosures to the Government** Article 1711(5) of NAFTA states- If a party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the party shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use. Article 1711(6) of NAFTA states-Each party shall provide that for data subject to paragraph 5 that are submitted to the party after the date of entry into force of this agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during the reasonable period of time after the submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the persons effort and expenditures in producing them. Subject to this provision, Article 1711(7) provide, there shall be no limitation on any party implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.
2	CAFTA	**Article 15.10: Measures Related to Certain Regulated Products** 1. (a) If a Party requires, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the submission of undisclosed data concerning safety or efficacy, the Party shall not permit third persons, without the consent of the person who provided the information, to market a product on the basis of (1) the information, or (2) the approval granted to the

		person who submitted the information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party. (b) If a Party permits, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, third persons to submit evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval, the Party shall not permit third persons, without the consent of the person who previously obtained such approval in the other territory, to obtain authorization or to market a product on the basis of (1) evidence of prior marketing approval in the other territory, or (2) information concerning safety or efficacy that was previously submitted to obtain marketing approval in the other territory, for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date approval was granted in the Party's territory to the person who received approval in the other territory. In order to receive protection under this subparagraph, a Party may require that the person providing the information in the other territory seek approval in the territory of the Party within five years after obtaining marketing approval in the other territory. (c) For purposes of this paragraph, a new product is one that does not contain a chemical entity that has been previously approved in the territory of the Party. (d) For purposes of this paragraph, each Party shall protect such undisclosed information against disclosure except where necessary to protect the public, and no Party may consider information accessible within the public domain as undisclosed data. Notwithstanding the foregoing, if any undisclosed information concerning safety and efficacy submitted to a Party, or an entity acting on behalf of a Party, for purposes of obtaining marketing approval is disclosed by such entity, the Party is still required to protect such information from unfair commercial use in the manner set forth in this Article. 2. Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to

		rely on evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval in the territory of a Party or in another country, that Party: (a) shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the previously approved product or its approved use during the term of that patent, unless by consent or acquiescence of the patent owner; and b) Shall provide that the patent owner shall be informed of the request and the identity of any such other person who requests approval to enter the market during the term of a patent identified as claiming the approved product or its approved use.
3	**Australian Free Trade Agreement with United States**	**Article 15.10: Measures Related to Certain Regulated Products** 1. (a) If a Party requires, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the submission of undisclosed data concerning safety or efficacy, the Party shall not permit third persons, without the consent of the person who provided the information, to market a product on the basis of (1) the information, or (2) the approval granted to the person who submitted the information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party. (b) If a Party permits, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, third persons to submit evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval, the Party shall not permit third persons, without the consent of the person who previously obtained such approval in the other territory, to obtain authorization or to market a product on the basis of (1) evidence of prior marketing approval in the other territory, or (2) information concerning safety or efficacy that was previously submitted to obtain marketing approval in the other territory, for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date

		approval was granted in the Party's territory to the person who received approval in the other territory. In order to receive protection under this subparagraph, a Party may require that the person providing the information in the other territory seek approval in the territory of the Party within five years after obtaining marketing approval in the other territory. (c) For purposes of this paragraph, a new product is one that does not contain a chemical entity that has been previously approved in the territory of the Party. (d) For purposes of this paragraph, each Party shall protect such undisclosed information against disclosure except where necessary to protect the public, and no Party may consider information accessible within the public domain as undisclosed data. Notwithstanding the foregoing, if any undisclosed information concerning safety and efficacy submitted to a Party, or an entity acting on behalf of a Party, for purposes of obtaining marketing approval is disclosed by such entity, the Party is still required to protect such information from unfair commercial use in the manner set forth in this Article. 2. Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval in the territory of a Party or in another country, that Party: (a) shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the previously approved product or its approved use during the term of that patent, unless by consent or acquiescence of the patent owner; and (b) shall provide that the patent owner shall be informed of the request and the identity of any such other person who requests approval to enter the market during the term of a patent identified as claiming the approved product or its approved use.
4	**Moroccan Free Trade**	**ARTICLE 15.10: MEASURES RELATED TO CERTAIN REGULATED PRODUCTS** 1. If a Party requires, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the

	agreement with United States	submission of: (a) safety and efficacy data, or (b) evidence of prior approval of the product in another territory that requires such information, the Party shall not permit third persons not having the consent of the person providing the information to market a product on the basis of the approval granted to the person submitting that information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party's territory. For purposes of this paragraph, a new product is one thatContains a new chemical entity that has not been previously approved in the Party's territory. 2. If a Party requires the submission of (a) new clinical information that is essential to the approval of a pharmaceutical product (other than information related to bioequivalency), or (b) evidence of prior approval of the product in another territory that requires such new information, the Party shall not permit third persons not having the consent of the person providing the information to market a pharmaceutical product on the basis of such new information or the approval granted to the person submitting such information for at least three years from the date of approval in the Party. A Party may limit such protection to new clinical information the origination of which involves considerable effort. 3. With respect to patents covering pharmaceutical products, each Party shall make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process. 4. With respect to any pharmaceutical product that is subject to a patent, and where a Party permits authorizations to be granted or applications to be made to market a pharmaceutical product based on information previously submitted concerning the safety and efficacy of a product, including evidence of prior marketing approval by persons other than the person that previously submitted such information, that Party: (a) shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent during the term of that patent, unless by consent or with the acquiescence of the patent owner, and (b) if it allows applications[15] to be made to market a product

		during the term of a patent covering that product, shall provide that the patent owner shall be notified of the identity of any such other person who requests marketing approval to enter the market during the term of a patent notified to or identified by the approving authority as covering that product.
5	**Jordan Free Trade agreement with United States**	**Measures Related to Certain Regulated Products** Pursuant to Article 39.3 of *TRIPS*, each Party, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products that utilize new chemical entities,[10] the submission of undisclosed test or other data, or evidence of approval in another country,[11] the origination of which involves a considerable effort, shall protect such information against unfair commercial use. In addition, each Party shall protect such information against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the information is protected against unfair commercial use. With respect to pharmaceutical products that are subject to a patent: (a) each Party shall make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the patent term as a result of the marketing approval process. (b) the patent owner shall be notified of the identity of any third party requesting marketing approval effective during the term of the patent.

Source: www.ustr.gov

Annex II

No	Country	National Legislation for the Protection of Test data
1	**Australia**	DATA EXCLUSIVITY PROVISION OF THE THERAPEUTIC GOODS ACT When the Secretary must not use protected information (1) When evaluating therapeutic goods for registration, the Secretary must not use information about other therapeutic goods that is protected information.(2) Information is protected information if:(a) the information was given to the Secretary in relation to an application to register therapeutic goods (the new goods):(i)not being therapeutic devices; and(ii)consisting of, or containing, an active component; and(b)the information is about the active component and is not available to the public; and(c)when the application to register the new goods was lodged:(i)no other therapeutic goods consisting of, or containing, that active component were included in the Register; and(ii)no such therapeutic goods had been included in the Register at any time before then; and(d)the new goods became registered on or after the commencement of this subsection; and(e)**5 years have not passed since the day the new goods became registered;** and(f)the person in relation to whom the new goods are registered has not given the Secretary permission in writing for the Secretary to use the information.(3)For the purposes of subsection (2), an active component, in relation to therapeutic goods, is a substance that is, or one of the substances that together are, primarily responsible for the biological or other effect identifying the goods as therapeutic goods.(4)The use of protected information contrary to subsection (1) does not render the Commonwealth, the Secretary or a delegate of the Secretary liable to a person in respect of loss, damage or injury of any kind suffered by the person as a result of, or arising out of, the use of that information.
2	**Brazil**	Protection Against Unfair Competition Article 195 - A crime of unfair competition is committed by he who divulges, exploits or uses, without authorization, the results of tests or other undisclosed data the elaboration of which involved considerable effort and which has been presented to government entities as a condition for approving the commercialization of products. (Period of Protection not mentioned)
3	**Bolivia**	Andean Pact Article 266 of decision 486 dated 12/1/00 Member countries, when requiring, as a condition for 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 any unfair commercial use. In addition, member countries shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use. Member countries may take steps to guarantee the protection provided for under this article.(Period of Protection is Five years)
4	**Colombia**	Data Protection Decree No. 2085 – September 19, 2002 Article 2: Where the commercialization of a new chemical entity is approved, the related undisclosed information may not be used directly or indirectly as supporting information for the approval of a separate application relating to the same new chemical entity. PARAGRAPH. - Generating the undisclosed information the use of which is protected hereby must have required considerable effort on the part of the person submitting same to the competent sanitary authority. Article 3: The protection of the undisclosed information regulated herein shall be as follows: 3 years counted as of the date of approval of commercialization in Colombia for those applications filed during the first year following the date on which this decree comes into force. 4 years counted as of the date of approval of commercialization in Colombia for those applications filed during the second year following the date on which this decree comes into force. 5 years counted as of the date of approval of commercialization in Colombia for those applications filed during the third year following the date on which this decree comes into force. As long as this rule is fully observed, nothing shall preclude the use of summary approval procedures which are based on bioequivalence and bioavailability studies. Article 4: The protection referred to in this decree does not apply in the following cases: When the holder of the sanitary registration of a new chemical entity has authorized the use of non-disclosed information as support for another subsequent application. When the new chemical entity whose sanitary registration is applied for is similar to another that has been approved and commercialized in Colombia and the term of protection in Article 3 has expired. When it is necessary to protect the public, as qualified by the Ministry of Health. When the new chemical entity that is the object of the sanitary registration has not been commercialized in the country one year after the issuance of said commercialization authorization (Period of Protection is 3-5 years)

5	**Canada**	Food and Drug Regulations, Section C.08.004.1 5. Where a manufacturer files a new drug submission, an abbreviated new drug submission, a supplement to a new drug submission or a supplement to an abbreviated new drug submission for the purpose of establishing the safety and effectiveness of the new drug for which the submission or supplement is filed, and the Minister examines any information or material filed with the Minister, in a new drug submission, by the innovator of a drug that contains a chemical or biological substance not previously approved for sale in Canada as a drug, and the Minister, in support of the manufacturer's submission or supplement, relies on data contained in the information or material filed by the innovator, the Minister shall not issue a notice of compliance in respect of that submission or supplement earlier than five years after the date of issuance to the innovator of the notice compliance or approval to market that drug, as the case may be, issued on the basis of the information or material filed by the innovator for that drug. 6. Subsection (1) does not apply where the manufacturer of a new drug for which a notice of compliance was issued pursuant to section C.08.004 gives written permission to another manufacturer to rely on the test or other data filed in respect of that new drug. 7. Subsection (1) does not apply where the data relied upon by the Minister was contained in information or material filed by the innovator before January 1, 1994.
6	**China**	In compliance with Article 39.3 of the TRIPS Agreement, China agrees to provide effective protection against unfair commercial use of undisclosed test or other data submitted to authorities in China as required in support of applications for marketing approval of pharmaceutical or of agricultural chemical products which utilized new chemical entities, except where the disclosure of such data was necessary to protect the public, or where steps were taken to ensure that the data are protected against unfair commercial use. This protection would include introduction and enactment of laws and regulations to make sure that no person, other than the person who submitted such data, could, without the permission of the person who submitted the data, rely on such data in support of an application for product approval for a period of at least six years from the date on which China granted marketing approval to the person submitting the data. During this period, any second applicant for marketing authorization would only be granted market authorization if he submits his own data. This protection of data would be available to all pharmaceutical and agricultural products which utilize new chemical entities, irrespective of whether they were patent protected or not. Implementing Regulation Drug

		Administration Law of China Article 31 – Draft of February 19, 2002 1) The government shall protect against unfair commercial use by any other person the clinical trial data and other data submitted by an applicant in obtaining marketing approval of a drug containing a new chemical entity. 2) Within six years from the date of obtaining marketing approval for the drug containing a new chemical entity, an application for manufacture or marketing approval by another using the above data without the express consent of the original applicant shall not be approved by drug administration authorities. As used herein, the term "marketing approval" refers to any certificate that permits a drug to be sold in China. The drug administration authorities shall not disclose the data mentioned in provision 1 except in the following situations (1) when necessary to protect the public provided that any disclosure shall be limited to only that portion of the data necessary for this purpose and (2) only if measures have been taken to ensure such data is protected against unfair commercial use. This regulation is effective from China's entry into the World Trade Organization on December 11, 2001. (Period of protection is 6 years)
7	**Dominican Republic**	Industrial Property Law Article 181 of Law 20-00 When the procedure before the national competent authority to authorize the marketing or the sale of a pharmaceutical or agrochemical product containing a new chemical component requires the presentation of secret data or information, these are protected from unfair commercial use by third parties. The secret data or information referred to in the preceding paragraph is protected against disclosure. The disclosure may be carried out by the national competent authority when it is necessary to protect the public, or when adequate measures have been adopted to ensure that the data or information are protected against their unfair commercial use by third parties. (Period of Protection not specified)
8	**Honduras**	Industrial Property Law, Article 73 and 74 When submittal of data or trade secrets are required for procedures carried out before competent local authorities to obtain licenses, permits or authorizations for the commercialization or sale of a pharmaceutical or agrochemical products that contains a new chemical component, trade secrets shall be protected against commercial or unfair practices of third parties. Secret data or information referred to in the previous article shall also be protected against disclosure. However, local competent authority may disclose it when necessary to protect the public or when adequate measure have been adopted to ensure that data or information remain protected against third party commercial or unfair use.(Period of protection not mentioned)

9	**Nicaragua**	Article 125 of Nicaragua New Law of Patents 3) The Pharmacy Division is required to prevent information provided to it by pharmaceutical firms from being disclosed to, acquired or utilized by third parties. The Pharmacy Division shall catalog the information as secrets in the following instances: 3.1) When it is not accessible by persons who normally handle information regarding medications. 3.2) When it has commercial value in order to be secret (Period of protection not specified)
10	**Panama**	When the Members require, as a condition for approval of the sale of pharmaceutical products or chemical agricultural products that use new chemical entities, the filing of undisclosed test and other data the assembling of which requires a considerable effort, they shall protect these data from any unfair trade use. In addition, the Members shall protect these data from any disclosure except as may be necessary to protect the public, unless measures are adopted to ensure protection of the data from any unfair trade use. (Same as Article 39.3 of TRIPS Agreement)
11	**Denmark**	Article 10(1)(a)(iii) of Directive 2001/83 In derogation of Article 8(3)(i), and without prejudice to the law relating to the protection of industrial and commercial property:(a) The applicant shall not be required to provide the results of toxicological and pharmaceutical tests or the results of clinical trials if he can demonstrate:(iii) that the medicinal product is essentially similar to a medicinal product which has been authorised within the community, in accordance with community provisions in force, for not less than six years and is marketed in the Member State for which the application is made; this period shall be extended to 10 years in the case of high technology medicinal products having been authorised according to the procedure laid down in Article 2(5) of Council Directive 87/22/EEC; furthermore, a Member State may also extend this period to 10 years by a single decision covering all medicinal products marketed on its territory where it considers this necessary in the interest of public health. Member States are at liberty not to apply the six-year period beyond the date of expiry of a patent protecting the original medicinal product. Article 13(4) of Regulation (EEC) No. 2309/93 Medicinal products which may have been authorized by the Community in accordance with the provisions of this Regulation shall benefit from the ten-year period of protection referred to in point 8 of the second paragraph of Article 4 of Directive 65/65 [superseded by Article 10.1(a)(i) of Directive 2001/83/EC].

12	**Switzerland**	Decree on Medications – Section 3, Article 17 In the case of an application for approval of a medication that is essentially the same as an already approved medication (original preparation) and is designed for the same use, the application can be based on the results of its pharmacological, toxicological, and clinical tests, if: a. The permit holder of the original preparation approves in writing; or b. Ten years have passed since the approval of the original preparation. If a new indication, a new method of administration, a new method of dispensing, a new dosage, or application to a new target animal species has been approved, an application as described in paragraph 1 can be based on the pertinent test results if: a. The permit holder of the original preparation approves in writing; or b. Three years have passed since the approval of the original preparation. Upon request the Institute shall extend the protective period under paragraph 2-b to five years if a significant therapeutic improvement is achieved thanks to the new method of administration, new method of dispensing, new dosage, or application to a new target animal species. The protective term is indicated with the permit. (Period of protection is for 10 years)
13	**Turkey**	Annex 8 on Protection of Intellectual, Industrial and Commercial Property of the Customs Union Agreement Article 9 provided that the following conditions are documented and supported sufficiently, it may not be necessary to submit with the application form the pharmacological and toxicological test results or clinical studies on the medicinal product a) If the product in question is completely identical to a product previously licensed by the Ministry (with the proof that it is the same qualitative and quantitative composition, has the same pharmaceutical form, is administered via the same route, and if applicable has the same bioavailability); b)If its active ingredient(s) are proved, with reference to the published literature, to have a known activity, acceptable safety and established medical use. In this case the applicant shall submit previously published literature and information on the efficacy and safety of the medicinal product in question. (Period of protection not mentioned)

14	**Bulgaria**	Law on Drugs and Pharmacies in Human Medicine, Article 18 (1) The manufacturer or the person authorized by him referred to in paragraph 5 of Art. 17 shall submit to the Executive Drug Agency an application following a specimen approved by the Minister of Health. (2) For an original medicinal product, the application shall be accompanied by a dossier which contains administrative, chemico-pharmaceutical, pharmacotoxicological and clinical data in conformity with the requirements to these data specified in a regulation by the Minister of Health. (3) The applicant shall not be required to provide the results of pharmacological and toxicological tests or the results of clinical trials for a product which is essentially similar to an original medicinal product which has been granted marketing authorization if he can demonstrate that: 1. The marketing authorization holder of the original medicinal product has consented in writing to the pharmacological, toxicological and clinical references being used for the purpose of examining the documentation of the essentially medicinal product; 2. There is published scientific literature from which it is evident that the medicinal substances in the composition of the medicinal product proposed for obtaining marketing authorization have a well established medicinal use, with recognized efficacy and an acceptable level of safety; 3. That the medicinal product is essentially similar to an original medicinal product which has been authorized in the Republic of Bulgaria for not less than six years since the date of the first marketing authorization or 10 years in the case of high-technology medicinal products in the European Union or the Republic of Bulgaria. In these cases, the abovementioned six-year, or 10-year period, respectively, beyond the date of expiry of a patent protecting the original medicinal product on the territory of the Republic of Bulgaria, shall not be applied. (4) When the medicinal product for which marketing authorization is requested is proposed for different therapeutic indications or is intended for administration by a different route or in doses different from the doses of the original medicinal product, the results of the necessary pharmacological and toxicological tests and/or the results of clinical trials shall be submitted.
		Regarding the approval of Regulations on data exclusivity For medicinal products for human use Art. 23 – (1) Original medicines authorized for the release on the market in Romania receive exclusivity of the data for a period of 6 years, respectively for 10 years for the products of high technology, since their authorization date in the European Union or in the country of origin.

15	**Romania**	(2) The phrase exclusivity of the data means the right granted to the producer of an original medicine for being, for the period of time stipulated in article (1), the exclusive beneficiary of the pharmaceutical, toxicological and clinical studies performed in order to release the original medicine on the market. (3) During the data exclusivity period, another medicine similar with the original cannot be authorized – another medicine containing the same active substance as the original product – unless the new producer presents the results of its own pharmaceutical, toxicological and clinical studies or has the written approval of the producer of the original medicine. (4) After expiration of the data exclusivity period, similar medicines may be authorized based on the results of the pharmaceutical, toxicological and clinical studies of the original product. (Period of protection is 6-10 years)
16	**Saudi Arabia**	Saudi Arabia provides de facto 39.3 protection. International treaties are deemed self-executing. However, no separate legislation exists.
17	**South Africa**	Medicines Control Act 101 of 1965, Section 34 The general confidentiality section in the Medicines Control Act has a general confidentiality provision. Section 34 Preservation of secrecy: No person shall, except for the purpose of the exercise of his powers or the performance of his functions under this Act, or for the purpose of legal proceedings under this Act, or when required to do so by any competent court or under any law, or with the written authority of the Director-General, disclose to any other person any information acquired by him in the exercise of his powers or the performance of his functions under this Act and relating to the business or affairs of any person, or use such information for self-gain or for the benefit of his employer. In practice, this provision does not always prevent reliance of the innovator's dossier during the period of exclusivity. However, the net effect of this breakdown is usually not commercially significant due to the existence of product patents.
18	**Hong Kong**	Pharmacy and Poisons Ordinance In Hong Kong, pharmaceutical products must be registered with the Department of Health under the Pharmacy and Poisons Ordinance (Cap.138) before sale. For a product to be registered, the manufacturer concerned is required by Cap.138 to provide the necessary scientific documentation to substantiate the safety, efficacy and quality of the product. If the applicant does not provide his own documentation, the Department of Health will not refer to other sources. Undisclosed documentation submitted by another manufacturer to the Department of Health in support of the application for registration of another pharmaceutical product is never referred to, nor is it relied on, by the Government examiners so as to protect data contained therein against unfair

		commercial use. Any data supplied in respect of the registration of pharmaceutical products is kept in the Confidential Registry of the Department of Health. The data is viewed only by a limited number of Government officers on a need-to-know basis for registration and is never used in other registration applications unless under written authorization from the supplier of the original data.
19	**Japan**	Japanese Drug Regulation, Article 18-3 As a general rule, application for approval of new drugs, or those products that are subject to re-examination, must accompany a variety of data including clinical trial results. Once the new drug is approved (generic) applicants other than the developer are not allowed to simply refer to the information on file. Any application of the same product by a third party is subject the following requirement: In case where an application is made for a drug which appears to be identical to a [previously approved] new drug in terms of the ingredient and content, directions and dosages, and indications and effects, during the re-examination period of the said new drug, the application must include such data that will be equivalent or superior to those of the said new drug. This re-examination period is what the Law defines as a surveillance period during which an approved product is subject to Good Post-Marketing Surveillance Practice monitoring (including phase IV investigation) and efficacy. The idea is that no further approval be granted for the same product without a full data set until the safety and efficacy of the pioneer product has been demonstrated clinically.
20	**New Zealand**	Medicines Act 1981 (New Zealand) Protection of confidential supporting information about innovative medicines—Where the Minister receives, or received not more than 5 years before the commencement date, an innovative medicine application and confidential supporting information, the Minister, during the protected period in relation to that confidential supporting information, Shall take reasonable steps to ensure that that confidential supporting information is kept confidential to the Minister; and Shall not use that confidential supporting information for the purposes of determining whether to grant any other application. History Sections 23A to 23C were inserted, as from 1 January 1995, by s 2 Medicines Amendment Act 1994 (1994 No 128). See reg. 2 Medicines Amendment Act Commencement Order 1994 (SR 1994/298).
21	**Pakistan**	Drugs Act, 1976. Section 43 of the Drugs Act This Act provides de facto 39.3 protection. It permits the Federal Government to frame the necessary secondary (subordinate) legislation to carry out the purposes of the Act. The relevant rules are the Drugs (Licensing, Registering and Advertising) Rules, 1976. The Rules require extensive information to be provided to the Drugs Registration Board for registering drugs. There is no

		provision in the Rules requiring or permitting a disclosure of this information to any third person. Reference should, however, be made to section 40 of the Act, which is in the following terms: 40. Publication of result of test or analysis, etc. it shall be lawful for the Federal Government to publish, in such manner as it may be deemed fit, the result of any test or analysis of any drug for public information and to pass such orders relating to the withdrawal of such drug from sale and its disposal as it may consider necessary. The Federal Government may, if it considers necessary in the public interest so to do, publish for public information, in such manner as it may deem fit, any information relating to a drug or to the use of a drug in specified circumstances.
22	**Thailand**	Trade Secret Act, Chapter 3, Section 15 The recently enacted Trade Secret Act provides for the "Preservation of Trade Secrets by Government Entity." Section 15 of the Act provides that in cases where the law requires the applicant for a permit to produce, import, export, or sell Drugs or Agricultural Chemical Products using new chemical substances, to submit information supporting the request for a permit, and if such information, either wholly or partly, is a Trade Secret in the form of test results or other information regarding its preparation, discovery, or development which has involved great effort, and the applicant has requested in writing to the government entity to preserve such trade Secret, the government entity therefore has the responsibility to preserve and prevent such Trade Secret from being disclosed, taken away, or unfairly used for commercial purposes, according to the regulations prescribed by the Minister.

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SELECT BIBLIOGRAPHY

Primary Sources

GATT (1994): The Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal texts, Geneva, June.

GATT (1994): Agreement on Trade Related Aspects of Intellectual property Rights, Marrakesh Agreement Establishing the WTO; Annex 1C, 15 April 1994 reprinted in GATT (1994) pp.365-403.

GATT(1994) Understanding of Rules and procedure Governing Settlement of Disputes, Annex 2 of Marakkesh Agreement establishing the WTO in GATT (1994), pp.403-433.

GATT (1988): MTN. GNG/NG11/W/26: Guidelines and Objectives Proposed by the European Community for the Negotiations on Trade Related Aspects of Substantive Standards of Intellectual Property Rights, 7 July.

GATT (1989): MTN.GNG/NG11/W/35: standards and Principles Concerning the Availability, Scope and Use of Trade Related Intellectual Property Rights- Communication from India, 10 July.

GATT (1989): MTN. GNG/NG 11/W/57: Communication from Brazil, 11 December.

GATT (1990): MTN. GNG/NG11/W/68: Draft Agreement on Trade Related Aspects of Intellectual Property Rights- Communication from European Communities, 29 March.

GATT (1990): MTN. GNG/ NG11/W/70: Draft Agreement on Trade Related Aspects of Intellectual Property Rights- Communication from United States, 11 May.

GATT (1990): MTN. GNG/ NG11/W/73: Draft Agreement on Trade Related Aspects of Intellectual Property Rights- Communication from Switzerland, 14 May.

GATT (1990), Communication from Argentina, Brazil, Chile, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania and Uruguay, WTO Doc. MTN. GNG/NG11/W/71, 14 May 1990.

WIPO (1967) Paris Convention for the Protection of Industrial Property, March.20, 1883, as last revised at Stockholm on July.14, 1967, 21 U.S.T 1583,828 U.N.T.S 305.

WIPO (1971) Berne Convention for the Protection of Literally and Artistic Works, Sept.9,1886, as last revised at Paris, July 24, 1971, 828 U.N.T.S 221.

WIPO (1996) Model provisions on Protection against Unfair competition available at http://www.wipo.int/cf diplaw/en/trips/doc/unfair_competition. Doc.

North American Free Trade Agreement. US-Can-Mex, 107 stat2057, 32 ILM 605 (1993).

Free Trade Agreement US-Singapore, available at http;// www.ustr.gov/new/fta/singapore/find 2004-01-15-final.pdf

Vienna Convention on Law of Treaties, May 23, 1969, 1155 U.N.T.S 331.

WTO (1999), Argentina- patent protection for pharmaceuticals and Test Data protection for agricultural chemicals; Request for consultation by US WT/DS171/1, IP/D/18; WT/DS 196/1.

WTO, TRIPS and Public Health, Submission by African Group, WTO Doc. IP/C/W/296.

WTO (2000): Communication from India: Proposals on Intellectual Property Issues, IP/C/W/195, 12 July.

WTO (2001); Communication from the EU and its Member States on the relationship between the provisions of the TRIPS Agreement and the access to medicines, IP/C/W/280, 12 June 2001.

WTO (2001): Communication from the United States, WTO DOC. MTN. GNG/Ip/C/M/31, 10 July 2001.

WTO (1997): Report of the Appellate Body on US Complaint concerning India's Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS 50/ AB/R, December 1997.

WTO (1998): Report of the Panel on European Communities Complaint concerning India's Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS 79/ AB/R, 24 August 1998.

WTO (1999): Report of the Panel on United States- Section 301-310 of the Trade Act of 1974, WT/DS152/R, 22 December 1999.

USTR (2005): Report to Congress on Section 301 Developments, Available at www.ustr.gov.

Drug Price Competition and Patent Term Restoration Act (Hatch- Waxman Act), 1986 codified 15 U.S.C., 21 U.S.C., 28 U.S.C and 35 U.S.C.

Drugs and Cosmetics Act, 1940, Available at India Code.

Insecticides Act, 1968, Available at India Code.

Official Secrets Act, 1923, Available at India Code.

Secondary Sources

Books

Abbot Fredrick, T*he Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional free Trade Agreements* (Geneva: Quaker United Nations Office, 2004).

Beier, Fredrich-Karl and Schricker, Gerhad , *From GATT to TRIPS-The Agreement on Trade –Related aspects of Intellectual property Rights* (Germany :A IIC Studies, ,Max planck Institute for Foreign and International patent, copyright and Competition law,Munich,1996).

Bellmann, Christophe, Dutfield, Graham and Melendez Ricardo, *Trading in knowledge, Development perspectives on TRIPS Agreement, Trade and Sustainability* (London: ICTSD, Earth Scan Publishers, 2003).

Bhagwati, Jagadish., Hirsch, M, *The Uruguay Round and Beyond* (Heidelberg: Springer- Verlay Berlin, 1998).

Bodenhausen, G.H.C, *Guide to the Application of the Paris Convention for the Protection of Industrial Property* (Geneva: BIRPI ,1968).

Correa, Carlos, *Protection of Data submitted For the Registration of Pharmaceuticals; Implementing the Standards of TRIPS Agreement* (Geneva: South Centre Publication,2002).

Correa,Carlos and Yusuf, Abdulqawi, *Intellectual Property and International Trade. The TRIPS Agreement* (London: Kluwer Law International, 1998).

Correa, Carlos, *Intellectual property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options* (London: Zed Books, 2000).

Debroy,Bibek, *Intellectual Property Rights Beyond 2005(An Indian Perspective on the Debate on IPR protection and the WTO* (India: D.C School of Management, 2005).

Drahos, Peter and Mayne Ruth, *Global Intellectual property Rights, Knowledge Access and Development* (Palgrave Macmillan Publications for Oxfam, 2002).

Gamharter, Katharina, *Access to affordable medicines* (New York: Springer wein,2004).

Gervais Daniel, *The TRIPS Agreement Drafting History and Analysis* (London: 9 Sweet and Maxwell, 1998).

Gopakumar K.M, *TRIPS Agreement Implementation and Public Health Safeguards* (New Delhi: South Asian Year Book of Trade and Development, Centad, 2005)

Gopalakrishnan N.S , Kadavan.Benoy, *Study on Test Data Protection in India* (Lucknow; Eastern Book Company,2005).

Gorlin,Jacques, *An Analysis of the Pharmaceutical-Related provisions of the WTO TRIPS(Intellectual Property)agreement* (London: Intellectual Property Institute,1999).

Hoekman, Bernard and Michel Kostecki, The *Political Economy of the World Trading System* (Oxford: Oxford University Press, 2000) .

IIFT Study, *Article 39.3 of the TRIPS Agreement: Its Genesis and the Present Context* (New Delhi: Indian Institute of Foreign Trade, 2003).

Jackson, John H, *The WTO Constitution and Jurisprudence* (London :Chetham Home papers, The Royal Institute of International Affairs,1998).

Maskus,Keith, *Intellectual Property Rights in the Global Economy* (Washington :Institute of International Economics, 2000).

Michalopoulos, Constantine, *Special and Differential Treatment of Developing Countries in TRIPS* (Geneva: Quaker United Nations Office).

Musungu, Sislue F, Susan Villanueva and Roxana Blasetti, *Utilising TRIPS Flexibilities for Public Health Protection through South-South Regional Frameworks* (Geneva: South Centre,2004) .

Norton Joseph& Blood worth.L. Thomas, *NAFTA and Beyond, A New Frame Work for doing Buisness in the Americas* (London :Martinus Nijitoff Publishers,!995).

Trebilcock, Michael and Howse, Robert, *The Regulation of International Trade* (London:Routledge,1999).

UNCTAD/ICTSD, *Resource Book on TRIPS and Development: Undisclosed Information* (New York: Cambridge University Press, 2005).

Watal Jayashree, *Intellectual Property Rights in the WTO and Developing Countries* (London: Oxford University press, 2001).

Articles

Abbot, Fredrick, "Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework", *Vanderbilt Journal of Transnational Law*, Vol.22, 1989, P.689- 745.

Abbot, Fredrick, "The TRIPS Agreement Access to medicines and Ministerial Conference", *Journal of World Intellectual property,* Vol.5, 2002, Jan pp 15-52.

Abbot, Fredrick, "Toward a New Era of Objective Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism", *Journal of International Economic Law,* 2001, pp 77-100.

Arrivillaga.R.Lucas, "An International standard of protection for Test Data Submitted to Authorities to obtain marketing Authorization for Drugs, TRIPS Article 39.3", *Journal of World Intellectual property,* Vol.6,2002, Jan pp 139-154.

Bronckers, Marco & Ondrusek Petr, "Protection of Regulatory Data in the EU and WTO Law- The Example of Reach", *Journal of World Intellectual Property*, Vol.8, 2005, Sep pp 579-598.

Correa, Carlos, "Unfair Competition under the TRIPS Agreement; Protection of Data Submitted For the registration of Pharmaceuticals," *Chicago Journal of International law*, Vol. 3, 2002, pp 69-78.

Correa, Carlos, "Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines", *Case Western Reserve Journal of International Law*, Vol.36, 2004, pp 79-94.

Dannenmaier, Eric, "Trade Democracy, and the FTAA: Public Access to the Process of Constructing a Free trade Areas of the Americas", *Fordhan International Law Journal,* Vol.27, 2004, pp 1066-1117.

Dimatteo, Lary, "The Doha declaration and Beyond: Giving a voice to Non-trade Concerns within the WTO Trade regime", *Vanderbilt Journal of Transnational Law*, Vol.36, 2003, pp. 95-160.

Dinga, Razvan, "The Bermuda Triangle of Pharmaceutical Law, Is Data Protection a Lost Ship?" *Journal of World Intellectual Property*, Vol.8, 2005, pp 517- 563.

Drahos, Peter, "Bits and Bips Bilateralism in Intellectual Property", *Journal of world Intellectual property,* Vol. 7, 2004, pp-791-808.

Drahos, Peter, "The Regulation of Public Goods", *Journal of International Economic Law*, Vol.7, 2004, pp.321-339.

Endeshaw, Assafa, "Asian Perspectives on Post- TRIPS Issues in Intellectual Property", *Journal of World Intellectual Property*, 2003, pp 211-235.

Ethier, Wilfred, "Intellectual Property Rights and Dispute Settlement in the World Trade Organisation", *Journal of International Economic Law*, 2004, pp 449-458.

Fellmeth, Xavier Aaron, "Secrecy, Monopoly and Access to Pharmaceuticals in International Trade law, Protection of Marketing Approval data under the TRIPS Agreement," *Harvard International Law Journal,* Vol.45 , 2004, pp 443-502.

Geuze, Matthijs and Wager Hannu, "WTO Dispute Settlement Practice Relating to the TRIPS Agreement", *Journal of International Economic Law*,1999, pp 347-384.

Ghanotakis, Elena, "How the US Interpretation of flexibilities Inherent in TRIPS affects Access to Medicines for Developing countries", *Journal of world Intellectual property,* Vol.6, 2003, pp 563-591.

Hilaire, Alvin, "The United States and the New Regionalism/Bilateralism", *Journal of World Trade*, Vol.38, 2004, pp 603-626.

Lemely, Mark, A, "Property, Intellectual Property, and Free Riding", *Texas Law Review*, Vol.83, no.4, 2005, pp 1031-1076.

Maskus, Keith E. and Jerome H. Reichman, "The Globalisation of Private Knowledge Goods and the privatisation of the Global Public Goods", *Journal of International Economic Law,* Vol.7, 2004, pp.279-320.

Meitiner, Ingo, "Implementation of Test Data Protection According to Article39.3 of TRIPS-The Search for a fair Interpretation of the term Unfair Commercial Use", *Journal of World Intellectual Property*,Vol.8, 2005, No.2 Mar, pp123-139.

Naiki, Yoshiko, "The Mandatory/ discretionary Doctrine in WTO Law, the US-Section 301 Case and its Aftermath", *Journal of International Economic Law*, 2004, pp 23-72

Okediji.L. Ruth, "Public Welfare and the Role of WTO: Reconsidering the TRIPS Agreement", *Emory International Law Review*, Vol.17, 2003, No.2, pp.819-918.

Otten, Adrian, "Implementation of the TRIPS Agreement and Prospects for its Further Development", *Journal of International Economic Law*, Vol.1, No.4, pp. 523-536.

Otten. Adrian, "Compliance with TRIPS: The Emerging World View", *Vanderbilt Journal of Transnational Law,* Vol.29, 1996, pp 391-413.

Powell, Mark, "The European Union's Database Directive: An International Antidote to the Side Effects of Fiest", *Fordham International Law Journal*, Vol.20, 1997, pp 1215-1250.

Reichman.H.Gerome, "The TRIPS Agreement comes of Age; Conflict or Cooperation with the Developing countries?" *Case western Reserve Journal of International Law,* Vol.8 ,2002, pp 423-452.

Reichman, J. H, "Securing Compliance with the TRIPS Agreement after US v. India", *Journal of International Economic Law*, Vol.1, No.4, 1998, December, pp. 585-601.

Reichman.J.H and Samuelson Pamela, "Intellectual Property Rights in Data", *Vanderbilt Law Review,* Vol.51, 1997, pp52-163.

Reichman. J.H, "Universal Minimum Standards of Intellectual Property Protection under the TRIPS Component of the WTO Agreement", *The International Lawyer*, Vol.29, 1995, p 378.

Schaefer, Mathew, "Section 301 and the World Trade Organisation: A Largely Peaceful Coexistence to Date", *Journal of International Economic Law*, 1998, pp 156-160.

Schricker, Gerhard "Twenty five Years of Protection against Unfair Competition", *International Review of Industrial Property and Copyright Law*, Vol.26, 1995, pp.782-801.

Skillington,lee and Solovy.M. Eric, "The Protection of Test and other Data Required by Article 39.3 of the TRIPS Agreement", *North western Journal of International Law and Business,* Vol.24, 2003, No.1, pp1-52.

Sun ,Haochen, "Reshaping the TRIPS Agreement concerning Public Health- Two critical Issue" *,Journal of world Trade,* Vol.37,2003,.no 1, pp 163-198.

Timmermans, Karin, "Interwining Regimes: Trade, Intellectual property and Regulatory requirements for pharmaceuticals", *Journal of world Intellectual Property,* Vol.8, 2005, no.1, pp 67-74.

Tully, Danielle, "Prospects for Progress: the TRIPS Agreement and Developing Countries after the Doha Conference", *Boston College international and Comparative Law Review,* Vol.26, 2003, pp 129-143.

Verma, S.K, "Legal protection of Trade Secret and confidential Information", *Journal of Indian Law Institute,* Vol.44, 2002, .no.3, pp 336-353.

Verma, Surinder Kaur, "Protection of Trade Secrets under TRIPS Agreement and Developing countries", *Journal of World Intellectual property, Vol.1, 1998,* No.5, pp 723-742.

Watal, Jayashree, "TRIPS and the 1999 WTO millennium Round-Some reflections on fundamental issues related to IPRs in the WTO and the way forward For developing countries", *Journal of World Intellectual property*, Vol.3,2000, No.1, Jan, pp 3-29.

Watal, Jayashree, "The TRIPS Agreement and Developing Countries. Strong weak or Balanced Protection?" *Journal of World Intellectual Property*, Vol.1, 1998, No.2, Mar, pp 281-304.

Reports

Commission on Intellectual Property Rights, *"Integrating Intellectual Property Rights and Development Policy"*, London, September, 2002.

Correa, Carlos, *"Implications of the Doha Declaration on the TRIPS Agreement and Public Health"*, World Health Organisation, Geneva, 2002.

Correa, Carlos, *"Integrating Public Health in Patent Legislation in Developing countries,"* Report prepared for the Rockefeller Foundation, *New York*, 2002.

Correa, Carlos, *"TRIPS Disputes: Implications for the Pharmaceutical Sector"*, Quaker United Nations Office, Geneva, 2002.

Drahos, Peter *"Developing Countries and International Intellectual Property Standard-Setting"*, Commission on Intellectual Property Rights", London, 2002.

Gorlin, Jacques, Encouragement of New Clinical drug Development: The Role of Data Exclusivity (IFPMA, 2000).

Meir Perz Pugath, *"Intellectual Property and Pharmaceutical Data Exclusivity in the context of Innovation and Market Access"*, ICTSD- UNCTAD Dialouge on Ensuring Policy Options for Affordable Access to Essential Medicines, October, 2004.

Priapantja, Cita Cirtawinda, *"Trade Secret: How does this Apply to Drug Registeration Data"?* Paper presented at the ASEAN Workshop on "The TRIPS Agreement and its impact on Pharmaceuticals", Department of Health and World Trade organisation, Jakarta, 2-4 May 2000.

Reichman, Jerome , *"Undisclosed Clinical Trial Data: Under the TRIPS Agreement and its Progeny: A Broader Perspective"*, ICTSD- UNCTAD Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines, October, 2004.

Royal Society, *"Keeping Science Open: The Effects of Intellectual Property in the Conduct of Science"*, London.

Thorpe, *"Implementation of the TRIPS Agreement by Developing Countries"*, Commission on Intellectual Property, London, September 2002.

WHO, *"Report of an Asean Workshop on the TRIPS Agreement and its Impact on Pharmaceuticals"*, Asean Worksop, Jakarta, 2-4 May, 2000.