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Sara Yashar Aghamaliyeva
Baku State University
master student
sara.aghamaliyeva@gmail.com

THE CONFLICT BETWEEN PATENT RIGHTS AND THE RIGHT TO ACCESS MEDICINE AND HOW WE CAN CREATE THE BALANCE BETWEEN THEM

Abstract

Since patent protection grants the patent owner exclusive rights in the market, such as being the sole manufacturer or limiting the cost of the final product, all of us, as consumers, rely on the patent owner's decisions about the final product entering the market.

The amount of product entering the market, the markets in which the products will be sold, the price at which the producer enters the market, or even whether or not the patent holder will use his patent rights to produce the final product, all of these matters can be regulated only by the patent holder during the 20 years following the grant of patent protection. This may appear to be a minor issue at first glance, but concerns are more serious when talking about more essential products like medicine. Thus, this article describes the problem of the right to access to medicine and patent rights in more detail.

Keywords: *intellectual property law, patents, access to medicine, TRIPS Agreement*

Sara Yaşar qızı Ağamalıyeva
Bakı Dövlət Universiteti
magistrant
sara.aghamaliyeva@gmail.com

Patent hüquqları və dərman vasitələrinin əlçatanlığı hüququ arasındakı konflikt və onlar arasında balansın yaradılması üsulları

Xülasə

Patent müdafiəsi patent hüquqları sahibinə bazarda yeganə istehsalçı olmaq və ya yekun məsulun qiymətini müəyyən etmək kimi müstəsna hüquqlar verir və hamımız istehlakçı olaraq patent sahibinin bazara girməsi ilə bağlı verdiyi qərarlardan birbaşa asılıyıq.

Bazara daxil olan məhsulun miqdarı, məhsulların satılacağı bazarlar, məhsulun qiyməti, və hətta məhsulun istehsal edilib edilməyəcəyi kimi məsələlər patent hüquqları əldə edildiyi gündən 20 il müddətində yalnız patent sahibi tərəfindən tənzimlənir. İlk baxışdan problem görünməsə də, söhbət dərman vasitələrindən gedirsə, məsələ daha ciddi xarakter alır. Beləliklə, bu məqalədə patent hüquqları və dərman vasitələrinin əlyetərliyi hüququ arasındakı problem müzakirə olunur.

Açar sözlər: *əqli mülkiyyət hüququ, patent, dərman vasitələrinin əlyetərliyi, TRIPS Sözləşməsi*

Introduction

Recently, humanity experienced one of the most catastrophic worldwide pandemics in history – thecoronavirus pandemic. Prompt action without delay by pharmacy innovators and scientists resulted in the development of various vaccinations, diagnostic tools, and treatment approaches in the shortest possible time, saving millions of lives globally. However, the global crisis is still underway. While the initial wave of pandemic-related difficulties appears to be resolved, emerging or least developed nations continue to raise concerns about worldwide R&D and intellectual property, including patent policies. As a result, thepandemic has raised various challenges, including health inequalities and the balance between publichealth and individual rights such as intellectual property rights. In this article, three different aspects ofthe conflict between pharmaceutical patent rights and the right to access to medicine are discussed.

The primary reason states offer patent protection is to reward inventors and promote future innovationand R&D (Fisher, 2007: 448). To balance these rights, the patent protection duration is severely limited. There is a disclosure factor, which indicates that once the protection term expires, generic items will be able to jointhe market utilizing the released information, and societywill profit from scientific developments. In most countries, the protection period for innovation patents is 20 years; for utility patents and design patents,the time is significantly shorter - around ten years (Patent haqqında Azərbaycan Respublikasının qanunu, 1997).

Over decades, the fundamental concern has been whether it is ethical to extend patent protectionto pharmaceutical inventions. Before the TRIPS Agreement, most governments governed this issue by national legislation, and pharmaceutical products were excluded frompatentable innovation lists in certain countries (Cheron, Fouassier, 2009: 7). However, the adoption of the TRIPS required all member states to alter their legislation. Consequently, year by year, the conflict between the fundamental human right to access medicine and intellectual property rights reached a new level. It even can be found in international agreements like the Universal Declaration of Human Rights of 1948 and the United Nations International Covenant on Economic, Social, and Cultural Rights of 1966.

Achieving a fair balance is crucial because the concept of long-term benefit is the fundamental driving factor behind the growth of innovation. Investors and innovators have spent millions of dollars and years developing a pharmaceutical product without guaranteeing that the end outcome would be as anticipated after years of diligent labor. As a result, their expectation of appropriate compensation for their effort and a return on investment with additional profit is justified. On the other hand, millions of people depend on these pharmaceutical inventions and their accessibility.

The Agreement on Trade-Related Aspects of Intellectual Property Rights is an international legal agreement signed in 1994 by the members of the World Trade Organization to establish minimum standards for the regulation of intellectual property by the national legislation of the member countries. This agreement is the most comprehensive modern agreement regulating issues related to intellectual property, and after the adoption of which intellectual property was introduced to the multilateral global trading system. The TRIPS Agreement's main aim was to harmonize the national legislations of the WTOmember countries to make easy the process of seeking protection across the borders in all countries forthe inventors, authors, or other intellectual property producers and intellectual property holders (Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994). Also, states assumed that implementing stricter enforcement of intellectual property rights would incentivize future inventions and R&D and subsequently develop their economic welfare.

While the TRIPS had the flexibility to increase access to medicines, its implementation created tensionor disputes between the patent rights holders and the states. To clarify the provision of the TRIPS agreement regarding the flexibilities and help those countries with their implementation Doha declarationon the TRIPS Agreement and Public Health was adopted in November 2001.

Pharmaceutical companies fund the majority of health-related research. This indicates that commercialization and market incentives are the primary motivators for clinical research. As a result, only the pharmaceutical research domain, which will benefit more in the future, is favored and primarily sponsored. This type of incentive might be incredibly effective in every other aspect of the innovation. However, when the lives of millions of people are dependent on the performance of medical research, it is not ethical and direct discrimination against the right to health of low-income communities.

The lack of access to medicine is caused by several factors such as monopolization, the 10/90 gap, andpatent thickets.

1.The first factor is monopolization. The high cost of medicine is directly linked to the monopolization of the pharmaceutical industry. Medical Monopoly depicts how the healthcaresystem gradually evolved from a public benefit to a fundamental market, and profit-making inevitably takes precedence. The gradual acceptance of patenting has resulted in the development of health as a commercial commodity (Antiinhisar fəaliyyəti haqqında Azərbaycan Respublikasının qanunu, 1993).

2.The second factor is the 10/90 gap in pharmaceutical research and industry. If the expense of pharmaceutical items is one of the most severe issues, another is the lack of necessary pharmaceutical products caused by the 10/90 gap phenomena. The "10/90 gap" was establishedby the Commission on Health Research for Development in 1990 to describe the disparity between illness

burden and resources allocated to lead health-related research. Thus, just 10% of all financial investments in health-related research were spent on diseases that impact 90% of theworld's population.

3. Last but not least factor is the patent thickets. The term patent thicket refers to the problem that new entrants to the market face when attempting to enter the scientific space with existing patent rights, and it relates to the dense web of overlapping patent or other intellectual property rights that entrepreneurs must navigate to commercialize their new invention. Patent thickets might beowned by a single prominent market participant or can stem from fragmented technological domains where numerous small entrepreneurs possess relevant patents. They, in turn, generate the "thicket" through which each new entrepreneur seeking to enter the market must navigate.

The abovementioned problems can be solved on different levels by implementing several policies. The Agreement on Trade-Related Aspects of Intellectual Property Rights is an international legal agreement signed in 1994 by the members of the World Trade Organization to establish minimum standards for theregulation of intellectual property by the national legislation of the member countries. This agreementcontains several flexibilities member states can apply to achieve access to medicine in the country, suchas exhaustion of the intellectual property rights and compulsory licensing.

1. The exhaustion doctrine is a notion in intellectual property law that states that an owner loses or exhausts some rights following the first use of the subject matter of intellectual property rights. The extent to which intellectual property owners may control the distribution of their products is referred to as intellectual property exhaustion. For example, a patent owner's ability to maintain a product's subsequent sales, price, or distribution area is generally exhausted when the product is sold. This word is usually used in the context of parallel imports and may thus apply domestically, regionally, or globally.

2. Compulsory licensing is one of the remedies available under international intellectual property law to address the unintended impact of pharmaceutical patents on access to essential medicines. The issue of forced licensing is equally crucial in the subject of patent thickets. It is feasible to overcome a patent owner's resistance to license their technology in specified situations bygranting a compelled license with the aid of patent thickets. As a result, a vital issue with thickets would be avoided: "blocking" patents, which restrict technological or financial advancement in manufacturing a product (Stirner, Thangaraj, 2013: 9).

The policies implemented at the governmental level are the policies adopted by the member states toachieve access to medicine in the country and can be in the form of the patent box policies or state-fundedprize systems.

1. The Patent Box is a tax incentive policy created and adopted by the states to attract and encourage entrepreneurs to keep and commercialize their intellectual property, generally patents and software copyrights (7). The effects of such tax reductions vary from country to country. One of the goals of such policies was the introduction of more accessible items, mainly pharmaceutical products, into the market due to lower production costs (European patent box regimes, Japan External Trade Organization, 2013).

2. Government-funded prize system is a state policy that rewards the innovators developing successful new medicine with a cash prize and, in return, makes them surrender the IP to the government. Subsequently, the government-funded prize system can be a good alternative for patents in medicine. In contrast to the grant system, the prize is given to the already successful drug inventors who are at the end of their invention, waiting to get patent protection to enter the market. As a result, not only the inventor manufacturer but also generic manufacturers enter the market simultaneously. The immediate competition between the inventor and generic manufacturers creates a more competitive market with reduced prices for pharmaceutical products making able access for all the consumers.

The patent pools and patent pledges are other forms of policies that are neither TRIPS-based nor governmental.

1. A patent pool is an arrangement between two or more patent owners to license one or more of their patents to each other or other parties. Also, patent pools are the aggregation of intellectual property rights subject to cross-licensing, whether they are transmitted directly by the patentee to the licensee or through another mechanism, such as a joint venture, set up to precisely administer the patent. Consequently, the patent pools are one of the most effective ways to battle the patent thickets. Collaboration among pharmaceutical patent holders can result in significant economic and technological

efficiency, resulting in more accessible drug markets. At the same time, governments should enact normative legal acts connected to competition regulation to prevent patent pools from creating potential new monopolies (World Intellectual Property Organization, 2014).

2.Patent pledges assure developers and inventors that the patent holders issuing the pledges will not litigate them for patent infringement if specified terms and circumstances are met. A patent holder who makes a patent pledge willingly relinquishes a potentially valuable right without specified remuneration. Far from being unreasonable, this conduct is generally backed by substantial economic motives. Such philanthropic acts by the pharmaceutical entrepreneurs result in lowering the cost and accelerating the process of the entrance of generic medicine into the markets.

Conclusion

In Conclusion, with the cooperation of the governments, international organizations, and the private market players, with the implementation of versatile strategies and systems, a fair balance between the right to access medicine and patent rights can be reached.

References

1. Fisher, M. (2007). "Fundamentals of Patent Law Interpretation and Scope of Protection". Hart Publishing. 448 p.
2. Patent haqqında Azərbaycan Respublikasının qanunu. (1997). 25 iyul qəbul edilmişdir. Bakı: Azərbaycan Respublikasının Qanunvericilik Toplusu.
3. Cheron , C., Fouassier, E. (2009). "Acces des pays en developpement aux medicaments : vers une nouvelle flexibilite juridique du droit des brevets ?". Medecine, Droit, Vol. 2009 ; Iss. 95. 7 p.
4. Agreement on Trade-Related Aspects of Intellectual Property Rights. (1994). Annex 1C of the Marrakesh Agreement Establishing the WTO. World Trade Organization – Morocco.
5. Antiinhisar fəaliyyəti haqqında Azərbaycan Respublikasının qanunu. (1993). 4 mart qəbul edilmişdir. Bakı: Azərbaycan Respublikası Ali Sovetinin Məlumatı.
6. Stirner, B., Thangaraj, H. (2013). "Learning from practice: compulsory licensing cases and access to medicines". Pharmaceutical Patent Analyst. 19 p.
7. https://taxfoundation.org/patent-box-regimes-europe-2021/
8. European patent box regimes, Japan External Trade Organization. (2013). PwC.
9. World Intellectual Property Organization. (2014). Patent Pools, and Antitrust, A Comparative Analysis. WIPO, Secretariat.

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