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Protectionism

Brazil-US controversy on the impact of patenting in biotechnology: some relevant questions for pharmaceuticals

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The controversy over intellectual property rights in biotechnology between the USA and Brazil is discussed. The pressures applied by the USA seem justified only from a strictly commercial viewpoint. The harmonizing of IPR rules does not allow any distinction between developing and developed countries, which may jeopardize the development of local capacity in countries like Brazil. It seems that the current trends will be detrimental to Latin American countries and they can project increasing difficulties in accessing scientific and technological information.

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IN THE LAST FOUR decades, new innovation poles, especially in informatics, have led to extensive restructuring in diverse sectors of productive activity, with some declining and others emerging. This structural change is associated with the technological progress originated in the industrialized countries and is greatly affecting the opportunities for economic development in newly industrialized economies (NIEs), such as Brazil.[1]

Among these technological changes, the current medical procedures based on genetic engineering methods and techniques have emerged as revolutionary tools. The outburst of these techniques in the medical field favored, internationally, new interfaces between public and private institutions. It is also stimulating strategic alliances between large and small pharmaceutical enterprises.

In the international commercial scenario, the new biotechnology has been one of the main alleged reasons why developed nations have introduced new protectionist procedures and barriers to the world-wide transfer of the technology. As a consequence, new challenges have been created for North-South negotiations of scientific and technological co-operation.

In this context, intellectual property rights (IPR) in biotechnology have appeared as a major issue, surrounded by controversies and uncertainties. The central questions evoked in the international debate on IPR are related to the diffusion process of these modern technologies within key activities of all economic sectors.

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This paper focuses on some of these questions. The main objective is to identify, from a policy viewpoint, some possible international constraints to the social applicability of modern biotechnology in Brazil within the health sector. With this in mind, we will analyze the current controversy between Brazil and the USA on patents in biotechnology.

To sum up, our aim is to identify some of the most relevant determinants and constraints that could influence, in a medium-term perspective, the diffusion of biomedical innovations in the health sector in Brazil.

The main questions are:

- What is the explanation for the US pressures on Brazilian Law regarding the introduction of patenting in biotechnology, if Brazil is a long way from being an important competitor, such as Japan, in this field?
- What will be the consequences for Brazil of current trends in the international legal and commercial framework for IPR regarding the access to scientific and technological information?

Landmarks of the controversy

Since the 1980s, the Brazilian press has been reporting a new front of commercial conflict between the United States and Brazil. This was motivated by the non-patentability of pharmaceutical drugs, as defined by article 9 of the Brazilian Industrial Property Code (Law no 5772 of 21 December 1971). The basic issue of the controversy was that, since 1945, Brazil has not accepted patents for pharmaceutical products, and, in the 1971 Code, the protection of processes for developing drugs was excluded.

In 1988, supported by Section 301 of the Trade and Tariff Act, the Reagan government penalized Brazil for the first time for the absence of patent protection in pharmaceuticals. The United States applied commercial sanctions which affected exportation sectors not related to pharmaceuticals, such as paper, pulp, chemicals and electronics. This retaliation made evident the high North American sensitivity to issues related to intellectual property of advanced technologies. This Reagan government position supported a world-wide banner against the so-called 'piracy' in pharmaceutical industrial activities.[2]

This policy led to a 'task force' to confront 'unfair practices' joining diverse North American agencies, such as International Trade Administration (ITA), Patent and Trademark Office (PTO), United States Trade Representative (USTR), State and Commerce Departments and the Copyright Office linked to the Congress Library.

In Brazil, since 1989, just before the first direct democratic elections for President which ended more than two decades of authoritarian military government, there were some signs of possible changes in the 1971 Industrial Property Code. On 26 June 1990, the newly elected Collor government announced its Industrial and Commercial Policy[3,4] which included in its general principles the intention of reviewing the 1971 Code, widening its scope to extend patent protection to pharmaceutical processes and products.

In 1990 , with the prospect of a new Brazilian Law harmonized with existing international standards, the United States Trade Representative (USTR) was prepared to eliminate sanctions against Brazil. In May 1991, the Brazilian government sent its Law Project (PL 824/91), incorporating the main North American suggestions, to the National Congress.

In 1992, after a turbulent impeachment process, Collor de Mello was removed, amidst accusations of involvement in corruption practices, and Itamar Franco was nominated President of Brazil. An inter-ministries commission updated the revision of the Code and the National Congress accelerated its discussions as a response to renewed strong pressures from the United States.

In mid-1993, the Brazilian House of Representatives of the National Congress, approved a new Law extending patents to pharmaceutical products and processes and to microorganisms developed in the laboratory applicable to a process generating a specific product. Although the reform of the Brazilian IPR system coincides with the main North American requirement, especially introducing patents in pharmaceuticals, the controversy between the two countries persisted.

The American reaction to the approval of the new Brazilian Law was immediately negative, despite its greater level of international harmonization.

The Clinton administration, which assumed office in January 1993, nominated Mickey Kantor as the new White House commercial representative. The North American position regarding IPR apparently was not changed. The new American representative announced that investigations against Brazil would be reopened, under the allegation that there were no advances, particularly in terms of microorganisms being developed.

In this context, a new dilemma emerged: should patenting in biotechnology be included in this general review of the Brazilian law or should a specific law to deal with this aspect be elaborated later? In the Brazilian debate surrounding this emergent issue, biotechnology was considered by the press and the different political actors as a synonym of modified microorganisms and genetic material.

The main concern was the possible impact of patenting biotechnology on national efforts to research and develop new drugs for prevention, diagnosis and therapy of diseases such as malaria and

The main concern in Brazil about patenting biotechnology was the possible impact on national efforts to research and develop new drugs for prevention, diagnosis and therapy of diseases such as malaria and Chagas

Chagas in Brazil. Another important issue, boosted by the United Nations Conference on Environment and Development (UNCED), held in mid 1992 in Rio de Janeiro, was the controversy over the risk of private and foreign appropriation of the Brazilian rain forest germplasm, which would impede local R&D and manufacturing in the field of medicinal plants.

All this was surrounded by a strongly emotional argument, considering that internationally patenting of genetic material still is a very controversial issue legally, as we will see later.

During a long period of debate, the new Brazilian Law received more than 1,000 amendments. This large number of revisions made evident the complexity of the negotiation process, the power of the lobbies and the high degree of uncertainty surrounding patenting in biotechnology. Therefore, despite the significant level of external pressure, the Brazilian reform of the IPR system was not simple.

Main arguments

The following interest groups should be considered in the Brazil-USA controversy on the impact of patents in biotechnology:

- on the American side, the Executive, the House of Representatives, the Supreme Court, commercial chambers, representative associations of pharmaceutical and biotechnology industries, lawyers, federal agencies (EPA (Environmental Protection Agency), OTA (Office of Technology Assessment), NIH (National Institutes of Health), among others), universities and research institutes and NGOs (non-governmental organisations).
- on the Brazilian side, the Executive, the Brazilian Congress, federal agencies, representative associations of national and foreign pharmaceutical and biotechnology industries, the Catholic Church, universities, research institutes, lawyers and NGOs.

On the Brazilian side, the main arguments of those who opposed reviewing the Code as a response to international pressures, especially when they were expressed through the strong and coordinated lobby of foreign enterprises, focused on the threats to the internal market, the risk of stagnation of national industry and the decreasing incentive to the research activities in the country.

For some of them, the introduction of patenting in the pharmaceutical sector expressed the Collor government's submission to foreign interests, with the United States finally succeeding in overcoming the Brazilian resistance to change the Code.

Included in this opponent position were the representative associations of the national chemical and pharmaceutical enterprises and other representatives of leftist political segments in the health sector.

Arguments opposed to the Code revision were often labeled by the press as *xenofobos* (extreme nationalism) and *xiitas* (a synonym for political radicalism).

On the opposite side of this controversy, the representative associations of foreign companies together with those associations representing the Brazilian biotechnology enterprises commemorated the announcement of the new political posture. The arguments favoring the introduction of patents in biotechnology suggested that they were essential to accelerate the technological transfer process from the North Hemisphere to Brazil. They also assumed that patenting would stimulate Brazilian R&D activities.

Nevertheless, Brazilian researchers, through their main representative associations presented an opposing viewpoint: the Brazilian Association for the Advancement of Science (SBPC) proposed that the issue of patenting biotechnology should stay out of the new law (PL 824/91) and should be the subject of a specific law to be approved at a time that would allow it to benefit from further advances in the international conceptual debates.

Brazilian scientists argued that internationally the laws and regulations concerning patent protection for biotechnology products and processes are still evolving. They considered that the boundaries of patentable subject matter in biotechnology inventions may not be easily described. For them, such patents evoke many complex questions on ethics, safety and practical operational aspects that are still in debate. In addition, they argued that it is very doubtful whether new biotechnologies are protected at all by existing IPR laws, and the USA cannot expect the Brazilian Congress to deal with these problems if the US Courts and Congress have not fully resolved them.

On the American side, since the 1970s, there have been an impressive amount of public statements, publications and institutions arguing in favor of stricter intellectual property rights. This keen interest was motivated by the necessity to protect the so-called high-technology related to advanced industrial processes requiring a large

amount of investment in R&D, such as new biotechnologies and software.[5]

In the 1980s, the advanced technologies in the service sectors (informatics, telecommunication and robotics) clearly became the main competitive advantage for the USA. Awareness of this trend had a marked effect on international trade negotiations. North American elites complained that international markets were not favoring the diffusion of these high technologies, which were exposed to "unfair competition".

During the 1980s, the USA adopted an aggressive commercial policy directed to the reduction of its debt and to controlling unfair commercial practices.[6] Based on Section 301 of the Trade and Tariff Act of 1974, extended in 1984, the USA started to use procedures such as suspending preferential treatment and retaliation practices.

The 1988 Omnibus Trade and Competitiveness Act made evident the adoption of the intellectual property protection approach as a central priority of the United States commercial policy. The Omnibus Act, among other instruments, created the priority watch list, in which countries considered "unfair competitors" (such as Brazil, India and Japan) in commercial practices with the United States, are placed under observation and are therefore vulnerable to sanctions.

The North American legislation therefore permits the use of intellectual property rights to threaten other countries with commercial retaliation as a unilateral coercive procedure, unless they agree to the US impositions concerning these rights.

To strengthen its competitive position, the USA applied pressure to introduce the issues of intellectual property rights, services and investments in the Uruguay Round of the GATT (General Agreement on Tariffs and Trade). Within the GATT, the United States not only started to negotiate agreed proposals for the trade-related aspects of intellectual property rights (TRIPs), but also stimulated Japan, the EC (European Community) and other developed countries to do the same.

In the pharmaceutical and biotechnology fields, the powerful lobby from the North American Pharmaceutical Manufacturers Association (PMA) forced the US government to exert pressure in the GATT for more comprehensive patent and other intellectual property laws internationally. The absence of comprehensive laws was considered a 'non-tariff barrier' to trade.

The increased technological sophistication of many developing countries, led by India in the pharmaceutical sector, associated with their less restrictive national patent laws, were blamed for the loss of income in the US pharmaceutical industry.

PMA has made estimates of the financial loss they have suffered through reproducers in Argentina, Brazil, India and Mexico: in copied drugs it amounts to US$1.4 billion per year.[6] According to Nogues[7] this is certainly one of the reasons why the pharmaceutical drug companies are pressuring developing countries.

The lack of patent protection in Brazil led to some elevated estimates of total annual losses by PMA. However, as stressed by some authors, there is insufficient empirical support for these estimates.[7,8]

Some Brazilian studies[9] estimated that the revenues from national drugs which are similar to patented foreign products, reached a total of US$12.7 million, corresponding to only 0.6% of the national pharmaceutical market, which was estimated to be US$2.9 billion in 1991, ranking Brazil ninth in the world pharmaceutical drugs market.

American laboratories estimate higher values for their losses related to 'piracy' practices in Brazil, which would reach almost US$200 million, or 13% of total sales of ethics drugs (US$1.5 billion).

These conflicting estimates result from studies using different methodologies, chosen according to their suitability to diverse interests regarding the introduction of patents in pharmaceuticals.

Brazilian studies have estimated the revenues from national drugs similar to patented foreign products at US$12.7 million, while US laboratories estimate almost US$200 million: there are obviously vested interests in these estimates

New negotiation strategies

Analyzing the international trade-related aspects of intellectual property rights, Primo Braga,[10] without minimizing the influence of the lobby from the R&D-intensive industries, argued that it was misleading to attribute to them the main responsibility for the Brazil-USA controversy on patenting pharmaceutical process and products.

He stressed the qualitative changes which occurred during the 1980s in the international involvement of the North-American Government and of the industrialized nations of the European Community. These governments started to use their commercial policies as an instrument to exert pressure on developing countries, to obtain modifications in their intellectual property standards and thus introduce changes in regimes based on some basic concepts from the Paris and Berna conventions.

The central classic concept established in these Conventions is the liberal regime in which each country has complete liberty to legislate on intellectual property matters according to national interests and needs, concerning their social and economic development and security.

At the multilateral level, new negotiation strategies were introduced by the GATT's Uruguay Round launched in 1986. As suggested by Amorim ,[11] for the first time the GATT surpassed the limits of its traditional field — commerce of goods — by starting to negotiate rules on services, intellectual property and investments.

Within the Uruguay Round the expected changes include the extension of intellectual property protection to pharmaceutical and biotechnological products and processes, as well as widening the scope and the duration of the protection. The possibility has also been established of temporary protection for pharmaceutical and agrochemical inventions in the pipeline.

Among the main obligations that have been assumed by the 108 countries participating at the Uruguay Round, are those which refer to the patentability of inventions of microorganisms and non-biological or microbiological processes for the production of plants and animals. Excluded from patentability are the methods for diagnosis, surgery and therapy, as well as plants and animals and the essentially biological processes for their production.

According again to Amorim, the TRIPs' negotiations indicate a tendency towards an extension of the scope of intellectual property rights and of the governmental responsibilities concerning their control and protection. These negotiations are contributing to a reduction in the autonomy of the national legislations to define their own standards and therefore to establish certain rules harmonizing IPR systems internationally.

According to the former US commercial representative Carla Hills, the Latin American legislations on intellectual property were considered in general obsolete, with the exception of Mexico, which was suggested as a model to be followed by other countries. Since 1987, Mexico has adopted patents for medicaments, and announced in 1991 the intention of recognizing patents in biotechnology.

We consider that the results for Mexico of the negotiations relating to IPR within the North American Free Trade Agreement (NAFTA), provide some ideas on what can be expected by Brazil and other Latin American developing countries in their international negotiations concerning harmonization of national patent laws.

Other developing countries will probably be required to offer protection similar to those of NAFTA: DNA transfer to mammalian cells by use of bacteria or viruses (and for the resulting cells); DNA transfer by micro-injection and human genes that have been manipulated and placed in a foreign vector. Patent will not be required to protect a hybrid animal resulting from DNA transfer by micro-injection, such as the 'Harvard Mouse'.[12]

The patenting of DNA sequences or segments is a main issue to be clarified later in the Mexican biotechnology law, depending on NAFTA negotiations. Genetic material patenting (DNA sequences or segments) is still a very controversial issue within NAFTA.

New legal challenges

In the USA, defining IPR for third generation biotechnologies is becoming an increasingly difficult task. Currently the main challenge in the legal sphere is to conciliate the controversies about the role of patents in promoting product development (firms' interests) and their role in promoting basic research (public interest).[13] For the legal approach, as the use of patent inventions in the biomedical sciences becomes increasingly important to the progress of science (public interests), it also becomes increasingly threatening to the private interests of patent holders.

For Eisenberg

> "...as the line between basic and applied research becomes blurred in certain fields, patent protection increasingly threatens to encroach on the domain of research science, making it necessary to work out an accommodation between the two perspectives."[14]

Eisenberg examines patent law doctrine as applied to biotechnology inventions to determine whether and how patent law conflicts with scientific norms in this particular research context. She shows that, despite some parallels between both systems (patents and scientific norms are both oriented to disclosure), their conjunction may lead to delay in the dissemination of scientific innovation, aggravating the persistent conflict between norms and scientific rewards.

She recommends that a careful examination and selection of inventions and discoveries capable of exemption from patent infringement liability is an important first step to overcoming conflict between the private interests of the patent holder and the public interests of subsequent research and further advances.[15]

She shows that the controversy on the disinclination in the scientific community to secure patents also had a normative component. It was thought contrary to scientific norms to claim exclusive rights in research discoveries. On the contrary, disclosing information was viewed as an essential procedure to facilitate the progress of science.[16]

According to Eisenberg, the dominant viewpoint still ruling in the scientific community in the

biomedical field is that the disclosure of research results stimulates the free exchange of discoveries. Thus, the generation of new knowledge should be made available to serve humanity.

Another very important new legal issue is related to the dual structural-informational nature of the results of biotechnological R&D.[17]

For the purposes of assuring intellectual property rights for living organisms, the deposit of the physical object is an essential procedure. This occurs because the information is tied to the structure and cannot be communicated without this object (the microorganism, the cell line, the plasmid, the DNA molecule). For this reason, some authors refer to the DNA molecule as an "informational macromolecule" or an "informational macromolecule invention".[17]

The fact that the physical object carries in itself the information necessary for the creation of subsequent generations or future physical objects, has many and complex implications in the legal sphere.

Biological materials can be stored in 'depositary institutions'. A 'deposit of a micro-organism' means its transmittal to an international depositary authority, which stores it. Thus, the legal problems in this matter are related to limits between the concepts of 'tangible' and 'intangible' from the property rights point of view.

Other main discussions on life patenting refer to patent applications for human gene sequences, which are currently evoking new ethical and legal challenges world-wide.[18,19,20,21]

To sum up, as Correa22 pointed out, patents in biotechnology introduce a new and complex set of legal and ethical issues that the laws of most developing countries have not yet dealt with; that is the case of the private appropriation of materials existing in nature and of the conditions for the deposit of microorganisms in connection with disclosure obligations.

Discussion

The classical legal and conceptual framework of IPR consists of the concession by the State of temporary, but exclusive, privileges for the creators in the utilization of the new knowledge and technologies, against the complete, broad and public disclosure of information. We have seen that this double rationale — private appropriation and public disclosure — permeates the current international controversies on intellectual property rights.

Since the 1980s, the boost in the international market of the commercial value of intangible goods, that is, scientific and technological information, parallels the increasing importance of technological innovations in the demarcation of the comparative advantage of nations and industrial competitiveness.

Most developing countries consider that the advanced technologies are a critical tool for their development strategies considering the degree and the character of their insertion in the international market

It is widely acknowledged that technological modernization is, in the contemporary world, crucial for attaining better economic performance. It is also true that developing countries could find solutions for most of their needs in the conventional technologies that are in the public domain, that is, those already standardized and with expired patents. Nevertheless, most of them consider that the advanced technologies are a critical tool for their development strategies considering the degree and the character of their insertion in the international market. In addition, some believe that that technological leap is feasible in their development strategies.[23]

In the USA the emergence of strategic new technologies, contributing to economic productivity and to respond to domestic and international demands, placed the public responsibility of universities as a central question in the debate on public-private relations. The direct contribution of science to the development of these new technologies added a new variable to the old discussion on the role of the university in the satisfaction of crucial public needs.[24]

Currently, most major American universities are searching for collaborative mechanisms with industry that do not jeopardize their academic values.

Concerns over potential conflicts of interest emerging in the university-industry research relationship in biotechnology are not new.[25-27] However, there is now renewed discussion in the USA, particularly on the risks of the amount of money involved becoming the major incentive for research in biotechnology, rather than the quality of knowledge created. Harvard and other American universities are rewriting their codes of ethics to provide the necessary safeguards regarding the involvement of academic personnel with the private sector. This trend confirms that in the USA a growing number of cases of conflict of interest, as well as some cases of scientific misconduct, are emerging from the introduction of financial gains in the academic world.[28-35]

We argue that the increasing anxiety in the relations among government, scientists and entrepreneurs indicates that the results of basic biomedical research are becoming the main issue underlying the conflicts of public-private interests in biotechnology in the USA. This occurs because

the distance between basic science and technology in the new biotechnology field is very short, and their links are crucial to economic productivity and payoffs.

Another relevant question relates to the internationalization of links between science and technology in the current globalization scenario. There are still many theoretical and empirical gaps in the knowledge about the economic impact of basic science and its implications for international trade and foreign policies. Concerning this trend, we ask with Pavitt: are the technological benefits from science becoming increasingly international?[36]

Here we propose that the blur of public-private boundaries in scientific research in the USA will contribute to raise new protectionist barriers to North-South technological transfer. However, it is important to note that this blur will not necessarily affect the technology transfer between the USA and developed countries in the same way. Currently, most strategic alliances established by US biotechnology enterprises involve partnership with firms based in developed countries, mainly Europe and Japan.[37]

The different political implications of protectionist barriers result from the obvious fact that the main competitor countries in biotechnology are in the northern hemisphere, where national interests are frequently identified with both public and private interests.

On the contrary, in developing countries, particularly in Brazil, the public-private relations involving science are not so clear, particularly because the demarcation of the scope of State intervention in this domain persists as a main political concern and the local biotechnology industry capacity is still in its early stages.

Notwithstanding these differences, the rate and volume of technology transfer between the biotechnology scientific community and industry became a national policy concern in both the USA and Brazil, because, in this field, industrial strategies assume scientific and technological information is essential for innovation.

Among the new barriers and challenges which are emerging to the international free flow of scientific and technological information, are those resulting from the extremely restrictive nature gradually acquired by IPR for the new biotechnologies.

At the multilateral level, we understand that the introduction of a uniform world-wide intellectual property rights system will have negative consequences for scientific and technological information interchange between developed and industrialized developing countries. This will occur because the political positions in the GATT assumed by developed countries is contributing to the disintegration of the fragile equilibrium between protection of rights and diffusion of new knowledge, conferring to the patent owner a strong and broad control over the scientific information.[38]

Conclusions

Biotechnology patenting was considered here as being a crucial political decision for Brazil. With this in mind we analyzed the economic and political processes underlying the controversy. The purpose of the paper was not merely to formulate additional arguments in favor of, or in opposition to, the introduction of patent protection for biotechnological and pharmaceutical products and processes in Brazil. Neither did it intend to provide blind support to US positions on this matter. On the contrary, we have attempted to examine the main arguments in the current controversies concerning genetic engineering within the USA and to anticipate some possible consequences for Brazil.

Concerning the first question of our paper on the explanation for the US pressures on Brazil, it is possible to conclude that they do not express a clear conflict between different 'national interests'. In fact they express the demands of different interest groups in the two countries. Thus, these pressures seem justified only from a strict commercial standpoint: although Brazil, unlike Japan, is not yet an important competitor in this domain, it has an immense emergent internal market.

So far, it is not possible to anticipate whether these pressures will result in the formulation of specific bilateral agreements at the diplomatic level. The US-Brazil controversy shows that Brazil is not open to accepting a new international rule restricting its right to legislate with autonomy in a vital area such as biotechnology patenting.

Nevertheless, if the emergence of new biotechnologies world-wide threatens the American leadership as well as the development opportunities of Brazil, this certainly requires a search for diplomatic consensus, overcoming unilateral decisions in the international scenario.

The USA and other developed countries have tended to harmonize for developing nations, such as Brazil, the same IPR rules and commercial policies designed for stronger competing countries. Therefore, our main conclusion here is that current harmonization trends do not discriminate developed from developing competitors and thus may jeopardize the development of local capacity in some NIEs like Brazil.

Finally, our answer to the second question proposed at the beginning is that there is enough reasonable evidence indicating that the consequences for Brazil and other Latin American countries of these current trends will be detrimental. These countries should project increasing difficulties in accessing the bulk of scientific and technological information, which could jeopardize

the autonomous control of the potential effects of new biotechnologies in their health sector.

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