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PUBLIC HEALTH AND INTELLECTUAL PROPERTY

Abstract:

As a consequence of the growing life expectancy there is a growing cost for public health policy, since there is a growing number of degenerative diseases. There are new diseases appearing and also the necessity of new medicaments in order to grant a better life quality for the population. But the cost to acquire these new medicaments is increasing and that doesn't happen to the income, especially in developing countries. In order to satisfy the necessities of the society, the pharmaceutical industry has been trying to develop researches. Under these conditions the public policies must be oriented, but not in order to hinder the technological development; and one of these possibilities is the patent system. It must also be considered that new diseases appear and that the immunological system must be strengthened as a consequence of an acquired resistance to virus and bacteria to the used medicaments. The constant evolution of the health condition and the need of security in the use of new medicaments, which also include its cost, consist in a frequent dilemma of the policy makers.

It must be considered that the simple fact of importing technology does not mean the capacity to develop it, which has to be done by establishing adequate policies in order to fulfil the international completion. This question becomes delicate, when considering the case of pharmaceutical products, where the patent protection has the objective of market domination. We must also consider that technology transfer will be hindered if there is the possibility of losing markets, by the implementation made by the importer, in order to develop local technological procedures. Technology has its economic importance, which originated from its capacity to improve equilibrium between social and economical development. Technological policies are one of the most relevant bases for economical development. This analysis involves two questions: how can the legal system grant the improvement of the pharmaceutical industry, in order to implement the necessary innovation with the aim of assuring life quality? How assure that the State has the necessary means to implement health policies that assure the objective of the first question?

Keywords:

Patent Publich Health Research Development Welfare

JEL Classification: H51, K33, L38

As a consequence of the social development, including facilities like food and drugs supply, there is an increasing life expectancy, which is not limited to developed countries, but also includes poorer nations. This point is mentioned in the 2011 Report of the World Health Organization and the following graphics are relevant[1]:

	Male						Female						Both sexes					
	Life expectancy at birth (years)[i]			Life expectancy at age 60 (years)[i]			Life expectancy at birth (years)[i]			Life expectancy at age 60 (years)[i]			Life expectancy at birth (years)[i]			Life expectancy at age 60 (years)[i]		
	2011	2000	1990	2011	2000	1990	2011	2000	1990	2011	2000	1990	2011	2000	1990	2011	2000	1990
Africa	55	49	48	16	15	14	58	51	51	17	16	16	56	50	50	16	15	15
Americas	73	71	68	21	19	18	79	77	75	24	23	22	76	74	71	22	21	20
South-East Asia	65	61	58	16	16	15	69	64	60	18	17	16	67	63	59	17	17	15
Europe	72	68	68	19	18	17	79	77	76	23	22	21	76	73	72	21	20	19
Eastern Mediterranean	67	64	60	17	17	16	70	67	63	19	18	17	68	65	61	18	18	17
Western Pacific	74	70	68	20	18	17	78	75	72	22	21	20	76	72	70	21	19	18
Global	68	64	62	19	17	17	72	68	67	21	20	20	70	66	64	20	19	18

This expectancy can also be analyzed, considering the income, according to a report of the World Bank[2]:

	Male						Female					
World Bank Income Group	Life expectancy at birth (years)			Life expectancy at age 60 (years)			Life expectancy at birth (years)			Life expectancy at age 60 (years)		
	2011	2000	1990	2011	2000	1990	2011	2000	1990	2011	2000	1990
Low income	59	53	51	16	15	15	62	56	54	17	17	16
Lower middle income	64	60	58	16	16	15	68	63	61	18	18	17
Upper middle income	72	68	66	19	17	16	76	73	71	21	20	19
High income	78	75	72	22	20	18	83	81	79	26	24	23
Global	68	64	62	19	17	17	72	68	67	21	20	20

As a consequence of the growing life expectancy there is a growing cost for public health policy, since there is a growing number of degenerative diseases. There are new diseases appearing and also the necessity of new medicaments in order to grant a better life quality for the population. But the cost to acquire these new medicaments is increasing and that doesn't happen to the income, especially in developing countries. In order to satisfy the

[1] http://apps.who.int/gho/data/view.main.690?lang=en, access 01.10.2013
[2] http://apps.who.int/gho/data/view.main.690?lang=en, access 01.10.2013

necessities of the society, the pharmaceutical industry has been trying to develop researches. The increasing costs of public health is an international phenomena, according to the Canadian Health Service[3]:

> Canada is not alone in facing growth in public expenditures on healthcare. On a per capita basis, Canada spent US$3,895 on healthcare in 2007, of which US$2,726 was paid for with public funds. Norway spent the highest, at US$4,005 per publicly insured person. In general, public sector spending on healthcare has been increasing over the last decade for OECD countries. Canada subsidizes about 70% of all healthcare expenditures with public funds, which is below the OECD average of around 73%. As a share of GDP, France was the highest spender of public dollars on healthcare at 8.7%.Canada ranked in the middle of OECD countries at 7.1%. Total healthcare expenditures as a share of GDP have increased for many OECD nations.
> ....
> A population's demographic structure can increase pressure on healthcare expenditures in two ways. First, as the size of the population grows, healthcare spending rises in order to service the needs of the larger population. Second, population aging—defined as an increasing proportion of older persons in the population—heightens demand for healthcare and increases the level of healthcare expenditure. For example, per capita healthcare spending for seniors is higher than
> for younger age groups, especially during their last two years of life.

Under these conditions the public policies must be oriented, but not in order to hinder the technological development; and one of these possibilities is the patent system. It must also be considered that new diseases appear and that the immunological system must be strengthened as a consequence of an acquired resistance to virus and bacteria to the used medicaments. The constant evolution of the health condition and the need of security in the use of new medicaments, which also include its cost, consist in a frequent dilemma of the policy makers.

The industry involved in this field is relevant to the national economy. In Germany, this kind of industry employs 126,000 workers and in the year 2008 had a turnover of 41,5 billion Euros and an income of 27,1 billion Euros . It also represents 64,4% of the goods exported and had an increase of 4% on 2007.[4]

It is also to be considered that the State has an important rule, since it has to establish rules to implement the industrialization of the medicaments and the previous tests that have to be made to assure the necessary security of the consumers. In the European Union a survey was made about the procedures of licensing of new medicaments, with following results[5]:

Subjective Point of view	Evaluation
Medicine Experts (total of 45)	0,52
Micro industries	0,57
Small and middle business	0,77

[3] Constant, Alexandra. In the health sector and proposed policy options, pg. 11
[4] Mandry, Tilo. The Pharmaceutical Industry in Germany pg. 2
[5] Lindner, Ralf. Op cit., pg. 154

Big business	0,88
R&D	0,44
Clinics	0,31

0= no comments 0,33= bad evaluation 0,66= regular 1=very good

Therefore the definition of technology is important.

> "Technology is defined for this project as all the knowledge necessary for the productive functioning of an enterprise. The term can embrace hardware, such as factories, machines, products, and infrastructures (laboratories, roads, water distribution systems, storage facilities) and software, including non-material ingredient such as know-how, experience, organizational forms, knowledge, and education. It is a dynamic, continuing, sequential, and complex process."[6]

The protection of intellectual property constitutes one possibility of its implementation, which is relevant in the developed countries, but has caused frustration in many developing countries in Latin America.[7] It's controversial, but it is possible to consider that the protection of intellectual property may hinder the economic development. This idea is justified by observing the economic development of many countries, which have adopted rigid standards of intellectual property protection, after achieving its objectives. They tend to consider that this achieved knowledge will ensure a continuous development process.[8] Technology constitutes nowadays an important product, because of its value, if compared with commodities, especially considering the environmental impacts. The majority of the developed countries adopted**,** during the process of progress**,** a liberal standard of intellectual property protection, such as the German Patent Law, of 1870, which did not protect chemical and pharmaceutical products. In the 19th century, the industry had the liberty to research, in order to improve its technological capacity, without the limitations brought by a strict patent protection system. At the present time, the non-developed countries have become an importer of technology, which has as consequence the payment of royalties. It must also be considered, that this importation does not assure the implementation of new research fields nor the development of new technologies by these countries.[9]

[6] Barbosa, Denis Borges. O Comércio de Tecnologia: Aspectos Jurídicos - Transferência, Licença E Know How, page 2, (www.denisbarbosa.addr.br), access em 10/06/2009

[7] Barbosa, Denis Borges. Propriedade Intelectual – A Aplicação do Acordo Trips, pg 11

[8] Anderson, Robert. Intellectual Property, Technology Diffusion and Growth, pg 71

[9] Correa, Carlos. Intellectual Property Rights, the WTO and Developing Countries, page 30

It must be considered that the simple fact of importing technology does not mean the capacity to develop it, which has to be done by establishing adequate policies in order to fulfil the international completion.[10] This question becomes delicate, when considering the case of pharmaceutical products, where the patent protection has the objective of market domination.[11] We must also consider that technology transfer will be hindered if there is the possibility of losing markets, by the implementation made by the importer, in order to develop local technological procedures. Technology has its economic importance, which originated from its capacity to improve equilibrium between social and economical development.

The technological research, by using and copying the products commercialised in the international market, was one of the strategies used by Japan in order to achieve its development standard, because it used its capacity in order to develop these products. Therefore the level of intellectual property protection has a direct impact on the investments made in this sector. On the other hand, it must be considered that countries which just import technology are not capable of improving research, since these procedures are licensed and not locally developed. It is also to be considered that technology holder countries are more propitious to transfer it to countries with high level of intellectual property protection.[12] Consequently, the patent system may be considered an efficient promoter of technology development, in countries where there is an adequate research and science policy. It must be considered that Brazil has developed technology in the offshore prospection of oil and gas and also in the pharmaceutical public Institutes (Butantã and Farmanguinhos)[13]. Ensuring an intellectual protection system will ensure the stimulation of technology investments.[14] The developed countries established their international trade policy, by the imposition of intellectual property minimum protection standards, which may be implemented by bilateral agreements, which also establish the investments made.[15]

It is not possible to ensure that a rigid patent protection constitutes a condition for economic development. In Brazil, a new Patent Law came into force in 1996, but the numbers of Brazilian patent files did not increase so much. The highly concentrated technological knowledge and the insufficient investment in R&D have as consequence a lower development rate, especially if considered the lack of interchange between University and Companies.

[10] David, Eduardo Gonçalves. O Futuro das Estradas de Ferro no Brasil, page 250
[11] Tachinardi, Maria Helena. A Guerra das Patentes, page 45
[12] Correa, Carlos M. op.cit pg 30
[13] Correa, Carlos M. op. cit, pg 39
[14] Guisse, Monica Steffen. Propriedade Intelectual no Mundo Contemporâneo: Fomento ao Desenvolvimento (http://www.buscalegis.ufsc.br/revistas/index.php/buscalegis/article/viewFile/27743/27301, access em 02/07/2009)
[15] Basso, Maristela. Propriedade Intelectual na era pós-OMC, pg 42

But on the other hand, the privilege concerning intellectual property law should be granted in order to fulfil public interest and it must be pondered that a patent restrains competition rights and that compulsory license, as established in many Patent Laws, should be used in order to prevent the misuse of this monopoly. Trade Related Aspects of Intellectual Property Rights (TRIPS) also authorizes the granting of compulsory license and according to a World Trade Organisation (WTO) Resolution, in Doha 2001, human health and the access of proper medication must be considered as a human right. The conflict between the consumers and pharmaceutical industry must consider this statement.[16] This Resolution was possible after the terrorist attack of Sept. 11, 2001 and the biochemical terrorism, by using Anthrax, in the USA. The difficulties of granting a compulsory license and also the lack of capacity of local industries to manufacture the medicaments were taken into account, which had the consequence of allowing the import of these goods, without constituting an infringement of patent rights. In this case the TRIPS Council has to be notified.[17]

The participation of Universities and Research Centres in the technological development is crucial. But it is also important to have a proper legal protection as well as an efficient enforcement system in order to assure this development. It is therefore important to understand that the patent protection is nowadays nationally granted, but the expansion of regional agreements will have as consequence the change of this structure.

Technological policies are one of the most relevant bases for economical development. It is considered vital by many countries, so they have established goals to be reached within a period of 10 years and consequently research projects are made by Universities. Germany established the innovation policy for the period until 2020, when certain fields will be stimulated, such as transport, security, environment.[18]

A product is commercialised because the consumer wants its benefit, which is called consumer's values. According to Hans Verhulst[19] "benefits can be of technical, economic, social, environmental or service nature. Cost of ownership is composed of price, time and conflict." The importance of technology is as a result of it's development, after the World War II, with the recovery of the economy of European Countries, which is demonstrated by the following table[20]:

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[16] Sichel, Ricardo Luiz. Das Gemeinschaftspatentübereinkommen und TRIPS, pg 99

[17] Amaral Jr., Alberto. Licença Compulsória e Acesso a Medicamentos nos Países em Desenvolvimento (http://islandia.law.yale.edu/sela/SELA%202005/Alberto%20Amaral%20(Final%20Portuguese%20Version)%20v%201.0.pdf. , access em 02/07/2009)

[18] German's Government Report

[19] International Trade in Technology – Licensing of Know-How and Trade Secret – www.wipo.int - access 19/04/2012

[20] Verhust, Hans: International Trade in Technology – Licensing of Know-How and Trade Secret – www.wipo.int - access 19/04/2012

	MARKET DEMANDS	COMPANY EMPHASIS
1950-1970	PRICE	VOLUME AND EFFICIENCY
1965-1985	+ QUALITY	QUALITITY ASSURANCE
1980 – 1995	+ SPEED	SUPPLY CHAIN MANAGEMENT
1990….	+ NEW UNIQUE	INNOVATION MANAGEMENT

But the development of technology process, especially with the relocation of industrial plants to countries with low labour costs, has a consequence of protection of know-how and added, in the international negotiations agenda, the establishment of minimum standards of intellectual property protection. The objective is to prevent that the transferred technology may be used to compete against them and hindering the rich countries to have the financial profits of the investment made.[21] As a consequence, many rich countries prefer to maintain the R&D Centres and this is also caused not only by deficient legislation, but also by the lack of adequate enforcement procedures.

The investment of technological industrialisation process is the most adequate in order to get a higher added value to the product and enables the detainer to transfer it**,** getting royalties of it, with less environmental impact and also a higher value of its export, particularly if compared with commodities. The benefits for economical development of the country depend on long term investments, which are not limited to the industries, but also to the education, because there in no technological development, without highly educated researches and labour.

This analysis involves two questions: how can the legal system grant the improvement of the pharmaceutical industry, in order to implement the necessary innovation with the aim of assuring life quality? How assure that the State has the necessary means to implement health policies that assure the objective of the first question? It has its focus of study in the implementation of health policy, that on one hand promotes the innovation in the pharmaceutical sector and therefore assures an adequate patent protection, but on the other hand assures that the public budget has the means in order to conduct health policies to grant fair distribution of medicaments with reasonable price.

The first question is not easy to answer, because we must consider that the world economy is mostly based on the free competition and, on the other hand, the State has the obligation of providing the minimum conditions of social justice and also the means for everyone to have access to health treatment.

[21] Verhust, Hans: International Trade in Technology – Licensing of Know-How and Trade Secret – www.wipo.int - access 19/04/2012

Therefore, in order to assure the proper means, in many countries the possibility of compulsory licensing of patents is granted by law.

Another point to be considered is the Canadian Legislation, specially the following article of the Patent Act:

> 80. (1) A patentee of an invention pertaining to a medicine shall, as required by and in accordance with the regulations, provide the Board with such information and documents as the regulations may specify respecting
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> (a) the identity of the medicine;
>
> (b) the price at which the medicine is being or has been sold in any market in Canada and elsewhere;
>
> (c) the costs of making and marketing the medicine, where that information is available to the patentee in Canada or is within the knowledge or control of the patentee;
>
> (d) the factors referred to in section 85; and
>
> (e) any other related matters.
>
> 83. (1) Where the Board finds that a patentee of an invention pertaining to a medicine is selling the medicine in any market in Canada at a price that, in the Board's opinion, is excessive, the Board may, by order, direct the patentee to cause the maximum price at which the patentee sells the medicine in that market to be reduced to such level as the Board considers not to be excessive and as is specified in the order.
>
> (2) Subject to subsection (4), where the Board finds that a patentee of an invention pertaining to a medicine has, while a patentee, sold the medicine in any market in Canada at a price that, in the Board's opinion, was excessive, the Board may, by order, direct the patentee to do any one or more of the following things as will, in the Board's opinion, offset the amount of the excess revenues estimated by it to have been derived by the patentee from the sale of the medicine at an excessive price:
>
> (a) reduce the price at which the patentee sells the medicine in any market in Canada, to such extent and for such period as is specified in the order;
>
> (b) reduce the price at which the patentee sells one other medicine to which a patented invention of the patentee pertains in any market in Canada, to such extent and for such period as is specified in the order; or

(c) pay to Her Majesty in right of Canada an amount specified in the order.

This implementation of health policies have also to consider the way the pharmaceutical industry works, how much it invests in R&D and the risks taken into account. According to the WTO the definition of health policy is[22]:

> Health policy refers to decisions, plans, and actions that are undertaken to achieve specific health care goals within a society. An explicit health policy can achieve several things: it defines a vision for the future which in turn helps to establish targets and points of reference for the short and medium term. It outlines priorities and the expected roles of different groups; and it builds consensus and informs people

In the specific case of medicament patents the WTO states[23]:

> In the health sector, intellectual property rights can provide an important stimulation for the development of new drugs and medicines. However, a significant proportion of the world's population, especially in developing countries, have yet to derive much benefit from innovations that are commonplace elsewhere. The reasons range from weak supply systems to unaffordable prices. The factors that drive innovation are often biased against conditions that disproportionately affect the populations of developing countries. For example, of the
> 1 325 new medicines launched between 1975 and 1997, only 11 were specifically for tropical diseases. Innovation to address conditions primarily affecting poor people is held back by a combination of market failure and under-investment by the public sector. The process of bringing a new product to the market is both expensive and lengthy. Because of the resource implications and the uncertainties involved, creating an environment conducive to successful innovation is essential.
>
> The exclusive right to market a product during the life of a patent allows the holder to recoup some or all of their initial investment, by charging more for the product. This in turn has an impact on price, which affects access to medicines. Although price is only one of the factors that determine access, it is a highly significant one. Three recent studies, each using different methodologies, predict price increases of twofold or more once the TRIPS agreement requirements are fully implemented in developing countries.

[22] http://www.who.int/topics/health_policy/en/, access 20/05/2014
[23] http://www.who.int/trade/glossary/story055/en/, access 20/05/2014

> Reconciling the needs of patients and patent-holders is a challenge to efforts to improve access to essential health care. Given the potential impact of intellectual property rights on price, there has been a growing interest in mechanisms designed to bring about the most favourable pricing for developing countries. Relaxed patent requirements, tiered pricing, voluntary licensing, compulsory licensing, bulk purchasing and corporate donations have each been evaluated as potentially effective mechanisms to achieve the most favourable pricing of patented medicines in developing countries. The analysis suggests that those approaches which facilitate competition have the greatest impact on reducing prices.
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> These approaches need to be evaluated both individually and in combination to ensure that the balance between exclusive patent rights - and the investment stimulus they provide - is balanced against the objective of reducing prices. The impact of these approaches needs to be monitored in different national contexts.

Therefore, it is not possible to have an uniform answer to this question, it depends on the local peculiarity in order to enable the Government to fulfill its obligation. The National Authorities must also take into account the reality of the national budget and its possibility to afford the expense in order to grant proper health care. The patent laws in many countries admit the possibility of compulsory license and there are examples of its application[24]:

> Canada
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> In a September 2001, Speech on the Myriad Gene Patent, the Ontario Health Minister called for compulsory licensing of patents on genes relevant to test for breast cancer.
>
> Israel
>
> In January 1992, BTG-Israel filed an application in the Israeli Patent Office for a compulsory license to manufacture BTG's Bio-Hep-B und Biogen's Israeli patent which license, upon approval, would enable BTG to produce vaccine in Israel and likely to export the vaccine to countries in which neither Biogen nor others have granted a blocking patent. In September 1995 the Registrar ruled an interlocutory decision that BTG-Israel is entitled to a compulsory license to the Biogen patent. Biogen's appeal of the interlocutory decision was rejected.

Compulsory license is not often the better solution. The fact that the licensee must be able to produce the patented product, with its quality must also be considered and it means to have the proper means to do it. The misuse

[24] http://www.keionline.org/misc-docs/recent_cls_8mar07.pdf, access 20/05/2014

of it will have terrible consequences, because it may be considered a factor of inhibition of new investments in R&D in one field that have always up-to-date.

Conclusion

In conclusion, it is important to assure that the conflict between public health policy and pharmaceutical industries is a difficult task to solve, because the State has the obligation to grant the principles of a free market and completion, but on the other hand it has also the obligation to prevent the abuse of economic power. The Intellectual Property confers not only protection by patents, but also by registered trademarks. The health policy also has the interest of the implementation of R&D, which is based on private investments.

The solution of many problems in this Sector can't be solved by a single country, but it has to resolved by the International Community, specially if considering the poorest countries in the world. The access to new technologies, the live expectancy and the new pharmaceutical products, with their increasing cost, consist a permanent challenge for the Public Authorities, who also have to its local circumstances and the way the local society faces the problem.