

Global health and Brazilian foreign policy: the negotiations on innovation and intellectual property

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Abstract *Since the TRIPS Agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights) came into effect, Brazil, like other developing countries, has become more assertive in multilateral negotiations and begun to argue that the present international system of intellectual property should be better adapted to its needs and interests. In doing so, the country has emphasized that intellectual property is not a subject exclusively associated with trade, but also with public health and human rights. This paper discusses the activity of the Brazilian government in multilateral negotiations that involve public health, innovation and intellectual property. The conclusion from looking at Brazil's diplomatic activity in this area is that Brazil has been a protagonist in this debate, seeking solutions that mitigate the adverse effect of the present international intellectual property system on access to drugs, and other medical technologies, in the developing countries.*

Key words *Public health, Innovation, Intellectual property, Brazilian foreign policy*

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Introduction

Historically, we see that health and international relations have been in a mutual dialogue since the 18th century, when this connection related exclusively to control of epidemics and disease that could harm specific material interests related to international trade and the accumulation of wealth, in the context of strategies for dominance and control practiced by the hegemonic elites and powers¹.

During the 20th century health was treated as a marginal issue and frequently neglected by those responsible for the process of decisions in foreign policy. However, as this period progressed, specifically starting in the 1990s, with the advent of something referred to as the New World Order, health began to endure a greater prestige in the international agenda, and as a result, in Brazilian foreign policy¹.

This paper starts from the premise that foreign policy is a public policy (and examines it as such), in which foreign policy is truly influenced by the action of constitution and transformation of the State, and by the relationships between government and society. In this scenario, there also stands out the growing connection between domestic and international policies, which requires that Brazilian decision processes need to consider, more explicitly, international dimensions and trends – increasingly, domestic policies become internationalized, and international policy is progressively internalized². Further, various issues assume transnational dimensions and the resulting problems are not able to be resolved in isolation; while policies decided in an international forum come to also influence the domestic dynamics³.

Thus we propose to analyze Brazilian foreign policy and see how its association develops with health in the international context, specifically in the international negotiations that affect the relationship between public health, innovation and intellectual property.

On this three-part subject, it is worth remembering that the TRIPS agreement established minimum standards to be observed by countries both domestically (by adapting their domestic legislation) and also externally (in the preparation and signature of international trade agreements). The impact on public health and on access to drugs was clear, and this caused an immediate reaction by the international community affecting the debate on health and trade in the discussions held in the most varied multinational forums.

Indeed, the hypotheses that have guided this paper are centered on those aspects, namely: that the TRIPS agreement caused a series of negative effects on access to medication, especially in the developing countries, leading to this discussion being held in a very wide range of multilateral forums, including the WHO, even though *a priori* that institution does not officially have the competency to deal with subjects related to international trade.

The basic methodology was review of the bibliography and analysis of documents, in primary and secondary sources, notably the texts of international agreements, information, data and reports from Brazilian government bodies (the Health Ministry (*HM*); the Science, Technology & Innovation Ministry (*MCTI*); the Development, Industry & Foreign Trade Ministry (*MDIC*); the Ministry of Foreign Relations (*MRE*); the National Health Supervision Authority (*Anvisa*); the Brazilian Cooperation Agency (*ABC*); the Oswaldo Cruz Foundation (*Fiocruz*); the National Industrial Property Institute (*INPI*)), and international organizations (WHO, WTO, and the World Intellectual Property Organization (WIPO)).

As well as analysis of documents, analysis of content, as employed by Bardin⁴, was used in this step of the methodology for two basic reasons: (a) its procedures make possible an analysis based on inferences extracted from contents of documents based on an interpretation controlled through variables or indicators, which provide the analyst with greater liberty, without losing the objectivity of the investigation; and (b) it is an analysis based on technical reports, and also on official documents, especially those of the WHO and the Brazilian Ministry of Foreign Relations, whose characteristics in terms of form are homogenous. We judged that the use of a method fundamentally directed by content of what is being said is the most appropriate practice for studies in which the documents analyzed have a high degree of homogeneity of form⁵. Our use of Content Analysis divided the study of the input to the inquiry into three phases: Pre-analysis, exploration of the material, and treatment of the results (inferences and interpretations).

With these methodological instruments, the overall objective of this work is in analysis of Brazil's activity in the context of the multilateral negotiations relating to public health, innovation and intellectual property. The intention has been to find out whether there was alignment of Brazil in this context, and identify the main arguments

that instigated the debates. The intention is also to find out whether the articulations promoted by the Brazilian government reflected the hypothesis that the present international system of intellectual property had a negative effect on access to medication and other medical technologies in the developing countries.

Brazilian foreign policy and the dialogue on health

Brazilian foreign policy is the subject of our analysis and study on how the Brazilian State conducts its relations with other States, projecting itself into the international context and basing its activity on formulation, implementation and evaluation of everything from external factors in the interior of the State, to its position in international society. This is not to be confused with international relations, as long as it is focused on the action of the State and on the elements of conflict and interest that condition and influence this action. In spite of the predominance in the analysis of the prerogatives of the State, it can be influenced by a range of variables, such as the sub-national entities and organized civil society⁶.

Contemporary Brazilian foreign policy, which we could see as between 1989 and the present day (2015), is marked by Brazil's new institutional structures and practices in external action. The changes created by the end of the Cold War are an important factor: dilution of the economic frontiers; opening of the domestic market; and the reforms of the State carried out in accordance with the 'Washington Consensus'. Internally, the political picture is marked by the transition from the military regime to democracy; and in the economic aspect, we see the exhaustion of the nationalist development model⁶.

In this context, since the Lula government (2003-2010), there are analyses that give a high-light role to Brazilian diplomacy, in the sense of changing the geography of power on the global scale, especially in relation to the North-South relations, in contrast to the Cardoso government (1995-2002), which committed itself in terms of program to dismantling of the developmentist State, and the path towards liberalization and integration of the interests of capital and international trade⁷.

The Rousseff government (2011-2015) aimed for continuity from the previous government, maintaining the multilateral initiative of participation in summit meetings and groups for spe-

cific purposes, but abandoning the entrepreneurial approach to high and active foreign policy of Lula and his foreign Minister Celso Amorim. Showing the focus on domestic policy as compared to external policy, there is less emphasis on the figure of the President. Rousseff made less foreign trips, visited less foreign countries, and the number of foreign diplomatic posts and vacancies in the Diplomatic Service was reduced. She is more technical, more pragmatic, and this can be seen as due to various areas of past experience – social, educational, and in terms of experience, ambition and views of the world that were different from her predecessor⁷.

One observes, on this point, that an earlier diplomatic agenda, based on economic and commercial debate, is increasingly having added to it a "soft" agenda, the central premise of which involves a supposed capacity to strengthen the relative position of the developing countries by taking a protagonist role in debates relating to social development, human rights, the environment, and other themes of a broad social agenda. It also involves a growing perception on the part of various social actors, including non-state actors, that the social issues – involving public health, education, hunger, human rights – require concerted global actions, with a view to overcoming the tensions between social needs and economic interest⁸.

There thus emerges the fact that Brazil is seeking to apply the "structuring cooperation" approach in its South-South cooperation in health, based fundamentally on five strategic, political and technical aspects that are inter-related: (a) prioritization of horizontal cooperation; (b) focus on the development of capacities in health; (c) initiatives coordinated in the regional context; (d) strong involvement of health ministers in the construction of strategic and political consensuses; and, nationally, (e) stimulation for the domestic partnership between the Health Ministry and the Foreign Relations Ministry⁹.

One sees, thus, the deepening of a dynamic that already was taking place since the 1990s, but is more visible as from the Lula government: *horizontalization* of the competencies, or *horizontal decentralization* of the process of decision for formation and execution of Brazilian foreign policy, within the Executive Power itself, taking the historic exclusivity in the conduct of foreign policy away from the Foreign Ministry (known as 'Itamaraty')².

This reality is confirmed by the fact that the organs of the Federal Executive Power, from the

Presidency of the Republic to the Ministries, today have competencies to operate in the international area, above all in international cooperation. Although this administrative structuring is not new in historical terms, in today's world and in the current democratic context it gains more importance, and makes Brazil international relationships more complex, especially in the sphere of cooperation¹.

The actors in this Brazilian thrust for cooperation in health are various, each one of them putting in their values and their institutional culture, and also their demands. But this exclusivity is not strictly linked to the Ministry of Health itself, since, according to França & Sanchez³, some 50% of the bodies of the presidency and of the ministries have internationalized structures and a permanent dialogue with Brazilian foreign policy. Among the bodies linked to the Health Ministry, we would highlight the Health Ministry International Advisory Group (*Aisa/MS*), the National Program For Sexually Transmitted Diseases and Aids (*PN-DST/Aids*), the National Cancer Institute (*Inca*), the National Health Foundation (*Funasa*), the National Health Supervision Authority (*Anvisa*), and the Oswaldo Cruz Foundation (*Fiocruz*). On the side of foreign relations, a highlight, clearly, is the Brazilian Cooperation Agency (*ABC*), which is responsible for negotiation, coordination and follow-up of the group of technical cooperation projects¹⁰.

In relation to health, although Brazil has in the past developed projects of cooperation for some decades, especially with countries of the South and on specific subjects, since some time in the 2000s health has been recognized as a predominant theme in the national agenda for South-South cooperation, revealing an unprecedented approximation between the Foreign Relations Ministry and the Health Ministry¹¹.

One sees, on this point, that the Health Ministry has been asked to cooperate internationally both on the North-South axis, and also on the South-South axis, and that the greater part of this cooperation is horizontal, being provided mostly in terms of technical cooperation, and on a lesser scale in scientific and technological cooperation; and it can be said that the Ministry usually receives more than it provides¹¹.

In 2012, for example, of the 107 health projects in progress, 66 dealt with Latin America and the Caribbean, 38 with Africa, and 9 with the Middle East and Asia; 24 of these programs dealt with mothers' milk banks, 17 with HIV/Aids, 10 with health supervision and 10 with blood and

blood derivative projects, as reported in the report *Participation by the Health Ministry in the international health scenario*, published by that Ministry, in 2012¹⁰.

It is concluded that Brazil, through the partnership between the Health Ministry and the Foreign Relations Ministry, has also been assuming leadership, in coordination with other countries of the North and of the South, in efforts to build more consistent relationships between health and foreign policy. In this connection, it has been acting with a firm sense of purpose in the specific international forums of the area, such as the World Health Organization and the World Health Assembly¹. The Health Ministry states Goal 14 of its Strategic Planning for the 5-year period 2011-2015 as follows: *To promote, internationally, Brazilian interests in the field of health, and also to share the experience and knowledge of the SUS with other countries, in accordance with the directives of Brazilian Foreign Policy*. Thus, Brazil presents a foreign policy in the field of health which, according to Ventura¹⁰, *operates with a motivation of solidarity when it defends, for example, the submission of international trade to human rights, in the matter of intellectual property; that the social determinacy of health should have priority in the global agenda; and that a reform of the WHO should make it more independent in relation to the large-scale private sources of finance*.

On this point, there is a range of proposals that relate to health and which are discussed in the most varied international platforms. One of these proposals that has most generated polemic, and currently promotes further debate, is on the relationship between health, innovation and trade. This is because it involves the question of access to drugs, which are the most important products in the interaction between trade and health. On this aspect we see that the conflict between the right of access to essential drugs and the right of intellectual property as part of a complex reality, in which various developing and less-developed countries see themselves in a situation of technological deficit, subject to the market conjurings created by the pharmaceutical multinationals. The countries at the periphery are also impacted by the absence of therapeutic alternatives for the so-called neglected diseases, which occur more frequently in the poorer regions of the planet, and for which in the 21st century there are still no alternatives for cure, due to the lack of investment in research and development by the pharmaceutical industry.

This abstruse context – one which places global public health in a situation of penury – brings numerous countries up against the position of extreme vulnerability. The audacious positioning of Brazil, in the context of international negotiations that involve the triangle public health-innovation-intellectual property, have been of fundamental importance in aggregating the interests of the developing countries and those that are relatively less developed. Thus, the next item explores, below, the fragile relationship between public health, innovation and intellectual property, and also the action of the Brazilian government in specific multilateral forums, seeking alternatives to enable the present international system of intellectual property to meet the specific interests of developing countries on the question of the rights to health, and access to medication.

The Brazilian government's activism in the negotiations on intellectual property and health

In relation to intellectual property rights, Brazil, and also a range of developing and less-developed countries, denied patentability to pharmaceutical products, aiming to remove themselves from the cycle of economic and technology dependence on the international pharmaceutical manufacturers, so that drugs produced in these countries can be used free from the situation of technical protection that exists in the industrialized countries – reducing cost of production, and thus enabling wider access to the medications that are available¹².

In Brazil, which itself has disallowed patentability of drugs since Decree-Law 7903 of 1945, and reinforced this barrier by its International Property Code of 1971 (Law 5772/1971), the external pressure to change the law in this direction has been as clear as day. As from the 1980s, the United States exercised a strong pressure for change in Brazilian intellectual property legislation, when they began the debate on the economic losses of the great pharmaceutical manufacturers, and of the countries where they are headquartered, in view of the 'copycat' right to copy pharmaceutical products. The positions of controversy between Brazil and United States on patents for the chemical/pharmaceutical sector, principally in the area of drugs, resulted, in 1988, in the US adopting extreme measures – imposing a 100% additional import duty on several Brazilian products including paper, chemicals and electronics¹³.

The stand-offs in the international area persisted until the signature of the TRIPS agreement, an international treaty, which was part of a group of agreements signed in 1994 that completed the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), and created the World Trade Organization¹⁴.

Indeed, even though the defenders of intellectual property justified that this was necessary to ensure that investments in research and development returned to the inventor, causing a positive cycle in which there would be greater investments in the R&D due to the concession of a temporary monopoly for the exploration of the invention, it was found, in the sphere of public health, that the inequities in relation to access to drugs and technologies in relation to the neglected diseases simply became deeper.

The discussion on inequalities in global health, relating to the issue of access to drugs, and also the scarcity of financing for research and development for the illnesses that most affected the developing and less-developed countries, gained a highlight position in the context of the foreign policy of companies at the beginning of the 2000s decade, with the signing of the Millennium Declaration. This process in which health rose to become part of the center of discussions between the member-states in the most varied international forums was named by Ambassador Santiago Alcazar as the "Copernican revolution in health"¹⁵. In its own words that document *provides the preparation of a group of goals that must be pursued to maintain the high principles of human dignity, equality and equity*.

On the subject of health, the Millennium Development Goals, that were attached to the declaration, proposed that: (i) between 1990 and 2015, reduction of mortality of children under the age of five by two-thirds and reduction of maternal mortality by three-quarters; (ii) the propagation of HIV/AIDS should be deterred and begin to be reversed; as should also be the case for malaria and other serious diseases.

These objectives, extremely ambitious, could only be met if there were an effort by the whole of the international community toward promoting greater accessibility for drugs, vaccines and diagnostic kits, which would have to be efficacious, sufficient and of good quality. This highlighted the need to create new partnerships and find new mechanisms of sustainable financing. To meet this aim there emerged the *Global Alliance for Vaccination and Immunization* (GAVI), the *Stop TB Partnership*, the *Global Fund to Fight AIDS*,

Tuberculosis and Malaria, the *President's Emergency Plan for AIDS Relief* (PEPFAR), *Unitaid*, and other organizations.

In 2001 the *Doha Declaration on the TRIPS Agreement and Public Health* was signed under the aegis of the WHO, a multilateral attempt to strengthen the right of the developing countries to use the flexibilities that are present in the TRIPS, mitigating the adverse effects of intellectual property policies, so that they might respond better to the real needs of public health and development.

Faced with the need to conduct these debates by health authorities, in 2003 the WHO established the *Commission on Intellectual Property Rights, Innovation and Health* (CIPRH), which sought to find evidences of the possibility of reaching an equilibrium between rights of intellectual property and innovation and the interests of public health. With its 60 recommendations, it revealed the problems of access caused by the current international system of intellectual property and by the lack of innovation, especially for illnesses that disproportionately affect the developing and less-developed countries¹⁶.

The studies of the CIPRH did not in practice find any evidence that the implementation of the TRIPS agreement in the developing countries had significantly boosted research and development of pharmaceutical products. It found that the principal reason for this is the insufficiency of market incentives¹⁶.

In 2004 Brazil and Argentina, supported by another thirteen developing countries, presented a proposal to the World Intellectual Property Organization (WIPO), to establish a development agenda¹⁷. This organization, created in 1967, is one of the 16 specialized agencies of the UN; its purpose is to promote protection of intellectual property around the world through cooperation between States. However, one sees that the activity of the Brazilian government, in that forum, also is in the direction of the ideal that the international intellectual property system should be better adapted to the interests and needs of the developing countries.

The proposal of Brazil and Argentina included amendments to the WIPO convention, including: stimulating enhancement of technical cooperation; creation of a *Commission on Intellectual Property and Technology Transfer* that would guarantee an efficacious means of transfer to developing countries; and organization of international seminars jointly with the WHO and the UN Conference on Trade and Development.

After three years of discussion the development agenda, with 45 recommendations, was agreed by the member States of the *Provisional Committee on Proposals Related to a WIPO Development Agenda* (PCDA), in its sessions of February and June 2007, and duly ratified by the General Assembly, in September and October 2007¹⁸.

In the next year, 2008, the activity of the Brazilian government was once again outstanding for its progressive positioning in relation to access to drugs, this time in the context of the World Trade Organization, so that this access would not be the subject of blockages created by restrictive international trade policies. This activism was able to be seen when a cargo of 570kg of the active ingredient *Losartan Potassium*, used in the production of drugs for high blood pressure, was held up for 36 days in the Port of Rotterdam, Holland, under the allegation of being falsified. The ingredient was imported by the Brazilian pharmaceutical company EMS from a manufacturer in India. In Brazil and in India, the product is not protected by a patent, and may be sold freely. The German manufacturer Merck, which owns the intellectual property, asked for the substance to be held up in Holland.

The incident generated diplomatic conflicts between the two countries. Brazil accused the European Union of restricting the flexibilities granted to the developing nations to buy or import generic substances or drugs. The European managers beat back against the accusations alleging the right to inspect medications coming through the Customs to combat illegal trade and falsified products. Although litigation in the Dispute Settlement System did not go forward, it was clear that international trade policies cannot function as a block on access to drugs in the developing countries¹⁹.

It could be seen, in the meanwhile, that both the WTO and the WIPO are bodies that do not act directly on questions of health and human rights, and for this reason are often criticized for their lack of transparency and for the imposition of the private interest over the public²⁰. Thus, it is important for us to note how the conflicted relationship between public health, innovation and intellectual property is being debated in the multilateral forum that is competent for dealing with issues related to health.

As a consequence of the studies of the CIPRH, the WHO created, through its Resolution WHA59.24, the Intergovernmental Working Group on Public Health, Intellectual Property and Innovation (IGWG), which asked the Direc-

tor-General of the UN to establish an intergovernmental workgroup open to all member States interested in developing a global strategy and a plan of action that would, specifically, ensure a greater and sustainable base for the needs of research and development in health, pertinent to the diseases that disproportionately affect the developing countries, proposing concrete objectives and clear priorities, and estimating the need for financing in this area²¹.

Thus, in 2008, after almost two years of intense debate and negotiations between the various actors involved, through Resolution WHA61.21, the Global Strategy Plan of Action on Public Health, Intellectual Property & Innovation (GSPOA) was approved. The main objective of this strategy is: *to promote a new thinking on innovation and access to drugs, and also [...], a medium-term situation able to guarantee a solid and sustainable base for R&D in health guided by the needs of, and centered on the illnesses that disproportionately affect, developing countries, proposing clear objectives and priorities for R&D, and estimating the needs for financing in this area*²².

In this context Brazil was an outstanding protagonist in the process of negotiation, with its proposal in a multilateral forum of initiatives that were already practiced internally, such as participation of the health sector in the process of concession of patents in pharmaceuticals (Prior Consent by Anvisa). Becoming one of the leaders of the bloc of developing countries that raised the pro-access flag, it was very active from the birth of the IGWG, when Resolution WHA59.24, approved at the 59th World Health Assembly in 2006, reiterated the need for member-states to consider the flexibilities of the TRIPS Agreement and, based on the preliminary proposal presented by Brazil and Kenya, determined the creation of the Intergovernmental Workgroup on Public Health, Innovation and Intellectual Property²³.

WHA Resolution 60.30, which was approved while the negotiations of the IGWG were still in progress, entitled “*Public Health, Innovation and Intellectual Property*”, at the 60th World Health Assembly, in 2007, largely resulted from the Brazilian proposal, and established a commitment of the Director-General of the WHO, Dr. Margaret Chan, to give technical support to the countries that wanted to use the flexibilities of the TRIPS agreement. The resolution suffered strong resistance from the developed countries, which questioned the limits of the mandate of the WHO for treatment of the subjects relating to the negotiation, such as intellectual property, which they

allege to be the province of the WTO and the WIPO²⁴.

During the negotiations of the IGWG, Brazil's activity was fundamental for aggregating the interests of the countries of the Latin American and Caribbean region (*Grulac*), promoting and acting as facilitator of the sub-regional meetings, which later took substance in the form of the *Rio Document*, the principles of which adhered to the content of the *Global Strategy*, conferring upon the document an orientation in support of public health that had not existed in the previous drafts. Brazil's activity was also determinant in the aim of guaranteeing that the theme of intellectual property was inserted into the agenda of the WHO and ensuring the effusion of the flexibilities of the TRIPS agreement and other international agreements, which favor public health. Finally, Brazil's activity was decisive in the proposal to ensure that the point of view of health was applied to negotiations of intellectual property that had effect on public health²⁵.

After the Doha Declaration of 2001 on the TRIPS agreement and public health, the Global Strategy was the most important multilateral attempt to alter the policies on intellectual property so that they would better respond to the real needs of public health²⁶. As soon as it was the health authorities that were discussing the subject, we can see that the question of the inequities between public health and intellectual property gained a highlighted position among the policies and actions planned in the largest multilateral forum on health subjects.

After approval of the Strategy, a paradox that sustained the present R&D system was revealed, consisting of two diametrically movements: one moved by the commercial interests of patent holders, which seeks to strengthen the monopoly through expansion of the existing rules, and the other, oriented by the public interest, proposing resistance to the present model of intellectual property and innovation.

As a final observation it can be stated that the current state of contention between countries demonstrates that the present international system of intellectual property and of encouragement for R&D generates a complex structure of problems, in which the innovative products and research investigations in progress are insufficient to meet the very great health needs of the developing countries²⁷. In this model – which is still the current situation today – private investments are directed to the health issues and markets that provide the highest profitability, while

those diseases that principally affect the least favored populations are neglected.

Conclusion

Analyzing the activity of the Brazilian government in the context of international negotiations that involve the three-part issue of public health, innovation and intellectual property, it is concluded that the positive action of the Brazilian foreign ministry in the context of the social right to health and universal access to drugs has been a protagonist in the struggle of the developing countries and the less-developed countries in their quest to change policies on intellectual property so that they respond more appropriately to the real needs of public health.

It should be highlighted that the activity of Brazil was also important in the objective of ensuring insertion of the theme of intellectual property into the agenda of the World Health Organization, and in guaranteeing diffusion of the

flexibility of the TRIPS agreement and other international agreements, so that they would favor public health. Finally, Brazil's activity has been decisive in ensuring that negotiations on intellectual property that have effects on public health should be seen through the lens of health itself.

We expect Brazil to continue to be a strong protagonist in this debate in the near future, seeking alternatives that aim to mitigate the adverse effects of the present international system of intellectual property on access to drugs and other medical technologies in the developing countries. We believe that in the multilateral negotiations involving public health, innovation and intellectual property, Brazil should continue to hold high the flags of avoiding "*TRIPS-plus*" clauses in the negotiations of regional agreements, promoting the use of the flexibilities specified in the TRIPS agreement and reinforced in the Doha Declaration, and stimulating regional partnerships in R&D that are able to fill the current gap in relation to the therapy alternatives for the so-called neglected diseases.

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