OBLIGATIONS UNDER ARTICLE 39.3 OF TRIPS: THE DATA EXCLUSIVITY V. DATA PROTECTION DEBATE IN THE INDIAN CONTEXT

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Abstract

Protecting test data submitted to governments by pharmaceutical industries (data exclusivity or data protection), is a hotly debated issue of intellectual property. While on one hand, longer data exclusivity for a broader range of data can prove beneficial to R&D in the pharmaceutical industry, the flip side is the lack of widespread access to affordable medicines, and the possibility of a public healthcare crisis if the safety and efficacy of the drug cannot be accessed and verified.

In India, recent proposals to extend data exclusivity to 10 years in the pharmaceutical industry is indicative of the wave of arguments for and against longer protection times to data. A difference is required to be drawn between the data protection regimes mandated by Article 19.3 of the TRIPs regime and the data exclusivity regimes imposed by the TRIPs Plus regimes.

In order to balance the public health objectives of a short and narrow data exclusivity regime with the requirements and benefits of the R&D industry, a multitude of factors need to be taken into consideration. The need for life-saving drugs at affordable costs, the trade-off between incentivising R&D and access to health, the lack of opposition or revocation of drug approvals, or the possibility of ever-greening of drugs in the Indian market needs to be pitted against the arguments that the Indian economy could greatly benefit from strengthening data exclusivity norms, increased innovation, and the need to protect investments. These arguments are also to be viewed in the light of mounting pressure on India from regional and international trade co-operations and long-standing trade partners to strengthen secrecy norms. The authors aim to provide policy recommendations to ensure that India does not give way to mounting foreign pressure while still safeguarding investment interests.

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I. INTRODUCTION

In 2014, the European Medical Agency ('EMA') settled a lawsuit with the pharmaceutical giant AbbVie.[1] AbbVie wished to obtain market approval for its new drug and had conducted extensive and expensive clinical trials to prove its effectiveness. As procedure mandated, this data was provided to the medical agency to check for safe consumption. The medical agency published this data in a bid to improve transparency in public healthcare. However, AbbVie commenced litigation, fearing that such publication would make it easier for generic drug manufacturers to obtain approvals for their bio-similar drugs, and rob it of any advantage (and therefore a return on the investment in clinical trials) of being the innovator and first producer. This litigation was settled when AbbVie agreed to provide redacted documents, which, according to the company, adequately safeguarded its commercial interests, and according to the EMA, will not affect the readability of the reports and will serve the purpose of lifting the veil of secrecy that currently shrouds the pharmaceutical industry.[2] However, similar litigation that commenced simultaneously by InterMune is still underway.[3]

The basis for such cases against regulators stems from the idea of data exclusivity (or data protection, based on whom you ask), which protects hitherto undisclosed data (such as clinical trial data) submitted to a pharmaceutical regulator in order to obtain approval for a new chemical entity to enter the market.[4] Finding its origins in anti-trust law, data exclusivity seeks to protect the investment that drug-innovating companies put in from drug-replicating ones. It is assumed that data submitted to obtain approvals for drugs is of commercial significance, and therefore it should be protected (usually

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[1] *AbbVie drops legal action in EU drug secrecy case*, THOMSON REUTERS, (Jan. 15, 2018), https://in.reuters.com/article/us-europe-medicine-secrets/abbvie-drops-legal-action-in-eu-drug-secrecy-case-idINBREA321HA20140403.

[2] Ed Silverman, *European Ombudsman Questions EMA Redactions of AbbVie Trial Data*, THE WALL STREET JOURNAL (Nov. 12, 2014), http://blogs.wsj.com/pharmalot/2014/11/12/european-ombudsman-questions-ema-redactions-of-abbvie-trial-data/.

[3] *Europe's Regulator Digs in for Drug Data Fight*, THOMSON REUTERS, (Jan. 15, 2018), https://in.reuters.com/article/europe-medicines-data/update-2-europes-regulator-digs-in-for-drug-data-fight-idINL6N0DH3A520130430.

[4] Janene Boyce, *Disclosure of Clinical Trial Data: Why Exemption 4 of the Freedom of Information Act Should Be Restored*, 3 DUKE L & TECH. REV. 36 (2005).

for a period ranging from 4 years to 7 years) from competitors. The onus in this regard is on the Government, through its regulatory agencies, to keep the data submitted to it in secrecy and confidence. While this obligation lies equally in terms of pharmaceutical products as well as agro-chemical products, this essay will focus only on pharmaceutical products, since the access to medicine movement weighs heavily on policy and interpretations of the law in this regard.

II. THE TRIPS PLUS AGENDA: A MINUS FOR DEVELOPING NATIONS

The obligation to safeguard data submitted to regulators is mandated under Article 39.3 of the Agreement on Trade-Related Aspects of Intellectual Property Rights, 1995[5] ('TRIPs'), wherein such data is to be protected against unfair commercial use.

Member States may devise their own regulatory regimes for the pharmaceutical industry within the broad ambit of Article 39.3 and many governments permit generic drug manufacturers to use data already submitted by the originator company to obtain approvals.[6] However, a data exclusivity period, usually also incorporated within this regulatory regime, lays down how long generic drug manufacturers or bio-similar drug manufacturers have to wait before obtaining access to data submitted by the originator company, or the time period that has to pass before a regulatory body can rely on previously submitted data to approve the entry of a bio-similar drug.[7] The data exclusivity regime, strictly interpreted, is stricter than the data protection regime envisaged by Article 39.3 of the TRIPs Agreement, and is usually justified by citing high R&D and the time costs involved in developing new chemical entities.[8] The inclusion of the concept of data exclusivity was a brainchild of *TRIPs-Plus*, the post TRIPs movement where developed countries demanded greater trade protection. Developing nations are

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[5] Article 39.3 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (adopted Jan. 1, 1995).

[6] Wael Armouti & Mohammad F.A. Nsour, *Data Exclusivity for Pharmaceuticals: Was It the Best Choice for Jordan Under the U.S.-Jordan Free Trade Agreement?* 17 ORLANDO REV. INT'L 261 (2016).

[7] *Id.*

[8] John Graham, *Crisis In Pharma R&D: It Costs $2.6 Billion To Develop A New Medicine; 2.5 Times More Than In 2003*, FORBES (Jan. 12, 2017), https://www.forbes.com/sites/theapothecary/2014/11/26/crisis-in-pharma-rd-it-costs-2-6-billion-to-develop-a-new-medicine-2-5-times-more-than-in 2003/&refURL=https://www.google.co.in/&referrer=https://www.google.co.in/.

often strong armed into including them in trade agreements with developed nations.[9] With respect to Article 39.3, Free Trade Agreements ('FTAs') such as the USA-Vietnam FTA,[10] the USA-Malaysia FTA[11] and the USA-Singapore FTA[12] include strong data exclusivity regulations, that are as onerous as the domestic legislations of USA and the EU. For instance, in the Singapore FTA, a generic drug manufacturer, apart from waiting for the data exclusivity period to end, has to also show consent from the innovator before approval is granted to a bio-similar, under Chapter 16, Article 8.4(c). The Trans-Pacific Partnership was heavily criticised for its data exclusivity provisions which stated that a minimum period of 5 years had to be granted, for all 'new pharmaceutical products',[13] regardless of their patentability. Further, new uses, new formulations or new dosages were to be granted protection of a minimum of 3 years. The TPP does not provide for any qualifications as to unfair commercial exploitation, which is the only requirement under the TRIPS Agreement. After the US' withdrawal from the FTA, The Comprehensive Progressive Agreement for Trans-Pacific Partnership, between the remaining 11 countries was signed in March, 2018. However, this Agreement provides for the suspension of Articles 18.50 and 18.51 until such time members decide to remove the suspensions.[14]

Similar to the provisions in the TPP, the Regional Comprehensive Economic Partnership ('RCEP'), between ASEAN members, Australia, China, India, Japan, South Korea and New Zealand, also seeks to impose data exclusivity obligations on members. Rules

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[9] Tojo Jose, *What is TRIPs Plus? What is Data Exclusivity?*, INDIAN ECONOMY (May 10, 2017), https://www.indianeconomy.net/splclassroom/what-is-trips-plus-what-is-data-exclusivity/.

[10] Agreement between the United States of America and the Socialist Republic of Vietnam on Trade Relations, (July 2000), https://ustr.gov/sites/default/files/US-VietNam-BilateralTradeAgreement.pdf.

[11] Robert Galauntucci, *Data Protection in a U.S.-Malaysia Free Trade Agreement: New Barriers to Market Access for Generic Drug Manufacturers*, 17:4 FORDHAM INTELL. PROP. MEDIA & ENT. L.J.1088 (2007).

[12] United States-Singapore Free Trade Agreement, May 06, 2003, 42 I.L.M. 1026, https://ustr.gov/trade-agreements/free-trade-agreements/singapore-fta/final-text.

[13] Article 18.51.1 of the Trans-Pacific Partnership Agreement, (Feb. 4, 2016), https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacificpartnership/tpp-full-text.

[14] Article 2 of the Comprehensive and Progressive Agreement for Trans-Pacific Partnership, Annex, (Mar. 8, 2018), https://www.mfat.govt.nz/en/trade/free-trade-agreements/free-trade-agreements-concluded-but-not-in-force/cptpp/comprehensive-andprogressive-agreement-for-trans-pacific-partnership-text/.

proposed by Japan and Korea,[15] under Article 5.16, provides that a regulatory authority has to provide exclusivity to the first applicant of data submitted for regulatory approval of new chemical entities, and further that the authority is obligated to prevent others from relying on that data. In essence, it prevents regulatory review of generic drugs.[16] However, Indian negotiators were opposed to such obligations being imposed by the FTA,[17] and bilateral meetings to discuss the IP Chapter took place in February, 2018.[18]

The North American Free Trade Agreement[19] ('NAFTA'), in Articles 1771.5 and 1771.6 lay down the data exclusivity obligations of USA, Canada and Mexico. These provisions make it mandatory to ensure non-disclosure of data submitted to governments, and also stipulate that the government must not allow for its unfair commercial use. However, clause 6 goes on to prohibit the use or reliance on data submitted, without the originator's permission, for approval of other products, for a minimum period of 5 years.

The US-DR-CAFTA,[20] between the US, Dominican Republic, Costa Rica, El Salvador, Honduras and Guatemala is another such example of a trade agreement seeking to impose onerous data exclusivity obligations on member states. It requires the grant of exclusive rights to the originator, for a minimum of five years, regardless of the data being undisclosed or otherwise non-protectable under TRIPS.[21] By not limiting these

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[15] Single Working Document on the Intellectual Property Chapter, Regional Comprehensive Economic Partnership (RCEP) Free Trade Agreement, KEI , (Oct. 15, 2015), http://keionline.org/sites/default/files/RCEP-IP-Chapter-15October2015.docx.

[16] Dr. Burcu Kilic, *Data Exclusivity in the Regional Comprehensive Economic partnership (RCEP)*, PUBLIC CITIZEN, https://www.citizen.org/system/files/case_documents/rcep-data-exclusivity_0.pdf.

[17] India to Oppose Anti-generics Proposals at RCEP Meet, (Oct. 24, 2017), https://www.livemint.com/Industry/fkn3MeuV9youkAFyBK1CKM/New-Delhi-to-oppose-antigenerics-proposals-at-RCEP-meet.html.

[18] Leena Menghaney, *Delhi's RCEP Talks on Intellectual Property Shouldn't Forget India's Role as 'Pharmacy of the World'*, THE WIRE, https://thewire.in/diplomacy/delhis-rcep-talks-on-intellectual-property-shouldnt-forget-indias-role-as-pharmacy-of-the-world.

[19] North American Free Trade Agreement, signed on 17 December 1992, [1994] CTS 2 (entered into force 1 January 1994).

[20] The United States–Central America–Dominican Republic Free Trade Agreement, U.S.–CAFTA–DR, Jan. 28, 2004, 43 I.L.M. 514 (2004), https://ustr.gov/trade-agreements/free-trade-agreements/cafta-dr-dominican-republic-central-america-fta/final-text.

[21] *Id.* at Art. 15.10.1.

provisions to 'undisclosed test data', generic manufacturers cannot rely on data submitted, regardless of whether the originator has kept the data in question confidential or not.

While it is undisputed that the data referred to under Article 39.3 deserves protection within the rationalities of intellectual property rights, recent events surrounding the efficacy and side-effects of certain approved drugs have raised the question of the impact of such norms on public health.[22] This flipside to data exclusivity was seen by the introduction of unsafe HPV vaccines into the Japanese market.[23] While regulatory authorities did not have sufficient money to replicate certain clinical trials and they permitted the medicine to enter the market regardless. It turned out that the vaccine was not meant to be approved and it produced fatal side effects. This could have been prevented if the generic drug companies were provided the data as they would have discovered an error in efficacy while replicating the clinical tests.[24]

One must also keep in mind the highly international nature of this problem, since the decision of one regulatory agency impacts the data submitted to and the decision made by a regulatory agency in a different jurisdiction. [25] With such far reaching consequences, stringent secrecy norms may require relaxation.

However, such controversies have not initiated appropriate responses. In 2016, the EU released a Directive regarding trade secrets[26] and the US promulgated the Defend Trade Secrets Act of 2016 ('DTSA'),[27] which have both strengthened the protection

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[22] *Health Action International Criticises Support for EU Trade Secrets Directive Report*, HAI WEB, http://haiweb.org/publication/health-action-international-criticises-support-for-eu-trade-secrets-directive-report/.

[23] Mizuho Aoki, *Suit Opens in Tokyo over Cervical Cancer Vaccine Side Effects*, THE JAPAN TIMES, https://www.japantimes.co.jp/news/2017/02/13/national/crime-legal/suit-opens-tokyo-court-cervical-cancer-vaccine-side-effects/#.WmORkqiWZPY.

[24] Jim E. Riviere and Gillian J Buckley, *Ensuring safe Foods and Medicines through Stronger Regulatory Systems Abroad,* NATIONAL ACADEMIES PRESS, Washington (2016) 23.

[25] Weisfeld V, *International Regulatory Harmonization amid Globalisation of Drug Development*, *1st edn. Forum on Drug Discovery, Development, and Translation;* Board on Health Sciences Policy; INSTITUTE OF MEDICINE (2013).

[26] Clinical Trial Data Publication, European Medicines Agency, http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000555.jsp&mid=WC0b01ac05809f363e.

[27] Defend Trade Secrets Act, Pub. L. No. 114-153, *U.S. Statutes at Large,* 114 (2016).

regimes in two of the most developed pharmaceutical markets in the world, causing public health activists to raise concerns about repetitions of public health concerns caused by such 'pro-IP' policies'.[28]

There are two primary problems with 'pro-IP' data exclusivity norms: public health concerns relating to safety and efficacy of the approved drugs which affect both developed and developing nations, and access to medicines and stymying the generic drug industry; which largely affects developing nations, which not only house most of the generic drug manufacturers but also are most in need of timely and cheap drugs.

The solutions however, are the same: relaxing data exclusivity provisions and creating data protection regimes. This will allow non-competing research organisations, public health activists, journalists and, in some cases, the government itself to use the submitted data to ensure that nothing is amiss in the regulatory process. In addition, allowing generic drug manufacturers to rely on the data in measured ways, as detailed later, will greatly boost the access-to-medicine agenda.

The issues that arise out of this policy struggle are two-fold: under Article 39.3, how strong the data exclusivity regime is expected to be, and whether the regime that exists in developing countries, especially in India, is adequate to meet that threshold. Therefore, the following discussion surrounding existing regimes in the US, the EU and India will focus on a critique through the lens of these problems.

III. DATA EXCLUSIVITY: USA AND THE EU

In the US, the Food and Drug Administration ('FDA') is the regulatory authority that collects and processes clinical trial data to establish the safety and efficacy of new drugs before granting market access.[29] A right of data exclusivity is granted by the Food, Drugs and Cosmetics Act ('FDCA').[30] The protection of such data is governed by the Uniform Trade Secrets Act ('UTSA') at the State level,[31] though in May 2016, a move was made to make it federally governed by the introduction of the DTSA. Disclosure of data

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[28] *Supra* Note 13.

[29] *How FDA Evaluates Regulated Products: Drugs*, FDA, www.fda.gov/About FDA/Transparency/ Basics/ucm269834.htm.

[30] Federal Food, Drug, and Cosmetic Act, June 25, 1938, ch. 675, § 1, 52 Stat. 1040.

[31] Uniform Trade Secrets Act, Pub. L. No. 109-186, *U.S. Statutes at Large,* 109 (1985).

regarding a pending Non-Disclosure Agreement, depends upon whether there is data already in the public domain; in which case data to that extent is disclosed and no more. Further, all data regarding disapproved and abandoned applications as well as applications for which approval is withdrawn are disclosed upon request. However, such requests, once denied are not appealable.[32] For all approved applications, a summary of disclosed data is released, though what makes it to the summary and what is considered confidential in this regard is completely as per the discretion of the FDA.[33] Further, a data exclusivity period of five years also exists for New Molecular Entities under the Hatch-Waxman Act of 1984.[34]

The earlier view of the FDA was that all non-public data was entitled to protection. However, courts have since then held that clinical trial data does not qualify within the FDA definition of a trade secret, as there is no direct relationship between the data and the manufacturing process.[35] This requirement has since then been adopted by the FDA by way of an amendment in 1994.[36] However, this question continued as far as 2000, where a drug manufacturer argued that granting access to clinical trial data will enable competitors to create competing products, and that it would reduce the number of patients who sign up for these trials in the first place, making it difficult for R&D to improve.[37] The court ordered the FDA to release the requested data, and did not accept these arguments as clinical trial data is specific to the drug it is submitted for and cannot be used by competitors.

The underlying test that the FDA must consider is if and whether competitors can use the information that they are releasing. However, the FDA regards it as confidential commercial information as it has commercial value. Therefore, the FDA does not

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[32] *Development and Approval Process (Drugs), U.S Food and Drug Administration,* FDA, (2014), http://www.fda.gov/Drugs/DevelopmentApprovalProcess/.

[33] Code of Federal Regulations, 21 CFR 20.61, (1994).

[34] Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, *U.S Statutes at Large,* 98 (1984).

[35] Public Citizen Health Research Group v. Food and Drug Administration, et al, 704 F.2d 1280 (D.C. Cir. 1983).

[36] *Supra* note 24.

[37] Public Citizen Health Research Group v. Food and Drug Administration, 2000 U.S. Dist. LEXIS 4108 (D.D.C. 2000).

release this data as it is confidential commercial information and it is exempted from being released under the Freedom of Information Act ('FOIA').[38]

In the European Union, the European Medicines Agency ('EMA') is the regulatory agency established to grant market access.[39] The EU has an eight year data exclusivity term, and a two year market exclusivity term currently in force. The EMA classifies clinical data as clinical reports and individual patient data ('IPD'). Since January 2015, the EMA has been publishing clinical trial data which includes:

- the *clinical overview*, providing a critical analysis of the clinical data in the submission package, including the conclusions and implications of the clinical data;
- the *clinical summary*, which provides a detailed factual summarisation of all the clinical information submitted;
- the *study reports* on the individual clinical studies;
- three *appendices to the clinical study reports*, namely the study protocol, the sample case report form used to record information on an individual patient and documentation of the statistical methods used to analyse the data.[40]

Prior to this policy being implemented, the frontrunner case in the EU to ensure that clinical trial data was released was the *Nordic Cochrane Centre* v. *EMA* case.[41] The Ombudsman concluded that the requested clinical trial data was to be released if the drug was already patented, as then the IP related information regarding composition was already publicly available and therefore not deserving of protection.

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[38] *Human Medicines: Regulatory Information*, EMA, http://www.ema.europa.eu/ema/index.jsp?curl =pages/regulation/landing/human_med icines_regulatory.jsp.

[39] *Hma/Ema Guidance Document on The Identification of Commercially Confidential Information And Personal Data Within The Structure Of The Marketing Authorisation (Ma) Application - Release Of Information After The Granting Of A Marketing Authorisation*, EMA, http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/03/WC500124536.pdf.

[40] *Clinical Trial Data Publication*, EMA, http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000555.jsp&mid=WC0b01ac05809f363e.

[41] *Ibid.*

However, the recent *EU Trade Secret Directive* has changed that perception and has public health activists and journalists up in arms about the coming changes in this field.[42] The new directive has a broad definition of trade secrets, which could be read to include clinical trial data. While public health groups have always advocated for removing clinical trial data from the definition of trade secrets conclusively, and for ensuring that such data is not protected as confidential commercial information as it is in the US, this Directive broadens the scope of trade secrets. While the EU has allayed fears that this directive will affect the obligations of pharmaceutical companies to disclose data to the EMA,[43] public health activists are fearful that situations such as the AbbVie controversy will find more place in the EU pharmaceutical sector. However, since the Directive is still recent, it remains to be seen if drug manufacturers will use the broad definition of a trade secret in it to defeat the disclosure policy of the EMA.

Both the US and the EU regimes are recognised as going above and beyond the requirements of TRIPs, and also posing a barrier to compulsory licensing regimes and access to medicines.[44]

IV. DATA PROTECTION REGIMES: INDIA

As part of her obligations under WTO and TRIPs post 1995, India under Article 39.3 is also bound to protect undisclosed information or trade secrets. Like other common law countries, there is at present no legislation protecting trade secrets in India; and indirect means found under contract law, common law and fiduciary position are used to provide protection for illegal use of trade secrets.[45] However, apart from the usual problems faced by innovator companies submitting data to Indian regulators, there is

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[42] Directive (EU) 2016/943, Protection of Undisclosed know-how and Business Information (trade secrets) against their Unlawful Acquisition, Use and Disclosure, European Parliament and of the Council, 8 June 2016.

[43] *Frequently Asked Questions: Protection against the unlawful acquisition of undisclosed know how and business information (Trade Secrets)*, The European Commission, https://ec.europa.eu/growth/industry/intellectual-property/trade-secrets/faq_en.

[44] Correa C, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement*, SOUTH CENTRE, Geneva; (2002), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5490222/#CR1.

[45] Jaya Bhatnagar and Vidisha Garg, *Information Security Risk Management*, MONDAQ, (May 21, 2009), http://www.mondaq.com/india/x/79418/Information+Security+Risk+Management /Data+Exclusivity.

also the problem of illegal access and data theft in India. The information disclosed to the government is not protected with secrecy clauses and is frequently accessed illegally.[46]

The obligation of India under Article 39.3 only exists when usually '*undisclosed information is disclosed to the government for approval.*'[47] Once this information has been submitted, India must ensure that generic drug manufacturers do not receive access to this information or rely upon it to obtain approval of a generic bio-similar.

Similar to US law, India differentiates between commercial and non-commercial use. In the case of *Mayo* v. *Prometheus*[48] in 2012, the Supreme Court said that data exclusivity is only allowed for commercial use prevention. The case was pertaining to the exclusion of dosage methods from data exclusivity. The court considered the natural law aspect of the biological correlations between therapeutic efficacy and the patented matter. It stated that the dosage quantity was such a natural law correlation of the product itself that excluding it would lead to unnecessary monopolisation. The finding of a new dosage method was necessary for the patent and not a unique factor that involved investment and needed to be excluded. It had non-commercial connotations and data exclusivity was therefore not applied. It is important to then mention protection against commercial use alone in our statutes. Our courts, while interpreting, can then differentiate between ancillary test data and data pertaining to the manufacturing process which is alone to be protected.

V. PUBLICISING DATA FOR PUBLIC GOOD

Several opposition groups are against this idea of protecting clinical trial data. The first reason is that within India, the obligation to provide clinical trial data is for "*new chemical entities*."[49] These chemical entities require vast amounts of time and money to create and discover. When the information will be provided to the Drug Controller of India, the Indian regulatory authority it will not have sufficient funds to conduct

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[46] M. D. Nair, *Protection of trade secrets, undisclosed information*, THE HINDU, (November 22, 2001), http://www.thehindu.com/thehindu/biz/2001/11/22/stories/2001112200060100.htm.

[47] Dr. N. S. Gopalakrishnan and Adv. Benoy K. Kadavan, *Study on Test data Protection in India*, Department of Commerce, Ministry of Commerce and Industry, Government of India (2003) 5.

[48] Mayo v. Prometheus, 132 S. Ct. 1289 (2012).

[49] Animesh Sharma, *Data Exclusivity with regard to clinical data*, Indian Journal of Law and Technology, Vol. 8 (2007), 82, 87.

research into the efficacy or the safety of the drug. The companies filing for approval will essentially test the drug themselves and decide whether it complies with regulations in India. This system can be remedied if the test data is published, which will provide other companies the opportunity to test out the data themselves and figure out if the process adheres to the drug controllers' guidelines or not.

Second, the *long gestation period* to conduct clinical test trial data will further delay the arrival of life saving drugs at an affordable price in the market. This will therefore have a detrimental impact on public health as there will be an absence of affordable generic drugs for diseases such as HIV/AIDS and diabetes.[50] In countries such as India with minimal to no research in medicine, the provisions of data exclusivity will only further hinder R&D.[51] We can take the example of the Atazanavir drug priced at USD 10,000, which was sold in the Guatemalan markets. This drug was a part of HIV treatment and was provided data exclusivity for five years under the relevant law. Due to such protection, it took a considerable period, even after 2009, for the generic medicine to hit the market.[52]

Third, there is a fear in the mind of the legislators that these laws protecting trade secrets will prevent the Drug Controller from accessing the information that has been provided to the Controller previously and may allow for filing of therapeutically equivalent versions. This may lead to the '*ever-greening*' of drugs that are being filed.[53] Ever-greening is the extending of patent protection beyond the period of 20 years by filing for another patent application after inducing a negligible change in the product. Ever-greening is bad for the economy, especially of developing countries because it

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[50] Sarah Hiddleston, *India and the Data Exclusivity Trap*, THE HINDU, (August 29, 2006), http://www.thehindu.com/todays-paper/tp-opinion/india-and-the-data-exclusivity trap/article18469036.ece.

[51] *Drug Companies Should Not Have a Monopoly over Clinical Trial Data*, http://www.bio-medicine.org/medicine-news/Drug-Companies-Should-Not-Have-a-Monopoly-Over-Clinical-Trial-Data-18366-1/.

[52] *Data Exclusivity & Access to Medicines in Guatemala, Doctors without Borders/Médecins Sans Frontières, Campaign for Access to Essential Medicines*, (February 2005), http://www.cptech.org/ip/ health/ trade/cafta/msf022005.html.

[53] *Report on Steps to be taken by Government of India in the context of Data Protection Provisions of Article 39.3 of TRIPS Agreement*, Department of Chemicals and Petro-chemicals, (May 31, 2007), http://www.chemicals.nic. in/DPBooklet.pdf.

extends patent protection to certain life-saving drugs than that which is required.[54] This can be seen by the case of Novartis which had changed the structural composition of the compound but not the efficacy.[55] The Supreme Court stated that this counted as ever-greening and could not be permitted. However, this fear seems a little unfounded as the law can accommodate the Controller by allowing it access to the information that had been previously submitted to it. The Centre for Intellectual Property Rights ('CIPR')[56] and Commission on Intellectual Property Rights, Innovation and Public Health ('CIPIH')[57] have interpreted Article 39.3 to state that the government must protect against '*unfair commercial use*' and checking the application to prevent ever-greening does not count as an unfair commercial use.

Fourth, there is also an argument against the interpretation of Article 39.3 that includes data exclusion. Article 39.3 itself does not speak of protection of test data but follows from Article 39 which speaks of protection of undisclosed information. Therefore, the extra protection awarded to test data for pharmaceutical companies has been questioned by organizations in developing countries which are against it. This was supported by India's *88th Parliamentary Report on Patents and Trademarks Systems, 2008* where it was held that the Uruguay round had rejected the possibility of data exclusivity and therefore including the same would be overstepping the TRIPs mandate and reaching into TRIPs-Plus.[58] India is not required to oblige with TRIPs-Plus conditions and therefore does not need to include this.[59] On an international front, India's stand is pro-generic (and by extension, domestic) drug manufacturing industries. The Indian Delegation's comment in the current debates surrounding TRIPs reiterates that Article 39.3 does not mandate protection of undisclosed test data from anything apart from unfair commercial use.[60] The obligation under this Article is about

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[54] Lawrence A. Kogan, *Brazil's IP Opportunism Threatens U.S. Private Property Rights*, University of Miami Inter-American Law Review, Vol. 38, No. 1 (2006) 1, 34.

[55] Novartis A.G. v. Union of India, (2013) 6 SCC 1.

[56] Commission on Intellectual Property Rights (2002), 51.

[57] Commission on Intellectual Property Rights (2006), 144.

[58] 88th Parliamentary Standing Committee Report on Patents & Trade Marks System in India, Parliamentary Standing Committee on Commerce, Rajya Sabha (2008).

[59] *Supra*, Note 9.

[60] Anoo Bhuyan, *New Government Report Affirms India's Patient-First Commitment on Pharma Patents*,

"*protecting certain data against unfair commercial use and not about creating exclusive rights on such data*." The comment points out the mounting pressure on India to adopt exclusive rights, and states that "*The adoption of such standards may lead to a restriction of legitimate generic competition for products which are already in the public domain*."

Fifth, to compete with the original drug, generic drug companies will be required to conduct their own trials and expend time researching on material which is already available. This is both *unethical* and *wasteful*. Unethical, as the trial will require risky experimentation on animals and humans. Wasteful, as the research facilities will spend months on appropriate test data which is already with the government.[61]

Sixth, test data cannot be shared with statutory compulsion as Section 84 of the Indian Patents Act, 1972 does not provide for it. Section 84 stipulates that when a patented product is needed in greater quantity in the market, the government can order for its compulsory licensing to companies who also wish to manufacture it.[62] Thus, compulsory licensing of essential patents will not make a difference if the test data cannot also be disclosed under compulsion.[63]

Seventh, the US is India's largest exporter in pharmaceuticals.[64] Further, generic Indian drugs reduce the costs by 98%.[65] If the data exclusivity law comes into place the exports from India will be reduced by a considerable margin and this will affect both, our domestic manufacturers and the HIV plagued people across the world. Nearly 6.5 million people are plagued with HIV but only 1.3 million receive medicine.[66] Data exclusivity will seriously deter access to healthcare at reasonable costs across the globe.

THE WIRE, https://thewire.in/health/new-government-report-affirms-indias-patient-first-commitment-on-pharma-patents.

[61] Vanessa Perlman, *Understanding the TPP: Data Exclusivity for Biologics*, JOLLY LAW GROUP, (Oct. 7, 2015), http://www.jolleylawgroup.com/understanding-the-tpp-data-exclusivity-for-biologics/.

[62] Section 84, Indian Patents Act, 1970.

[63] *Indian pharma at odds with US trade group over USTR Priority Watch List*, PHARMA LETTER, https://www.thepharmaletter.com/article/indian-pharma-at-odds-with-us-trade-group-over-ustr-priority-watch-list.; Ellen 'T Hoen, *TRIPs, Pharmaceutical Patents, and Access to Essential Medicines: A long way from Seattle to Doha*, 3 CHI. J. INT'L L. 27, 33 (2002).

[64] Bhavik Narsana, Soumyadhari Chattopadhyaya and Yashashree Mahajan, *Clinical Trials and Data Exclusivity: In Search of a Fine Balance*, KHAITAN AND CO., https://www.khaitanco.com/PublicationsDocs /Khaitan&Co-PharmaBioWorldMarch17.pdf.

[65] *Id.*

[66] *Id*.

The trade off to big pharma companies securing costs at higher margins cannot be that medicines are provided after five years to those who need them.

Eighth, data exclusivity offers no chance of opposition or revocation. An ordinary drug company cannot appeal against a decision for non-disclosure. This inability to question what should or should not be revealed creates paranoia in the industry.[67] This exponentially increases the possibility of ineffective, and even worse, potentially harmful drugs entering the market. Further, not providing anyone access to the data submitted would only further delay the process of discovering ineffective and harmful drugs, by which point the damage may already be done.

India adheres to TRIPs in complying with what would constitute '*protected data* or *undisclosed information*'. The data therefore relates to the details of results of safety and efficacy testing of drugs which pertain to humans, animals and plant health. '*Other data*' which may fall under the protection of such law may be other manufacturing, packaging and conservation methods. The other data is only protected information if it relates to the extent of requiring a market approval for the drug. What constitutes requirement for '*market approval of drug*' is a relative term and can be open to all forms of interpretation. To decide which information to disclose, India chooses to stand by the opposition. Paragraph 4 of the DOHA Declaration on TRIPs Agreement and Public Health[68] held that "*TRIPs 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 for all.*"[69] Therefore, the test data is left deliberately unprotected to meet our interests as a developing nation.

VI. PROTECT INFORMATION TO PROTECT INNOVATION

There are also arguments in favour of exclusivity. First, the longer time taken and assurance of protected investment will allow companies to be thorough in their testing

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[67] Krishna Sharma, *Of new drugs, safety and data exclusivity side-effects*, BUSINESS LINE, http://www.thehindubusinessline.com/specials/pulse/by-invitation/article9549392.ece.

[68] Clift C, *Data Protection and Data Exclusivity in Pharmaceuticals and Agrochemicals, in Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*, *Oxford, UK and PIPRA, Davis, USA*, 434, www.ipHandbook.org.

[69] Grabowski H, *Data exclusivity for new biologicals, Duke University*, Department of Economics Working Paper (2007), 3.

of new drugs. This increases safety of the medicines marketed to India. Second, in line with the most trite IPR argument, greater protection incentivises innovation. Third, our research is insufficient in comparison to U.S and European companies. As per the Special 301 Committee Report prepared annually by the Office of the United States Trade Representative ('USTR'), India is one of the countries posing trade barriers to intellectual property protection.[70] The Special 301 report has three categories, the Priority Foreign Country (countries providing least protection), the Priority Watch List (countries providing inadequate IPR protection) and the Watch List (for countries where certain rights are not protected). India's National Manufacturing Policy which includes compulsory licensing has dissatisfied the US Trade Chief who believes that it disincentives innovation.[71] As a result, India is on the Priority Watch List. Its purpose is to provide a list of countries that the U.S will impose unilateral sanctions on for loss of investment. Although, India has not yet had any sanctions imposed on it, Ukraine has previously been sanctioned with increased tariffs for inadequate protection of copyright against piracy. The possibility of a charge from the US is a palpable and their inaction should not lead us to disregard it. Even if, no such sanction is imposed, companies with requisite R&D become wary of visiting India and this deters our development. Fourth, India is receiving mounting pressure to provide adequate IPR protection not only from these countries but also regional trade co-operations. Recently, at the 18th round of the RCEP held in Philippines, Japan and South Korea requested that data exclusivity for a period of four years at least be introduced. According to the Humanitarian aid organisation Médecins Sans Frontières ('MSF'), if such a measure is taken, India will not remain as the 'pharmacy of the world'. Its production from generic companies will come to a halt and it will stop being one of the greatest exporters of medicine.[72] The RCEP is a trade agreement with ASEAN Countries and six other nations such as Australia, New Zealand, Japan, Korea etc. It will play the role of a very important trade

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[70] *Supra*, Note 46.

[71] *India to US: Will not tighten IPR rules beyond TRIPS mandate*, BUSINESS LINE, http://www.thehindubusinessline.com/economy/policy/india-to-us-will-not-tighten-ipr-rules-beyond-trips-mandate/article9246323.ece.

[72] *MSF comment on official statement from Indian Minister against 'Data Exclusivity'*, Médecins Sans Frontières, https://www.msfaccess.org/content/msf-comment-official-statement-indian-minister-against-%E2%80%98data-exclusivity%E2%80%99.

bloc after the fall of the Trans Pacific Partnership which was scrapped by President Trump as a job killer.[73] The RCEP will play an important role for India's economy since the Free Trade Agreement that was meant to be signed with the EU back in 2007 has been in the doldrums due to India's refusal to agree with the data exclusivity regime.[74]

VII. TO EXCLUDE OR NOT TO EXCLUDE? INDIA CHOOSES BORDERLINE SOLUTION

To assuage companies from other nations, the Department of Chemicals and Petrochemicals ('DCPC'), under the Ministry of Chemicals and Fertilizers in February 2004, convened the *Satwant Reddy Committee* to decide whether data exclusivity should be granted for test data for pharmaceutical products.[75] By the year 2007, the report was formulated and it contained two primary recommendations for pharmaceutical test data. First, it stated that the time limit should be five years for the data exclusivity for pharmaceutical products.[76] Second, it stated that data exclusivity should not apply to drugs for life threatening diseases such as HIV/AIDs.[77] Third, the committee suggested upgrading the technical infrastructure to ensure that leaks of test data information did not occur. A transitional period during the time of regulatory checks was recommended where minimum data protection would be afforded. The post transition period (when regulatory approval has been granted) will be of five years. During this period, the Drug Regulatory Authority will not be permitted to access data submitted by the originator, even if to check for subsequent market approval. India has attempted to compromise the standards expected by these nations and its domestic

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[73] *Trump pulls US out of 'job killer'*, THE TRIBUNE, (January 24, 2017), http://www.tribuneindia.com/news/world/trump-pulls-us-out-of-job-killer-pacific-trade-deal/354596.html.

[74] Nayanima Basu and Joe C Mathew, *Data exclusivity still key hurdle to India-EU FTA*, BUSINESS LINE, (January 27, 2011), http://www.business-standard.com/article/economy-policy/data-exclusivity-still-key-hurdle-to-india-eu-fta-1110127000341.html.

[75] Notification No.11025/7/2003-PI-II, Department of Chemicals and Fertilizers, Ministry of Chemicals and Fertilizers (2004), 822.

[76] Sarah Hiddleston, *An important win for domestic pharma industry*, THE HINDU, (June 5, 2007), http://www.thehindu.com/todays-paper/tp-national/An-important-win-for-domestic-pharma-industry/ article14772743.ece.

[77] Satwant Reddy Committee, *Report on steps to be taken by Government of India in the context of Data Protection Provisions of Article 39.3 of TRIPs Agreement*, (2007).

needs by implementing a data exclusivity plan for agro-chemical products instead and will also increase the time limit in 2017.[78]

There is already a provision for data exclusivity under Rule 122E of the Drugs and Cosmetics Rules, 1940. This rule states that a 'new drug' is a drug which has previously not been approved in India. This new drug status persists for four years and during this time Rule 122B applies to any similar drug being registered. Schedule Y under Rule 122B provides that the clinical tests of reaching that bioequivalence must be established for the similar drug to be registered.[79] Resubmission of clinical data implies that a four-year data exclusivity plan should be at play. It is now the same provision that is causing a furore in the Indian scenario. The DTAB wishes to extend the four-year limit to ten years, increasing the time limit of data exclusivity.[80] However, there may not, in fact, be any actual cause for concern. This can be observed by Rule 122E (3), which allows the Director General to waive off clinical test data proof if bio equivalence can be established with the new drug.[81] Test data from the foreign applicant is presumed to apply if bio-equivalence is demonstrated. According to the 59th Report of the Parliamentary Standing Committee on Health, this clearance by the Director General is now a norm.[82] If that is the case, then the clinical test data is not even required by the pharma companies and we can ride past the fear of data exclusion. The fear instead in the minds of foreign companies, only grows. They lose out on investment by merely providing their test data to the committee as a bio-equivalent drug will be registered regardless. While, this seems to not be a fearful thing for Indian pharmaceutical companies, the system is a farcical idea of data protection that all international MNCs have looked through. Therefore, the call for data exclusivity persists and the discussion is pertinent even today.

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[78] Swaraj Paul Barooah, *Data exclusivity back on the table for India*, SPICY IP, (March 27, 2015), https://spicyip.com/2015/03/data-exclusivity-back-on-the-table-for-india.html.

[79] Drugs and Cosmetics Rules, 1940.

[80] Abantika Ghosh, *Increasing the period of surveillance data may delay entry of generic drugs: Commerce secretary Rita Teotia*, THE INDIAN EXPRESS, https://indianexpress.com/article/ business/business-others/pharma-regulation-generic-drugs-rita-teotia-4375924/.

[81] *Supra,* Note 79.

[82] 59th Department Related Parliamentary Standing Committee Report, *The functioning of the Central Drug Standard Control Organisation (CDSCO),* Government of India, (2012), 12.

Since our laws only provide ambiguous and half-hearted protection to both the MNCs and India's own pharma companies in certain instances, new methods of implementing data exclusivity must be considered.

What must be considered is the impact of any changes on not only Indian generic manufacturing, but also foreign companies that currently have a fear of entering the Indian market.[83] The population problem has stymied the chance of adequate health care and instant cheap access to medicines is to be the end goal in deciding these policy changes.[84] It is undisputed that given the lack of current innovation in India, the generic industry is the only way forward to provide access to medicine, and therefore, foreign research data is required to be accessible in India.[85] The question is whether the time delay in the entry of generics is justifiable, or whether it can be tackled using different policies.

Analysing the economy, it is to be expected that regardless of generic variants, the strength of India's consumer market may be strong enough to entice pharma companies to sell their products. In that event, these companies may delay introducing their drugs by two to three years and not beyond that. The exclusivity period of five years then is only detrimental to us. On the flipside, these drugs will not be introduced *at all* in our markets for 2-3 years

The secretary of the Indian Pharmaceutical Alliance (domestic pharma lobby group), Dr. D. G. Shah has requested that India be taken off US's priority watch list.[86] The concerns of the USTR pertain mostly to the ambiguous compulsory licensing provisions in India and not the data exclusivity arguments immediately. However, under Section 85 of the Indian Patents Act, 1972, only 2 cases of compulsory licensing have occurred with US pharma companies. India's presence on the priority watch list is uncalled for

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[83] Nayanima Basu, *US investors still concerned over compulsory licensing in India*, BUSINESS LINE, http://www.thehindubusinessline.com/news/us-investors-still-concerned-over-compulsory-licensing-in-india/article9565821.ece.

[84] *Chinese Pharma Maintains Decent Growth and Prospects Amid Deepened Reform*, Wicon International Group LLC, <http://www.pr.com/press-release/713398>.

[85] *Id.*

[86] P.B. Jayakumar, *Indian pharma asks US to exclude India from list of IPR offenders*, BUSINESS TODAY, (February 10, 2017), http://www.businesstoday.in/sectors/pharma/indian-pharma-asks-us-to-exclude -india-from-list-of-ipr-offenders/story/246151.html.

as TRIPs allows for compulsory licensing if the prices and competitive behaviour of the firms is unreasonable.[87] Further, India's data exclusivity provisions consider its needs as a developing country and US is only strong-arming India into changing its policy. Therefore, the alliance has moved an appeal against this move. These drug companies are also affected as India is the US's largest medicine exporter. If data exclusivity comes into place, the exports will produce drugs after 5 years and they will become outdated from the market. Therefore, data exclusivity will be more potentially damning for Indian pharma companies, who would have to invest their own R&D and develop the drugs.

VIII. POLICY RECOMMENDATIONS

India is required to take a more liberal view of data exclusivity as it is one of the largest suppliers of generic medicine with a vast population of the country suffering from life threatening diseases such as AIDs and cancer. The recommendations which have been provided by the *Satwant Reddy Committee* prove to be correct on both counts of (i) time for exclusivity and (ii) the items that can be limited. However, the Committee has not dealt with regulating the audience that can be provided with this information. For example, to ensure that ever-greening does not take place, the Drug Controllers Authority should be allowed to review previous applications to check if the new patent application is therapeutically equivalent.[88] Therefore, government entities should be allowed to monitor and have access to the information provided. Next, the authority may not have sufficient funds to conduct research on the data; therefore certain research institutes should be provided with access to the information to consider the test data. Such a use would be a non-commercial use and would not lead to exploitation. The time limit of 5 years for the test data is an appropriate time limit. Further, India cannot afford to prevent generic versions of life saving drugs from entering the market. This is in line with other patent provisions that can be found in the Indian Patent Act, 1970 and TRIPs as well to ensure that the public health is read into the provisions of TRIPs. Therefore, for certain provisions TRIPs provides for 'public

[87] *Id.*
[88] *Supra* Note 54.

non-commercial use' along with the provisions regarding medical emergency.[89] This is done to allow for public use even if there is no emergency to use that technology.[90]

This leaves us with the matter of the implementation of the Satwant Reddy Commission report, which has still not been implemented a decade after it came out. The principle behind data exclusivity is to provide the companies some time to recoup investment that was spent on testing to finalise the product. Once that is achieved the test data can be released to the public. This creates an incentive for the multi-national companies from developed countries to introduce their products in the Indian markets - an act that will not be accomplished if there is no legislation in India which provides the *Satwant Reddy Committee* report the authority of law.

Lastly, instead of having a restriction on data exclusivity we can adopt the Compensatory Liability Model.[91] Data is not restricted from being used; instead compensation is paid for using such data. Data exclusivity is, after all, a *slippery slope*. If the US could induce India to introduce it into our laws they could keep petitioning for sanctions against us and include even more data than required within this criterion. Compensation will prevent restriction entirely and the situation will not come to pass.

In conclusion, India's current stance on data protection is TRIPs compliant, and even has space for further leniency in provisions. While it is understandable that having no period of data exclusivity, though TRIPs complaint, would potentially scare innovator companies away, a shorter period of data exclusivity, or a more liberal interpretation of non-commercial use may be preferred. Further, there is every need to keep in mind the larger goal of access to medicine as a public health issue while deciding on India's national policies, and by becoming less protective of innovator clinical data, India will pave the way for more developing nations to take a stance and interpret Article 39.3 in a more liberal fashion.

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[89] *Obligations and exceptions under TRIPS: What are member governments' obligations on pharmaceutical patents*, WTO, https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e .htm.

[90] *Id.*

[91] Alisha Merchant, *Law of Data Exclusivity*, JAIN KINKAR AND CO., http://www.jain kinkar.com/article5.pdf.