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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This Note is an exploration of two competing fields of law — human rights and intellectual property (IP). It explores how the two legal regimes, with their frameworks, interact and clash over a fundamental issue — access to medicines.

The right to health is recognized by international law as a fundamental part of human rights. One of its key components is granting access to medicines to all who need it. Meanwhile, however, IP laws aim to protect the owners of the information and formulation necessary to produce medicine from exploitation, given that it is these same owners who invested financially and creatively in the research and development of the medicines involved. IP law thus tends to favor originator companies, i.e., the pharmaceutical companies that first invested billions of dollars in formulating the drug. On the other hand, human rights law, inasmuch as it leans towards access to medicines for all, tends to take the stance which hastens wider availability in the market — thus, it favors earlier access granted to generics companies.

To examine the intricacies of this juxtaposition, the Author zeroes in on the particular experience of India and the evolution of its laws on patents, particularly with regard to pharmaceuticals. For years, India has been the generics provider of the developing world, and is therefore the source of

medicines for many serious diseases such as HIV/AIDS. By reason of the State's signing of the Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), India adapted changes into its laws which ultimately espoused data protection, as opposed to data exclusivity. Data exclusivity is a practice whereby generics companies are prohibited from availing of bio-equivalency tests for a certain period. As such, government regulatory boards cannot rely on data submitted in relation to an already approved drug in order to make conclusions about a new drug's efficacy, safety, and quality. As a result, new entrants, the more affordable generics, are not able to enter the market.

However, an impending Free Trade Agreement (FTA) between India and the European Union may require India to amend its patents law once more and integrate data exclusivity. Such exclusivity, as highlighted by the Author, would make it difficult to access to medicines for HIV/AIDS, and have ramifications to the Philippines and other developing nations, which relies heavily on pharmaceutical imports.

Through this Note, the Author discusses how the FTA could be a potential roadblock for the continued manufacturing of cheap, accessible, generic medicines in India. The Author discusses the legal frameworks of both human rights and IP law and attempts to answer this pressing question — which should prevail?