

A NEW INCENTIVE SYSTEM FOR TECHNOLOGICAL INNOVATION IN DEVELOPING COUNTRIES

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Introduction

This work has been inspired by the analysis and discussion of Professor Joseph E. Stiglitz's critical elaboration exposed in his book "Making Globalization Work"¹, particularly in Chapter 4, "Patents, benefits and people", which analyses the problems related to trade agreements, the protection of intellectual property rights and their connection with the development of innovations as well as with the access to health, a basic human right, and to the necessary medicines that may effectively treat globally extended diseases and pandemics, such as HIV-AIDS, malaria, tuberculosis and dengue.

The credit and budget restrictions existing in many developing countries have represented an actual limitation to the design of public policies aimed at stimulating and promoting research and development activities on a steady and permanent basis in scientific areas related to human health.

Such restrictions are being intensified by the world economic crisis that developed in the last semester of 2008; however, we consider that the issue of incentives for innovation in research on new technologies and products is absolutely current and appropriate. At the same time, developing countries should maximize their creativeness at the moment of designing public policies aimed at the purpose before mentioned.

In the latest years, there has been much criticism and questioning about the present system of pharmaceutical patent protection. The system is rooted in the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement), which is part of the Results of the Uruguay Round of Multilateral Trade Negotiations.

It has been Professor Joseph E. Stiglitz who recently proposed a modification of the international property rights protection system for developing and least developed countries, based on his deep concerns on the use of one same approach on intellectual property protection for both developed and developing countries, adopted in the TRIPs Agreement.

The aspects related to the design of a specific fund to encourage and promote scientific innovation and research activities, in which private corporations would be actively involved, bring two advantages to developing countries. The first one relates to the possibility of having better access to funds for the promotion of local research and development, while the second one –no less relevant- would imply the possibility of modifying the application of the TRIPs-derived intellectual property regulations on pharmaceutical formulations or molecules resulting from the research and development processes to be financed by such fund.

¹ Taurus Publishers, Buenos Aires, 2006.

The first part of this work analyses the Multilateral Trade Negotiations and the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter, the TRIPs Agreement). The second part synthesizes Professor Stiglitz's opinions and his assessment of the ten years of enforcement of the TRIPs Agreement. The third part analyses Professor Stiglitz's proposals. The fourth part proposes a new approach on the problems of research and development (hereinafter, R&D) in developing countries, in particular, the design of a new Innovation Fund. The last section draws some conclusions about the proposal of a New Innovation Fund Plan for companies in developing countries.

1. The Multilateral Trade Negotiations and the Agreement on Trade-Related Aspects of Intellectual Property Rights.

The Uruguay Round of Multilateral Trade Negotiations was initiated in 1986 in Punta del Este, Oriental Republic of Uruguay. The Round ended in December 1993, and its Final Act was signed in Marrakech, in April 1994. The Agreements became effective from January 1st 1995, date on which the World Trade Organization (WTO) started operating.

One of the most significant conclusions of the Uruguay Round was, precisely, the creation of the World Trade Organization, which is an institutional organization of member countries that operate on a permanent basis, with the purpose of promoting trade liberalization, supervising and monitoring the consistency of its Member countries' trade policies with the Agreements signed in the Round, and enforcing the Dispute Settlement Understanding.²

The Dispute Settlement Understanding incorporates a set of transparent rules and conditions meant to effectively solve controversies in the WTO, leaving behind the resource of unilateral measures, the "grey area"³ measures and informal arrangements, frequently resorted to by developed countries in the '80s, which damaged significantly the credibility of the multilateral trade system.

The Uruguay Round introduced highly significant changes in the development of international economic relations. On one hand, developing countries were able to incorporate two production sectors into the multilateral negotiations, that had not been present in any other negotiating round prior to the Uruguay Round: the agricultural and the textile and garment sectors. On the other, developed countries included issues in the negotiations which, though extremely important for them, had not given rise to any multilateral negotiations: agreements on intellectual property rights, trade-related investment measures and the agreement on trade in services.

Upon the execution of these agreements, the WTO member countries are bound to fulfill the commitments undertaken and adapt their local legislations in line with the rules provided for

² The second post-world war agreements comprised the establishment of the International Monetary Fund, the World Bank and the International Trade Organization. The creation of the latter could never be achieved due to opposition by the US Congress; therefore, the GATT could not become an international intergovernmental agreement, but just one that regulated the international trade relations of an originally reduced number of nations.

³ Set of selective restriction measures of commercial nature that openly damaged developing countries.

in the agreements; in the case of intellectual property, domestic rules should be adapted to the minimum standards of the TRIPs Agreement.

Until then (1995), the international protection of intellectual property had been governed by agreements executed within the frame of the World Intellectual Property Organization (WIPO). Actually, the main goal of GATT's successive multilateral trade negotiations was to reduce import fees, eliminate non-tariff restrictions and liberalize related commercial rules and disciplines (safeguards, anti-dumping, compensation measures (subsidies), phytosanitary and health measures, technical obstacles to trade, etc.).⁴

Another extremely important conclusion of the Uruguay Round was the progress of multilateral rules and regulations on the autonomy of local policies, in particular commercial policies and those affecting the production and trade of goods and services, as well as those related to new areas covered by the Round Agreements, such as investment, services and intellectual property rights.

The protection of technological innovations, either of products or processes, is more associated with the countries' economic development policies, rather than matters, rules and disciplines related to the international trade of products and services.

It becomes paradoxical that such a discipline as patent law was included in these agreements, granting the innovative company exclusive product marketing and/or manufacturing for a term of twenty (20) years, i.e. the company is granted a monopoly to exploit the invention subject to the fulfillment of the inventive step, novelty and industrial application standards.

The argument to justify seeking and using such privilege has been that the inventor must receive encouragement to develop his innovative abilities and be guaranteed the return of the investment he made upon developing all the stages of his innovation process.

However, the Uruguay Round Agreements and, particularly, the TRIPs Agreement, state and assume that a real balance should be verified between:

- The interests of developing and developed countries.
- The monopoly costs and the innovation benefits for the population
- The remuneration to the innovator and the higher costs borne by consumers.

The analysis of the relationship between these three factors and the particular solution adopted by the TRIPs Agreement necessarily pose the following questions:

- Is the appropriation of monopoly rents the only way to encourage the development of innovations and enable the inventor to recover his investment?
- How has the pharmaceutical patent protection system worked in the world in the latest years?

⁴ For an analysis on the relationship between international trade, equity and development in trade agreement negotiations, see chapter 3: "Making trade fair", in Professor Stiglitz's book, "Making globalization work".

Let us review the answers provided by Professor Joseph E. Stiglitz.

2. Professor Joseph E. Stiglitz's opinion on the application of the TRIPs Agreement over the last 10 years.

One largely discussed topic in the economic literature on intellectual property issues is how to balance the existence of clear innovation incentives and the lowest possible degree of competition distortion in the market, which is a sign of economic efficiency and maximization of the consumers' benefits, based on the right to apply prices equivalent to the marginal production cost.

The patent regime, adopted worldwide as a tool to protect the intellectual property rights of technological innovations, leads to the existence of monopoly conditions in the market for a period of time, as a tool to ensure a rent for the innovators. Moreover, the system ensures the continuity of incentives to invest in R&D; therefore, the progress and movement of the technological barrier is promoted.

Criticism on the economic justification of a monopoly as a tool to protect pharmaceutical innovations has led to the evaluation of different alternative ways to protect intellectual property that may be more suitable for countries and economies with a lower relative development level.

The implementation of the TRIPs Agreement has raised a high level of disapproval and questioning in terms of its design and of the policy tools adopted to compensate and encourage innovations and the development of new drugs and manufacturing processes, as the system has caused serious problems of access to essential medicines in developing and least developed countries. This is the case of drugs to treat different pathologies, in particular, the HIV-Aids pandemic, malaria and other diseases.

According to Professor Stiglitz, the TRIPs Agreement was designed under two assumptions:

- a) High prices promote and boost innovation; and
- b) The more importance is given to intellectual property rights, the better the behaviour of economy will be".⁵

Stiglitz concludes that none of the concepts are true and that "the intellectual property regimes designed inappropriately not only reduce access to medicines but, also, result in a lower economy efficiency and may even slow down the rhythm of innovations, with weakening effects, particularly serious in developing countries".⁶

At the same time, patents inhibit the dissemination and use of knowledge; therefore, they hinder research efforts. Since almost all innovations derive from former ones, global technological progress becomes affected.

⁵ Joseph E. Stiglitz, Making globalization work, page 146.

⁶ Joseph E. Stiglitz, Making globalization work, pages 146 and 147.

Stiglitz considers that critics of the TRIPs Agreement are right and that it is necessary to balance the inventors' desire to protect their innovations, as well as the incentives and benefits derived from such protection, with the needs of the population, which benefits from wider access to knowledge, increased innovations and price reductions derived from higher competition. In other words, he considers it necessary "to find a more balanced enforceable regime, ... not only in developing countries, but in the developed world as well".⁷

According to Joseph E. Stiglitz, the current system for the protection of research and development is inefficient and unequal for the following reasons:

- It poses obstacles to basic research, which would benefit better from an open structure.
- While basic or experimental research is funded by governments, big corporations transform it into products which they introduce into the market, being the recipients of all the benefits.
- The difference between price and cost may be considered a consumer tax which, in the case of medicines, is paid by citizens of poor and rich countries alike.

He also emphasizes that the argument that high prices benefit research is false, due to the fact that:

- Multinational pharmaceutical corporations spend much more in advertising than in researching.
- Research is significantly focused on lifestyle medicines or life-extending drugs and less in medicines that treat poverty-inherent diseases, mostly prevalent in least developed countries.
- The multinational pharmaceutical corporations account for one the highest profitability rates in the world.

According to Stiglitz, a well-designed intellectual property regime should achieve a balance between innovation benefits and market monopolization costs. In his opinion, the present regime applied by the TRIPs Agreement, adopted by the WTO, can achieve this goal only in developed economies, but not in developing countries, due to the different characteristics of their economies.

The benefits of innovation are lower in developing countries compared to developed countries, since the high cost of medicines often turns these unaffordable for the level of income of a developing country. Also, the field that patented medicines covers fulfills the developed countries demands and disregards the specific local diseases existing in developing countries. Moreover, monopoly costs are higher in these countries, as often their markets are relatively small and characterized by the presence of few companies.

Therefore, Stiglitz concludes that the patent regime now in force in the world may very well adapt to central or developed countries, but it disregards the inherent circumstances of developing countries.

⁷ Joseph E. Stiglitz, Making globalization work, page 147.

From Stiglitz's perspective, the present patent regime causes many more disadvantages than benefits, the latter mostly absorbed by laboratories and not by the society. These disadvantages affect competition and the innovation process. In the first case, because they generate monopoly rents in pharmaceutical markets. In the second case, the innovating researchers or laboratories, fearing the possibility of encountering already existing patents, prefer to avoid certain research areas, restricting the possibilities of improvement in such fields.

The scope of these effects will depend on the degree of restrictiveness of patents, in terms of their term, extension and complexity.

Finally, Stiglitz considers that the costs derived from the application of a uniform intellectual property approach worldwide, without distinction in terms of the level of income of each country category (developed, developing and least developed countries) have exceeded its benefits.⁸

3. Professor Joseph E. Stiglitz's proposal

According to Professor Joseph E. Stiglitz, an adequate intellectual property system design should:

- a) Balance monopoly costs with innovation benefits.
- b) Limit the patent term.
- c) Require the disclosure of patent data so that others can make use of them.
- d) Limit the possibility of a patent being used to create an abusive monopoly.

Stiglitz proposes three basic or core modifications related to the international agreements or treaties:

- To establish different intellectual property regimes, according to the level of development of countries.
- To promote an International Agreement that recognizes the Protection of Traditional Knowledge, therefore preventing bio-piracy and protecting traditional medicines.
- To urge all countries in the world (including the United States) to sign the Convention on Biological Diversity, which should be included in the TRIPs Agreement.

In order to make his recommendations practical, he proposes two specific measures or tools aimed at establishing a system of protection for innovations, upon new premises:

⁸ "We should support differentiated intellectual property regimes for least developed countries, average income countries and developed countries", Joseph E. Stiglitz, *Making Globalization Work*, page 162.

- Developed countries' administrations should establish a Guarantee Fund which would ensure a certain amount of money to purchase an innovative medicine or vaccine to treat a disease such as, for example, AIDS. An Innovation Fund should be created to reward researchers for the value of their discoveries, which would directly boost research efforts aimed at developing and least developed countries.

The main characteristics of these measures are as follows:

- Rewards system to compensate researchers according to the value of their innovations.
- Researchers achieving the most significant discoveries will receive the highest rewards.
- Higher incentives for innovation medicines compared to minor innovations.
- Medicines would be marketed at competition prices.
- The system makes it possible to disseminate new knowledge, which would ease follow-on research.

Stiglitz' perspective opens an attractive scenario for R&D in developing countries, through a system that promotes local capitals and generates a more efficient and equitable institutional frame of protection.

In addition to the enforcement of differentiated intellectual property regimes for least developed countries, average income countries and developed countries, it proposes to grant poor countries improved decision-making capabilities for the enforcement of active industrial policies.

Through the reforms proposed by Professor Stiglitz, it is possible to create the necessary space and consensus to generate real opportunities of development for successful R&D projects by locally-owned pharmaceutical companies in developing countries.

4. A new approach on R&D in developing countries. The Innovation Fund.

One of the distinguishing characteristics of the pharmaceutical markets in developed and developing countries is the huge difference existing between the volume of sales of the main multinational pharmaceutical companies and that of the locally-owned pharmaceutical companies in developing countries. This characteristic significantly restricts the self-financing capabilities of the latter to engage in R&D projects. This means that the financial restrictions represent a strong barrier that hinders the development of specific research projects, including those between local companies and public or university research institutes.

Such lower absolute sales volume of pharmaceutical companies in developing countries, such as Argentina, compared to the research and development costs for a new molecule or a chemical entity, implies a severe financial limitation for such companies when they decide to engage in specific research and development projects. Such limitation requires a solution by means of financial resources made available by the governments of developing countries,

in order to ensure financial access by researchers and innovating companies of those countries for the development of new innovations, and the creation of competitive conditions in the markets, in order to prevent distortions and inefficiencies in the monopoly system of incentives and rewards for inventions.

It is for this reason that, based on Professor Joseph E. Stiglitz' proposals, we have developed some ideas and suggestions on a New Innovation Fund Scheme for developing countries, with more specific characteristics oriented to the generation of financial resources that help researchers, public research centers and institutions, including universities as well as pharmaceutical and pharminochemical companies, develop specific research and development projects.

Added to the original proposal by Stiglitz are modifications and additional elements to design and propose a New Innovation Fund Scheme, which characteristic elements are, inter alia: ex-ante financing of innovation projects, two alternative modalities for the exploitation of innovations and a collection system for the Fund.

This design seeks to simultaneously benefit local R&D in the pharmaceutical sector and improve market competitiveness.

The inherent characteristics of the New Innovation Fund Scheme for developing countries are as follows:

- It is a public policy aimed at promoting R&D in the pharmaceutical sector.
- It is a model of collection and accrual of resources to finance the Fund.
- It is a transparent and socially efficient fund allocation system for R&D projects.
- It has all the necessary characteristics to attract the assistance of international financial institutions.
- It changes the economic standard for R&D financing projects in developing countries, as it is carried out with the Innovation Fund resources (*ex-ante* concept), as opposed to the prize approach proposed by Professor Stiglitz (*ex post* concept) and the traditional model in which companies fund the R&D projects and recover their investment through the monopoly rent appropriation derived from the exploitation of a patent during its life term.⁹

The scope and application of the Innovation Fund is initially local¹⁰; therefore, resources will be funded by local bodies. The Innovation Fund may also receive contributions or credits from the regional financial entities. At the beginning, the process must be necessarily national, since the use of this Fund by an innovating company will necessarily imply, as a

⁹ 20 years as from the date of patent application, approximately between 12 and 13 years of effective exploitation.

¹⁰ The fact that the scope of the Innovation Fund might be wider should not be ruled out, for instance, at the Latin American level, or it could even be a Fund with participation from developing countries that agree with this proposal. Its initial application in a country such as, for example, Argentina, might significantly contribute to the further promotion of this innovation incentive policy.

binding condition, that the latter will waive its monopoly patent, that is, manufacturing licenses will be awarded to other companies of the same country willing to exploit the innovation, by paying the proper royalties disposed for.

The following have been considered as possible financing sources for the New Innovation Fund Scheme:

- Specific item of the Health Ministry budget, equal to its annual 4%.
- Bank debit and credit taxes contributed by pharmaceutical companies.
- A hundred per cent of the amounts contributed as export taxes by the pharmaceutical and pharminochemical industry.
- Contributions from pharmaceutical and pharminochemical companies on their payrolls
- Share (17%) of the collection of taxes on tobacco products, firearms, alcoholic beverages and games of chance
- Royalties paid by laboratories willing to produce the innovative medicines obtained by other laboratories, resorting to the innovation fund.

Taking into account the aforementioned funding sources, their estimation determines that the annual flow of resources is estimated to reach USD 1.51 bn in the first five years, and it would increase to an amount of USD 3.67 bn in the tenth year. This means that it would be possible to fund research and development projects for that amount during the first ten years of the Innovation Fund enforcement.

The existence of such New Fund Scheme will enable the promotion of projects based on scientific innovation, which contents must be related to a combination of factors, such as:

- Addressing developing countries diseases.
- Strengthening ongoing research projects or lines of scientific work that demand higher resources.
- Identifying scientific knowledge accrued by the local human capital, which may be potentially developed to obtain new national products.

The setting in motion of the Innovation Fund should take place as an essential component of the National Scientific and Technological Policy, so that the scientific and technological system and the Health Ministry may define the composition of the project selection committee, and the scientific, technical and public health criteria to apply in their selection, ensuring the transparency and involvement of all the corporations and institutions of the technological and scientific system and of the universities. Such criteria should privilege projects engaged in jointly by the locally-owned private pharmaceutical companies and the

aforementioned institutes. This new Innovation Fund Scheme, locally funded, is the first differential concept between this proposal and the one set forth by Professor Stiglitz.¹¹

The second differential element is that any company choosing to develop a specific project in a country such as Argentina and finance it through the Innovation Fund resources must waive the monopoly exploitation of the patent in Argentine territory and allow competitors, if they decide so, to exploit the invention in such territory, paying royalties to the Innovation Fund. The innovating company is exempted from paying such royalty, which sets an advantage for them in front of the third party corporations that manufacture and market the invention, paying royalties to the Innovation Fund.¹²

Also, the innovative company may file the corresponding patent applications of the innovative medicine in third developed countries and engage in the monopoly exploitation of the invention, if the company decides to do so.

Although this Innovation Fund system is based on a national frame and application, it is possible to consider and promote the idea of being adopted by other Latin American and developing countries of other regions and that such extension of the system could lead to the design of international agreements between those countries, based on the mutual acknowledgement of the innovation incentive system being proposed.

If a developing country subscribes a bilateral agreement with Argentina recognizing the respective systems of promotion and incentives to innovation in the field of medicinal specialties manufacturing, the companies of such third developing country seeking to manufacture and market the innovation in its own country, could receive a license subject to payment of the corresponding royalties to the innovating company. For such purpose, the innovating company should issue a license in favor of the company of that third country interested in producing the innovative medicine.

Two alternative plans for the exploitation and protection of innovations are put forward, both associated with different financing percentages for the projects, funded through the Innovation Fund resources:

A. Composite System of Monopoly/Competitive exploitation

- Financing supplied by the Innovation Fund, which consists of non-refundable contributions equal to 40% of the total project amount. This percentage increases to 50% if the company signs a research and development agreement with institutes

¹¹ In our proposal, the Innovation Fund resources come from each country's funds, without prejudice of other contributions received from international sources. On the other hand, the Innovation Fund resources proposed by Professor Stiglitz would be supplied by international donations; the decision about their allocation should also be a matter to consider.

¹² The proposed alternative may be implemented without modifying the TRIPs Agreement now in force or the local patent laws. Such modification would imply complex international negotiations; it has been observed that the policies of some developed countries have consisted, so far, in including TRIPs-plus standards in several free trade agreements signed between a developed country, e.g. USA, and Latin American developing countries. This alternative does not prevent developing countries from promoting international negotiations aimed at achieving the approval of a new agreement on intellectual property rights that includes different protection criteria according to the relative level of development of countries, considered in the specific proposals designed by Professor Stiglitz.

belonging to the scientific and technological system or with public national universities.

- During the first 2 years, the innovative laboratory holds a monopoly position.
- From the third year, competition is open to third companies, and payments are made to the Innovation Fund. The innovating company is exempted from paying such royalty.

B. Competitive exploitation system

- Financing supplied by the Innovation Fund, which consists of non-refundable contributions equal to the 60% of the total amount of the project. This percentage will be increased to 70% if the company signs a research and development agreement with institutes belonging to the scientific and technological system or with public national universities.
- Freedom to manufacture and market innovations, complying with the requirement of royalty payment to the Innovation Fund. The innovative company is exempted from paying the royalty.

Both systems for the exploitation of a certain invention have the following advantages:

- They finance important R&D projects for the Health System, through non-refundable contributions.
- The best research projects are selected based on an assessment carried out by an Ad Hoc Scientific Committee. The Ministry of Sciences, Technology and Innovation and the Ministry of Health will define the composition of that Committee and the scientific, technical, public health and economic criteria to be applied to such selection and to the assignment of resources.
- The Innovation Fund is assigned by stages.
- Each project is audited by an Ad Hoc Committee composed by professionals and scientists from the Ministry of Science, Technology and Innovation and the Ministry of Health, which verifies that the stages are being complied with within the pre-agreed terms, before carrying out a new fund assignment.
- Once an innovative product is selected, it receives a patent (which includes a compulsory license for which royalties are paid to the Innovation Fund), which commercial exploitation will be performed in a competition frame within the national territory. The innovative company may enforce its rights in third developed countries and sign license agreements with corporations belonging to developing countries with which an agreement was signed to acknowledge the respective systems of incentive and promotion of innovations.
- The medicine may be freely manufactured and marketed, complying with the required manufacturing standards and payment of royalties to the Innovation Fund.

This system is an alternative to Stiglitz' proposal of having different patent protection systems, depending on whether developed or developing countries are involved. It also represents an alternative to the current system derived from the TRIPS Agreement, as it offers public resources such as non-refundable contributions in favor of companies with approved projects, which sign an agreement with the INPI to waive their rights to enforce their patent rights and be bound to issue licenses as requested, with the corresponding payment of royalties to the Innovation Fund.

A regime of competitive exploitation is therefore created, from a financing fund for innovations, with a socially-efficient allocation of resources.

5. Conclusions on the New Innovation Fund Scheme for R&D projects in developing countries.

The New Innovation Fund Scheme will make it possible to:

- Incorporate flexibility into the present monopoly patent regime, generating a competitive scenario in the pharmaceutical market for companies that decide to resort to the Innovation Fund.
- Create a new financing system for national innovations.
- Strengthen the technological and scientific systems in developing countries.
- Improve public policies on local industry support.

The idea of generating a new national Innovation Fund Scheme is a rational response to the financing deficit for the development of innovations by the local pharmaceutical and pharminochemical industries of developing countries.

It is a new proposal with high possibilities of promoting a legal flexibilization of the models of protection of innovations, that complies with the international agreements in this field, and that may be implemented without need of awaiting their modification.

This does not exclude the possibility of initiating discussions and debates aimed at promoting the amendment based on the criterion of the intellectual property protection regimes, adapted to the countries' development levels.

The initiative generates strategic alliances between the knowledge accumulated by the local human capital and the capital of the national pharmaceutical companies that jointly achieve the development of new local, affordable medicines that address the needs of the regional population. At the same time, it makes it possible to promote and install the idea of the creation of an Innovation Fund in the national and Latin American political and economic agenda.

Clearly, the starting point of this new Innovation Fund proposal consists in achieving the highest level of commitment from all the local pharmaceutical and pharminochemical companies for a fast and effective implementation of the system.

On the other hand, other developing countries would be able to adopt this Innovation Fund proposal, and countries applying similar systems to promote and incentive research and innovation efforts in medicine specialities may sign agreements for the mutual recognition of their respective systems of promotion of innovations.

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