CURRENT DEVELOPMENT OF CANADA'S DATA EXCLUSIVITY REGIME: HOW DOES CANADA REACT TO NAFTA, TRIPS AND DANGLE BETWEEN PHARMACEUTICAL INNOVATION AND PUBLIC HEALTH?

Pei-kan Yang*

ABSTRACT

As data exclusivity has first been incorporated into the North American Free Trade Agreement in 1993, the Government of Canada has endeavored to implement its international obligations by introducing the data exclusivity regime into section C.08.004.1 of Food and Drug Regulations with a view to encourage the pharmaceutical innovation and investment. On the other hand, it has also struggled to implement the data exclusivity regulations in a way to ensure the Canadian having the access to affordable medicines so that the rule will not be detrimental to the public health.

This essay surveys the historical development of data exclusivity regulations in Canada by examining Regulation C.08.004.1, the 1998 judicial ruling in Bayer Inc. v. Canada and the 2006 newly-amended data exclusivity regulations, and tries to argue that despite being criticized to be detrimental to the public heath, some of amended data exclusivity provisions aims to mitigate the potential impacts on access to affordable medicines, and this Canadian model can be referred to especially for those countries have no choice but to introduce the data exclusivity

* Assistant Professor of Law, Graduate Institute of Financial and Economic Law, Feng Chia University, Taichung, Taiwan. J.D., Duke University School of Law, U.S.A.

regime. Even though, current Canadian regime is devoid of health-friendly provisions to exempt the application of data exclusivity to drugs in solving national health crisis. It is suggested that compulsory license exception or early working exception be provided under data exclusivity regime.

KEYWORDS: *Data Exclusivity, Data Protection, NAFTA, TRIPS, Undisclosed Test Data, Trade Secret, Generic Drugs, TRIPS-Plus Provisions*