



Intellectual property rules and its impact on access to medicines

N Fathi*

Department of Pharmacoeconomics and Pharma Management, Shahid Beheshti University of Medical Sciences, Tehran, Iran

*Corresponding author. E-mail: nazilafathi@yahoo.com

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DESCRIPTION

Today, more than 2 billion people in developing countries do not have access to affordable medicines, including many patients in countries negotiating under the Trans-Pacific Partnership (TPP) Free Trade Agreement. Two key factors limit access to treatment. In particular, the high prices of new patent-protected drugs and the lack of drugs and vaccines to treat neglected diseases that are consequence of a lack of Research and Development (R&D). Intellectual Property (IP) comes in many forms but when it comes to access to medicines, we'll talk about patents. Patents are a public policy tool aimed at stimulating innovation. The government seeks to encourage research and development by providing monopoly through patents that give the inventor an economic advantage and at the same time, the people are benefiting from technological advances. This compromise underpins patent systems everywhere. Governments need to strike the right balance between inspiring innovation and ensuring widespread availability of new products. High levels of IP protection in developing countries exacerbate rather than solving the problem of access to affordable medicines. Extensive patent protection for new drugs delays the start of competition for generic drugs and since generic drug competition is the only proven way to keep drug prices down, such high levels of intellectual property can be very damaging to public health.

Intellectual property and patents are one of the most controversial issues related to access to medicines since the establishment of the World Trade Organization (WTO) and the entry into force of the agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS). Patents are not the only barrier to access to life-saving medicines but they can play an important or decisive role. During the term of patent protection the ability of patent owners to set prices without competition can make medicines affordable for most people in developing countries. This aims to present important issues in the

area of access to medicines and intellectual property and also discusses and defines some basic terms and concepts in this relatively new area of pharmaceutical policy, the trade-related aspect of intellectual property rights that govern the research, development and supply of pharmaceuticals and health technology.

The agreement signed between parliamentary leaders and the Bush administration on May 10, 2007 to reduce the so-called TRIPS plus rules in Free Trade Agreements (FTA) with Peru, Panama and Colombia. It broke this trend of implementing stricter IP protection measures. This agreement was very important. Not only did it confirm the importance of the Doha Declaration on TRIPS and public health, but also realized that higher levels of intellectual property would actually serve the benefits of public health and the goals of trade and development contrary to the United States. Under that agreement, which had become to be known as May 10 agreement, the three major TRIPS plus clauses that Oxfam believes to be the most damaging to slowing the competition for generics have been reversed. This meant that patent linking and patent term extensions became voluntary and included significant flexibility in the data protection clause (DE) to accelerate the introduction of generic drugs.

Patent linkage prohibits the drug regulatory agency in that country from approving the drug if the patent is valid. Regulators need to supervise patents in addition to their core task of assessing the safety and efficacy of medicines.

Patent extension is the patent renewal clause allows companies to request an extension of the patent term of 20 years to compensate for administrative delays by the Patent Office and drug regulators. (Such delays are

unavoidable in developing countries where these offices are chronically underfunded and are facing more and more patent applications).

Data exclusivity creates a separate monopoly from patents by prohibiting drug regulators in a country from approving generic drugs based on clinical trial data provided by the original manufacturer.

CONCLUSION

Not all TRIPS plus rules have been abolished in the May 10 deal, but Oxfam sees it as a step in the right direction after a long time from going in the wrong direction. This reflects a significant effort to ensure that US trade policy better aligns intellectual property protection and public health considerations in developing countries. Oxfam

fully hoped that this new approach to US trade policy would continue. MSF has repeatedly warned that unless measures are found to reduce the prices of expensive patented medicines, people in poor countries will be less able to obtain essential medicines. Prompt action is needed to prevent further crises in developing and least developed countries. One of the solutions that have been promoted is the creation of regional drug supply centers that increase access to affordable medicines through economies of scale and collaboration. However, as mentioned above, the main obstacle to procuring affordable medicines remains the Trade-Related aspects of Intellectual Property Rights (TRIPS). Until further changes are made, developing countries and least developed countries should take advantage of existing TRIPS margins as much as possible.