Life, Death, and Data: Examining the Human Rights Implications of Introducing Data Exclusivity to India's Pharmaceutical System, in light of the Global Situation of Diseases such as HIV/AIDS in the Philippines and Other Developing Countries

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I. INTRODUCTION

> *Medicine is the restoration of discordant elements; sickness is the discord of the elements infused into the living body.*
>
> — Leonardo Da Vinci[1]

Ever since human beings have known life, they have known illness. Our history is punctuated by periods of disease, which have ravaged populations, but from which humankind has, for the most part, managed to recover. While a number of diseases remain serious, as science and technology progress, an increasing number of diseases are turning less into death sentences and more into manageable inconveniences. The plague, which once swept through regions of Europe, is now very rare, and in any case, treatable by antibiotics.[2] The outlook for an infected person today is

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1. LEONARDO DA VINCI, NOTEBOOKS 262 (2008 ed.).
2. Mayo Clinic Staff, Diseases and Conditions: Plague — Overview, *available at* http://www.mayoclinic.org/diseases-conditions/plague/home/ovc-20196753 (last accessed May 12, 2017).

certainly less grim than it would have been during the Middle Ages.[3] Tuberculosis, a disease caused by bacteria affecting the lungs, can now be controlled by a series of drug treatments, which, once finished, will eliminate the bacteria altogether.[4] It is hard to believe that it was only a little more than 20 years ago that tuberculosis was the seventh leading cause of death in the world.[5]

One particular disease whose treatment has undergone significant progress is HIV/AIDS. The term HIV/AIDS connotes two different aspects. HIV, which stands for Human Immunodeficiency Virus, is the virus that infects persons, and which, if not treated, would lead to AIDS, which, in turn, stands for Acquired Immuno Deficiency Syndrome.[6] HIV works to destroy "key parts of [a person's] immune system [—] [the] T-cells or CD4 cells."[7] If it destroys enough of these cells, a person's immune system becomes compromised and the person in turn develops AIDS, which "is the final stage of HIV infection."[8] People with AIDS have extremely weak immune systems, and have little chance of fending off various illnesses, which could in turn kill them. HIV/AIDS has been called "an unprecedented public health emergency"[9] and has "already caused enormous

3. Center for Disease Control and Prevention, Plague — Frequently Asked Questions, *available at* https://www.cdc.gov/plague/faq (last accessed May 12, 2017).

4. Center for Disease Control and Prevention, Tuberculosis — Treatment, *available at* http://www.cdc.gov/tb/topic/treatment/default.htm (last accessed May 12, 2017).

5. Joshua Salomon, Global burden of tuberculosis in the year 2000 (A Report from the Epidemiology and Burden of Disease Department of the World Health Organization) at 1, *available at* http://www.who.int/healthinfo/statistics/bod_tuberculosis.pdf (last accessed May 12, 2017) & Christopher J.L. Murray, et al., The Global Burden of Disease: A comprehensive assessment of mortality and disability from diseases, injuries, and risk factors in 1990 and projected to 2020, at 4, *available at* http://apps.who.int/iris/bitstream/10665/41864/1/0965546608_eng.pdf (last accessed May 12, 2017).

6. AIDS.gov, What is HIV/AIDS, *available at* http://aids.gov/hiv-aids-basics/hiv-aids-101/what-is-hiv-aids (last accessed May 12, 2017).

7. *Id.*

8. *Id.*

9. Jai P. Narain, *AIDS in Asia: The Epidemic Profile and Lessons Learnt So Far, in* AIDS IN ASIA: THE CHALLENGE AHEAD 19 (2004).

ill health and mortality worldwide."[10] It has been almost [40] years since the epidemic first came to light, and "there is still no vaccine and no 'cure.'"[11]

However, in 1987, the first antiretroviral (ARV) drug was approved in the United States (U.S.)[12] and within a decade, "new classes of [these] drugs and their use in combination have dramatically changed the management of HIV infection."[13] While not complete cures for HIV/AIDS, the treatments which have developed through these drugs have had a number of notable effects, including "improved rates of mortality and morbidity, prolonged lives, [and] improved quality of life[.]"[14] HIV/AIDS has been transformed "from a plague to a manageable, chronic illness."[15]

Developments in the field of medicine have meant much for the lives of people in general. Medical developments, however, did not come without concurrent developments in the industries surrounding them. In today's world, it is rare for independent scientists to come out with treatments for certain diseases. Most research is commissioned by certain institutions — sometimes, these are governments, but most of the time, these are pharmaceutical companies.[16] The latter are responsible for manufacturing and distributing the commercial drugs once a working formula is found. Before distribution for consumption, however, these companies also take charge of testing the medicine and filing for its approval with the regulatory boards of a certain territory where they wish to distribute the drug.[17]

These steps take money, and the cost of putting a certain drug onto the market is very high.[18] These companies then try to recover costs through the

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10. *Id.*

11. *Id.* at 20.

12. AIDS.gov, A timeline of AIDS, at 3, *available at* https://www.aids.gov/pdf/aidsgov-timeline.pdf (last accessed May 12, 2017).

13. Emanuele Pontali, et al., *Antiretroviral Treatment in Resource-limited Settings, in* AIDS IN ASIA: THE CHALLENGE AHEAD 286 (2004).

14. *Id.*

15. *Id.*

16. *See* University of California Museum of Paleontology, Who pays for science?, *available at* http://undsci.berkeley.edu/article/who_pays (last accessed May 12, 2017).

17. MedicineNet.com, Drug Approvals — From Invention to Market ... A 12-Year Trip, *available at* http://www.medicinenet.com/script/main/art.asp?articlekey=9877 (last accessed May 12, 2017).

18. *See* Matthew Herper, The Cost Of Creating A New Drug Now $5 Billion, Pushing Big Pharma To Change, *available at* http://www.forbes.com/sites/

prices of the drugs themselves.[19] However, once a drug is out on the market, techniques such as reverse engineering may allow other companies to produce similar drugs without spending what the originator had spent to research and test it.[20] This would allow them to produce drugs at a lower cost, and would also allow them to price drugs cheaper.[21] While this situation sounds favorable to those in need of medicines, especially those from the poorer sectors of the population, it is not favorable for the originators — the drug companies who produce the formula of the effective drug. To protect their investments and avoid this situation, the pharmaceutical industry has turned to a particular area of law for protection — the law on intellectual property.[22]

Intellectual property (IP) law, which includes patents, copyrights, and trademarks, "enable people to earn recognition or financial benefit from what they invent or create."[23] The function of IP law is to protect IP rights, which is a specie of the more basic right to property.[24] For the pharmaceutical industry, patents and exclusivity periods have been the relevant forms of IP protection until recently. The World Intellectual Property Organization (WIPO) defines a patent as "an exclusive right granted for an invention [—] a product or process that provides a new way

matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine (last accessed May 12, 2017).

19. *See* Matthew Herper, The First Drug With A $1 Million Price Tag May Already Be On The Market, *available at* http://www.forbes.com/sites/matthewherper/2012/05/01/the-first-drug-with-a-1-million-price-tag-is-already-on-the-market (last accessed May 12, 2017).

20. Arvind K. Bansal & Vishal Koradia, The Role of Reverse Engineering in the Development of Generic Formulations, *available at* http://www.pharmtech.com/pharmtech/article/articleDetail.jsp?id=173676 (last accessed May 12, 2017).

21. *Id.*

22. *See* Cheri Grace, The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China: Considerations for Access to Medicines, at 15, *available at* http://www.who.int/hiv/amds/Grace2China.pdf (last accessed May 12, 2017).

23. World Intellectual Property Organization, What is Intellectual Property?, *available at* http://www.wipo.int/about-ip/en (last accessed May 12, 2017).

24. World Intellectual Property Organization, What is Intellectual Property? (A Handbook Published by the World Intellectual Property Organization) at 3-4, *available at* http://www.wipo.int/edocs/pubdocs/en/intproperty/489/wipo_pub_489.pdf (last accessed May 12, 2017) [hereinafter WIPO Handbook].

of doing something, or that offers a new technical solution to a problem."[25] A patent provides patent owners with protection for their inventions; "protection is granted for a limited period, generally 20 years."[26] For pharmaceutical companies, this would mean that should they obtain a patent over a new drug, they alone would be allowed to reap the benefits of the formulation of such drugs, and no companies may put out a like product for a given number of years. This would effectively protect the investment that originator companies have poured into their drugs, and allow them to recover without worry or fear of competition from cheaper products in the market. Data exclusivity periods, as will be explained later, work to achieve a similar effect as patents, impeding not the production of similar products, but their approval for distribution and consumption.

This regime of IP protection has not gone without criticism. Especially considering that the subject of the IP protection in this case are medicines — some of which are used for serious diseases such as cancer and HIV/AIDS — questions have arisen regarding the propriety of patenting medicines or implementing exclusivity periods for their relevant data. In particular, questions have arisen regarding the balance between IP protection, on the one hand, and human rights, such as the rights to health and life, on the other.[27] This tension between human rights and IP protection of pharmaceuticals is best illustrated by the events in 2001 involving Cipla, an Indian pharmaceutical company, some western drug companies, and AIDS treatment given to select parts of Africa.[28] Cipla was able to formulate a "three-drug cocktail" designed to address AIDS, priced at U.S. $350 per annual treatment, and offered it to Médecins Sans Frontières, otherwise known as Doctors Without Borders, for their operations in Africa.[29] The leading western manufacturers had going rates of about U.S. $10,000 to U.S. $12,000 per annual treatment.[30] Even at discounted rates from the western

25. World Intellectual Property Organization, What is a patent?, *available at* http://www.wipo.int/patents/en (last accessed May 12, 2017).

26. *Id.*

27. *See generally* Jamie Crook, *Balancing Intellectual Property Protection with the Human Right to Health*, 23 BERKELEY J. INT'L L. 528 (2005).

28. Donald G. McNeil, Jr., *Indian Company Offers to Supply AIDS Drugs at Low Cost in Africa*, N.Y. TIMES, Feb. 7, 2001, *available at* http://www.nytimes.com/2001/02/07/world/indian-company-offers-to-supply-aids-drugs-at-low-cost-in-africa.html (last accessed May 12, 2017).

29. *Id.*

30. *Id.*

drug companies, Cipla's price was still much lower.[31] In response to the situation, Glaxo, one of the western companies, contacted both Cipla and the distributor of the drug in Ghana, saying that "sales of a generic version of [its] drug Combivir would be illegal because [Cipla and the drug distributor] would be violating company patents."[32] Hence, on the one hand, Cipla ceased distributing the cheaper medicine in Ghana, which caused a major uproar in the international community.[33] African authorities, on the other hand, responded that these patents were not recognized, or were otherwise invalid in Ghana.[34]

A. The Point of Intersection: TRIPS and Domestic Law

Each country has their own method of formulating and implementing IP laws. Before the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement),[35] most countries were left to their own devices as to what IP rights were protected and how such protecting would be done. A significant example is India. Before joining the World Trade Organization (WTO) in 1995,[36] India had a distinctive patenting system. Its Patents Act, 1970 (Patents Act),[37] before any of the amendments found today, allowed only "process patents" and not "product patents" for certain items.[38] Process patents protect the methodology by which a certain invention is produced, but not the invention itself.[39] In contrast, a product

31. *Id.*

32. EDWIN CAMERON, WITNESS TO AIDS 224 (2007).

33. McNeil, Jr., *supra* note 28.

34. Mark Schoofs, Glaxo Attempts to Block Access to Generic AIDS Drugs in Ghana, *available at* http://www.pnhp.org/news/2001/december/glaxo-attempts-to-block-access-to-generic-aids-drugs-in-ghana (last accessed May 12, 2017).

35. Agreement on Trade-Related Aspects of Intellectual Property Rights, *concluded* Apr. 15, 1994, 1869 U.N.T.S. 299 (entered into force Jan. 1, 1995) [hereinafter TRIPS Agreement].

36. World Trade Organization, Member Information: India and the WTO, *available at* http://www.wto.org/english/thewto_e/countries_e/india_e.htm (last accessed May 12, 2017).

37. The Patents Act, 1970, No. 39, Acts of Parliament 1970 (India) [hereinafter Patents Act of 1970].

38. *Id.* § 5.

39. Tarun Kabiraj, Product vs. Process Patenting and R & D Incentives (A Report Written for the Indian Statistics Institute) at 4-5, *available at* http://www.isical.ac.in/~eru/erudp/2005-11.pdf (last accessed May 12, 2017).

patent prohibits the production of a similar invention regardless of how it is made.[40] Under the Patents Act, "substances intended for use, or capable of being used, as food[,] medicine[,] or drug[s]"[41] were not patentable, and manufacturers could only apply to patent their manufacturing processes.[42] Medicines could not be patented in India. The effect of this patent regime saw a boom in India's local pharmaceutical industry, as well as a drop in prices of medicines.[43] Smaller generics companies thrived under the then-prevailing patent regime specifically designed to address the medical needs of India's poor populations, as well as encourage "low-cost manufacturing."[44]

When India joined the WTO in 1995, the country was required to comply with the TRIPS Agreement, which the WTO members had adopted the year before.[45] The TRIPS Agreement set forth "certain minimum standards in [IP] laws [for Member States of the WTO.]"[46] India was given 10 years to amend its domestic laws to comply with the TRIPS Agreement.[47] The end result was the deletion of Chapter II (5) of the original Patents Act, effectively allowing patents on previously untouchable products such as medicine.[48] While this move worried many of those benefiting from the combination of India's lax patent laws and booming generics industry, the Indian government was careful not to completely abandon its previous system of IP law.

While the Patents Act was amended to include product patents, the amendments also introduced the concept of the "compulsory license." Compulsory licensing, found in Section 55 (92A) of Chapter XVI, was

40. *Id.*

41. Patents Act of 1970, § 5 (a).

42. *Id.*

43. Janice M. Mueller, *In Depth Analysis of Indian Patents Law*, 68 U. PITT. L. REV. 491, 515 (2007).

44. Sara Beth Myers, *A Healthy Solution for Patients and Patents: How India's Legal Victory Against a Pharmaceutical Giant Reconciles Human Rights with Intellectual Property Rights*, 10 VAND. J. ENT. & TECH. L. 763, 766 (2008).

45. *See* Jeffrey Colin, *Coming into Compliance with TRIPS: A Discussion of India's New Patent Laws*, 25 CARDOZO ARTS & ENT. L. J. 877, 877 (2007).

46. *Id.* at 885.

47. Laura Thomson, Changing times for patenting in India (An Excerpt from the KnowledgeLink Newsletter of Thomson Scientific, a Branch of Thomson Reuters) at 1, *available at* http://ip-science.thomsonreuters.com/m/pdfs/klnl/2005-02/patenting-india.pdf (last accessed May 12, 2017).

48. Colin, *supra* note 45, at 889.

introduced by the amendment of 2005,[49] and allows India to export products to other nations that do not possess a sufficient pharmaceutical manufacturing sector of their own, despite the product being patented.[50] Two conditions must be met for compulsory licensing to take effect. First, the product in question must be used to "address public health problems."[51] Second, the receiving country must consent in the form of granting or allowing the compulsory license.[52]

The amendments also added to the existing Chapter II (3) (d). The amended law now states that patents will not be granted for

> the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine[,] or apparatus unless such known process results in a new product or employs at least one new reactant.[53]

Explained simply, the law as it stands in India will not grant or renew a patent for a product if whatever change the proponent puts forth to justify the application does not make the product more effective, or if a new process used does not create a completely new product.

Both the new and more stringent requirements on products before a patent is issued and the availability of compulsory licenses address many of the accessibility issues which some feared would arise by reason of compliance with the minimum standards set by the TRIPS Agreement. This was most evident in the 2009 case of *Novartis AG v. Union of India and Ors.*,[54] where the denial of an application for renewal of a patent for the drug Glivec was affirmed by the Supreme Court of India. Glivec was a drug designed to treat leukemia, and Novartis sought to renew its patent

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49. The Patents (Amendment) Act, 2005, No. 15, § 55 (92A), Acts of Parliament, 2005 (India) [hereinafter Amended Patents Act of 1970].

50. *Id.*

51. *Id.*

52. *Id.*

53. *Compare* Amended Patents Act of 1970, § 3 (d) *with* the original version of the law, which only stated that patents would not be granted for "the mere discovery of any new property of new use for a known substance or of the mere use of a known process, machine[,] or apparatus unless such known process results in a new product or employs at least one new reactant[.]" Patents Act of 1970, § 3 (d).

54. Novartis AG v. Union of India and Ors., Civil Appeal No. 2706-2716 of 2013 (Apr. 1, 2013) (India).

application in order to extend the protected period.[55] Novartis claimed that the new formulation met the requirements of inventiveness and innovation under the Patents Act as amended, and a renewed patent should therefore be granted.[56] The Supreme Court of India denied the appeal saying that contrary to Novartis' claims, the new version of Glivec failed to reach the standards set by the Patents Act for product patents.[57] Cases involving drugs such as Tenofovir, a first-line treatment for HIV/AIDS, have met a similar fate.[58]

While there has been some debate on whether India's new patent law is compliant with the TRIPS Agreement, it has been almost 10 years since the last amendment to the law, and the status quo seems to favor India, in that they are considered as complying with the minimum standards.[59] After all, the TRIPS Agreement does have a feature of flexibility, shown by the fact that it leaves to each Member State the discretion as to how the minimum standards dictated by the TRIPS Agreement are to be protected or met through domestic laws.[60] However, while the TRIPS Agreement dictates the minimum standards for IP rights protection to be adhered to by Member States, it does not prohibit them from enacting higher standards of protection.[61] Provisions intending to build or add on to the protection provided by the TRIPS Agreement are commonly described as "TRIPS Plus,"[62] and it is the emergence of these TRIPS Plus instruments that have once again gotten a section of the population concerned due to their implications for access to medicine.

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55. *Id.* ¶ 2.

56. *Id.* ¶¶ 10–13.

57. *Id.* ¶ 195.

58. In the Matter of patent Application no. 2076/DEL/1997 (Gilead Sciences Inc. v. Cipla Ltd.), at 18 (July 30, 2009).

59. *See* Rajarshi Banerjee, *The Success of, and Response to, India's Law against Patent Layering*, 54 HARV. INT'L L. J. 204 (2013).

60. Alhaji Tejan-Cole, et al., Flexibilities in the TRIPS Agreement and its Impact on National Intellectual Property, *available at* http://www.belipo.bz/wp-content/uploads/2011/12/TRIPS-FLEXIBILITIES.pdf (last accessed May 12, 2017) & World Intellectual Property Office, Advice on Flexibilities under the TRIPS Agreement, *available at* http://www.wipo.int/ip-development/en/legislative_assistance/advice_trips.html (last accessed May 12, 2017).

61. *Id.*

62. Médecins Sans Frontières, TRIPS, TRIPS Plus and DOHA, *available at* http://www.msfaccess.org/content/trips-trips-plus-and-doha (last accessed May 12, 2017).

1. TRIPS Plus Agreements: Crossing the Line or Simply Drawing New Ones?

Formally called the Broad-based Trade and Investment Agreement, the Free Trade Agreement (FTA) currently being negotiated by the European Union (EU) and India covers a wide array of trade related issues, as well as IP matters.[63] A main concern many have regarding the terms of the EU-India FTA is the possibility of the inclusion of "data exclusivity clauses." Data exclusivity is a limitation on access by third parties to information generated by a party often called the originator.[64] These provisions ensure that "the data generated by [an originator] may not be referred to or used by another person or company for a specific period of time."[65]

In the context of India and its pharmaceutical industry, a data exclusivity clause would prevent what are known as bio-equivalency tests. Bio-equivalency tests involve the comparing by a regulatory board of the chemical composition of one drug (the generic) with data submitted by the applicant of an already approved drug (the originator drug), in order to show the chemical and biological equivalence of the products to each other.[66] Generics companies use this method to bypass the more resource intensive route taken by the originators, which involve large-scale trial and testing. Bio-equivalency tests, which are allowed in India,[67] have played a large role in the proliferation of generic medicine in the country.

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63. Geethanjali Nataraj, India-EU FTA: Problems and Future Prospects (An Article from World Commerce Review) at 1, *available at* http://www.worldcommercereview.com/publications/article_pdf/934 (last accessed May 12, 2017).

64. International Federation of Pharmaceutical Manufacturers Associations, Encouragement of New Clinical Drug Development: The Role of Data Exclusivity (A Document Submitted to the Commission on Intellectual Property Rights, Innovation and Public Health of the WHO) at 1, *available at* http://www.who.int/intellectualproperty/topics/ip/en/DataExclusivity_2000.pdf?ua=1 (last accessed May 12, 2017) [hereinafter IFPMA Document].

65. *Id.*

66. World Health Organization, Briefing Note: Access to Medicines (Briefing Note by the World Health Organization dated March 2016) at 1, *available at* http://www.searo.who.int/entity/intellectual_property/data-exclusively-and-others-measures-briefing-note-on-access-to-medicines-who-2006.pdf [hereinafter WHO Briefing Note].

67. The Drugs and Cosmetics Act, 1940, No. 23, Acts of Parliament, 1940 (India) & *See* Central Drugs Standard Control Organization, Guidelines for Bioavailability & Bioequivalence Studies, *available at* http://cdsco.nic.in/html/

While there has yet been no official copy of the FTA finally negotiated and signed, there is reasonable ground to be concerned about the possibility of data exclusivity clauses. Aside from drafts of and reports about the EU-India FTA itself, the EU has introduced similar provisions with recent FTA agreements concluded with Korea,[68] Colombia,[69] and Peru.[70] There are also reports that they seek to do the same with the FTA currently being negotiated with Thailand.[71] For the U.S., the EU's neighboring superpower, data exclusivity is a general rule with their FTAs.[72]

The emergence of the issues surrounding data exclusivity has renewed the debate on the place of IP rights vis-à-vis human rights. Concern is intensified because of the possibility that these kinds of provisions may now bind India, the "pharmacy of the developing world."[73] Affected drugs would include those designed to treat fatal diseases including HIV/AIDS. When medicine is a matter of life and death, and drug prices become the impenetrable wall that separates one from the other, is it legally justifiable, under accepted principles of human rights law, to impose data exclusivity clauses? Where does data exclusivity fall in the balance of private and public interests? Does a property right gain primacy over the right to life and the right to health? These are but some of the questions this Note seeks to

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be%20guidelines%20draft%20ver10%20march%2016,%2005.pdf (last accessed May 12, 2017).

68. Hee-Eun Kim, Drug Patent Protection in Korea under the EU-Korea Free Trade Agreement, *available at* http://www.insideeulifesciences.com/2013/06/10/drug-patent-protection-in-korea-under-the-eu-korea-free-trade-agreement (last accessed May 12, 2017).

69. *See* Thomas Fritz, The Second Conquest: The EU Free Trade Agreement with Colombia and Peru (A Publication made with the Assistance of the EU and Submitted to the Center for Research and Documentation Chile-Latin America) at 14-15, *available at* https://www.tni.org/files/download/Fritz-2010_The%20Second%20Conquest_Colombia-Peru-EU-FTA.pdf (last accessed May 12, 2017).

70. *Id.*

71. Tessel Mellema, The EU-Thailand FTA: What Fate For Access to Medicines, *available at* http://www.ip-watch.org/2013/12/12/the-eu-thailand-fta-what-fate-for-access-to-medicines (last accessed May 12, 2017).

72. *See* Pedro Roffe, *Intellectual Property Chapters in Free Trade Agreements: Their Significance and Systemic Implications*, *in* EU BILATERAL TRADE AGREEMENTS AND INTELLECTUAL PROPERTY: FOR BETTER OR WORSE? 24 (2014).

73. Timothy Bazzle, *Pharmacy of the Developing World: Reconciling Intellectual Property Rights in India with the Right to Health: TRIPS, India's Patent System and Essential Medicines*, 42 GEO. J. INT'L L. 785, 786 (2011).

explore through an examination of the legal framework surrounding international human rights obligations, and the nature of IP rights.

This Note seeks to outline the effects of data exclusivity through instruments, such as FTAs, on the accessibility, among other things, of medicines, which are integral to treating serious diseases — in this case, HIV/AIDS. It will also discuss the implications of these effects on the rights to life and health, and ultimately attempt to interweave this information into a coherent discussion on whether or not FTAs such as the EU-India FTA should include data exclusivity provisions, considering international human rights obligations and the unique position of India in the fulfillment of said obligations.

This Note will first run through the concept of "data exclusivity" — its nature as a component of IP and property rights in general, its effects, and its relative costs and benefits — before going into discussions on the rights to health and life. The discussion will then venture into the matter of the significance of the India-EU FTA and data exclusivity to the Philippines, both regarding the access to medicines in general and treatment of HIV/AIDS in particular. The Note will then conclude with a synthesis which will attempt to answer the questions initially posed in its earlier parts.

II. DATA EXCLUSIVITY

Data exclusivity is traditionally considered a part of IP law because it protects information gathered and owned by a certain entity, often related to the manufacture of a certain product.[74] IP law is, in turn, a species of the more general right to property. Before going into data exclusivity, an initial discussion on the right to property — and how to grapple with its role as part of human rights and as the source of IP law — is in order to set a better premise for this Note's latter parts.

74. *See* Erika Lietzan, *The Myths of Data Exclusivity*, 20 LEWIS & CLARK L. REV. 91, 104 (2016) (citing Pharmaceutical Research & Manufacturers of America (PhRMA), Special 301 Submission 2015, at 2-11, *available at* http://www.phrma.org/sites/default/files/pdf/PhRMA-2015-Special-301-Rev.pdf (last accessed May 12, 2017)).

A. The Right to Property: An Interplay of Intellectual Property and Human Rights Law

The right to property has been described as both controversial and complex.[75] It is multidimensional, considering the fact that it "is closely related to the realization of the right to life and of other human rights of the individual [but] [a]t the same time, [ ] its limitation may be necessary for the realization of other human rights of other individuals."[76] It has been said that "no other human right is subject to more qualifications and limitations and, consequently, no other right has resulted in more complex case-law [from the European Court of Human Rights (ECtHR)]"[77] than the right to property. An important principle to be gleaned from said jurisprudence is the concept that the right to property is "not absolute, since deprivation of property is possible if such action is not arbitrary[.]"[78]

Perhaps one of the most well-known iterations of the right to property is that found in Article 17 of the Universal Declaration of Human Rights (UDHR),[79] which states that "[e]veryone has the right to own property alone as well as in association with others. No one shall be arbitrarily deprived of his property."[80] Jurisprudence from both the ECtHR and the Inter-American Court of Human Rights (IACtHR) has also played a part in expressing and expounding on the right, particularly in terms of its

75. It states that although the right to property "is seen by some as central to the human rights concept," it is "considered by others to be an instrument for abuse, a right that protects the 'haves' against the 'have-nots.'" *See* Icelandic Human Rights Centre, The Right to Property, *available at* http://www.humanrights.is/en/human-rights-education-project/human-rights-concepts-ideas-and-fora/substantive-human-rights/the-right-to-property (last accessed May 12, 2017).

76. Cristophe Golay & Iona Cismas, Legal Opinion: The Right to Property From A Human Rights Perspective (A Legal Opinion Commissioned by the International Centre of Human Rights and Democratic Development) at 2, *available at* https://poseidon01.ssrn.com/delivery.php?ID=756021072024120100123087091007031069015032009051054004022004119025031120094098068078007052003023030014055089115105097091064115056022088032093122080121095074088000025053006012092086100015073082092105017074080095097108102093085018086018064095107127090064&EXT=pdf (last accessed May 12, 2017).

77. Icelandic Human Rights Centre, *supra* note 75.

78. Golay & Cismas, *supra* note 76, at 3.

79. Universal Declaration of Human Rights, G.A. Res. 217 (III) A, U.N. Doc. A/RES/217(III) (Dec. 10, 1948) [hereinafter UDHR].

80. *Id.* art. 17 (1).

regulation.[81] "Extensive case law has been established to protect individuals against abuse of property, while some limited legislation has been developed to counterbalance possible imbalances caused by the accumulation of property, and to provide additional protection for those dependent on the property of others."[82] Regulation of property is often related to its social function, and this has been expressed in domestic laws of different States. In India, the Constitution declares that no law which allows government to acquire or temporarily manage property in the public interest shall be considered void.[83] In the Philippines, its Constitution notes that

> [t]he Congress [should] give highest priority to the enactment of measures that protect and enhance the right of all the people to human dignity, reduce social, economic, and political inequalities, and remove cultural inequities by equitably diffusing wealth and political power for the common good ... [t]o this end, the State shall regulate the acquisition, ownership, use, and disposition of property[.][84]

Property covers both movable and immovable property, and is not limited to physical goods, but includes intangible objects having value.[85] IP represents some of these non-physical goods. It therefore follows that IP is likewise subject to the qualifications and restrictions which are applied to property in general, albeit with some nuances to accommodate its intangible nature. These restrictions, sometimes termed as "interferences,"[86] are commonly classified along the dividing line of whether they effect total deprivation of the property or merely control of its use.

Compulsory licensing, which allows one party to exploit a patented product or produce similar products without the permission of the patent owner for certain reasons provided by law, is an example of interference as applied to IP rights.[87] Compulsory licenses function by countering the

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81. Icelandic Human Rights Centre, *supra* note 75.

82. *Id.*

83. INDIA CONST. art. 31 (A).

84. PHIL. CONST. art. XIII, § 1.

85. Golay & Cismas, *supra* note at 76, at 12 & Ursula Kriebaum & Christoph Schreuer, *The Concept of Property in Human Rights Law and International Investment Law, in* HUMAN RIGHTS, DEMOCRACY, AND THE RULE OF LAW 745 (S. Breitenmoser ed., 2007).

86. Smith & Hopen, Intellectual Property Glossary — Interference, *available at* http://www.smithhopen.com/glossary_term/31/Interference (last accessed May 12, 2017).

87. *See* Laurence R. Helfer, *The New Innovation Frontier? Intellectual Property and the European Court of Human Right*, 49 HARV. INT'L L. J. 1, 13 & 27 (2008).

exclusivity that patent rights provide. By analogy, bio-equivalency tests can also be considered a form of interference with a property right, in the same way that it allows others to use someone else's property.

Interferences are not absolutely prohibited. They are allowed for as long as they "satisfy certain conditions cumulatively: the principle of legality, a general or public interest character[,] and a proportionality test."[88] To illustrate, in a case dealing with compulsory licenses, the European Commission "held that [such an] interference was justifiable and [ ] did not violate [the right to property.]"[89] Compulsory licenses, they ruled, "pursued the legitimate aim of 'encouraging technological and economic development.'"[90] Other justifiable reasons for interfering with the right to property, including IP, include the general interest of the community, public health, public welfare, community development, and national security.[91]

Bio-equivalency tests — the process by which data submitted by one company is used in order to decide the approval or disapproval of another company's product[92] — can also be considered as a form of interference. Like compulsory licenses, it cuts into one of the primary rights of property ownership — the right to deprive others of the enjoyment of the property. This is because bio-equivalency tests allow for others to use the property in question. However, it does not rise to the level of deprivation or expropriation, as the originators of the data still retain full positive use of the information, and it is not taken away from them despite them submitting it to government agencies.[93]

In India, bio-equivalency is provided for in the Drugs and Cosmetics Act (DCA), 1940 and its corresponding implementing rules.[94] Bio-

88. Golay & Cismas, *supra* note 76, at 15.

89. Helfer, *supra* note 87, at 33.

90. *Id.*

91. *See* LAURENT SERMET, THE EUROPEAN CONVENTION ON HUMAN RIGHTS AND PROPERTY RIGHTS 33 (1992).

92. *See* Association of Southeast Asian Nations, ASEAN Guidelines for the Conduct of Bioavailability and Bioequivalence Studies, at 6, *available at* http://www.fda.gov.ph/attachments/article/95567/1%20ASEAN%20Guidelines%20for%20the%20Conduct%20of%20Bioavailability%20and%20Bioequivalence%20Studies.pdf (last accessed May 12, 2017).

93. *Id.* This states that a bioequivalence study is "basically a comparative bioavailability study designed to establish equivalence between test and reference products." *Id.*

94. *See* Animesh Sharma, *Data Exclusivity with regard to Clinical Data*, 3 INDIAN J. L. TECH. 82, 96-97 (2007).

equivalency is legislated into both law and its implementing rules and regulations, and therefore, follows the requirement of interferences being provided for by law. It also serves a public purpose, at least impliedly, as generics companies which avail of these bio-equivalency tests are able to produce medicine which is more affordable to the population. Still, even given the legitimacy of bio-equivalency tests, its presence is undeniably what has spurned the push for an effective countermeasure such as data exclusivity.

B. Data Exclusivity: Background and Definition

In the pharmaceutical industry, there are those from whom test data originates, sometimes called pioneer companies,[95] and those who rely on data produced by these companies, called generics companies.[96] In relation to these two sets of parties, data exclusivity "refers to a practice whereby, for a fixed period of time, drug regulatory authorities do not allow the [test data] of an originator to be used to register a therapeutically equivalent generic version of that medicine [to which the test data relates]."[97] This test data can include information "relating to a drug's quality, safety, clinical efficacy, and physical and chemical characteristics[.]"[98] Data exclusivity has also been defined as that which "prevent[s] a pharmaceutical applicant from obtaining a marketing [authorization] for its drug through a facilitated procedure entailing reliance on pre[-]clinical and clinical data generated by a previous applicant to support a successful application for its own drug[.]"[99]

Developing a drug is a long process that involves intensive research and experimentation. In designing treatment for a certain illness, it is often "necessary for the originator [company] to conduct extensive testing on animals and humans in pre-clinical and clinical trials as well as toxicology, manufacturing feasibility[,] and other scientific studies."[100] As research on the

95. In this study, these companies are referred to as originator companies or simply, the originator.

96. Sharma, *supra* note 94, at 83.

97. Médecins Sans Frontières, Data exclusivity in international trade agreements: What consequences for access to medicines? (A Technical Brief) at 1, *available at* http://www.citizen.org/documents/DataExclusivityMay04.pdf (last accessed May 12, 2017) [hereinafter MSF Technical Brief].

98. Rosario G. Cartagena & Amir Attaran, *A Study of Pharmaceutical Data Exclusivity Laws in Latin America: Is Access to Affordable Medicine Threatened?*, 17 HEALTH L.J. 271, 274 (2009).

99. Sharma, *supra* note 94, at 83.

100. Jacques Gorlin, Encouragement of New Clinical Drug Development: The Role of Data Exclusivity (A Work Commissioned by the International Federation of

drug progresses, the information relevant to its efficacy, composition, and other components grows. Often called a "dossier," this compilation of relevant information becomes more valuable over time, and represents a considerable amount of resources poured into obtaining its contents.[101] The dossier is closely guarded and kept confidential for the most part.[102] However, for a drug to enter into the commercial market, pharmaceutical companies need to gain the approval of the drug regulation authority of the territory within which they wish to distribute the drug.[103] Approval procedures often entail the submission of the information contained in the dossier, for purposes of "ensur[ing] that only medicines of assured safety, quality[,] and efficacy are available on the national market."[104] For drugs which are the first of their kind, there is no other way to answer questions of safety and efficacy but to surrender such information. Such is the case for originators.

Generics companies, however, may avail of a different route. Requirements by drug regulatory authorities are "designed to ensure the safety, quality, and efficacy of products being developed for use by humans[.]"[105] At the onset, the regulating authorities merely want to know how suitable a drug is for its purported market, and many have fashioned an alternative way of finding out. Bio-equivalency tests — a procedure by which the chemical or biological aspects of a drug for which approval is sought is compared to the data submitted for an already approved drug[106] — are "much smaller in scale than full-fledged clinical and pre-clinical trials"[107] and are therefore less costly. Generics companies, which, by definition, produce medicines that are similar to already available drugs, usually turn to bio-equivalency tests to get their version of the medicine approved, bypassing the resource intensive testing undertaken by originators. This is because "few [generics] companies have the capacity to repeat all the

Pharmaceutical Manufacturers Associations) at 2, *available at* http://www.who.int/intellectualproperty/topics/ip/en/DataExclusivity_2000.pdf (last accessed May 12, 2017).

101. Cartagena & Attaran, *supra* note 98, at 271.

102. *Id.*

103. WHO Briefing Note, *supra* note 66, at 1.

104. *Id.*

105. Charles Clift, *Data Protection and Data Exclusivity in Pharmaceuticals and Agrochemicals*, *in* INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES 431 (2007).

106. WHO Briefing Note, *supra* note 66, at 1.

107. *Id.*

necessary tests and clinical trials"[108] needed to obtain information found in an originator's dossier.[109] It is at this point that the presence or absence of data exclusivity becomes relevant. Because data exclusivity prohibits reliance on data submitted by an originator for purposes of approving a similar drug,[110] the option to avail of bio-equivalency tests may be foreclosed, at least for a certain period.

Some things to note regarding how data exclusivity works: first, data exclusivity is a time-based mechanism, the crucial part of any data exclusivity rule being the period during which the originator's data cannot be relied on or disclosed.[111] Second, if a data exclusivity rule is in place, information submitted is automatically granted protection, and need not be applied for.[112] In addition, this automatic protection is an obligation of the government, and it is the government agencies which have "the responsibility [of] preventing copiers [from] taking advantage of proprietary data during the period of data exclusivity."[113] Third, "data exclusivity rules are never an absolute barrier to the entry of generic medicines to a market,"[114] since generics companies are "free" to produce the test data themselves.[115] Finally, and in relation to the immediately preceding point, data exclusivity is an anti-competitive measure, as "the cost of replicating the investment in trials to satisfy regulatory requirements would be sufficiently prohibitive to deter a potential competitor."[116]

Data exclusivity also differs from patents, though they can work together to protect essentially the same interests. It is noted that "data exclusivity qualifies as an independent [IP] right[,]"[117] and that "[p]atents and data exclusivities are awarded independently."[118] One can work even when the other is not present. Data exclusivity, on the one hand, prohibits relying on data submitted relevant to a certain product, but does not prohibit the manufacture of a similar product. Patents, on the other hand, impose such a

108. Cartagena & Attaran, *supra* note 98, at 274.

109. *Id.*

110. *See* Gorlin, *supra* note 100, at 5.

111. *Id.* at 2-3.

112. Cartagena & Attaran, *supra* note 98, at 274.

113. Gorlin, *supra* note 100, at 6.

114. Cartagena & Attaran, *supra* note 98, at 270.

115. *Id.*

116. Clift, *supra* note 105, at 431.

117. Sharma, *supra* note 94, at 84.

118. *Id.*

prohibition.[119] A patent right is "the right to exclude others from making, using, selling, offering for sale, or importing the patented product."[120] Aside from differing in protected subject matter, patents and data exclusivity also differ as to efficacy. "[U]nlike a patent, data exclusivity is automatic (rather like copyright). No fees are incurred for application or maintenance of the right [to data exclusivity], and there is a more limited scope than exists in patent law for legal challenges, which are expensive to mount and to defend."[121]

The two also differ as to enforcement. While it is up to "the originator to pursue [ ] patent rights[,]"[122] on the one hand, if there is a perceived violation, it is, on the other hand, the government who has the burden of implementing the data exclusivity period, as it is the one responsible for using or not using the data.[123]

Finally, some are of the opinion that data exclusivity is a stronger form of protection.[124] Although patents often operate for longer periods of time, "unlike patent[s], there are no exceptions or flexibilities that allow governments to tailor the law to national circumstances [in the case of data exclusivity]."[125]

C. Data Exclusivity and the TRIPS Agreement: An Absence of Convergence

Although data exclusivity existed before the TRIPS Agreement, the latter played a role in pushing the concept of data exclusivity to the forefront of the debate on access to medicines. However, it is not even clear that the TRIPS Agreement contains data exclusivity at all. During the negotiations for the TRIPS Agreement, developed countries advocated strongly for data exclusivity to be included in the text of the agreement.[126] The outcome was Article 39 (3) of the TRIPS Agreement, which states —

> Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data

119. At least, in the case of product patents (as opposed to process patents).

120. Gorlin, *supra* note 100, at 3.

121. Clift, *supra* note 105, at 433.

122. Gorlin, *supra* note 100, at 7.

123. *Id.*

124. Clift, *supra* note 105, at 433.

125. *Id.*

126. MSF Technical Brief, *supra* note 97, at 3.

> 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.[127]

Countries such as the U.S., Switzerland, and the Member States of the EU seem to agree that the above Article obligates Member States to impose a form of data exclusivity.[128] They interpret "unfair commercial use" as including "reliance, by regulatory authorities or third parties, on the [originator's] data for the marketing of subsequent versions of [a] drug during the period of exclusivity without the originator's consent[,]"[129] — exactly the behavior data exclusivity proscribes. This interpretation, however, is not shared by all. Some contend that a closer look at Article 39 (3) shows that the TRIPS Agreement falls short of imposing data exclusivity. They note that the text merely states that "WTO Members should protect 'undisclosed test or other data' against 'unfair commercial use' and 'disclosure[,]'"[130] and that "[n]owhere does [the TRIPS Agreement] state that countries should provide exclusive rights to the originator of the data for a given period."[131]

What seems safer to assert is that the TRIPS Agreement imposes data protection, and not data exclusivity. It is clear that the TRIPS Agreement promotes data protection, which compels governments to protect test data from unfair commercial use, while not completely foreclosing the possibility of a justified disclosure or referral.[132] That the obligation extends to granting a period of exclusivity to the data is, as some feel, already stretching the meaning of the text.[133] Article 39 (3)'s "main purpose is not to prevent the use of [test data] by governments, but to prevent unfair use by competitors."[134]

It is also noted that nothing in the text of Article 39 (3) states that a period of exclusivity is the only way data can be protected.[135] Commentaries also clarify that while data protection is meant to guard against unwarranted disclosure of trade secrets in the name of unfair competition, something for

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127. TRIPS Agreement, *supra* note 35, art. 39 (3).

128. Gorlin, *supra* note 100, at 4-5.

129. *Id.* at 5.

130. MSF Technical Brief, *supra* note 97, at 3.

131. *Id.*

132. *See* Clift, *supra* note 105, at 432.

133. *Id.* at 432-33.

134. Sharma, *supra* note 94, at 91.

135. *Id.*

which no time limit is specified (because indeed it is a perpetual obligation), data exclusivity is not so much for protection as it is a commercial tool used to stall the entrance of generics into the market, which is why it is necessarily tied to a time period.[136]

Some arguments advanced for why the TRIPS Agreement, in particular, Article 39 (3), espouses data protection and not data exclusivity center around the interpretation of "unfair commercial use." Proponents of the data exclusivity interpretation would insist that unfair commercial use would include using the originator's data for the benefit of a competing product. This argument is answered by the claim that in the procedure where bio-equivalency is utilized, the generics company does not actually "use" the test data.[137] In fact, the test data is never disclosed to them and they do not have access to it, as everything is submitted directly to the government agency responsible for approving drugs.[138] The data is not used to make a similar product, either by the government or by the generics company.[139] Furthermore, the only "use" taking place is in the hands of the government agency, and "this is not commercial use, since the regulatory agency is not a commercial organization."[140] Experts have also noted that "the term 'unfair commercial use' refers to, and prohibits, practices, such as industrial espionage, but was not meant to provide exclusive rights."[141] In addition, even the United Nations (U.N.) Conference on Trade and Development does not interpret Article 39 (3) as preventing use of previously submitted data "to assess subsequent applications by third parties for the registration of similar products."[142]

Perhaps the strongest argument for why the TRIPS Agreement should be considered as obligating data protection but not exclusivity is the fact that a time period — the defining element of data exclusivity provisions — were

136. Clift, *supra* note 105, at 433.

137. *See* WHO Briefing Note, *supra* note 66, at 2.

138. *Id.*

139. *Id.*

140. *Id.*

141. *Id.* (citing Carlos M. Correa, Implications of the Doha Declaration on the TRIPS Agreement and Public Health (A Publication of the World Health Organization) *available at* http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf (last accessed May 12, 2017)).

142. Sharma, *supra* note 94, at 91-92.

in drafts of the TRIPS Agreement but failed to make it into the final text itself.[143] In particular, the Brussels Draft stated —

> Parties, when requiring, as a condition of approving the marketing of new pharmaceutical products or of a new agricultural chemical product, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. Unless the person submitting the information agrees, the *data may not be relied upon for the approval of competing products for a reasonable time, generally no less than five years,* commensurate with the efforts involved in the origination of the data, their nature, and the expenditure involved in their preparation. In addition, parties shall protect such data against disclosure, except where necessary to protect the public.[144]

In contrast, the text of Article 39 (3) of the TRIPS Agreement makes no mention of a period of five years, or any period whatsoever.[145] Some observers note that had data exclusivity truly been intended, it would have been easy to include it explicitly, such as what is contained in the Brussels Draft, or even the North American Free Trade Agreement (NAFTA),[146] which had been existent prior to the TRIPS Agreement.[147] In particular, NAFTA's Article 1711 (6) reads —

> Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them.[148]

Note that, in the NAFTA, the above paragraph is preceded by one which mimics Article 39 (3) of the TRIPS Agreement.[149] Experts then point out that had data exclusivity truly been the intention, as was in the case of

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143. Cartagena & Attaran, *supra* note 98, at 275.

144. *Id.* at 276 (emphasis supplied).

145. *See* TRIPS Agreement, *supra* note 35, art. 39 (3).

146. North American Free Trade Agreement, *entered into force* Jan. 1, 1991, 32 ILM 289 [hereinafter NAFTA].

147. Clift, *supra* note 105, at 434.

148. NAFTA, *supra* note 146, art. 1711 (6).

149. *Id.* art. 1711 (5).

the NAFTA, "drafters of [the] TRIPS [Agreement] certainly had the opportunity to impose more specific requirements of data exclusivity, but [they] chose not to do so."[150] The conclusion many draw, then, is that "it is entirely consistent with the language of [Article 39 (3)] to simply require that data submitted for drug approval be kept confidential by the government authority while allowing the authority to rely on this data to approve subsequent generic applications[,]" and thus not imposing any exclusivity period.[151]

D. The Logic and Incentive of Data Exclusivity: What For, and Why

Even with data exclusivity's weak grounding in the TRIPS Agreement, many WTO Member States still push for this kind of interpretation, or in the alternative, for supplementary agreements in order to be able to apply it.[152] The motivation can be explained largely by the commercial nature of data exclusivity. As it effectively prevents competition from entering the market, it allows originator companies to recover costs and turn a profit from their pharmaceutical products.

A new drug can cost anywhere from U.S. $500 million to U.S. $800 million, and can take as long as 15 years to study, test, and release to the market.[153] The costs go mostly to the generation of data needed to be able to register the drug and show that it meets a government's requirements of safety, quality, and efficacy,[154] with about 60% of whatever is spent "incurred in the conduct of trials."[155]

Many pharmaceutical companies say that they need the opportunity provided by an exclusivity period to "recoup the enormous costs involved in generating [the required data.]"[156] Furthermore, companies argue that the opportunity is not just a need but an incentive as well, to continue producing the drug and researching better ones.[157] The result of a lack of data exclusivity, as claimed by many in the pharmaceutical industry, is "free-

150. Sharma, *supra* note 94, at 91.

151. *Id.*

152. *See* World Trade Organization, The Policy Context for Action on Innovation and Access, *available at* https://www.wto.org/english/tratop_e/trips_e/trilatweb_e/ch2b_trilat_web_13_e.htm (last accessed May. 12, 2017).

153. Gorlin, *supra* note 100, at 6 & Clift, *supra* note 105, at 431.

154. Gorlin, *supra* note 100, at 6.

155. Clift, *supra* note 105, at 431.

156. Gorlin, *supra* note 100, at 6.

157. *Id.* at 7.

riding" by the generics companies on data produced by the originators.[158] Because these generics companies did not incur the cost of investing in the drug's research and production, they are able to price their version of the medicine lower.[159] Some also observe that without data exclusivity, originators would not produce the original data at all, saying that "[i]f these data were immediately available to third parties, there would be no incentive for a company to generate [the] data in the first instance, unless the investment in terms of both time and costs were protected by [other] means."[160]

This talk of cost recovery and production incentive, however, when applied to India, fails to take into account other factors that go into the decision of manufacturing in that specific country and subjecting one's self to its laws — laws that allow bio-equivalency tests and do not provide data exclusivity periods. It has been noted, for example, that

> [t]he costs of setting up a [U.S. Food and Drug Association (FDA)] approved plant in India is up to 50% lower than in developed countries. As a result, outside the [U.S.,] India currently has the highest number of [U.S.] FDA approved plants. Further, production costs in India are on average 40% to 70% lower because of local equipment sourcing, tax incentives[,] and a focus on process innovation.[161]

Also, the cost of labor in India is "60-70% lower than in developed countries due to the availability of a large pool of highly qualified personnel with strong chemistry skills."[162] While originator companies may feel they are at a disadvantage to be functioning in a country without data exclusivity periods, it cannot be denied that there are other incentives which urge them to start and continue business in places such as India, despite that disadvantage.

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158. *See* Sharma, *supra* note 94, at 85.

159. *Id.*

160. Gorlin, *supra* note 100, at 2. Note, however, that regardless of data exclusivity measures, the requirement of submitting test data to a government regulatory board in order for a certain drug to be approved still stands independently of whether such data will be allowed for reference subsequently, at least in the case of India.

161. Mukul Gulati & Karthik Bhat, The Upcoming Patent Cliff: Implications for Indian Pharmaceuticals (A Report on the Indian Pharmaceutical Industry), *available at* https://www.vccircle.com/upcoming-patent-cliff-implications-indian-pharma (last accessed May 12, 2017).

162. *Id.*

Another angle proponents point out is data exclusivity's ability to stimulate innovation. The absence of exclusivity periods, it is argued, would "[reduce] incentive ... to engage in the important [research and development] activities that will ultimately benefit patients through the availability of new and innovative drug therapies."[163] Pharmaceutical companies are commercial entities, and it is claimed that they are not likely to engage in activities which do not earn profit.[164] Without the incentive of profit to be had from a period of exclusivity, "big pharmaceutical companies would not invest in research and would not produce innovations."[165]

As regards India, some speculate that "[d]rugs catering to the needs in India will only be developed if data exclusivity laws exist in India. It is only when sufficient protection is accorded to drug manufacturers that they will come to India and spend their resources and time on developing drugs for diseases endemic to India."[166] Essentially, it is claimed that medicines more endemic to developing countries will only be researched and developed if the manufacturers know that their data would be protected in such developing countries.

The link, however, between data exclusivity, or IP protection in general, and innovation, is not as clear cut as it is often made out to be. Some are of the view that IP protection measures such as data exclusivity — which create monopolies of sorts by stunting competition — stifle innovation as well. For one thing, the granting of data exclusivity has nothing to do with how innovative a product is, unlike in the case of patents.[167] Data exclusivity is granted automatically, and there is no threshold of inventiveness that need to be met in order for the protection to take effect.[168] Because of the absence of this standard, some note that "data

163. Gorlin, *supra* note 100, at 2.

164. *See* Stela Bivol & Viorel Soltan, Express Analysis: Negative Impact of Data Exclusivity on Access to Medicines (A Publication Constituting Part of the Health Monitor Project Implemented by the Center for Health Policies and Studies in Chisinau, Moldova) at 3, *available at* http://aids.md/aids/files/1273/express_analysis_1_2012_en.pdf (last accessed May 12, 2017).

165. *Id.*

166. Sharma, *supra* note 94, at 98.

167. European Generic Medicines Association, Data Exclusivity: A Major Obstacle to Innovation and Competition in the EU Pharmaceutical Sector (A Position Paper of the EGA, which Represents over 400 Companies in Europe) at 5, *available at* http://198.170.119.137/pol-ipdataex.htm (last accessed June 24, 2013) [hereinafter EGA Position Paper].

168. *Id.* at 6.

exclusivity provisions [could] undermine genuine innovation ... since it would encourage originator companies to focus their activities on product changes, rather than focus on developing new innovative and beneficial products."[169] In relation to this absence of patent-like standards, the European Generic Medicines Association notes that "[i]f product variations or new uses cannot gain patent protection because they cannot demonstrate novelty and [an] inventive step, it is simply wrong that they should be able to obtain market protection through the backdoor by gaining data exclusivity."[170] While patents are not the same as data exclusivity measures, the resulting effect may be comparable considering that they aim at the shared goal of preventing the entry of similar products. The effects of data exclusivity may even be more serious when considering that, at the very least, patents have some initial standard of innovation that must be met. Data exclusivity works on the principle of using secrecy to avoid competition, which do not always lead to the most conducive environment for actual innovation.

In sum, there are various reasons why originator pharmaceutical companies lobby hard for data exclusivity: considerations of recovering costs, turning a profit, and stimulating innovation all populate the discourse. It seems largely driven, however, by how an originator's products will do in the market, more than whether it will spark innovation. After all, "controlling access to the data is nearly tantamount to controlling access to the market, and that is why originator companies care about [data exclusivity] so deeply."[171]

E. On the Receiving End: What Data Exclusivity Means for Patients and other Stakeholders

But what about its effect on the other side of the spectrum, that is, the consumer side? What about data exclusivity's effect on access to medicine? As previously stated, data exclusivity does not have the effect of banning production of a certain generic drug;[172] that is the province of a patent. What data exclusivity does is to create a barrier to entry into the market, not through prohibiting production of the generic drug, but by setting an obstacle to its approval by government agencies. Data exclusivity is "designed to delay the introduction of generic competition[.]"[173]

169. *Id.* at 3.

170. *Id.* at 6.

171. Cartagena & Attaran, *supra* note 98, at 270.

172. *Id.* at 274.

173. MSF Technical Brief, *supra* note 97, at 4.

For as long as there is an exclusivity period in play for the data submitted by an originator, "generic producers would have to submit their own data to prove safety and efficacy, which would oblige them to repeat the clinical trials and other tests. This is something that would cause significant delay, and that many generic manufacturers cannot afford [to do]."[174] It is more realistic to think that generics manufacturers would instead opt to wait out the period, "[diminishing] the likelihood of speedy marketing of generics, and [delaying] competition and price reductions [for brand-name drugs]."[175]

Many accuse companies of utilizing data exclusivity to maintain "artificially high prices, thereby restricting access to medicines."[176] Considering the fact that data exclusivity makes it very unlikely for cheaper alternatives to enter the market, thus facilitating a monopoly of sorts for the brand-name drug, "[data] exclusivity [also precludes] possible reductions in the cost of medicines ... keeping healthcare costs higher."[177] While this can happen in both developed and developing countries, the burden it creates for the populations of the latter is distinctive, as "significant differences [exist] in the capacity of the [governments of developed and developing countries] to respond to [that] burden."[178] For example, "[m]any EU member countries employ price control strategies and generic prescription to ensure access to [medicines by] their populations."[179] While developing countries can employ these methods as well, the extent to which they can shoulder costs, when balanced with other basic priorities such as food and education, set against a backdrop of an expanding population, is questionable.[180]

Because data exclusivity is being pushed by industrialized countries onto other countries, studies have been undertaken to see by just how much access to medicines will be affected. Studies involving patents were also scrutinized, because patents and data exclusivity have a similar effect of impeding the entry of generic medicine into the market, whether it is by affecting their production or approval.

For the period of 2000-2007, the EU undertook a series of studies on patent abuse, whereby they studied the practices which lead to over-

174. WHO Briefing Note, *supra* note 66, at 1.

175. *Id.*

176. MSF Technical Brief, *supra* note 97, at 1. *See also* Bivol & Soltan, *supra* note 164, at 4.

177. Clift, *supra* note 105, at 434.

178. Bivol & Soltan, *supra* note 164, at 4.

179. *Id.*

180. *Id.*

extension of patents granted to certain drugs.[181] Due to the abusive practices, generic medicines were delayed by up to seven months, "costing Europe three billion euros."[182] When Colombia was considering entering into an FTA with the EU, it undertook a study to assess the impact of combined efforts of patents and data exclusivity to the generic industry and access to generics. What they found was that market monopoly would reach approximately 63% for brand-name drugs, and that "the national generic industry could lose up to 57% of the value of its current market share."[183] These effects were also predicted to translate into a 40% "increase in the price index for medicines and by 2020, a [U.S. $]919 million increase in spending on medicines, which is equivalent to health-care expenditures for 5.2 million people enrolled as contributors in [Colombia's] social security system that year."[184] Furthermore, that 40% increase in spending was also related to the alternative of "40% reduction in consumption with consequences for access to medicine, particularly for low income people and families that cannot afford the higher costs."[185]

For Peru, a study estimated that "a 10-year test data exclusivity period would lead to an increase of more than [$]300 million [ ] in medicines expenditure in 2025."[186]

Moldova, a State with a population of about 3.5 million people[187] would see treatment for about 2,000 people denied for about 10 years considering the implementation of data exclusivity.[188]

Ukraine, which has a data exclusivity period of six years in place, has seen the discontinuation of three generic ARV drugs since 2010.[189] The price of the brand-name drug has since increased.[190]

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181. *Id.*

182. *Id.*

183. *Id.* at 5.

184. Bivol & Soltan, *supra* note 164, at 5.

185. *Id.*

186. *Id.* (citing IFARMA HAI Europe, Impact of the EU-Andean Trade Agreements on Access to Medicines in Peru, *available at* http://haieurope.org/wp-content/uploads/2010/12/11-Nov-2009-Report-IFARMA-Impact-Study-on-EU-Andean-Trade-Agreement-in-Peru-EN.pdf (last accessed May 12, 2017)).

187. The World Bank, Population (Total), *available at* http://data.worldbank.org/indicator/SP.POP.TOTL (last accessed May 12, 2017).

188. Bivol & Soltan, *supra* note 164, at 5.

189. *Id.*

In Jordan, where a FTA between it and the U.S. introduced data exclusivity, it was shown that prices for medicines had increased during the period of 2002-2006, leading to "additional expenditures for medicines estimated at between U.S. $6.3 million and U.S. $22.04 million."[191] In a similar fashion, the U.S.-Costa Rica FTA is projected to increase prices for pharmaceutical products utilizing active ingredients by up to 40% by 2030, "requiring increased public spending in the range of U.S. $2 million to U.S. $3.357 million,"[192] due to a combination of patentability criteria and test data exclusivity.[193]

"That data exclusivity can prevent generic drug manufacturers [from] entering the market is obvious and beyond question; indeed[,] that is [its] *raison d'être*."[194] Aside from understanding how data exclusivity works to prevent bio-equivalency tests, however, it is also important to understand how it works in relation to a country's patent situation and compulsory licensing capability, to fully understand how data exclusivity affects the entrance by generics into the market. For example, some observers note that "[t]he biggest impact of data exclusivity is on medicines that are not patented in some countries,"[195] as would be the case in India due to its high standards for granting patents. Data exclusivity hinders approval of generic medicine even if the originator's drug is not patented, as data exclusivity does not depend on the patent status of the product.[196] Thus, even without patents on their products, "multinational pharmaceutical companies are assured a minimum period of monopoly."[197] Again, this is true, even if the product itself does not meet standards of innovation or inventiveness for a new or extended patent.

The neutralization of the compulsory licenses has also become an issue in the data exclusivity debate. The WTO defines compulsory licensing as "when a government allows someone else to produce the patented product

190. *Id.*

191. World Health Organization, World Intellectual Property Organization, & World Trade Organization, Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade, *available at* https://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf (last accessed May 12, 2017).

192. *Id.*

193. *Id.*

194. Cartagena & Attaran, *supra* note 98, at 292.

195. MSF Technical Brief, *supra* note 97, at 2.

196. WHO Briefing Note, *supra* note 66, at 2.

197. MSF Technical Brief, *supra* note 97, at 2.

or process without the consent of the patent owner."[198] The compulsory license is meant to address the roadblock produced by a patent, but not by an exclusivity period.[199]

"[I]f a generic[s] manufacturer is granted a compulsory license to overcome [a] patent, it will not be able to make effective use of the license if it has to wait for the expiry of data exclusivity before it can get its generic version [of a drug] approved ... and put on the market."[200] Compulsory licenses are issued to overcome patents for compelling reasons which Member States under the TRIPS [Agreement] are free to determine, as declared during the WTO's Fourth Ministerial Conference in Doha, Qatar, in 2001.[201] However, no such conditions exist for data exclusivity, mostly because compulsory licenses were developed around patents. Those who disfavor data exclusivity even argue that it "is a much stronger right than a patent, because it has no exceptions; even in times of national emergency[,] it does not allow the governments to curtail [IP] rights."[202]

Data exclusivity also raises ethical issues. When a generics company is denied access to bio-equivalency tests, they have two choices. The first is to wait out the period of exclusivity in order that they may avail of the bio-equivalency test at some later point in time. The second is to produce data on their own, which means conducting, among other things, testing on human subjects, the same as what was presumably already done by the originator. Aside from the cost this would entail, it also poses an ethical dilemma. The World Health Organization (WHO), for example, considers it unethical to conduct trials on actual sick persons when the compounds to be tested are already proven to be effective,[203] especially when such testing would be for commercial purposes only.[204] Another aspect of the ethics issue is the fact that testing for the efficacy of drugs will involve "control groups"

198. World Trade Organization, TRIPS and Health: Frequently Asked Questions — Compulsory Licensing of Pharmaceuticals and TRIPS, *available at* https://www.wto.org/ENGLISH/tratop_e/trips_e/public_health_faq_e.htm (last accessed May 12, 2017).

199. *See* Cartagena & Attaran, *supra* note 98, at 274.

200. MSF Technical Brief, *supra* note 97, at 2.

201. World Trade Organization, TRIPS: TRIPS and Public Health — The separate Doha Declaration explained, *available at* http://www.wto.org/english/tratop_e/trips_e/healthdeclexpln_e.htm (last accessed May 12, 2017).

202. Cartagena & Attaran, *supra* note 98, at 274 (citing Clift, *supra* note 105, at 431).

203. WHO Briefing Note, *supra* note 66, at 1. *See also* Bivol & Soltan, *supra* note 164, at 4.

204. WHO Briefing Note, *supra* note 66, at 1.

or groups who are not treated with the drug.[205] While this may be acceptable in cases of pioneer drugs, its acceptability is cast into doubt for repetitive tests which would be conducted by generics companies, considering that they will be treating a group of ill people despite an already proven therapy.[206]

It was noted that the "use of equivalency trials [was] a potential alternative to the use of placebo controls, as these allow researchers to examine whether the altered regimen is approximately as effective compared to the standard regimen."[207] In fact, as early as 1997, bio-equivalency tests have been used as a way to answer this ethical issue with regard to human experimentation.[208]

One of the universal requirements for ethical research involving human testing is value. "It is never appropriate to involve human subjects in frivolous research."[209] Bio-equivalency effectively addresses this concern by eliminating the need for repetitive experimentation on human subjects. At the same time, it allows the fulfillment of another requirement, that of relevance to the local situation.[210] Bio-equivalency allows for research and study to go into treatments that would actually be accessible and affordable to the country wherein the study is conducted, a requirement that curiously, may not be fulfilled by many pioneer companies. Many of the ethical issues that arise in testing medicine are effectively addressed by bio-equivalency.[211] However, data exclusivity pushes bio-equivalency tests out of the picture for extended periods of time, which consequently brings back the ethical dilemmas.

There are numerous things to consider when studying data exclusivity in light of a possible FTA. Currently, India is not bound to any data exclusivity rules, either through TRIPS Agreement or by any of its domestic laws. Bio-equivalency tests are explicitly allowed under the DCA and its corresponding implementing rules.[212] Under the DCA, originator drugs are required to

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205. Clift, *supra* note 105, at 432.

206. *Id.*

207. *Id.*

208. *Id.*

209. *Id.* at 166.

210. CAROL HOLTZ, GLOBAL HEALTH CARE: ISSUES AND POLICIES 168 (2008).

211. *See* Ranjit Prasad Swain & Shilpa P. Satyajit Panda, *Ethical Guidelines and Study Design for Bioavailability and Bioequivalence Study*, 8 ASIAN J. OF PHARM. & CLIN. RES. 28 (2015).

212. Sharma, *supra* note 94, at 96.

submit data on safety and efficacy, as well as the results of a certain level of clinical trials, depending on the type of drug to be approved.[213] Generics companies, however, "are only required to prove that the generic version is bio[-]equivalent to [an already approved drug]."[214] This provides for a market environment where generic medicines proliferate. Data exclusivity, however, can change this substantially, and its primary effects will be felt by people in terms of their enjoyment of two basic rights — that to health and to life.

III. THE RIGHT TO HEALTH

The right to health is recognized as a "fundamental part of human rights"[215] as well as an integral element of a life of dignity.[216] It is well established in various documents in international human rights law,[217] and is often expounded on as the right "to the highest attainable standard of physical and mental health."[218] This highlights the fact that the right to life actually "refers to the right to the enjoyment of a variety of goods, facilities, services[,] and conditions necessary for [the right to health's] realization."[219]

A. A Landscape of Recognition: The Right to Health in Local and International Documents

213. *Id.*

214. *Id.* at 96-97.

215. Michael Lindsay, Right to Health, Right to Life: Why We Need to Act Now on HIV and Human Rights (A Discussion Paper Developed for the High Level Meeting on HIV and Human Rights in the European Union and Neighboring Countries) at 12, *available at* http://ec.europa.eu/health/sti_prevention/docs/ev_20130527_discussion_paper_en.pdf (last accessed May 12, 2017) & United Nations Office of the High Commissioner for Human Rights, The Right to Health (Fact Sheet No. 31 dated June 2008) at 1, *available at* http://www.refworld.org/docid/48625a742.html (last accessed May 12, 2017) [hereinafter OHCHR Fact Sheet No. 31].

216. *Id.*

217. *Id.* at 9. *See also* Jonathan J. Edwin, Access to Medicines as a Right to Health, and the conflict between Innovators and Generics: with a focus on India as the 'pharmacy of the developing world' (Nov. 28, 2012) (A MPH dissertation, University of British Columbia), *available at* https://circle.ubc.ca/bitstream/handle/2429/45113/Edwin_Jonathan_SPPH581A_Access_to_medicines.pdf?sequence=1 (last accessed May 12, 2017).

218. OHCHR Fact Sheet No. 31, *supra* note 215, at 9.

219. *Id.* at 5.

Though not responsible for making it a binding obligation on States, "[t]he WHO Constitution was the first international legal document to mention the right to health."[220] Its preamble states that "[t]he enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic, or social condition."[221] It further defined health as "a state of complete physical, mental[,] and social well-being and not merely the absence of disease or infirmity."[222] The World Health Assembly, a sub-organ of the WHO, has subsequently issued "numerous resolutions mentioning and reaffirming the right to health,"[223] which, like the WHO Constitution, were instrumental in molding the concept of the right to health, although not legally binding.[224]

The UDHR also mentions the right of everyone to health and access to medical needs. Specifically, it states that "[e]veryone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing[,] medical care[,] and necessary social services."[225] The right to health is also mentioned in various human rights treaties aimed at particularly vulnerable groups, such as the Convention on the Rights of the Child,[226] the Convention on the Elimination of All Forms of Discrimination against Women,[227] and the International Convention on the Elimination of All Forms of Racial Discrimination.[228] "Every State has ratified at least one international human rights treaty recognizing the right to health."[229] This includes members of the EU States, all of them further recognizing that the right to health, as well as other rights such as the right

220. HOLGER HESTERMEYER, HUMAN RIGHTS AND THE WTO 113 (2007).

221. Constitution of the World Health Organization pmbl., Apr. 7, 1948, 14 U.N.T.S. 185 [hereinafter WHO Constitution].

222. *Id.*

223. HESTERMEYER, *supra* note 220, at 114.

224. *Id.*

225. UDHR, *supra* note 79, art. 25 (1).

226. Convention on the Rights of the Child, G.A. Res. 44/25, art. 24, U.N. Doc. A/44/49 (Sep. 2, 1990).

227. Convention on the Elimination of All Forms of Discrimination against Women, G.A. Res. 34/180, art. 12, U.N. Doc. A/RES/34/180 (Dec. 18, 1979).

228. International Convention on the Elimination of All Forms of Racial Discrimination, G.A. Res. 69/161, art. 5 (e) (iv), U.N. Doc. A/RES/69/161 (Dec. 18, 2014).

229. OHCHR Fact Sheet No. 31, *supra* note 215, at 1.

against non-discrimination, are "critical to an effective HIV response[.]"[230] Domestically, "the right to health ... is recognized in at least 115 constitutions."[231]

As for India, its 1950 Constitution notes that "[t]he State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties[.]"[232] Legal scholars Anand Grover and Brian Citro have also opined that "[t]he right to health is a fundamental right in India, judicially recogni[z]ed under [A]rticle 21 of [its] Constitution."[233] Article 21, in turn, contains the rights to life and liberty, implying that aside from being a separate right, the right to health also finds legal basis under the right to life.[234] In the Philippines, the 1987 Constitution notes that "[t]he State shall protect and promote the right to health of the people and instill health consciousness among them."[235]

B. In Focus: Health in Times of the ICESCR

Perhaps the one treaty most responsible for creating a binding obligation relative to the right to health is the International Covenant on Economic, Social and Cultural Rights (ICESCR).[236] It is "widely considered as the central instrument of protection for the right to health."[237] Article 12 of the ICESCR states:

> 1. The [State] Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
>
> 2. The steps to be taken by the [State] Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
>
> ...

230. Lindsay, *supra* note 215, at 11.

231. OHCHR Fact Sheet No. 31, *supra* note 215, at 10.

232. INDIA CONST. art 47.

233. Edwin, *supra* note 217, at 6 (citing Anand Grover & Brian Citro, *India: access to affordable drugs and the right to health*, 377 LANCET 976 (2011)).

234. *Id. See also* INDIA CONST. art 21.

235. PHIL. CONST. art. II, § 15.

236. International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200A (XXI), U.N. Doc. A/6316 (Jan. 3, 1976) [hereinafter ICESCR].

237. OHCHR Fact Sheet No. 31, *supra* note 215, at 9.

(a) The prevention, treatment and control of epidemic, endemic, occupational[,] and other diseases;

(b) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.[238]

The right to health is considered inclusive, which means it entails conventional components such as access to healthcare, and more non-traditional but important factors for health, such as community support and non-discrimination.[239] The meaning of the right to health being inclusive is that it contains a variety of freedoms and entitlements. The entitlements which constitute the right to health "include the right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health."[240] Other entitlements include "[t]he right to prevention, treatment[,] and control of diseases; [a]ccess to essential medicines; ... [e]qual and timely access to basic health services; [and] [t]he provision of health-related education and information[.]"[241] Under the ICESCR, particularly, and also under more general conceptions, "the right to health must be understood as a right to the enjoyment of a variety of facilities, goods, services[,] and conditions necessary for the realization of the highest attainable standard of health."[242]

Under the ICESCR, the right to health has four "interrelated and essential elements."[243] These are: availability, accessibility, acceptability, and quality.[244] These four are intended to describe whatever facilities, goods, and services the right to health includes. As regards availability, for example, General Comment No. 14 states that "[f]unctioning public health and health-care facilities, goods[,] and services ... must be available in sufficient quantity within a State."[245] The same can be said, according to the General Comment, about "essential drugs, as defined by the WHO Action Programme on Essential Drugs."[246]

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238. ICESCR, *supra* note 236, art. 12.

239. *See* OHCHR Fact Sheet No. 31, *supra* note 215, at 6–8.

240. U.N. Committee on Economic, Social and Cultural Rights, *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)*, ¶ 8, U.N. Doc. E/C.12/2004/4 (Aug. 11, 2000) [hereinafter *General Comment No. 14*].

241. OHCHR Fact Sheet No. 31, *supra* note 217, at 3–4.

242. *General Comment No. 14*, *supra* note 240, ¶ 9.

243. *Id.* ¶ 12.

244. *Id.*

245. *Id.*

246. *Id.*

Accessibility has four dimensions: non-discrimination, physical accessibility, economic accessibility, and informational accessibility.[247] In particular, economic accessibility, or affordability, means that the right to health is "based on the principle of equity, [and State Parties must ensure] that these services, whether privately or publicly provided, are affordable for all, including socially disadvantaged groups."[248] "The facilities, goods[,] and services should also respect medical ethics, and be gender-sensitive and culturally appropriate. In other words, they should be medically and culturally acceptable."[249]

Quality, in turn, implies that health services must be "scientifically and medically appropriate" and administered by competent professionals.[250] In addition, medicines have to be approved and unexpired.[251]

C. Immediate Effect and Progressive Realization: Duties under the ICESCR

The obligations under the right to health in the ICESCR are divided into two. There are those that are subject to progressive realization, and those that are considered as taking immediate effect. In making room for obligations subject to progressive realization, the State Parties to the ICESCR take into account the availability of resources and the development context in a certain State.[252] In other words, "States have the obligation to *progressively achieve* the full realization of the [right to health]. This is an implicit recognition that [S]tates have resource constraints and that it necessarily takes time to implement the treaty provisions."[253] The recognition of obstacles such as resource constraints, however, "does [not] absolve [a State] from having to take action to realize the right to health."[254]

Obligations that must take immediate effect are sometimes called core obligations or minimum core obligations.[255] "At a minimum, States must

247. *Id.* ¶ 12 (b).

248. *General Comment No. 14*, *supra* note 240, ¶ 12 (b).

249. OHCHR Fact Sheet No. 31, *supra* note 215, at 4.

250. *Id.*

251. *Id.*

252. *Id.* at 5.

253. *Id.* at 23 (emphasis supplied).

254. *Id.* at 5.

255. *See* HESTERMEYER, *supra* note 220, at 107.

show that they are making every possible effort, within available resources, to better protect and promote all rights under the [ICESCR]."[256]

As the U.N. is quick to point out, "[t]he right to health is [not] only a programmatic goal to be attained in the long term."[257] Even considering limited resources, there are obligations which are effective immediately, including the passing of legislation and creation of government programs devoted "towards the full realization of [the] right."[258] Expounding on the core obligations of the government under the right to health, "the Committee on Economic, Social and' Cultural Rights [(CESCR)] has underlined that States should, at a minimum, adopt a national strategy to ensure to all the enjoyment of the right to health, based on human rights principles which define the objectives of that strategy."[259] Aside from legislative and policy action, states are also required to "to ensure a minimum level of access to the essential material components of the right to health, such as the provision of essential drugs[.]"[260]

In connection with the obligation relative to essential medicines, States are also obliged to move towards disease control, treatment, and prevention. To the CESCR, the "core obligations include at least the following obligations: (a) [t]o ensure the right of access to health facilities, goods[,] and services on a non-discriminatory basis, especially for vulnerable or marginalized groups; [and] (b) [t]o take measures to prevent, treat[,] and control epidemic and endemic diseases[.]"[261]

D. Respect, Protect, Fulfill: The Three Dimensions of the Right to Health

General Comment No. 14 also offers another way of classifying obligations to which States must adhere with respect to the right to health. This way divides the obligations into three: to respect, to protect, and to fulfill. "While steps may depend on [their] specific context, all States must move towards meeting their obligations to respect, protect[,] and fulfil[l],"[262] especially given the CESCR observation that "for millions of people throughout the world, the full enjoyment of the right to health still remains

256. OHCHR Fact Sheet No. 31, *supra* note 215, at 23.

257. *Id.* at 5.

258. *Id.*

259. *Id.* at 24.

260. *Id.* at 5.

261. *General Comment No. 14*, *supra* note 240, ¶ 43.

262. OHCHR Fact Sheet No. 31, *supra* note 215, at 5.

a distant goal [and] ... in many cases, especially for those living in poverty, this goal is becoming increasingly remote."[263]

The obligation to respect "requires States to refrain from interfering directly or indirectly with the right to health."[264] This requires that "[S]tates refrain from denying or limiting equal access for all persons, including prisoners or detainees, minorities, asylum-seekers[,] and illegal immigrants, to preventive, curative[,] and palliative health services[.]"[265] The CESCR has also noted that "State [P]arties have to respect the enjoyment of the right to health in other countries."[266]

The obligation to protect basically "requires States to prevent third parties from interfering with the right to health,"[267] as well as its guarantees.[268] It is an obligation of States to protect against actions of third parties. This includes

> [adopting] legislation or [taking] other measures ensuring equal access to health care and health-related services provided by third parties; [ensuring] that privatization of the health sector does not constitute a threat to the availability, accessibility, acceptability and quality of health facilities, goods and services; [and controlling] the marketing of medical equipment and medicines by third parties[.][269]

The CESCR has also pointed out that the obligation to protect extends to actions which may affect other countries, and not just a particular state itself. The Committee noted that "States should prevent third parties from violating the right to health in other countries ... [and] when negotiating international or multilateral agreements, States should take steps to ensure that these instruments do not have an adverse impact on the right to health."[270]

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263. *General Comment No. 14*, *supra* note 240, ¶ 5.

264. *Id.* ¶ 33.

265. *Id.* ¶ 34.

266. *Id.* ¶ 39.

267. OHCHR Fact Sheet No. 31, *supra* note 215, at 24.

268. *General Comment No. 14*, *supra* note 240, ¶ 33.

269. *Id.*

270. OHCHR Fact Sheet No. 31, *supra* note 215, at 26 (citing *General Comment No. 14*, *supra* note 240, ¶ 50).

Finally, the obligation to fulfill imposes on States a duty to "adopt appropriate legislative, administrative, budgetary, judicial, promotional[,] and other measures to fully realize the right to health."[271]

The obligation to fulfill has three aspects. It "contains obligations to facilitate, provide[,] and promote."[272] The General Comment on the right to health explains in brief what these three mean —

> The obligation to fulfil[l] (facilitate) requires States inter alia to take positive measures that enable and assist individuals and communities to enjoy the right to health. [State] parties are also obliged to fulfil[l] (provide) a specific right contained in the Covenant when individuals or a group are unable, for reasons beyond their control, to realize that right themselves by the means at their disposal. The obligation to fulfil[l] (promote) the right to health requires States to undertake actions that create, maintain[,] and restore the health of the population.[273]

While the ICESCR primarily imposes obligations on States towards their own population, it also seeks to regulate conduct by states with each other and with the populations of other States, as alluded to earlier. The CESCR notes that States should "respect the enjoyment of the right to health in other countries[.]"[274] In addition, should certain States have influence over third parties who have the potential of violating the right to health in other countries, States should try and sway these parties, either by legal or political means, to act in a way that would protect the right to health.[275] With regard to international agreements relating to health, State Parties should endeavor to "[develop] further legal instruments" when needed to duly acknowledge the right to health.[276] "In relation to the conclusion of other international agreements [not related to health], States should take steps to ensure that these instruments do not adversely impact upon the right to health."[277] Aside from State to State interaction, it is also recognized that the right to health is the responsibility of non-State actors, and all should act in a manner favorable to such right. In a resolution, the U.N. Human Rights Council recognized

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271. *General Comment No. 14*, *supra* note 240, ¶ 33.

272. *Id.*

273. *Id.*

274. *Id.* ¶ 39.

275. *Id.* ¶ 33.

276. *Id.* ¶ 39.

277. *General Comment No. 14*, *supra* note 240, ¶ 39.

> the need for States, in cooperation with international organizations and civil society, including nongovernmental organizations and the private sector, to create [favorable] conditions at the national, regional[,] and international levels to ensure the full and effective enjoyment of the right of everyone to the highest attainable standard of physical and mental health.[278]

E. Finding the Fit: Positioning Access to Medicines Under the Right to Health

During a meeting of the EU and its neighboring States on the issue of HIV/AIDS, the view was expressed that "[a] fundamental component of the right to health is access to affordable good-quality medicines[.]"[279] The last of the eight Millennium Development Goals — centering on global partnerships for development — includes a target which aims to "provide access to affordable essential drugs in developing countries"[280] with the help of pharmaceutical companies.[281] In relation to this goal, Professor Paul Hunt, the former U.N. Special Rapporteur for the Right to Health, has said that "medical care and access to medicines are in fact essential components of the right to the highest attainable standard of health."[282]

Some have characterized access to medicines more specifically as a prerequisite for realizing the right to health.[283] Posing the same sentiment in negative terms, others have characterized the absence of access to medicines as "[p]erhaps the most obvious threat to human rights[,]"[284] stating more

278. Edwin, *supra* note 217, at 10 (citing Right of everyone to the enjoyment of the highest attainable standard of physical and mental health, U.N. Human Rights Council Res. 6/29, U.N. Doc. A/HRC/RES/6/29 (Dec. 14, 2007)).

279. Lindsay, *supra* note 215, at 15.

280. Goal 8: Develop a Global Partnership for Development, *available at* http://www.un.org/millenniumgoals/global.shtml (last accessed May 12, 2017).

281. *Id.*

282. Edwin, *supra* note 217, at 10 (citing Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, 63d Session of the General Assembly, U.N. Doc. A/63/263 (Aug. 11, 2008) (by Paul Hunt)).

283. Stephen P. Marks, *Access to Essential Medicines as a Component of the Right to Health*, *in* HEALTH: A HUMAN RIGHTS PERSPECTIVE 84 (2009) (citing MDG GAP TASK FORCE, MILLENNIUM DEVELOPMENT GOAL 8: DELIVERING ON THE GLOBAL PARTNERSHIP FOR ACHIEVING THE MILLENNIUM DEVELOPMENT GOALS: MDG GAP TASK FORCE REPORT 2008 36 (2008)).

284. Marks, *supra* note 283, at 82 (citing ANDRES CLAPHAM, HUMAN RIGHTS OBLIGATION OF NON-STATE ACTORS 175 (2006)).

specifically that "[t]he lack of access to life-saving and health-supporting medicines for an estimated two billion poor people stands as a direct contradiction to the fundamental principle of health as a human right."[285]

Some are of the opinion that originally, the right to health did not contain as an essential component access to medicines, or at least, that it was not the main concern of those who drafted instruments containing a declaration of the right to health, labelling the right to access to medicines as a "derivative right."[286] However, due to the rise of HIV/AIDS and its spread around the world, "the vital need for treatment of HIV positive individuals contributed to the progressive acknowledgement that access to essential medicines, including [ARV treatments], was an internationally recognized human right[.]"[287] This was bolstered in the 1990s, when "a number of actors began to advocate for the importance of access to medicines, particularly in relation to the HIV/AIDS pandemic and the expected negative impact of the [TRIPS Agreement] on the availability of low-cost generic medicines."[288]

The next decade saw the advent of numerous "political declarations, civil society initiatives, academic publications, and [ ] discourse and practices [by] governments, intergovernmental organizations, and the pharmaceutical industry" which displayed "a relatively strong and stable norm [emerging] regarding access to medicines in developing countries[.]"[289] One such declaration was Resolution 2002/32 issued by the Office of the U.N. High Commissioner for Human Rights,[290] which dealt with access to medication in the context of HIV/AIDS. The resolution notes that in the context of HIV/AIDS, for the full realization of the right to health, "access to essential medicines is a fundamental element."[291] The same resolution also equated

285. Marks, *supra* note 283, at 84 (citing MDG GAP TASK FORCE, *supra* note 283, at 36).

286. Marks, *supra* note 283, at 96.

287. *Id.*

288. Suerie Moon, *Respecting the Right to Access to Medicines: Implications of the UN Guiding Principles on Business and Human Rights for the Pharmaceutical Industry*, 15 HEALTH HUM. RTS. 32, 34 (2013) (citing Ellen 't Hoen, et al., *Driving a decade of change: HIV/AIDS, patents and access to medicines for all*, 14 J. INT. AIDS SOC. 15 (2011)).

289. *Id.*

290. United Nations High Commissioner for Human Rights, Access to medication in the context of pandemics such as HIV/AIDS, 2002/32, E/CN.4/Res/2002/32 (Apr. 22, 2002).

291. Edwin, *supra* note 217, at 8.

respect for human rights to honoring relevant international agreements which obligated States to "avoid limiting equal access to treatment for all"[292] and to make needed pharmaceutical products available at an affordable price.[293] Because of these numerous declarations and instruments, some authors have concluded that "[a]ccess to essential medicines has gradually come to be recognized as part of the human right to health, enforceable under both international and national laws."[294]

Access to medicines is now heavily entwined with the right to health, and it is well accepted that it cannot be separated from any human rights discourse on the highest attainable standard of health.[295] There is a consensus "that human rights should [now] incorporate the ability of individuals to maintain and restore good health through access to at least a basic level of primary care, including essential medicines[.]"[296]

With regard to access to medicines under the ICESCR, "[t]he [CESCR] authoritatively recognized access to medicines as a means of fulfilling the right to health in General Comment [No.] 14."[297] In particular, "[p]aragraph 43 of General Comment [No.] 14 stated clearly, for the first time, that [S]tate [P]arties are obliged 'to provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs' and 'to ensure equitable distribution of all health facilities, goods[,] and services.'"[298] The provision of essential drugs, "especially for vulnerable or marginalized groups [is] part of [the] minimum core obligations [under the ICESCR]."[299] The ICESCR protects access to medicine as an integral part of the right to health.[300]

The second paragraph of Article 12 of the ICESCR provides various ways in which the right to health can be fulfilled.[301] Specifically, it notes that full realization of the right to health should include "[t]he prevention,

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292. *Id.*

293. *Id.*

294. Moon, *supra* note 288, at 33.

295. Marks, *supra* note 283, at 84.

296. *Id.*

297. Moon, *supra* note 288, at 33(citing *General Comment No. 14*, *supra* note 240).

298. Moon, *supra* note 288, at 33 (citing *General Comment No. 14*, *supra* note 240, ¶ 43).

299. HESTERMEYER, *supra* note 220, at 107.

300. *Id.* at 102.

301. *Id.* at 104.

treatment[,] and control of epidemic, endemic, occupational[,] and other diseases[,]"[302] as well as "[t]he creation of conditions which would assure to all medical service and medical attention in the event of sickness."[303] Some authors note, in relation to these two obligations, that

> [n]owadays, [ ] prevention, treatment, and control of most diseases rely on medicine as an integral, vital, indispensable part of the therapy. Treatment of serious infections without antibiotics, of fungal infections without antifungal agents, and increasingly, of viral infections without antiviral agents is unthinkable — it would constitute malpractice. Hence, access to medicine is necessary for the prevention and treatment of most diseases as well as the control of communicable diseases. Medical service and medical attention in the event of sickness equally necessitate the provision of drugs.[304]

As part and parcel of the right to health under the ICESCR, access to medicines must fulfill the essential elements of availability, accessibility, acceptability, and quality.[305] Economic accessibility is particularly important for developing nations.[306] The obligations to respect, protect, and fulfill apply as well to access to medicines.[307] The obligation to respect would mean that "a [S]tate has to refrain from denying or limiting equal access to essential medicine[s] and from action that interferes with access to medicine."[308] However, the action of preventing a private party from interfering does not fall under the obligation to respect.[309] It is only actions of the State itself which can lead to a failure to respect.[310]

As regards medicine, the obligation to protect is most important for the element of accessibility, "as pharmaceuticals are almost entirely manufactured and marketed by the private sector[,]"[311] and these private sector players have much say in the status of access to medicines for the general population. In particular, they control pricing, and "high prices limit the economic

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302. ICESCR, *supra* note 236, art. 12 (2) (c).

303. *Id.* art. 12 (2) (d).

304. HESTERMEYER, *supra* note 220, at 104 (emphasis supplied).

305. *Id.* at 105.

306. *Id.*

307. *Id.* at 108–10.

308. *Id.* at 109.

309. *Id.*

310. HESTERMEYER, *supra* note 220, at 109.

311. *Id.*

accessibility of the drugs where patients have to bear the cost."[312] It has been said that one way a State can protect access to medicines in the face of the threat of economic inaccessibility is "by constructing their patent system in a way that it does not result in excessive pricing."[313] This shows that the obligation to protect extends to the kinds of laws a State enacts to regulate, whether directly or indirectly, the actions of third parties.

For the obligation to fulfill, States "have to provide information on available pharmaceutical treatment for diseases[,] such as HIV/AIDS[,] and [ ] have to adopt a pharmaceutical policy, including a policy on generics."[314] The duty to fulfill the right to health also includes giving "assistance to indigents by providing them with essential medicine."[315] It is noted that the obligation to fulfill will often be limited by financial constraints, because State action under it has "severe budgetary implications."[316] The ICESCR recognizes that States, especially developing ones, are often pressed to make the most of very little, and therefore, the fact that a State is not immediately compliant with their obligations to fulfill (as well as the other obligations) may be excused by lack of resources.[317] This, however, depends on the situation. To justify non-compliance with minimum core obligations for example, a "State must demonstrate that every effort has been made to use all resources that are at its disposition in an effort to satisfy, as a matter of priority, those minimum obligations."[318] Financial deficits also cannot be used as absolute excuses. "Where the right to health can be realized to a greater extent without committing resources[,] it is unreasonable not to do so."[319] In the context of access to medicines, "[w]here [S]tates are financially unable to provide medicine for their population, they have to guarantee economic accessibility by other means."[320] Some other means that have been

312. *Id.*

313. *Id.* (citing U.N. Committee on Economic, Social and Cultural Rights, *General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of Which He or She is the Author (Art. 15, Para. 1 (c) of the Covenant)*, U.N. Doc. E/C.12/GC/17 (Nov. 11, 2005) [hereinafter U.N. CESCR, *General Comment No. 17*]).

314. HESTERMEYER, *supra* note 220, at 110.

315. *Id.*

316. *Id.*

317. *Id.*

318. *Id.*

319. *Id.* at 112.

320. HESTERMEYER, *supra* note 220, at 112.

suggested include changes to patent legislation and the implementation of competition laws.[321] "As these options do not require significant financial resources, States cannot evade their obligation by pleading [ ] lack of resources."[322]

It must also be remembered that the rule is the same for access to medicines as it is for the right to health in general — States must move, however slowly, towards fulfillment of the right to health. Movement must be progressive and not retrogressive. Where a State is already in a position where medicine is accessible, its move to make medicines less so is burdened by a heavy presumption of unjustifiability.

But which medicines are included in the demandable right of access to medicines? The ICESCR talks about essential medicines. According to the WHO, essential medicines are those that "satisfy the priority health care needs of the population"[323] and "are intended to be available within the context of functioning health systems at all times in adequate amounts[.]"[324] These medicines are the ones most vital, and which are often involved in what is known as the access gap. This term "refers to the fact that [ ] one[-] third of the world's population or [two] billion people do not have access to [essential] medicines, and 10 million deaths occur annually from diseases that are treatable by existing medicines."[325] This is often because "when medicines are produced which have potential therapeutic benefits in the developing world[,] they are not properly adapted for these populations."[326] Illustratively, the WHO considers various ARV drugs designed to treat or prevent transmission of HIV/AIDS as essential medicines, and thus falling under the obligation of access to medicines.[327]

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321. *Id.*

322. *Id.*

323. World Health Organization, Medicines: Essential Medicines, *available at* http://www.who.int/medicines/services/essmedicines_def/en (last accessed May 12, 2017).

324. *Id.*

325. Edwin, *supra* note 217, at 2 (citing World Health Organization, Progress of WHO Member States in Developing National Drug Policies and in Revising Essential Drug Lists, *available at* http://apps.who.int/iris/bitstream/10665/64468/1/WHO_DAP_98.7.pdf (last accessed May 12, 2017)).

326. *Id.* at 3.

327. World Health Organization, *WHO Model List of Essential Medicines*, 18th document (Apr. 2013).

F. Violating the Right to Health: Acts and Omissions

With rights and obligations comes also the possibility of violations. It is important to note that there is a distinction between "the inability [and] the unwillingness of a State [P]arty to comply with its obligations under [A]rticle 12."[328] For example, "[a] State which is unwilling to use the maximum of its available resources for the realization of the right to health is in violation of its obligations under [A]rticle 12."[329] In contrast, a State who fails to realize the right to health to the same extent as other compliant States despite allocating the maximum possible resources towards it should not be considered in violation. However, "a State [P]arty cannot, under any circumstances whatsoever, justify its non-compliance with the core obligations[,] ... which are non-derogable."[330]

The General Comment on the right to health notes that there are two kinds of violations — those by direct action, and those by omission.[331] Violations by direct action, on one hand, frequently involve "[t]he adoption of any retrogressive measures incompatible with the core obligations under the right to health."[332] These retrogressive measures "include the formal repeal or suspension of legislation necessary for the continued enjoyment of the right to health or the adoption of legislation or policies which are manifestly incompatible with pre-existing domestic or international legal obligations in relation to the right to health."[333] Violations by omission, on the other hand, refer to the "failure of States to take necessary measures arising from legal obligations."[334] This includes "the failure [of the State] to take appropriate steps towards the full realization of everyone's right to the enjoyment of the highest attainable standard of physical and mental health[.]"[335]

The duties to respect, protect, and fulfill may also be violated respectively. Notably, as regards the duty to respect, the General Comment had this to say —

328. *General Comment No. 14*, *supra* note 240, ¶ 47.

329. *Id.*

330. *Id.*

331. *Id.* ¶¶ 48 & 49.

332. *Id.* ¶ 48.

333. *Id.*

334. *General Comment No. 14*, *supra* note 240, ¶ 49.

335. *Id.*

> Violations of the obligation to respect are those State actions, policies[,] or laws that contravene the standards set out in [A]rticle 12 of the Covenant and are likely to result in bodily harm, unnecessary morbidity[,] and preventable mortality. Examples include the denial of access to health facilities, goods[,] and services to particular individuals or groups[;] the suspension of legislation or the adoption of laws or policies that interfere with the enjoyment of any of the components of the right to health; and the failure of the State to take into account its legal obligations regarding the right to health when entering into bilateral or multilateral agreements[.][336]

A State violates the duty to protect when it fails to regulate actions of third parties, causing infringement on the right to health of people within the State's jurisdiction.[337] It may also result from a lack of safeguards aimed directly at the population, as opposed to the third parties.[338] While a State violates it obligation to fulfill "through [its] failure ... to take all necessary steps to ensure the realization of the right to health. Examples include the failure to adopt or implement a national health policy designed to ensure the right to health for everyone[.]"[339]

G. The Right to Health and Data Exclusivity: An Analysis

Data exclusivity is proven likely to cause two things. The first effect is that it will impede entry of generic medicine into the market. This is because generics companies will be deprived of the option to use bio-equivalency tests, at least for a certain time. Generics companies are often incapable of the other choice when applying to get medicine approved, and that is submitting their own test data. The second effect is that, because generics will not be in the market, the brand-name drugs will be the only drugs available, if not at all, then at least in sufficient quantity. These are drugs which, as the data show, are more expensive than generics. This situation is also aggravated by the possibility that because of lack of competition and the virtual monopoly brand-name drugs hold over the market, they will not be pressured to lower their prices, and may even raise them.

As regards the right to health, access to essential medicines is accepted as part and parcel of the right to health, and obligations relative to the right in general are also applicable to the right to access to medicines. For the enjoyment, therefore, of the right to access medicine, medical drugs must be

336. *Id.* ¶ 50.

337. *Id.* ¶ 51.

338. *Id.*

339. *Id.* ¶ 52.

all of four things: available, accessible, acceptable, and of good quality. Furthermore, States have, under the ICESCR, obligations to respect, protect, and fulfill the right to access to medicines.

When it comes to the obligation to respect the right to access to medicines, States must not perform acts which interfere with the availability, accessibility, acceptability, or quality of the medicines. At the same time, however, an analysis of the obligation to respect should make the distinction between the State's actual interference with the State's creation of the possibility of interference by a third party.[340] The latter does not fall within the obligation to respect.[341] A pharmaceutical company raising drug prices due to a State's patent policy, for example, does not constitute a violation of the right to respect.[342]

The Author submits that the imposition of data exclusivity on India would constitute a violation of the right to respect, particularly with regard to availability of medicines, and to some extent, their accessibility. Data exclusivity would affect the availability of medicines, because its practical effect is to stop generic medicine from entering the market for a certain time period, which can be anywhere from five to 10 years or more. Cheaper medicines would not be available, not only for dependents in India, but also to developing countries, and organizations like MSF, who obtain their drugs from India.[343] It would be a failure to respect on the part of the State because the making available or unavailable of the bio-equivalency tests is an act of the State. As was previously discussed, in the sense of bio-equivalency, the data are "used" not by third parties, but by the government.[344] Data exclusivity affects not production, as patents do, but approval, a province of

340. HESTERMEYER, *supra* note 220, at 109.

341. *Id.*

342. *Id.*

343. *See* Letter *from* Dr. Unni Karunakara, International President, Médecins Sans Frontières *to* Dr. Manmohan Singh, Prime Minister of India (Mar. 14, 2013), *available at* http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/Access_Letter_MSFtoDrSingh_ENG_2013.pdf (last accessed May 12, 2017). *See also* Stockholm Network Blog, Blog Post, Mar. 22, 2011, WORDPRESS, *available at* https://stockholmnetworkblog.wordpress.com/2011/03/22/eu-india-free-trade-agreement-includes-data-exclusivity (last accessed May 12, 2017). Paul Cawthorne, MSF's Access Campaign Coordinator in Asia, was quoted as saying that "more than 80 percent of the AIDS drugs [MSF's] medical practitioners use to treat 175,000 people in developing countries are affordable generics from India." *Id.*

344. WHO Briefing Note, *supra* note 66, at 2.

government agencies. The government denies an avenue for approval of generics, thereby interfering with their availability in the market.

With regard to the obligation to protect, it seems that data exclusivity affects the State's fulfillment of this obligation, in relation to the accessibility and acceptability of medicines. It has already been shown that one main impact of data exclusivity has been on the prices of medicine in the market. Aside from the fact that because of the absence of generic medicine in the market, only brand-name drugs would be available, thereby making the drugs available financially inaccessible to poorer sectors of the population as well as to poorer countries, there would be no competition in the market. Knowing that they are the only sources of drugs which include essential medicines, there is no incentive, at least financially, for originators to reduce prices, and the even have an incentive to raise them. Data exclusivity allows for a monopoly by those who charge higher prices, and creates an environment wherein prices can be raised even more. A State's signing of an FTA with data exclusivity provisions would be a failure on their part to prevent third parties, in this case, originator companies, from interfering with the financial accessibility of medicines. It would also be a failure on the part of the State to respect accessibility, as they interfere with the current state of accessibility of medicines in the market, acting in such a way that the only medicines available are in fact financially inaccessible for many who need them.

Data exclusivity also affects compliance by the State to protect the acceptability of medicines.[345] Acceptability entails that medicine made available to the population be culturally and ethically sound.[346] On the off chance that there are generics companies who would choose to not wait for the data exclusivity period to lift, and to conduct their own tests, their actions would have serious ethical implications. Submitting their own test data would mean conducting their own tests, and a large part of these tests would include human subjects, particularly, persons who are ill and who need treatment. Current ethical standards for human experimentation require that tests must have a scientific purpose.[347] This could either be

345. *See generally* Tim K. Mackey & Bryan A. Liang, Patent and Exclusivity Status of Essential Medicines for Non-Communicable Disease, *available at* http://apps.who.int/medicinedocs/documents/s19999en/s19999en.pdf (last accessed May 12, 2017).

346. *See generally* Fabrice Ruiz, et al., *Standardized method to assess medicine's acceptability: Focus on paediatric population*, 69 J. PHARM. & PHARMACOLOGY 406, 406 (2016).

347. HOLTZ, *supra* note 210, at 168.

something like discovering the efficacy or safety of a drug.[348] However, what generics companies would be doing would be experimenting on drugs with already known effects, and they would be doing this for approval to put generics on the market. It would not be for scientific, but for commercial purposes. Furthermore, the problem with experimentation is that standard scientific experimentation models would require a control group, a group that is not given the medicine being tested, usually by giving them placebo or leaving them with no new substance intake at all, in order to prove that any change in the group given the variable element — in this case, the drug being tested — is in fact caused by such element.[349] In the case of generics, they would be using persons who are ill, even in the control group. They would be denying treatment to people who are ill even if there is already a known treatment. Considering that illnesses in these tests include life threatening ones such as HIV/AIDS, the ethical implications become extremely serious, and greatly affect how ethically acceptable these medicines would be to persons.

Finally, with respect to the right to fulfill access to medicines, India without data exclusivity has, in fact, realized this obligation to fulfill quite well. Fulfillment of the right to access to medicines would entail adopting a policy on generics and helping facilitate the provision of essential medicines to vulnerable groups like the poor. Post-TRIPS Agreement, India has adopted the system of product patenting, but at the same time, it amended its laws in such a way as to prevent the practice of evergreening of pharmaceuticals, as well as to allow easy entrance of generics into the market by allowing for bio-equivalency tests. The effects of this has been shown, as India supplies close to 90% of generic medicine to developing countries and is home to companies which sell essential medicines at a fraction of the cost of their brand-name counterparts.[350]

With the implementation of data exclusivity however, many of the effects of the realization by India of its obligation to fulfill would be nullified. Data exclusivity would hinder generic medicines from entering, despite whatever leeway is afforded by India's patent laws. Furthermore, the very ease by which generic medicine is allowed into the market (because of bio-exclusivity) will disappear, as there would be no other choice for generics companies other than to submit their own data. Additionally, it has been

348. *Id.*

349. *See* Clift, *supra* note 105, at 432 & Biology Online, Definition-Control group, *available at* http://www.biology-online.org/dictionary/Control_group (last accessed May 12, 2017).

350. Bivol & Soltan, *supra* note 164, at 7.

noted that while resource constraints may acceptably limit the extent to which a State can comply with its obligation to fulfill, when the State has found a way to fulfill the obligation even despite resource constraints, it is unjustifiable not to do so.[351] This is exactly what India has done in its current legal system, and to introduce data exclusivity would constitute an inexcusable obstacle to the continuation of this already achieved level of realization of the obligation to fulfill.

It is with the obligation to fulfill that progressive realization finds most relevance. Of the three obligations (respect, protect, and fulfill), it is the one which involves the most positive steps. While fulfillment of the right to access to medicines may be slow, it must move in the direction of realization — of fulfillment. India has already achieved a level of realization as regards the obligation to fulfill the right to health. It is a country where patents are not over-extended nor liberally granted to pharmaceuticals. It is also a country that currently produces a large percentage of generics available today, including those designed to treat patients with serious diseases such as HIV/AIDS. Generic medicine is the main player in this level of fulfillment which India has reached. To obstruct the release of generic medicine into the market through data exclusivity would be a retrogressive measure on the part of the Indian government, and this move carries a presumption of unjustifiability under the ICESCR.

However, is it actually unjustifiable? Retrogressive measures are not completely prohibited by the ICESCR. They are allowed provided that a State has taken into consideration all other possible alternatives, and that they are justified, taking into account all other rights in the Convention as a whole.[352] Two elements then go into justifying retrogressive measures: (1) they must be necessary in relation to fulfillment of other rights and the general welfare; and (2) there must be no better alternative.[353]

There appears to be no right in the ICESCR whose further achievement or fulfillment would be benefitted by a curtailment of the right to health in the way data exclusivity would effect, except, it would seem, the right "[t]o benefit from the protection of the moral and material interests resulting from any scientific, literary[,] or artistic production of which [a person] is the author."[354] On its face, it appears that this right would be benefitted should data exclusivity be put in effect. However, is data exclusivity, which is a

351. HESTERMEYER, *supra* note 220, at 112.

352. *Id.*

353. *Id.*

354. ICESCR, *supra* note 236, art. 15 (1) (c).

form of IP protection, actually covered by Article 15 (1) (c), which covers the right to benefit from protection of moral and material interests to intellectual creations?

General Comment No. 17[355] talks about Article 15 (1) (c) of the ICESCR, what it covers, and how it should be understood in relation to other rights. To begin with, the right contained in the Article 15 (1) (c), the General Comment says, is "a human right which derives from the inherent dignity and worth of all persons."[356] The right is fundamental, inalienable, and universal.[357] The General Comment then distinguishes it from IP rights, which are "temporary ... and can be revoked, licensed, or assigned to someone else."[358] The General Comment then notes that "[i]t is ... important not to equate [IP] rights with the human right recognized in [A]rticle 15, paragraph 1 (c)."[359] IP rights are not human rights. They are entitlements which "because of their different nature, are not protected at the level of human rights."[360] Furthermore, General Comment No. 17 points out that only natural persons, and in some instances, communities, may be the beneficiaries of human rights, including the right in Article 15 (1) (c).[361]

General Comment No. 17 further clarifies that the right in Article 15 (1) (c) protects only those things that are "creations of the human mind."[362] Are test results — the object protected by data exclusivity — products of the human mind? Recall that the object of data exclusivity is not the final product itself, nor even the formulation or the composition of said product. The objects of data exclusivity's protective mantle are the results taken from testing the product in various settings. They are observable results. Even the conclusion drawn from the test results are not products of the mind of the pharmaceutical companies, as the data are submitted to a government

355. U.N. Committee on Economic, Social and Cultural Rights, *General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of Which He or She is the Author (Art. 15, Para. 1 (c) of the Covenant)*, U.N. Doc. E/C.12/GC/17 (Nov. 11, 2005).

356. *Id.* ¶ 1.

357. *Id.*

358. *Id.* ¶ 2.

359. *Id.* ¶ 3.

360. *Id.* ¶ 7.

361. U.N. CESCR, *General Comment No. 17*, *supra* note 313, ¶ 7.

362. *Id.* ¶ 9.

regulatory board and it is up to this board and their own experts to determine whether the data are sufficient to merit a drug's approval for general consumption.[363] It is this Note's submission that data exclusivity does not protect anything that can be considered a "creation" of the human mind in the same way that paintings, inventions, or even scientific publications are. Strictly speaking, the data gathered from testing were not created by human minds. This does not mean that they cannot be protected through other means, indeed that is the province of IP, but it cannot be considered the kind of creation protected as part of the human right found in the ICESCR.

Evident throughout General Comment No. 17 is the insistence that the right to benefit from protection found in Article 15 (1) (c) should not be pushed to the detriment of other rights, and that it should be balanced along with the need to realize the rest of the ICESCR. Specifically, it notes —

> The right of authors to benefit from the protection of the moral and material interests resulting from their scientific, literary[,] and artistic productions cannot be isolated from the other rights recognized in the Covenant. States [P]arties are therefore obliged to strike an adequate balance between their obligations under [A]rticle 15, paragraph 1 (c), on one hand, and under the other provisions of the Covenant, on the other hand, with a view to promoting and protecting the full range of rights guaranteed in the Covenant. In striking this balance, the private interests of authors should not be unduly favored and the public interest in enjoying broad access to their productions should be given due consideration. [State] [P]arties should therefore ensure that their legal or other regimes for the protection of the moral and material interests resulting from one's scientific, literary[,] or artistic productions constitute no impediment to their ability to comply with their core obligations in relation to the rights to food, health[,] and education ... Ultimately, [IP] is a social product and has a social function. [State] [P]arties thus have a duty to prevent unreasonably high costs for access to essential medicines ... from undermining the rights of large segments of the population to health, food[,] and education.[364]

In sum, the right under Article 15 (1) (c) does not apply to corporations, as it is a human right.[365] Furthermore, it is doubtful as to whether the object of data exclusivity's protection falls under the scope of protected creations

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363. Although the data submitted may come with their own conclusions, the relevant conclusion — and the conclusion which will be used as basis for any subsequent approval using the same test data — remains with the government agency.

364. U.N. CESCR, *General Comment No. 17*, *supra* note 313, ¶ 35.

365. The document uses the term "peoples." *See* ICESCR, *supra* note 236, art. 1.

under the ICESCR. Additionally, even if it did, the ICESCR specifies no form of protection, for as long as it is effective and allows the authors an adequate standard of living. Finally, this right must not be taken in isolation, and must not be exercised to the detriment of other rights such as that to health. Given this and the reality, both of already existing legal safeguards in India and in the TRIPS Agreement, as well as the additional effect data exclusivity would have, it hardly seems arguable to claim that data exclusivity is necessary in order to see a corresponding balanced fulfillment of the right under Article 15 (1) (c) of the ICESCR. Furthermore, with regard to alternatives, various less severe forms of data protection are in place for India, either through domestic law or the TRIPS Agreement. Data exclusivity then can only be seen as a retrogressive measure that cannot be justified according to the standards required.

Having examined each obligation, as well as the question on retrogression, it is thus this Note's submission that adopting a data exclusivity provision would violate the right to health under the ICESCR. It violates the right with respect to India's obligation to respect availability of medicine, to protect accessibility and acceptability of medicine, and to fulfill the right to access to medicine in general, as it is an unjustifiable retrogressive measure.

While the right to health plays a big role in any human rights discussion regarding access to medicines, it is not the only right implicated in the debate. Because of the characteristic of diseases such as HIV/AIDS as that which unnecessarily shortens lives and infects millions of people despite it being treatable, severely affecting the quality as well as the length of their lifespan, the right to life has also taken the forefront in the access to medicines debate.

IV. THE RIGHT TO LIFE

The right to life "is the most basic of all rights"[366] and it is even argued that the right has "attained [*jus cogens*] status under international law."[367] The right is found in both the UDHR[368] and the International Covenant on Civil and Political Rights (ICCPR).[369] The right to life is also recognized in various regional and domestic instruments. India's own Constitution

366. Alicia Ely Yamin, *Not Just a Tragedy: Access to Medication as a Right Under International Law*, 21 B.U. INT'L L.J. 325, 330 (2003).

367. *Id.*

368. *See* UDHR, *supra* note 79, art. 3.

369. International Covenant on Civil and Political Rights, G.A. Res. 2200A (XXI), art. 6, U.N. Doc. A/6316 (1966) (Mar. 23, 1976).

recognizes the right to life in its Article 21, which states that "no person shall be deprived of his life or personal liberty except according to procedure established by law."[370] The Philippines has a similar line in its Bill of Rights, which says that "[n]o person shall be deprived of life, liberty, or property without due process of law, nor shall any person be denied the equal protection of the laws."[371]

A. A Broader Look at the Right to Life: Dignity, Quality, and Health

Conventional interpretations of the right to life have often focused on the fact that it is a negative obligation. That is, it has found significance most in dictating what States cannot do — deprive someone of life arbitrarily.[372] There are, however, expanding interpretations of the right to life, and these are not all together new. General Comment No. 6, although largely devoted to the application of the right to life in times of use of force, dedicates one paragraph to the "positive" side of the right. It notes —

> [T]he right to life has been too often narrowly interpreted. The expression 'inherent right to life' cannot properly be understood in a restrictive manner, and the protection of this right requires that States adopt positive measures. In this connection, the Committee [on Civil and Political Rights] considers that it would be desirable for States [P]arties to take all possible measures to reduce infant mortality and to increase life expectancy, especially in adopting measures to eliminate malnutrition and epidemics.[373]

The U.N. Human Rights Committee has in fact recognized that health-related concerns such as malnutrition and epidemics are real threats to the right to life.[374] In relation to this, authors have also noted that there has been a movement by international institutions and national constitutions to interpret the right to life as covering "conditions that sustain life, including a right to minimum standards of health."[375] Consequently, this has also led to

370. INDIA CONST. art. 21.

371. PHIL. CONST. art. III, § 1.

372. U.N. Human Rights Committee, *CCPR General Comment No. 6: Article 6 (Right to Life)*, ¶ 3, (Apr. 30, 1982) [hereinafter U.N. HRC, *General Comment No. 6*].

373. *Id.* ¶ 5.

374. *Id.*

375. Melissa McClellan, *"Tools for Success": The TRIPS Agreement and the Human Right to Essential Medicines*, 12 WASH. & LEE J. C. R. & SOC. JUST. 153, 164 (2005).

observations that the right to life, broadly interpreted, is applicable to "cases involving access to medications."[376]

One concept that has emerged from this movement to broadly interpret the right to life is that of "standard threats," sometimes called "typical major threats."[377] A standard threat is a serious threat which people may suffer from, but to which there is a practical treatment available[378] — basically major threats to life that need not be. It is thought that "for a person to enjoy the substance of [the right to life], he must be able to demand that the right be protected against the 'typical major threats' to life"[379] and that "it seems reasonable to suggest that treatable diseases pose a standard threat to the enjoyment of the right to life."[380] Author Henry Shue, who pioneered the concept, illustrates its application to the issue of health thus — "[t]oday, we have very little excuse for allowing so many poor people to die of malaria [which is both preventable and treatable] and more excuse probably for allowing people to die of cancer [which is still incurable]."[381]

In the case of HIV/AIDS, many authors are quick to point out that it is now a treatable disease, and treatments are available to improve the quality and length of life of an infected person. It is a threat, but it is one to which there are practical solutions. ARV drugs "can significantly prolong the life of HIV-positive patients."[382] However, since many people do not have access to these drugs, many people are suffering from the standard threat of HIV/AIDS. "[HIV/AIDS] has been turned from a preventable and manageable disease into a life threatening pandemic by ignorance, neglect, and violation of the right to access to medicine."[383]

B. The Right to Life in the Inter-American Court of Human Rights

Authors Steven R. Keener and Javier Vasquez point to an interesting development regarding the expanding interpretation of the right to life

376. Yamin, *supra* note 366, at 330.

377. McClellan, *supra* note 375, at 169.

378. *Id.*

379. *Id.*

380. *Id.*

381. *Id.* (citing HENRY SHUE, BASIC RIGHTS: SUBSISTENCE, AFFLUENCE, AND U.S. FOREIGN POLICY 33 (2d ed. 1996)).

382. Chuan-feng Wu, *Transnational Pharmaceutical Corporations' Legal and Moral Human Rights Responsibilities in Relation to Access to Medicines*, 7 ASIAN J. WTO & INT'L HEALTH L. & POL'Y 77, III (A) (2012).

383. *Id.*

involving a series of cases emanating from the IACtHR.[384] In the case of *Yakye Axa Indigenous Community v. Paraguay*,[385] the Court affirmed the expansive interpretation of the right to life when they said that "[e]ssentially, [the right to life] includes not only the right of every human being not to be arbitrarily deprived of his life, but also the right that conditions that impede or obstruct access to a [dignified existence] should not be generated."[386] From the *Yakye Axa* case, commentators note that "[w]ithin the Inter-American system [ ] the right to life [has] come to include more than protection from arbitrary murder. Enjoying the right to a dignified life now required medicine, food, clean water, and sanitation."[387]

In a subsequent case, *Sawhoyamaxa Indigenous Community v. Paraguay*,[388] the IACtHR "found violations of the right to life, not only for the destitute condition of the community, but also for the individuals who died as a result."[389] *Sawhoyamaxa* provided a standard by which violations of the right to life could be judged. The first element for a violation was that "authorities knew or should have known about the existence of the situation posing an immediate and certain risk to life of an individual or of a group of individuals,"[390] and the second element was "that the necessary measures were not adopted within the scope of their authority which could be reasonably expected to prevent or avoid such risk."[391]

The case of *Ximenes-Lopes v. Brazil*,[392] also decided by the IACtHR, solidified the relationship between the obligations under the right to life, and

384. *See* Steven R. Keener & Javier Vasquez, *A Life Worth Living: Enforcement of the Right to Health Through the Right to Life in the Inter-American Court of Human Rights*, 40 COLUM. HUM. RTS. L. REV. 595 (2009).

385. Case of the Yakye Axa Indigenous Community v. Paraguay, Inter-Am. Ct. H.R., (ser. C), No. 125, Merits, Reparation and Costs (June 17, 2005).

386. Keener & Vasquez, *supra* note 384, at 607 (citing *Case of the Yakye Axa Indigenous Community*, Inter-Am. Ct. H.R., (ser. C), No. 125, ¶ 161).

387. Keener & Vasquez, *supra* note 384, at 611.

388. Case of the Sawhoyamaxa Indigenous Community v. Paraguay, Inter-Am. Ct. H.R., (ser. C), No. 146, Merits, Reparation and Costs (Mar. 29, 2006).

389. Keener & Vasquez, *supra* note 384, at 612.

390. *Id.*

391. *Id.*

392. Case of Ximenes-Lopes v. Brazil, Inter-Am. Ct. H.R., (ser. C), No. 149, Merits, Reparation and Costs (July 4, 2006).

the obligation to provide healthcare, and clarified that the obligation "includes an affirmative duty to regulate healthcare systems."[393]

This interpretation of the right to life as including the right to a quality life or a dignified life is not confined to the Americas. Even in India, "[t]he right to life ... has been held to include a right to livelihood and a right to live with dignity; [t]he protection of health has been adjudged to be among the minimum requirements of the thus understood right to life."[394] In the Philippines, the right to life has been famously explained by eminent constitutionalist Fr. Joaquin G. Bernas as not merely the right to live but the right "to a good life."[395]

C. The Right to Life and Data Exclusivity: An Analysis

Given the immediately preceding discussion on how the right must be understood, what then are the effects of data exclusivity in relation to the right to life? The first question relevant to the analysis of the right to life is answering the question of why the broad interpretation of the right to life should be accepted. It is the submission of this Note that the broader interpretation should be accepted because it finds basis in the General Comment on the right to life — the authoritative interpretation on the particular Article in the ICCPR. General Comment No. 6 notes that the right to life should not be interpreted narrowly, and that positive obligations needed for improving the quality of life are likewise contemplated by the ICESCR.[396] Furthermore, this interpretation has found acceptance in domestic courts such as those of India, the Philippines, and, as will be seen in the following sections, countries in Africa, Europe, and South America as well.

The IACtHR was able to establish a standard by which to judge whether there had been a violation of the right to life, interpreted in its broad sense.[397] This standard involved two elements: (1) knowledge by the government of the presence of the risk to a person or persons and (2) a failure on its part to adopt measures which may reasonably protect from that

393. Keener & Vasquez, *supra* note 384, at 615.

394. HESTERMEYER, *supra* note 220, at 117.

395. JOAQUIN G. BERNAS, S.J., THE 1987 CONSTITUTION OF THE REPUBLIC OF THE PHILIPPINES: A COMMENTARY 110 (2009 ed).

396. *See* U.N. HRC, *General Comment No. 6*, *supra* note 372, ¶ 5.

397. *See* Keener & Vasquez, *supra* note 384.

risk, within the scope of its authority.[398] While it is only the IACtHR that has set out this definition, this Note submits that it may be used in testing whether there would be a violation of the right to life in the case of data exclusivity between the EU and India. This is because while only the IACtHR has expressed the standard in concrete elements, most of the cases involving violations of the right to life interpreted in the broad sense from other countries, whether they be relevant to environmental or health threats, found violations based on more or less the same elements: knowledge by government and failure to reasonably address the situation.

Taking into account the effects of data exclusivity on access to medicines — some of which are life-saving medicines meant to treat serious diseases such as HIV/AIDS — is there a violation of the right to life? First of all, the question lies on whether the Indian government, in negotiating the FTA, is aware of the threat to life facing the persons affected. This threat may be interpreted as the threat posed by HIV/AIDS itself, or the threat posed by data exclusivity to the availability of medicines which address HIV/AIDS. As to whether the Indian government is aware of the threat of HIV/AIDS, it can be said that they are. India has been spearheading an effort to fight the epidemic since it came to light in the 1990s.[399] The year 2001 saw the adoption of the National AIDS and Control Policy in India.[400] The government even has a specialized agency, the National AIDS Control Organization, for addressing the disease.[401] The government of India is well aware of the threat to life HIV/AIDS poses, with former Prime Minister Atal Bihari Vajpayee calling it "one of the most serious health challenges facing the country."[402]

398. *Id.* at 619. The standard for finding a violation of the right to life has actually three prongs, as provided by Keener and Vasquez. These are: "(1) finding of life-threatening conditions, (2) governmental knowledge of those conditions[,] and (3) failure to act." *Id.*

399. Binod Dubey, *India 'winning' battle against HIV-AIDS: UNAIDS report*, HINDUSTAN TIMES, Nov. 20, 2013, *available at* http://www.hindustantimes.com/world-news/india-winning-battle-against-hiv-aids-unaids-report/article1-1153607.aspx (last accessed May 12, 2017).

400. *See* AVERT, HIV & AIDS in India, *available at* http://www.avert.org/hiv-aids-india.htm (last accessed May 12, 2017).

401. National AIDS Control Organization, About Us, *available at* http://www.naco.gov.in/about-us (last accessed May 12, 2017).

402. India Today, Combating AIDS, *available at* http://indiatoday.intoday.in/story/combating-aids/1/231809.html (last accessed May 12, 2017).

India is also well aware as regards the effects of data exclusivity, or even the possibility of it entering the FTA. Statements, in particular, by Commerce and Industry Minister Anand Sharma, reflect an awareness of data exclusivity, as well as its impact. He notes, "India does not provide data exclusivity for pharmaceuticals and agro-chemicals which is in the paramount interest of our generic pharmaceutical industry as grant of data exclusivity would have considerable impact in delaying the entry into the market of cheaper generic drugs[.]"[403]

The next question is whether in introducing data exclusivity into its collection of legal obligations, India would then be neglecting to adopt measures reasonably expected to address the risk, within the scope of its authority. In the matter of the right to life, adopting data exclusivity obligations is not merely a failure to adopt reasonable measures to address risks to life. It is actually adopting a measure which creates or heightens the risk of HIV/AIDS and non-access to medicine. While the standards set by the IACtHR speak of an omission, it is this Note's submission that actions which nullify previous measures already taken by a government to address a risk to life, or actions which heighten the risk to life, should be considered just as much a violation as an omission. In this respect, taking into account the broader interpretation of the right to life, as well as the elements courts have often considered in declaring the presence of a violation, it is this Note's submission that adopting data exclusivity provisions, given their effect on access to life saving medicines, constitutes a violation of the right to life.

The effects of a data exclusivity provision within the legal system of India will certainly be felt beyond its borders. Being a major hub for generic medicine, any domestic restriction on its pharmaceutical players will affect the access of many States who are dependent on India for their supply of drugs. The Philippines in particular is positioned to be affected by data exclusivity in other States in two distinct ways: first, because it is a country where majority of the population can only afford generic medicine due to high prices of drugs, and second, because it is one of the few countries where the number of those affected with HIV/AIDS is rising.

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403. Business Standard, *India will not provide data exclusivity: Anand Sharma*, BUS. STAND., Mar. 30, 2011, *available at* http://www.business-standard.com/article/economy-policy/india-will-not-provide-data-exclusivity-anand-sharma-111033000021_1.html (last accessed May 12, 2017). *See also* The Economic Times, *India against inclusion of data exclusivity in any FTA*, ECON. TIMES, Apr. 6, 2011, *available at* http://articles.economictimes.indiatimes.com/2011-04-06/news/29388653_1_data-exclusivity-drug-seizure-issue-data-protection (last accessed May 12, 2017).

VI. THE PHILIPPINES: POSSIBLE OVERREACHING IMPACTS OF THE FTA

A. Medicine and Medical Care in the Philippines

In the Philippines, medical expenses, particularly drugs, are mostly shouldered by the private sector.[404] While there is a substantial budget allocated by the government for purchasing medicines for the population, it is a small percentage compared to the overall value of the pharmaceutical sector.[405] In 2010, for example, the value of the pharmaceutical market was estimated at around ₱124.6 billion.[406] This includes expenditure by the Philippine Health Insurance Corporation (PhilHealth), but does not include those of local governments to supply pharmaceuticals using their own programs. Local governments by comparison were estimated to have spent only four to five billion pesos for procuring drugs.[407]

PhilHealth is a government corporation attached to the Department of Health (DOH)[408] which is charged with the administration of the National Health Insurance Program.[409] While the law creating PhilHealth has made health insurance mandatory, thus making universal coverage possible,[410] the services offered by PhilHealth relative to access to medicine is plagued with certain difficulties and limitations. It has been noted that "[t]he limited scope and support levels of ... PhilHealth benefits, the difficulties in accessing such benefits, and the lack of information on how to do so all reduce levels of financial protection [for persons covered]."[411] Thus, even if "concessions are made for certain groups to receive medicines free of charge"[412] and free

404. Department of Health, Philippines Pharmaceutical Country Profile (A Report Produced in Cooperation with the World Health Organization) at 10, *available at* http://www.who.int/medicines/areas/coordination/Philippines_PSCPB NarrativeQuestionnaireEndorsement_13062012.pdf (last accessed May 12, 2017) [hereinafter Philippine Pharmaceutical Country Profile].

405. *Id.* at 12.

406. *Id.* at 13.

407. *Id.*

408. Philippine Health Insurance Corporation, Agency's Mandate and Functions, *available at* http://www.philhealth.gov.ph/about_us/mandate.html (last accessed May 12, 2017).

409. *Id.*

410. An Act Instituting a National Health Insurance Program for all Filipinos and Establishing the Philippine Health Insurance Corporation for the Purpose, [National Health Insurance Act of 1995], Republic Act No. 7875, § 6 (1995).

411. Philippine Pharmaceutical Country Profile, *supra* note 404, at 12.

412. *Id.* at 33.

medicines are likewise provided for persons afflicted with particular illnesses,[413] because of the way PhilHealth is structured, coupled with its shortcomings, persons often still spend for their own medicines. In particular, "drugs account for about half of household health spending among Filipinos."[414] Notably, "[PhilHealth's] low support value and its persistent preference for hospital-based coverage over out-patient care"[415] aggravate the situation. To illustrate, a Pharmaceutical Country Profile created by the government in cooperation with the WHO notes that it is often the case for public insurance systems (including PhilHealth) that "[on one hand] [f]or outpatients[,] 100% of payments are shouldered by the patient. [On the other hand,] [m]edicines coverage for inpatients[']' medicines is only valid up to a capped amount per single period of confinement[.]"[416] Furthermore, while the National Health Insurance Act of 1995 envisions universal coverage and mandates health insurance, the reality is that there are still many people, particularly the poor, who are not part of the PhilHealth system, or other forms of "risk pooling" such as those provided by private entities or the local government.[417] This contributes to why private spending still makes for a very large portion of the pharmaceutical market. This also explains "[w]hy [ ] drugs take up a large proportion of household medical care costs, especially among the poor[.]"[418]

As can be assumed, the fact that healthcare is mostly privately paid for in the Philippines affects most of all the poor sector of the population. For those falling in this sector, essential medicines are often inaccessible because of their cost. In fact, it has been said that one of the most notable reason for why access to essential drugs is hampered in the Philippines is "the low capacity to pay[.]"[419] In a 2009 household survey conducted by the WHO, it

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413. *Id.* at 33-34.

414. Oscar F. Picazo, Review of the Cheaper Medicines Program of the Philippines (A Discussion Paper Submitted to the Philippine Institute for Development Studies) at 9, *available at* http://dirp4.pids.gov.ph/ris/dps/pidsdps1213.pdf (last accessed May 12, 2017).

415. Philippine Pharmaceutical Country Profile, *supra* note 404, at 13.

416. *Id.*

417. Picazo, *supra* note 414, at 12.

418. *Id.*

419. Allan Grand A. Sobrepeña, Drug Regulation in the Philippines (A Working Paper Submitted to the National College of Public Administration and Governance of the University of the Philippines) at 2, *available at* http://www.esocialsciences.org/Download/repecDownload.aspx?fname=Document116620091 60.1892511.pdf&fcategory=Articles&AId=2073&fref=repec (last accessed May 12, 2017).

was found that among poor households, 77.5% of adults who had chronic conditions did not take all medicines prescribed to them because they could not afford them.[420] Among the same households, 74.5% of children with acute conditions also did not take all medicines prescribed for the same reason.[421]

Given the fact of private spending, it is not a surprise that drugs remain largely inaccessible to the poor, considering the drug prices in the Philippines. It has been observed that, "[in Asia,] the Philippines has some of the highest drug pricing levels when set against per capita income."[422] Additionally, whether evaluated according to geographic area or economic situation, the Philippines' drug prices are some of the highest when compared with other countries.[423] In fact, in Asia, only Japan has higher drug prices.[424] It is also estimated that Filipinos "are paying more than twice the price of the same branded off-patent drugs that are being sold in India and Pakistan."[425]

There are a number of factors that keep drug prices high in the Philippines. Some make the connection between high drug prices in the country and a "multinational drug cartel" which is particularly strong in the Philippines.[426] More obviously (and perhaps less inflammatory of an "accusation") however is the fact that the Philippine pharmaceutical industry has a largely monopolistic character to it. "At the wholesale distributor level, [on one hand,] Zuellig Pharmaceuticals, Inc. together with its subsidiary Metro Drug, Inc. distributes around 80% of the drugs sold in the market."[427] For retailers, on the other hand, Mercury Drugstore holds an estimated 80% share of the market, despite the many "players" in the industry.[428] Retailers also get their supply from Interphil Laboratories which control 80% of the

420. Philippine Pharmaceutical Country Profile, *supra* note 404, at 50.

421. *Id.*

422. Ames Gross, 2013 Philippine Pharmaceutical Market Update, *available at* http://www.pacificbridgemedical.com/publications/2013-philippines-pharmaceutical-market-update (last accessed May 12, 2017).

423. Picazo, *supra* note 414, at 9.

424. Sobrepeña, *supra* note 419, at 5.

425. *Id.*

426. Boo Chanco, *Botika ng Bayan needs more support*, PHIL. STAR, June 3, 2005, *available at* http://www.philstar.com/business/280192/botika-ng-bayan-needs-more-support (last accessed May 12, 2017).

427. Sobrepeña, *supra* note 419, at 8.

428. *Id.* at 8-9.

toll manufacturing from foreign pharmaceutical companies (which make up majority of the Philippine pharmaceutical market).[429] In turn, Interphil Laboratories is 70% owned by Zuellig Pharmaceuticals.[430] Given this set-up, it has been very easy to mark-up drug prices across a wide portion of the market, with consumers having limited alternatives.[431]

Aside from the monopolistic character of the pharmaceutical market, drug prices in the country have also been previously affected by the unavailability of generic medicine —

> Another key factor in the local pharmaceutical market is the overwhelming share of branded medicines. Before the end of the previous decade, the overwhelming demand for drugs [was] for originator brands and 'branded generics;' true generics accounted for a very small percentage (about [three] percent) of sales, whereas it accounted for as much as 50[%] of the U.S. market.[432]

The situation of a "sheer lack of supply of generic alternatives to households wanting them ... persisted until past the middle part of [the] 2000s when generics finally emerged on their own, thanks in part to initiatives [such as] parallel drug importation, village pharmacies ... and the like[.]"[433] The low price of generics has done much to slightly ameliorate the bleak situation of drug pricing in the country, and has contributed in part to combating the effects of the monopolistic environment.

There are two laws which are credited with improving the position of generic medicine in the Philippines. These are the Generics Act of 1988 (Generics Act)[434] and the Universally Accessible Cheaper and Quality Medicines Act of 2008,[435] more commonly known as the Cheaper Medicines Act. The Generics Act has many notable features, including

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429. *Id.*

430. *Id.* at 8.

431. *Id.* at 7-9.

432. Picazo, *supra* note 414, at 13.

433. *Id.*

434. An Act to Promote, Require and Ensure the Production of an Adequate Supply, Distribution, Use and Acceptance of Drugs and Medicine Identified by their Generic Names [Generics Act of 1988], Republic Act No. 6675 (1988).

435. An Act Providing for Cheaper and Quality Medicines, Amending for the Purpose Republic Act No. 8293 or the Intellectual Property Code, Republic Act No. 6675 or the Generics Act of 1988, and Republic Act No. 5921 or the Pharmacy Law, and for Other Purposes [Universally Accessible Cheaper and Quality Medicines Act of 2008], Republic Act No. 9502 (2008).

requiring prescriptions by all medical practitioners to be written in generic form (with brand name added if so desired).[436] It also mandated domestic pharmaceutical manufacturers to produce generic versions of their branded medicine.[437] Generic drugs are now required to be used in public hospitals, due to the Generics Act. It has been noted that "[a]s more doctors prescribe [generic] drugs, they are gaining acceptance among Filipinos."[438]

Despite the gains achieved by the Generics Act, brand-name drugs were still more widely available, even given the greater acceptance and sometimes also preference of the public for generic medicine. While the Generics Act mandated local manufacturers to produce generic medicine,[439] this was not sufficient to supply the needs of the pharmaceutical market, which can reach up to medicines worth two billion dollars every year.[440] This was mainly because "[t]he Philippines is one of the few countries whose market for medicines is dominated by foreign companies[.]"[441] It was estimated that, "[i]n 2012, [foreign pharmaceutical companies] captured three quarters of the Filipino drug market."[442] In addition, there was a time when "the country [did] not allow imported generics to participate in government procurement."[443] Generic medicines — unless their counterpart brand-name medicines were no longer protected by patent — could also not be imported by private parties due to the Philippines' laws on IP protection at that time.[444] The prevailing legal and administrative set-up simply did not allow for a sufficient amount of generic medicine to enter the market.

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436. Generics Act of 1988, § 6 (b).

437. *Id.* § 8.

438. Gross, *supra* note 422.

439. Generics Act of 1988, § 8.

440. Gireesh Chandra Prasad, *Philippines set to source generic drugs from India*, ECON. TIMES, Mar. 19, 2007, *available at* http://economictimes.indiatimes.com/news/industry/healthcare/biotech/pharmaceuticals/philippines-set-to-source-generic-drugs-from-india/articleshow/1776230.cms?intenttarget=no (last accessed May 12, 2017).

441. Amy R. Remo, *'Botika ng bayan' makes cheaper medicines available to poor*, PHIL. DAILY INQ., Mar. 8, 2007, *available at* http://newsinfo.inquirer.net/breakingnews/metro/view/20070318-55594/%91Botika_ng_bayan%92_makes_cheaper_medicines_available_to_poor (last accessed May 12, 2017).

442. Gross, *supra* note 422.

443. Prasad, *supra* note 440.

444. *Compare* An Act Prescribing the Intellectual Property Code and Establishing the Intellectual Property Office, providing for its Powers and Functions, and for Other Purposes [INTELL. PROP. CODE], Republic Act No. 8293, § 72.1 (1997)

While there were efforts by the DOH to introduce parallel importation in the 2000s, it was limited to government programs and public procurement activities. This all changed with the enactment of the Cheaper Medicines Act. The passing of the law was "intended to achieve universally accessible[,] cheaper[,] and quality medicines by pursuing an effective competition policy[,]" among other things.[445] It allowed for parallel importation by private parties through the issuing of compulsory licenses.[446] This meant that although a particular medicine was patent protected, if any of the grounds in the law were met, a compulsory license could be issued, allowing both the government and private third parties to either import or manufacture a generic version of the medicine.[447] Grounds for compulsory licensing include: "national emergency or other circumstances of extreme urgency,"[448] reasons of public interest,[449] and when the demand for a

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with Universally Accessible Cheaper and Quality Medicines Act of 2008, § 7. Section 72 of the Intellectual Property Code, before amendments, reads —

> The owner of a patent has no right to prevent third parties from performing, without his authorization, the acts referred to in Section 71 hereof in the following circumstances:
>
> 72.1. Using a patented product which has been put on the market in the Philippines by the owner of the product, or with his express consent, insofar as such use is performed after that product has been so put on the said market;

INTELL. PROP. CODE, § 72.

The amendment to the Intellectual Property Code to be found in the Cheaper Medicines Act states that Section 72.1 should now read as such —

> Using a patented product which has been put on the market in the Philippines by the owner of the product, or with his express consent, insofar as such use is performed after that product has been so put on the said market: *Provided*, That, with regard to drugs and medicines, the limitation on patent rights shall apply after a drug or medicine has been introduced in the Philippines or anywhere else in the world by the patent owner, or by any party authorized to use the invention: *Provided, further,* That the *right to import the drugs and medicines contemplated in this* [*S*]*ection shall be available to any government agency or any private third party*;

Universally Accessible Cheaper and Quality Medicines Act of 2008, § 7 (emphasis supplied).

445. Picazo, *supra* note 414, at 7.

446. Universally Accessible Cheaper and Quality Medicines Act of 2008, §§ 10 & 11.

447. *Id.* § 10.

448. *Id.*

patented product is not being met on reasonable terms.[450] This law opened the door for imports from countries like India, which have "developed their pharmaceutical industry well enough to manufacture... drugs that could be sold as generics."[451] In fact, the passing of the Cheaper Medicines Act and the consequent amendment of the Intellectual Property Code fulfilled the claims of a Philippine delegation which was sent to India before the Cheaper Medicines Act was enacted, that laws would be amended because the Philippines wanted to "import inexpensive generic drugs from India."[452] Now, the Philippines is included in the list of countries who benefit from the importation by India's generics manufactures of around $11 billion worth of medicines every year.[453]

The influx of generic medicine into the country, thanks to the amended legal system, as well as the existence of generics powerhouses such as India, has had a profound effect on the Philippines. Although prices of brand-name drugs are still comparatively high, they "have gone down through [competition brought by] their generic counterparts [sold by public and private sources] throughout the country. It is as if the [establishments] selling generics have brought down the once-dominant sellers of innovator drugs, causing them to lower their prices dramatically."[454] It has been noted that "[i]n order to compete with the generic drugs ... many foreign pharmaceutical firms are slashing the prices of their own branded drugs by as much as 60[%]."[455] More importantly, generic medicine is now more readily available, cutting down the money spent on health by Filipinos. "Through the generic drugs and related goods produced by the Indian pharmaceutical companies, the prices of commonly used drugs by the Filipinos have been

449. *Id.*

450. *Id.*

451. Chanco, *supra* note 426.

452. Prasad, *supra* note 440.

453. Wenceslao E. Mateo Jr., Biron's bill: The better version of the Cheaper Medicine's Act, *available at* https://thedailyguardian.net/option/birons-bill-the-better-version-for-the-cheaper-medicine-act (last accessed May 12, 2017). *See also* Embassy of India, Bilateral Trade and Economic Relations, *available at* http://www.indembassymanila.in/eoi.php?id=Bilateral (last accessed May 12, 2017). The list provides that pharmaceutical product placed third in the most number export products of India to the Philippines.

454. Picazo, *supra* note 414, at 27.

455. Gross, *supra* note 422.

brought down to half the cost."[456] A report produced in 2012 stated that during that year, "[five to six] out of 10 Filipinos [ ] purchased generic drugs. [Also,] an increasing proportion of Filipinos [were] buying cheaper generic drugs, and the proportion of households who did not buy medicines (for any reason) [ ] declined significantly."[457] The same report noted that generic medicine sold "at prices 55-80[%] lower than their branded counterparts."[458]

The importation of generic medicine from places such as India have also given life to many government projects intended to help facilitate the poor's access to medicine.[459] One of these included the *Gamot na Mabisa at Abot Kaya* (GMA 50) Program, which involved the Philippine International Trading Corporation (PITC) using parallel importation to import generic drugs "mostly from India and Pakistan"[460] and the distribution of these drugs by the DOH "in its 72 DOH-retained hospitals and three [local government unit] hospitals in the Autonomous Region of Muslim Mindanao[.]"[461] This reportedly caused "an estimated average of 60.9[%] price reduction of drugs,"[462] as found by the DOH's Pharmaceutical Management Unit.[463]

Other significant programs helped along by the availability of generic drugs from other countries such as India include the Botika ng Bayan and Botika ng Barangay projects. These initiatives were partnerships between the public and private sectors to set-up drug stores which would sell generic medicine supplied by PITC which, like the GMA 50 program's medicines, are mainly imported from India and Pakistan. By 2007, "there were about 1,300 Botika ng Bayan outlets ... and more than 7,000 Botika ng Barangay stores" in the country.[464] An article notes that together, these small drug stores have a wider reach than Mercury Drug stores, the leading drug store in the country.[465] Although there is still much to be desired from the programs, the drug stores set up by the Botika ng Bayan and Botika ng

456. Jose B. Santarita, India Matters: A Philippine Perspective on 'Rising India,' *available at* http://philippinesintheworld.org/?q=node/1613 (last accessed May 12, 2017).

457. Picazo, *supra* note 414, at 11.

458. *Id.*

459. Santarita, *supra* note 456.

460. Picazo, *supra* note 414, at 15.

461. *Id.*

462. *Id.*

463. *Id.*

464. Remo, *supra* note 441.

465. Chanco, *supra* note 426.

Barangay initiatives have succeeded in improving the availability of affordable generic medicines in the country. The initiatives have also been shown to have

> important demonstration effects. Realizing that low-cost retail of drugs can be profitable (as shown by the best [Botika ng Bayans]), for-profit drug franchise operations have mushroomed quickly, most notably The Generics Pharmacy, the first generics retail pharmacy to franchise in the Philippines. It is now reputed to have 1,100 franchisees nationwide[.][466]

The rise of Botika ng Bayan branches, Botika ng Barangay branches, and private pharmacies specializing in generic medicines have done much for the availability of affordable medicine in the Philippines. The rise of these drug stores also helps in addressing the dilemma of distribution. Previously, even if the government did obtain generic medicine, it only distributed through government hospitals (as shown in the GMA 50 program), which have a 2.3% share of the market.[467] Since most Filipinos get their medicines from drug stores — 80.1% of drugs are coursed through drug stores[468] — generics were not effectively distributed and the monopolistic character of the pharmaceutical marketing industry was greatly felt from the prices. With the rise of public-private partnership powered drug stores and private generics drug stores, two main reasons for large drug prices are being addressed. Generics are being made widely available as an alternative to more expensive brand-name drugs, and the monopoly's market share is also lessening.

The availability of generics however, is highly dependent on importation, as the Philippines does not have the manufacturing capacity to supply enough generics to meet the demand of its population.[469] Partnerships between India and the Philippines relevant to importing medicines have even been described as lifelines for the Botika ng Barangay and Botika ng Bayan projects.[470] It is easy then to see how a stopping of the supply of generic medicines could affect the gains achieved by the Philippine government and other players so far relevant to access and availability of medicines.

B. AIDS in the Philippines

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466. Picazo, *supra* note 414, at 29.

467. Sobrepeña, *supra* note 419, at 9.

468. *Id.* at 7.

469. *See* Philippine Pharmaceutical Country Profile, *supra* note 404, at 20–21.

470. Santarita, *supra* note 456.

While an absence in the supply of generic medicine can be a cause of concern for all persons who have to deal with the effects of diseases, it is particularly troubling for people who live with HIV or AIDS, and who depend on affordable ARV medicine, literally, for their life. It is a cause for alarm for the Philippines, in particular, as the country "is one of only two countries in Asia, and one of seven globally,"[471] whose numbers of persons living with HIV/AIDS (PLHIV) are rising.[472] The other six are Armenia, Bangladesh, Georgia, Kazakhstan, Kyrgyzstan, and Tajikistan.[473]

In 2016, "the number of people known to need HIV [ARV] medication is more than 38,000."[474] The first nine months of 2011 alone saw almost 1,700 new reports of HIV cases.[475] Reports have noted that "when looking at [t]he Philippines[']] HIV epidemic as a whole, there has been a 1,490[%] increase in HIV diagnoses between 2005 and 2012."[476] The recorded increase from 2012 to 2013 was at 79%.[477] By the end of 2013, a new case was being reported every two hours.[478] In 2014, the month of February saw 486 new cases of HIV, 36 of which had already developed into AIDS.[479]

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471. United Nations Children's Fund, Philippines: Issue, *available at* http://www.unicef.org/philippines/hivaids.html#.U4RC2nKSxXk (last accessed May 12, 2017). *See also* Philippine Daily Inquirer, *26 new HIV cases daily*, PHIL. DAILY INQ., Dec. 1, 2016, *available at* http://opinion.inquirer.net/99661/26-new-hiv-cases-daily (last accessed May 12, 2017).

472. *Id.*

473. HDT/Sunnex, DOH rejects call to declare HIV emergency, *available at* http://www.sunstar.com.ph/manila/local-news/2014/05/27/doh-rejects-call-declare-hiv-emergency-344989 (last accessed May. 12, 2017).

474. Laurindo Garcia, No more shame: Living with HIV in the Philippines, *available at* http://cnnphilippines.com/life/culture/2016/12/01/living-with-HIV-in-the-Philippines.html (last accessed May 12, 2017).

475. Bernadette A. Parco, The cost of treating HIV, *available at* http://www.sunstar.com.ph/cebu/feature/2011/12/02/cost-treating-hiv-193728 (last accessed May. 12, 2017).

476. AVERT, *supra* note 400.

477. United Nations Children's Fund, *supra* note 471.

478. Philippines National AIDS Council, Global AIDS Response Progress Reporting 2014 (A Country Progress Report on the Philippines) at 6, *available at* http://files.unaids.org/en/dataanalysis/knowyourresponse/countryprogressreports/2014countries/PHL_narrative_report_2014.pdf (last accessed May 12, 2017) [hereinafter Global AIDS Response Progress Reporting 2014].

479. Tina G. Santos, *HIV cases rose 43% to 486 in February; 16 AIDS deaths reported — DOH*, PHIL. DAILY INQ., Apr. 1, 2014, *available at* http://newsinfo.inquirer.

This was "a 43[%] increase from figures seen in the same period in 2013"[480] according to the DOH.[481] Of the people living with HIV in the Philippines, the key population whose numbers are rising, according to Ms. Teresita Marie P. Bagasao, Country Director of the Joint United Nations Programme on HIV/AIDS (UNAIDS) Philippines, are those of males, aged 16-30.[482] She notes, furthermore, that certain hotspots exist in the country, mostly urban areas, where incidences of HIV/AIDS seem to be more concentrated, or at least, more prevalent.[483] Regarding the number of cases in the Philippines, Bagasao notes that the numbers both UNAIDS and government departments such as the DOH have do not reflect all of the actual cases present in the country.[484] In fact, she estimates that the Philippines is under-reporting anywhere between 50%-80%, and that measures to address the situation of HIV/AIDS in the country are not reaching 50% of key populations.[485]

HIV/AIDS, because of its status as an emerging concern for the country, and because of the number of cases present domestically, takes up a considerable amount of the Philippines' resources. In just a span of three years (2009-2011), "[a] total of [₱]1.7 billion [ ] (U.S. $37 million) was spent on AIDS ... or an annual average of [₱]560 million [ ] (U.S. $12.4 million)."[486] Of this amount, 48% was sourced from international "development partners," 27% from the private sector, including private foundations, and 25% from the Philippine government. Funding for various AIDS-related programs became a concern some time in 2010 when "[a] significant decrease in spending was observed among international sources primarily because of the closure of two grants of the Global Fund."[487] This in turn, was made up for by both private and public expenditure.[488] In the

net/590915/hiv-cases-rose-43-to-486-in-february-16-aids-deaths-reported-doh (last accessed May 12, 2017).

480. *Id.*

481. *Id.*

482. Interview *with* Teresita Marie P. Bagasao, *in* Makati, Philippines (June 2, 2014).

483. *Id.*

484. *Id.*

485. *Id.*

486. Philippines National AIDS Council, Global AIDS Response Progress Reporting 2012 (A Country Progress Report on the Philippines) at 21, *available at* http://files.unaids.org/en/dataanalysis/knowyourresponse/countryprogressreports/2012countries/ce_PH_Narrative_Report.pdf (last accessed May 12, 2017).

487. *Id.*

488. *Id.*

2014 version of the report from which the 2009-2011 figures were culled, it was observed that spending on HIV/AIDS was rising from 2011 to 2013.[489] In 2011, international and public sources combined for a total of P346 million spent to address HIV/AIDS, ₱401 million in 2012, and ₱412 million in 2013.[490] This does not include private sector spending, data of which was not available for the report. Bagasao estimates that around 30% of spending comes from the government, while 50% comes from foreign/external funding, the rest being personal and local foundation expenses.[491]

Currently, the Philippines provides free HIV/AIDS medication to the population.[492] However, the late Dr. Alberto G. Romualdez, Jr., former Secretary of the DOH, once noted that should numbers keep increasing, the cost would not be something the Philippines could bear.[493] He said,

> AIDS patients require a steady supply of expensive medicines and they can live a long time. Because of this, the disease can put a tremendous burden on [the country's] health care system. [The] country cannot afford to have a full-blown AIDS epidemic on top of the usual diseases like tuberculosis and dengue.[494]

Drugs, which are shouldered by government and is a large chunk of what the budget is spent on, play a role in two major components of HIV/AIDS spending in the Philippines — prevention, and care and treatment.[495] Drugs given to prevent mother-to-child transmission of HIV belong to the former, and ARV drugs for those already infected belong to the latter. Other than drugs, however, prevention also comprises of other reproductive health products such as condoms, and information materials.[496] Other components of spending include social services, program

489. Global AIDS Response Progress Reporting 2014, *supra* note 478, at 21.

490. *Id.*

491. Interview *with* Teresita Marie P. Bagasao, *supra* note 482.

492. *See* Mayen Jaymalin, *DOH: Over 10,000 HIV patients getting free treatment*, PHIL. STAR, July 6, 2015, *available at* http://www.philstar.com/headlines/2015/07/06/1473818/doh-over-10000-hiv-patients-getting-free-treatment (last accessed May 12, 2017).

493. Ana P. Santos, [DASH OF SAS] Is HIV going out of fashion?, *available at* http://www.rappler.com/move-ph/ispeak/47038-hiv-going-out-of-fashion (last accessed May 12, 2017).

494. *Id.*

495. Global AIDS Response Progress Reporting 2014, *supra* note 478, at 20.

496. *Id.*

management, and administrative strengthening.[497] Indeed, in the Philippines, addressing HIV/AIDS is a costly endeavor, and the number will only rise as both the population and the number of HIV/AIDS cases grow.

For every PLHIV, the cost for initial or "first-line" treatment would amount to about ₱7,920 (2011) to ₱9,000 (2014) a year.[498] If one develops AIDS, and therefore becomes more susceptible to opportunistic diseases, the cost of medicines goes higher, and is pegged at about ₱11,520 (2011) to ₱18,000 (2014) per year.[499] These figures already reflect the lower prices of medicines made available for the poorer countries of the world, and made possible by various firms from India,[500] and other manufacturers such as Thailand.[501] In contrast, before the so-called "price breaks" on these medicines, a year's supply of a brand-name AIDS cocktail — a term used for the combination of ARV drugs used for AIDS — would be priced at around $12,000.[502] However, considering that most funding is outside of State control (as much as 70% of funds are not from the government), the rising cost of HIV becomes a pressing issue, one that the Philippines may not always be able to address. When asked during the interview if she thought that the Philippines could sustain the programs it has to address AIDS relying solely on government funding, Bagasao affirmed that no, it definitely could not.[503]

VII. CONCLUSIONS AND RECOMMENDATIONS

A. The Problem with Data Exclusivity

This Note began with the question of how data exclusivity affects human rights. More specifically, it sought to examine how implementing a data exclusivity clause in the FTA between India and the EU would affect access to medicine, considering India's position as a major generics manufacturer,

497. *Id.*

498. Interview *with* Teresita Marie P. Bagasao, *supra* note 482 & Parco, *supra* note 475.

499. *Id.*

500. Donald G. McNeil, Jr., *AIDS: A Price Break for Antiretroviral Drugs in 70 of the World's Poorest* Countries, N.Y. TIMES, May 23, 2011, *available at* http://www.nytimes.com/2011/05/24/health/24global.html?_r=0 (last accessed May 12, 2017).

501. Through programs known as "South to South Cooperation." Interview *with* Teresita Marie P. Bagasao, *supra* note 482.

502. *Id.*

503. Interview *with* Teresita Marie P. Bagasao, *supra* note 482.

and whether access to medicine could be reasonably positioned within the rights to health and life, as recognized in international law and expounded on by jurisprudence, domestic laws, and issuances from international bodies such as the U.N. In the course of attempting to come to an answer regarding these issues, this Note has also shown other issues to factor in when discussing the matter of data exclusivity. These issues include the proper place of the right to property vis-à-vis other human rights, the logic behind the data exclusivity provisions, an expanding definition of the right to life in international law, as well as what the data exclusivity clause could mean for parties beyond India and the EU — the Philippines in particular.

Data is considered property, and is a species of property protected by IP law. The owners of this data are called originators. These are pharmaceutical corporations who are responsible for researching, developing, and testing "pioneer" drugs which are to be released into the market. In the course of this research, they gather the data needed to have these drugs approved by government regulatory boards who are in charge of allowing various pharmaceutical products onto the public market. These data represent a substantial investment, an investment that originator companies seek to recoup. Admittedly, recovering costs is made harder if there is competition in the market provided by generic medicine, which is more affordable, and, for the most part, just as effective as pioneer or brand-name drugs.

Companies that produce generic medicine do not conduct their own testing.[504] Instead, they rely on the data submitted by the originator companies to the government regulatory boards, or by purchasing samples of the brand name drug. These boards in turn employ what are called bio-equivalency tests.[505] These tests compare the data submitted by originator companies with the composition of the generic medicine, in order to infer whether a product seeking approval is as safe, effective, and appropriate for its target market. In this manner, generics companies are able to bypass the costly and resource intensive research that originator companies have to go through in order to gain approval for their pharmaceutical products. By making bio-equivalency tests an option for generics companies, India has become a hub for cheap but effective generic pharmaceutical products,

504. This is oftentime due to the incapacity and incapability of those companies to repeat all the necessary tests and trials. Cartagena & Attaran, *supra* note 98, at 274. *See also* Erin Fox, How Pharma Companies Game the System to Keep Drugs Expensive, *available at* https://hbr.org/2017/04/how-pharma-companies-game-the-system-to-keep-drugs-expensive (last accessed May 12, 2017).

505. For example, in the U.S., the "board" is the Food and Drug Administration, which just requires that companies follow the current good manufacturing practices. Fox, *supra* note 504.

supplying not only its own population but also catering to the needs of various developing countries all over the world, including the Philippines.

Data exclusivity functions by preventing parties other than the originator from relying on data originators have submitted for purposes of obtaining approval from regulatory boards and entering the market. The foremost concern with data exclusivity is the impact it will have on the availability and affordability of medicines.[506] Studies using both projections and actual data have shown that the general trend for countries implementing data exclusivity is a rise in the price index of medicine (which may result in a decrease in medicine consumption for poorer countries) and even a loss or shortage of certain drugs in the market.

The TRIPS Agreement does not espouse data exclusivity. It merely obliges States to protect data from unfair commercial practices and undue disclosure. As a response to this, many States have instead turned to FTAs in order that they may compel a State without domestic laws on data exclusivity to enact such provisions. The fact that data exclusivity provisions are a possibility in the EU-India FTA currently being negotiated is a cause of concern for many, considering India's position as the provider of generic medicine to the developing world, and the adverse impacts data exclusivity is known to have on the availability of more affordable pharmaceutical products.

Since the subject matter which data exclusivity affects in this case is medicine, it is unavoidable that the discussion on the propriety of data exclusivity would mostly center on the human rights to health and to life.

The right to health imposes three main obligations on States: to respect, protect, and fulfill. As to what these obligations refer to, commentators recognize that the three obligations describe how States should address the availability, accessibility, quality, and acceptability of the right to health and its components, one of which is access to medicine. Access to medicine now solidly plays a role in the realization of the right.

Data exclusivity endangers India's compliance with a number of its duties under the right to health. First and foremost, the effects of data exclusivity can lead to a violation of India's duty to respect accessibility and availability of medicines. Considering the ethical implications of repeating human testing, it may also affect the obligation to protect medicine's

506. *See* Interview *by* Médecins Sans Frontières *with* Janice Lee (NOV. 4, 2010), *available at* http://www.doctorswithoutborders.org/news-stories/field-news/why-indias-generic-medicines-industry-so-important (last accessed May 12, 2017).

acceptability. Finally, data exclusivity implemented through the FTA could affect the obligation to fulfill the right to health in general, as it constitutes a retrogressive measure because it disturbs India's already achieved level of fulfillment with regard to access and affordability of medicine. Furthermore, such retrogressive measure cannot be justified as it is not needed for a balanced and substantial realization of other rights in the ICESCR.

The effects of data exclusivity also spell concerns for the realization of the positive component of the right to life. States are obligated to ensure conditions which will help sustain life and improve its quality. A State's refusal to provide medical care or access to basic health services can constitute a violation to the right to life. If India and the EU were to implement an FTA with data exclusivity provisions, many would have a harder time accessing medicines on which their lives depend. This may also amount to a violation of the right to life as it is a conscious act by the government — much more damning than omissions which are the standard when determining whether a State has violated the right to life.

B. The India-EU FTA

India should not sign the FTA with the EU, which include data exclusivity provisions. Introducing data exclusivity through an FTA into India's legal system would mean substantial consequences for India's compliance with the obligations under the right to life and the right to health. Nations such as the Philippines should also be concerned, given that it is not only India's citizens who will be affected but the citizens of other developing countries who rely on importation of medicines from India as well.

An alternative would be for any data exclusivity measure to be not a blanket prohibition. Rather, different time periods should be put in place depending on the kind of medicine which is seeking approval. An example would be classifying the medicine according to the kinds of illnesses they treat, or whether or not they are on the WHO list of essential medicines. Drugs for serious illnesses for example such as HIV/AIDS, malaria, and tuberculosis should have no exclusivity period. Drugs for less serious illnesses such as fevers or colds can have a shorter exclusivity period, while medicines which have more general usage such as antihistamines and painkillers can have a longer exclusivity period.

Another option could be to add a compulsory license provision to the FTA. This, in effect, would allow others to rely on the data for approval even without the originator's consent, should there be valid grounds. Valid grounds should include reasons such as public health emergencies, epidemics, and export to aid developing countries without capacity to produce their own medicine. To better assure proportionality between the control applied

to serve public interest and the property rights of the owner, the FTA can provide for reasonable compensation or other concessions by way of other areas relevant to trade such as taxes and quotas.

C. Philippine Measures

The Philippines does not have direct standing in this issue as it is not a party to the EU-India FTA. It will, however, be affected since India is a source of affordable medicine. The Philippines is a country whose pharmaceutical industry is highly dependent on foreign players.[507] It is not a country which has the capacity to manufacture enough medicine to answer for the pharmaceutical demand its population produces every year. It, thus, relies heavily on importation of medicines from other countries. Additionally, because much of the population is still considered to be poor, efforts have also been made to educate the public about generic medicine and to encourage the use of such medicines, which are more affordable.

HIV/AIDS is of particular concern for the Philippines, as the country is one of seven in the world whose number of persons living with HIV/AIDS is rising.[508] While the government currently has programs in place for providing free medicine for those who have contracted HIV/AIDS, much of our spending is dependent on international financing. Government funds account for at most only 30% of spending for HIV/AIDS treatment.[509] For now, the government is able to carry out its measures addressing HIV/AIDS in the country because there is an agreeable balance between how much treatment, research, and other factors cost, and how much money is being given. Should the price of medicine rise even further, the 30% spent by the State will account for less and less of what is needed to completely address HIV/AIDS in the Philippines. Additionally, whether there will be a corresponding rise in international funding is beyond the control of the government. A rise in the cost of HIV/AIDS treatment is not something the Philippines can afford. While certainly, India is not the only place which produces generic medicine, even for serious diseases such as AIDS, it is one of the few places which has the capacity to produce not only for its burgeoning population, but for other countries as well.

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507. *See* Gross, *supra* note 422.

508. Philippine Daily Inquirer, *supra* note 471 & Claudeth Mocon-Ciriaco, *PHL sex stance in focus as HIV/AIDS cases rise*, BUS. MIRROR, Dec. 20, 2016, *available at* http://www.businessmirror.com.ph/phl-sex-stance-in-focus-as-hivaids-cases-rise-2 (last accessed May 12, 2017).

509. Interview *with* Teresita Marie P. Bagasao, *supra* note 482.

The Philippines should prepare in case the data exclusivity provisions be approved and implemented in the EU-India FTA. The Philippine National AIDS Council (PNAC) should monitor the situation with India, as well as other drug producers with which EU is looking to negotiate a treaty with, such as Thailand. Depending on the developments, the PNAC should make recommendations for where local funds should go, and which aspects of the HIV/AIDS program of the Philippines should be prioritized considering the foreseeable rise in their cost.

The Philippines should also consider passing legislation and investing in strengthening the pharmaceutical manufacturing capacity of the country.

Access to medicines is part and parcel of the right to health and the right to life. It is now unthinkable to imagine fulfilling the right to health, especially in the context of serious but treatable diseases such as HIV/AIDS without considering the need for treatments through pharmaceutical products. In the same light, because of the very nature of life-saving medicines and the situations which call for them, they are demandable under the right to life. To lose or even shorten any number of lives to a treatable disease is unacceptable, especially that it should happen in our time, a period of unparalleled development in the areas of science and technology.

Data exclusivity, in the context of an imposition on India, is a one-sided measure. It seeks no balancing act. It caters to private interests without considering the disproportionate impact on the public good.

Human rights are personal, but also universal; established but fluid; sometimes violated, but always enduring. However, they are rendered for naught without those who are willing to defend them. In this day and age, when threats to human life, health, and dignity are taking newer forms, our understanding too of human rights must develop, and so should our willingness to push for them. This is especially true for the rights to life and health, rights which go to the very core of a person's existence. They are rights which greatly determine the capacity to enjoy other rights. It is no exaggeration to say that everything must be done before they are compromised. To implement data, exclusivity however, would be compromising them for much less.