SETTLEMENT OF DISPUTES RELATING TO INTERNATIONAL TRADE CONTRACTS WITH PHARMACEUTICAL PRODUCTS

- Summary of doctoral thesis -

INTRODUCTION

International trade with pharmaceutical products is a current reality that manifests itself in multiple forms, being carried out by professionals, but in which consumers alike are also involved. Pharmaceutical companies develop new products in a state, perform clinical trials in another state, purchase raw materials from other partner companies abroad and manufacture finished products – medicines, in the territory that offers them more economic advantages. At the same time, the consumer or the patient seeks to identify and acquire new, effective, safe and affordable drug treatments. Thus, the consumer, having access to an international market by using the Internet, is determined to acquire the desired medicine from the market where it is available and affordable.

Currently, companies operating in the pharmaceutical industry would not sustainably conduct their operations without access to the international market, a situation determined by factors such as: the impossibility of recovering investments made towards research and development of new products; the inability to acquire all necessary raw materials from the local market; the need for permanent access to the latest technologies developed at international level in the pharmaceutical sector; the wish of companies to maximize their profits by expanding into new markets or reducing production costs by outsourcing processes in other states. Thus, trade with pharmaceutical products exceeds the country's borders at least in carrying out a process in the research-development, production or marketing activities of medicines.

Trade with pharmaceutical products inherently acquires an international character, on a local basis, the mission of pharmaceutical companies to produce and market new and affordable products in an industry sector characterised by competitiveness and innovation.

International trade with pharmaceuticals involves the conclusion of contracts. The contractual relations between the pharmaceutical companies, on the one hand and between them and the final consumers, on the other hand, do not always take place without misunderstandings, divergences, conflicts or even litigation. In the doctoral thesis "*Settlement of disputes regarding international trade contracts with pharmaceuticals*", the aim is to present the means that the parties have at their disposal to resolve the conflictual problems that arise during their collaboration.

The structure of this doctoral thesis comprises an introductory part and three chapters aimed at the analysis of the three main categories of means of resolving disputes – amicable means of resolving disputes, arbitration and

proceedings before the state courts – and ends with the conclusions reached and with a few proposals of *lex ferenda*.

The content of the thesis is organized in a logical and symmetrical manner in addressing the three means of dispute resolution, highlighting in each situation the settlement procedure, the advantages and disadvantages of their use, the standard terms of choice of how to resolve disputes used in international trade with pharmaceutical products. Each chapter ends with a section of preliminary conclusions on the analysis.

THE INTRODUCTORY PART presents the history of pharmaceutical sciences, the emergence and importance of pharmaceutical products for society. The second section is dedicated to presenting the terminology and clarifying the concepts specific to the pharmaceutical industry used throughout the thesis. The third section reveals the specifics of international trade with pharmaceutical products, specifying the participants, principles and regulations governing these trade relations.

In order to carry out the proposed research, it was necessary to make a summary of international trade contracts with pharmaceutical products representing the source of disputes in the pharmaceutical industry. Given that a wide variety of contracts are used in the international trade with pharmaceutical products, we have carried out a classification according to the time of conclusion, by reporting to three distinct stages: research-development of pharmaceutical products, their manufacture and their introduction into the trade circuit.

The main contracts analysed are: the confidentiality agreement, the supply agreement of pharmaceutical raw materials, the manufacturing contract, the products` quality technical agreement, the international marketing contracts (where we include the sales contract and the purchase order, online marketing, the distribution contract, the agency contract and the licensing agreement), the international transport contract of pharmaceutical products and the merger agreement. Disputes concerning international trade contracts with pharmaceutical products and their main generating causes are analysed in the last section of the introductory part.

In practice, the process of negotiating, drafting and concluding a contract of international trade with pharmaceutical products involves a long period of time, as the parties seek to include as explicitly as possible and in detail how cooperation will be conducted and, sometimes, the remedies for unlocking activities or resolving misunderstandings. Moreover, in most cases, the performance of the contract does not begin immediately after the signing of the contract, and it is necessary to fulfill pre-marketing actions, such as obtaining the marketing authorisation for the pharmaceutical product in the destination state. In situations where the parties do not provide contractual arrangements for resolving misunderstandings and the issue arises, the parties will assess from an

economical and legal point of view, the opportunity to file the action to the court, arbitration or alternative dispute resolution method.

CHAPTER I is devoted to presenting the means of amicable dispute resolution, except for arbitration, which is treated in a separate chapter.

Alternative means of dispute resolution can become the forum chosen for the majority of medical-pharmaceutical disputes, a justifiable choice by their advantageous characteristics. The complexity of pharmaceutical disputes and the willingness of the parties to continue cooperation, combined with the advantages of amicable settlement means, determines the parties to choose them at the expense of the courts and arbitration.

In the first section of the chapter, the legal nature of the alternative dispute resolution means and the principles under which these procedures take place, principles such as the principle of freedom of contract, the impartiality of the neutral third party or the confidentiality are analysed.

The second section comprises the presentation of alternative means of resolving international trade disputes, namely, negotiation, conciliation, mediation, expert determination, disputes board, mini-trial, binding advice.

Section three is reserved for the presentation of advantages and disadvantages of alternative means, in the context of their use in international trade disputes with pharmaceutical products.

We believe that the foundation underlying all the modalities of amicable dispute resolution is represented by the consensus of the parties. The trade relationship between the parties begin as a result of their agreement manifested by the concluding of the contract. Resolving a dispute resulting from an international trade agreement cannot be effective and allow the parties to continue their trade relations as long as they do not reach consensus again.

International trade with pharmaceutical products does not lead to immediate profitability, with the parties having to invest financial and temporal resources, which makes it possible to resolve any misunderstandings by means of enabling the continuation and development of economic cooperation relations. The alternative dispute resolution means, therefore, provide varied possibilities for resolving misunderstandings in a fast, effective and cost-efficient manner.

CHAPTER II is aimed to arbitration, an alternative form of dispute resolution which, considering its advantages, is well-know by the specilized literature as the main way of resolving international trade disputes. Due to important features such as the flexibility and confidentiality of the arbitration procedure, the specialisation of arbitrators and the binding force of the arbitral award, a large proportion of international trade contracts contain an arbitration clause whereby the parties agree that any future dispute may be resolved through arbitration. In view of the confidentiality of arbitration proceedings and the lack of bibliographical material on the resolution of international trade disputes with

pharmaceutical products, we have conducted an empirical legal research in order to identify the modalities of the pharmaceutical industry's specific resolution.

Thus, the first section of the chapter consists in presenting the methodology used in the empirical legal research and the results obtained. In the second section of the chapter both of the premises for which arbitration can be used as a mean of resolving pharmaceutical disputes, and the conditions which a dispute must satisfy in order to be resolved by arbitration are presented. Section three is intended for the analysis of the arbitration convention, in its three forms, the arbitration clause, the compromise and the unambiguous implicit arbitration convention.

The principle of autonomy of will is essential in international trade contracts and allows the contracting parties to determine the manner of resolving disputes and the law that is applicable to them. The arbitral tribunal, on the basis of the agreement of the parties, may resolve the dispute in equity, but most of the time, the parties specify in the arbitration convention the law governing the contract and on the basis of which the dispute will be judged. Given the importance of the law applicable to the dispute, in section four we paid attention to capturing the criteria underlying the choice of parties, their relevance and implications.

In section five, the arbitration procedure is presented, and in the sixth section, the modalities for the constitution of the arbitral tribunal and the importance of choosing the place where the arbitration is carried out are highlighted. In choosing the place of arbitration, the parties shall consider if the state in which the arbitration procedure is conducted is a signing-party to the New York Convention of 1958 on the Recognition and Enforcement of Foreign Arbitral Decisions, precisely in order to have a minimum guarantee that the resulting solution can be enforced if the unsuccessful party fails to execute its obligations on a voluntary basis.

The issue of arbitrary award is dealt with in the last section of the chapter, focusing our attention on the effects it produces and the conditions under which it is recognised and enforced.

During the analysis of the procedure and the arbitral judgement, the practices of the permanent arbitration institutions were envisaged, making a parallel between the arbitration rules of the International Chamber of Commerce of Paris (*ICC Arbitration rules*), the World Intellectual Property Organisation' Arbitration and Mediation Centre (*WIPO Arbitration Rules*) and other international arbitration institutions.

The parties to a contract of international trade with pharmaceutical products will choose arbitration taking into account two essential aspects, namely, the confidentiality of the procedure and the legal force of the arbitral award. Confidentiality is one of the most important advantages of the arbitration procedure. In the conduct of disputes in this industrial sector, the parties are required to change a large amount of technical data on products, manufacturing

processes, business strategies, which requires the arbitration institution to ensure a high level of confidentiality. This high level of security and protection of confidential information can only be achieved within a private framework, possibly only within the framework of arbitration or ADR procedures.

Due to the costs of an arbitration process, we consider it appropriate to use escalation clauses whereby the parties provide for the obligation to use amicable means of resolving disputes in a first step, and if they are unsuccessful, the dispute should be brought to the arbitral tribunal for settlement.

CHAPTER III is dedicated to analysing the dispute resolution of international trade contracts with pharmaceutical products before state courts. The state courts shall resolve international trade disputes and may, on request, intervene in the case of amicable means in order to give a decision to take note of the transaction of the parties or, in the case of arbitration, where the arbitral judgment is challenged with action for annulment or is not voluntarily enforced.

The first section of the chapter highlights the modalities for resolving disputes before the state courts as the parties have chosen or not the competent court. In a first step, it is analysed the jurisdiction convention by which the parties indicate the national court where they wish to settle the dispute and, in the second step, it is presented the method of identifying the competent court by reference to the provisions of the European Regulation Brussels I and the Romanian Code of Civil Procedure.

The second section is aimed at analysing the applicable law to the international trade contract with pharmaceuticals, continuing research in a dual manner, given the situations in which the contracting parties have chosen or not a law governing the relationships between them. The parties` choice of the applicable law and the limits of the autonomy of will in this choice will be analysed by reference to the rules of immediate application incident in the international trade with pharmaceutical products. Where the contracting parties have not chosen the applicable law to the contract at the European Union level, the determination of the applicable law shall be carried out in accordance with the Rome I Regulation on the law applicable to contractual obligations, which is why the analysis will be carried out by reference to contracts used in the international trade with medicinal products.

Section three presents a detailed analysis of disputes in the matter of international trade contracts with pharmaceutical products, focusing on liability actions for defective pharmaceutical products.

International trade with pharmaceutical products is a complex area, with a pronounced technical and over-regulated character at national and regional level, which causes courts to turn to experts to clarify certain aspects of disputes that they have been seised with. The need for courts to appeal to surveys to resolve disputes, generates a domino effect on the costs and deadlines necessary to resolve a process.

A point which may subclass the courts from the top means of resolving disputes (as resulted from the empirical legal research conducted) is the principle of publicity of the trial, the systems for the protection of confidential information and trade secrets, making the pharmaceutical companies vulnerable. In this matter, the confidentiality of the procedure guaranteed in the arbitration process or the means of amicable dispute resolution frequently determines the parties to choose them at the expense of state courts.

Regarding the legal force of the dispute settlement act, unlike mediation, where the agreement of the parties has the legal nature of a contract, the judgment of the state courts is binding on the parties, which can be recognised in a foreign state and enforced in the event that the unsuccessful party does not voluntarily execute it. At regional level, the European Union has regulations on the recognition and enforcement of judgments of foreign courts in civil and commercial matters, but given the lack of international conventions in this matter, as is the case of arbitration, there is a possibility that the court's judgment may not always be effective.

According to the results of the empirical research on how to resolve international trade disputes with pharmaceutical products, in practice, most of the time, the law chosen by the parties to govern the contract coincides with that of the state in which the competent court designated by the jurisdiction clause is located. The same study demonstrates that state courts are the preferred dispute resolution method for pharmaceutical companies and legal professionals working for these businesses.

Settlement of disputes before state courts remains the method of resolving conflicts that provide the most guarantees regarding the viability, recognition and enforcement of judgments.

CONCLUSIONS

Disputes arising from operations carried out in the pharmaceutical industry are of interest, since the consumption of medicinal products can cause widespread negative effects on the health or life of consumers. In practice, the majority of international trade disputes are resolved by ways that guarantee a high level of confidentiality of the solution, the parties and the object of the dispute, so that the issues that might be of public interest are kept secret. If we report to the quality of the parties at issue, we believe that pharmaceutical professionals will prefer to settle disputes between them by amicable means, and if this is not achieved, they will turn to arbitration. In the situation of disputes between professionals in the pharmaceutical industry and consumers or public institutions, predominantly, these will be resolved before national courts.

The legal doctrine on how to resolve international trade disputes with pharmaceutical products is almost non-existent and often vague, referring in an extensive manner to resolving disputes in the sector of life-sciences, which

includes fields such as medical, pharmaceutical, biomedical, etc. However, the existing bibliographical materials present arbitration as the right and preferred way for the participants in the pharmaceutical trade in order to resolve potential disputes.

The present thesis, supported by the results of the empirical research conducted, however contradicts the majority opinion of legal doctrine at international level, highlighting the fact that, in practice, pharmaceutical companies prefer state courts for dispute settlement, to the detriment of arbitration, which is in a second place. We believe that arbitration has multiple advantages in resolving international trade disputes with pharmaceutical products, but at the time of conducting the empirical research, the preference of professionals has turned to conciliation and, in case of failure, to the courts. At the same time, we must emphasise that any dispute of international trade with pharmaceutical products must be analysed individually, its specificities and the interests of the parties involved representing determinants in the choice of dispute resolution means.

Following the research carried out, we can state that the parties of a contract of international trade with pharmaceutical products will provide a clause confering jurisdiction and choice of applicable law, taking into account the economic interests in the medium and long term, the economic and competitive ascendant on the other party and, indirectly, the likelihood of being actioned in court or arbitration in the event of a breach of contractual obligations. If the parties have not provided a way to resolve potential disputes, it will be chosen at the time of the conflict and will be influenced by the economic interest of each party and the evidence at its disposal. Thus, depending on the interest of the injured party, we can distinguish three possible scenarios: a) the injured party because of non-execution or non-compliance of the contractual clauses is required, for economic reasons, to continue cooperation (e.g. the costs necessary for the identification and authorisation of a new supplier of raw materials would be prohibitive), reason for which it will not initiate any action against the other party; b) the injured party initiates an amicable approach to resolving the misunderstanding, thereby seeking to repair the damage and continue the contractual relationship; and c) the party which has suffered damage as a result of non-execution or non-compliance of the contract shall act the other party in court or arbitration for the total recovery of the damage, not beeing interested in the continuation of the economic relationship.

The dispute resolution procedures show a different degree of formalism, which is emphasized in the case of national courts and less in arbitration, becoming almost informal in amicable settlement modalities. These gradual differences can be identified and even overlapped above the level of availability manifested by the parties in continuation of the contractual relationship and subsequent to resolving the dispute. Thus, if the parties pursue the continuation and development of the business in an efficient and viable manner after resolving

the dispute, they will appeal to amicable settlement arrangements. Where the parties do not pursue the continuation of contractual relations, they shall seek to obtain a binding and definitive judgment issued by a court or an arbitral tribunal, which shall resolve the dispute and allow the enforcement if the unsuccessful party will not voluntarily execute its obligations.

By reporting to the advantages and disadvantages of each dispute settlement, we can state that amicable settlement methods (ADR) are an alternative to arbitration procedure, and arbitration is the alternative to the trials before national courts.

As regards the resolution of international trade disputes with pharmaceutical products, we consider it necessary to establish well-defined mechanisms to address both the disputes between professionals and the disputes between professionals and consumers.

For the efficient and rapid resolution of *business-to-business* conflicts, we consider it appropriate to establish an organisation specialised in the resolution of medical-pharmaceutical disputes. Such an organisation should be independent and shall provide trust to the parties in terms of celerity, confidentiality of procedures and the specialisation of neutral third parties that resolve the dispute. From an economic point of view, such an organisation could be self-financed from the fees levied to settle disputes or be financed by pharmaceutical companies carrying out international trade operations through compulsory annual contributions. We consider that such a dispute settlement centre could be located in Basel, Switzerland – the pharmaceutical industry hub.

Taking into account both the public interest existing in the marketing operations of medicinal products, but also the need to protect the weaker part at issue – the consumer – we consider it appropriate to establish a dispute settlement centre within the World Health Organisation, with the role of resolving the misunderstandings of both consumers and pharmaceutical companies, but also between the state health institutions and pharmaceutical suppliers. By establishing an ADR centre within an international profile organisation, such as the World Health Organisation, it would ensure an independent, efficient and specialised way of resolution which would respect the public health and the principles of good practice in the pharmaceutical field.

At the same time, a possible ADR centre for health disputes should also provide the possibility for parties to resolve disputes online through an ODR platform. Online *business-to-consumer* dispute resolution would be successfully used in the context of digitalisation of pharmaceutical outlets. Thus, if a pharmaceutical product is marketed online, it is exposed for sale on an international market and can result in disputes with consumers in many states. Online resolution of such conflicts is for the benefit of both parties – the online pharmacy and the final consumer, as they will allocate far fewer financial and temporal resources to resolving the misunderstanding.

Inherently, technological progress and digitalisation have modeled the pharmaceutical industry and the behaviour of consumers of pharmaceutical products. Online resolution of international trade disputes with pharmaceutical products between consumers and professionals should be analysed as an element of an integrated and personalized health system in which medicines are bought online, drug treatments are customized for each individual, IoT devices are used to monitor or manage health. In this context, including the settlement of disputes in this industrial sector should be swift, efficient and achievable at a distance. The digitization of dispute resolution methods could be total, in which case the entire procedure would be carried out exclusively online or partially, the hybrid situation in which the settlement procedure would be carried out both online and offline, face to face.

In the context of digitization of all dispute settlement methods, whether we refer to national courts, arbitration or ADR modalities, artificial intelligence technologies could be used to streamline the procedures and resources used by the parties. In the pharmaceutical industry, the use of *AI* could have a positive impact on how to resolve any dispute, as this technology could manage, analyze and correlate an impressive amount of data, without the need to involve an expert or specialist, and could also generate objective solutions in real time.

We conclude by saying that disputes concerning international trade contracts with pharmaceutical products have specific particularities, and their effective resolution can only be achieved by legal professionals with experience in the pharmaceutical field through rapid, flexible and confidential procedures.