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Review Articles

Intellectual property policy on pharmaceutical products: a view in the beginning of the 2000 decade

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Abstract
This paper aims at an analysis of the intellectual property policy in the health field by emphasizing the program of production and distribution of antiretrovirals and the generic drugs market, also reviewing the process of articulation and implementation of the intellectual property policy in this sector. From a methodological viewpoint, the paper favors the analysis of data related to the structuring of the pharmaceutical products market and of impacts both from the new institutionality and the intellectual property policies developed by the Ministry of Health in the first half of the 2000's decade.

Keywords
intellectual property; policy, health; pharmaceutical products

Introduction

The reform of the intellectual property legislation occurring in Brazil in the second half of the nineties, a result from the TRIPS Agreement, can be seen as bringing about different opportunities and constraints. The latter can be related to the type of protection (in the industrial property field, if patents, brands, geographic indications; if copyrights in a wider sense, or more specifically, computer programs; in the *sui generis* protections fields, if protection of varieties and protection to biological diversity), or related to inventions object of protection (Carvalho & Pessanha 2001, Carvalho 2002a).

It should be emphasized that a major characteristic of the TRIPS Agreement was to connect the intellectual protection to foreign trade. Historically, especially since the 1883 Paris Convention, the agreements in the intellectual property area connected the intellectual property to the technological and economic development of the countries participating in such agreements. This shift of emphasis presents some relevant issues: one of them is to widen the asymmetries between the greater relative development countries as compared to the others. Such asymmetries tend to repeat themselves within the context of developing countries. Thus the impacts can still be further regressive to the economies lacking infrastructure and technical, scientific and industrial capacity to assimilate technologies which are more strongly protected as of the TRIPs Agreement (Juma 1999, Aded 2001, Dutfield 2001).

Some authors, among them Coriat (2002), understand that the changes in the legislation of the intellectual property rights led to the creation of institutional barriers which reserve the exclusive use of new knowledge to the benefit of major multinational companies of central countries while imposing such rights through international agreements on the domestic markets of developing countries. However, the TRIPS Agreement presents two relevant characteristics which can be considered positive from the developing countries' standpoint such as Brazil. The Agreement resulted in the creation of a multilateral jurisdiction for the resolution of disputes which take place through panels in the World Trade Organization (WTO). Another relevant feature relates to the maintenance of possibility of granting compulsory licenses and utilization of parallel imports. This is a controversial issue going back to the 1883 Paris Convention itself, but exercised throughout the 20th Century. It enables to increase the intervention by the TRIPS Agreement signatory countries in the flexibility of intellectual property rights without however violating the latter Agreement (Aded 2001, Carvalho 2003).

Such points are also added of a new foreign trade regulation structure which restricts the use of incentive policies to the national production in the formats which guided the developing countries' industrialization process, especially those of replacement of imports based on direct subsidies and closing of domestic markets. The policies of support to industrialization and expansion of competitiveness and the scientific and technological policy tend to embody the innovation in their core, thus increasingly converging towards the sciences, technology and innovation policies. Within such context of innovation and industrial policy, the intellectual property is a major benchmark and a jurisdiction which involves specific actions to increase the positive impacts and reduce the potential constraint which may be caused by the restrictions derived from the TRIPS Agreement on the technological and national development (Carvalho 2003).

Specific policies can (and should) be developed by the State, particularly from the national scientific and technological base. Brazil displays a remarkable example of intellectual property policy applied to specific industries: the Fiocruz' role in the issue involving the drug "cocktail" of the Brazilian Government AIDS Program. Fiocruz, through its pharmaceuticals production unit, Far-Manguinhos, provided the Ministry of Health with the cost structure of the drugs forming the cocktail used in the AIDS Program, by identifying the molecules and technologies required to the production thereof. It is worth mentioning that these drugs were not covered by the mechanism provided for in the 1996 Industrial Property Law, of retroactive recognition for the remaining term of the protection, called pipeline (Carvalho 2002b).

At Fiocruz a new research organization pattern was observed: the search for private alliances and sharing of proprietary results. That was made possible by the concurrent search for complementary competences which would be impossible to be incorporated in one individual research institution or national capital economic agent. The public research performance logic may be centered on the markets where their results are inserted without losing sight of the mission and the logic of generation of technical and scientific knowledge (Salles-Filho et al. 2001).

It should be emphasized that this is a phenomenon which goes well beyond the boundaries of lower relative development countries. The OECD countries changed the intellectual property reference benchmarks of results from research developed in public research institutions or private agents backed up by public funds. The US universities' patents went through a substantial growth as of the Bayh-Dole Act in the eighties and some provisions in the antitrust law were amended to expand the process of technology transfer (and patent licensing) to the private sector. In Brazil, the proposal in the Innovation Law which proceeding was resumed at the end of 2003 and sanctioned in 2004 also provides for the flexibilization of the legislation regulating the public tenders, by enabling the utilization of a government purchasing mechanism to the support of innovative companies and facilitating the transfer of technology from the public to the private sector (OECD 1999, Buainain 2004).

However, despite the governmental action success in specific areas throughout the nineties, the remittances abroad as a result of technology transfer agreements have strongly increased. The exploration of patents which

represented US$ 3 million in 1990 reached US$ 200 million in 1996 and 1998. Remittances related to technology supply agreements went up from US$ 32 million in 1990 to near US$ 600 million in 1998. Specialized technical services justified remittances abroad around US$ 1,400 million in 1998 and 99 against US$ 140 million in 1990 (Carvalho 2002a). These are data which allow the visualization of regressive effects and important costs resulting from the adoption of a protection pattern in the formats agreed upon at TRIPS.

The intellectual property protection statutes managing structure also influences the protection effectiveness. The capacity of analysis of applications for priorities of invention, filing of marks and brands, definition of indications of precedence, protection of plant varieties, definition of mechanisms of access to genetic heritage associated with the traditional knowledge are elements which expand or depress the incentives and constraints provided by the recognition of intellectual property rights, especially within the context of the reformulation occurred in the nineties arising out of the signature of the TRIPs Agreement (Barbosa 1999, Carvalho 2002a, b).

The management of such statutes when disconnected from the references of policy of innovation and support to the national economic development tends to acquire a clerical or notarial nature by emphasizing the issue of documents and certificates of protection and recognition of rights assured in such statutes. This is a core element of the Intellectual Property System (and the recovery of institutional structures such as the National Institute of Industrial Property is a clear proof of such centrality) which in no event should be ruled out. However, the development and implementation of wide-natured intellectual property policies is a previous requirement to increase the positive effects and reduce the negative effects of the recognition of such rights. Such positive effects include the incentive to technological empowerment, innovation and technology transfer. The following item addresses in further details the relations between the new form of appropriation resulting from the Post-TRIPs institutional change and the national capacity in the development of pharmaceuticals.

Industrial property policy on pharmaceutical products

Just as the seed market in Brazil, the pharmaceuticals market was strongly affected by the effectiveness of the TRIPS Agreement. The Country did not recognize industrial property rights (IP) under form of patents in drugs for products since 1945 and for process since 1969. From this standpoint it could be considered even as analogous situation to the seed market. There are, however, differences related to the competition dynamics, the importance of the presence of transnational companies in the Brazilian market, the role played by the State in R&D, the peculiarity of R&D activities (not) developed by the national companies and particularly the fact that process of adaptation of drugs to the national market does not imply the transnational companies' need to maintain their own structures of research or development of products or processes or the association with national research institutions in the Country. Thus the design of public policies oriented to the industry becomes different from those oriented to the seed market as the public opinion's role in matters related to human health is more prominent (Salles-Filho et al. 2001).

The Pre-TRIPS Agreement Brazilian market comprised to major categories: one of brand pharmaceutical products protected by patents in other countries and the other segment comprising the similar medicines, those not protected by patents and which were sold under its generic denomination or commercial name. The discussions of the new Industrial Property Law in the nineties reinforced the perspective of equally discussing the adoption of a legislation which would address the generic drugs, those referring to the medicines with expired patents and considered in the public domain. Actually this was an initiative based on the US legislation, the Hacth-Waxman Act of 1983, which, aiming to expedite the process of commercialization of pharmaceuticals which patents had gone into public domain (expired) promoted the reduction of the registration term of these pharmaceuticals. The legislation logic was to promote a greater competition through the alternative of creation of a segment where the costs associated with the registration and clinical tests as well as those related to advertising and setting of brands would not pressure the prices upwards (Hasenclever 2004).

In 1993 in Brazil, thus before the legislation which would regulate the generic drugs, Decree 793/93 was enacted, requiring that the name of the active principles should appear in the packages of medicines marketed in the Country. The expectation was that by increasing the degree of information both to prescribers and users a choice could be made between medicines with the same active principle thus increasing the competition in the pharmaceuticals market. That is, a mechanism to reduce the impact of the price differentiation strategy via advertising and setting of brands.

However before the enactment of the Industrial Property Law the figure of the generic drug did not exit and therefore the registration thereof was not possible. The figure of generic drug started being recognized as of the approval of Law 9787/1999 by establishing an institutionality similar to that occurring in several countries which recognize patents for drugs (Hasenclever 2004).

Yet, before going into the impacts of the generic drugs policy in Brazil, we should discuss a little further which elements guided the pharmaceuticals policy generally in the Country. In this aspect, the constraints and opportunities deriving from the TRIPS Agreement for pharmaceutical products should be highlighted in the analysis.

Coriat et al. (2003) draw our attention to the fact that the Pre-TRIPS environment was characterized at world level by the possibility of the lower relative development countries being able to set forth national industrial structures from the strategy of copy of molecules developed in other countries. The drugs derived

from such molecules were offered in the national market at prices consistent with the existing income levels in those countries. Even in the developed countries which recognized intellectual property rights for pharmaceuticals, they attempted to do so in a way that the protection would not fall on the molecule, but rather on the process. Thus, other technological trajectories to reach the molecule would not be hindered by the recognition of intellectual property rights, thus maintaining alternatives in the innovation process in pharmaceuticals drugs.

The authors at hand understand that the scenario derived from the TRIPS Agreement changed the health-related protection logic in such way that the latter was addressed in a set of exception of rights including the possibility to compulsorily license drugs in emergency situations which would put human life at risk. Another issue raised by the authors refers to the strategy used by the developing countries with technical, scientific and industrial capacity for the local production of medicines.

Thus, two lines of intellectual property policy in health were established. One referring to the policy of universal treatment of HIV patients and the other related to the creation of a national market of generic drugs, as mentioned above. The basic condition to establish these policies is based on the scientific and technological capacity to maintain a course of copy of patent-protected products developed by other countries. Before the TRIPS Agreement such course was feasible and legal within the institutional scenario in force at the time. However such scientific and technological capacity depends on the industrial capacity to produce such medicines.

In relation to the Aids epidemics treatment an interesting international scenario was created. On one side, the developed countries with the front figure of United States, started creating constraints to the developing countries electing the strategy of utilization of the compulsory licensing clause for the ARV (antiretrovirals) used in the treatment of HIV patients, with their production under form of generic drugs. On the other side, those countries which, although not having used the flexibilities of the TRIPS Agreement, have set forth intellectual property policies aiming to bet around the constraints imposed by the IP legislation they implemented.

Coriat et al. (2003) show that such public health policies in relation to Aids are based on the reduction of costs of the drug distribution program aiming to keep their universality. From this standpoint, the utilization of the cheapest active principles possible became the essential point of said policy. And also created another type of articulation: the supply of active principles should occur from the countries which used the TRIPS flexibilities in terms of non-recognition of the already existing intellectual property rights for drugs. Two important premises of this type of policy are: maintenance of the international free trade of active principles and development of the domestic production capacity of such active principles.

From the price standpoint, the authors understand the policy of ARVs production in the developing countries such as Brazil had positive impacts. Not only did the price of medicines used in the programs of distribution of generic ARVs went down but these same drugs, when sold under patent protection also had their prices dropped, with the prices of generic drugs and those patent-protected tending to converge.

Such policies could be developed within an international context where new social players stood out and had a relevant role in the pressure on international organisms, transnational pharmaceutical companies and particularly on the US Government. Hoen (2003) draws attention to the discussions taking place in Seattle and Doha. Such mobilization had as relevant reference the discussion around the dispute between pharmaceutical companies and the South African Government in relation to the alleged violation to the TRIPS Agreement. The alleged violation arose out of the replacement by generic drugs of those drugs which, although with expired patents by lapse of protection term, were still sold by the companies holding such patents using the figure of parallel import; and requiring the price transparency to all pharmaceutical drugs. Such dispute brought about two important manifestations: one of legal nature by recognizing the developing countries' right to make use of the TRIPS Agreement's flexibilities, and the other was the importance of the pressure by these new social players, especially the NGOs on the transnational pharmaceutical companies in the countries of origin by imposing upon them heavy costs on their image (and their sales) in such way that it forced them, at least, at short tem, to the adoption of less aggressive strategies. And equally important it also caused a review of the pressures by the US Government, as they were applied at the time.

At the Doha ministerial meeting of the World Trade Organization (WTO), although the issue of public health and access to medicines were not in the original agenda, they were incorporated into the discussions. The existence of protected drugs in the World Health Organization (WHO) list of essential medicines put the US Government under the protests of the human rights activists and more specifically of those defending the access to medications by AIDS patients. South Africa had, by the US Government, a position of encouragement in the President Clinton's speech, in terms of review of the Department of Trade's policy. Somehow the condition was created for the breaking of the taboo of impossibility of the US acceptance in terms of utilization of compulsory licensing for the use of generic drugs for the distribution of massif programs for HIV-positive patients.

Also according to Hoen (2003) such situation was a result from international organizations' stands highlighting, in addition to the already mentioned WHO, the UNAIDS (United Nations Organization for AIDS), the World Bank, the 77 Group (developing countries which got together to defend their interests in relation to the constraints caused by the TRIPS Agreement) and at last, for the WTO's own acceptance of the developing countries' demands on the matter. The fact that the Doha Ministerial Conference in June 2001 not only

discussed the issue but also had a Statement on TRIPS and Public Health at the end shows the relative success of such endeavor.

Hoen (2003) shows that the negotiation process in Doha resulted in a text which recognizes the countries' rights to develop and enforce policies as well as take actions to assure the protection of public health and the population's access to medicines. Such actions may be taken from the TRIPS Agreement flexibilities. However the issue related to exportation to countries applying the compulsory licensing but with no industrial capacity to produce them was pending. By not addressing this issue, the compulsory licensing under TRIPS terms, becomes harmless since the treaty addresses only the local production for the exercise of the compulsory licensing.

Thus the national policy of intellectual property in health is inserted within such context. Concurrently to the setting of new intellectual property legislation in terms of the TRIPS Agreement, but without using the flexibilities offered by the Agreement, Brazil ended up by being forced to adopt a series of initiatives to face the situation created by the legislation implemented within the Agreement scope.

Orsi et al. (2003) point out that the decision of assurance of universal access to all AIDS patients occurred in 1996 (it is worth recalling that it is the same year when the new legislation related to IP was enacted in Brazil)[1]. The relevant legislation also set forth that, for the enforcement of the program, a strategy of cost reduction should be followed so that the program could be feasible. Some restrictions were imposed at the time of the development of the program. One of them referred to the restrictions derived from the TRIPS Agreement previously noted. Another referred to the Brazilian legislation requirement of international biddings since 1993. Combined with the low incentive provided to the national pharmaceutical industry[2], one of the consequences was the utilization of importation of active principles from countries which, unlike Brazil such as China and India had used both the TRIPS flexibilities and stimulated their pharmaceutical industry.

The way to overcome such constraints was to cause the new drugs which would form the group of medications to be provided to the patients and which would be under intellectual protection should be compulsorily licensed and marketed as generic drugs. Such procedure is consistent with TRIPS, likely to be used in national emergency (the AIDS epidemics may be included therein) and economic abuse situations (Aded 2001, Dutfield 2001, Hasenclever 2004).

Another legal-natured constraint yet with no connection to the international scenario referred to the Brazilian Bidding Law (Law 8666/93) which establishes rigidity in the governmental contracting process. However such legislation addresses a series of exceptions which could comprise the purchase of pharmaceuticals. Thus, if, on one side, the constraints derived from the legal provision could be overcome, the agreement with the WTO which reduced the import rates for pharmaceuticals, together with Law 8666/93 which revoked the figure of preference for local production and national companies, created new constraints for the connection between the drug distribution policy and incentive to the development of the national pharmaceutical industry (Orsi et al. 2003).

The enforcement of the drug distribution program in the AIDS program had as central element the participation of official labs. The reduction in the prices of medications in 1996-2001 was 75%. However a substantial part of such reduction was due to the import of active principles from India and China somehow relegating the national pharmaceutical industry in the process. Equally relevant was the multinational pharmaceutical industry's participation in this process, since they took part in biddings by offering protected drugs at prices near those which would be practiced if they were produced as generic.

As to the generic drug market, used out of the free and universal distribution program to the HIV patients, the national pharmaceutical industry's participation was significant. The Brazilian Government generics policy was guided by the expansion of access to the medications by the population out of the official free distribution programs.

Hasenclever (2004) points out three major expected impacts in relation to the generics policy: i – deconcentration of the market structure due to the larger share of generic drugs in the pharmaceutical industry sales; ii – reduction of average sale price provided by the higher competition between generic and brand drugs, as well as between the generic drugs themselves; and iii – expansion of sales of medicines leading to the population's access especially the lower income population. By using data from the Rio de Janeiro State University (UERJ) Social Medicine Institute (IMS)[3] and from ANVISA – National Health Surveillance Agency the author shows that the Sales of generics in the wholesale market between June 2000 and April 2001 increased by 385%, while the industrial sales increased by 114%[4].

Hasenclever (2004) understands that the generic drugs significantly affected the drugs market structure. While the in the period analyzed the reference drugs[5] dropped 9.5 percentage points (went from 73.4% of market share to 64.4%) the generic drugs went up 9.3 percentage points (going from 0% in the market share to 9.3%). One important point is that the generics impact seemed to concentrate in the segment of reference drugs, since the similar drug market did not present significant variations in the period. In terms of impacts forecast in the generics policy, the reduction of the average price practiced follows the deconcentration of the market structure. It was equally observed an increasing insertion of substitute drugs in the market. The pharmaceutical companies' strategy has been to maintain the generics prices (around 40% lower) in relation to the reference drugs and additionally not to "pressure" the prices of reference drugs, including by the pressure arising out of the governmental price control. Salles Filho et al. (2001)

indicate that part of the price control effectiveness results from the scientific and technological capacity reached by such institutions as Fiocruz/Far-Manguinhos. The capacity to verify the reference drugs production costs created more solid bases of negotiations between the Government (Ministry of Health) and the pharmaceutical industry.

In to amounts sold, Hasenclever (2004) shows that the drug market as a whole in the analyzed period displayed a reduction around 15% in the amounts sold, also emphasizing that in the segments where the generics were introduced, this reduction was higher reaching little over 17%. Yet the increase of amounts sold of generics increased by five times (over 600%). The author speculates that part of the result verified is due to the database used as well as the strategies adopted by the leading companies in the reference drug market. The generics competition may have created such pressure that these leading companies may have been concentrated in market segments where they held a monopoly position and consequently lower pressure in their profit margins.

Another relevant point of the Hasenclever (2004) survey refers to the national companies' share in the generics market. By using data related to the registration of generic drugs, the author points out 1.124 registrations thereof in 4.448 presentations in April 2004. Half of those are by six national companies while four multinationals answer for 18% thereof. The remaining 32% of generics registrations are from different labs with equally different capital origin.

We can consider that the intellectual property policy related to pharmaceuticals presents two lines of thought with very different impacts and dynamics. In both lines, the basis of the intervention was the national technical, scientific and industrial capacity. In the case of distribution of drugs forming the basket universally and freely provided by the government to Aids patients, the official labs had an important role, both in terms of industrial production capacity of drugs and in terms of price regulation. Any intellectual property would be doomed to failure without such state industrial capacity, including and mainly to pressure the private sector.

Another important economic agent in the program of drug production for the Aids basket was the figure of the multinational company. From the state technical, scientific and industrial base it was possible to carry on a negotiation process with the multinational pharmaceutical industry so that its participation in the program with patent-protected drugs would be such as not to compromise the price reduction strategy for the feasibility of universal distribution and sustainability thereof. In this aspect the possibility of using the compulsory licensing operates as a business mechanism where its effective utilization not always is the best alternative. However without the actual perspective of using the compulsive licensing (which includes the capacity to copy the drug and produce it) such negotiation would be doomed to fail.

Conclusion

The pharmaceuticals market presents a peculiar situation. It may be worth insisting in the point referring to the maintenance of its own R&D structures or in alliances and partnerships with the pharmaceutical industry. In order to enter the Brazilian market the multinationals do not need to maintain their own structures. Furthermore, as mentioned by Nicolsky (2004), before the 1996 Industrial Property Law, the national industry would innovate its catalog by manufacturing similar products, that is, copies, whether modified or not, of innovative products launched in the foreign and domestic market. After 1997 when the new legislation went into force, the national producers' traditional catalog of drugs started tending to therapeutic aging due to the impossibility of the previous practice of copies with the exception of the existing ones.

The governmental policy of universality of distribution of drugs to Aids patients in Brazil, in turn, was not able to articulate the development of the national industry, there understood as private national capital companies, from a massive program of governmental purchases. At this point it is worth recalling that the IP legislation negotiation logic which resulted in the current legislation was highly regressive in relation to the industry and national interest. By giving up the flexibilities offered by the TRIPS Agreement especially the possibility to obtain up to ten years for the recognition of new drugs, even adopting the pipeline statute, the Country saw the local production of active principles by the national industry become unfeasible.

Ina certain aspect the situation created was unusual. In order to get around the obstacles caused by the adopted legislation the Country had to set forth an intellectual property policy in the pharmaceuticals area to overcome such constraints created by the Country itself. If the intellectual property policy showed unequivocal signs of success in relation to production and distribution of drugs, such success is strongly connected to the state labs' capacity and the assertive stand in the international negotiations which followed the decision of production of drugs patented as generics; ironically something which might not have been necessary with the adoption of a less restrictive IP legislation and within the provisions in the TRIPS Agreement.

It is also worth pointing out that in the intellectual property policy related to generics sold out of the Aids program, the national companies found an important niche where they present competitiveness and manage to face the foreign companies. However such competitiveness is strongly dependent on the importation of active principles from India and China which used the TRIPS Agreement flexibilities aiming to extend the recognition of new drugs for ten years.

It is understood that the negotiations following the WTO Doha Round did not present a most promising scenario to give continuance to the intellectual property policy adopted by Brazil. The best possibilities in terms of obligation of local production bump into the devel-

oping countries' stand, especially the negotiation of the Local Production Related Actions Agreement (TRIM) (Geneva Letter, several numbers). The developed understand that the best actions of incentive to local production are those related to a strong system of protection of intellectual property which, by the Brazilian experience, are not exactly those best meeting the national interests (therein including the national capital companies).

Before concluding it is worth emphasizing that, despite the contradictions of the adopted policy, it was able to meet the challenges imposed by the IP legislation. The Country managed to overcome a large part of constraints by transforming them into industrial development opportunities. Such opportunities however will not be sustainable in time without a clear articulation between the IP policy and the innovation policy concentrated on the expansion of competence and capacity of the national private company, in the maintenance of excellence of state labs and mainly in the creation of incentives and stimuli, either as induction or imposition natured, to the international pharmaceutical companies so that they will associate part of their efforts in R&D to the national scientific and technological structure. Without a shadow of doubt, the intellectual property protection instruments will play a leading role in this process.

Notes

1. However since 1988, in a proceeding where the NGOs had great importance, by the Ministry of Health determination, the distribution of the first effective medicine (AZT) for extension of the HIV-positive patients should be made by the public network of authorized health stations and hospitals.

2. We should not forget the trade liberalization of the beginning of the nineties and of the TRIPS itself.

3. The author points out several biases in the analysis based on the IMS data. She estimates that the calculation period between June 2000 and April 2001 only 48$ of sales of generics were captured. This implies that there is underestimation of the generics market share from said database.

4. The differences in growth are due to the greater impact arising out of the governmental pressure on purchases it makes by imposing the use of generics to the wholesale market and dependence on the consumer's and prescriber's (doctor's) acceptance of the generic drug, or by the inclusion of new consumers.

5. Reference drugs are those medications patent-protected and marketed under one brand. Similar drugs are those which patents are expired or under public domain and may be marketed under brand or without brand.

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