WYDZIAŁ PRAWA
i ADMINISTRACJI
Uniwersytet Łódzki

Anna Laszczyk

Patent Settlements in the Pharmaceutical Sector as Agreements Restricting Competition – Law and Economics Analysis – Summary

Ph.D. dissertation prepared at
the Department of Theory and Philosophy of Law
under the supervision of
dr hab. Mariusz Jerzy Golecki, prof. UŁ

Łódź 2018

Whether competition law should use rigid "per se" rules or rather standards, which are based on the more economic approach, has been heavily debated in the literature on competition law. It seems that this debate has slightly relaxed, however, it did not finally settle. Currently, the competition authorities more and more often need to analyse market practices whose welfare effects are ambiguous. This, again, poses a question about legal tests that need to be applied.

An example of the above is a market conduct of the pharmaceutical companies. Its ambiguous impact on competition is mainly caused by the peculiarities of the pharmaceutical industry (such as R&D intensiveness, high risk, high costs, the critical importance for society), the significance of the IPR and finally administrative tight regulations.

In 2009 the European Commission published the Final Report, in which it identified practices of the originator companies (i.e. companies that engage in R&D activities and develop novel medicinal products) that aim at delaying the market entry of the generic companies (i.e. companies manufacturing medicinal products that are bioequivalent to the products of originator companies). Such practices may be anticompetitive. The theory of harm is based on the alleged harm done to consumers resulting from a delayed market entry of generic products. Moreover, given that the governments usually reimburse the purchase of certain medicinal products by consumers, these delays may also harm the national health systems by generating additional costs.

An example of delaying practices are patent settlements concluded between a pharmaceutical originator and generic companies aimed at terminating a patent dispute. The European Commission considers as potentially anticompetitive patent settlements that include a restriction of generic companies' market entry. At the same time, the European Commission is suspicious about patent settlements that, besides market entry restriction, also include a value transfer. This value transfer usually takes the form of a payment of a lump sum of money (a reverse payment).

The European Commission explained that patent settlements including value transfer may restrict competition because they delay the market entry of generic pharmaceutical products. This type of agreements are named pay-for-delay agreements due to the fact that the value transfer is allegedly offered in exchange of the obligation to resign from an independent market entry. So far, the European Commission issued three

decisions concerning pay-for-delay agreements and considered them to be competition infringement by object (however in one of the cases, it also analysed effects of the agreements).

The approach adopted by the European Commission raised doubts among the scholars and practitioners. These doubts pertain to the relationship between intellectual property rights and competition law, the existence of the potential competition between the generic companies and innovative companies, whether the patent is an absolute barrier to entry and whether the market entry at risk may be considered as a sign of at least potential competition.

It is also doubtful whether the patent settlements should be classified as competition restriction by object. Given the absence of a well-established case law on patent settlements, it is arguable that the European Commission should analyse the effects of the patent settlements.

The approach of the European Commission raises concerns in relation to the broadening of the aims of the competition law that are not related to the functioning of the market. By a way of example in one of the decisions, the European Commission found that considering patent settlements as competition restriction is justified in the light of the need to ensure the access to the pharmaceutical products and the sustainability of the health protection system.

The doubts presented above prove that patent settlements deserve a thorough scrutiny. Despite the pharmaceutical sector being already analysed numerous times, including competition law scrutinises, the position of the European competition authorities towards patent settlements in the pharmaceutical sector has been known for a relatively short time. By a way of example, a non-provisional, public version of one of the decision issued by the European Commission was published only in July 2017.

The subject of this thesis are patent settlements concluded by an originator pharmaceutical company holding a patent and a generic company alleging invalidity of this patent or potentially infringing this patent as agreements restricting competition under the Article 101 TFEU and its national equivalents.

The research purpose of the thesis is to thoroughly consider, from the legal and economic perspective, conditions under which the patent settlements in the pharmaceutical

sector may be agreements restricting competition. To this end, the research purpose translates into providing answers to the following research questions:

i. what is the test applied by the European Commission and NCAs to the patent settlements under the Article 101 TFEU and its national equivalents,
ii. whether this test correctly incorporates the principles of finding a competition law infringement,
iii. whether this test sufficiently considers the particularities of the pharmaceutical sector and the features of the patent system,
iv. whether this test is justified in the light of the economic framework of creating rules and standards,
v. to what extent is it justified to draw parallels between the enforcement of patent settlements in the U.S. and in the EU.

Answering all these questions will enable fulfilling the ultimate research purpose of this thesis, i.e. to propose a legal test for the assessment of the patent settlements in the pharmaceutical sector.

The above analysis is conducted on the basis of the law and economic examination of the process of making legal norms, i.e. the choice between rules and standards. The starting point of the economic analysis is the model by Louis Kaplow. This model is further developed and supplemented on the basis of the findings of other prominent law and economics scholars.

This thesis employs a law and economic analysis, a doctrinal research, a case law analysis and a critical analysis. To a certain extent a comparative method is also applied. This is because the choice between rules and standards was widely discussed in the U.S. literature. The U.S. courts also have abundant experience in assessing patent settlements. Therefore, by failing to explain, discuss and compare the U.S. approach with the EU approach one would risk an incomplete and therefore erroneous analysis of patent settlements.

This thesis is organised into six chapters, an introduction and final conclusions. First five chapters aim at setting the scene, i.e. they present the main economic framework applied throughout this thesis as well as discuss aspects necessary for understanding the complexity of patent settlements in the pharmaceutical sector and difficulties with their

assessment from the competition law perspective. The last chapter offers original solutions to the research questions by providing a critical assessment of the current state of the competition law analysis of patent settlements and proposing a novel test for their analysis.

The first chapter introduces the concept of rules and standards. In the introduction, possible formulations of legal norms are discussed from the perspective of the theory of law. Further, these considerations are followed by the law and economic analysis. This chapter aims to explain (i) what the rules and standards are, (ii) how to determine the optimal choice between them, (iii) what values associated with rules and standards are and (iv) whether the distinction of rules and standards them is still valid.

The second and the third chapters explain the prohibition of the anticompetitive agreements both in the U.S. and EU antitrust law. These chapters serve two objectives, firstly they seek to familiarise the readers with the analytical framework of the prohibition of the anticompetitive agreements. Second, this framework is analysed from the perspective of the rules vs. standards. In the course of this analysis two hypotheses are verified, i.e.: (i) whether the rules vs. standards framework is applicable to the competition law and (ii) whether an object restriction/ per se rule concepts are rule alike whereas the analysis of effects/ rule of reason concepts resemble standards.

The first part of the analysis is based on the provisions of the relevant legal acts and case law. A separate brief part of the third chapter discusses the relations between the EU competition law and intellectual property law. The principles governing the application of competition law to cases involving IPR are also assessed from the perspective of rules vs. standards model.

The fourth chapter explains, from the economic and legal perspective, the idiosyncrasies of the pharmaceutical sector. The analysis aims to verify the hypothesis assuming that the features of the pharmaceutical market make the intellectual property rights of critical importance. Firstly, the economic peculiarities of the supply and demand side, the role of innovation and competition conditions are analysed. Then, the legal analysis addresses tools aimed at ensuring such a protection, i.e., patents, data exclusivity, SPC. Also, proceedings concerning obtaining marketing authorisation are briefly described. This analysis presents factors, both economic and legal, that enable to verify the

hypothesis assuming that the competition law intervention into the matters concerning the exercise of the intellectual property rights should be limited.

The fifth chapter discusses on patent settlements. It explains what patent settlements are, when they are concluded, how they are categorised from the competition law perspective. It also offers an economic analysis of the settlements. Further, it provides a detailed description of the EU and U.S. case law. The main aim of this chapter is to explain the anticompetitive potential of patent settlements, possible ways of competition law review and test applied by competition authorities and courts.

The sixth chapter provides two objectives. First, by applying the rules vs. standards framework, it critically assesses the approach adopted by the European Commission and national competition authorities with regard to patent settlements. This analysis is aimed at verifying the hypothesis assuming that the reasoning on the patent settlements presented by the competition authorities does not adhere to the principles of finding a competition law infringement as well as it does not adhere to the rules vs. standards model.

Further, by applying rules vs. standards model, it is attempted to create an original test for the competition law assessment of patent settlements in the pharmaceutical sector. The creation of this test is aimed to verify the hypothesis that it is possible to create a more differentiated rule that combines rules and standards in a way that: (i) strikes a right balance between accuracy and predictability, (ii) complies with the principles of competition law and the case law and (iii) considers the peculiarities of the pharmaceutical market and the features of the patent protection in the pharmaceutical sector. The proposed test encompasses three elements: (i) a safe harbour exempting certain patent settlements from the prohibition of the anticompetitive agreements, (ii) circumstances justifying the application of the by object restriction and (iii) circumstances justifying the application of effects analysis.

R/10/2018
Anna Lassalle