

A QUALITATIVE-EMPIRICAL ANALYSIS OF HEALTH COOPERATION IN THE SINO-BRAZILIAN LEGAL RELATIONSHIP: THE CASE OF THE IMPORTATION OF CHINESE PHARMACEUTICAL INPUTS

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ABSTRACT: The paper presents a brief empirical-comparative analysis of the Sino-Brazilian relationship in health cooperation. It uses the qualitative methodology, using the inductive approach, from the so-called grounded theory, which gives the researcher a certain degree of distance from the research object, besides the possibility of constructing a theory from the analysis of raw data. In order to make this analysis more sophisticated, we opted for the adoption of the Atlas.ti Qualitative Analysis Software, given the volume and complexity of the bilateral acts analyzed. The purpose of this essay is to explore the way in which such interactions are constructed and to understand the relevance of this sector in the policies and economy of both countries.

KEY-WORDS: Health cooperation — China — Brazil — pharmaceutical inputs

I. Introduction

The research on health cooperation in the Sino-Brazilian relationship is part of the research "Law and economic relations between Brazil and China: empirical evidence in contrast"¹, which has in its scope the analysis of the relations between Brazil and China, based on the fact that the latter is Brazil's largest trading partner today.

This relationship seems to be embedded in a process of movement and coordinated action proper to the Brazilian Foreign Policy whose objective is the construction and establishment of common exchange spaces². In view of the nuances of this interaction process, this investigation demands an accurate analysis.

Thus, carrying out an empirical mapping from the design of the relationship between Brazil and China, this study seeks to analyze the bilateral legal instruments typical of this relationship in order to find relevant practical and theoretical implications.

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² MOROSINI, Fábio (Org.); SANCHEZ BADIN, Michelle (Org.). *A nova diplomacia econômica das relações Brasil-Angola: desvendando os seus instrumentos políticos, jurídicos e econômicos*. 1. ed. Brasília: IBDC. Grupo de Pesquisa C&DI, 2017. v. 1. 269 p. 10.

To this end, this essay, when analyzing legal systems as diverse as Brazilian and Chinese, uses the existing debate on the relevance and legal nature of Comparative Law, presenting the main arguments and theories in its presentation as a method and as a science.

Thus, the research uses the qualitative methodology, using the inductive approach, from the so-called grounded theory, which gives the researcher a certain degree of distance from the research object, besides the possibility of constructing a theory from the analysis of raw data³. In order to make this analysis more sophisticated, we opted for the adoption of the Atlas.ti Qualitative Analysis Software, given the volume and complexity of the bilateral acts analyzed. The choice of the method of procedure is based on relations in health cooperation between Brazil and China.

The initial concern that motivated the research came from the observation of a growing relationship between Brazil and China in the area of health, involving both public institutions and private companies. Among investments, trade flows and technical cooperation, what seems to stand out in this relationship are the Chinese pharmaceutical inputs and their entry into the Brazilian market, which poses new challenges to this market⁴. Although India is the major global drug producer among developing countries and remains a traditional Brazilian partner on this agenda, China's presence in this sector has grown by leaps and bounds in Brazil.

In this sense, the initiative to carry out an initial mapping of the bilateral acts aimed at finding answers on the Sino-Brazilian political-economic interaction in health, through the presentation of its actors, instruments, mechanisms and modes of implementation.

Thus, the purpose of this essay is to explore the way in which such interactions are constructed and to understand the relevance of this sector in the policies and economy of both countries, since there is a significant amount of bibliographical works dealing with economic and commercial relationship of these two countries, without, however, the same volume regarding the specific analysis of the drug sector.

The division of this study into sections is due to a procedural sequence necessary for a better understanding of the object of analysis. Thus, the essay is segmented into four sections. Initially, an incursion into the debate on the relevance and legal nature of Comparative Law is carried out to carry out this research. The following is a brief explanation of the empirical-qualitative research methodology.

In the third session, a descriptive and exploratory passage was chosen with regard to the analysis of the bilateral acts between Brazil and China, in which the content analysis of said normative documents was carried out. Finally, a preliminary analysis will be elaborated on the pharmaceutical industry in bilateral relations, bringing to the fore a reflection on the political-economic relations between the two countries.

³ CHARMAZ, Kathy *Constructing Grounded Theory*. Edition: 2nd Revised edition. SAGE Publications Ltd. 2014

⁴ Pharmacochemical, pharmaceutical or active pharmaceutical ingredient (IFA) are terms that correspond to the active principle of the drugs, the molecule that has pharmacological activity and therapeutic effect for the treatment, cure or prevention of diseases that affect health.

II. The Dichotomy in the Analysis of the Legal Nature of the Comparative Law: Method or Science?

A first investigation into the concept of Comparative Law runs through the analysis and determination of its nature, which involves the debate about whether this is a method or a science. This brief essay, however, does not intend to present with exhaustion the arguments or proponents of each of these theses, but only to expose the existing debate on the two conceptions prevailing in the definition of the nature of Comparative Law⁵.

For René David, comparative law is nothing more than a comparison of rights, since in the author's reading there were no rules in comparative law, just as they would exist in civil or criminal law. In the same vein, Gutteridge emphasizes the lack of a definite set of rules for attributing the status of science to Comparative Law⁶.

However, for Caio Mário da Silva Pereira, for comparative law to be considered a method, it is not enough to empirically compare norms and institutes in more than one legal system, for the author, "this process is not enough to make the comparator a comparativist"⁷.

In other words, some theorists argue about the classification of Comparative Law as a science from the analysis of the aspects that define the concept of science. In this way, Luís Washington Vita presents: "(...) it is understood by science a set of knowledge about a certain object, obtained with certain methodical and systematic criteria in a logically constructed organism."⁸

For this current, Comparative Law would meet the main requirements of the definition of science: "knowledge acquired in a methodical way, without the character of improvisation; universal validity of the knowledge produced; and that this knowledge has passed through the sieve of systematic observation."⁹

The latter, however, is not the option of the author, who joins the current that treats Comparative Law as a method. Thus, during this essay, when analyzing the Sino-Brazilian relationship through the bilateral instruments concluded between the two countries, we start with the use of Comparative Law as an auxiliary method to the qualitative-empirical method used.

III. The Qualitative-Empirical Methodology

In this research we opted for the use of grounded theory, a method of qualitative research presented by Glaser and Strauss in the work "The Discovery of Grounded Theory", published in 1967.¹⁰

⁵ That said, because there are definitions constructed by other authors, like Lambert, who considers Comparative Law as science and art. Cf.: OVÍDIO, Francisco. Aspectos do Direito Comparado. Revista da Faculdade de Direito da Universidade de São Paulo, São Paulo, v. 79, p. 161-180, 1984. p. 162.

⁶ OVÍDIO, Francisco. Aspectos do Direito Comparado. Revista da Faculdade de Direito da Universidade de São Paulo, São Paulo, v. 79, p. 161-180, 1984. p. 162.

⁷ PEREIRA, Caio Mário da Silva. Direito Comparado e seu estudo. Revista da Faculdade de Direito de Minas Gerais, 1955, p. 7.

⁸ OVÍDIO, Francisco. Aspectos do Direito Comparado. Revista da Faculdade de Direito da Universidade de São Paulo, São Paulo, v. 79, p. 161-180, 1984. p. 162.

⁹ OVÍDIO, Francisco. Aspectos do Direito Comparado. Revista da Faculdade de Direito da Universidade de São Paulo, São Paulo, v. 79, p. 161-180, 1984. p. 162.

¹⁰ GLASER, Barney.; STRAUSS, Anselm. The discovery of Grounded Theory. Chicago: Aldine, 1967.

As regards the stages of the research technique, the research opts for the grounded theory which is subdivided into the three phases presented by Bardin. The initial phase would be the pre-analysis; then the exploration of the research material would be carried out to finally treat the results.¹¹

In this sense, the pre-analysis phase comprises the organization of the research material through four procedures: i) floating reading, which allows an initial reading and allows the codification of the textual elements in a literal way; ii) selection of documents to be analyzed; iii) formulation of hypotheses and iv) development of indicators.¹²

The next stage consists of the exploitation of the material with the formulation of categories and the identification of the registration units. This phase is of crucial relevance for the development and sophistication of the research, insofar as it allows an analytical description of the material collected from the hypotheses and theoretical references.¹³

The last phase corresponds to the process of treatment and interpretation of results. During this phase, a maturation of the research is performed based on a critical analysis of the research object analyzed in the previous phases.¹⁴

The epistemological material of the grounded theory research of this essay is found in the analysis of the 118 bilateral acts celebrated between Brazil and China. The legal documents were taken from the Concordia Platform of the Brazilian Ministry of Foreign Affairs.¹⁵

As regards the analysis of the research material, it is found, unlike what was predicted, that the establishment of commercial relations between the two countries occurred at a remote moment in history, the first agreement being celebrated in 1881. Another relevant aspect is the low incidence of agreements, protocols, adjustments or other bilateral instruments that deal with subjects related to health.

In this sense, only seven documents present the topic of health cooperation in its text. It is also seen that the approaches are diffuse and multiple in the sector, since there are documents that deal from cooperation in matters of phytosanitary surveillance to instruments that analyze cooperation in traditional Chinese medicine.

According to the design of the research method, initially we performed the floating reading of the documents in the Atlas.ti Software, since this stage allows an initial reading, which allows the codification of the textual elements in a literal way. A second reading was then performed in order to filter relevant codes. Finally, new categories were built, which made it possible to set up an organization chart of the relevant bilateral acts on health cooperation.

¹¹ MOZZATO, Anelise; GRZYBOVSKI, Denize. Content Analysis as a Qualitative Data Analysis Technique in the Field of Administration: Potentials and Challenges. *Revista de Administração Contemporânea*, v. 15, n. 4, p. 731-747, 2011.

¹² BARDIN, Laurence. *Análise de conteúdo* (L. de A. Rego & A. Pinheiro, Trads.). Lisboa: Edições 70. (Obra original publicada em 1977). 2006.

¹³ BARDIN, Laurence. *Análise de conteúdo* (L. de A. Rego & A. Pinheiro, Trads.). Lisboa: Edições 70. (Obra original publicada em 1977). 2006.

¹⁴ BARDIN, Laurence. *Análise de conteúdo* (L. de A. Rego & A. Pinheiro, Trads.). Lisboa: Edições 70. (Obra original publicada em 1977). 2006

¹⁵ Although the epistemic cut of the research is 118 legal documents, it should be noted that there are a total of 121 bilateral acts between these countries. However, three of these instruments are not available.

IV. Analysis of The Brazil-China Bilateral Acts on Health Cooperation

As we mentioned in the introduction of this essay, only seven agreements were considered to be relevant in relation to cooperation in health matters:

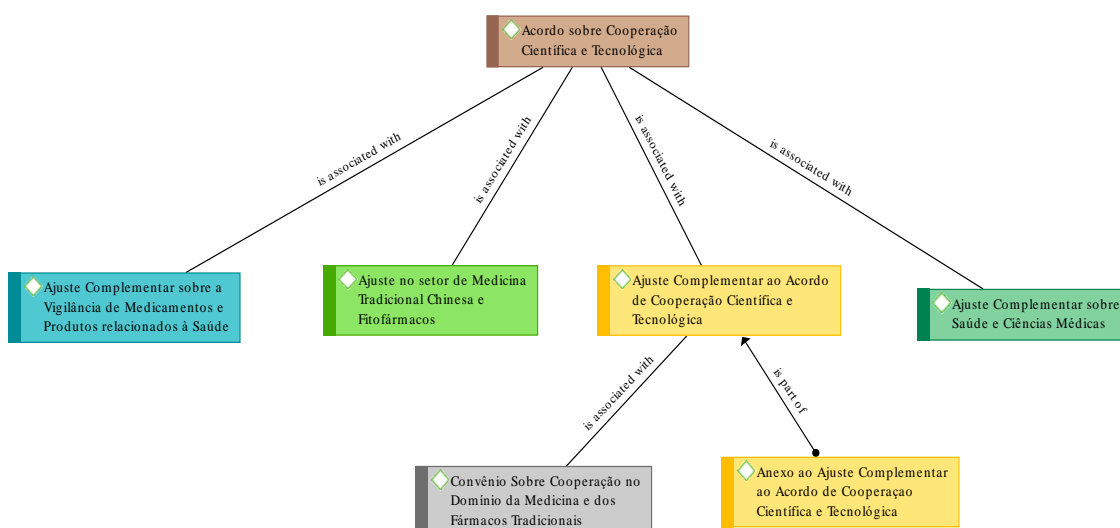
- i. Agreement on Scientific and Technological Cooperation;
- ii. Complementary Adjustment on Health and Drug Surveillance of Medicines and Products;
- iii. Adjustment in the field of Traditional Chinese Medicine and Phytopharmaceuticals;
- iv. Complementary Adjustment on Health and Medical Sciences;
- v. Agreement on Cooperation in Medicine and Traditional Drugs;
- vi. Annex to the Supplementary Agreement to the Agreement on Scientific and Technological Cooperation.

In analyzing these documents, we noted that a large part of the obligations assumed were not formalized through the instruments known as "agreements", which correspond to only one document among the seven analyzed. There is, however, a significant amount of "adjustments" and an "annex".

Next, the investigation finds that the legal instruments under analysis cover a number of themes in the health axis. In this sense, one can find acts dealing with traditional Chinese medicine or acts that deal with aspects of domestic legislation on sanitary inspection.

Another relevant aspect concerns the degree of abstraction of documents. Some of them have only generic commitments, while others provide specifications on the bodies, instruments, and mechanisms for implementing cooperation.

Figure 1. Network with agreements on cooperation in health



Source: Designed by the authors using Atlas.ti software.

Finally, it is relevant to observe the relationship between all documents analyzed and the central agreement on Scientific and Technological Cooperation signed by the Brazilian and Chinese governments in 1982, according to the organization chart above.

V. Brazil and China: A Preliminary Analysis on the Pharmaceutical Industry in Bilateral Relations

The Brazilian pharmaceutical market has grown in recent decades with high annual growth rates. Although Brazilian-owned pharmaceutical companies have managed to increase their share of the Brazilian market, achieving a leading position in retail revenues in the country, the same cannot be said for the pharmaceutical industry, which produces the main raw material of active pharmaceutical ingredients (IFA's). Between 2005 and 2015, the average share of imports in drug consumption by Brazilian pharmaceutical companies was approximately 90%.¹⁶

Most of the drugs consumed by the Brazilian pharmaceutical industry originate in the Asian market, especially India and China. It is estimated that about two-thirds of the world's commercially-produced IFAs come from Asia¹⁷. The process of internationalization of the pharmachemical industry towards Asia began in the 1980s. The goal was to reduce costs through the opening of subsidiaries and the hiring of independent companies (outsourcing).

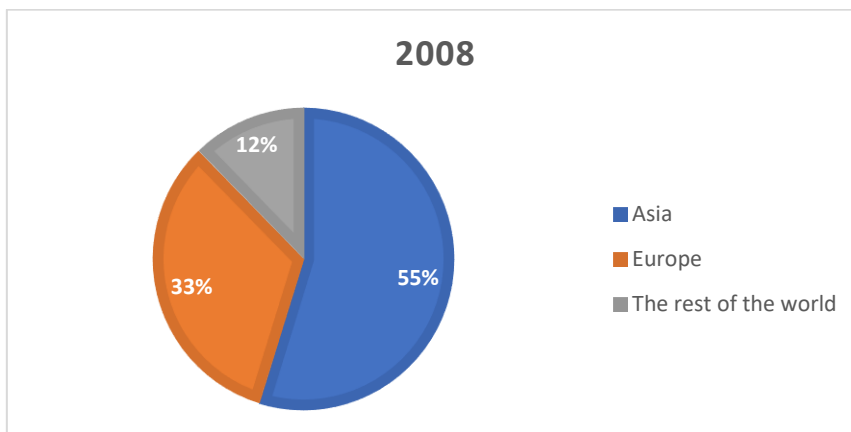
Based on incentives from various public policies, the Asian countries were able to strengthen their domestic companies and gain competitiveness in the industry. With an industry focused mainly abroad, in 2012, Indian industry already exported 90% of the active ingredients produced and the Chinese, 75%¹⁸. The graphs below show the expansion of Asian industry producing non-exclusive IFAs in the international market between 2008 and 2012.

¹⁶ MITIDIARI, Thiago L; PIMENTEL, Vitor P.; BRAGA, Clarice de A.; PIERONI, João Paulo. Há espaços competitivos para a indústria farmoquímica brasileira? Reflexões e propostas para políticas públicas. *Complexo Industrial da Saúde. BNDES Setorial* 41, p. 43-78, 2015.

¹⁷ MITIDIARI, Thiago L; PIMENTEL, Vitor P.; BRAGA, Clarice de A.; PIERONI, João Paulo. Há espaços competitivos para a indústria farmoquímica brasileira? Reflexões e propostas para políticas públicas. *Complexo Industrial da Saúde. BNDES Setorial* 41, p. 43-78, 2015.

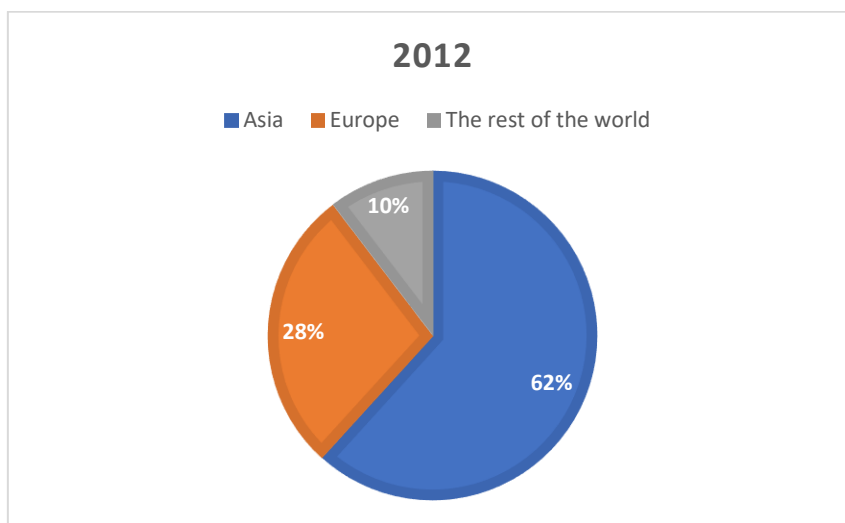
¹⁸ MITIDIARI, Thiago L; PIMENTEL, Vitor P.; BRAGA, Clarice de A.; PIERONI, João Paulo. Há espaços competitivos para a indústria farmoquímica brasileira? Reflexões e propostas para políticas públicas. *Complexo Industrial da Saúde. BNDES Setorial* 41, p. 43-78, 2015.

Chart 1. Non-exclusive IFAs intended for the market, production by geographic area - 2008



Source: Data available in Mitidieri, Pimentel, Braga and Pieroni, 2015. Designed by the authors

Chart 2. Non-exclusive IFAs intended for the market, production by geographic area – 2012



Source: Data available in Mitidieri, Pimentel, Braga and Pieroni, 2015. Designed by the authors.

Brazil ranks 27th in the ranking of countries exporting pharmaceutical products, with US \$ 1.61 billion exported. While the world average of growth reached 2.40%, the Country registered only 0.44%. India and China, for example, grew 21.31% and 3.24%, ranking 11th and 13th respectively in 2013. In the ranking of the main pharmaceutical importing countries, in turn, Brazil was the 16th in the general ranking and the leader among Latin American countries, responsible for 1.54% of the world imports of pharmaceutical products. As shown by the evolution of the Brazilian trade in medicines,

there was a positive change of 758% in the commercial flow of drugs between Brazil and China between 2005 and 2014, the second highest growth in the period.¹⁹

When considering only the active principles traded in the market, which corresponds to 39% of world consumption (US \$ 44 billion), it is noticed that non-exclusive products have gained participation in an accelerated way. Because of the strong growth of emerging markets in the 2000s, boosted by generic drugs, active ingredients without patent protection grew at twice the rates compared to proprietary IFAs (under patent protection) and now account for the bulk of the market, privileging the Chinese rise in this market.

As a result of recent FDA (Food and Drug Administration) enforcement actions, which have pointed to several regulatory nonconformities, the Asian pharminochemical industry has been questioned internationally. The new quality paradigm for the pharmaceutical chain may be considered a non-tariff barrier to maintaining the growth of the Asian pharmaceutical chain.

Although in Resolution no. 2001/31 (Access to Medication in the Context of Pandemics such as HIV / AIDS) the UN recognizes definitively that access to essential medicines is a fundamental human right, requiring that States refrain from decisions that limit or deny access conditions to biopharmaceutical technologies, used in the prevention or treatment of infections or pandemic diseases that are frequent in the population, and encouraging non-exclusive drugs, there is still a long way to go in the regulatory framework of the sector, especially with regard to sanitary issues, in order to guarantee the quality of the substances produced.

This issue is central to the analysis of drugs in Brazil-China relations, especially after the identification of Chinese medicines with suspected ineffectiveness. One of these cases occurred in 2017, when the Brazilian Ministry of Health purchased L-asparaginase for the treatment of children with acute lymphoid leukemia, which contains the substance leuginase, manufactured by Beijing SL Pharmaceutical Laboratory. Tests carried out in Brazil pointed out that while the German reference drug has three contaminants, 398 impurities were found in the Chinese drug, 130 times more, which could jeopardize its effectiveness.²⁰

VI. Concluding remarks

The paper presents a brief empirical-comparative analysis of the Sino-Brazilian relationship in health cooperation. In spite of the low treatment of the subject, considering the quantity of agreements or bilateral instruments concluded between the two countries in qualitative terms, it seems to us that the relation established in the field of cooperation in health appears very relevant.

¹⁹ INTERFARMA. *Comparações Internacionais no Comércio de Produtos Farmacêuticos e Balança Comercial Brasileira de Medicamentos Evolução em 10 anos*. São Paulo, maio 2015. Interdoc VOLUME VI.

²⁰ SOCIEDADE BRASILEIRA DE ONCOLOGIA CLÍNICA (SBOC). *Medicamento chinês sem eficácia comprovada pode comprometer tratamento de câncer infantil*. Disponível em: <https://www.sbo.org.br/noticias/item/980-medicamento-chines-sem-eficacia-comprovada-pode-comprometer-tratamento-de-cancer-infantil>. Acesso em 01/10/2018.

This is because the significant growth in imports of drugs by Brazilian pharmaceutical companies between 2005 and 2015 reveals the construction of a new commercial flow in relations between Brazil and China.

This research, although still in progress, evidences the relevance of the theme and some impacts and challenges of the vertiginous growth of commercial relations between these two countries in this specific branch. One of them is Brazil's level of dependence on Asian countries, since most of the drugs consumed by the Brazilian pharmaceutical industry originate in India and China. The second is regulatory challenges, since the quality and effectiveness of these drugs have been questioned by international organizations and may affect Brazilian health policies.

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