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Patent Races and Institutional Solutions of Health Care Policy in Developed Countries

Abstract

Objectives: To identify the methods of the state's influence on health care system through intellectual property law mechanisms.

Research Design & Methods: Literature review based on the economic analysis of law.

Findings: An active role of the state in innovations in the pharmaceutical branch could bring benefits in the health care system. This role does not have to be limited to being a shareholder in selected projects (as a capital supplier).

Implications / Recommendations: The state is able to influence the speed, the structure, and the direction of patent races by setting a real width of the patent (court verdicts) and patent height (patent office's decisions) as well as the manner and the scale of compulsory licences usage.

Contribution / Value Added: Making changes in the speed, the structure, and the direction of patent races has got a strong impact on health policy. Appropriate influencing of the state on innovation activity in the pharmaceutical branch allows one to generate large benefits in the health care system.

Article classification: theoretical article: original literature review

Keywords: health care policy, patent, intellectual property, innovation, pharmacy

JEL classification: I18, L38, O30

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Introduction

Health care systems in developed countries have been shaped under the strong impact of the New Public Management and the Governance approach. Despite this fact, in the context of intellectual property, the scale of state-entrepreneurs collaboration is very minimal. This is the result of not recognising the common area of innovation policy and health policy. This area relies on patent for medicine and medical device. In spite of the fact that many reforms have been based on decentralisation, the usage of market mechanisms, and cross-collaboration, collaborations in the intellectual property creation have never been popular.

In this context, the implementation of the Governance and the New Public Management could be the solution for the permanently underfunded health. It would help the recipients of public services to understand the limitations and difficulties which appear in the system (Możdżeń, 2015, pp. 22-36). What is worth emphasising is the fact that the health care area is seen as extremely expensive even in developed countries. The main reason for that is the fact that they have to face the problem of the ageing society. Beside the Governance and New Public Management approach, the efficiency of the health care system could be achieved as a result of the co-creation of intellectual property, which also is the aim of this text.

Material and methods

The analysis of this paper is restricted only to developed countries, because over there one can observe the space to conduct more sophisticated policies in the area of innovation and health protection (Grodzicki & Geodecki, 2016, pp. 377-404). In the poorer countries, the health care systems focus only on providing basic care. What can be observed there is that innovation is replaced with imitations. However, the results of E. Adang and G. Borm's (2007) research revealed that there was no strong correlation between society satisfaction and financial input on a selected public policy area. It means that in certain circumstances society satisfaction can be achieved even without innovations.

The aim of the text is to identify the methods of state influencing on health care policy through shaping the model of legal intellectual property protection and active innovation policy in the pharmaceutical branch. As a result of a separation between the above-mentioned public policies, states deprive themselves of the opportunity to use one of the strongest grounds for an active policy in the area of pharmaceutical innovation. Thus, the society could be more in favour of investing a huge amount of money in the pharmaceutical branch if benefits were not almost entirely privatised. It is about situations when an active innovation policy in the pharmaceutical branch provides a significant share in the benefits of introducing a new drug into the state. Naturally, it would be realised in the form of savings in health care.

Moreover, the form of the collaboration with the pharmaceutical branch does not have to be limited to being a shareholder in the selected projects, or playing a role which makes risk management easier. The state is able to provide many different stimuli, whose results affect the health care system. Those stimuli can be based on the shaping of many phenomena related to intellectual property law. In this text, the subject of the analysis is the question of the possibility to make an impact on the speed, the structure, and the direction of patent races. Additionally, what is analysed is the reaction of the state to some inconveniences in this area – especially in the context of the above-mentioned risk-management.

Literature review

As H. Rothang (2010, p. 237) mentioned, "Healthcare systems can be characterized by the ways they fulfil three basic functions: financing, service provision and regulation, which can be conceptualized as the dimensions of a healthcare system. (…) Considering all dimensions of the healthcare system, the most remarkable development over the last 40 years is that distinct healthcare

system types have become hybrids. The systems have thus, converged in the sense that they now have more similarities and are much less distinct systems than at the beginning of our observation period in the 1970s. Variation between healthcare systems has declined and the corridor for national features of the healthcare system has narrowed markedly."

According to OECD research (Kikuzawa et al., 2008, p. 386), health care systems are under the similar pressure worldwide. However, there are different answers involved, since in every country there are various debates about the organisation and financing of health care systems. Sometimes, the main topic is the issue of the total spending on that purpose (like in the US). In other countries, people discuss the role of the government in financing costs (Sweden, Canada) or the issue of restrictions in health care (Germany, the Netherlands). However, in public debates it is always just a small element of this complex issue.

There is research which suggests (Brest et al., 2012, p. 423) that citizens who live in centralised health care system or in a national system are more eager to support stronger government engagement in health policies. On the other hand, people who live in insurance systems are much more sceptical in this matter. It seems that it could be explained through the aversion of societies to experiment in the area of such important public policies. Therefore, we can observe such an attachment to the existing model and the acceptance of its deepening, because such actions are less risky than implementing elements from foreign models. Moreover, it is mentioned that health care systems can be characterised as CAS – Complex Adaptive Systems. It is the consequence of a high level of the unpredictability and resistivity of implementing changes in an imperious way.

In the second half of the 20th century, the triumphant concept of the welfare state has led to an exponential increase in spending money on social and health care. Moreover, now it is magnified with the process of ageing societies. This has led many countries – even the most developed ones – to significant problems in financing such extended benefits. In addition – according to the public choice theory – in the face of the awoken public expectations, politicians do not want to have any cuts in the guaranteed benefits. Some authors indicate that the solution can be found in the strict cooperation with universities (Mamica, 2018) or local government units (Kudłacz, 2017). However, such a cooperation usually requires financial incentives from external sources (Kwaśny, 2017).

The only way to produce improvement in the financial situation of the discussed area (without drastic reduction in the quantity and quality of the benefits) was to undertake reforms aimed at improving the efficiency of the system. Therefore, it was natural to reach for postulates of the New Public Management that had been very popular since the 1980s. Hence, the introduction of reforms stimulating competitiveness, freedom of choice, and assessment through results, was visible in many countries. Moreover, the rules for the division of budget funds were predominantly based on performance indicators (Kodate, 2010, pp. 263-264).

Results

One of the most important elements of the new model based on shared management in the public sector is the public-private partnership (PPP). It is a model of cooperation between public finance sector entities and private partners, which is very popular in the world. In a typical PPP model, the private partner is responsible for providing a predetermined public service, not just for providing some assets for this service. It significantly differentiates such a model of cooperation from the traditional public procurement model, where the private sector is only responsible for providing assets.

In this context, the PPP model is very attractive from the public-interest point of view, because on the one hand it ensures the optimal spending of public funds (the decision to choose a PPP as the best form of implementation is preceded by

many analyses) and on the other hand it guarantees the supervision and control of the public party over the type and quality of services commissioned to be provided by a private partner (Kalecińska & Herbst, 2011, p. 7).

There are international findings saying that PPP in health care most often takes the shape of two models of solutions:

1. contracting construction/modernisation and operation of a hospital in which medical services are provided by a public entity – a typical PPP model in health sector in the world; an option widely known and accepted by the market;
2. contracting medical services from a private entity (provided in a hospital built/modernised and operated by this entity) – an option quite rare; well-known examples in Spain, Portugal, and Australia.

Therefore, there is no formula in which co-operation within the framework of PPP would take place in the creation and commercialisation of drugs, which would then be used in the treatment of patients in health care system covered by the state. Undoubtedly, it would be a much more complicated and time-consuming formula. However, it would facilitate the management of risk by pharmaceutical companies. Moreover, the state would get a better chance of directing research, e.g. in order to take more cases of medicine for rare diseases into account.

In this context, it is worth mentioning that an interesting solution was adopted by the US Congress in the Orphan Drug Act in 1983. This document was supposed to be at least a partial solution to the problem of insufficient benefits for the drug inventor under standard patent protection due to the rarity of the disease, which naturally translates into a potentially low demand. It has been determined that a rarely used drug refers to diseases or conditions occurring in less than 200,000 people in the United States. Under the Act, drug manufacturers were granted tax concessions for clinical trial costs and other subsidies in order to cover the manufacturing costs of these products. In addition, producers obtained stronger exclusivity for seven years – during this period alternative medicine with different chemical composition was not allowed. This exclusivity could be revoked when the entity did not provide the patients with the drug, or when they ceased production.

The problem of too much focus of pharmaceutical companies on providing solutions for common but less serious ailments is perceived by many countries. It results in introducing various incentives in the form of general acts of law. Yet the same effect can also be achieved as part of PPP. Additionally, it would not be the only positive effect for the state, since it would also cause savings in providing health care.

The analysis of various forms of PPP shows that the combination of health policy and the regime of intellectual property protection is relatively rarely seen. In the area as sensitive as health and human life, the subject of patent racing seems to be the key issue. A patent race is the competition in which the main question is about which inventor will reach such a high level of advancement first so that they are able to submit a patent application successfully. The shape of the patent race does not only affect how quickly a solution can be found, but also for how many people it will be available during the first twenty years (during the period of validity of the patent whereby the manufacturer benefits from the monopoly privileges).

One of the basic determinants of the intensity of the patent race is the size of the prize, which is created by the length of the patent (duration), width, and height of the patents granted. The width of the patent determines how different the imitation must be in order not to infringe the patent. However, the height plays a special role here, as V. Denicolo (2000, pp. 488-501) has indicated. The height refers to the second type of a potential infringement, which is the improvement of the patented invention – mainly in the context of a small effort in relation to the increase in usability. The bigger height is when the more advanced future improvements are included in the original patent granted for the basic invention.

Even in the patent system which is globally strongly unified, individual states have got a certain space to conduct a separate policy. In principle – except for the length of the patent, which is regulated by international agreements – the question of specifying its width and height is in the hands of the law-abiding entities. Therefore, even without major legislative changes, it is possible to shift court judgments in imitation cases as well as in the manner of patent offices decisions (how a far-reaching improvement of the existing state of the art makes it possible to achieve a separated patent). On the one hand, the length, width, and height of the patent affects the degree of the acceleration of research, and on the other hand they cause a proportional increase in the phenomenon of duplication.

The innovation process has got several stages. The existence of these phases gives the legislator the opportunity to choose the moment from which it is possible to apply for a patent. A proper determination at this point can allow one to minimise the social loss associated with the patent race. Granting the possibility of applying for patents in advance – i.e. in a situation where the invention has not already been developed in an advanced form – would result in the competitors abandoning similar projects which generate the costs of research duplication. However, this stage cannot take place too early, because it could result in the invention being developed too slowly as the inventor with a patent has got a weaker pressure.

It is necessary to distinguish between a competition within the patent race and the one that takes place on the market of finished products. Although these are two different rivalries, in many cases they interact with each other. If the market for the product becomes strongly monopolistic, competition in the patent race will be more intense. As a result, the monopoly on the final market causes – indirectly, by stimulating the patent race – an increase in the pace of innovation. In addition, each form of uncertainty (Dasgupta & Stiglitz, 1977, pp. 25-27) is an important factor which discourages one from engaging in R&D. However, it is partly a natural feature of the innovation process or an immanent property of a business. Wherever it is possible to reduce uncertainty, legal regulations are needed to this end in order not to limit the degree of incentives for an inventive activity.

The issue of disclosing discoveries even before filing patent applications is usually seen in terms of non-cooperative strategies, where the only purpose is to improve the inventor's own situation, usually related to the deterioration of the competitive position. The disclosure of such information can take the form of a defensive publication. It puts the solution into the state-of-the-art technology and, as a result, this solution cannot be patented by anyone, because the criterion of novelty cannot be met. Therefore, this strategy is based on blocking opponents from developing a certain solution, because it would be non-profitable due to the lack of patentability (and exclusivity). Defensive publications are useful in the situation where the company is not afraid of using a certain solution for competitors, and where the only goal is to exclude the possibility to be blocked by a patent, gained by a competitor. Defensive publication is easier than patenting, because it can be done on an earlier stage and it does not require going through a long and expensive procedure. Nevertheless, it can be a significant blockade and it can deprive the business competition project out of its meaning. Thus, it is a situation in which the company does not only decide on taking part in the patent race, but simply destroys its meaning, because no one will be able to receive an exclusivity prize.

However, S. Baker and C. Mazzetti (2005, pp. 188-189) noticed that this procedure might also be adapted and used as part of cooperative strategies. They provide an example of two companies that work on the same invention. For both parties, it would be beneficial to coordinate research, share first results, or specialise in a specific aspect of the invention. However, such a cooperation would be difficult due to the necessity of formulating an agreement specifying duties and entitlements related to the technology that will be created and

developed. The sole possibility of publishing the results of works can serve as an alternative punishment for the player who failed. Therefore, it could be an enrichment for the system of invention stimulation with non-legal elements.

The research results (Judd et al., 2007, p. 27) indicate that the unconventional duration of a patent race is, in most cases, an optimal policy. Naturally, the unquestionable advantage of the patent race is the exclusion of enterprises characterised by the low efficiency in cost management. This happens somewhat automatically without involving the state, which, after all, does not have data in this area, on the basis of which it could make its decisions. However, looking from a different perspective, it may turn out that the need to eliminate less effective enterprises is very doubtful. Especially so in the face of the threat that players who are thrown out of a market can re-appear as 'patent trolls', who significantly worsen the overall balance of costs and benefits in the inventories protection law system.

Therefore, the aim is to balance it on the basis of the economic analysis of law so that the patent races generate an appropriate cost/benefit balance. In this context, costs do not only include the ones related to duplicating research, but they also regard the inconvenience resulting from the limitations of access to the invention (the level of that depends on the strength of the granted patent). Consequently, the acceleration of the research is not a goal in itself, which can be considered without any restriction. Due to the above-mentioned costs, in some situations the pace of research can be considered as too high from the social point of view. In the context of health protection, the following interchangeability can be observed: the drug will appear faster (owing to the fast patent race), but the granted monopoly will be strong, which will limit drug availability in the first years. Or, in another scenario, the drug will appear later, but the monopolistic power will be weaker and, thus, the drug will be cheaper and more available.

Naturally, the pricing strategy of a company even with a very strong monopolistic position will take into account the price flexibility of demand. However, in the name of maximising profit, the number of patients for whom the drug will be available will became much less important. It should also be remembered that in this situation price regulation based on demand does not work in a standard way. Furthermore, in many cases, buyers are not individuals, but, rather, it is about the state as part of a healthcare system. Moreover, even if the drugs are purchased by the patients themselves, in many developed countries there are widespread subsidy policies which greatly affect the actual availability of some treatments.

Without a large-scale research, it is difficult to answer the question about whether the current system of legal protection of inventions generates an appropriate, too little, or too high level of incentives affecting research in relation to the corresponding costs. On the one hand, the public is irritated by the high prices of innovative products, because their availability is extremely limited.

In principle, the legislator has to take into account three aspects affecting the economic analysis of the patent race. Firstly, at what stage it should be possible to apply for a patent; secondly, what the losses caused by the duplication of research will be; and, finally, what the costs of the monopoly would be. The general relation observed in such a profiled model is the following – an indication of the earlier stage of applying for a patent reduces the costs of the duplication of research, which is the effect of shortening the race. The weaker patent reduces the monopoly costs, but at the same time it slows down the innovation process. However, the patent race is a positive phenomenon, which increases the probability of granting the patent to the most effective entrepreneur (Judd et al., 2007, p. 3).

Individual entrepreneurs can differently value a patent which is a reward in the specific race. Generally, monopoly companies in a given market value the patent more (which will allow them to maintain this position) than potential new players, who would start gaining a given sector just on the basis of an exclusive right. The different

value of the patent is also the result of unequal expectations regarding the discounting level of the innovative product as well as the different effectiveness of entities in the R&D area. To a large extent, this calculation is also dynamically influenced by the distance, which, in the opinion of a given entrepreneur, divides them from the finish line (Harris & Vickers, 1985, p. 195).

Discussion

Individual countries have the opportunity to influence the size of the patent race awards and, thus, the pace of these races and their shape. Changes in this area also affect the structure of innovative activities in the industry – the issue of broadening/narrowing the list of problems over which pharmaceutical companies work. It is worth considering remodelling the patent races with the alleviation of their fundamental rule – 'the winner takes everything'. It makes the patent race highly risky (which already at the beginning discourages entities which have risk aversion) and it generates huge losses for losers even if they were just behind the winner and incurred significant expenses. One of the forms of alleviation of these difficulties is to reconcile certain forms of the participation of losers in the benefits resulting from the created post-innovative equilibrium (Denicolo, 2000, p. 253).

However, the practical implementation of such an operation would be very complicated. It would be difficult to evaluate the involvement of individual entities in a specific race. Additionally, it would weaken the patent of the winner. Therefore, a better solution would be to weaken the patent *a priori*, which means that the involvement in the race will be smaller and, as a result, the loss of losers will be smaller, too. Moreover, the value of a patent will be easier to determine. By eliminating the risk of subsequent arbitrariness, it would be a sufficient incentive to invest in innovation. It is an intervention which would not complicate the industrial property law and would prevent the inventor from expanding the state of uncertainty.

Consequently, if the state is meant to be a more active player in pharmaceutical innovations in the name of benefits achieved in health care system, it is possible to take actions that will reduce the risk of entrepreneurs or direct their actions towards health policy objectives. Moreover, countries are entitled to grant compulsory licences (to force the delivery of a patented product at an arbitrarily-set price). The scale of using this mechanism is also an important stimulus for pharmaceutical concerns. Too much danger of arbitrariness in breaking the patent monopoly can effectively discourage the investment in new drugs, because this activity becomes even more risky. However, this does not mean that the policy of granting compulsory licences based on clear and reasonable premises cannot be part of the system which generates benefits in health protection through the impact on innovation in pharmacy by means of the mechanisms of intellectual property rights.

Conclusion

The role of the legal system is to construct a system of incentives for inventors in order to ensure that the patent race is of a moderate intensity. It is a phenomenon that naturally favours the realisation of the fundamental goal of industrial property rights, i.e. stimulating innovation. Yet it can generate extremely high risks as well – especially duplication research costs. Patent races are also an effective tool in the implementation of health policy. They influence the provision of the new drugs.

Thus, it needs to be remembered that from the social point of view the high speed of innovation is not an ultimate goal in itself. In all legislative works concerning the protection of inventions, this implies the necessity of a detailed analysis of the costs appearing on the social side. However, cost estimation is a difficult task. Moreover, societies have got different expectations regarding the pace of the inventions.

According to the intellectual property law, countries have got tools that allow them to play

an active role in innovation processes in the pharmaceutical industry. The need for such actions can be noticed only if one takes into account those benefits which appear in health care system. States as large entities can solve problems related to running innovative activity in the pharmaceutical industry much more effectively. As a result, such an active policy is also accepted by entrepreneurs. It is possible, because profit would be the result of the surplus generated by the earlier described higher state efficiency. Consequently, the abovementioned benefits in health care will not appear at the expense of the profits of the pharmaceutical companies.

All this into account, the state cannot only be a shareholder in the selected research projects in order to provide capital for a later share in profits. Intellectual property law gives countries the chance to influence the pace of the patent race and its direction. In addition, the authorisation to introduce compulsory licences allows states to influence the pricing policy of pharmaceutical companies. All of these changes do not apply to consumers. To a large extent, they have consequences for the state itself, because in the majority of developed countries a broadly defined health policy has been implemented. Therefore, the perception of these connections is one of approaches when looking for efficiency in spending public funds on extremely expensive activities related to health protection.

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