

Challenges of the Intellectual Property System in Pharmaceutical Innovations Resulting from Artificial Intelligence

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Abstract

The patent system has long been criticized for limiting access to medicines. Dramatic advances in artificial intelligence and machine learning technology present a revolutionary opportunity in drug discovery, formulation and testing of dosage forms. The pharmaceutical industry claims that patenting is necessary to encourage innovation in the risky, lengthy, and costly research and development (R&D) process. But it still does not provide logical evidence about the actual effects of patents on innovation. The increasing use of artificial intelligence in research is intensifying the debate about pharmaceutical patents. Inventions created or enabled by artificial intelligence raise questions about patentability and patent policy in general. Faster and more efficient research and development weakens the justification for pharmaceutical patents. Research findings suggest that despite the necessity of continuing incentives for drug research and development, lawmakers should consider alternative systems that prioritize access alongside incentives to advance healthcare as a human right.

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Introduction

Medicine and health care basically get benefits from artificial intelligence (1). Artificial intelligence in the health care industry for purposes such as increasing the capabilities, technical knowledge, expertise of doctors and medical specialists, helping to examine the patient's conditions in a continuous and comprehensive manner, increasing the quality of life of people with special diseases or disabled people, predicting diseases and customizing treatment is used. Artificial intelligence systems are also used in different stages of the drug development process, from the initial review of the drug to the design of clinical trials (2).

The pharmaceutical industry is one of the most important research industries in America (3). However, researchers limit their ability to innovate effectively and quickly. The implementation of artificial intelligence is on the verge of creating a significant transformation in the way of managing the pharmaceutical industry with supply chain operations (Figure 1). Artificial intelligence increases performance and reduces development and research costs. Pharmaceutical companies use artificial intelligence to improve development and research capabilities, increase efficiency and reduce the time and investment required

in the drug development process (4). Machine learning is used in drug discovery to help researchers understand the relationships between chemicals and their activity.

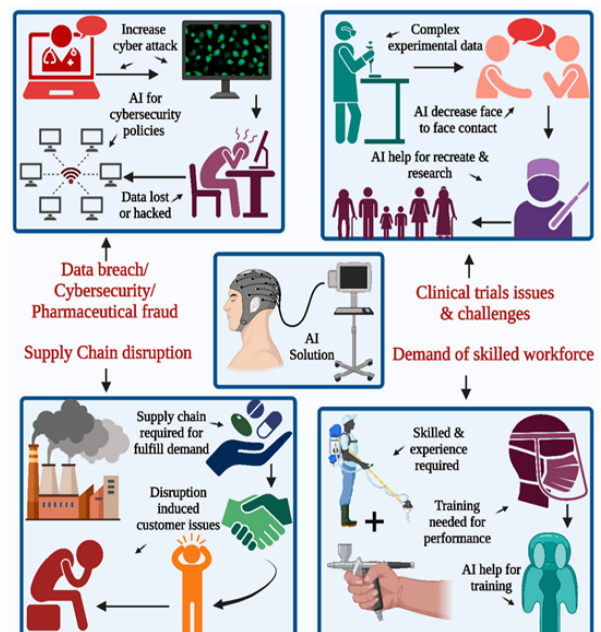


Figure 1. shows a possible artificial intelligence (AI)

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solution to the challenges of the pharmaceutical industry: obtaining a skilled workforce is a prerequisite in all sectors to use their expertise, skills and talent in product innovation. The second relates to supply chain disruptions and clinical trial challenges. The incidence of cyber-attacks is increasing, and data breaches and security are emerging as major concerns for the industry.

A new technology platform and solution is needed to implement effective cyber security in the office and for remote workers ¹. In addition, special attention should be paid to data security and penetration techniques. Technology is also needed to address political fraud and many cases have been reported, especially during pandemics in the last few years around the world. It is therefore necessary to take appropriate measures to prevent healthcare fraud along with constant encouragement for internal discussions about fraudulent behavior that can help prevent it.

Deep learning has the ability to process a large amount of data in order to accurately predict the effects of molecules. These predictions can help researchers focus on the smaller number of drug trial candidates who are likely to pass clinical trials. Artificial intelligence systems can also increase the number of tested compounds from a million to several billion, while reducing the time to test these compounds from a few months to a few days (5).

Recent years have seen an increase in the number of artificial intelligence applications in innovation. An artificial intelligence system analyzes data from clinical trials and academic papers to find candidates for new drug trials, which within a week will reveal the results of the trials on the candidates, one of which was on a drug to treat ALS disease (ALS). Another artificial intelligence system analyzed oncological data and discovered a treatment for pancreatic cancer, which is currently in the second phase of clinical trials. Researchers use the predictive capabilities of the machine learning system to reduce the number of tests on new drugs up to seventy percent (6).

Artificial intelligence is used as a powerful tool in pharmaceutical science (7). Recently, a machine learning algorithm that can screen 100 million chemical compounds in a few days has helped researchers to identify a new antibiotic compound that kills many of the most complex pathogenic bacteria, including some strains resistant to well-known antibiotics. They are resistant, be killed. Another artificial intelligence system has led to the development of a new compound for the treatment of obsessive-compulsive disorder, which is the first compound created through artificial intelligence to be tested on humans. There are other cases that are avoided in the present research (8).

1. . Drug discovery is the first stage of drug development in which researchers identify target diseases and test drug candidates against such targets.

Importance of drug research and development

The importance of pharmaceutical research can be examined from two aspects:

- a. Their most important effect is on human health. Because medicines are known to be the main and most widely used source in the prevention and treatment of diseases as old as mankind.
- b. The commercial and economic importance of drug production and sales. Because the pharmaceutical industry is still one of the most profitable industries.

From the side of drug demand in the market, the lack of reliable and accurate information causes limited research on the effect of intellectual property rights on research and development in the drug industry. Tyler and Silberston (1973) conducted field research on industrial activists regarding the effect of patents (patent licenses) on research and development incentives and concluded that the pharmaceutical industry is highly dependent on patent protection (patent licenses). Until the year 2000 Several researches were conducted in this field which showed that pharmaceutical companies have a high tendency towards patents and research managers have reported that it is very important to ensure the competitive advantages of patents and if patent protection Without relevant research, the work of research and development in the field of medicine will be greatly reduced. Statistical studies on the impact of changes in patent protection on research and development have had mixed results. In a sample study, Chian (2007) found much less evidence regarding the relationship between the extent of patent protection and internal innovation indicators in the pharmaceutical industry in 92 countries using a rigorous economic research method to control for cross-country differences. had. Case studies have shown the impact of intellectual property rights on drug research and development costs in different countries. Scherer and Weisbrust (1995). A clear effect on the reduction of patents (patent licenses) for drug production in Italy in 1982. not found However, the introduction of the compulsory exploitation license (licence) system in Canada in the 1970s. It led to a drastic reduction in the amount of research and development in the Canadian pharmaceutical industry, and its elimination in the 1990s has had equally positive effects. Indirect assessment of the effects of changing intellectual property rights on research and development profitability, such as estimating the different effect of the stock market evaluation of pharmaceutical companies based on research and development compared to manufacturing companies, has shown a completely fundamental effect in some countries.

Supporting research and development

In order to promote public health, governments try to encourage pharmaceutical companies to conduct medical research and drug innovation by providing incentives such as patents. In this way, both the society's need for access to new and more effective drugs according to the current conditions will be provided, and the pharmaceutical companies will benefit from the special rights resulting from the registration of the drug as an invention. A subtle and important point that should be noted in the implementation of this policy is that a reasonable balance should always be established between the rights of the general public to enjoy health and the interests of drug manufacturing companies. On the one hand, with insufficient support for pharmaceutical research, it is feared that sufficient motivation for research and development of drugs to cure diseases will decrease; On the other hand, with the extreme support of new pharmaceutical discoveries, the way for large pharmaceutical companies to monopolize one of the most important areas of health is paved.

In this way, the new use of medicine is not exempted from this rule, and the legal protection of such innovations should follow the policies and general principles governing patent registration. It can be imagined that a drug was originally invented for the purpose of treating cancer, and then years later another use was found for this drug. For example, the drug zidovudine from the 1960s. It was used as an anti-cancer drug and in the 1980s. It was used in a new application in the treatment of the infection caused by the HIV virus (AIDS) and to deal with the weakness of the body's immunity.

Beyond patent protection, trademarks are another form of intellectual property rights used to identify and market pharmaceutical products. Trade secrets and protection of clinical trial data are other important elements of this industry. As a result, a set of intellectual property system of a country becomes important when the options of domestic pharmaceutical production are considered (10). The subtle and important point in the implementation of this policy is that it is always necessary to establish a logical balance between the rights of people to enjoy health and the interests of drug producing countries. On the one hand, with the lack of legal support for pharmaceutical research, there is a fear that the motivation for research and development of drugs to cure diseases will decrease, and on the other hand, with excessive support for new pharmaceutical discoveries, the way to a wide monopoly of large pharmaceutical companies on one of the most important fields Health becomes smooth (11).

This issue in 1984. It was examined by the Supreme Board of Appeals and in its decision it was announced that the application of the word use in Article 54 paragraph 5 of the 1973 Convention. It also includes the second and subsequent medicinal use, and this article does not differentiate between the first and subsequent uses. Of course, inventors who want to register their applications on the subject of second and subsequent medicinal use must prepare their claims in the "Swiss form" format (11).

In fact, a difference has been made between the claims that are about the ingredients and compounds of a drug (known and lacking the description of being new) and between finding a new medicinal use for them (having the condition of being new). For example, in a case in the British patent court, the subject of the invention was the discovery of the antidiarrheal property of the chemical guanidine as a well-known substance for the prevention and treatment of mammals and poultry (11).

The appropriate level of intellectual property protection can vary between industry sectors. For example, in a country, the domestic generic drug industry can lean towards a flexible patent system that allows the initial entry of similar products to enter the field of activity and competition. Therefore, it is necessary to pay attention to an environment that balances the long-term interests of society with the interests of domestic producers in various sectors of business needs. In such cases, a unified approach to how a country's intellectual property rights laws should communicate between monopoly rights on the one hand and competition promotion on the other hand (11) is debatable.

Due to certain reasons, the protection of pharmaceutical inventions was not included in the laws of many countries, such as Article 28, Paragraph 3 of the Trademarks and Inventions Registration Law of 1310 Sh. Iran also excludes pharmaceutical formulas and preparations from patentability and there is no doubt about the unsupportability of patents in this field (18).

Patents in the context of artificial intelligence systems and pharmaceutical innovation

Artificial intelligence has created a huge revolution in many businesses by performing tasks that usually require human intelligence to solve them (12). The most important justification of patent rights is that it provides a way for inventors to use the benefits of their inventions and the return of development and research investment and encourages them to innovate and progress. The

pharmaceutical industry often requires patents that are essential to innovation, as they provide ways to offset the high costs of drug-related research and development.

Ability to patent artificial intelligence systems and inventions resulting from artificial intelligence

Two issues are at the intersection between artificial intelligence and patents. The first issue is the patentability of innovations from these systems. Artificial intelligence is treated as a software invention for the purpose of being patentable in the United States and other territories. However, assuming the economic, social and ethical effects of these systems, some commentators argue that their patentability should be evaluated separately from other software innovations. Essential medicines derived through artificial intelligence should be subject to different patentability standards due to similar considerations (13). The importance of access to essential medicines in ensuring that the human right to health benefits from all the innovation and disruption of AI requires a higher barrier to patentability for essential medicines developed through AI.

The role of artificial intelligence systems in the innovation process is different from one invention to another (14). In some cases, all artificial intelligence systems act autonomously, going through all the stages of the innovation process without human intervention. Patentability issues arise when the role of artificial intelligence systems in the process of invention and human intervention is lost. In order to answer the question of whether inventions resulting from artificial intelligence can and should deserve patent protection or not, several issues need to be resolved. These issues, many of which have been raised in the request of the US Patent and Trademark Office for commenting on the patenting of artificial intelligence inventions, include the legal definition of invention, standard interpretation of patentability, obviousness, and the need for incentives.²

2. 1. The request for comments refers

"[i]nventions that use artificial intelligence, as well as inventions developed by artificial intelligence" as artificial intelligence inventions, and seek to answer the following questions: . . .

2. What are the different ways that a natural person can contribute to an idea for an AI invention and qualify for named inventorship? . . .
3. Do current patent laws and regulations regarding inventions need to be revised to include inventions where an entity or entities other than a natural person have contributed to the concept of the invention?
4. Should an entity or entities other than a natural person or a company to which a natural person assigns an invention, be able to own the patent of an artificial intelligence invention? . . .
5. Are there patent eligibility considerations unique to AI inventions?
6. Are there considerations related to the unique disclosure of artificial intelligence inventions? . . .
7. How can patent applications for AI inventions best comply with enablement requirements, particularly given the degree of unpredictability of some AI systems?
8. Does artificial intelligence affect the level of people with ordinary skill in art? If so, how? For example: Should assessment of the level of ordinary skill in art reflect the capabilities of artificial intelligence?
9. Are there prior art considerations unique to artificial intelligence inventions?
10. Are there new forms of intellectual property protection needed for AI inventions, such as data protection?

The issue of whether innovations resulting from artificial intelligence require incentives is directly related to the economic justification of patent rights. The purpose of the patent system is to motivate innovation, and it is not clear whether innovations resulting from artificial intelligence require motivation or not (16). While it is clear that artificial intelligence systems themselves do not need to be incentivized to innovate, some commentators argue that the patent system should promote artificial intelligence innovations, just as patents provide the necessary incentives for the developers of these systems. have.

A second issue that arises with the increasing use of artificial intelligence in the innovation process is whether the obviousness standard of patentability should be reevaluated. The issue of indebtedness is particularly important, because it is not only related to innovations resulting from autonomous artificial intelligence systems, but also to innovations provided by these systems (15).

Inventions must be non-obvious to be patentable. Patent law refers to a hypothetical person of ordinary skill in the art (PHOSITA) in determining whether an invention is obvious. An invention is not patentable if the difference between the invention and the relevant prior art is obvious. The resulting fields, such as medicine, will require a higher skill level. However, the more educated Fusita (a person with ordinary art) is, the more likely it is that the new invention of Bidhi will be considered. Some commentators have demanded the redefinition of the concept of Fusita and the standard of Bidiyah (15).

The independence of artificial intelligence

The issue of the autonomy of artificial intelligence raises its nature in the light of existing legal categories: whether it should be considered as a natural person or a legal person, an animal or an object, or whether a new category with specific characteristics and consequences in relation to the assignment of rights and duties. including responsibility for damages.

American courts pay attention to the corrective aspect of the law, not the preventive aspect. Courts assess liability and damages based on legal precedent. In cases where harm is alleged to have been caused by artificial intelligence programs, courts are asked to discover the new technology and apply inappropriate jurisdictional rules to determine liability. For example, US common law tort claims often focus on anthropocentric concepts of fault, negligence, science, intent, and reasonableness. What happens when artificial intelligence program replaces human reasoning? What happens when AI is the agent or the victim? Claims related to artificial intelligence are novel and there is no valid case law in this field (15).

Case Study

The last and perhaps the most important issue leveled by the innovations resulting from artificial intelligence systems is that these systems can be recognized under the existing patent system. Neither the patent law nor the USPTO are explicit barriers against the patentability of artificial intelligence inventions. It is said that the patent law introduces the inventor as a person who invented or discovered the subject of the invention, and failure to correctly cite the ability to innovate can lead to the invalidity of the patent. Thus, the requirement that inventors not only does not prevent artificial intelligence systems from having patent rights. Back, which was also a patent, does not prevent the resulting invention. Case studies One of the most important recent developments in this field includes patent applications for two autonomous inventions resulting from the artificial intelligence system, which the system itself is recognized as an innovator. This system, which is called DABUS, uses neural networks and general information in a field to create problems and provide new solutions without human intervention. There is no need to delegate or delegate the task of solving specific problems. It has the ability to identify problem areas and provide completely autonomous solutions.

The inventor of this system and a team of experts have applied for a patent in the United States, the European Union, and the United Kingdom, and under the cooperation agreement, they have filed a patent for two inventions from DABUS. For the first time, the applications listed the AI system as the inventor, not the inventor. The United States Patent and Trademark Office (USPTO), the European Patent Office (EPO) and the UK Intellectual Property Office (UKIPO) discussed the issue of inventive step in their responses to the request. The US Patent Office issued a notice to fill in the unspecified parts of the application due to not specifying the legal name of each inventor. In its final decision, this department discussed the request of the applicant to cancel the notification of the issue of inevitability and machine inventors. In this decision, it was emphasized that the legal definition of invention according to Article 100a of the Patent Law refers to an individual and by using the phrase "anyone who invents or discovers" in Article 101 and the use of the pronoun "himself" in Article 115 of the Patent Law. that the inventors must be real persons. The Office noted that the Patent Act exempts several local interpretations to interpret the phrase inventive step to include machines. In the continuation of this decision, it is explained that the human initiative theory has been supported by several federal opinions(16).

The European Patent Office also rejected the request with the argument that "they do not comply with the requirements

of the European Patent Convention that the inventor of the requested design must be a human and not a machine." This department pointed out in its discussions that artificial intelligence systems do not have legal personality and Benarian cannot enjoy the rights that an innovator has. The statement also rejected the applicants' argument that they should be entitled to patent-related rights as employers of DABUS, stating that AI systems cannot be employed (hired) nor can rights be granted. transfer them to the successor who has the right of ownership. In the same way, focusing on the issues of inevitability, the UK Intellectual Property Office concluded that the request did not include a suitable expression of inventiveness and ruled in its assessment that DABUS is a machine and not a person and cannot be considered innovative (16).

Conclusion

The patent system is widely criticized for its effects on restricting access and hindering subsequent innovation. The effect of patents in the pharmaceutical industry is particularly a matter of great fortune. Health care is a human right that cannot be realized without proper access to medicine.

Artificial intelligence has revolutionized pharmaceutical innovation. Faster and more efficient research and development (R&D) resulting from artificial intelligence undermines the justification for pharmaceutical patents. Artificial intelligence is a "game changer" in the healthcare industry, and law must keep pace to ensure that society reaps its benefits. The main goal of legal science in the context of the subject of this research is to amend the existing laws to fill the gap and void of pharmaceutical innovation with the help of artificial intelligence and in this way the right to human health is realized in every way. Artificial intelligence innovations face issues regarding patentability and patent policy in general. Recent developments show that patent law reforms are inevitable. Due to the lack of evidence regarding the efficiency of the patent system and placing health care as a right to health, the pharmaceutical industry is lagging behind in this field. Artificial intelligence innovation gaps give legislators the opportunity to take appropriate action to fill this gap.

Conflicts of interest

All authors declare no competing interests.

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Challenges of the Intellectual Property System in Pharmaceutical

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