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ScienceDirect
Research in Social and Administrative Pharmacy 12 (2016) 633–637
RESEARCH IN SOCIAL & ADMINISTRATIVE PHARMACY

Commentary

The Trans-Pacific Partnership and pharmaceutical innovation

Robert A. Freeman, Ph.D.*

Department of Pharmacy Practice and Administration, School of Pharmacy and Health Professions, The University of Maryland Eastern Shore, Princess Anne, MD 21853, USA

Summary

Trade agreements are an overlooked area of research and policy analysis that affect market access, pricing and reimbursement decisions by pharmaceutical manufacturers, and research and development decisions in the long term. The Trans-Pacific Partnership (TPP) is the most recent multi-national agreement under considerations that may have profound implications in developed and developing countries in the Pacific Rim. As in the case of other trade arrangements, the TPP negotiations are not transparent, but a major leak of the most recent draft has been published in WikiLeaks. The leaked document has raised a number of concerns about intellectual property rights (IPR) and regulatory data protection (RDP) that have implications for public health and economic policy throughout the region. In particular, IPR and RDP go beyond the minimum standards set under the World Trade Organization (WTO) and may affect drug access negatively by delaying generic drug and biosimilar product availability and by raising prices by removing national regulations dealing with drug pricing and reimbursement. Of particular concern is the establishment of a litigation process where multi-national companies can sue individual countries before a panel of private attorneys who are appointed by the World Bank or United Nations. This paper addresses these concerns along with a commentary on the likelihood of occurring and the need for future research.

Keywords: Trade policy; Global pharmaceutical industry; Trans-Pacific partnership; Intellectual property; Regulatory data protection; Innovation

Introduction

The Trans-Pacific Partnership (TPP) is an ongoing series or rounds of trade negotiations involving The United States, Canada, Australia, New Zealand, Mexico, Chile, Peru, Brunei, Malaysia, Singapore and Vietnam. The value of exports from the USA to the 11 other countries involved in the partnership negotiations approached $700 billion in 2013. The ultimate goal of the TPP is to give a level playing field by eliminating tariffs and other anti-competitive national laws that present trade barriers or trade inefficiencies. The TPP is not a treaty, which requires two-thirds of the houses of Congress for approval, but, rather, it is a joint legislative-executive agreement that requires a simple majority in both houses to become effective. Also, the agreement is scheduled for a "fast track" approval

* Corresponding author.
E-mail addresses: raf@freemangroupllc.com, rafreeman@umes.edu.

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http://dx.doi.org/10.1016/j.sapharm.2015.11.012

in the USA, which means the Congress must conclude its review in 90 days following the agreement's completion. The fast track review also excludes amendments to the proposed agreement.

For the United States, negotiations are led by the United States Trade Representative (USTR) who represents interests of the USA's public, labor, agriculture and business. In practice, a variety of competing interests are balanced by the USTR and other nations in the negotiations that attempt to achieve a net positive economic balance to a nation's balance sheet as a result of the agreement. Although the outcomes of negotiations are often spun was "win-win" for agreements between trade partners, in reality the economic theories underlying trade are based on relative "competitive advantages," which suggest that a "win-lose" outcome is more likely at least in the short-to intermediate term.

Little is currently known about the TPP's details because the specifics under discussion are not transparent. As is customary in international trade negotiation the specific details of trade negotiations are not disclosed publically until a final agreement is reached and presented to national governments for ratification. In recent months, WikiLeaks (2014) obtained a draft document comprised of 30 chapters plus an annex (2015).[1,2] Reaction has been mixed and varies across stakeholders (Silverman 2015, Stieglitz 2015).

A key component of the TPP is the proposal to expand strong intellectual property protection and enforcement. The TPP is not unlike other trade relationships that govern Intellectual Property Rights (IPR) and Regulatory Data Protection (RDP) treatment. The Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) already contains language covering both patents and RDP, setting minimum standards for nations that belong to the World Trade Organization. The section on IPR and RDP are priority areas for the multi-national pharmaceutical and biologics industry, and one of the greatest area of controversy. In reality, IRP is a major initiative of the USA and encompasses the interests of industrial sectors beyond those of the pharmaceutical industry.

It is commonly acknowledged that patents are absolutely essential to incentivize innovation. Without patents innovators could not generate sufficient profits and cash flow to sustain research and development. Patents, however, are only one part of the TPP talks and IP. The other distinct component is RDP, which consists of proprietary 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. While patent length 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 amongst nations. The TPP negotiations are focusing on standardizing the length of the RDP for biologics to a period of 12 years.

For patients and consumers, as well as for research based health industries, IP and RDP protections encourage and support investment in the development of new treatments and cures. The legacy of this investment is cheap generic drugs upon expiry of IP and RDP protections. 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 by regulatory agencies.

Obviously generic manufacturers prefer to access the innovator's data because it is significantly less expensive to use existing data instead of conducting original research. The data that form the basis of a product's safety and efficacy submitted for marketing approval typically includes the following: the basic science data such as chemistry, toxicology, pharmacology, and clinical data originating from Phase II and III trials (the product's indications, efficacy, tolerability, pharmacokinetics, drug interactions, adverse events, side effects, contra-indications, precautions, warnings, use in pregnant women, adverse effects, dosage and route of administration).

Many of the most effective new medicines under development are biologics. Unlike chemical drugs, it is not possible to produce a bioequivalent generic copy. Rather, biosimilar copies 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 biosimilar product.

RDP is essential to ensure commercial viability and is the basis for research based industries efforts (supported by many patient advocacy