A New IP Balancing Act: Clinical Trial Transparency versus Trade Secrecy and Beyond

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This article aims to address a new tension between public health and IP interests. In particular, this article focuses on how to promote public health by increasing "clinical trial transparency" without violating IP interests of drug companies. Essentially, the goal is to make more underlying clinical data behind regulatory approval (or denial) of drugs public to avoid safety problems, wasted money and duplicative research. This is essential since data reviewed by regulators is generally more comprehensive, and sometimes different than data that appears, if at all, in published articles. Although independent researchers may develop their own data. However, thus far that has been the process since companies have long asserted that data submitted to regulatory agencies such as the FDA constitute trade secret information. Moreover, since the WTO/TRIPS agreement, some companies have alleged that their claims are further supported by TRIPS article 39, the first-ever international provision protecting any type of trade secrecy.

Although there are some domestic regulations requiring greater disclosure of clinical trial data, not only is compliance low, but companies may have grounds to challenge such disclosure as violating their IP rights, with TRIPS playing a major role. In particular, EU regulations proposing to increase clinical trial transparency may for the first time test to scope of one of the most contentions TRIPS provisions – the requirement that countries protect data submitted for regulatory approval from "unfair commercial use" and also "protect such data from disclosure except where necessary to protect the public."
This article will explain how the relevant TRIPS provision should be properly interpreted consistent with public health goals and without completely vitiating the rights of companies. The article will also explain why such actions should not be challenged as violations of any intellectual property rights under so-called "investor-state" provisions that exist in many free trade agreements. Finally, the article aims to explore additional methods to promote the public health interests beyond regulations mandating greater disclosure in lack of inadequate compliance.