

Study of Intellectual Property Laws in Iranian Pharmacology and Drug Industries

Mahboubeh Babaee^{1*} and Abdol Ghaffar Ebadi²

¹Department of Laws, Jouybar branch, Islamic Azad University, Jouybar 47761-86131, Iran.

²Department of Agriculture, Jouybar branch, Islamic Azad University, Jouybar 47761-86131, Iran.

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Todays, the role of pharmaceutical and drug industries in Iranian medical economics and market are very eminent and reached to 80 billion dollars (15% of incomes in this region) because 96% of anti-microbial and anti-cancer drugs produce by Iranian companies. One of the main concerns in Iranian pharmaceutical sectors is about agreement on trade aspects of Intellectual Property laws (TRIPs). In this paper, with usage of recent findings from library references and also Iranian medical association, different aspects of Intellectual Property laws, limitations, Obstacles and other national and international effects in Iranian pharmaceutical and drugs industries will discuss. Based on results, Commitment related to proposed Intellectual Property laws by TRIPs should implement by all countries' members like Iran and all members will give commitment and respect to Patents about pharmaceutical products and produce the generic form of drugs only when the duration time of patent is finished.

Keywords: Pharmaceutical and drug industries, Intellectual Property laws, Iran, Patent.

Iranian pharmaceutical factories have been considerable growth after Iranian revolution and great factories established such as Zahravi Co., Shahhed Ghazi Co. in Tabriz city, Farabi Co., Amin Co. in Isfahan, Lorestan Co., and others and made great economic incomes and benefits for the country. Many official documents show that new Iranian government after revolution, generic project formed in order to terminate of dominance of foreign drug multinational companies that resulted limitation in foreign factories shares and license rights and also production of drug under generic name made and consumed by local peoples that show kind of independency in this industry. From Profitability view, based on classification of 53 profitable industries in the world according fortune magazine, pharmaceutical industries were the most profitable ones after network and

internet industries with different of 1% (Fortune, 2009) (Table 1). The intellectual property laws is a new legal concept that protects from intellectual activities and products in trade, scientific, literature, arts and also pharmaceutical. It divides two parts, industrial properties and art & literature properties. In part of industrial properties some issues have been discussed that mainly are patents, industrial and commercial trademarks, industrial designs and geographical indications, and in the literary and artistic property, rights of authors, composers, artists and creators of computer software in relation with copyright considered (Sheikhi, 2007; Salazar, 2001; Zahedi, 2012; Fortune journal report, 2009).

Intellectual property rights in Iran

In Iranian laws, protection of industrial property rights has a long history and numerous laws adopted in relation to industrial property laws that the first law was in relation to industrial property to be passed into law in 1926.

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* To whom all correspondence should be addressed.

Tel: +981142566191;

E.mail: mahbub_babaee@yahoo.com,

mahboubeh_babaee@jouybariau.ac.ir

the first law that was passed in the Iran in relation to industrial property returns to law 1926. In the Universal Declaration of Human Rights and the International Covenant on Economic - social rights, cultural, civil and political benefit from material and spiritual interests and the need to take appropriate measures by the government to provide, maintain, develop and promote literary and artistic works, has been emphasized. And holding several regional and international conventions in this regard represents the world's attention to this issue. World Trade Organization in 1995 and the outcome of the negotiations on the General Agreement on Tariffs and Trade (GATT) was created. It was established with aims to facilitate and expand trade at the international level, to achieve sustainable development with regard to the optimal utilization of global resources (economic principle of comparative advantage), protect the environment, increase the share of developing countries and least developed of the growth of international trade and create a mechanism to resolve trade disputes between countries; In a way that it became as a symbol of globalization in economics and commerce. Over time, more and more countries joined the organization and currently 160 countries are members of organizations and 24 countries are in the process of membership. One of the main challenges facing the country after accession to the World Trade Organization is endanger of domestic industries life including the pharmaceutical industry after removing or reducing barriers for importing foreign products as well as barriers to the presence of foreign companies in the country. In this article we're going to review the accession of China to this organization, the most important obligations related to the drug to the membership in this organization (Zahedi, 2015; Daneshyar et al., 2006; Fortune journal report, 2009; Rudin and Weissleder, 2003; Yoshiyama et al., 2004; Ahou and Lee, 1991).

The most important obligations related to drug Reduction of tariff barriers

One of the most concrete commitments to countries in the process of accession to the WTO is the reduction of tariffs on the importation of products from other Member States. During the bilateral negotiations of market access on individual areas of interest will be discussed by the negotiator, and therefore one of the objectives of

the working group of Member States, is minimizing tariff barriers to trade with countries seeking to join. In the case of medicine, what is predictable is struggling negotiating parties with the powerful pharmaceutical industry, such as America and Europe to reduce import tariffs on medicines and active participation in the pharmaceutical market of Iran. In the process of China accession negotiations; this country was committed to a maximum of two years after accession, to reduce the average tariff import pharmaceutical products from 6.9 to 2.4%. Now the average tariff of import drugs for goods is subject to tariff of 32% which is much higher than usual. In addition, bans and severe restrictions to import generic drugs that exist inside are inconsistent with the principles of the World Trade Organization (Charmaz, 2006; Cheraghali, 2010; Cooper and Dayna, 2013; Ahou and Lee, 1991).

Remove one or gradual removal of nontariff barriers

Remove non-tariff barriers of trade among is of common obligations of countries in membership. Of course, based on WTO rules, each country is allowed to maintain the safety of imported products and protect the health of its population, implement and set the minimum and standards clearly. But this principle shouldn't be used to limit the access of foreign companies to the domestic market, because any base regulations and standards should also be considered for licensing to domestic production. In fact, in many cases the removal of non-tariff barriers means Trans parenting domestic regulations to allow the use of regulations to be applied to different types of discrimination in trade. For example, in Iran the optimization production standards for imported products, is mandatory but for companies inside is not followed seriously that is inconsistent with this principle. In the case of other regulations, standards and procedures, as well as attention to the same procedures for all domestic and foreign companies is essential. In the case of the provisions related to the issuance of import licenses medicines in China, and the Agreement on Sanitary and Phytosanitary Measures and Agreement on Technical Barriers to Trade and the principle of national treatment, this country based on pharmaceutical law can issue license for import of pharmaceutical products. It can also apply optimal standards of production

and optimization principles of warehousing and distribution for foreign companies in the production and distribution. It should be noted that the Agreement on Technical Barriers faced by trade have been approved with the goals of protecting human health, protect the health or life of plants and animals, protect the environment and to avoid misleading and deceptive practices. Because different countries have various technical regulations, standards and conformity assessment procedures of their own in this area, a key aim of this agreement is that to avoid the abuse of these provisions in order to create barriers on trade. One of most important of this case is agreements in the same direction and coordination efforts of the regulations and standards. This means that countries are committed. If there are regulations and international standards on the subject use them and adapt them with its internal rules. In discussing technical barriers facing trade in the pharmaceutical sector, China is pledged that all regulations as nontariff barriers and limiting imports that are used, be modified (Eisenhardat, 1989; Triantaphyllou, 2000; Truesdell, 1980; UBOS, 2011; Ahou and Lee, 1991).

Obligations related to intellectual property rights

Is one of the main concerns of the pharmaceutical sector and in particular indigenous pharmaceutical industry, are the commercial aspects of Intellectual Property Rights Agreement (TRIPs). The agreement includes 70 articles that contain all previous conventions on the rights of intellectual property, including the Berne Convention, Paris, Rome and Washington as well. One important aspect of this agreement that is more important link with drug industry is the issue of patents (patents). Membership applicant countries will be obliged to respect the right to patents on medical products and only after the period of patent protection can produce the generic form of the drug. Generic drug is a drug that is prescribed dosage, safety, strength, quality, impact practices, methods and ways of attracting consumers, the brand is the same drug, but enters into the market by companies other than the company that first made it. For example, the drug "atorvastatin" for the first time was produced by the company "Pfizer" and entered the market called "Lipitor" and when other companies are attempting to make

the drug molecule, their production is generic form of atorvastatin. This of course can have significant effects on the access of developing world to new drugs. Our country has not committed itself to this principle; so many products currently produced in the country are protected by patents. This of course has brought benefits to Iranian patients, including access to inexpensive generic samples of new drugs (UN, 2014; WHO, 2004; WHO, 2009; WHO, 2010; World Research Inc., 1999).

Data exclusivity

One of the sensitive issues for the country's pharmaceutical sector is related to the TRIPs agreement on the issue of data exclusivity. In the pharmaceutical sector the order of information, are the results of clinical trials and animal innovative pharmaceutical companies on drugs. Innovative pharmaceutical companies to obtain authorization to enter the market of a country should provide information to regulatory bodies. Generic companies do not need to do these tests and in providing documentation to the regulatory body refer to innovative companies results. But if data exclusivity law exists in the country's pharmaceutical regulations and the time limit for the other companies of the results of these studies is determined, generic companies should do test or until the completion of data exclusivity stop producing the product. However, this provision of the TRIPs Agreement requires Members to protect confidential information (undisclosed) against unfair trade, so the above paragraph does not refer directly to the issue of the monopolization of commercial of confidential

Table 1. The comparison of Profitability of Pharmaceutical industries with others based on fortune magazine reports (2009)

Industry name	Profit rate
Network	20.4
Internet	19.4
Pharmaceutical	19.3
Medical	16.3
Rail roads	12.6
Financial data	11.7
Mining crude	11.5
Securities	10.7
Oil and gas	10.2
Scientific	9.9

data but may be at the heart of this issue beyond the TRIPs negotiations it is imposed to a country's membership. In process of China's accession and in negotiations with the working group, members have requested China to create the necessary reforms in its domestic laws to protect confidential data with the use of pharmaceutical products and agricultural business and a period of 6 years old in the protection for the issue. China has promised that provide necessary changes in regulations and internal rules in order to establish ensure the protection of data on pharmaceutical and agricultural products. Accordingly, China has committed 6 years protection from the date of confidential data and testing pharmaceutical products and agricultural supervisory institution. This issue has nothing to do with patents being or not and is about pharmaceutical products and agriculture, and the new valid composition. In the meantime, what is certain is that accession to the WTO in the country will create challenges for the drug, as well as opportunities for putting this industry in development circuit. However, to take advantage of opportunities and cope with challenges, the issue of preparing this section and activists in it as a long-term Meta policy should be considered seriously. It is obvious that to achieve a successful incorporation in the pharmaceutical sector and other sectors we need to prepare the business environment and the gradual reform of inter-sectorial and cross-sectorial regulations and it would But achieved with spend enough time and use the knowledge and experiences of individuals and entities associated with these issues (Sheikhi, 2007; Salazar, 2001; Zahedi, 2012).

CONCLUSION

With regard to the issues raised in the first place, the pharmaceutical industry, like other industries is not safe from the structural problems of the economy, especially recession these days because of some cases, including sanctions there are difficulties against the activists of the industry in order to access resources and raw materials, obstacles such as lack of liquidity, particularly in the context of updating structure and technology pharmaceutical industry should be added. In the meantime, what is certain is that accession to the WTO in the country will create challenges

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