

Emerging Issues: Pharmaceuticals and Patents in Developing Countries

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Abstract: *This article analyses the Intellectual Property Rights (IPR) debate on pharmaceuticals, an issue introduced by TRIPS, a World Trade Organization(WTO) Agreement on Trade Related Aspects of Intellectual Property Rights which included pharmaceuticals as subject to patents, equivalent to any other product in the market. Available research results indicate that patenting life saving products, such as antiretroviral (ARV) drugs, is controversial, since it creates a temporary monopoly and restricts circulation of knowledge, delaying innovation and leading to a significant increase in the prices of drugs. In Brazil, in 1996, the country immediately complied to this international agreement and implemented a National Industrial Property Law in many aspects more restrictive than TRIPS, with detrimental impacts on the national pharmaceutical enterprises. Contrasting with the Brazilian IPR option, China and India adopted a different strategy and waited for a decade to build their national capacity for research and development for pharmaceuticals and ARV drugs, before deciding to comply to TRIPS. We discuss the consequences of these three different policy options, examining the implications of the premature compliance of Brazil to TRIPS and anticipating its possible impacts on the successful country's policy of free and universal access to ARV.*

Palavras-chave: pharmaceuticals, Intellectual Property Rights, developing countries.

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1. Introduction

The new biotechnology, resulting from advances in molecular biology and genetic engineering, plays a crucial role in the dynamics of scientific and technological development in the contemporary world. In

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a global scenario where economic competition is increasingly driven by knowledge and innovation, the new developments in the pharmaceutical industry, resulting from biotechnology, have been extraordinary. In this scenario, recombinant vaccines and drugs have emerged as important breakthroughs, radically changing the strategies for prevention and treatment of a broad range of infectious and chronic diseases.

The global pharmaceutical market for these products is spiraling and the new processes and products resulting from these innovations are challenging both developed and developing countries to the implementation of new regulations and new intellectual property rights (IPR), raising several controversies.

The debate is related to the fact that recent international IPR procedures have extended their scope far beyond the need to protect innovators and have become increasingly subordinated to monopolistic market strategies. Multinational pharmaceutical enterprises in the developed countries are increasingly using these regulatory IP constraints as important economic barriers, limiting the access by the developing world to favorable international trade conditions to drugs and other health products, thus increasing the gap between the North and the South.

The introduction of these new regulatory barriers favoring unbalance in the international trade of life saving drugs has been supported by an international system for patenting life and life saving products, which has emerged after the Uruguay Round in 1984 and the creation of the World Trade Organization (WTO). The new IPR system introduced by TRIPS (The WTO Agreement on Trade Related Intellectual Property Rights, signed in 1995) included pharmaceutical products as subject to patents, equivalent to any other product.

This regulatory scenario, imposed by TRIPS, related for the first time intellectual property protection of pharmaceuticals to the international trade, subordinating patent policy of drugs to WTO rules. The new IPR scenario for pharmaceuticals contrasted sharply with the previous more favorable international regulatory framework, where domestic firms in developing countries like Brazil had been so far allowed to copy patented pharmaceuticals and to produce generic drugs.

In addition, this trend towards increasingly strong intellectual property rights regimes related to international trade, has been recently confirmed and aggravated by the so-called “TRIPS Plus” bilateral commercial agreements, signed by the United States and other developed nations with developing countries, imposing to these countries even stronger IPR constraints related to trade.

We discuss here the impacts of these international constraints by TRIPS and “TRIPS Plus” agreements on developing nations, focusing in the Brazilian case, examining different IPR policy options and indicating how they have affected the access of their poorest populations in these nations to life saving drugs.

2. Emerging infectious diseases: AIDS in the complex global scenario

Infectious diseases are still the main causes of death in the contemporary world, killing more people than heart disease or cancer. Their incidence and spread have increased in the last two decades, although scientists and policy-makers in the 1960s believed they could be kept “under control” by development, sanitation, new medical technologies, and advances in the pharmaceutical industry. The unexpected phenomena of emergence and re-emergence of infectious diseases and drug-resistant diseases, whose incidence is increasing rapidly, will certainly change the global epidemiological scenario in the near future.

Social and ecological processes, such as extreme poverty, population movements, urbanization, and deforestation, favor the emergence and resurgence of infectious syndromes and diseases and increase their epidemiological complexity. The intensification of international travel and migration has also helped to amplify these processes, accelerating the movement of humans, animals, and plants and the global proliferation of viruses, bacteria, and fungi.

Global changes resulting from human activity and from the rapid incorporation of new technologies and amplifying the impacts of urbanization, unemployment, social exclusion, and poverty, aggravate the

consequences of these social and ecological processes in ways never before imagined (Levins et al., 1986).

These changing conditions have favored the global emergence and resurgence of various infectious diseases with complex and dynamic cycles, such as HIV/AIDS, tuberculosis, dengue, yellow fever, malaria, leishmaniasis, leptospirosis, hantavirus, pulmonary syndrome, and many others. The rapid spread of these diseases worldwide challenges national health systems, particularly affecting developing countries like Brazil, a nation plagued by social exclusion and environmental degradation and with a rapidly aging population.

HIV/AIDS is a complex emerging disease, which has disseminated rapidly in the last two decades into a global pandemics, with dramatic economic and social consequences, particularly the poorest countries. WHO data (WHO, 2004) indicate there are 33 million HIV infected people in the world and 75% are in Africa. Every year around 3 million people get infected and 2 million died of AIDS in 2007.

Infectious diseases such as HIV/AIDS, related to population mobility, population concentration, social exclusion and poverty are increasing and becoming an important trend in the global health transition scenario, creating new challenges for the development of innovative drugs and vaccines.

As we indicated in previous articles (Possas and Marques, 1994; Possas, 2001), despite being, as shown by Olshansky et al. (1993) a major demographic transition trend in the contemporary world, population aging does not necessarily lead to an exclusive tendency towards non-infectious chronic and degenerative diseases, such as cardiovascular diseases and cancer.

In most cases, the novelty is not in the pathogenic agent itself, existing in nature for millions of years, but in the rapid transformation of social, environmental and behavioral conditions favoring the emergence and dissemination of new infectious diseases, such as HIV/AIDS and Avian Flu. This epidemiological complexity poses new theoretical challenges and the need for an integrated view based on evolution theory and on an eco-social perspective.

In a previous publication (Possas, 2001) we examined the tension between these historically dissociated paradigms and proposed a transdisciplinary approach, social ecosystem health, in order to incorporate them into a comprehensive theoretical framework, supporting alternative strategies to anticipate risks and prevent the amplification of risk conditions.

From this perspective, anticipation of risks and interventions should be examined simultaneously from a social sciences perspective, as social and political processes, and from an ecological perspective, as an evolutionary force in ecosystems. Contrary to common sense, evolution can be affected by social and health policies, since the time scales in evolutionary processes are not necessarily large or even secular. Natural selection can be fast, as an expression of evolutionary plasticity in the evolution among pathogens, and can be influenced by intervention (Levins, 1994; Levins et al., 1994, 1995).

The notion of complexity is thus at the core of modern biology and is crucial for understanding phenomena related to the emergence of pathogens and diseases, such as HIV/AIDS. However, since most biological processes related to emergence and re-emergence of pathogens and diseases are triggered by human activity, in order to approach their complexity it is necessary to deal with complexity in other areas of knowledge: complex social and economic systems.

3. Compliance to TRIPS and local responses to ARV demand: Brazil, India and China

In order to adjust developing countries IPR legislations the new international rules, the TRIPS conceded a 10 years grace period. Therefore, the developing nations were expected to conclude in 2005 their compliance process, incorporating into their national IPR legislations new laws forbidding copies and sales of patented drugs.

So countries were left with a timing option to implement in their local legislation the new IPR rules. Surprisingly, due to strong lobbies by the multinational pharmaceutical industry in the Congress and threats of retaliation in exports of agricultural products, Brazil made an option

for a premature compliance to the new international IPR regulations and implemented a national IPR Law in many aspects even more restrictive than TRIPS.

With this decision, Brazil made a choice not to benefit from the possibility, provided by the TRIPS to wait until 2005 for compliance with its provisions and, different from India and China, lost the opportunity to build in the ten years allowed by TRIPS the national industrial capacity in the pharmaceutical sector.

Additionally, the new Brazilian IPR law introduced an absurd provision, which recognized patent of pipeline drugs and this was not required by TRIPS. With this provision, the new law allowed the deposit of patent requests and obtaining patents related to products defined as non-patentable by the previous IPR law.

Another flaw of this premature IPR law is that it did not include the possibility of parallel import provided by TRIPS (according to article 27, member countries cannot discriminate: they should apply patent rights *without discrimination* about products being imported or produced locally). This law is detrimental to the local explorer of a patent, when, after obtaining the license, he tries to explore the patent by import when he prepares his industry to the local production of the patented product.

The Brazilian pharmaceutical market is one of the ten largest in the world and it is highly concentrated on multinational enterprises. The new IPR law certainly contributed to aggravate this oligopolistic market profile, with negative consequences on local industry, threatening the successful policy of universal access to ARV.

There are some indications on the impacts of TRIPS on Brazilian pharmaceutical industry. As a consequence of TRIPS and the low investment in local pharmaceutical enterprises, national industry reduced its scope and 1.700 industrial units producing synthetics pharmaceutical intermediates in Brazil were closed in the end of the 1990s (Orsi et. al. 2003). Several national enterprises closed and some public pharmaceutical institutes continued to operate, but with a very high idle capacity (estimated in 70%).

Some opponents of this viewpoint on the decline of national pharmaceutical production, argue with the success of the Brazilian generic

law, which happened in the context of the new IPR law. In fact, it is true that the national generic policy after 2002 played an important role and allowed a significant increase in the participation of national pharmaceutical enterprises in the market, from 28,2% to 40,6% (Capanema, 2006).

However, it is important to note that the successful Brazilian generic policy for pharmaceuticals and ARV drugs from 2002 to 2005 could happen in spite of the restrictions of the Brazilian Industrial Property Law, since Brazilian generic producers benefited from imports from non-patented inputs from China and India, countries who made the option to benefit from the 10 years compliance period conceded by TRIPS. In other words, the Brazilian legislation did not benefit from the TRIPS compliance deadline, but benefited from India and China's option to delay compliance.

But after the conclusion of the compliance to TRIPS in 2005, the international IPR scenario changed dramatically, with important consequences for domestic pharmaceutical production in the developing world. The possibility of importing cheap inputs for generics from India and China has been closed for Brazil and other developing nations, making them increasingly dependent on compulsory licensing, which was conceived in TRIPS as an exception and not a routine provision.

Contrasting with this restrictive Brazilian IPR option, which has clearly undermined local capacity for ARV production, China and India adopted a different strategy and waited for a decade to build their national capacity for research and development of ARV drugs, before deciding to comply with TRIPS.

In fact, India became, with its local capacity strategy in the ten years grace period before compliance to TRIPS, the first producer and exporter of generic ARV in the world and therefore a leading exporter of generic drugs to Brazil.

China, in a similar strategic approach, became the main provider of low cost raw materials and active principles for ARV drugs to multinational enterprises and generic firms worldwide and has been since the main exporter of these products to Brazil.

These three countries cases with different strategies and time frames suggest that national responses to TRIPS IPR constraints should not be

interpreted only as a consequence of external commercial pressures under WTO. In fact they resulted, as illustrated in the cases of Brazil, China and India, in diverse domestic options and national pharmaceutical capacity outcomes, with important consequences to local innovation and to national production of ARV drugs.

4. Brazil: universal access to ARV and compulsory license

Brazilian HIV/AIDS Program is supported by law and since 1996 provides universal coverage of ARV therapy to all HIV/AIDS patients. In only six years, from 1996 to 2002, this policy resulted in a dramatic decline of 70% in mortality, 80% in morbidity, resulting in a decline of 70% in hospitalizations, with an economy for the country of U\$ 2.2 billion.

This policy decision was then opposed by several international organizations, since they anticipated that adopting universal coverage for ARV therapy instead of the prevention policy they recommended for developing countries, would lead to a significant increase in viral resistance.

On the contrary, available research data (Brindeiro, Tanuri et al. 2003) indicate that universal coverage of ARV in Brazil seems related to low viral resistance to treatment. In fact, while in other countries (U.S., U.K., Spain, France and Argentina) the viral resistance rates ranged from 15% to 26%, in Brazil it remained at low levels (6,6%). A possible explanation is that universal coverage might contribute to reduce the pace of viral transmission and replication from person to person.

Another issue was the high prices of ARV therapy. In the last decade the prospect to produce locally some of the first generation ARV drugs and to import API from China and India made it possible for Brazil to negotiate reduction of prices with multinational pharmaceutical enterprises. In fact, in some developing countries, like Brazil, the possibility of introduction of generic drugs in their markets was viewed as a strategy to overcome the high prices of ARV therapies in these countries (Orsi et al. 2003).

In fact, the sharp decline of price of first line ARV drugs in the international market and the price negotiation strategy with multinational

pharmaceutical enterprises by the National STD-AIDS Program in the Ministry of Health contributed to lower prices of some ARV drugs in Brazil in almost 40% in the last decade.

Nevertheless, the introduction of increasingly expensive new second and third generations of ARV drugs protected by patents in the market have reverted this trend towards declining prices and imposed limits to the price negotiations strategies by the Brazilian government.

The problem is aggravated by the increasing demand for ARV drugs (180.000 patients in treatment and 20.000 new patients every year) and particularly, as we have discussed so far, by the compliance of India and China to TRIPS in 2005, increasing prices of formerly low cost generics, raw materials and active principles for ARV drugs imported by Brazil.

Once API import and generic competition are eliminated, ARV prices will spiral. An additional concern is that these new second and third generations of ARV in the market are much more expensive than the first line ARV drugs, accelerating the spiral of prices.

Some argue that the existing flexibilities in the TRIPS agreement and the interim agreement signed in 2003 after the Doha Declaration should be explored by developing countries in the production of generic drugs.

In contrast, other argue that it is very difficult to implement these flexibilities, since local government authorities are often paralyzed by the legal uncertainties and complexities of procedures of compulsory licensing and often subject to political difficulties and international and national pressures to implement them.

Taking into account the international constraints to generic production of ARV after the deadline to compliance of India and China to TRIPS, the Brazilian Ministry of Health considered in 2005 compulsory licensing for four high cost ARV drugs protected by patents, with high margins of profit:

1. Efavirenz (Merck, Sharp & Dome) – cost/patient/year US\$ 574.80;
2. Nelfinavir (Roche) – cost/patient/year US\$ 1,537.00;
3. Lopinavir/ritonavir (Abbott) – cost/patient/year US\$ 2,847.00;

4. Tenofovir (Gilead Sciences) – US\$ 2,803.00.

These four patent ARV drugs accounted for almost 70% of the Ministry of Health budget of ARV therapy (15 drugs).

Despite the threat of compulsory licensing of these drugs by different Ministers of Health in the country in the last decade, it never happened at that time. Nevertheless, this threat increased the bargaining power of the government in the negotiation of ARV prices with multinational and from this viewpoint the strategy was successful, with reduction of prices ranging from 40% to near 65%.

However, the dramatic increase of the prices of second and third generation ARV drugs limited the possibility of negotiations based exclusively on the threat of compulsory license. So, it became evident in the end of 2004 that compulsory license was necessary and could not be postponed. The cases of the U.S. and Canada, countries where compulsory license for drugs have been frequently used, supported this view.

Therefore, in 2005, after a political decision for compulsory licensing by the Brazilian President a legal instrument was prepared for compulsory licensing of these four ARV drugs. This decision was made supported by an evaluation by the National STD-AIDS Program, Ministry of Health, on the local capacity for ARV production, which identified 3 national enterprises (Cristalia, Nortec and Genvida) and two public research institutes (Far-Manguinhos and Lafepe) with capacity to produce these drugs.

However, the Minister of Health, who was so far committed to this Presidential decision, surprisingly gave up in the last minute to sign the compulsory licensing of these four drugs. He justified his decision with several arguments: lack of production capacity by national industry (contrasting to evaluations by the Ministry of Health on national pharmaceutical capacity, provided by the National STD-AIDS Program and later supported by evaluations by the UNDP and REBRIP).

The decision of the Minister also opposed the decision of the National Health Council, the top deliberating forum of the Brazilian National Health System – SUS, which had voted in favor of compulsory licensing of these ARV drugs.

Recently, in 2007, the new Minister of Health finally issued the compulsory license of Merck's Efavirenz, after an intense political debate opposing different interest groups. A lesson from these different attempts to implement compulsory licenses is that it is an exception instrument, very difficult to be implemented because of political and economic pressures, from the pharmaceutical industry and also from agricultural enterprises involved with biotechnology, dominant in the international trade and related to the pharmaceutical sector. The possibility of commercial retaliations from the U.S agricultural enterprises came often to the political scene in the debate of compulsory licenses of ARV drugs in Brazil.

5. Preventing future IPR constraints to innovative products

From the public health perspective, patenting life saving pharmaceutical products differs from patenting any other industrial and commercial product in the market.

For this reason, the international debate on pharmaceutical IPR is concentrated now on how to conceive IPR regimes more adequate to protect new research developments, such as new and more effective ARV drugs and future preventive and therapeutic HIV vaccines in the global health scenario.

Despite extraordinary advances in ARV therapy, there are still important challenges to overcome in pharmaceutical R & D in this area.

The first is the research and development of new ARV drugs without the secondary effects (lipodistrophy, metabolic disorders, neuropathies and other) of current therapeutic schemes. Once developed, these drugs should be immediately produced and come rapidly into local health systems and therefore should be subject to more flexible IPR regimes.

The second and even more important issue is the development of HIV vaccines. There has been in the last two decades a significant international effort by the scientific community in this direction, since it can have an enormous social and economic impact in the world, saving millions of lives, with an economy of billions of dollars with hospitalizations and welfare.

From the policy perspective, a concern of those involved with research and development of HIV vaccines, preventive or therapeutic (immunotherapy), is that we should avoid in the future the constraints we have now with the IPR of ARV drugs, impacting on prices and limiting the access in the poorest countries. Former experiences with Hepatitis B and HPV vaccines, where issues related to IPR and prices have created obstacles to their introduction in the routine of local services have contributed to increasing awareness that innovation is important, but not sufficient: after the discovery of a recombinant vaccine, such as HIV vaccine, there are other challenging obstacles to overcome: more flexible IPR regime should be conceived and this new knowledge should be rapidly disseminated and incorporated through technology transfer mechanisms into national enterprises in the developing countries, allowing them to produce the vaccine locally, and distribute it in health services.

There are now more than 30 clinical trials with HIV vaccine candidates under way in the world (IAVI, 2006) and the main concern is that it will be necessary to go far beyond the innovation challenge. Once a new HIV vaccine is discovered (it is expected that in the next three to five years we can have new partially effective vaccines in the market), it will be necessary to overcome all the obstacles (and IPR constraints are one of them) to develop and produce new vaccines at feasible price and to provide access to the poorest populations who most need them.

The specificity of funding vaccine research makes the IPR issue in this area even more complex. Different from ARV drugs, the global funding for HIV vaccine research and development comes mainly from the public sector and NGOs, since there are few multinational enterprises in research and development of HIV vaccines. These multinational enterprises are basically concentrated in the drug market and they are only contributing 10% of the total spending from their own resources (IAVI, 2006). Representatives of multinational enterprises explain this low investment in HIV vaccine research complaining that they have few incentive mechanisms to support this kind of research.

Incentive mechanisms have been proposed in order to lower the costs of R & D and to ensure adequate markets for future HIV vaccines.

They can be economic incentives from the government, such as tax credits and anticipated price and quantity purchase guarantees (this is a crucial issue for Brazilian enterprises, since in Brazil the new Innovation Law allows technological purchase of innovations by the government, exempt from traditional bidding process). Other incentives are in the regulatory procedures (expedited, “fast-track”, regulatory approvals) and in IPR legislation (more flexible IPR protection).

6. Strategies for R & D compensation

Some argue it is not feasible to change the existing international IPR framework since it would undermine current R & D and innovation capacity in multinational pharmaceutical industries. In contrast, other pose the question: from the global social and public health perspective, is it feasible to insist in the current IPR model?

From the perspective of multinational pharmaceutical enterprises, the case for ARV drug patents relies on the very high costs of bringing these new drugs into the market. However, it has been estimated by economists (Boldrin and Levine, 2008) that these multinational enterprises account only for about one third of biomedical research and development in the world, since in the U. S and in many other developed countries research in this area is mainly developed by scientists in universities and research institutes, with a strong support by the federal governments. Additionally, these enterprises benefit from high tax credits from the government, around 20%.

Many HIV/AIDS patients are grateful for the new advances in ARV therapy brought by these multinational enterprises into the market, improving the quality of their lives. But it should be recognized that the most significant innovations in this area have not come from these enterprises, but from the academia, with significant public funding. A good example is the highly potent ARV therapy, the “cocktail”, invented by Harvard researcher David Ho.

There is increasing awareness, particularly in developing countries, that the international IPR system should be urgently reviewed and become

more flexible, creating new mechanisms for compensating investments made by companies and governments in research and development.

Incentive mechanisms have been proposed, such as the Research and Development Fund, in the case of compulsory licensing, with a direct payment to the patent owner and a percentage to the R & D Fund and a participation of the patent owner in the Fund (Love, 2005, 2006). This Fund was incorporated in the legal instrument proposed (but not signed) for compulsory licensing of ARVs in 2005 in Brazil.

Patent pools for licensing (Love, 2005) can be created as non-profit entities, as collaboration for the collective management of patent rights.

Finally, a new system of remuneration to support innovation was conceived, the Medical Innovation Prize Fund, where a new system of remuneration was conceived where the market for products is separated from the market for innovations, so that products can be made available to the public at generic prices, while innovators benefit from a separate system (Love, 2005).

7. Conclusions

In summary, national patterns in the pharmaceutical sector in the developing world concerning IPR and strategies for local capacity, are shaped not only by external forces in international trade but by the specific *national innovation systems* (Archibugi and Michie, 1995; Freeman, 1995, Bartholomew, 1997) and policy options in each country.

In our view, the contrasting local responses to TRIPS' legal constraints from India, China and Brazil discussed here should be examined from this perspective, considering how each country has historically organized its institutional and legal framework to deal with innovation and build its national pharmaceutical capacity.

In addition, as the global economic competition becomes more intense, the contrasting international political trends become more evident. On one hand, there are intense pressures towards a more flexible IPR regime. There is increasing awareness from the developing countries of the urgent need to overcome the detrimental consequences of

patent protection and social exclusion, since most HIV/AIDS patients are in the poorest developing countries and ARV drugs and treatment are available in the developed ones. This awareness has contributed to an intense international mobilization by civil society organizations and NGOs for extending access to ARV generic drugs.

On the other, despite the flexibilities the Doha Declaration and its implications for the TRIPS agreement (Correa, 2002), subordinating IPR to public health, there are international movements towards more strict IPR regimes.

However, evidence provided so far indicates that free circulation of knowledge and innovation is crucial and necessary to confront emerging and threatening infectious diseases, such as HIV/AIDS and Avian Flu. Excessively strong IPR can be impeditive of this flow of scientific information and even lower the pace of innovation (Stiglitz, 2004).

Temporary IPR monopolies to ARV drugs may be delaying the generation of new knowledge in this area and undermining the incorporation of innovation by local industries in developing countries, therefore limiting the possibility to control the HIV/AIDS pandemics. These public health goods should not be subject to the same IPR rules applied to other products in the global market.

An important concern for policy makers comes from forecasting models on markets trends for ARV consumption and availability of active principles (API) for the production of ARV (WHO/UNAIDS 2006). Some of the global scenarios indicate increasing demand, increasing costs on suppliers and scarcity of raw materials and API. The international demand for these inputs is exponentially increasing with the pandemics and the number of international enterprises providing these inputs is still limited.

The conclusion of compliance to TRIPS by some developing countries in 2005 has certainly represented to these countries a drastic move backwards with important economic, social and epidemiological implications worldwide. Additionally, as we mentioned before, the recent bilateral commercial agreements signed by the United States with developing countries (the so-called "TRIPS Plus" agreements) have imposed to these countries high levels of intellectual property protection, even more restrictive than TRIPS.

This international legal scenario after 2005, restricting the possibility of production of generics, is making developing countries increasingly dependent on compulsory licensing in their attempts to assure access of patients to cheaper ARV drugs, and this situation is illustrated by the case of Brazil. As we mentioned before, compulsory licenses is an exception instrument, very difficult to be implemented because of political and economic pressures, from the pharmaceutical industry and also from agricultural enterprises involved with biotechnology, dominant in the international trade.

Developing nations, particularly those countries in extreme poverty, such as those in Africa, should be exempt from these international IPR constraints and should not be vulnerable to the multinational enterprises and so dependent on the decisions of these enterprises to do humanitarian licensing.

If local industries in developing countries are not allowed to incorporate technology to produce these raw materials and active principles for the production of ARV, due to increasing IPR constraints, maybe the world will face an impasse and the aggravation of the consequences of the AIDS pandemics.

Existing flexibilities in TRIPS (compulsory license and parallel imports) are difficult to apply in developing countries, due to political and trade pressures. But developing countries are now becoming increasingly dependent on compulsory licensing, which should be an exception IPR instrument, since the possibility of generic production of patented drugs has become severely restricted after the compliance of countries to TRIPS in 2005.

On the other hand, National Patent Offices in many of these countries tend to reproduce procedures of developed nations and to approve non-innovative secondary patents. Some countries are now making an effort to review their routines.

Therefore that is an urgent need to review the current international IPR legal framework and introduce new flexibilities and fast track procedures, particularly for the developing countries with limited local capacity to produce generic ARV, creating new international IPR rules within WTO.

During the 31st Session of the World Intellectual Property Organization (WIPO) in 2004 in Geneva the delegations of several developing countries, the Group Friends of Development (Argentina, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Egypt, Iran, Kenya, Peru, Sierra Leone, South Africa, Tanzania and Venezuela) co-sponsored a proposal to establish a “Development Agenda” for the WIPO tabled as document WO/GA/31/11 (Group Friends of Development 2004).

In the HIV/AIDS agenda, developing countries are also networking in scientific and technological cooperation for research and development (R & D) of preventive and therapeutic inputs (ARV drugs, vaccines, microbicides, kits for diagnosis and monitoring and preservatives). In the XV International AIDS Conference in Bangkok, Thailand, in 2004, the Brazilian government started a technological cooperation network in these areas with China, Russia, Nigeria, Ukraine, Thailand, later Cuba and Argentina joined this network. The success of this initiative indicates that new alliances are emerging in developing countries in the pharmaceutical R & D.

Despite prevailing pessimism on future prospects for institutional and legal reforms towards a more flexible international IPR approach, these legal and institutional changes are crucial and necessary from the social and public health perspectives. If there is international political support, they can occur, making IPR rules more adequate to developing countries’ needs.

Assuntos Emergentes: indústria farmacêutica e patentes em países em desenvolvimento

Resumo: Este artigo analisa o debate de Direitos de Propriedade Intelectual (DPI) na indústria farmacêutica, um assunto introduzido pelo TRIPs, o Acordo sobre Aspectos Relacionados com o Comércio de Direitos de Propriedade intelectual, o qual inclui a indústria farmacêutica como sujeita a patentes, equivalente a qualquer outro produto no mercado. Os resultados disponíveis das pesquisas revelam que patentear produtos que salvam vidas, tais como os medicamentos antiretrovirais (ARV), é controverso, dado que ele cria um monopólio temporário e restringe a circulação de conhecimento, retardando a inovação e conduzindo a

um significativo aumento de preços nos medicamentos. O Brasil, em 1996, imediatamente atendeu os compromissos do Acordo sobre Aspectos Relacionados com o Comércio de Direitos de Propriedade intelectual, implementando uma Lei de Propriedade Industrial Nacional em muitos aspectos mais restritiva que o TRIPs, em detrimento das empresas farmacêuticas de capital nacional. Em desacordo à posição brasileira sobre DPI, China e Índia adotaram uma estratégia diferente e esperaram uma década para construir sua capacidade nacional de P&D para o desenvolvimento da sua indústria farmacêutica e dos medicamentos ARV antes de decidir atender os acordos TRIPs. Nós discutimos as consequências de estas três diferentes opções políticas examinando as implicações do prematuro cumprimento do Brasil ao TRIPs e antecipando seu possível impacto sobre o sucesso da política nacional de acesso livre e universal ao ARV.

Palavras-chave: indústria farmacêutica, direitos de propriedade intelectual, países em desenvolvimento.

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