

I-MAK
INITIATIVE FOR
MEDICINES, ACCESS
& KNOWLEDGE

**THE IMPACT OF ARTICLE 39.3 IN
INDIA: A PRACTICAL PERSPECTIVE**

JULY 2006

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INITIATIVE FOR MEDICINES, ACCESS & KNOWLEDGE (I-MAK)

The vision of I-MAK is to bring new and practical perspectives to issues impacting medicines, access and knowledge.

As such, our objective is two-fold:

We seek to offer new tools for patients, indigent communities and the public at large who are struggling to access medicines, resources, and treatment. The voices of all groups deserve to be heard in debates which affect these basic rights.

Our aim is also to bring together the expertise of practising intellectual property (IP) lawyers, treatment-access specialists, civil society groups, established academics, policy makers, and patients in order to provide a holistic, pragmatic approach to IP and health issues. We hope to bridge theory and policy with practice, and to engage in action that shapes the law.

Through this approach we intend to challenge inequities which exist today, simplify technocratic issues, and help amplify the voices of those who seek information, justice and health.

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PREFACE

In the coming weeks, India will decide whether it needs to adopt a data exclusivity regime for pharmaceutical test data. This decision could impact how patients in India, and developing countries elsewhere, are able to access essential medicines.

During the negotiations of the Agreement on Trade Related Aspects of Intellectual Property (TRIPS) and following India's accession to the World Trade Organisation (WTO), India adopted the position that Article 39.3 does not require that pharmaceutical test data be granted exclusivity for any period of time. However, as subsequent bilateral and free trade agreements between the United States and developing countries have impressed a reading of Article 39.3 requiring data exclusivity, India's stand against such a regime has become much more subdued.

The debate surrounding Article 39.3 has largely concentrated on textual interpretation and how to "balance" the investments by innovator companies against the interests of generic pharmaceutical manufacturers and public health. Given the ambiguity regarding what the minimum requirements of Article 39.3 are, commentators more recently have offered an alternative reading of the text, and have proposed that data exclusivity is not required by Article 39.3 but that "compensatory liability" is. While this new textual interpretation may not be accurate, it is being raised as a possible way to appease those Member States demanding a strict data exclusivity regime.

An Inter-Ministerial Committee, set up in 2004 to decide on how to implement Article 39.3 of TRIPS, recently convened a meeting which tabled a number of proposals and recommendations, including the payment of a royalty to the originator of the data. However, many of the proposals and recommendations appear to have been made in the abstract, without examining the practical implications a data exclusivity regime would have on actual medicines on the market today.

Due to this gap in the ongoing discussions, a different perspective addressing these practical realities is necessary. Decision makers and stakeholders need to be aware of the potential pitfalls of proposals that may seem attractive on paper but have the potential to become problematic in practice.

This paper is premised on the assumption that the reader already has an understanding of the academic and legal discussions around Article 39.3. We have set out below a consolidated analysis of the current debate in India, this time with a view toward the practical effects of the various proposals. Using examples of medicines that are already on the market, and some which do not yet have marketing approval in India, we attempt to demonstrate how the current proposal of a three-year data exclusivity period would impact access to these medicines. Additionally, we provide analysis and recommendations relating to the current proposals being considered, which we hope will provide further thought to the debate.

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I. INTRODUCTION

There are two primary positions in the ongoing discussions about Article 39.3. The contrasting positions and interpretations of Article 39.3 have been well documented to date, and from this documentation, it is evident that these prominent interpretations are polarised.

One side of the debate is led by the United States, the European Union and the multinational pharmaceutical industry, which interpret Article 39.3 as requiring a standard of “data exclusivity” that includes preventing regulatory bodies of Member States from relying on data submitted by the originator company for a “reasonable” period of time.¹

The other side includes some Member States, legal experts and health specialists, who believe that Article 39.3 only requires protection of data from disclosure and fraudulent use of test data, but not data exclusivity.² These groups argue that Article 39.3 does not prevent regulatory bodies of Member States from relying on data submitted by the originator company when deciding whether to register a generic version of the same product.³

More recently, some commentators and legal experts have suggested a possible “middle road” for interpreting the intended minimum requirement expected of

¹ See, e.g., European Union (EU), *Compulsory Licensing and Data Protection* (2001); International Federation of Pharmaceutical Manufacturers Associations (IFPMA), *Encouragement of New Clinical Drug Development: The Role of Data Exclusivity* (2000).

Within India, the Ministry of Chemicals and Fertilisers, Nicholas Piramal Ltd. and the Organisation for Pharmaceutical Producers India have also expressed support for a data exclusivity regime. See *Minutes of the Inter-Ministerial Meeting held under the Chairmanship of Secretary (C & PC)* [hereinafter *Inter-Ministerial Minutes*] (22 May 2006), at 16-17.

² The words “Members, when requiring...” in Article 39.3 have been interpreted by some in this group to mean that TRIPS only requires members to protect data where it is condition to submit such information to obtain marketing approval for pharmaceutical or agrochemical products and does not apply where regulatory authorities of Member States grant marketing approval by relying on the existence of a prior registration elsewhere. See UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (2004), at 530.

³ See, e.g., TRIPS Council–Africa Group et al., *TRIPS and Public Health* (paper submitted to the TRIPS Council by the Africa Group, Barbados, Bolivia, Brazil, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand, and Venezuela), IP/C/W/296 (29 Jun. 2001) (“Article 39.3 does permit a national competent authority to rely on data in its possession to assess a second and further applications, relating to the same drug, since this would not imply any ‘unfair commercial use’”); Carlos Maria Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement* (South Centre, 2002); UNCTAD-ICTSD, *Resource Book*, supra n.2, at ch. 28; Commission on Intellectual Property Rights, *Innovation and Public Health [CIPRH], Public Health, Innovation and Intellectual Property Rights* (WHO, 2006), at 143.

The Ministry of Commerce, Indian Pharmaceutical Alliance and Indian Drug Manufacturers Association have adopted the position (during the Inter-Ministerial Meeting) that Article 39.3 only requires data protection and that data exclusivity is TRIPS-plus. See *Inter-Ministerial Minutes*, supra n.1.

Member States when implementing Article 39.3.⁴ However, many of these suggestions do not stem from a definitive legal interpretation of Article 39.3, but are due to the current trend in developing countries toward implementing data exclusivity regimes as a result of the political pressure of bilateral and free trade agreements.⁵

This paper does not seek to reproduce previous debates on data exclusivity, rather it attempts to offer insights into current proposals and issues in India:

Section II examines the impact of a data-exclusivity model on essential medicines. Using the Inter-Ministerial Draft Proposal as a baseline, we offer five case studies, using differing assumptions and variables, to demonstrate the potential impact. We attempt to model outcomes in situations where:

- (i) patents are not granted in India;
- (ii) patents are granted in India and a compulsory license is issued; and
- (iii) future marketing approval applications for drugs are impacted.

Section III sets out the model of compensatory liability. In this section, we examine whether compensatory liability is required for India to be TRIPS compliant. This section describes both existing and proposed schemes, focusing on cost-sharing. We attempt to highlight experiences with this model and potential consequences of implementing this option.

Section IV assesses whether India's existing legal framework is sufficient to meet its TRIPS obligations. This section considers the common law, the Drugs and Cosmetics Act and the Official Secrets Act. We examine whether retaining the existing framework is practically viable and whether it provides adequate safeguards for the minimum requirements of TRIPS.

Section V concludes this paper by offering recommendations for India's compliance with Article 39.3. We propose the minimum amendments required under TRIPS, but reject the adoption of a data exclusivity model.

⁴ See, e.g., Shamnad Basheer, *Data Protection under Article 39.3 of TRIPS: A 'Compensatory Liability' Model?* (Oxford Intellectual Property Research Centre, 2006); Judit Rius Sanjuan et al., *A Cost Sharing Model to Protect Investments in Pharmaceutical Test Data*, CPTech Policy Brief No.1 (18 May 2006); Aaron Xavier Fellmeth, *Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data Under the TRIPS Agreement*, 45 Harvard Int'l.L.J. 443 (Sum. 2004); Jerome H. Reichman, *Undisclosed Clinical Trial Data under the TRIPS Agreement and its Progeny: A Broader Perspective* (paper submitted at UNCTAD-ICTSD Dialogue on Moving the Pro-Development IP Agenda Forward: Preserving Public Goods in Health, Education and Learning conference, Bellagio, 29 Nov.–3 Dec. 2004).

⁵ Countries which have implemented data exclusivity regimes as a result of bilateral or free trade agreements with the United States include, but are not limited to: Chile, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Mexico, Morocco, Nicaragua, Jordan and Laos.

II. THE REAL LIFE IMPACT OF DATA EXCLUSIVITY

As this section will demonstrate, data exclusivity could potentially impose tremendous costs on all but the originator, and cause severe delay to the introduction of drugs to the market.

The debate over compliance with Article 39.3 and data exclusivity has generated significant controversy in India. In this section, we provide examples that illustrate the effects of creating data exclusivity obligations in India.

We have used essential drugs in these case studies, some of which currently are pending patent applications in India. However, for illustration only, we have created scenarios which consider how data exclusivity can impact access to medicines where these pending patents are granted, where a compulsory licence is issued for granted patents, or where the patent is rejected.⁶

Our starting point is the three-year data exclusivity proposal outlined in the Inter-Ministerial meeting on data protection.⁷ The Inter-Ministerial proposal includes important safeguards designed to mitigate the impact of a three-year data exclusivity on access to medicines (*see box*). In **Part A**, we demonstrate the importance of some of these safeguards.

However, even with the proposed safeguards, serious concerns remain with the Inter-Ministerial proposal. In **Part B**, we illustrate how even the Inter-Ministerial draft in its current form would block generic manufacturers from marketing or distributing certain medicines—and lead to significant increases in the prices of these drugs.

Inter-Ministerial Three-Year Data Exclusivity Proposal

- Exclusivity would be granted for three years from the date of first marketing approval anywhere in the world.
- Exclusivity would be limited to “New Chemical Entities,” defined as drugs for which there was “no prior application for. . . the same drug.” New indications, dosage forms, isomers, etc. would be excluded.
- Application in India within one year of first marketing approval would be required to gain benefits of data exclusivity.
- Data exclusivity would “not exceed the patented term” for patented drugs.
- Data exclusivity may be waived by the government in certain circumstances upon payment of “reasonable royalties” to the original data submitter.

⁶ It should be noted that this paper is not concerned with the patentability of the pending patent applications discussed in these examples. The illustrations provided are not legal opinions of any kind, and should not be taken to suggest that such medicines are or are not patentable under the 2005 Indian Patent (Amendment) Act.

⁷ See *Inter-Ministerial Minutes*, *supra* n.1.

A. PROTECTIONS FOR PATIENTS IN THE INTER-MINISTERIAL DRAFT

Case Study 1. Atazanavir: The Importance of the First Global Filing Date

Facts:

Atazanavir, a crucial second-line Human Immunodeficiency Virus (HIV) medication, is marketed by the pharmaceutical company Bristol-Myers Squibb. It is widely used in the United States, Europe and Brazil to treat patients once they experience treatment failure on their first-line regimen.

Atazanavir is currently not available in India. It does not have marketing approval in this country, although it was first approved in the United States on 20 June 2003.⁸

At the time of this writing, Atazanavir is under patent examination in India.⁹ Solely for purposes of this first case study, we assume the patent on Atazanavir is rejected in India.

Potential Impact of Data-Exclusivity:

Under the Inter-Ministerial proposal, Bristol-Myers Squibb would not be entitled to data exclusivity in India for two reasons. First, the company would have lost the right to data exclusivity for failing to file for approval in India within one year of its first international approval. Second, even had it applied in India in a timely manner, its three years of data exclusivity would have commenced from Atazanavir's first approval worldwide, 20 June 2003, and hence would now have expired.

The outcome would be substantially different if a data exclusivity regime were passed without the safeguards of the Inter-Ministerial proposal—i.e. where the data exclusivity period did not begin with the first global filing date, and originator companies were not required to file in India within one year of their first approval worldwide. If Bristol-Myers Squibb filed for regulatory approval of Atazanavir following the passage of such a data-exclusivity provision now, it would effectively have exclusive rights to manufacture and market the drug in India until 2009. This would be the case even if Bristol-Myers Squibb's patent application on the drug were rejected, as is assumed for this case scenario.

In all likelihood, Bristol-Myers Squibb's resulting monopoly would lead to significant increases in price. As India has already experienced in the Gleevec case, such price increases are likely to drive the cost of treatment far beyond the reach of those in need.¹⁰ This increase in expense would seriously prohibit public procurement of the drug and private HIV treatment efforts, particularly if the price increase reflects the

⁸ See the Indian Ministry of Health web site, at http://www.cdsc0.nic.in/html/new_drugs_app5.html, and U.S Food and Drug Administration web site, at http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=021567&TABLE1=OB_Rx.

⁹ Patent Application No. 805/MAS/1997, claiming priority from Swiss Patent Application Nos. 1018/96, 29/97 and 223/97.

¹⁰ See, e.g., Smita Deshmukh, *Rs 1.2 lakh: Cost of life?*, Times of India (Aug. 27, 2004).

cost of Atazanavir in the United States, where it is more than USD\$10,000 per person per year.¹¹

Case Study 2. Heat-Stable Ritonavir: Defining “New Chemical Entity”

Facts:

Ritonavir, marketed under the brand-name Norvir®, is a critical HIV drug marketed by the pharmaceutical company Abbott Laboratories. Ritonavir is required as a “booster” for all protease inhibitor-based therapies, including Atazanavir (which otherwise is broken down too quickly by the body). Abbott not only markets Ritonavir as a distinct drug, but also in combination with Lopinavir, Abbott’s own protease inhibitor, known by the brand name Kaletra®.

Since Ritonavir is a pre-1995 molecule¹² it is not patentable under the Patent Act.¹³ Currently, some Indian companies do market the drug in India.

However, marketing approval of a new heat-stable formulation of Ritonavir/Lopinavir was granted in the United States in 2005. Approval in Europe followed thereafter in 2006. Unlike Ritonavir gel-caps, which break down rapidly at temperatures above 40° C, the hard heat-stable pills can be stored for long periods even in warm climates. This feature makes the new formulation critical for use in rural areas in India, as well as in developing countries where refrigeration is not possible. Historically, many of these developing countries have depended on Indian manufacturers for supplies of life-saving HIV-medications.¹⁴

Based on information available, no patent has been granted to date anywhere in the world on the heat-stable formulation of Ritonavir or Lopinavir/Ritonavir.¹⁵

¹¹ Doctors Without Borders/Medicines Sans Frontieres, *Data Exclusivity & Access to Medicines in Guatemala* (February 2005), available at <http://www.cptech.org/ip/health/trade/cafta/msf022005.html> (“Today, the US price of atazanavir is more than US\$10,000 per person per year—there is no differential price for developing countries and it must be combined with at least two additional ARVs.”)

¹² See U.S. Patent No. 5,674,882 for Ritonavir, claiming a priority date of December 1993.

¹³ Until 2005, patent applications for new medical substances could only be filed under section 24(B) of the Patent Act, 1970 as amended by the Patent (Amendments) Act, 1999. Section 24(B) was removed by the Patent (Amendments) Act, 2005, when it became obsolete. Protection under this section is only available for inventions that were filed for “on or after the 1st day of January, 1995.” See Section 24(B)(a).

¹⁴ See, e.g., Medicines Sans Frontieres, *More Empty Promises: Abbott Fails to Supply Critical New AIDS Drug Formulation to Developing Countries* (Press Release, 27 Apr. 2006).

¹⁵ The U.S. Food and Drug Administration “Orange Book” which lists all relevant patents for drugs approved in the U.S., lists no patents for heat-stable Kaletra. U.S. patent application 10/650,178, filed in August 2003, but not yet granted, appears to be an application for a patent on the heat stable form. The U.S. application is cited as the priority document for Patent Cooperation Treaty (PCT) Application No. WO/2005/039551. As yet, a preliminary examination report has not been filed for this application.

Potential Impact of Data-Exclusivity:

Under the Inter-Ministerial proposal, Abbott would not be able to use data exclusivity as a “back door” to obtain a limited monopoly right on the heat-stable version of Ritonavir that they could not attain through a patent. The Inter-Ministerial draft would limit data exclusivity to “new chemical entities,” defined as drugs containing an active pharmaceutical substance which has not been previously approved anywhere in the world, but excluding modifications such as new indications, formulations, combinations, salts, esters, crystalline forms and new dosage forms. Since heat-stable Ritonavir would not be a new chemical entity (it includes the same active substances as previously approved forms), it would not be entitled to data exclusivity. (For a more detailed legal analysis of options for defining “new chemical entity,” see Annexure II.)

Under a data exclusivity regime with a less carefully tailored definition of “new chemical entity” the outcome would be different. If heat-stable forms of Lopinavir and Ritonavir could be categorized as “new chemical entities,” Abbott would have exclusive rights to manufacture and market those forms of the drugs in India until 2008 or 2009.¹⁶

Given the importance of the heat-stable forms of these drugs for treatment of HIV in some of the world’s high-prevalence countries, including India, the human cost of this new monopoly right could be significant.¹⁷ In El Salvador and Peru, a one-year course of Ritonavir/Lopinavir is priced at more than double the per capita GDP.¹⁸ If a heat-stable version of Ritonavir is unavailable, protease inhibitors like Atazanavir, which require a booster such as Ritonavir, could not be used in settings where refrigeration is unavailable.

Case Study 3. Atazanavir: The Need for a Public Health Exception

Facts:

We discussed the basic background of Atazanavir in Case Study 1. As we mentioned, the patent application on Atazanavir is currently pending in India. We now examine a scenario in which this patent is granted.

¹⁶ Depending on whether the period of exclusivity commences from the first global marketing approval or from the first approval in India.

¹⁷ For example, Brazil reported in 2003 that it was spending 63% of its total HIV drug budget on just three second-line ARV products, one of which is Abbot’s Lopinavir/Ritonovir—even though these products represent a relatively small share of ARVs used in Brazil. These three ARVs allowed originator companies to extract monopoly rents. In the context on India’s growing HIV population of 5.7 million, see BBC News Online, *India ‘has most people with HIV’* (30 May 2006), available at <http://news.bbc.co.uk/2/hi/health/5030184.stm>, such an expense could result in access to critical drugs being denied.

¹⁸ Ashwin Vasan, et al., *The Pricing and Procurement of Antiretroviral Drugs: An Observational Study of Data from the Global Fund*, 84 Bulletin of the World Health Organization 393, 395 (2006). Abbott also has used its control of Ritonavir to increase the price of even those protease inhibitors that it does not control, but which must be administered in combination with Ritonavir as a booster. See Bob Huff, *Abbott’s Norvir Price Hike Is Bad Medicine*, The Body (Jun. 2004), <http://www.thebody.com/gmhc/issues/mayjun04/abbott.html>.

Given the importance of this medicine for treatment of HIV patients that become resistant to first-line treatment—both in India and in countries around the world who rely on Indian manufacturers to supply ARVs—we assume for purposes of this case study that the government also decides to issue a compulsory license for Atazanavir. (See, however, our cautionary comments below, in Case Study 5, on the difficulty of obtaining compulsory licenses.)

Potential Impact of Data-Exclusivity:

If a compulsory license is issued on Atazanavir, the Inter-Ministerial draft would allow data exclusivity obligations to be waived, subject to the payment of “reasonable royalties.”¹⁹

In the absence of a public health exception allowing a waiver of data exclusivity in appropriate circumstances as proposed in the Inter-Ministerial draft, a compulsory license on Atazanavir could be rendered moot. Although the compulsory license would prevent patent obligations from standing in the way of needed domestic production of Atazanavir or a similar drug, production of the drug would still be blocked by data exclusivity. In short, the very purpose of the compulsory licensing provisions in the Patent Act would be defeated.²⁰

**Summary: The Importance of the Selective Safeguards
in the Inter-Ministerial Draft**

- The term of data exclusivity starts running from the **first filing date worldwide**, and a company must file for marketing approval **within one year** of this date to get the benefits of data exclusivity. Hence, companies cannot claim data exclusivity on drugs like **Atazanavir**, which have long been available in other jurisdictions, but which the originator company has failed to register in India.
- Exclusivity is limited to “**new chemical entities**” **defined strictly**, and is not available for new indications, dosage forms, isomers, etc. Hence companies cannot use data exclusivity to obtain monopolies on new drug forms like **heat-stable Kaletra** that are not patentable.
- Data exclusivity could be waived to safeguard **public health**, so that access could be approved for needed drugs like **Atazanavir** if a compulsory license is issued under the Patent Act.
- In addition to the safeguards, the longer the exclusivity period, the greater the detriment there will be to patients.
- Even with selective safeguards, the Inter-Ministerial Draft **still proposes an exclusivity regime that will negatively impact patients.**

¹⁹ “In the case of a specified situation such as drugs of mass consumption, anti-HIV drugs, etc. the Government can direct the Regulatory Authorities that they can place reliance on the data submitted by the applicant subject to the second applicant willing to pay the reasonable royalty to the first applicant for utilizing the data created and submitted by first applicant.” *Inter-Ministerial Minutes, supra* n.1, at 16.

B. SHORTCOMINGS OF THE INTER-MINISTERIAL DRAFT

While the examples above demonstrate the importance of the safeguards in the Inter-Ministerial proposal, the following examples demonstrate that even with these safeguards, significant concerns remain.

Case Study 4. Zidovudine and Stavudine: Data Exclusivity and Unpatentable “New” Drugs

Facts:

Zidovudine and Stavudine were two of the first medications approved for use on HIV, and are two of the most important HIV medications in the world. Stavudine currently represents 25-27% of the total volume of ARVs taken in the world, and Zidovudine another 5%.²¹ The onset of production of Stavudine by Indian generics manufacturers as part of a fixed dose combination drove the price down for treatment worldwide, and is cited by many as a watershed in the global battle against AIDS.

Both Zidovudine and Stavudine were first discovered in the 1960s,²² long before they were developed for use as an HIV therapy. According to available information, the Stavudine and Zidovudine molecules were not patented anywhere in the world at the time the drugs were first approved for use against HIV.²³ Both of these drugs are currently unpatentable under the Indian Patent Act, and would have been unpatentable²⁴ at the time the drugs were first approved for use against HIV.

Potential Impact of Data-Exclusivity:

Although Zidovudine and Stavudine would not have been “new” for patent purposes, when Bristol-Myers Squibb and GlaxoSmithKline applied for approval of these two drugs, both would have been considered “new chemical entities” under the definition proposed in the current Inter-Ministerial draft. The Inter-Ministerial draft defines a new chemical entity as any drug not formerly approved for clinical use anywhere in the world. Prior to its approval for use against HIV, Stavudine had not been approved

²⁰ Indeed, TRIPS explicitly acknowledges the need for a public health exception for data protection—whether countries’ Article 39.3 obligations are implemented as data exclusivity or otherwise.

²¹ AIDS Medicines and Diagnostics Service (AMDS) Secretariat, *Relative Market Share of Different Antiretroviral Compounds in Low and Middle Income Countries in 2004 and 2005: An Analysis of Two Public Domain Data Bases* (Oct. 2005), at 4, available at <http://www.who.int/entity/hiv/amds/consumptionAMDS.pdf>.

²² Zidovudine was first discovered in 1964, Stavudine in 1966.

²³ U.S. Patent No. 4,978,655 was granted on the *use* of Stavudine to treat AIDS. See <http://www.cptech.org/ip/health/aids/gov-role.html>. Similar patents were granted for Zidovudine. Such patents are prohibited in India under section 3(d) of the Patent (Amendment) Act, 2005, which specifies that a mere “new use for a known substance” is not patentable.

²⁴ Assuming the current provisions of the Act were in existence at that time, these drugs would have been unpatentable as they constituted a “new use for a known substance” under section 3(d).

for use in the United States, or, as far as our research has revealed, anywhere else.²⁵ Both were originally tested for use against cancer, but ultimately abandoned as cancer treatments.

Had the Inter-Ministerial's proposed data exclusivity regime been in effect at the time of Stavudine or Zidovudine's introduction into the marketplace, including in India, Bristol-Myers Squibb and GlaxoSmithKline would have been able to use the data exclusivity law to block approval of the generic versions—again, notwithstanding the fact that no patent could legally be obtained on the medicines. Using this exclusivity, the two companies could have made access to the medicines impossible for all but the wealthiest patients in the world—as it was not until Indian companies began manufacturing competing versions that the cost of Stavudine went down almost 100-fold from Bristol-Myers Squibb's original pricing.²⁶

Case Study 5. Oseltamivir: Problems With Compulsory Licensing

Facts:

Oseltamivir, exclusively marketed by the pharmaceutical company Roche under the brand-name Tamiflu®, is currently the only treatment for avian influenza.

Roche has indicated that it will not be able to produce sufficient supplies of Tamiflu to respond to global needs. Roche has issued voluntary licenses to Hetero Drugs in India and Shanghai Pharmaceutical Group in China to secure additional production.²⁷ Still, concerns have been raised that even with these additional producers, supplies will be insufficient to meet global requirements in the case of an epidemic.²⁸

Given governments' needs to possess sufficient quantities of Oseltamivir to respond in case of a bird-flu epidemic, the question of a compulsory license for Oseltamivir inevitably has arisen.

Oseltamivir is under patent examination at the time of this writing. For this example, we assume that the patent is granted.

Potential Impact of Data-Exclusivity:

The Oseltamivir case illustrates the difficulty in translating the theoretical availability of a compulsory license into the actual grant of such a license. The political obstacles frequently may be insurmountable. Even with the substantial concerns surrounding an avian influenza pandemic, no compulsory license has yet been issued. Indeed, no

²⁵ Because both drugs were originally developed in their capacities as anti-cancer medications in the United States, we assume that approval would have been sought there, if anywhere.

²⁶ See Amy Kapczynski et al., *Addressing Global Health Inequities, An Open Licensing Approach for University Innovations*, 20 Berkeley Tech. L.J. 1031, 1034-36 (Spr. 2005).

²⁷ Cipla also has marketing approval to produce a generic version of Oseltamivir. However, Cipla currently does not have a license from Roche should Roche's patent application be granted.

²⁸ See, e.g., Shamnad Basheer and Tahir Amin, *Taming of the Flu: Working Through the Tamiflu Patents in India*, 11 J. of Intellect. Prop. Rights 113, 114 (Mar. 2006).

compulsory license has been granted under the Patent Act in its entire thirty-six-year history.²⁹

In the presence of a data exclusivity regime, the hurdles become even greater. *Two* licenses, granted by two separate government bodies,³⁰ could be required by any company seeking to enter the Oseltamivir market,³¹ should the four existing suppliers³² prove unable to satisfy the global need. Similarly, any entrant likely would be required to pay double royalties, once for remunerating the patent rights and once for remunerating the exclusivity rights.

A more effective approach would be to have an automatic waiver of data exclusivity automatically triggered by the issuance of a compulsory license under the Patent Act.³³ The difficulties of obtaining the initial license from the Patent Controller would remain for production of a drug like Oseltamivir, but the hurdle of obtaining a *second* license at the discretion of the Drug Controller-General would be eliminated.

Summary: Shortcomings of the Inter-Ministerial Draft

- Data exclusivity would still **block generic production for certain unpatentable drugs**, like **Stavudine** and **Zidovudine**.
- Because of the need for an independent waiver, data exclusivity could still **block generic production for drugs even when a compulsory license has been issued**. Hence, needed production of drugs like **Oseltamivir**, required for response to the avian influenza epidemic, could be blocked. A more effective approach would be to make waiver of data-exclusivity automatic upon grant of any compulsory license under the Patent Act.

²⁹ See Suresh Koshy, *The Effect of TRIPS on Indian Law: A Pharmaceutical Industry Perspective*, 1 Boston U. J. of Sci. & Tech. L. 4 (May 1995).

³⁰ The Patent Controller, for the compulsory license under the Patent Act, and the Drug Controller-General, for data exclusivity.

³¹ With the exception of Cipla, which apparently already has marketing approval.

³² Roche (the originator), Shanghai and Hetero (which hold a voluntary license from Roche), and Cipla.

³³ This compulsory license could be issued under Section 84, Section 92 or any other relevant provision of the Patent Act.

III. THE “MIDDLE ROAD”? COMPENSATORY LIABILITY MODELS

Developing countries are receiving substantial pressure from the United States and the European Union to implement exclusivity regimes. In Section II, we relied on case studies to demonstrate that data exclusivity may have a severe, detrimental impact on access to medicines. Data exclusivity, as mentioned earlier, is not required under TRIPS and India is under no obligation to introduce such an amendment.

In the interest of finding a compromise position, the Government of India is reportedly considering a “compensatory liability” model.³⁴ This compromise position focuses on the idea of compensating the initial registrant, an approach that does not provide for total exclusivity but does exceed the minimum requirements of TRIPS.

In Section III, we address whether such a compromise is required under TRIPS and conclude that it is not. We examine existing compensatory models and their possible effects, and conclude that adopting a compensatory model could cause significant delays in access to medicines and increased costs. Based on our review of existing documentation, we believe the potential effect of the Inter-Ministerial proposal is unclear. This proposal requires thorough examination of possible structures and potential impact, and we recommend that the Government undertake a rigorous study if it decides to introduce such a scheme.

A. IS COMPENSATORY LIABILITY REQUIRED UNDER TRIPS?

Current debates about compensatory liability focus on the issue of whether compensatory liability is required under TRIPS.³⁵ As India correctly maintained in 2001, there is no obligation under TRIPS to introduce a compensatory scheme.³⁶

The United States Draft Text in 1988 included the following provision:

“Contracting parties which require that trade secrets be submitted to carry out governmental functions, shall not use the trade secrets for the commercial or competitive benefit of the government or of any person other than the right holder except with the right holder’s consent, *on payment of the reasonable value of the use*, or if a reasonable period of exclusive use is given to the right holder.”³⁷ [emphasis ours]

There are two possible readings of this text.

One reading, argued by some commentators, is that the consent clause may be read conjunctively with the payment clause:

³⁴ *Inter-Ministerial Minutes*, *supra* n.1, at 15.

³⁵ *See, generally*, Basheer, *Data Protection under Article 39.3 of TRIPS*, *supra* n.4.

³⁶ TRIPS Council-Africa Group, et al., *TRIPS and Public Health*, *supra* n.3.

³⁷ Basheer, *supra* n.4, at 28-29.

“...Contracting parties...shall not use the trade secrets...except...
i. with the right holder’s consent, **[and]** on payment of the reasonable value of the use, or
ii. if a reasonable period of exclusive use is given to the right holder.”
[emphasis ours]

This reading would require the right holder’s consent for subsequent use of clinical trial data.³⁸ If this reading applies, then right holders who consent are mandated to obtain a payment of reasonable value for the use. This is not logical: practically speaking, a right holder’s consent likely would be conditioned on payment.

This requirement of a right holder’s consent, then, is in consonance with an exclusivity model and not a compensatory liability scheme. Accepting this reading means that the U.S. draft offered either an exclusivity scheme or an exclusivity scheme. Obviously, it is highly unlikely that the drafters intended such redundancy in their proposal.³⁹

The other reading, consistent with principles of grammar, requires that the clauses above be read disjunctively:

“...Contracting parties...shall not use the trade secrets...except...
j. with the right holder’s consent, **[or]**
ii. on payment of the reasonable value of the use, or
iii. if a reasonable period of exclusive use is given to the right holder.”
[emphasis ours]

This seems the more likely interpretation. Under this reading, the U.S. was proposing three options: a “voluntary licensing” model predicated on right holder’s consent, a compulsory licensing model containing a proviso for reasonable remuneration (“compensatory liability”), and a strict data exclusivity model barring other market entrants for a period of time.

Reading this section as three distinct parts reveals that the compensatory liability model was considered but not adopted. The compensatory liability model, therefore, cannot be the minimum requirement for compliance with 39.3.⁴⁰ Reading a compensatory liability requirement into Article 39.3 would “impose[] precisely the obligations that a large number of negotiators refused to countenance.”⁴¹ We

³⁸ *Id.*

³⁹ Another alternative reading would require consent of the right holder, with either a reasonable payment or period of exclusive use. Again, such a reading renders each option indistinct from one another, as they are both essentially data exclusivity schemes.

⁴⁰ It is necessary to reiterate here, however, that the language of the U.S. Draft Text is ambiguous. As noted by Jerome Reichman, “While this language seems deliberately ambiguous, it suggests that payment of compensation could become a trigger for consent unless a period of exclusivity was expressly provided. In other words, the initial U.S. position appeared willing to consider a cost-sharing or ‘liability rule’ approach...” See Reichman, *Undisclosed Clinical Trial Data under the TRIPS Agreement and its Progeny*, *supra* n.4.

⁴¹ See Fellmeth, *Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law*, *supra* n.4.

maintain, as argued persuasively by several experts, that non-disclosure is the minimum requirement under TRIPS.⁴²

B. THE MANY FACES OF COMPENSATORY LIABILITY

The concept of providing compensation to the originator of test data for subsequent approval of generic drugs is manifest in India's consideration of a "reasonable royalty" scheme.⁴³ To this date in India, no concrete standard exists as to what constitutes a "reasonable" royalty. Furthermore, despite an allusion to "reasonable" royalties in the Inter-Ministerial proposals, no models or options for structuring a compensatory scheme were articulated.⁴⁴

In light of the lack of consideration that has been given to a compensatory option, in this section we examine the various compensatory liability models which exist or have been suggested by commentators. The purpose of this section is to provide an understanding of these models and to highlight that if a compensatory liability option is to be exercised by the government, further consideration, research, and a practical analysis are required.

Discussed below are several compensatory liability models that already exist:

The *FIFRA Model* is based on the Federal Insecticide, Fungicide, and Rodenticide Act in the United States.⁴⁵ This legislation governs the use of specific chemicals and provides ten years of exclusivity to the initial registrant of a given chemical, with ten additional years of royalty rights from non-voluntary licenses. The originator of the test data submits not only the test data to the regulatory authority, but also the cost of generating the data. Based on this submission, the initial registrant obtains market exclusivity, subject to mandatory licensing by subsequent applicants as long as they pay adequate remuneration. Since "adequate remuneration" is undefined by statute, the initial and subsequent registrants first negotiate a voluntary license, where the parties attempt to settle on a mutually-agreeable amount. After ninety days, either party may elect for arbitration if they are unable to reach an agreement on remuneration, whereupon the arbiter will determine the final amount due to the originator.⁴⁶

Other *Cost-Sharing Models* envision registrants sharing costs with originators of test data, without providing exclusivity and without including an arbitration provision.

- The Per Capita scheme is one in which all registrants share the costs of generating the data, based on the originator's valuation of the total cost of generating the data. The Simple Division Royalties scheme, a version of the

⁴² See Correa, *Protection of Data*, *supra* n.3; TRIPS Council–African Group et al., *TRIPS and Public Health*, *supra* n.3.

⁴³ See *Inter-Ministerial Minutes*, *supra* n.1.

⁴⁴ *Id.*

⁴⁵ FIFRA is located online at http://www.access.gpo.gov/uscode/title7/chapter6_subchapterii_.html.

⁴⁶ *Id.*; see also Sanjuan et al., *A Cost Sharing Model*, *supra* n.4.

per capita scheme, is one in which all the costs would be divided equally amongst the originator and all registrants *in a given year*.⁴⁷

- The Market-Share or Pro-Rata Share of Costs scheme entails subsequent registrants paying costs based on relative or actual market share, thereby recompensing the originator in proportion to the percentage of global market share held.

Practically speaking, the implementation of any of these models is not required under TRIPS, and introducing such models will cause more cost and delay than necessary, and could discourage competition. Most importantly, the lack of practical evidence showing how these models work, and whether they are indeed effective, demonstrates the need for closer study before moving forward.

C. POTENTIAL CONSEQUENCES OF ADOPTING A COMPENSATORY LIABILITY APPROACH

If the Government of India decides to consider a compensatory liability model, careful examination is required. Structuring such a regime to meet the dual objectives of recompensing costs of obtaining marketing approval and encouraging competition requires an understanding of the benefits and drawbacks of existing and conceptualized schemes.

FIFRA Model. A key advantage to this model is that the originator and subsequent applicant are encouraged to work out a settlement wherein adequate remuneration is paid to the originator.⁴⁸ The parties have the option and incentive to arrive at an agreed amount, without the compulsory aspect of other models. Another advantage of the FIFRA model is that after the first ten years of exclusivity, subsequent registrants automatically are entitled to use the data and enter the market, even as the arbitration occurs.⁴⁹

The primary drawback of the FIFRA model is that there are still ten years of pure exclusivity that will preclude competitors from entering the market. Another significant lacuna is that there is no fixed computation or standard for the royalty the originator can receive, leading to potential ambiguity that may discourage investment in clinical trials and/or competition.⁵⁰ Since there is no cap on the amount the

⁴⁷ See Stafford and Wright, *Data Citation, Compensation and Cost Sharing: Pitfalls and Traps for the Unwary* (2002); see also Fellmeth, *supra* n.4 (proposing an alternative model that attempts to remedy the weaknesses of existing models). According to Fellmeth, the Readjustable Royalties scheme attempts to “correlate the benefits of market access with the costs of obtaining such access.” See Fellmeth, *supra* n.4, at 482. This model provides different variables for geographic scope of determining cost of generating data, and different factors impacting measurement of cost, e.g. inclusion of failed trials and parties actually incurring the generated costs.

⁴⁸ See Fellmeth, *Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law*, *supra* n.4, at 479.

⁴⁹ See Sanjuan et al., *A Cost Sharing Model*, *supra* n.4, at 6.

⁵⁰ See Fellmeth, *supra* n.4, at 480.

originator can recover, the result could be that the originator receives compensation greater than those costs incurred.⁵¹

The transaction costs to the parties involved are also considerable under the FIFRA model, particularly for arbitrations and negotiations.⁵² By one analysis, full arbitration of compensation amounts under FIFRA “can last two or more years and consume hundreds of thousands of dollars in transaction costs.”⁵³

It is possible that a better-designed compensation scheme could reduce this figure.⁵⁴ However, many of the difficulties in executing a compensatory regime are likely unavoidable.

For example, disputes inevitably arise over the proper calculation of original costs—especially where those costs are incompletely documented—and over what data were in fact required for regulatory approval.⁵⁵ Indeed, academic studies have shown the significant discrepancies that exist in calculating the costs of clinical trials and resulting data.⁵⁶ Since there is no standard calculation method, originator companies likely will seek to include all costs, including failed trials, whereas subsequent applicants will seek to limit their liability.⁵⁷

Per-Capita and Simple Division Royalties Models. These models, in which subsequent registrants each pay a proportion of the originator’s costs, present a different set of advantages and challenges. Foremost amongst the advantages are: the lack of exclusivity, which eliminates artificial barriers to entry; the absence of repetitive clinical trials; and the removal of arbitration and negotiation procedures.⁵⁸

Unfortunately, these models also contain at least three significant obstacles.⁵⁹ First, the ability of many manufacturers of generic drugs in developing countries to share in

⁵¹ *Id.*

⁵² See Fellmeth, *supra* n.4, at 480 (“It is in the interests of the initial registrant to draw out negotiations (which may last up to ninety days under FIFRA) during which time it maintains a monopoly on the drug. Arbitration may take months on top of the initial negotiation period. Following the arbitration, one of the parties may appeal on specified grounds, resulting in delays that can exceed a year before the data is made available. In short, under the FIFRA scheme, there are numerous ways for the initial registrant to maintain a monopoly, thereby preserving high drug prices and a limited supply.”).

⁵³ See Stafford and Wright, *supra* n.46.

⁵⁴ For example, FIFRA does not specify what formula should be used to estimate an applicant’s fair share of cost. This basic question is left to the arbitration process under FIFRA.

⁵⁵ See Stafford and Wright, *supra* n.46, at 5-7, 9-12; see also *Ruckelshaus v. Monsanto*, 467 U.S. 986, 992-95 (discussing the historical evolution of what data can be considered protected under FIFRA).

⁵⁶ See Joseph A. DiMasi, Ronald W. Hansen, and Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. of Health Econ. 151-85 (2003) (estimating the total cost of drug development at over USD\$800 million); Public Citizen Congress Watch, *Rx R & D Myths: The Case Against the Drug Industry’s R & D Scare Card* (July 2001)(estimating the total cost of drug development at under USD\$100 million).

⁵⁷ See Fellmeth, *Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law*, *supra* n.4, at 495.

⁵⁸ *Id.*, at 481.

⁵⁹ *Id.*

clinical trial costs incurred by manufacturers from developed countries may prove prohibitive. Second, the administrative aspects of reimbursement by later registrants to earlier registrants and the originator may be unwieldy. To illustrate, if four companies apply to market the originator's drug in the first year, each will pay 20%. If, however, two additional companies apply in the second year, the two additional companies will pay 14.3% and reimburse the others 5.7%. This creates a significant administrative burden of financial oversight that may not be worth the cost. Finally, the burden of demonstrating the cost incurred in generating the data lies with the originator. Most regulatory bodies will not have the expertise or the resources to question the claimed figures, and it is probable that disputes over claimed costs will move to litigation or arbitration.

Market-Share or Pro-Rata Share of Costs Model. This scheme provides for compensating the originator based on the benefit derived from global market sales. The pro-rata share of costs model is premised on generic producers from developing countries paying only the proportion of global market share that their sales encompass, thus enabling them to effectively participate in the global market.⁶⁰

An example offered by the Consumer Project on Technology envisions a situation in which the costs of generating test data are USD\$50 million. A generics manufacturer might owe \$10,000 a year for five years to the originator of regulatory approval data where the generic manufacturer held a .5% global market share. Since global market share in monetary terms remains relatively small for Indian manufacturers,⁶¹ market share-based payments may be modest.⁶²

This calculation demonstrates the advantage of the market-share model: it ensures that market entry remains feasible and preserves a competitive pharmaceutical market. Further advantages include the lack of exclusivity and arbitration, the elimination of duplicative clinical trials, and the equitable balance between compensating originators and allowing developing country companies to contribute proportionally to costs.

However, the model also raises the question of whether the transfer of such sums justifies the administrative burden of a compensation system. Additionally, for drugs that are lifesaving for developing country populations but not particularly lucrative, a market share model may serve as a disincentive for subsequent applicants to enter the market. Another prominent disadvantage is that manufacturers typically will not know what their ultimate compensatory liability will be when they decide whether to apply for approval of a drug.⁶³ This uncertainty may further deter applicants and become a barrier to competition.

⁶⁰ See Sanjuan et al., *A Cost Sharing Model*, *supra* n.4, at 5.

⁶¹ While data for individual drugs is proprietary, in value terms, total global market share of Indian manufacturers is usually estimated at between 1-2%. Ranbaxy, Ltd., which claims to be India's "largest pharmaceutical company," reported 2005 global sales of approximately USD\$1 billion, *see* <http://www.ranbaxy.com/profile.htm>, which would represent about .2% of the USD\$600 billion global pharmaceutical market in 2005, *see* IMS Health.

⁶² See Sanjuan et al., *supra* n.4, at 7.

⁶³ See Stafford and Wright, *supra* n.46, at 14.

Compensatory Liability Models: Further Analysis Required in India

A review of compensatory liability models demonstrates that both the per capita and market share approaches carry significant drawbacks. However, arbitrators under FIFRA have concluded that, in certain cases, they “can visualize the possibility of a mixture of the two methodologies.”⁶⁴ This idea presents a certain appeal, but requires further intensive study, particularly to adapt the model to the Indian context. At this point, this discussion remains abstract, as there are no practical examples from which to analyse the real impact of either type of model.

Even in developed country contexts, with relatively more efficient legal and regulatory mechanisms, these models have proven to be cumbersome. In the Indian context, with its overburdened bureaucracy and lengthy procedures, we are highly doubtful that this model could work effectively. At the very least, any model that is implemented in India must permit production and distribution irrespective of any delays in arbitration or litigation. Since a compensatory liability scheme is not required under TRIPS, India should not implement this scheme that will cause inevitable delay and an unnecessary increase in costs.

Summary: Compensatory Liability

- India is not obligated under TRIPS to implement a compensatory liability regime.
- Compensatory liability models are likely to be cumbersome and impose unnecessary costs and delays.
- The practical and economic impact of a compensatory liability scheme on Indian industry and consumers worldwide is unclear. More thorough examination of this model, particularly in the Indian context, is required before moving forward.

⁶⁴ *Id.* (citing *Ciba-Geigy v. Drexel*, unpublished arbitration decision)

IV. THE MINIMUM REQUIREMENTS OF ARTICLE 39.3

In Section III, we addressed the issue of whether India is obligated to introduce a compensatory liability scheme under TRIPS. We concluded that India is under no such obligation, and that a compensatory model could impose costs and delay that would ultimately have a negative impact on access to medicines. In Section IV, we examine what the minimum requirements are for India to be compliant with Article 39.3. We then consider whether India already has met its requirements by reviewing existing Indian legal frameworks. We conclude that India need only make minor amendments to its existing law to be compliant with TRIPS.

A. THE MINIMUM REQUIREMENTS OF ARTICLE 39.3

The negotiation and drafting history of Article 39, and in particular 39.3, of TRIPS clearly show the polarised positions which existed at the time the Article was drafted, and which still exist today.⁶⁵ During the negotiations and drafting of Article 39.3, specific wording for a data exclusivity regime, which would have prevented regulatory authorities of Member States from relying on test data for approving competing products, was proposed but ultimately removed from the final text.⁶⁶ The failure of Article 39.3 to impose a clear data exclusivity system has resulted in certain Member States, who are still hoping to encourage an exclusivity regime, resorting to bilateral and free trade agreements to achieve this end. As one commentator has highlighted:

*“Paradoxically, the ambiguity of the TRIPS Agreement on the issue of data exclusivity resulted in free trade agreements and regional trade agreements that require data exclusivity legislation according to the U.S. standards.”*⁶⁷

Despite these attempts to manoeuvre around the language of TRIPS, neither data exclusivity nor compensatory liability is the minimum standard, as discussed earlier in this paper. For purposes of assessing whether India has met the minimum requirements under Article 39.3, we rely on the baseline standard of non-disclosure of test data, and non-acceptance of fraudulently obtained data as “unfair commercial use.” Additionally, we believe the following acts may be considered unfair for purposes of Article 39.3:

- Government use of data to compete with the originator⁶⁸
- Government employee use of the data after leaving employment⁶⁹

⁶⁵ See UNCTAD-ICTSD, *Resource Book*, *supra* n.2, at ch. 28; see also Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (Sweet and Maxwell, London, 2003); Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (Oxford University Press, 2001), at ch. VI.

⁶⁶ See Gervais, *The TRIPS Agreement*, *supra* n.64, at 182 (citing paragraph 4A of the Brussels Draft).

⁶⁷ Meir Perez Pugatch, *Intellectual Property and Pharmaceutical Data Exclusivity in the Context of Innovation and Market Access* (paper submitted at UNCTAD-ICTSD Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines conference, Bellagio, 12-16 Oct. 2004).

⁶⁸ See Reichman, *Undisclosed Clinical Trial Data*, *supra* n. 4.

⁶⁹ *Id.*

- Acceptance of the data by the regulator under one set of terms, followed by use under a different set of terms⁷⁰
- Acceptance of fraudulently obtained data⁷¹
- Violation of an explicit contract with the originator of data⁷²

By the above standards, public non-commercial use—e.g. government use to provide medicines on a nonprofit basis—should not be considered “unfair commercial use.”⁷³

B. HAVE THE MINIMUM REQUIREMENTS BEEN MET IN INDIA?

Given the minimum requirements permitted under Article 39.3, as articulated above, the question remains as to whether India needs to codify provisions to meet its TRIPS obligations, or whether its existing legal frameworks already achieve this purpose. Part B explores this issue.

Suggestions have been made by commentators and during the Inter-Ministerial meeting⁷⁴ that India already meets its TRIPS obligations through its existing legal mechanisms. These existing mechanisms include the common law principles of equity and the law of confidence (otherwise known as “trade secrets” or “the law of breach of confidence”), s5 of the Official Secrets Act (“OSA”), and the current Drugs and Cosmetics Act of 1940 (“DCA”) and Drugs and Cosmetics Rules 1945 (“DCR”). The question is: does India actually need to make any changes to its laws to be in compliance with Article 39.3? This section briefly considers these existing legal frameworks in light of the minimum requirements of non-disclosure and unfair commercial use, and whether these frameworks suitably meet the standard required while providing sufficient safeguards for the public.

Implementing TRIPS

Article 1.1 of TRIPS provides that:

*“Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”*⁷⁵

⁷⁰ See *Ruckelshaus v Monsanto*, 467 U.S. 986, *supra* n.54.

⁷¹ Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals*, *supra* n.3.

⁷² See *Ruckelshaus v Monsanto*, 467 U.S. 986, *supra* n.54.

⁷³ See UNCTAD/ICTSD *Resource Book on TRIPS*, *supra* n.2, at 471.

⁷⁴ See *Inter-Ministerial Meeting*, *supra* n.1, at 14.

⁷⁵ Article 1.1 reads:

“Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”

Article 1.1 clearly provides that Members are only obliged to implement a minimum level of protection.

Even with a narrow construction, this sentence can be interpreted as allowing Members to implement Article 39.3 in a method to suit their own legal systems. This means that Members could adopt TRIPS provisions through statute, or give the Agreement direct effect and rely on the judiciary to implement it.⁷⁶ Given the language of Article 1.1, proponents supporting the position that India's existing legal frameworks already meet the requirements under Article 39.3 would not be incorrect. However, before reaching any conclusions, it is necessary to take a closer look at the existing frameworks and whether they actually achieve the minimum objectives set under Article 39.3.

Common Law and the Law of Breach of Confidence/Trade Secrets

Currently, India does not have a specific statute that addresses breach of confidence, trade secrets, or unauthorized use/disclosure of confidential information.⁷⁷ India slowly has begun to develop case law on trade secrets and confidential information, although the question of unauthorized use/disclosure of regulatory data has yet to be tackled.⁷⁸ Should the matter of unauthorized use/disclosure arise, given India's tendency to lend from U.K case law, its judiciary would not be out of step under the minimum requirements of Article 39.3 to rely on the well documented case *R v. Licensing Authority ex p Smith Kline* (H.L.) [1990] 1 A.C. 64.⁷⁹ To that end, it would be plausible to argue that India does not need to implement any specific data protection provisions within its existing law, but could rely on the judiciary to develop the law.

Leaving this matter in the hands of a judicial system, however, rather than codifying it into law with guidelines and safeguards, is not ideal and could lead to as much ambiguity as exists with Article 39.3 today. Worse, it could lead to a data exclusivity regime being implemented via common law.

⁷⁶ For a complete discussion of Article 1.1, see UNCTAD-ICTSD, *Resource Book on TRIPS*, supra n.2, at ch. 1.

⁷⁷ Unlike the United States, the United Kingdom does not have a statute for trade secrets or breach of confidence on its books, but instead has developed a body of case law under the principles of equity and the law of breach of confidence. In 1981 the Law Commission recommended that this area of law be codified and introduced a draft bill, *The Law Commission, Law Comm. No. 110, Breach of Confidence*, Cmnd 8388 (HMSO 1981). The bill was not codified.

⁷⁸ See Basheer, *Data Protection under Article 39.3*, supra n.4, at 37.

⁷⁹ In this case, the House of Lords held that under the Medicines Act of 1968:

“it was the right and duty of the licensing authority to make use of all the information supplied by any applicant for a product license which assists the licensing authority in considering whether to grant or reject any other application.....The use of such information should not harm the appellants and even if it were to do so, this is the price which the appellants must pay for cooperating in the regime designed by Parliament for the protection of the public and for the protection of the appellants and all manufacturers of medicinal products from the dangers inherent in the introduction and reproduction of modern drugs.” *R v. Licensing Authority ex p Smith Kline* (H.L.) [1990] 1 A.C. 64.

It should be noted that this decision was given after the period of data exclusivity for the product Cimetidine had expired in Europe.

The issue in this case was decided in the same manner in Canada, Australia and New Zealand. As commonwealth countries operating common law systems, these decisions could also serve as guidance to the Indian courts.

These concerns arise as a result of the judiciary's growing trend towards enforcing intellectual property rights more vigorously. It is known that some of the judiciary, along with the patent office staff and other related bodies in India, receive or attend courses on intellectual property and its enforcement through the World Intellectual Property Organisation (WIPO) and from developed countries, which advocate for stronger protection.⁸⁰ Should a situation arise where a data exclusivity regime is installed through common law, leaving the matter of interpreting terms such as "new chemical entities" to the judiciary, could lead the judiciary to reverting back to the current DCA's broad definition of a "new drug," thus making it more difficult to access generic drugs.⁸¹ (See Annexure II for a discussion on suitable definitions of "new clinical entities.") Therefore, while the flexibilities of common law could serve the needs of Article 39.3, such a system is not likely to maintain the minimum standards under TRIPS without further safeguards and clear direction.

Official Secrets Act 1923

The concerns raised in the paragraph above equally apply to Section 5 of the OSA, which has been interpreted as preventing the disclosure of confidential information. While the OSA may meet the minimum obligations for non-disclosure required under Article 39.3, it fails to provide the necessary safeguards against a data exclusivity regime. This is particularly so when its application would be left to the discretion of the judiciary. Moreover, it is questionable whether the OSA is a suitable piece of legislation to house the matter of data protection in commercial matters, given that its primary purpose is to protect against espionage and safeguard national secrets.

Drugs and Cosmetics Act and Rules

Rule 53 of the DCR currently prohibits the disclosure of information received by an officer of the Drug Controllers' Office, except for the purpose of official business, where it is required by a court of law, or with the permission of an official superior.

While the prohibition on the disclosure of information does not apply to the "official business" of the Drug Controllers' Office and, therefore, sits within the minimum requirements of Article 39.3, the exceptions listed may be seen as problematic. For example, as it currently stands, an official could disclose information if permitted by an official superior, which seems to contravene the minimum requirements of Article 39.3. As a result, it might be preferable to re-draft Rule 53 to ensure a clearer definition of non-disclosure within the context of the minimum requirements permitted under Article 39.3.

To that end, although India could technically meet its Article 39.3 requirements without implementing new legislation or amending existing laws, from a practical perspective, and one which safeguards the minimum standards, it is preferable to amend the DCA and the DCR.

⁸⁰ See, e.g., United States, Patent and Trade Mark Office, Intellectual Property Rights (IPR) Training Program Database, at 12 (available at <http://www.uspto.gov/web/offices/dcom/olia/niplecc2003/attachmentf.pdf>).

⁸¹ See Drugs and Cosmetics Rules 1945, Rule 122-E.

Summary: Minimum Requirements

- India may meet the minimum requirements of Article 39.3 through its common law. Given a lack of case law on protecting undisclosed/confidential information in India, it is likely that uncertainty may ensue.
- India should meet the minimum requirements under Article 39.3 by introducing amendments to the Drugs and Cosmetics Act. These changes should clearly define minimum obligations, such as the non-disclosure obligations, exceptions to non-disclosure, and the definition of “new chemical entities.”

V. RECOMMENDATIONS

In Sections II-IV, we have discussed the likely impacts of three distinct schemes for implementing Article 39.3: data exclusivity, compensatory liability, and a scheme with minimal amendments to existing law. In this section, we set out our recommendations in relation to each of the areas discussed above. These recommendations are not exhaustive, but are intended to serve as starting points for the current debate.

A. DATA PROTECTION: THE PREFERRED MINIMUM APPROACH TO TRIPS

In order to eliminate any ambiguity that exists under current law, section 53 of the DCA should be amended to include the following clarification:

- The Drug Controllers' Office is permitted to rely on undisclosed data for subsequent marketing approval of drugs and to disclose the data for research and experimental purposes. Such use shall not amount to disclosure of undisclosed data.

Protection against the following uses of previously undisclosed data should be codified:

- Disclosure when not otherwise allowed (under the exceptions listed in the paragraph below)
- Commercial use of data by the Government to compete with the originator
- Disclosure or commercial use of undisclosed data by a Government employee after leaving employment
- Acceptance of undisclosed data by the regulator under one set of terms followed by use under a different set of terms
- Acceptance of fraudulently obtained data
- Violation of an explicit contract with the originator of data

In addition, exceptions should be included to permit disclosure of undisclosed data in the following circumstances:

- For public non-commercial use, including Government use
- Where disclosure is necessary in the interest of the public or to safeguard public health, including disclosure of data relating to the safety and efficacy of a drug

All of the above should only apply in relation to new chemical entities. For this purpose, Rule 122-E of the Drugs and Cosmetics Rules should be amended as follows:

- The definition of a “new drug” should be limited to “a new drug that contains active moieties never before granted approval (anywhere in the world)”

B. COMPENSATORY LIABILITY AND COST-SHARING

We recommend that the Government of India adopt the minimum standards set out in section A above. In the event that consideration is given to the implementation of a compensation, royalty or cost-sharing model, we recommend that before adopting such a model, a committee that includes representatives from civil society and the public health community should be set up to study the working of such a system and its effects on domestic industry, access to medicines and public health.

In particular, we suggest that the following issues be looked into:

Compensation/Royalty Amounts and Cost-Sharing

- How royalty standards are set. This would include identifying and explicitly setting out the costs that would be subject to compensation. For example, guidelines should be provided that clarify whether costs relating to failed trials form part of an assessment for compensation.
- What mechanisms would be utilised for government verification of originator claims, possibly including the creation of a specific authority set up under the Ministry of Health and/or Drug Controller General in India.
- How to catalyse access to undisclosed information relating to the cost of clinical trials and market-share data.
- What laws exist relating to the discovery of costs of clinical trials and market share data.
- How to devise mechanisms that will monitor effectively the amount of compensation the originator will receive, and whether the amount exceeds the original investment.
- What cap should be set on compensation and the percentage of original investment that can be recouped by originator, e.g. 80% as suggested by Fellmeth.

Effectiveness and Procedural Aspects of Arbitration/Litigation

- Existing law and practice pertaining to arbitration in India.
- How to ensure that production of medicines is permitted during arbitration and litigation so that extended administrative procedures do not become a bar to competition.
- Whether a specialist arbitration panel composed of public health experts is needed for such arbitration.
- How to prevent delay by expediting arbitration and litigation in compensation cases.
- How and whether appeals can be made from arbitration decisions.

Impact on Competition

- Existing law, policy and practice relating to competition.
- What the relative bargaining position of different market players is likely to be at the commencement of arbitration, and how this will affect competition.
- How to prevent “gaming” of a market share system—for example, where an originator refrains from selling a drug after obtaining marketing approval, the generic company pays 100% of the costs of the data for that drug.
- What the impact of artificial barriers will be to market entry on economic growth.

Feasibility of Per-Capita and Market-Share Models

- Whether Indian industry is able to share in the costs of original investment, given that clinical trials will often have been conducted in the United States or Europe where costs are much greater, and whether the expense for Indian manufacturers would be prohibitive.
- How market share will be measured, and when will it be measured, because if assessments are not predictable, Indian manufacturers will not be able to assess risks or costs/benefits and make informed business decisions.
- Which Ministry will be responsible for monitoring implementation of the cost-sharing model, and other significant administrative aspects of this model, and how cumbersome these burdens will be to implement in practice.

C. DATA EXCLUSIVITY

As the Government of India has no obligation to enact a data exclusivity regime under TRIPS, we recommend that it reject this option. If the Government chooses to proceed with a data exclusivity model, the following safeguards *must* be incorporated in order to protect public health. As per the Inter-Ministerial draft:

- Exclusivity should last for three years only.
- The three years should commence from the date of first marketing approval of a new drug anywhere in the world.
- Exclusivity should be limited to “new chemical entities,” as described in Part A above (see also Annexure II).
- Application in India within one year of first marketing approval should be required to gain benefits of data exclusivity.
- For patented drugs, exclusivity should not exceed the term of the patent.
- Generic companies should be able to file for approval during the data exclusivity period and obtain tentative approval that becomes final on the day the exclusivity expires.

- Exclusivity should be waived for public non-commercial use, for drugs of mass consumption, in cases of need for public health or the public interest, in cases of abuse by the exclusivity-holder, and in emergencies.

In addition:

- Data exclusivity should not be available for unpatentable drugs, even if they are “new” under the definition outlined Part A of these recommendations.
- Exclusivity for a patented product should automatically be waived if any license is granted for production or sale of a drug under the Patent Act.

ANNEXURE I: TRIPS ARTICLE 39

ARTICLE 39, AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

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

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices(a) so long as such information:

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

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

Note (a): For the purpose of this provision, "a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

ANNEXURE II: DEFINING “NEW CHEMICAL ENTITIES”

What is the Minimum Standard for New Chemical Entities?

A critical issue within the data protection debate, and one that could significantly impact access to medicines, is how to define the words “new chemical entities” within Article 39.3. Simply put, a narrow and strict interpretation of the term for new drug applications would prevent the “evergreening” of data exclusivity periods. Every time the originator modifies an active ingredient or new chemical entity present in a drug, the originator would not be able to obtain an extension or new exclusivity period.⁸² Alternatively, a broader interpretation could mean even incremental additions to an active ingredient, or change in dosage forms may be entitled to data exclusivity, which could potentially delay the entry of cheaper generic variants of the drug.

As has already been established by several commentators, given that TRIPS does not define the word “new” in “new chemical entity” for the purpose of data protection, Members are free to determine the meaning they wish to give to the term.⁸³ Accordingly, India is free to provide a narrow definition of what amounts to a new chemical entity.

The current definition of a “new drug” under Rule 122E of the DCA Rules (1945) is clearly broader than what is necessary under Article 39.3.⁸⁴ Should the same definition be kept alongside any kind of data exclusivity regime, as discussed in this paper, additional data exclusivity periods could probably be granted for all types of

⁸² Pharmaceutical companies frequently make incremental changes to existing drugs, including changes to the dosage forms (e.g. .5mg to 1mg or 5mg to 10mg), the routes of administration, the alteration of the delivery system (e.g. from an injection to an inhaler) or to combine active ingredients of one or more approved drugs to produce a single new product.

⁸³ See Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals*, *supra* n.3, and UNCTAD-ICTSD, *Resource Book on TRIPS*, *supra* n.2, at ch. 28, which state that on the ordinary meaning of the terms used, Article 39.3 would not apply to new uses of known products, nor to dosage forms, combinations, new forms of administration, crystalline forms, isomers, etc., of existing drugs, since there would be no novel chemical entity involved. Members also are free to define whether a chemical entity is new based on whether there has been a prior application for approval of the same drug and whether the same drug was previously known. The broad definition also permits a “universal” standard for newness, meaning that “new” could mean the first application in the world.

⁸⁴ Under Rule 122-E of the DCA Rules (1945), a “new drug” is defined as: (a) a bulk drug substance which has not been used in the country to any significant extent and has not been recognised as safe and effective by the licensing authority; (b) a drug that is already approved by the licensing authority which is now proposed to be marketed with modified or new claims, namely, indications, dosage, dosage form (including sustained release dosage form), route of administration; or (c) a fixed dose combination of two or more drugs, individually approved for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims, namely, indications, dosage, dosage form (including sustained release dosage form), and route of administration. For the purpose of the Rules, all vaccines shall be new drugs unless otherwise certified and a new drug shall continue to be considered a new drug for a period of four years from the date of first approval or its inclusion in the Indian Pharmacopoeia, whichever is earlier.

minor modifications to existing medicines, thus delaying or even preventing the entry of generic products into the market.⁸⁵

In light of this, if a data exclusivity period in any form (including one which requires a compensatory model) is to be implemented, a strict definition of what amounts to a new chemical entity is a must to safeguard public health. The U.S Food and Drug Administration (FDA) provides a useful definition which would also meet the minimum requirements under Article 39.3, namely:

“a drug that contains no active moiety that has been approved by FDA in any other application.”⁸⁶

Articles 6 and 10 of the European Union Directive 87/21/EC (which recently has been amended by Directive 2004/27/EC) also provide some useful guidance for determining what should be considered a new drug for the purpose of data exclusivity and submission of test data. Article 6 essentially provides that where medicinal products have been granted an initial marketing authorisation, any additional strengths, pharmaceutical forms, administration routes, presentations, variations and extensions shall also be granted an authorisation and be considered as belonging to the same global marketing authorisation for the purposes of data exclusivity.⁸⁷ To that end such “additional forms” will not attract additional data exclusivity periods. Moreover, for abridged applications by generic companies, different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active ingredient, are considered to be essentially similar drugs unless they differ significantly in properties with regard to safety and/or efficacy.⁸⁸

⁸⁵ Technically, this would include the different salts, esters, ethers, dosage forms and new uses of the previously known active substance. Therefore, if the originator was to bring to market new forms or dosages of an existing product every three years (assuming that to be the period of data exclusivity), it could effectively have data exclusivity in perpetuity.

⁸⁶ The term “active moiety” means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance. See <http://www.fda.gov/cder/about/smallbiz/exclusivity.htm>.

⁸⁷ Article 6.1 of the 2001/83/EC Directive (as amended by Directive 2004/27/EC):

“No medicinal product may be placed on the market of a Member State unless a marketing authorization has been issued by the competent authorities of that Member State in accordance with this Directive or an authorization has been granted in accordance with Regulation (EEC) No 2309/93.

When a medicinal product has been granted an initial marketing authorisation in accordance with the first subparagraph, any additional strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions shall also be granted an authorisation in accordance with the first subparagraph or be included in the initial marketing authorisation. All these marketing authorisations shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the application of Article 10(1).”

⁸⁸ Article 10(2)(b) of the 2001/83/EC Directive (as amended by Directive 2004/27/EC):

“‘generic medicinal product’ shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In

Although the European Union Directive does serve to qualify what should be considered essentially similar drugs for the purpose of data exclusivity, it should be stressed that these definitions are still broader what is required under Article 39.3.

Therefore, taking the flexibility provided in Article 39.3, and combining it with the FDA's definition of a "new chemical entity," a suitable amendment to Rule 122E could look to include the following definition in order to define a new drug:

A drug that contains no active moiety and which has not been known to exist previously in India or any other part of the world;

Explanation: For the purpose of this rule, active moiety means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.

In addition to the above, safeguards should be adopted to ensure that in the event India adopts a data exclusivity regime, only a new chemical entity that has a significant clinical improvement over existing drugs should be granted any data exclusivity. This criteria is crucial as there are a number of instances where, although the active ingredient is a new chemical entity, it may have had no added clinical or therapeutic improvement over the existing drugs.⁸⁹

such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters, or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form."

⁸⁹ For example, it is generally accepted that drugs like Vioxx and Celebrex are no more effective against the pain and inflammation or arthritis than non-steroidal anti-inflammatory drugs such as ibuprofen and naproxen. Over a period of years, discovery of medicines that contain new active ingredients and also provide significant clinical improvement are rare. For the period from 1989 to 2000 only about 153 out of a total of 1,035 drugs approved in the U.S were of significant clinical improvement. This accounts for a mere 15% of the total drugs that were approved during that period, See NIHM-Changing patterns of Pharmaceutical Innovation, available at <http://www.nihcm.org>.