Center for Innovation Policy
Duke University School of Law

“New Approaches and Incentives in Drug Development”

Professor Jerome H. Reichman

November 22, 2013
2 Clinical Trial Articles


Jerome H. Reichman

Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

7 USC § 136
Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods


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

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

   (a) is secret in the sense that is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

   (b) has commercial value because it is secret; and

   (c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

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

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

The International Legal Status of Undisclosed Clinical Trial Data: From Private to Public Goods?
in NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES
(P. Roffe et al, eds., Earthscan, 2005) 133