

Book review

Comércio Internacional, Patentes e Saúde Pública

Monica Steffen Guise

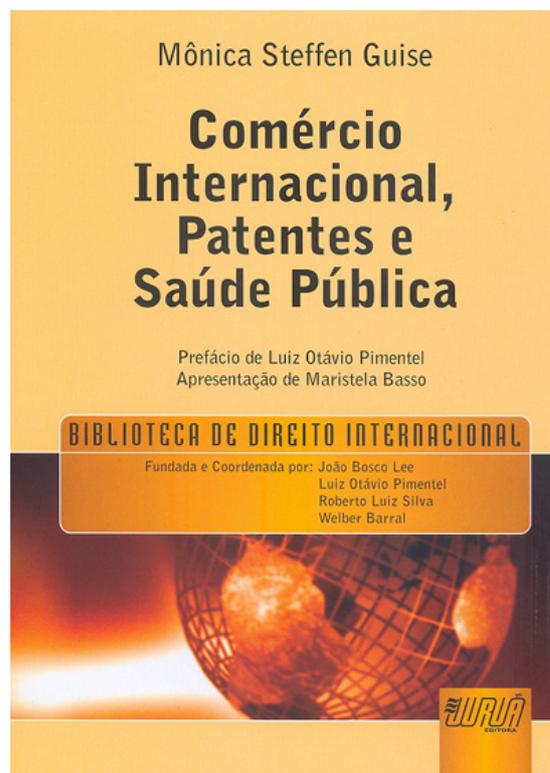
Juruá, Curitiba. 2008

ISBN-13: 978-85-3621-520-4

DOI: 10.3395/reciis.v4i1.358en

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Patent regulation has taken on new dimensions with the emergence of the Agreement on Trade-Related Aspects of Intellectual Property Rights (Trips Agreement). The Trips Agreement – attached to the agreement that ended the Uruguay round and created the World Trade Organization (WTO) in 1994 – unquestionably placed intellectual property within the sphere of international trade, and harmonized the protection of intellectual property rights at surprising levels, with resulting impacts on the economic and social life of the member states, notably in the public health systems. The Trips Agreement had remarkable effects on the access to medications, bringing about a series of problems never before

faced by the governments, companies, non-governmental organizations, and consumers.

The paper “International trade, Patents and Public Health”, written by Mônica Steffen Guise, elegantly deals with this boiling cauldron. The study focuses on understanding the reasons behind the adoption of the two main regimes of patent protection – the Paris Convention for the Protection of Industrial Property (PCPIP) and the Trips Agreement – and the study of the flexibilities concerning the right of exclusivity that patents provide the owner with. The author makes an effort to examine the subject from the standpoint of national public health policies and the access to medicines.

The book is divided into three main segments. The first concerns the international legal framework for intellectual property. The second part deals with the public health subject. The third part discusses the relations between patents and national public health policies, especially the management of flexibilities, with an emphasis on the Brazilian experience.

In the opening section, Guise makes use of the history of the evolution of the patent system to provide a background for the linkage between the Trips Agreement and international trade. The first patent harmonizing treaty was undoubtedly the PCPIP, as it created some facilities for the domestic ones to be able to obtain protection for patents in other countries. PCPIP introduced the principle of national treatment, which provides foreign products with the same advantages given to local ones by domestic laws. Additionally, PCPIP proposes the principle of patent independence. That is, the granting of a patent in France does not require Brazil to grant protection to that same invention. The principle of unionist priority is another key aspect of the PCPIP. Filing the first patent request creates a property right that binds it to applications in other countries for that same invention, respecting the deadlines defined by the Convention. These three principles were the fundamental pillars of the international patent system.

It is important to highlight that the PCPIP did not enforce the protection of areas related to human knowledge. Understanding this aspect is relevant since its alteration in the Trips Agreement resulted in serious effects for the health systems of developing countries. Thus, each member State was free to decide whether to include or not a certain area, such as pharmaceuticals, for instance, under their national law. It was, therefore, an asymmetry directly related to the industrial policy objectives of the country. Several countries, such as Spain, Japan and Switzerland, were slow to grant patents to pharmaceutical products, since that decision would not contribute back then to the strengthening of the pharmaceutical industry of those countries. This fact has been broadly reported by academic literature.

The migration of the "intellectual property" subject from the scope of the World Organization for Intellectual Property towards a forum of commercial agreements such as the General Agreement on Tariffs and Trade – GATT, and the World Trade Organization (WTO), at a later period, is well discussed by the author, who dissects the reasons of developed countries in this movement. She equally highlights the creation of a mechanism for controversy resolution in the WTO associated with the new protection standards. The intense lobby of multinational pharmaceutical companies is

seen as one of the most poignant explanations for the results obtained with the Uruguay round of the GATT.

Guise highlights the profound discrepancy of interests between developed and developing countries in the discussion of the subject in the Uruguay round. Countries such as the U.S. and England advocated a linear relation between patents and innovation. In other words, more patents, more innovation. This argument still lacks an empirical base, especially when one looks at the results obtained by developing countries after changing their legal ordainment. The granting of pharmaceutical patents in these countries was not accompanied by the implementation of research and development centers for new pharmaceuticals, or of factories for the local production of medications. On the contrary, what happened was a widespread replacement of an already scarce local production with import procedures.

In short, the desire to increase the possibility to obtain patent monopoly was victorious, and countries where technological capabilities were frail had to adapt themselves to a situation that favored technology holders, in a deeply unequal game of power.

The second part of the book focuses on the right to health as a fundamental constitutional principle. The author discusses the way the subject is dealt with not only by the Federal constitution, but also by Law 8080 of 1990, which addresses aspects such as health promotion and protection. In this context, health is an obligation of the State and a right of the citizen. Such concept naturally has an impact on and interacts with several policies, including patent policy, which may cause hindrances to the full accomplishment of the State's goals concerning the general welfare of the society.

At the international level, the author looks into the concept of health that emerges in the Constitution of the World Health Organization of 1948, and the contexts of health in the Universal Declaration of Human Rights, of 1948, and in the International Pact of Economic, Social and Cultural Rights, of 1966. At the core of the three documents there is the prevalence of health as a responsibility of the State and a right of Humankind. There noteworthy milestones are joined by the Millennium Goals Declaration, which has been providing guidance for several major decisions in the World Health Organization and in other international organization and domestic initiatives.

The book discusses a relevant set of Brazilian policies and initiatives for health enhancement, addressing the situation of communicable diseases, the tradition in biomedical research, the network of governmental laboratories for the

production of medicines, and the historical dependence on foreign laboratories for supplying medicines and other health related products.

The text places special relevance on the Brazilian STD-Aids, describing its complex and beautiful construction, which became reference in the world. Given the high and growing costs of the Program, its sustainability depends on several factors, including patent-related aspects. The existence of patents in this specific health field results in an exceptional rise in the costs of maintaining the program. The granting of pipeline patents in the field of HIV-Aids has aggravated the access problem.

The National Medicines Policy and Law 9787 of 1999, which regulates the adoption of generic drugs, are analyzed in light of policies that facilitate access to drugs, of cost reduction and of a wider variety of treatment options. In the case of patented inventions, generic drugs can only be made available after the patent has expired. Therefore, granting inadequate patents, or the presence of devices that unnecessarily prolong the validity of the patent go against the good implementation of the generics policy and the society's general interests.

Within this scenario, the National Health Plan contributes with the establishment of guidelines on the implementation of domestic sufficiency concerning pharmaceuticals and strategic input, and the improvement of the research board and technological qualification. Logically, the new framework of patent monopolies implemented along with the Trips age and all kinds of abuse that can be generically placed under the term Trips Plus establish borders and deadlines that are incompatible with the available budgets and the urgency of the population in the search for health solutions.

With the purpose of mitigating the historical scenario of technological frailty and industrial incipency, stress is being placed on the importance of the National Policy of Science, Technology and Innovation in the Health Sector, and of a specific industrial policy that fosters the production of medicines in Brazil.

The second part of the book still addresses the fundamental Declaration on the Trips Agreement and Public Health, which was approved by the WTO Ministerial Conference in Doha, 2001. It became known as the Declaration of Doha, and conciliated the understanding on the rights of member States to utilize the flexibilities provided for in the Trips Agreement. Surprising as it may seem today, back then multinational pharmaceutical companies dared to defy this possibility in the well known litigation of those companies against the South African government, which took measures on behalf

of access to medications by means of intellectual property. Doha helped conciliate the issue from the point of view of formal sanctions, but, in reality, the general scenario is far from uneventful concerning the use of flexibilities on behalf of health, and of restrictive order when it comes to monopolies.

The third part of the study aims at analyzing the conciliation of patent policy and public health goals in Brazil. Guise discusses the complex subject of the effectiveness of Trips in Brazil, more specifically the resulting internal and external obligations, as well as the issue of temporary provisions. The application period was at the center of much controversy, which is properly addressed in the text. The author looks into discussions, including those at the level of legal decisions.

The immediate application of the Agreement was not achieved without prejudice to public health, since Brazil did not have a solid technological and industrial base in the medications sector. Given these conditions, Brazil became dependant on Indian drugs. India did not give up the transitional period set forth in the Trips, and could manufacture drugs without patent protection during a while, until the full enforcement of the Trips. On the other hand, Brazil was subject to a polemic type of patent protection – pipeline patents.

Guise studies exceptions to rights granted by the patent, especially the regime of the exhaustion of rights, the Bolar exception, and utilization unauthorized by the holder that encompass compulsory license. The Law of Industrial Property deals with this type of license in articles 68 to 70, and provides for its application in a variety of situations. The lack of local exploration and issues related to national emergency and public interest are equally scrutinized.

In short, the book is more than welcome due to the need for revisions and academic analyses of the complex conflicts surrounding intellectual property and public health. Discussions about the Brazilian case are important in that they provide subsidies for decisions concerning public policies. This is an evolving subject characterized by many strains that periodically lead to some kind of decision capable of deeply affecting the public health systems of countries, especially those of developing countries. Those responsible for developing public policies are faced with the challenge of how to fulfill commitments made at an international level, deal with the pressure for the adoption of Trip Plus measures, and at the same time create a favorable environment for innovations and local manufacture. The proliferation of bilateral trade and investment agreements seems to put the negotiation of multilateral solutions for intellectual property at

risk. Additionally, new facts such as the seizure of medications in transit under the allegation of forgery bring about additional difficulties in a negotiation already full of them.

As a conclusion, Guise's study is an instigating starting point for understanding a system where there is a growing dissatisfaction with solutions that show little commitment to

the development of the less favored nations. The recipe is not simple, but will not emerge without a consistent humanitarian vision and with the implementation of mechanisms to facilitate the transfer of more advanced technologies, of programs to support local innovation, of the practice of fairer prices and of the permanent fight against the abuse of economic power.