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THE TUNISIAN PHARMACEUTICAL SECTOR IN TRANSFORMATION: INVENTORY OF FIXTURES AND INNOVATION PROSPECTS

Nejla YACOUB

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Abstract – Since the entrance of Tunisia to the World Trade Organisation (WTO) in 1995, the Tunisian pharmaceutical industry has recorded considerable changes. Notably, with the extension of patentability to pharmaceuticals, the sector is now at a dynamic stage of transformation, translated by a notable development of the industry of generics. The purpose of this paper is to analyze the mutations that have marked the Tunisian pharmaceutical industry over the last decade and study its potential of developing future innovation. In this purpose, the paper is divided into two main parts. In the first one, we are going to present the legal and economic changes in the Tunisian pharmaceutical sector and highlight the emphasis of the government on the production of generics. In the second part, the paper aims at studying the perspectives for innovation in Tunisia through the study of the innovation capabilities in the Tunisian pharmaceutical sector. The results show that in spite of some strengths of the Tunisian economy, the perspectives for pharmaceutical innovation remain handicapped by several financial and structural deficiencies of the national and pharmaceutical innovation systems.
Key Words: Generics; Innovation; Innovation System; Patents; Pharmaceuticals; Tunisia.

Résumé – Depuis l'adhésion de la Tunisie à l'Organisation Mondiale du Commerce (OMC) en 1995, le secteur pharmaceutique tunisien enregistre des changements considérables. Il se situe aujourd'hui à un stade dynamique de transformations, traduites particulièrement par le développement notable de l'industrie des génériques. L'objectif de cet article consiste donc à analyser les mutations ayant marqué le secteur pharmaceutique tunisien durant la dernière décennie et d'étudier son potentiel d'innovation. Dans cette perspective, l'article s'articule autour de deux grandes parties. Dans la première, nous allons exposer les changements réglementaires et économiques du secteur pharmaceutique tunisien et mettre l'accent surtout sur l'incitation du gouvernement pour la production des génériques. Dans la seconde partie, nous nous proposons d'étudier les perspectives d'innovation en Tunisie à travers l'étude des capacités d'innovation locales dans le secteur pharmaceutique. Les résultats montrent qu'en dépit de certaines forces qui caractérisent l'économie tunisienne par comparaison à d'autres Pays En Développement (PED) similaires, les perspectives d'innovation pharmaceutique demeurent handicapées par nombreuses défaillances financières et structurelles liées aux systèmes national et pharmaceutique d'innovation.
Mots Clefs : Génériques ; Innovation ; Système d'Innovation ; Brevets ; Secteur Pharmaceutique ; Tunisie.

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CONTENTS

INTRODUCTION

The last century has shown a considerable spread of patent rights among developing countries. This movement has been led, in a large part, by pressures exercised especially by the United-States. It is in this same vein that, in 1995, Tunisia took the engagement to establish and strengthen its patent system conformingly to the TRIPs[1] agreement. However, this engagement lifts up several conflicts about the mitigated impacts that are expected from patent enforcement on the Tunisian economy. This debate has become even more stretched with the extension of patent protection to the pharmaceutical industry, since, in addition to its economic dimension, the question has worn henceforth a social dimension dealing with public health. In fact, December 2004 represented the end of the transitory period granted to Tunisia (among other developing countries) to recognize pharmaceutical patents; an event that is expected to generate a major bend in the Tunisian pharmaceutical industry. Although pharmaceutical patents are relatively a recent issue in Tunisia, their short-term impacts have already started showing up on the Tunisian market, translated by a pharmaceutical policy more centered on the industry of generics. On the other hand, according to developed countries, the aim from establishing patent systems is at first enhancing the activity of innovation, which is a long-term impact. In this context, the questions that come into mind at this stage are: To what extent is improving the production of generics beneficial for the Tunisian pharmaceutical industry? And are the innovation capabilities in Tunisia promising for potential pharmaceutical innovation? In order to answer these questions, our paper will be divided into two main sections. In the first one, we are going to present the legal and economic changes in the Tunisian pharmaceutical sector and highlight the emphasis of the government on the production of generics. In the second section, we will focus on studying the innovation capabilities in the Tunisian pharmaceutical sector, extract its strengths and weaknesses and propose some corrective measures.

1. TRANSFORMATIONS OF THE TUNISIAN PHARMACEUTICAL SECTOR

The patentability of pharmaceuticals, expected since 1995 and put into practice since 2005, has generated several changes in the Tunisian pharmaceutical sector over the last decade. These changes have considerably marked the legal framework towards more improved patent rights and a pharmaceutical policy more centred on the industry of generics (1.1). In this same vein, the adjustment of the legal framework has in its turn generated economic transformations of the Tunisian pharmaceutical sector, especially in terms of the market structure, the distribution network organization and the notable increase of the local production, especially of generics (1.2). This last effect lifts up wonderings about how beneficial could this public policy be for the Tunisian pharmaceutical industry and more globally for the whole economy (1.3).

1.1. Pharmaceutical Patents in Tunisia: Evolution of the Legal Framework

Pharmaceutical patent rights in Tunisia seem to have roots far back in history. However, they have drawn attention only recently because of the considerable changes they have recorded since the mid-1990s. In fact, the changes in the legal framework have been translated not only by the patent law reform (1.1.1), but also by a pharmaceutical policy basically centred on the industry of generics (1.1.2).

1.1.1. The Patent Law Reform in Tunisia

According to the TRIPs agreement, a patent is defined as a strongly *exclusive* industrial property right which grants to its holder a temporary "*monopoly*" power over 20 years on his innovation. This monopoly power allows the patent holder to prevent third parties from exploiting the patented

[1] "TRIPs" is the abbreviation of Trade Related Intellectual Property Rights.

invention without his agreement (WTO, 1994, TRIPs). Patent protection in Tunisia is recognized since 1888. In fact, the decree of the 26th of December 1888 stipulates patent protection for inventions in all the industries. In this context, the decree defines a patentable invention as "*the invention of new industrial products, the invention of new means or the new application of already existent means in a way to generate a new or an improved industrial product*" **(**WIPO, 2000, Decree of December 26th, 1888, Article 1[2]). However, concerning the pharmaceutical sector, the decree does not recognize product patents: "*for inventions related to food or to pharmaceuticals, exclusively process patents can be granted but not product patents*" (WIPO, 2000, Decree of December 26th, 1888, Article 2). The main objective of the government was the protection of public health and, subsequently, guaranteeing the accessibility of the population to essential drugs. In fact, pharmaceutical patents are supposed to increase drugs prices and thus to make them less accessible to lower-income people; this explains the exclusion of pharmaceutical products from patentability.

Patent rights remain responsible for the increase of drugs' prices. At the same time, the main objective of the Tunisian government remains preserving public health. However, the laws have changed allowing patentability of pharmaceuticals in Tunisia since the ratification of TRIPs agreements in 1995. This change is rather an *obligation* for developing countries members of the WTO. In fact, the entry to the WTO means *automatically* the acceptation of all its agreements, including the TRIPs, conformingly to the principle of "*all or nothing*". Subsequently, all the member countries of the WTO have to adjust their intellectual property legislation conformingly to the TRIPs measures with a prerogative of a 5 years transitory period for developing countries to revise, progressively, their legislations and 5 additional years to recognize patents in some specific sectors, such as pharmaceuticals[3]. It is in this same vein that Tunisia reformed its patent system and started granting pharmaceutical patents since 2005. We mention here that the "National Institute of Standardization and Industrial Property" (INNORPI)[4] in Tunisia was assumed to accept pharmaceutical patent applications since 1995 and put them into a "mailbox". In other words, from 1995 to December 2004, pharmaceutical patent applications were examined and those of them accepted were put into the mailbox but not granted until January 2005, when the institute started granting them conformingly to the TRIPS measures (in terms of the conditions of patentability, the minimal protection period of 20 years, the exceptions for patentability … etc) (El Kateb, 2005; Musungu & Oh, 2006).

In these conditions, since 2005, any patented drug copied and produced in Tunisia is considered as an infringement to the patent and brings about problems to the producer, in this case considered as an imitator. However, local firms can contract licences or produce copies of the brand name drug once the patent expires; these copies are called "*generics*". In other words, a generic drug is a drug whose patent expired after a protection period of 20 years. The production of generics submits to a tight control by the World Health Organization (WHO) through the intermediation of local medical institutions[5] in order to guarantee the same high quality as the brand name drug **(**Coriat & Orsi, 2003). This explains that the patented drug and the generic one are medically equivalent therapeutics. However, generics remain much less expensive than the original version of the drug since they are freed from expenditures in R&D. In this context, pharmaceutical patent improvement in developing countries is meant to transform the status of drugs imitation from an illegal (counterfeiting) into a legal phenomenon. Generics can, in fact, be perceived as a kind of a "*legal imitation*" since they are approved by laws. At the same time, according to the definition of Schumpeter (1934), generics are considered as an innovation, since they are existent products newly brought to the local market, which is the case of Tunisia. In addition to generics, the patent law in Tunisia expects a certain number of

[2] The decree of December, 26th, 1888 was revised in 2000, generating the Law No. 2000-84 of August 24th, 2000, on Patents in Tunisia.

[3] The transitory period of establishing patent systems in the Least Developed Countries (LDC) is extended to 2016.

[4] Institut National de la Normalisation et de la propriété Industrielle (INNORPI).

[5] For example: The Central Pharmacy of Tunisia and the Pasteur Institute are supposed to control the production of generics in Tunisia.

exceptions in order to conciliate between protecting laboratories' interests and guaranteeing the accessibility of lower-income people to essential drugs.

i- The obligatory licences: according to the article 69 of the patent law N°2000-84 of the 24th of August, 2000, the Tunisian government authorises the grant of obligatory licences in 4 years counted from the date of patent application or in 3 years counted from the date of grant[6] and this in three cases (WIPO, 2000):

- 1st case: hen the patented invention was not industrially used within 4 years counted from the date of application or 3 years counted from the date of grant (the longest period is considered). Nevertheless, if the patented invention benefits from a preliminary market authorization, the obligatory licence could be granted after 6 years counted from the date of application or 3 years counted from the date of grant, on the basis of the longest period;
- 2nd case: if the quantities of the brand-name drug supplied by the patent holder do not cover the Tunisian market needs;
- 3rd case: when the patented drug has not been industrially or commercially used in Tunisia anymore for more than 3 years.

ii- The automatic licences: they represent another mechanism that restrains pharmaceutical patent protection. In fact, the article N°79 of the law N°2000-84 on patents allows the grant of an automatic licence of a patented drug that is not or insufficiently commercialized or sold at abnormally high prices on the Tunisian market. These licences aim at prevailing public health considerations above patent holders' interests.

iii- Exclusion from patentability: in order to facilitate the access to drugs, the article N°47 of the patent law in Tunisia stipulates that patentability can not be extended to pharmaceutical solutions prepared in pharmacies on the basis of a medical prescription and to necessary acts for the production of generics.

Hence, we notice that these exceptions are considerably inspired from the TRIPs agreement and especially from the measures inherent to the Doha declaration. In fact, the declaration adopted in Doha on the 14th of November 2001, is expected to conciliate between the interests of both developing countries and patent holders. However, some of the measures inherent to this declaration seem to be contradictory: on the one hand, in its 6th paragraph, the Doha declaration allows obligatory licences and calls for a measure that could enable using them in developing countries where production capabilities are insufficient. On the other hand, obligatory licences are allowed only for a certain number of diseases presented in a list published and revised yearly by the WTO. In fact, developing countries and non governmental organizations -*such as Doctors Without Borders*- estimate that obligatory licences are not very efficient since they are allowed only for: (i) diseases of which therapies exist but their patents have already expired; (ii) diseases for which there are no therapies yet and (iii) diseases for which R&D efforts are insufficient, in the sense that the probability of developing cures for these diseases is very small at least in the near future (DWB[7], 2003). Although the aim from the Doha declaration is to facilitate accessibility of lower-income countries to essential drugs, its measures, especially the exclusion of the most important patents from obligatory licences, show that this declaration benefits to pharmaceutical laboratories on the expense of developing countries. In this context, Tunisian pharmaceutical firms for example could not apply for an obligatory licence for cancer or AIDS treatments even in the presence of one or more of the three previously mentioned conditions that are required for granting obligatory licences. At this stage, the conclusion that comes into mind is that pharmaceutical patents do not have positive effects on developing countries. At the same time, it is obvious that in the absence of patent protection private pharmaceutical enterprises would not be incited to innovate and diffuse their innovations in the developing as well as in developed the countries. In this sense, the establishment of pharmaceutical patents in Tunisia would not only be the result of its entry to the WTO but also it would stem from a policy that aims at providing the appropriate legal infrastructure to improve the country's

[6] The shortest period is taken into consideration. If the patented drug benefits already from a preliminary market authorization, this period is of 6 years counted from the date of application or of 5 years counted from the date of grant.

[7] Doctors Without Borders.

attractiveness to pharmaceutical multinational firms as well as to enhance the motivation for the local firms to innovate.

1.1.2. The Emphasis on the Production of Generics in Tunisia

Among the objectives stated in the 8th development plan (1992-1996), the government aims at achieving a level of 60% of pharmaceutical local production by the end of 1996. Nevertheless, we notice that this goal was not achieved even 11 years later, since until 2007, the local production represents only 50%. It is in this context that Tunisia stresses currently much on enhancing the local production. In this purpose, the government expects several advantages which are specific to the pharmaceutical industry (WHO, 2003):
i- *Fiscal advantages*: pharmaceutical firms benefit of: exoneration from duties on the raw materials and the packaging items; reduction of the duties on imported equipments and an encouraging VAT[8] rate;
ii- *In a commercial framework*: the local pharmaceutical firms have the prerogative to ask the government for a suspension of imports of similar products, provided that the pharmaceuticals stock hold by the local producer satisfy the market demand in the lack of imports;
iii-The legal measures: by the law promulgated on of September the 10th, 1996, the cooperation between pharmaceutical laboratories and the optimisation of production capabilities have been made possible since the authorization to subcontracting between laboratories.

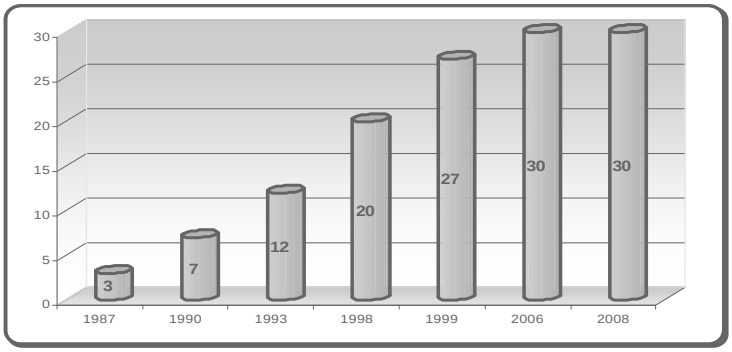
However, the most important measure remains the last reform of the social security system in July 2007 and according to which the National Fund of Health Insurance (CNAM) reimburses patients on the basis of the least expensive therapeutic equivalent on the market (MPH, 2008). Since generics are less expensive than the brand name and the licensed drugs, this reform aims at improving the market demand for generics and subsequently at enhancing their production. This reform is supposed to reduce health expenditures. In this context, a similar reform has been put into place in France. According to a survey led by the French National Fund of Health Insurance, this reform is expected to contribute at saving between 12 and 17 million Euros yearly in health expenditures in France (Icart, 2008). Since the health insurance reform in Tunisia is still new, its long-term impacts are not perceived yet. However, in the short-term we notice already important changes in the pharmaceutical market structure, particularly characterised by a greater potential of production especially in generics.

1.2. Main Characteristics and Evolution of the Tunisian Pharmaceutical Sector

The pharmaceutical industry in Tunisia is led by a strong public sector developed by the government since the early 1960s. In fact, until the mid-1980s there were only three pharmaceutical enterprises in Tunisia, all of them public. However, it is in the framework of the privatisation movement put into place since 1987 that the government started encouraging the development of the private investment in all the sectors including the pharmaceutical sector. Currently, the Tunisian pharmaceutical industry is represented by 30 firms: two public (the SIPHAT[9] and "Pasteur" Institute), 23 private and five subsidiaries of multinational firms (Pfizer, Baxter and BMS-UPSA from the USA and Pierre-Fabre and Sanofi-Aventis from France).

[8] Value Added Tax.
[9] La Société des Industries Pharmaceutiques de Tunisie: The Tunisian Pharmaceutical Industries Company

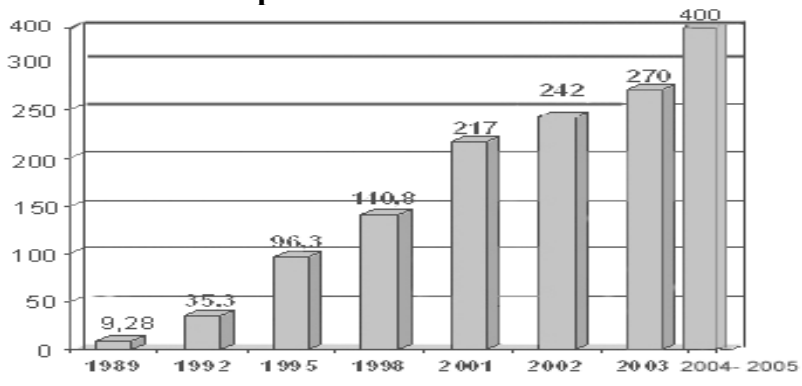
Graph -1- Pharmaceutical Firms in Tunisia: Number of Units (1987-2006)



Ministry of Public Health, 2008

In fact, the privatisation movement has contributed at "*freshening up*" the Tunisian pharmaceutical industry which recorded an annual average growth rate of 13% over the last ten years against a world rate of 7% (MPH, 2008).

Graph -2- Pharmaceutical Investment in Tunisia (1989-2005)

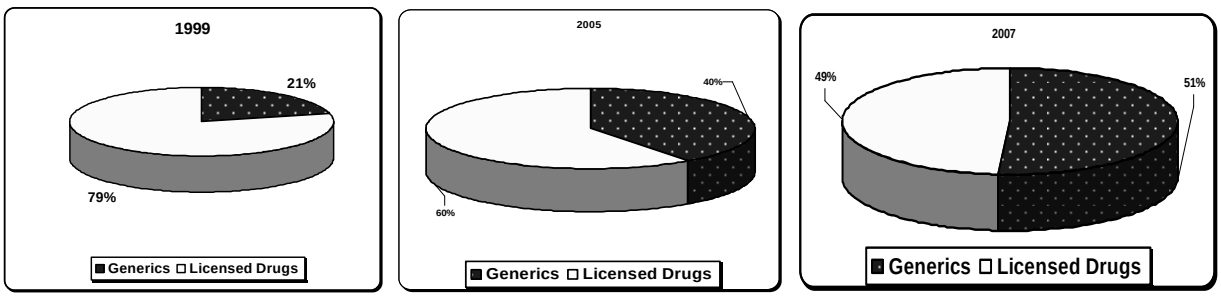


Ministry of Public Health, 2008

The foreign direct investments (FDI) led by multinational firms encouraged by the privatisation movement in Tunisia, have notably revivified the Tunisian pharmaceutical industry. The graph above describes the growth trends of the total investment in the pharmaceutical industry in Tunisia which has considerably grown up over the last twenty years by an approximate multiplication by 43: from 9,28 million TND in 1989 up to 400 million TND in 2005, of which the share of foreign subsidiaries represents an average value of 40%. In this same vein, the increase in the number of private pharmaceutical firms in Tunisia has generated a considerable augmentation of the local production; grown up from only 8% in 1987 to 44% in 1999 to achieve 50% in 2007 (WHO, 2003; MPH, 2008). The local production is constituted by generics as well as by licensed products. Lately, we notice a notable decrease in the share of licensed drugs for the profit of generics, which represent more than half of the local production. In fact, the share of generics increased from 21% in 1999 to 40% in 2005 to stand at 51% in 2007. Nevertheless, we notice a slight slow down in the growth rhythm of generics translated by an annual average growth rate of 13% over the period 1999-2005 and of 11,2% over the period 2005-2007. This slow down is explained by the increase of the market needs in treatments whose patents have not expired yet such as certain versions of anticancer medicines (MPH, 2008).

Graph -3- Composition of the Local Pharmaceutical Production in Tunisia (1999-2007)

1999 **2005** **2007**

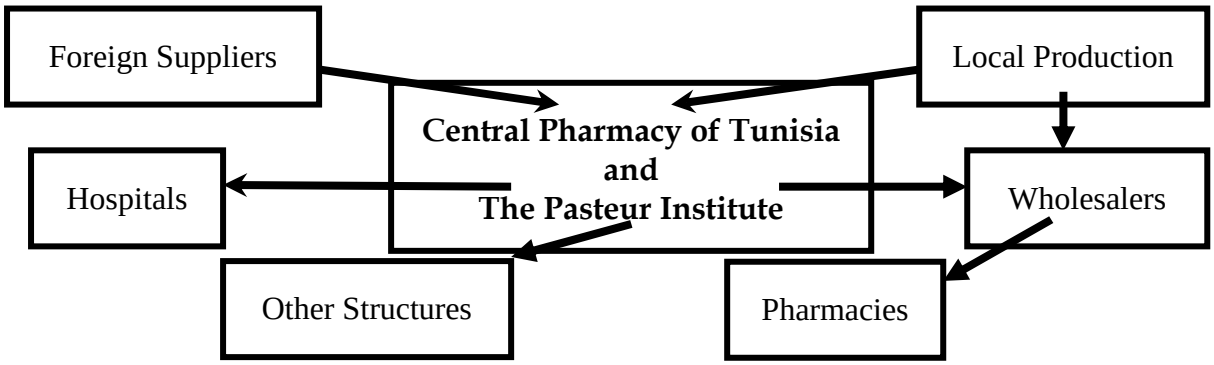


Ministry of Public Health, 2008

Furthermore, in spite of the improvement of the share of generics, exports remain at a low level, representing only 5 to 7% of the total production (the equivalent of 12 to 15 million Euros). Exports are intended for more than 23 foreign markets, some of them for political considerations (notably Iraq), some other for geographic factors (such as Morocco, Algeria, and Libya) and others for economic factors (such as France and Switzerland). Among these 23 countries, only six of them absorb 86,7% of these exports: Libya (40,5%), France (15,8%), Switzerland (9,8%), Morocco (8,7%), Algeria ((7,8%) and Iraq (4,1%). The other share of exports (13,3%) is basically in destination of some sub-Saharan African and Middle-eastern countries (MPH, 2008).

As for the other 50% of the market needs, they are covered by imports which are assured exclusively by the Central Pharmacy of Tunisia (CPT). In addition, the Pasteur Institute has the monopole of importing vaccines, serums and allergens[10]. These two institutions head the distribution network of the Tunisian pharmaceutical market. They have the exclusive right to import pharmaceuticals and distribute them to hospitals, wholesalers and some other public medical organisms such as social security institutions.

The Distribution Network of Pharmaceuticals in Tunisia



Source: The author on the basis of the Ministry of the Public Health's Data (2008).

Monopolizing pharmaceutical imports inside the public sector stems from a national policy that aims at a tighter control of imported products. This measure has become more judicious after the discovery of the virus of hepatitis C in a stock of blood imported from France (WHO, 2003). In this context, the privatisation of the pharmaceutical industry remains at the national level. In fact, lately the government allows the wholesalers to supply directly pharmacies with locally produced pharmaceuticals (licensed products and generics), without necessarily getting through the CPT while all imports remain assured by the public sector. We notice that the share of generics in the public distribution network (45%) is larger than in the private network (10%).

In response, the Tunisian government stresses more and more on improving the production of generics. This decision stems from a policy that aims basically -among other objectives- at countering the increase of drugs prices due to pharmaceutical patents on the one hand and to the evolution of exchange rates on the other hand. However, the industry of generics seems to be a double-edged sword, generating as much negative as positive effects.

1.3. Evaluation of the Tunisian Pharmaceutical Policy: Advantages and Limits of Generics

In terms of value, health expenditures have significantly grown up in Tunisia; according to the WTO report, we recorded a multiplication by 2,3 over the last decade (MPH, 2008). At the same time, due to the increase of imported and licensed brand-name drugs prices on the one hand, and to the continuous increase of carburant prices and the depreciation of the Tunisian currency on the other hand, Tunisia, as a country with limited financial resources, is in front of big challenges about how to

[10] An allergen is a non-parasitic antigen capable of stimulating a hypersensitivity reaction in atopic individuals.

assure the access to essential treatments. It is in this purpose that the government put into place a certain number of measures that are supposed to augment the share of local production and this through promoting the industry of generics. Nevertheless, too much emphasis on the industry of generics could be a double-edged sword for the Tunisian economy, presenting several limits (1.3.2) in addition to its numerous advantages (1.3.1).

1.3.1- Generics Production and the Development of the Tunisian Pharmaceutical Industry

As mentioned above, in terms of costs, it is obvious that generics are less expensive than the brand-name drugs.

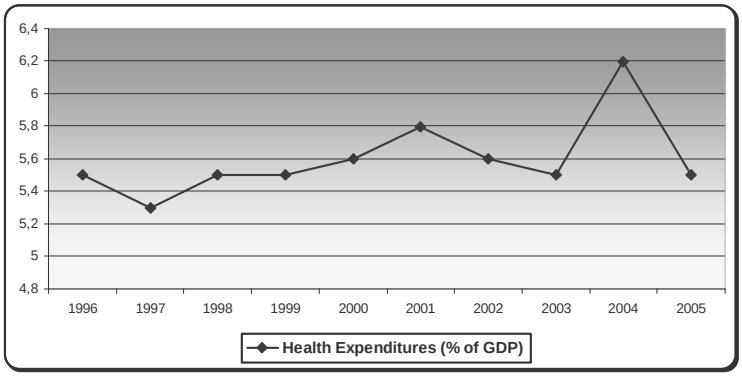
Table -1- Comparison between three Brand-name Drugs and Generics' Prices in Tunisia (in TND)

	Amoxicilline 500 mg	Diclofénac 25 mg	Glibenclamide 25 mg
Brand-name drug	7,5	24,5	28,2
Equivalent generic	4,6	12,6	7,0

Source: WHO (2007)

As shown in the table above, we notice that brand-name drugs are much more expensive than the equivalent generics. For example, for the case of Glibenclamide, which is a treatment for some diabetes, the price of the brand-name drug (28,7 TND) is four times more expensive than the generics version (7,0 TND). This difference influences considerably the accessibility of lower-income people to drugs especially for chronic diseases such as diabetic. Subsequently, substituting generics to imports allows the government to control and reduce health expenditures in Tunisia which have grown up in terms of value but are maintained almost stable in percentage of GDP, as shown in the graph below.

Graph -4- Health Expenditures in Tunisia (% of GDP)



Source: WHO (2007)

Furthermore, the increase of the production of generics will reduce the imports of pharmaceuticals and subsequently contributes at saving currencies. Particularly, saving currencies represents a major goal for Tunisia, especially with the continuous depreciation of the Tunisian Dinar against the Euro (we restate here that more that 80% of imports are from the European Union and are thus made out in Euro). To remedy to this problem, the government stresses much on promoting exports in all the fields. Nevertheless, as we previously mentioned, pharmaceutical exports in Tunisia remain under the estimated level representing only 5 to 7% of the total production. However, in terms of value, exports of generics have considerably progressed over the last four years growing up from 10,1 million Dinars in 2004 to 19,4 million Dinars in 2007, which makes a growth rate of 92%. This confirms that also the production of generics is more targeted to the local market.

Globally, the development of the industry of generics consolidates the local industrial tissue by promoting investment and consequently increasing the employment rate. It is noticed here that the

pharmaceutical firms employ 3700 persons of 32719 people employed by the chemical sector in Tunisia, which makes a share of only 11,3%. The pharmaceutical sector employs highly qualified workforce, especially pharmacists and engineers.

More globally, all the benefits inherent to generics and presented above are themselves a vector that generates a more important benefit to the Tunisian economy; that is the attraction of pharmaceutical multinational firms. In fact, the generics-based policy has drawn the attention of foreign investors to the high potential of production of the Tunisian pharmaceutical industry. Therefore, several foreign laboratories, which are world experts in generics production, are becoming more and more interested in investing in Tunisia. The most revealing example is that three of the most important Indian firms - Rambaxy, Cipla and Hetero Drugs- have signed joint-venture contracts with Tunisian pharmaceutical enterprises in order to produce anti-infectious, anti-cancer and anti-inflammatory generics (DEC, 2007).

In addition, the Tunisian economic policy encourages the production of generics as an alternative to avoid or at least to minimize the dependency of local licensees towards foreign firms. In fact, in opposition to generics, local firms have to negotiate with brand-name laboratories for licences. It is noticed here that in this kind of negotiations, local firms are the passive partner and consequently they have to accept the contract that serves most the interests of the foreign laboratory. This could have negative effects to the licensee especially in terms of drugs prices. At the same time, even after obtaining the contract, the industry of licensed pharmaceuticals submits to several conditions:
i- The licensee has to import raw materials exclusively from the owner of the brand name product at fixed prices, independently from the evolution of exchange rates. In case of depreciation of the Dinar, this negatively affects as much local consumers (due to the increase of prices) as the Balance of Payments (due to a bigger loss of currencies);
ii- The licensee can not export, even partially, his production;
iii-The owner of the brand name product has the exclusive right to retrieve the license at anytime, on the basis of a simple notification few months before. Therefore, the local production depends always on the owner's strategy and remains thus insecure for the licensee.
Similarly to any other phenomenon, in spite of its many advantages for Tunisia, generics production presents many limits.

1.3.2. Generics: A Short Term Strategy

The most important limit is that generics producers remain dependent on the original drug owner, since they sell only copies of the brand name drug and thus they have to wait until the patent expires so that they could produce a copy from the patented drug. In this sense, the local firms submit to a kind of a phase of "inertia" which is equal to the patent life of the brand name drug. This phase could have serious negative impacts, especially when dealing with diseases that need an urgent intervention, especially cancer. In fact, cancer deaths are more and more increasing in Tunisia. Despite the reimbursement by the social security, cancer cures remain very expensive and inaccessible for the lower-income class in Tunisia especially they are long duration treatments.

In addition, much emphasis on the production of generics in Tunisia could have the side effect of spreading a sort of *passiveness* towards innovating within local pharmaceutical firms. In other words, local pharmaceutical firms would be more willing to behave as *innovation takers* rather than as *innovation makers*, since the encouragement is put much more on the production of generics than on producing new products or ameliorating existing (Yacoub, 2008a). This consolidates the thesis that a generics-based pharmaceutical policy remains a *short-term solution*. In fact, this policy allows the country to counter many problems as mentioned previously but, all alone, it is inadequate to achieve the goal of establishing a solid pharmaceutical industry, which constitutes a long-term objective. In this perspective, the government should mobilize more efforts in order to kick-start the pharmaceutical industry. Theoretically, the establishment of pharmaceutical patents constitutes a determinant of

innovation in pharmaceuticals. However, the question here is whether they are sufficient to generate pharmaceutical innovation in Tunisia. A priori, it is obvious that pharmaceutical innovation requires more "*ingredients*" in addition to a strong patent system. In this perspective, the next section of this paper aims at studying the innovation capabilities in the Tunisian pharmaceutical sector.

2. PERSPECTIVES FOR PHARMACEUTICAL INNOVATION IN TUNISIA

Due to the disparate character of innovation, it is imperative to begin first by defining this concept and highlight its different types, in order to better understand its relationship with patents. According to Schumpeter (1934), innovation is defined as a new combination of the resources of production. More precisely, he enumerates five forms of innovation: producing new products, introducing new methods of production, opening up new outlets, using new inputs and realizing a new organization of the production. In these conditions, producing already existing generics by local producers represents an innovation for Tunisia, since these products are new for the Tunisian pharmaceutical market. Also, improving existing drugs by Tunisian pharmaceutical firms is considered as an innovation. Globally, the category of innovation depends much on the local production and innovation potential. It is in this purpose that we will study the input (2.1), throughput (2.2) and output (2.3) innovation indicators in the Tunisian pharmaceutical sector. This study allows us to expose the strengths and weaknesses of the Tunisian innovation capabilities and thus to suggest some corrective measures (2.4).

2.1. The Inputs of Pharmaceutical Innovation in Tunisia

To measure the inputs of innovation in the Tunisian pharmaceutical sector, we will take into consideration the main key indicators such as R&D expenditures (in % of GDP), tertiary school enrollment, and infrastructure equipments (transport, telecommunications …).

2.1.1. The Key Input of Innovation: Human Resources

The development of the activity of innovation could not take place in the absence of qualified human resources. Education is considered, according to Lucas (1988), as the main factor of knowledge acquisition and accumulation. Aware of the importance of human resources as an input of innovation, the department of scientific research and technology of the MHESRT[11] organizes, since 2003, a cooperation program between the local and the Tunisian immigrant researchers. This cooperation amounts to the organization of projects commonly developed by the local and the immigrant researchers which projects are financed by the MHESRT. In the framework of this program, Tunisian universities welcome yearly researchers for a period going from one to six months, in order to improve researches in prior and strategic fields such as technologies of information and communication, biotechnologies, agriculture, energy, environment, health, human and social sciences and engineering sciences (MHESRT, 2006a). To highlight the education level in Tunisia, we mention that in 2005, the tertiary school enrollment stands at 29%, which is relatively satisfactory, especially comparing with some other countries with similar economic indicators, such as Algeria (15%) and Morocco (12,2%).

In the purpose of better surround the local pharmaceutical innovation capabilities it is interesting to study the characteristics of pharmacy education. In Tunisia there is only one faculty of pharmacy. Since its establishment in 1975, the number of students has more than doubled (a multiplication by 2,4) between 1987 and 2007: from 595 students to 1436 (Table 2). However, we notice a light decrease in the number of pharmacy students over the three years from 2002 to 2004. This decrease could be explained by the increase of the unemployment rate in pharmacy. In fact, the number of

[11] Ministry of Higher Education and Scientific Research of Tunisia.

pharmacy graduate students on the waiting list[12] is continuously increasing due to the market saturation in pharmacies (MPH, 2008).

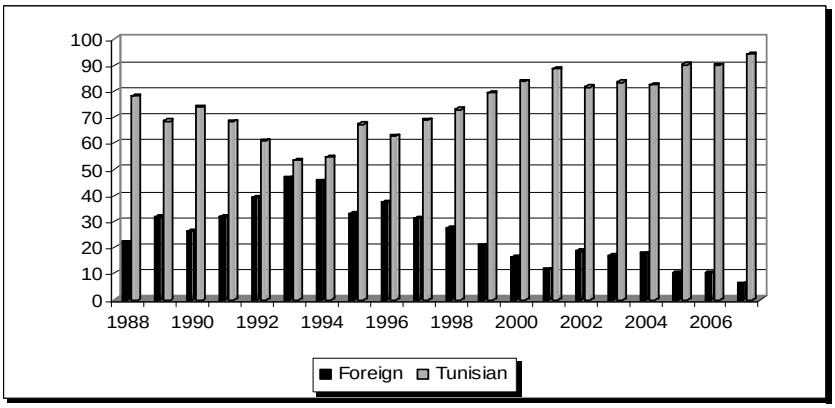
Table - 2 -Pharmacy students in Tunisia – Total Number (1976-2007)

Scholar Year	1987/88	92/93	97/98	99/00	00/01	01/02	02/03	03/04	04/05	05/06	06/07
Students	595	693	852	1144	1220	1281	1280	1270	1364	1399	1436

Ministry of Higher Education, Scientific Research and Technology (MHESRT), Tunisia, 2008

The pharmacy faculty of Monastir has a good reputation in terms of pharmaceutical formation comparing with other pharmacy faculties in the Arab Maghreb Union[13] and the Middle East **(MPH, 2008)**. This is proved by the important number of foreign students which has risen up to achieve 35 in 1997 and 1998 and 40 students in 2002. The graph 4 shows the decrease of the number of foreign pharmacy students, in terms of percentage of the total students' number. In fact, the part of foreign pharmacy students has also decreased over the last five years. This decline could be explained either by a decrease in the number of foreign students, or an increase in the number of Tunisian students, or by both a decrease in the number of foreign students and an increase in the number of Tunisian students. Actually, we notice the both effects i.e. an important increase (of 61%) of Tunisian pharmacy students between 2003 and 2007, and a decrease (of 35%) in the number of foreign students over the same period.

Graph -5- Tunisian and Foreign Pharmacy Students in Tunisia (in %) (1988-2007)

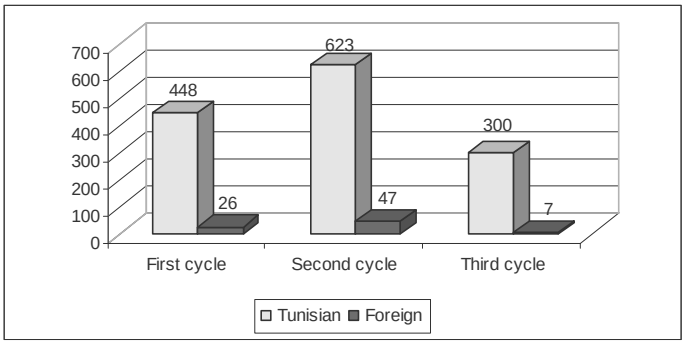


Ministry of Higher Education, Scientific Research and Technology (MHESRT), Tunisia, 2008

Since the establishment of the faculty of pharmacy, the number of Tunisian pharmacists is constantly increasing (from 1726 in 1990 to 2500 in 2001, reaching a number of 3497 in 2006) (MPH, 2008). In 1998, 56% of pharmacists work for the private sector (they have founded their own pharmacies). The other 44% are distributed between hospitals, public and private biology centers, teaching, administration, Central Pharmacy of Tunisia and pharmaceutical industry. Obviously, we notice that the majority of pharmacy graduate students are more willing to opt for the private sector i.e. opening pharmacies than for the field of pharmaceutical research (WHO, 2003). This shows the lack of inventive spirit within pharmacy students and explains the very low percentage of pharmacist working in the pharmaceutical industry.

[12] They are waiting for the agreement of the public health ministry that allows them to establish their own pharmacies.
[13] The Arab Maghreb Union includes five countries of North Africa: Algeria, Libya, Mauritania, Morocco and Tunisia.

Graph -6- Distribution of Pharmacy Students on the Three Cycles of Studies (2006/2007)



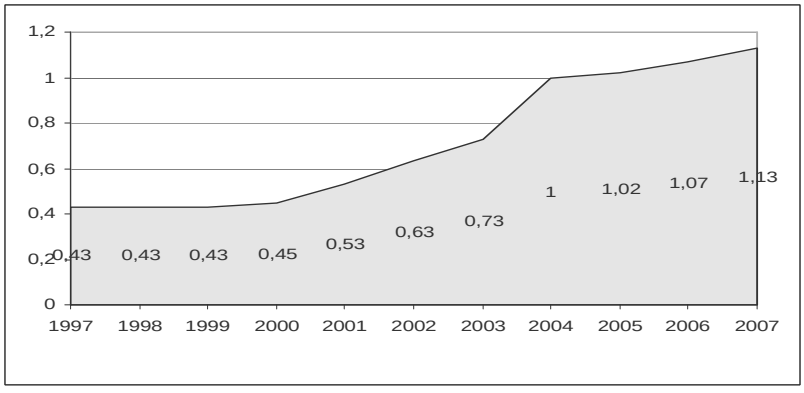
Ministry of Higher Education, Scientific Research and Technology (MHESRT), Tunisia, 2008

Indeed, the graph above shows that less than half of graduate pharmacy students carry out third cycle studies. The faculty of pharmacy of Monastir has founded three laboratories and 18 research units in different specialties; such as pharmacology, hematology, immunology and control of pharmaceuticals quality. However, we notice that graduate students generally choose to carry out their pharmaceutical studies in developed countries (especially in Europe, Gulf countries and the United States) to benefit from more appropriate conditions for research, especially in terms of financing and access to some essential raw materials that are not available in Tunisia. In this context, according to the survey led in 2006 by the Ministry of Higher Education, Scientific Research and Technology of Tunisia, we perceive 65 Tunisian pharmacy researchers living and working abroad. Almost 75,5% of them (49 researchers) are in Europe, 20% in gulf countries (13 researchers) and 4,5% (3 researchers) in the United States (MHESRT, 2006a).

2.1.2. Financial Resources

In response to the international challenges, the economic policy in Tunisia aims at establishing an economy of knowledge. In this purpose, the government insists on enhancing the investment in R&D and facilitating the access to information and knowledge. In fact, the activity of R&D in Tunisia is obviously in progress. This is thanks to the increase of funding dedicated to scientific research and technology. The graph below describes the evolution of the expenses in R&D in Tunisia in percentage of GDP, over the period going from 1997 to 2007.

Graph -7- Evolution of IERD[14] in Percentage of GDP in Tunisia (1997-2007[15])



Ministry of Higher Education, Scientific Research and Technology, Tunisia,(MHESRT, 2006b)

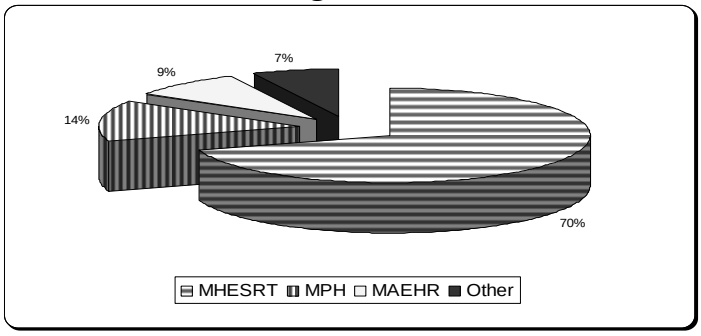
As shown in the graph above, the part of the IERD in percentage of GPD has considerably grown up during the last decade from 0,43% in 1997 to 1,13% in 2007. Predicted values for 2008 and 2009 are

[14] IERD: Internal Expenditures on Research and Development.

[15] For 2006 and 2007, the values on the graph are predicted values by the MHESRT (2006). These figures were overestimated since the real values are respectively 1,04% in 2006 and 1,11% in 2007 **(MHESRT, 2008)**.

respectively 1,19% and 1,25%. These figures seem to be satisfactory especially when compared with the situation in some southern European countries such as Italy (1,05%), Spain (0,96%) and Portugal (0,83%) in 2001. Due to the lack of statistics divided by sector of activity, we have been led to present the aggregate data. The aggregate data could give at least a general idea of the structure of R&D in Tunisia. In the graph below, we represent the distribution of public funding to R&D among ministries.

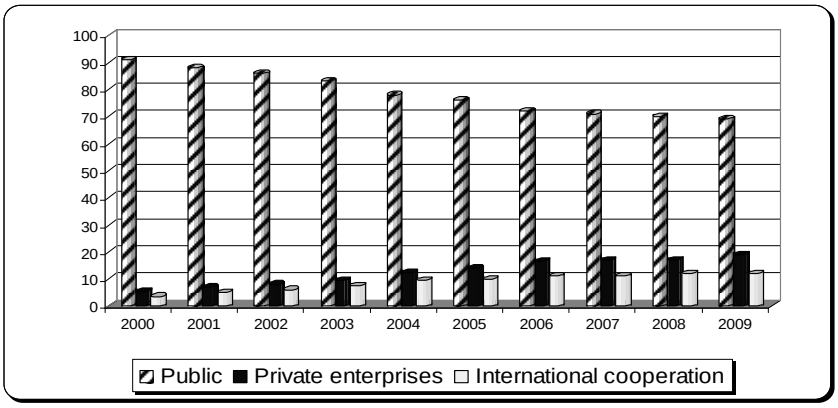
Graph -8- Distribution of R&D Funding between Ministries in Tunisia in % (2005)[16]



Ministry of Higher Education, Scientific Research and Technology, Tunisia (MHESRT, 2006a)

We notice that the Tunisian government focuses much on education and academic R&D to which it allocates a share of 70% of the funding dedicated to research in 2005, while the ministry of public health holds the second share (14%). In Tunisia, the government plays the major role in financing the activity of R&D, with a part of 91% in 2000. Over the last eight years, this part has declined, reaching 72% in 2006. The economic policy in Tunisia aims at reducing more and more this part and at improving the contribution of private enterprises and especially of international cooperation in financing R&D projects. The graph below describes the distribution of the IERD per financing source.

Graph -9- Distribution of IERD per Financing Source in % (2000-2006[17])



Ministry of Higher Education, Scientific Research and Technology, Tunisia (MHESRT, 2006b; 2008)

In these conditions, relying on public funds to finance R&D in a limited-income country like Tunisia seems an obstacle for the development of the local activity of innovation especially in the pharmaceutical sector which requires substantial funding. Therefore, we could conclude that the most braking factor to pharmaceutical innovation in Tunisia is the lack of financial resources. In spite of the measures taken by the government, the funds dedicated to scientific and technological research remain insufficient to establish a well based R&D activity in Tunisia. In fact, researches in general and especially in the fields of pharmaceuticals, require huge funding. In this context, as an example, we mention that some pharmaceutical multinationals dedicate about 15% of their turnovers to reinvestment in R&D; this amount exceeds sometimes the whole budget of a small developing country such as Tunisia. In opposition to theoretical researches, the distinctiveness of pharmaceutical researches is that they are "*applied researches*" and thus, they require highly equipped laboratories that allow researchers to put into practice their experiments. These equipments (machines, substances

[16] MAEHR: Ministry of Agriculture, Environment and Hydraulic Resources.
[17] The values from 2007 to 2009 are predicted figures by MHESRT (2006b).

…) are generally very expensive. In addition, for security reasons[18], a number of developing countries are deprived of some chemical substances considered as dangerous but necessary for pharmaceutical experiments. Subsequently, we restate that the most competent Tunisian researchers in the pharmaceutical fields are more willing to immigrate to developed countries so that they could exercise and develop their skills. This movement, called as the phenomenon of "*brains immigration*", contributes at generating a sort of "*impoverishment*" in local human resources and brakes more and more the activity of innovation in Tunisia (Yacoub, 2008a).

2.1.3. An Overview on the Tunisian Infrastructure

Even though Tunisia is a small developing country, it dedicates a particular attention to ameliorate the quality of the local infrastructure especially in terms of logistics and technologies of information and communication. Over the period from 1990 to 2001, the government has set aside 10 million US dollars for investment in infrastructure. Geographically, Tunisia is at a strategic position and represents a real platform as much for investment as for trade and production, which facilitates the exchanges in terms of raw materials and products through 8 commercial ports and 7 international airports[19] (MDIC[20], 2008). As well as the transport infrastructure, the telecommunication sector seems to record an important development (MCT[21], 2008). In fact, Tunisia disposes of fully digitalized telephone network covering 100% of the national territory and allowing access to more than 170 countries and an internet network covering all the country. The national policy aims at improving the society of knowledge in Tunisia in order to guarantee a continuous access to information by guaranteeing the openness to other countries, especially developed ones and the dissemination of the digital culture among Tunisian people.

2.2. The Throughputs of Pharmaceutical Innovation in Tunisia

We restate that due to the lack of sector-based statistics, we are led to use aggregate data. Actually, throughput indicators have a general dimension and are thus hard to quantify. To measure this kind of indicators, we will refer basically to the existence of a permanent R&D department within enterprises and on the sources and the means of acquisition of information (Hertog & Brouwer, 2000). The survey carried out in 2005 by the Tunisian Ministry of Higher Education, Scientific Research and Technology, reveals that over the 586 private Tunisian enterprises surveyed, less than half (248 enterprises, which makes 42,3%) declared having led an activity of R&D.

Table -3- Distribution of Enterprises in terms of Activity of R&D (2002-2004)

	Enterprises having a R&D activity		Enterprises setting aside a budget for R&D		Enterprises having a continuous R&D activity	
	Number	%	Number	%	Number	%
No	338	57,7%	156	62,9%	86	34,7%
Yes	248	42,3%	92	37,1%	162	65,3%
Total number	586		248		248	

Ministry of Higher Education, Scientific Research and Technology, Tunisia (MHESRT, 2005)

[18] Some developing countries are deprived from these substances either due to the lack of experience within the local laboratories or else to avoid the spread of terrorism in some Arab countries in particular, when these substances could be used as inputs to produce bombs.

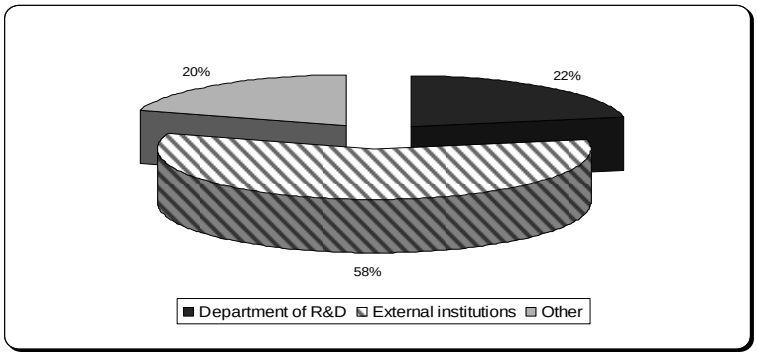
[19] An eighth international airport is currently under construction in Tunisia. The investment is undertaken by the Turkish firm "TAV" which aims -throughout this project- at building the most important intercontinental airport in Africa. The airport is expected to be inaugurated by the year 2009.

[20] Ministry of Development and International Cooperation of Tunisia.

[21] Ministry of Communication Technologies of Tunisia.

Over the 248 enterprises, 65,3% declare having managed a continuous R&D activity between 2002 and 2004; the activity of R&D within the other 86 enterprises (34,7%) is still occasional. However, only 37,1% of enterprises that run a continuous activity of R&D set aside a special budget to this activity. In a similar vein, the survey has analyzed the organisational structure of R&D enterprises. The results show that while only 22% of the questioned firms do have their own department of R&D, 58% of them choose to entrust the activity of R&D to external institutions such as research bureaus (27%) and method bureaus (31%).

Graph -10- The Organisational Structure of R&D of Enterprises (2002- 2004)



Ministry of Higher Education, Scientific Research and Technology, Tunisia (MHESRT, 2005)

It is obvious that the activity of innovation within Tunisian enterprises is still primitive. In these conditions, the government has a lot of work to do longer in order to improve investment in research and technology by implementing the spirit of innovation within firms. This is as much realizable as the Tunisian economy could eliminate a number of factors susceptible to foil the development of a special department of R&D within firms. According to the surveyed firms themselves, developing a special structure of R&D within the firm is a very costly organisation which is handicapped mainly by the small size and by the lack of financial resources of Tunisian enterprises. For these reasons, we notice that some Tunisian enterprises have access to R&D outputs from developed countries throughout licenses or subcontracting with foreign firms, hence, they do not require managing local investment in R&D.

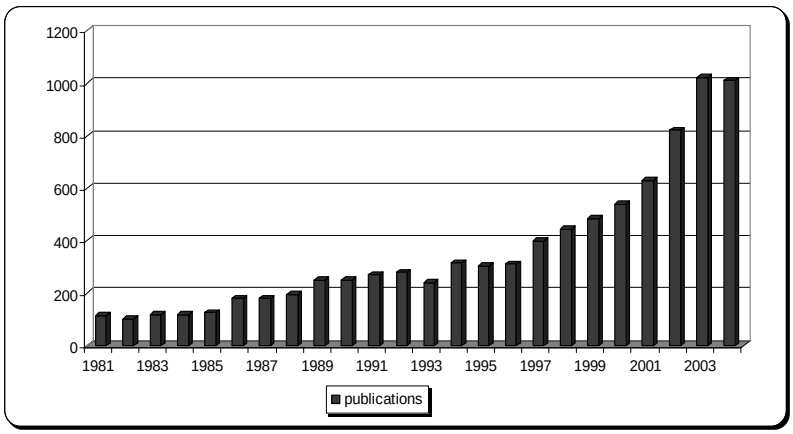
2.3. The Outputs of Pharmaceutical Innovation in Tunisia

The outputs of innovation are measured in general by the number of scientific publications and most of all by the number of patent grants. In fact, according to researchers, patents are considered as the most revealing indicator to measure innovation output. That is why we are going to use data on pharmaceutical publications (2.3.1) as well as data on pharmaceutical patent applications in Tunisia (2.3.2).

2.3.1. Growth Trends in Pharmaceutical Publications in Tunisia

Over the last 25 years, the number of scientific publications in Tunisia has considerably grown up from 115 in 1981 to 1010 in 2004.

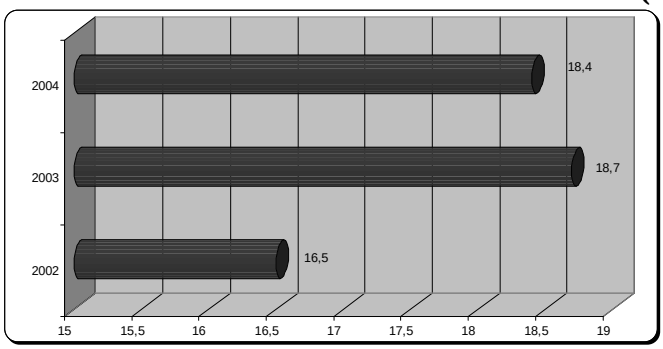
Graph -11- Growth Trends of Scientific Publications in Tunisia (1981- 2004)



Ministry of Higher Education, Scientific Research and Technology, Tunisia (MHESRT, 2006a)

However, we notice some drops in the growth trends of the number of publications. In fact, the graph above shows: a first decrease to 100 scientific publications in 1982 against 115 in 1981; a second one of 14% from 280 in 1992 to 240 in 1993 and lately a third one from 1023 in 2003 to 1010 publications in 2004. On the other hand, the number of pharmaceutical publications has notably risen up from 136 in 2002 to 191 in 2003, which makes a growth of 40% (MHESRT, 2008). As an example, Tunisian employees in the subsidiary of the French laboratory Sanofi Aventis localised in Tunisia succeeded at developing a new drug combined of the Aspégic and the molecule of vitamin C and called it "*Aspégic-Vitamine C*". This represents an important innovation since this new drug is the first to be at 100% designed and produced in Tunisia. This explains that it is going to be exported exclusively from the subsidiary localised in Tunisia (FIPA, 2006). However, the decrease in the total number of publications by the year 2004, has also affected the pharmaceutical domain, since the number has fallen down from 191 in 2003 to 186 pharmaceutical publications in 2004.

Graph -12- Pharmaceutical Publications in Tunisia in % (2002- 2004)



Ministry of Higher Education, Scientific Research and Technology, Tunisia (MHESRT, 2008)

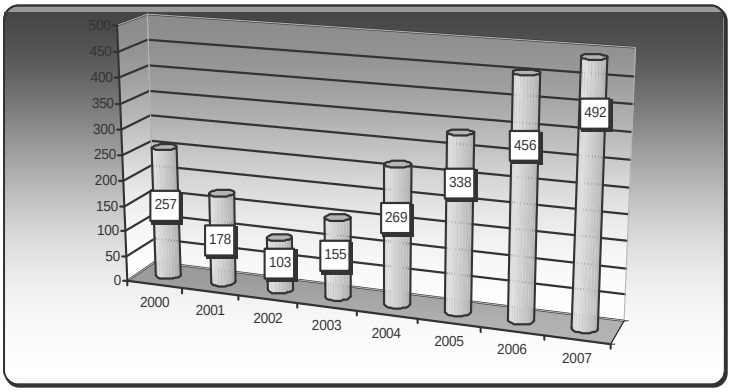
As well as in terms of the total number, the share of pharmaceutical scientific publications (in percentage of the total scientific publications) has grown up, reaching 18,7% in 2003 against 16,5% in 2002, but afterwards, has lightly declined in 2004 to a level of 18,4%. We notice that this decrease happens together with the decline of the number of graduate pharmacy students (from 1280 in 2003 to 1270 in 2004). In addition, according to the MHESRT (2006a) statistics, this decline has been compensated by the increase of the number of publications in other scientific fields between 2003 and 2004, such as social sciences, agriculture and biology and especially engineering, computer science and technology whose share are grown up to 384 in 2004 against 510 publications in 2003.

2.3.2. Pharmaceutical Patents Indicators in Tunisia

Patent applications and patent grants are considered as the major indicator to evaluate a country's potential of innovation. Patents are supposed to be an input as well as an output innovation indicator. On the one hand, patent is used to protect the result of the activity of innovation; it is perceived in this

case as an "output" indicator of innovation. On the other hand, information and knowledge - incorporated in the patent- and revealed once the patent disclosed, will be used as a basis for further researches, either by the patent holder himself or by any other third parties; in this case, the patent is perceived as an "input" indicator of innovation. If we consider here patent statistics as an output indicator of the activity of R&D in Tunisia, we notice that the number of patent applications remains low and more precisely, that the contribution of Tunisian enterprises remains marginal. Over the last eight years, the INNORPI[22] receives an average number of 250 patent applications per year. The following graph shows that the growth trends in patent applications have recorded both ups and downs over the last decade. In fact, the number of patent applications collapsed by 150%: from 257 in 2000 to 103 in 2002, but has recovered from then on, achieving 456 patent applications by the year 2006, which makes a boost rate of 35% with regard to 2005 and of 77% with regard to 2000.

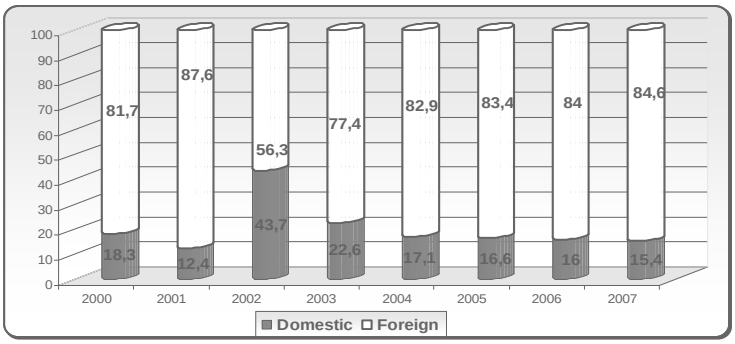
Graph -13- Total Patent Applications in Tunisia (2000- 2006)



INNORPI, Tunisia, 2008.

Another revealing character of patent applications in Tunisia is that most of them are filed by foreign applicants. In fact, from 1984 and 1994, there have been a total number of 1720 patent applications, of which only 285 (16,6%) were filed by domestic enterprises, the other 1435 patents were filed by foreign firms (Visentin, 2005). We notice the same trends from 2000 to 2007.

Graph -14- Growth Trends of Patent Applications by Domestic and Foreign Entities in % (2000- 2006)



INNORPI, Tunisia, 2008.

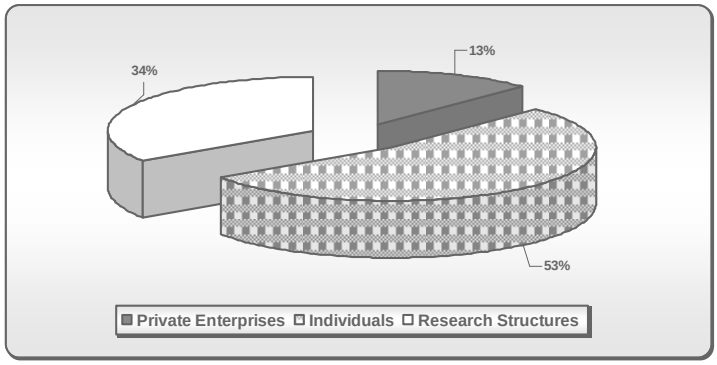
According to the INNORPI data, we notice that the share of foreign patent applications in Tunisia is very important (at an average level of 80%). Although it has declined to a proportion of 56,3% in 2002, it is from then on continuously increasing, reaching 84% in 2006. Besides, even the drop noticed in 2002 is explained more by the decrease of the number of foreign patent applications (a drop of 167% with regard to 2001) rather than by the increase of domestic patent applications (a rise of 104% with regard to 2001). The US firms are the most important patent applicants in Tunisia, representing 27% of the total number of patent applications in 2006. Tunisians are at the second rank with 73 applications (16%), French at the third with 68 patent applications (15%), Swiss at the fourth

[22] Institut National de la Normalisation et de la Propriété Industrielle : National Institute for Standardization and Industrial Property.

with 66 applications (14%), German at the fifth with 34 applications (7,5%) and Italian at the sixth with 20 applications (4,4%). In this framework, patent analysis confirms that the contribution of Tunisians in the activity of innovation remains at a low level, especially among private enterprises. Actually, according to the INNORPI, individuals hold the biggest share of patent applications in Tunisia (53%) of 288 patent applications[23] between 2000 and 2006.

Graph -15- Domestic Patent Applications within Different Types of Applicants

(Total number from 2000 to 2006)



INNORPI, Tunisia, 2008.

This share has reached 60,3% in 2006 while the contribution of private enterprises still stands at 7 patent applications, which makes a share of 9,3%. These figures show that the government should focus more on improving the activity of innovation within private firms. On a scetoral level, over the total number of patent applications in Tunisia between 1984 and 1994, there have been only 297 pharmaceutical patents, representing a share of 17,3%. Only 8 (2,7%) of these 297 pharmaceutical patents were filed by Tunisian enterprises while 289 (97,3%) patent applications were filed by foreign laboratories (INNORPI, 2008). From 1995 to 2001, the number of pharmaceutical patent applications at the INNORPI has grown up to 348 and then to 800 by the end of 2004 (El Kateb, 2005). These applications have been accepted in mail box. The procedures for their grant were postponed to January 2005[24].

Table -4- Pharmaceutical Patent Applications in Tunisia (1984-2001)

Years		**1984-1994**	**1995**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**	**Total number**
Number of applications		297	12	34	52	76	78	63	33	348
Origin of applicants laboratories	USA	-	8%	62%	71%	83%	95%	95%	100%	-
	Sweden	-	33%	15%	10%	10,5%	4%	5%	-	-
	France	-	8%	23%	19%	6,5%	1%	-	-	-
	Germany	-	51%	-	-	-	-	-	-	-

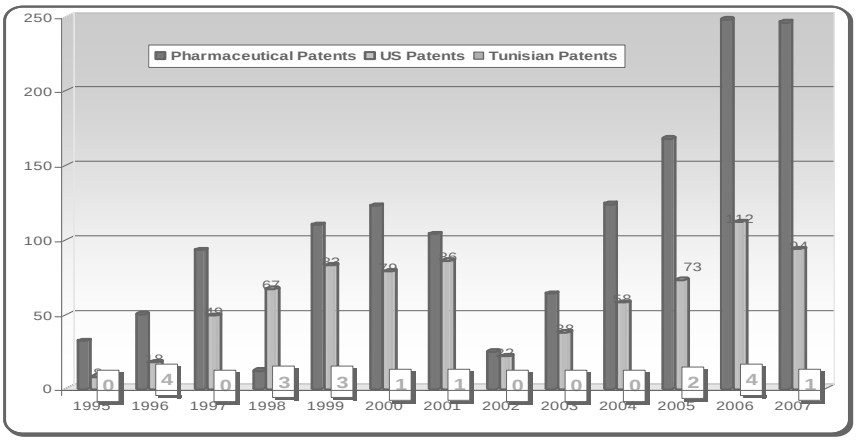
WHO (2003, p107)

As shown in the table 4, German pharmaceutical firms had hold more than 50% of patent applications in Tunisia. However, we notice that since 1996, US pharmaceutical laboratories are holding the main part of patent applications in Tunisia, with more than 60% of a total number of 34 applications, followed by French laboratories with a share of 23%. However, from then on, French laboratories have given up their place to Swedish laboratories whose share has reached 10,5% in 1998 against 6,5% for French pharmaceutical firms. By the year 2001, 100% of the patent applications received by the INNORPI were all filed by US laboratories.

[23] By the end of 2006, 324 domestic patent applications have been recorded in Tunisia. Almost 11% of them (36) are filed by other domestic applicants unidentified by the INNORPI.

[24] The mail box regime was abolished by the expiry of the transitory period granted to Tunisia until January 2005. From then on, pharmaceutical patents Tunisia are granted in accordance with the TRIPs' agreement.

Graph -16- US and Tunisian Pharmaceutical Patent Grants in Tunisia (1995-2007)



INNORPI, Tunisia, 2008.

In fact, we notice a considerable pre-eminence of US pharmaceutical patents granted by the INNORPI (46% in 2006 and 40% in 2007) while the contribution of nationals remain at a marginal level with a maximum number of four patents in 1996, 2001 and 2006 and just one patent granted in 2007.
Again, in addition to the other indicators, the marginal number of Tunisian patents confirms the lack of technological innovation in Tunisia in general and in the pharmaceutical sector in particular. In these conditions, what are the perspectives for growth and innovation in the Tunisian pharmaceutical industry? And what ameliorations should be brought to the pharmaceutical innovation system in order to benefit from patent enforcement?

2.4. Perspectives for Innovation in the Tunisian Pharmaceutical Sector

The incentives for innovation are narrowly related to the market structure. Consequently, the activity of innovation is narrowly connected to patent protection, since patent rights influence the market structure. Although from this point of view the role of patents as an incentive for innovation seems to be obvious, studies on their impact on the activity of innovation reveal controversial results. To explain this ambiguity, Combe & Pfister (2001) argue that innovation depends on several determinant factors (such as the firm's size, financial capabilities, the market concentration and opportunities … etc). Although patent protection is one of the most important of these factors, it is difficult to isolate their effect on innovation. Also, since establishing patent systems remains relatively recent, especially in developing countries, their effects on innovation have not been shown up yet. Indeed, the activity of innovation in a country requires a long-run period to be studied. Empirical studies reveal that patent protection in pharmaceuticals is supposed to be an incentive for innovation in developed countries (Saggi, 2000; Schneider, 2005; Xu&Chiang, 2005; Lévêque, 2006). Nonetheless, in developing countries, where the activity of innovation is handicapped by the lack of production and technologies absorption capabilities, pharmaceutical patents are expected to reduce the innovation through imitation but do not play a major role in promoting technological innovation.

Consequently, in Tunisia -as characterised by limited financial resources, a small market size, insufficient technological capabilities …- it is difficult to found a local pharmaceutical industry that could allow its independence from imports (Yacoub, 2008b). Therefore, with pharmaceutical patents in Tunisia, brand name drugs are expected to become more expensive and thus the accessibility of lower-income consumers will be reduced. At the same time, it is true that Tunisia has promising innovation inputs, especially in terms of human resources, infrastructure and statutory institutional incentives, but the financial obstacle represents, in addition to the centralized structure of the Tunisian innovation system, a major brake that inhibits the development of the activity of innovation.

Table - 5 - Balance-Sheet of Innovation Strengths and Weaknesses in the Tunisian Economy

Strengths	Weaknesses
+ qualified local human resources + local market with a promising potential of production + a good infrastructure especially in terms of telecommunications + an encouraging legal framework for innovation	- passive spirit towards innovation - small local market and firms size - bureaucratic and centralized system - limited financial resources

Source: Yacoub (2008a)

In this context, and on the basis of the inventory of fixtures of the Tunisian innovation capabilities, we can conclude that pharmaceutical patent protection in Tunisia seem to have an insignificant effect on enhancing technological innovation since the brakes for innovation in Tunisia are related to more important factors, the most important of them are the lack of financial resources and some structural deficiencies of the innovation system. On the other hand, it is obvious that Tunisia presents a promising potential of production, especially in the industry of generics and in these conditions, pharmaceutical patent protection "might" be an incentive for minor innovation, in the sense of ameliorating existing drugs and adapting them to the characteristics and needs of the local market, provided that the government proceed at some imperative corrective measures, especially by improving the interactions between the industrial and the educational sectors, by enhancing the research valorisation, by reducing bureaucracy and centralisation, by looking for new alternatives for funding through cooperation programs with foreign investors, … etc. In fact, globally, the main challenge associated to patent rights is to establish a "*fair balance*" between incentives for technological innovation and the dissemination of technologies. Economically, this means that patent protection has to guarantee a sort of a "*trade-off*" between *dynamic* efficiency and *static* efficiency. The establishment of this trade-off remains difficult to reach though (Lévêque & Ménière, 2004). In this context, Tunisian pharmaceutical firms could benefit from the imperfection of patent rights and invest in innovating "*behind*" (related to patent length), "*aside*" (related to patent breadth) or "*above*" (related to patent height) the pharmaceutical patent (Van Dijk, 1994) in order to bring improvement to already existing drugs.

Globally, patent protection in the Tunisian pharmaceutical sector generates differentiated effects, whether we talk about the short or the long term. In the short term, as we have shown, pharmaceutical patents have been associated to a generics-based pharmaceutical industry in Tunisia. As for the long term, the impacts are not perceived yet, but two potential effects are possible: either the same short-term impacts will persist, or by building and developing the local innovation capabilities. In fact, pharmaceutical firms require more important funds than those devoted by the state in order to engage investment in R&D, the results inherent to these researches are not always positive, though. For these reasons, it is true that it seems more workable for Tunisia to focus on the short-term solution; the production of generics and licensed drugs. However, at the same time, the government should keep a long-term vision for improving the Tunisian pharmaceutical industry.

CONCLUDING REMARKS

Strengthening patent rights and their extension to pharmaceuticals in Tunisia were an obligatory step inherent to the entrance to the WTO. However, it is imperative for the country to make this event profitable for the local economy, especially in terms of enhancing the technological innovation. In this context, we restate that the relationship between patent and innovation remains controversial (Laperche, 2004). On the one hand, it is obvious that more improved pharmaceutical patents are expected to increase the attractiveness of the Tunisian economy towards pharmaceutical multinational firms which represent a vector of technology transfer and hence of improving the activity of innovation in Tunisia. On the other hand, due to the insufficient innovation and absorption capabilities in Tunisia, the local firms can not perfectly benefit from this technology transfer. In this sense, the

government should emphasize on improving the intrinsic innovation capabilities within local firms in addition to insisting on the advantages of patents in terms of drawing foreign pharmaceutical investments. In this context, Tunisia has to put more attention on developing its national and pharmaceutical innovation systems, especially by improving the local competences and the interactions between the different actors, not only within and the pharmaceutical sector (laboratories, CPT, medical institutions, …) but also with other actors (public entities, universities, financial institutions, firms in other sectors, …).

In general, Tunisia has indeed put into practice several measures to consolidate its innovation system; the results show that it still needs to retarget its goals though. Taking the special case of the pharmaceutical industry, the Tunisian government has to focus as much on the long-term challenges by improving technological innovation as on the short-term benefits generated by the production of generics. Although generics allow the access of Tunisia to cheaper pharmaceuticals, they still represent a short-term and thus a "defensive" policy against the continuous increase of brand name medicines (Yacoub, 2008a). Nevertheless, certainly in the new international economic context, where innovation and competences development play a major role in economic progress, the government should stress more on encouraging technological innovation. Therefore, Tunisia is called to retarget its pharmaceutical policy towards defining long-term pharmaceutical strategies, especially by developing competences, looking for new alternatives for assuring financial resources, increasing the interactions between universities and the pharmaceutical industry … etc.

This is as much realisable as the government consolidates the national innovation system especially through consolidating the interactions between the different actors. In this purpose, some corrective measures seem to be imperative:

- Puts into place encouraging measures that target the pharmaceutical industry taking into consideration the specific characteristics of the sector which are different from the other manufacturing sectors. In other words, we notice that the programs put into place in order to encourage the innovative firms are not sectorally differentiated. In fact, sectors present very different characteristics; in this sense, a measure which is an incentive for innovation in textile for example, could be insignificant for the pharmaceutical innovation;
- Improves the cooperation between local pharmaceutical enterprises and foreign laboratories, especially in terms of financing and subcontracting;
- Assures more transparency and reduces bureaucracy in order to facilitate access to information and knowledge;
- Encourages pharmacy students to carry out third cycle studies in Tunisia and at the same time allows them to benefit from foreign experiences by assuring exchanging programs with foreign pharmacy students;
- Provides advantages to attract pharmaceutical foreign direct investments in order to benefit from technological transfer;
- Puts into effect a patent regime that stimulates innovation and the diffusion of knowledge and, at the same time, does not affect negatively the objectives of the health policy.

Once these objectives achieved, it would be possible to talk about the eventual positive impacts of patent protection on the pharmaceutical innovation in Tunisia. And to conclude, we highlight that Tunisian pharmaceutical laboratories should not forget that pharmaceuticals remain strategic products which have to be, at the same time: available, affordable and especially high quality products. These particular characteristics of pharmaceuticals increase the challenge for the Tunisian laboratories. To conclude about the legitimacy of pharmaceutical patents in Tunisia, we approve that public policies, the legal and judiciary architecture, financing mechanisms and socioeconomic practices are very the key institutional and environmental determinants of innovation capabilities and R&D activities in a country. In this context, certainly strengthening the patent system is insufficient all alone to kick-start and eventually to promote the local activity of innovation. Nevertheless, it remains an imperative condition that guarantees for potentially innovative enterprises the possibility of preserving their

competitive advantage. Consequently, Tunisia has to adopt a more "*voluntarist*" national innovation system to create incentives for R&D, especially by calling for resources to finance innovation next to foreign institutions, by establishing international partnerships and by targeting and upgrading more the human resources on the social dimension in order to transform the local spirit from an "innovation takers" spirit into an "innovation makers" spirit.

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