Research on the Adjustment of Patent Protection Standards under Emergencies: Based on the TRIPs Agreement

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Abstract. The patent system has a catalytic effect on innovation and imports, which could go some way to alleviating the current vaccine dilemma in the pandemic environment, i.e. insufficient capacity and inequitable distribution. This paper identifies this role through a review of the patent system and the TRIPs Agreement and argues that countries have the flexibility to adapt their patent systems to the current situation through the flexibility provisions of the TRIPs Agreement to maximize this facilitative role in addressing the vaccine issue. This paper suggests that in the current pandemic environment it is necessary to stimulate pharmaceutical companies to accelerate the process of vaccine development by reducing the inventive step testing requirements. In addition, to reduce market risk and maximize the extent to which patents can facilitate the vaccine development process, this paper argues that flexibility should not be used as an excuse for adjusting the duration of protection and requiring a complete patent waiver.

Keywords: Vaccines, Patents, TRIPs, Flexibility.

1. Introduction

It has been more than two years since the first infected person was identified, and the ongoing collaboration between countries around the world and the efforts of medical companies and research institutes to develop solutions to fight against the epidemic. However, the highly infectious and lethal nature of the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) causes the epidemic, the 2019 Coronavirus disease (COVID-19) still infects nearly half a billion people and causes more than six million deaths [1]. The development of a vaccine is often considered to be one of the most effective ways to combat the epidemic, so the question of how to develop and produce effective vaccines in large quantities and in a short time frame is a key issue in the fight against the Covid-19 [2-3].

To address the issue of production capacity, some developing countries, such as India, have argued that there is a wide disparity in vaccination levels between developed and developing countries and that some vaccine patents should be waivered in developing countries to facilitate production and equitable distribution of vaccines [4-5]. On the other hand, some opposition to these seemingly fair statements has emerged. Some developed countries and multinational pharmaceutical companies have claimed that patent waivers would not provide enough rewards for developers, thus hindering the process of vaccine development [6]. In addition, some scholars argue that even the adoption of patents waiver laws in developing countries does not guarantee increased production of vaccines, as the production of vaccines involves many trade secrets in addition to patents, and access to patents alone does not lead to the successful production of effective vaccines [7].

This paper argues that when vaccine development is slow or production capacity is insufficient, it is necessary for member states to use the flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) to tailor the details of patents to the dilemmas faced by their countries in order to address issues relating to vaccines. This paper will first discuss the history of the patent system and the international patent treaties, summarising the conclusions that the patent system has a catalytic effect on innovative behaviour. The second half of the paper focuses on the use of the flexibility provisions, arguing that countries can increase vaccine production by adjusting the inventive step requirement of patents where there is insufficient vaccine production capacity, but that

otherwise there should be no adjustment to the duration of patent protection and no requirement for a complete patent wavier on vaccines.

2. Overview of patent regimes

Although some scholars have argued that patents can be described as monopoly rights and that they lead to monopolies, however, a review of the history of patents and the relevant provisions shows that patents were created to facilitate the development of technology and international trade [8]. This section discusses this view in the function of intellectual property rights and the overview of the TRIPs Agreement.

2.1. The function of patent rights

The formal legal system relating to patent rights was born in Europe in the fifteenth century to break the organized secrecy of medieval kings, churches, and other workers' organizations and to encourage innovation by skilled workers. This legislative approach to encouraging innovation continues to this day, and indeed the core of today's patent system continues to promote innovation and importation by granting exclusive rights to inventors [9]. And considering the modern patent regimes, this paper argues that the function of patent rights in promoting innovation can also be derived from the following aspects. Firstly, patents have a limited term of protection. During this term of protection the patentee enjoys the right to control the content of the patent and has exclusive use of the product and technical details of the patent, however, when the term of protection expires, the technology documented in the patent enters the public domain and becomes public property. This term of protection, as provided for in Article 33 of the TRIPs Agreement, is at least twenty years. As the patentee does not have permanent exclusivity over the product or technology it has developed, in order to prevent its technology from being freely available to other companies after the expiry of the patent, the patentee must develop more advanced products or technologies before the expiry of the patent to maintain its competitive position. This term puts a certain amount of pressure on the patentee to conduct research and development, which to a certain extent pushes the patentee to make substantial and innovative improvements to its original patent or to develop new products and technologies on the basis of its original patent. In addition, the term of protection of a patent also prevents monopolistic behaviour to a certain extent, as the content of the patent can be legally used by other companies after the expiry of the term of protection and the patentee cannot rely on a patent to prevent other companies from competing forever.

Secondly, the disclosure of technical details of a product by a patent can facilitate secondary research and development (R&D) [10]. Unlike a trade secret, a patent application requires an application to be filed with the patent examining authority, which often contains a specification with sufficient detail to disclose the product or technology and claims declaring the boundaries of the rights. These documents are then made available to the public after the patent examiner has approved the decision to grant the applicant a patent. The consequence of this is that, although the patentee can safely enjoy the benefits of the patent, the fact remains that the details of the technology are already in the hands of others. While other companies or individuals must not infringe the patent rightfully owned by the patentee in accordance with the content of the claims, it is legal to conduct secondary research and development beyond the rights stated in the patent claims based on the technical details already available, which is also one of the best ways for companies or individuals to learn from advanced technology. The requirement to disclose technical details of a patent introduces the public to the details of the advanced technology or product, creating a de facto sharing of technology, allowing for imitation and secondary development of the original patent, which introduces a new incentive for competition in the marketplace.

2.2. Overview of the TRIPs Agreement

The TRIPs Agreement came from nearly a decade of lengthy negotiations, during the 1986-1994 Uruguay Round of the General Agreement on Tariffs and Trade (GATT). Some developing countries argued that the premature implementation of stricter IPR protection policies would stifle their economic development, and they engaged in several rounds of debate with the opposing developed and developing countries, with the result that the side that wanted higher standards of IPR protection facilitated international trade won [11]. Ultimately, in 1994, the TRIPs Agreement was finally published as part of the WTO dispute settlement mechanism and became the first comprehensive set of legally binding international treaties for the protection of intellectual property in international law [12]. Compared to other international treaties, the TRIPs Agreement is both procedural and substantive in content, with substantive provisions on the scope of patent rights and procedural provisions on dispute resolution mechanisms for infringement. In addition, to ensure that the agreement can be implemented in countries with very different national circumstances, the TRIPs Agreement explicitly introduces the concept of flexibility in Article 1.1, which emphasizes that the content of the TRIPs Agreement can be adjustable to adapt when the minimum requirements for the protection of IP rights are met [13]. The provisions on flexibility are also, to some extent, a product of the adaptation of the TRIPs Agreement to its mandatory provisions. In contrast to other international treaties, the TRIPs Agreement does not allow member states to pick and choose the provisions in the list of rights that are in their interest while reserving others but requires them to accept all the rights and obligations under the treaty, while only allowing some least developed countries (LDCs) to postpone the deadline for accepting their treaty obligations [14].

As mentioned above about the divergence of views between developed and developing countries in the Uruguay Round negotiations, the TRIPs Agreement has some obvious disadvantages for some developing countries, particularly the LDCs. Apart from the premature and onerous protection obligations for developing countries accession to TRIPS brings a risk of instability into the economic systems of developing countries. Although accession to the TRIPs Agreement has provided developing countries with a relatively well-developed system of IPR protection, and to some extent has led to an increase in the number of domestic applications for patents and other IPRs, in practical terms, particularly in LDCs, the majority of applications are for patents held by foreigners [15]. Not only does this illustrates that a stronger IP protection system is less effective in promoting technological progress in developing countries, but it also illustrates that markets in developing countries may be monopolised by foreign companies, which could undermine the general supply and demand relationship in the market, leading to the risk of market failures such as economic crises [16].

While for some LDCs, the TRIPs Agreement is an international treaty that puts pressure on them. For most other countries, however, the TRIPs Agreement is an intellectual property-related agreement whose implementation positively impacts the protection of intellectual property rights in member countries and international trade between them. Firstly, the TRIPs Agreement provides minimum standards in its various chapters, such as the minimum definitions of copyright, trademark and patent rights. This approach of setting minimum standards allows, on the one hand, for the establishment of national minimum standards for intellectual property rights and allows for general agreement on matters of principle such as the length of protection and the exhaustion of patent rights. On the other hand, the minimum standard approach also allows countries with national circumstances to adapt their IPRs protection provisions to the TRIPs Agreement. In fact, a significant number of developing countries have higher standards of domestic policy protection than the TRIPs Agreement, which they have adapted to their national circumstances regarding specific aspects of the TRIPs Agreement [13]. In addition, in regions where IP protection systems are not well developed, local countries have often joined together to form regional IP organizations such as the African Intellectual Property Organization (OAPI), which are able to coordinate IP protection policies between countries at a level that goes beyond the national level, and the TRIPs agreement does not put as much pressure on countries as previous scholars have feared [17]. Overall, accession to the TRIPs Agreement has

resulted in the harmonization of principles for member states, while leaving room for adjustment to national circumstances, making international trade in IPRs possible.

This section describes the role of the patent regimes in promoting innovation and provides a summary of the TRIPs Agreement and its impact. In general, the TRIPs Agreement is a double-edged sword that has been a blessing and a curse for some countries. While the global harmonization of the IP trade system has put economic and policy pressure on them, it has also provided them with a boost to innovation through offshore investment and a well-developed IP protection system, which is invaluable at a time when the Covid-19 epidemic is rampant.

3. Suggestions for adjusting the patent rights system

Although scientists have found the vaccine to be one of the most effective ways to fight against the Covid-19, the reality is that the vaccine is not sufficiently available and is unevenly distributed, with vaccination rates in the LDCs standing at a dismal 11%. It is for this reason, that the promotion of innovation by the IPR system mentioned above is repeatedly highlighted in this paper, as it can effectively mitigate the reality of the slow pace of research and development of vaccine production. This section argues that to make the role of patents as a catalyst for innovation more visible and to address the immediate problems, countries could use the flexibility provided by Article 1.1 of the TRIPS Agreement to adapt their patent regimes to obtain a more targeted response. This section will discuss the impact of flexibility on the vaccine development process for pharmaceutical companies in terms of the three areas in which one aspect should be adjusted and two others should not be adjusted.

3.1. Countries should adopt the inventive step test to national conditions

Compared to other categories of intellectual property, obtaining a patent is slightly more difficult. In terms of the procedure for obtaining a patent, an inventor must file an application with the patent examination department and undergo a lengthy patent examination period and incur high examination fees [18]. In terms of the content of the patent, the requirements for the substantive novelty of the products are also more stringent and are usually subject to prior or post-examination by the patent examination department [9]. While higher examination fees and better examination mechanisms could admittedly lead to a significant reduction in the number of useless patents, this paper argues that in order to give full play to the incentive effect of the patent system on research and development, it is possible to make it easier for pharmaceutical companies to obtain patents by adjusting the requirements for the inventive step of patents.

This suggestion is based on Article 27.1 of the TRIPs Agreement and is essentially intended to broaden the scope of patentable subject matter for pharmaceutical companies, thereby facilitating accelerated research and development. Under Article 27.1 of the TRIPs Agreement, a patentable product or technology should be novel and have an inventive step and be capable of being used in an industrial application. The inventive step, as detailed in S.3 of the UK Patents Act 1977, means that the step would not have been obvious to a person skilled in the art. The word ‘not obvious’ here is the key step in the whole test and can be used to distinguish whether the step is common knowledge or a novel approach that would not readily be thought of by others. To test whether the step is inventive, the English Court of Appeal in Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd ([1985] R.P.C. 59) introduced a four-part test, which involves identifying the relevant common knowledge of those skilled in the art and who should have it, identifying the inventive steps, identifying the steps involving the concept of innovation, distinguishing between the prior art and new technology and finally considering whether the difference is an incremental step that can be seen by those skilled in the art. Most countries around the world now judge inventiveness under the TRIPs Agreement by making tests like this, the purpose of which is to compare the new technology or product being patented with the prior art, and if the new technology is above the average level of the prior art, then it satisfies the requirement for the inventive step of the patent [19].

The reality, however, is that this test of obviousness, while seemingly capable of discerning the innovation of a patent, is not as effective as it could be assumed in areas such as biology and pharmaceuticals due to the inherent characteristics of particular disciplines [19]. This is evident in the following two aspects. Firstly, it is difficult to define the common sense of those skilled in the field of molecular biology. For example, mRNA vaccines immunize against viruses by incorporating mRNA into the recipient's own cells, causing the recipient's cells to produce specific antibodies against the virus [20]. This form of immunity is closer to that found in nature and is considered to be somewhat more effective [21]. However, the development of this vaccine is also fraught with uncertainty, as molecular biologists have developed it on the basis of active cells, and it is extremely difficult to exclude the influence of the biological activity variable on the outcome of each experiment, as the biological activity of the cells may influence the outcome. This combination of uncertainty and coincidence leads to the seemingly absurd fact that if the results of each experiment are likely to deviate from the previous one, it is questionable what results can be used as common knowledge for comparison with new techniques.

Secondly, it is difficult to define whether the new technology is more innovative than the previous technology. As mentioned above, the key mission of a patent is promoting innovation, which is an improvement of an existing product or technology. Focusing on the production of vaccines, while the immunity of a vaccine against a virus can be assessed statistically in clinical trials, the inventiveness of the process of vaccine development is difficult to determine. This difficulty also arises from the experimental uncertainty in the field of molecular biology. In molecular biology experiments, biologists are often trying to find the best way to achieve their experimental expectations based on a particular biological law. In the case of Japanese biologist Shinya Yamanaka's work on induced pluripotent stem cells (iPS cells), for example, after arriving at Kyoto University in Japan, he and his colleagues conducted experiments on each of the 24 groups of candidate genes that had been screened and eventually identified the group of genes that would enable the cells to exhibit pluripotency in the midst of the vast amount of experimental data [22]. The discovery of the iPS cell was so great that Shinya Yamanaka was awarded the Nobel Prize in Physiology or Medicine in 2012 for it, and there is certainly no denying his brilliant idea and experimental design. However, the way in which the final stage of his research has to be noted, as the success of his experiments was not due to the use of more advanced experimental methods, but rather to the fact that his exhaustive experiments eliminated 23 wrong answers from 24 sets of candidate genes. Such exhaustive experiments are also common in vaccine development, and the pharmaceutical companies that succeed in developing new vaccines often do so not by using more advanced manufacturing methods, but simply by finding the right way to produce them through countless trials based on existing technology. According to the traditional standard of the inventive step of a patent, this method of production is not an inventive adaptation of a process or procedure, but merely a change in production detail, it is doubtful that such a product will be patentable.

In summary, the traditional inventive step test for patents has been challenged in the field of vaccine production and has indeed raised the concerns of many scholars. This paper argues that, in order to achieve the goal of stimulating pharmaceutical companies to develop vaccines through the patent system, it is necessary for each country to further define the criteria for the inventive step test in the pharmaceutical industry according to its national circumstances. In particular, it may be difficult for developing countries to integrate the results of molecular biology experiments into a more uniform common knowledge, as their scientific strength or the expertise of their patent administration is somewhat less than that of developed countries. In this case, these countries can use probable explanations or explanations made by individual scientists as common knowledge for comparison with new technologies to complete the inventive step test. In addition, countries could also make adaptations to the inventive step test for exhaustive experiments, for instance, by patenting and legally protecting drugs with new ingredients and better efficacy, which could also help pharmaceutical companies in their own countries to obtain more diverse patent rights.

3.2. The term of protection of a patent should not be extended

The flexibilities provided for in Article 1.1 of the TRIPs Agreement give countries considerable flexibility to adapt their patent policies to a certain extent, however, in fact not all of these adaptations will improve the IPR dilemmas faced by countries. As mentioned earlier, patents are usually protected for 20 years, a time that balances the need for companies to recover the costs of research and development with the need to reduce the risk of monopoly [23]. Typically, it takes roughly 10 to 15 years from the time a drug is developed to the time it reaches the market, during which time pharmaceutical companies spend hundreds of millions of dollars on the discovery of drug formulations and clinical trials [24]. This is one of the reasons why pharmaceutical companies are willing to apply for patents, as they can receive a high return on their investment during this period and do not have to worry about the risk of misappropriation of the technology used to make the drug. Because of this benefit, it would seem that extending patent protection in the face of the current Covid-19 epidemic would provide an incentive for pharmaceutical companies to engage in research and development, thereby alleviating the shortage of vaccines. However, this is not the case, as pharmaceutical companies have often obtained exclusive marketing periods of well over 20 years through what has been described as an 'evergreening' strategy, and further increases in patent protection are unnecessary and may even introduce a greater risk of market failure [25].

Evergreening is a strategy often used by pharmaceutical companies to extend the exclusive period of their products. It refers to the practice of pharmaceutical companies filing multiple patents on different features of their original products or filing new patents on only minor changes to their original product that do not affect its functionality [26]. For example, a company producing spray in cans could first patent its nozzle design and then, after the patent on the nozzle has expired, patent the can, so that producer could enjoy a fairly long period of exclusivity for the same product or technology. Long-term, unrestricted exclusive sales would encourage unfair competition by pharmaceutical companies, allowing patentees to increase the price of their products or reduce the quality of their services in an uncompetitive environment without suffering the consequences of losing customers, or they could replace old products that are still effective with secondary patented products that do not have a particularly substantial improvement, simply to make more money [27].

The potential for bad outcomes from a pharmaceutical company's evergreening strategy runs counter to the design of the patent system itself to promote innovation, while increasing the duration of patent protection may add to the long-term exclusive period of the company. 20 years of patent protection combined with an evergreening strategy already allows pharmaceutical companies to recover the costs of research and development from their products for a significant period, so extending the patent protection period is unnecessary and cannot be done.

3.3. Full patent waiver should not be claimed

The patent exemption referred to here refers to a proposal published by India and South Africa with the World Health Group during the pandemic, the core idea of which is that each country has the right to produce vaccines for its nationals, a move designed to reduce barriers to vaccine production and distribution, particularly for low-income countries [28]. The reality, however, is that this proposal is well-intentioned but may not achieve the desired result. As noted above, the expertise required to produce a vaccine is not limited to the patents held by the pharmaceutical company but also resides in the company's proprietary trade secrets, and the technical standards for producing a vaccine based solely on what is documented in the patent are so high that simply asking for an exemption from the patent will not enable the vaccine to be produced competently in developing countries [29].

Secondly, there are arguments against exempting vaccines from patenting because some developing countries have a poorly regulated pharmaceutical industry and abandoning patent rights could lead to disruption. As some scholars have feared, a patent exemption would be like offering developing countries a recipe that would be difficult to turn into a helpful dish due to a lack of quality raw materials and a large skilled workforce, as well as a lack of regulation of their production and

distribution processes [30]. The problem is similar in the case of vaccine production, where developing countries lack a sufficiently rigorous regulatory framework for both production and distribution, some of which do not even meet minimum biosafety standards, and there are inevitable concerns about the safety of vaccines produced by such unregulated production lines and questions about the fairness of distribution [31-32].

In addition, the reason for opposing the request for exemptions from vaccine patents in some developing countries is that current vaccines are not effective. As mentioned above one of the greatest values of patent rights is to facilitate the innovation process of the inventor, an exemption now would probably defeat this facilitation effect, in short, there may be an increase in the production of vaccines in the short term, but people would lose access to more advanced and effective vaccines, which in the long term would not be worth the cost.

4. Conclusion

Based on the TRIPs agreement, this paper examines the role of the patent regime as a catalyst for vaccine production in the current pandemic environment and further explores how this role can be maximized within the existing regulatory framework. The paper seeks to clarify that the patent system is an inherent facilitator of innovation and importation, which is important for vaccine development in a pandemic environment. This facilitation can be maximized by adopting national IPR provisions within existing regulatory frameworks using the flexibilities allowed by the TRIPs Agreement. More specifically, the test for the inventive step in the existing regulatory framework should be adjusted as it does not fit well with the current state of modern molecular biology, for instance, the criteria for determining inventiveness for exhaustive experiments should be relaxed. Finally, in order to reduce market risk and maximize the extent to which patents can facilitate the vaccine development process, this paper argues that flexibility should not be used as an excuse for adjusting the duration of protection and requiring a complete patent waiver.

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