Journal of Developing Drugs
ISSN: 2329-6631

Freeman, J Develop Drugs 2015, 4:4
DOI: 10.4172/2329-6631.1000e145

Editorial Open Access

Why it is Important to Protect Intellectual Property and Data Confidentiality in Trade Agreements

Robert Freeman*

Department of Pharmacy Practice and Administration, Eastern Shore School of Pharmacy, The University of Maryland, Maryland, USA

Although economic policy is seldom explicitly considered in drug discovery and development, international trade agreements is a significant factor in the overall decision-making process regarding current and future developmental portfolios. This observation is based on the key role that trade agreements play in standardizing patents and regulatory data protection across the member nations. The European Union (EU), for example, has benefited the pharmaceutical industry by harmonizing patent life across the member states and facilitated regulatory approval by establishing a central regulatory authority. Unfortunately, the EU has also facilitated parallel trade by allowing the unfettered movement of prescription drugs from "low price" countries to "high price" countries.

The Trans-Pacific Partnership (TPP) is an ongoing series of trade negotiations involving The United States, Canada, Mexico, Australia, New Zealand and a number of other countries in the Pacific Rim. Some of the countries are consider developed (e.g., The USA, Australia and New Zealand) while others are developing (e.g., Vietnam and Malaysia). It is an open agreement in that other countries may enter at any point in the negotiations. Although the World Trade Organization (WTO) sets minimum standards for patent protection and removes tariff and other restrictions on trade, it is often necessary to strengthen these accords through additional bi-lateral or regional trade agreements such as the TPP.

The ultimate goal of the TPP is to give a fully transparent, level playing field by eliminating tariffs and other trade barriers. In effect, this goal is accomplished by requiring that a member states treat foreign and domestic firms on an equitable basis. Although the TPP address a variety of industrial, agricultural, and labor sectors, it is especially relevant to the pharmaceutical and biologics industry because of the importance that patents and data protection have in the negotiations.

Accordingly, the TPP is not unlike other trade accords that govern Intellectual Property Rights (IP) and Regulatory Data Protection (RDP) treatment. The Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) contains language covering both patents and RDP, setting minimum standards for nations that belong to the World Trade Organization (WTO). TRIPS also contain remedies that countries can pursue when a member state egregiously violates the agreement's provisions.

It is commonly acknowledged that patents are absolutely essential to incentivize innovation. Without patents innovators could not generate sufficient profits and revenues to sustain research and development. Patents, however, are only one part of the TPP talks and IPR. The other distinct component is RDP, which consists of proprietary, confidential information about a new drug's or biologic's safety and efficacy. While the topic is not in the public's eye, data confidentiality, or privacy, is essential to the commercial success of a new drug because patents in and of themselves do not assure commercial success. Although patent length for small molecule drugs and for biologics is standardized by the World Trade Organization, RDP length is decided at the local country level and is set for a limited time and varies greatly amongst nations. A particularly contentious issue in the negotiations is the length of time for RDP. The developed countries led by the USA are pushing for a 12-year data exclusivity period for biologics, while other countries are lobbying for a 7-year period. Given the inherent technical difficulties in developing biosimilars, the longer data exclusivity period is essential.

For patients and consumers, as well as for research based health industries, IPR and RDP protections encourage and justify private investment in the development of new treatments and cures. Upon expiry of IP and RDP protections, consumers and public and private third-party prescription drug payers benefit by the introduction of generic drugs and the lower prices that follow. For a generic drug to become available following patent expiry, the generic manufacturer must either produce safety and efficacy data through research or through the use the safety and efficacy data in the innovator's regulatory file that was originally submitted for marketing approval.

Obviously generic and biosimilars manufacturers prefer to access the innovator's data because it is significantly less costly for the generic company to use existing regulatory data instead of being required to conduct original research to establish safety and efficacy of their formulation. Many of the most effective new medicines are biologics. Unlike chemical drugs, it is not relatively easy to produce a bio-equivalent generic copy. Rather, biosimilars can be produced upon expiry of patents and regulatory data protections, but because biosimilars are not identical to the originator products additional clinical research is required to determine the safety and efficacy of a biosimilars product. If the biosimilars drug is found to produce essentially the same effectiveness as the original product it can be interchangeable.

RDP is essential to ensure commercial viability and is the basis for the research-based industry's efforts to secure the 12-year data exclusionary period under the final TPP accord. If these data are readily accessible by generic competitors, the financial returns of drug discovery and development are simply too low to merit the expenditure of up to $1.2 billion to bring a drug or biologic (a new chemical entity) to market.

It should also be noted that approval to market a new drug does not insure its profitability. It is estimated, for example, that only one in three marketing drugs covers its research and development costs and makes a profit. Patents and RDP are essential and necessary components of intellectual property law to make the high financial

***Corresponding author:** Robert Freeman, Department of Pharmacy Practice and Administration, Eastern Shore School of Pharmacy, The University of Maryland, Princess Anne, Maryland, USA, Tel: 410-651-8395; E-mail: rafreeman@umes.edu

Received September 14, 2015; **Accepted** September 16, 2015; **Published** September 21, 2015

Citation: Freeman R (2015) Why it is Important to Protect Intellectual Property and Data Confidentiality in Trade Agreements. J Develop Drugs 4: e145. doi:10.4172/2329-6631.1000e145

risk of pharmaceutical innovation worth the investment. Critics of the industry's position on this issue are basing their opinions on conjecture. Regardless of their concerns, a robust intellectual property law covering both patents and regulatory data protect is essential for future innovation.

The TPP final agreement will likely take years to finalize. Pharmaceutical and biologic R & D development will continue, of course, but the environment requires monitoring and continued industry lobbying to ensure that the future will be positive for innovation.