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Is Patent Protection an Incentive for Innovation?

Literature and Case Study of the Tunisian Pharmaceutical Industry

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Abstract – The end of the twentieth century has shown profound economic changes, marked by a significant acceleration of technical progress. In this new economic context, increasing the "innovation" rate has become a main component of national economic policies to guarantee the survival of both, firms and countries. This explains the emergence, at the end of the 1980s, of the concept of "National Innovation Systems (NIS)". In addition, strengthening patent rights seems to be particularly connected to innovation since patents are considered as the most convenient tools to protect intellectual property. Nevertheless, the recent wave of establishing and enhancing patent protection worldwide lifts many controversies between developed and developing countries, especially about the impacts of intellectual property rights on innovation. This paper aims at putting the light on these controversies and studying whether patent enforcement is an incentive for innovation. The paper is divided into two main parts. First, we are going to skim through the theoretical and empirical studies that link innovation to patent rights. Second, we will focus the analysis on the evaluation of the role played by patent protection in encouraging pharmaceutical innovation in Tunisia.

Key Words: Intellectual Property Rights (IPRs); Patents; Patent Enforcement; Innovation; Pharmaceuticals; TRIPs[1], Tunisia.

Résumé – La fin du vingtième siècle a enregistré des mutations économiques profondes marquées par une accélération significative du progrès technique. Dans ce nouveau contexte économique, l'accroissement du rythme de « l'innovation » est devenu une composante principale des politiques économiques nationales et ce dans le but d'assurer la survie non seulement des firmes, mais aussi des pays. Ceci explique bien l'émergence, à la fin des années 1980, du concept des « Systèmes Nationaux d'Innovation (SNI) ». Parallèlement, le renforcement des droits de brevets semble particulièrement lié à l'innovation, dans la mesure où les brevets sont considérés comme étant l'outil le plus approprié pour la protection de la propriété intellectuelle. Toutefois, la récente vague mondialement généralisée d'établissement et de renforcement de la protection des brevets, soulève maintes controverses entre les pays développés et ceux en développement, notamment à propos des impacts des droits de la propriété intellectuelle sur l'innovation. L'objectif de ce papier consiste à mettre en lumière ces controverses et à étudier si le renforcement des droits de brevets constitue, en effet, une incitation à l'innovation. Dans cette perspective, le papier s'articule autour de deux principaux axes : dans un premier temps, nous allons effectuer un survol des principaux travaux théoriques et empiriques ayant lié l'innovation aux droits de brevets. Dans un second temps, nous allons

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[1] Trade Related Intellectual Property Rights.

focaliser l'analyse sur l'évaluation du rôle joué par la protection des brevets dans l'incitation à l'innovation pharmaceutique en Tunisie.

Mots clefs : ADPIC[2] ; Droits de Propriété Intellectuelle (DPI) ; Brevets ; Renforcement des Brevets ; Innovation ; Secteur Pharmaceutique; Tunisie.

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[2] Accord sur les Droits de Propriété Intellectuelle qui touchent au Commerce.

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I- Introduction

The last century has been marked by notable economic transformations, characterized by a general movement of globalization and an important acceleration of technical progress. In this context, not only firms but also countries are called or even led to "innovate" in order to respond to the new imperatives of competition and to the continuous changes in consumers' requirements. We notice also the emergence, at the end of the 1980[s], of the concept of "National Innovation Systems (NIS)". As well as the acceleration of the innovation rhythm, intellectual property has shown considerable changes worldwide, especially during the last two decades and it is now at a dynamic stage of transformation. Actually, strengthening patent rights seems to be particularly connected to innovation since patents are considered as the most convenient tools to protect intellectual property.

In fact, since the end of the 1980s, several developing countries such as China, Taiwan and Argentina, have begun establishing and strengthening their Intellectual Property Rights (IPR) systems, partially, due to politic and economic pressures exercised by the United States (USA). In this context, there have been several intellectual property agreements, most of them signed into a free-trade agreements framework **(Smith, 1999)**, such as the North America Free-Trade Agreement (NAFTA) which includes measures that make Mexico adopt and respect intellectual property of US and Canadian firms **(Maskus, 1997; Combe & Pfister, 2001)**. However, the most important fact in the whole history of the evolution of IPRs remains the signature in 1994, of the Trade-Related Intellectual Property Rights (TRIPS) agreement which sets up minimum standards of IPRs to be adopted and respected by all the World Trade Organization (WTO) members[3].

Nevertheless, there are conflicting attitudes toward TRIPS agreement especially between developed and developing countries. On the one hand, IPRs are supposed to create incentives for innovation. On the other hand, intellectual property, especially patent protection creates monopolies allowing patent holders to set high prices and thus, limits access of people in developing and poor countries to patented technologies. According to the economic literature, it seems obvious that enhancing patent protection is in favor of innovators from developed countries but does not take into consideration the interests of poor people in terms of accessibility to some crucial products, such as drugs. The debate about the TRIPS agreement has in fact become more stretched after the extension of patentability to pharmaceuticals. The question has, henceforth, carried a social dimension since dealing with public health.

In this context, for developing countries, such as Tunisia, where almost half of local needs in medicines are assured by patented imports from the European-Union, pharmaceutical patent

[3] "The decision by the WTO's Council for TRIPS extends the transition period for least-developed countries to July 2013. The transition period was due to expire on January, 1st, 2006; eleven years after the TRIPS Agreement came into force. Due to this extension, least developed countries benefit of an additional transition period by seven years and a half to give effect to the provisions of the TRIPs agreement" **(WTO, 2005)**.

enhancement affects significantly access of local patients to treatments and consequently affects public health. Neither theoretical nor empirical literature does provide a clear and generalized framework on the impact of patent enhancement on innovation. Moreover, we notice that very few works have studied the case of the Tunisian economy. Therefore, this paper aims at combining researches on these two issues by studying the impact of patent protection on incentives for innovation in Tunisia and targeting the special case of pharmaceuticals. In other words, the purpose of this study is to bring answers to the following questions:

1- What is the role of patents in the National Innovation System (NIS)?
2- To what extent patent protection is an incentive to innovate?
3- Does the impact of patent protection differ among countries and industries?
4- In the light of patent protection, what are the perspectives for a small developing country such as Tunisia to guarantee access to patented pharmaceuticals?
5- Does the generic based strategy represent an efficient and satisfactory long-run solution to build a "*healthy*" pharmaceutical industry in Tunisia?

To answer these questions, our research is going to be organized in two main parts: First, it seems imperative to go back to the theoretical foundations of the relationship between IPRs and innovation. Then, in a context of National Innovation Systems, we are going to skim through the recent theoretical and empirical literature dealing with the role played by IPRs in creating incentives for innovation. Second, the focus is going to be on the case of the Tunisian pharmaceutical industry. At this stage, the paper aims at studying the status of innovation in Tunisia by analyzing the inputs, throughputs and outputs pharmaceutical innovation indicators.

II- Theoretical Foundations of the Relationship between Patent Protection and Innovation

Before studying the effects of patent rights on innovation, it seems convenient to linger on some preliminary concepts such as the notion of National Innovation Systems (II.1). Intellectual property is very narrowly connected with innovation and constitutes subsequently a main component of the NIS. That is why it is important to linger as well on the theoretical foundations of IPR (II.2), in order to provide a better overview of the impact of patent protection on innovation (II.3).

II.1- National Innovation Systems

Schumpeter (1934) defines innovation as a new combination of resources of production. The **OECD (1994)** gives a more technical definition and interprets that innovation is the transformation of an idea:

- into a new or an improved product introduced on the market;
- or into a new or an improved operational process used in industry or commerce;
- or into a new approach of a social service

This definition shows that innovation results from much more than the simple investment in R&D. In fact, it is the "fruit" of a whole set of human activities which put into interaction the market forces. Functional organizations had to be expected in order to assure this mission. In this context, **Lundvall (1985)** has introduced the concept of the Systems of Innovation, lately extended by **Freeman (1987)** to "National Innovation Systems", defined as "*The network of institutions in the public and private sectors whose activities and interactions initiate, import, modify and diffuse new technologies*". Later, the definition presented by **Lundvall (1992)** describes national innovation systems as "*the elements*

and relationships which interact in the production, diffusion and use of new, and economically useful, knowledge ... and are either located within or rooted inside the borders of a nation state". According to **Dodgson & Bessant (1996)**, these networks are extremely complex and include the financial, educational and the science and technology institutions. In other words, national systems of innovation are the "*set of institutions that (jointly and individually) contribute to the development and diffusion of new technologies. These institutions provide the framework within which governments form and implement policies to influence the innovation process. As such, it is a system of interconnected institutions to create, store, and transfer the knowledge, skills, and artefacts which define new technologies*" **(Metcalfe, 1995)**. In this framework, economists make a distinction between two conceptual versions: "the narrow" and the "broad" definitions of national innovation systems **(Lundvall, 1992; Freeman, 2002; Edquist, 2005)**. As illustrated in the table 1 below, **Freeman (2002)** explains that in the narrow approach, national innovation systems include the institutions which promote the acquisition and diffusion of knowledge and are thus the main sources of innovation.

Table -1- The Broad and the Narrow Versions of National Innovation Systems

Broad definition of the British national innovation system during 18^{th} –19^{th} century	Narrow definition of the national innovation system during the 20^{th} century: "narrow" institutions (sources of innovations)
• Strong links between scientists and entrepreneurs • Science has become a national institution, encouraged by the state and popularised by local clubs • Strong local investment by *landlords* in transport infrastructure (canals and roads, later railways) • Partnership form of organisation enables inventors to raise capital and collaborate with entrepreneurs (e.g. Arkwright/Strutt or Watt/Boulton) • Profits from trade and services available through national and local capital markets to invest in *factory* production and in infrastructure • Economic policy strongly influenced by classical economics and in the interests of industrialisation • Strong efforts to protect national technology and delay catching up by competitors • British productivity per person about twice as high as European average by 1850 • Consulting engineers develop and diffuse best practice technology in waterwheels, canals, machine-making and railways • Part-time training, night school, and apprenticeship training for new factory technicians and engineers • Gradual extension of primary, secondary and tertiary education	• Industrial in-house R&D in all industries, "Big Science and Technology", Research Councils, NSF, etc., Ministries of Science and Technology, Service Industries R&D, Networks

Source: Freeman (2002, p194)

The approaches relative to the OECD adopt the narrow version, by defining the national innovation systems according to five key actors: government, institutions, enterprises, universities and other public and private organizations **(Casadella & Belahcen, 2006)**.

According to the broad approach, these institutions -in spite of being a main part of the national innovation system- are just a component of "*a much wider socio-economic system in which political and cultural influences as well as economic policies help to determine the scale, direction and relative success of all innovative activities*" **(Freeman, 2002, p 194)**.

Either narrow or broad, the national innovation system is completely devoted to guarantee the flows of information among the different institutions of the system in order to help firms developing their knowledge capital, renewing their activities and increasing their production capabilities **(Laperche, 2007; Laperche & Uzunidis, 2007)**. To accomplish this mission, **Laperche & Uzunidis (2007)** affirm that national innovation systems have to respond to the challenges of the growth policy and satisfy to some preliminary conditions. In this context, the government plays a primal role in managing the national innovation system and defining policies that encourage the economy of knowledge. This is as much reachable as the government increases: the number of the institutions of knowledge, the inter-firms cooperation and the cooperation between public and private entities, the financial resources etc. To guarantee the organization, the coherence, the functioning and the evolution of the national innovation system, the government establishes a set of rules which constitute the "*legal framework of accumulation*" such as the rules of competition, the market structure, industrial policy and IPRs **(Laperche & Uzunidis, 2007)**. In this context, government is called to establish a patent system that encourages the dissemination of innovation and allows the re-appropriation of the R&D output.

Does this mean that the strength of the patent system has to be very delicately set or else, it would not provide the expected results in terms of encouraging innovation? In other words, is there a specific dosage of patent strength for each economy? In this case, what is the optimal patent system and how could it be set? And what are the consequences on investment in innovation when the patent system differs from the optimal combination? All these questions are dealt with in the next paragraph.

II.2- Theoretical Foundations of Patent Rights

Although intellectual property has recently been spread worldwide, it is a concept with roots far back in history. Most of economic historians refer to the fifteenth century as the date of birth of the oldest patent system in Venice [4]. Other historians go back in time even further and mention ancient Greece as the origin place of birth of intellectual property, where a one year monopoly right was granted to cooks who had invented new and extraordinary recipes **(Van Dijk, 1994)**. The purpose from this prerogative was to stimulate the cooks' innovative capabilities in Greece either by inventing new recipes or by improving the rewarded ones **(Brinkhof, 1988)**. In spite of its primitiveness, this monopoly right reminds us the current patent systems since they present similar aspects and seek the same objective. At the origin, the term patent stems from the Latin "*Litterae Patentes*" which means "open letters". In this context, open is perceived as "used more than once". In fact, ordinary letters containing special rights were sealed on the outside. Once opened, the seal was broken and subsequently the letter had no more value or use. In opposition to those letters, open letters are sealed on the inside and the special right could thus be used more than once without diminishing its value **(David, 1993)**. Comparatively, the patent right is an "open right" and can be used more than once. Nowadays, patent systems became more sophisticated and the patent is described as an exceptionally exclusive industrial property right that grants to the patent holder a temporary monopoly right, allowing him to prohibit third parties from using his patented invention **(Benlakhdar & Foucault, 2004)**. Nevertheless, third parties could have access to the patented invention if the patent holder decides to concede his patent or a license on his patent in exchange of a return. The patent can even be transmitted as a succession (**Moschini, 2001)**.

[4] On the nineteenth of March, 1474, the first "General Patent Law" was passed by the Venetian Senate (David, 1993).

Since patent right can be conceded and inherited, jurists consider it as just a particular configuration of material property **(Chavanne & Burst, 1998)**. Nevertheless, intellectual property is particularly different in the fact that it deals with immaterial creations which are difficult to protect since their use does not affect their quantity or their value: they are, thus, considered as "*non-rival*" goods, according to the theory developed by **Arrow (1962)**. The concept of *non-rival* goods supposes that a good can be used simultaneously by several consumers without reducing its utility.

With reference to Arrows' definition, knowledge **(Saggi, 2000)** and information **(Lévêque & Ménière, 2004)** are *non-rival goods* since they can be used by several agents at the same time without necessarily interfering with each other's decisions. This does not mean, however, that non-rival goods are transferred across agents at zero cost[5] **(Saggi, 2000)**.

According to **Arrow (1962)**, the concept of non-rival goods stems from the existence of a significant gap between the very high "production cost" of these goods and their neglected "reproduction cost". This gap would have the consequence of a "free riders" behaviour within agents involved in the production and exploitation of non-rival goods. In addition, the expected results inherent to the investment in non-rival goods are always uncertain. Therefore, agents would be discouraged to invest in the production of costly and probably non-profitable goods if there was no reward to their effort and expenditure. In the absence of such rewards, all the agents would be willing to have access to these goods via "reproduction" (almost free) rather than via "production" (very expensive). In other words, in order to acquire at free the output of the investment in information and knowledge production, each firm would not be likely to get engaged the first in this kind of activity[6] **(Coriat & Orsi, 2003)**. In this case, it is not possible to reach an optimal allocation of production factors. Subsequently, there would be an underinvestment in knowledge production **(Arrow, 1962; Coriat & Orsi, 2003; Depret & Hamdouch, 2004)**. It is therefore imperative to avoid these market failures by setting special mechanisms that would encourage people to invest in knowledge production. **Arrow (1962)** has called these mechanisms as "*institutional arrangements*". Three types of institutional arrangements are distinguished here:

i- Research and knowledge production could be financed by public establishments and the output of this activity will be the basic groundwork for private scientific researches **(Duguet & Lelarge, 2004)**.

ii- Governments can reduce the high costs associated to investment in R&D by taking some arrangements such as: granting public subsidies to the investors in R&D **(Coriat & Orsi, 2003; Duguet & Lelarge, 2004; David, Hall & Toole, 2000)**; encouraging cooperation in R&D **(Duguet & Lelarge, 2004)** or also granting fiscal favours in order to help investors covering totally or partially their expenses in R&D **(Coriat & Orsi, 2003 ; Duguet & Lelarge, 2004 ; Hall & Van Reenen, 2000)**.

iii- In order to encourage private investment in R&D, governments generally make appeal to IPRs **(Duguet & Lelarge, 2004)**. In fact, "*Intellectual property rights are the first tools that come in mind when dealing with the protection of enterprise's knowledge capital*" **(Laperche, 2007, 31)**. Economists affirm that the other arrangements, such as subsidies to R&D, are indeed efficient but they remain more difficult to set than a patent system **(Van Dijk, 1994)**. Most of economists believe, in fact, that patent rights are the most appropriate mechanism to protect non-rival goods **(Van Dijk, 1994)**. Subsequently, they are considered

[5] If this was true, "*the room for policy intervention with respect to international assimilation of technology would be severely limited since any technology transfer that would yield even a minutely positive return to any agent would take place automatically*" **(Saggi, 2000)**.

[6] This sentence is a translation from the original French version of Coriat and Orsi's paper « *afin de bénéficier à titre gratuit des investissements effectués dans la production des informations et connaissances, il est de l'intérêt de chaque firme, à son propre niveau, de ne pas s'engager la première dans ce type d'activité* », **(Coriat et Orsi, 2003, p156).**

as the most suitable institutional arrangement that allows avoiding the market failures inherent to the investment and the dissimulation of non-rival goods **(Coriat & Orsi, 2003).**

Hence, the specific characteristics of the non-rival goods are the main theoretical foundations of the emergence and the development of patent rights, not only to encourage research and knowledge production, but also to encourage the dissimulation of the output of investments in R&D and knowledge **(Depret & Hamdouch, 2004)**. Patents allow patent holders to transform their "knowledge" into "rights" **(Wang, 2004)** and consequently they can get back, even partially, the expenses -sometimes huge- they have spent in R&D **(Fai, 2005)**.

However, it is obvious that patent enhancement lifts up several controversies. On the one hand, patent rights are an incentive for innovation. On the other hand, they lead to market inefficiency due to the monopoly right granted to patent holders. The next paragraph deals with the effect of patent protection on innovation and aims at studying the advantages and the disadvantages of patent rights for both inventors and third parties.

II.3- Advantages and Drawbacks of Patent Protection for Innovation

Studies on the impact of patent protection on 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.

II.3.1- Patent Rights as an Incentive for Innovation

We restate that studies on the implications of patent protection for the activity of innovation reveal controversial results. Some of these studies show that patent rights have played a major role in encouraging innovation in biotechnologies **(Benlakhdar & Foucault, 2004)**. In their study, **Allred & Park (2007)** have led a survey with 706 manufacturing firms in 29 countries. The results lead up to a significantly positive relationship between patent protection and the motivation of firms to invest in innovation. However, the impact is differentiated among industries. It is found to be more significant for innovation in chemicals and scientific equipments. In fact, while centralised management instruments of innovation reveal problems related to information and administration, patents represent a non-centralised management instrument that allows inventors recovering their expenses on the one hand, and having access to each other's invention on the other hand and subsequently, encourages innovation **(Lévêque, 2006)**.

Nevertheless, many economists minimize the role played by patents as an incentive for innovation. Others notice that the impact depends on the patent characteristics themselves. In this context, **Nordhaus (1969)** was the first to study the impact of patent *length* on innovation. He shows that longer patent protection induces a higher motivation to invest in R&D because the expected returns are higher. The incentive for innovation is as much higher as the patent lifetime is longer, as the R&D costs are important and as the market demand is elastic **(Nordaus, 1969; Schmutzler, 2006)**. Shall we notice, however, that in his study, **Nordhaus (1969)** assumes that the patent provides a perfect protection from competition. This differs from the reality, though, where patents could not exclude totally the entry of imitators to the market. In addition to patent length, patent breadth plays an important role in encouraging innovation. For example, as well as **Gilbert & Shapiro (1990)**, **Yiannaka & Fulton (2006)** suggest that "narrower" patents provide stronger protection. Considering

both of patent dimensions and in opposition with **Gallini (1992)**, **Maurer & Scotchmer (1998)** assert that optimal protection is provided by both, "longer" and "narrower" patents.

In contradiction to these analyses, other studies lead up to different results, showing that patent protection is not always an incentive for innovation.

II.3.2- Patent Rights as a Brake to Innovation

The high costs related to patent application, maintain and bureaucracy, makes patent system too costly and even "*unattractive*" **(Van Dijk, 1994)**. Sometimes, the patent rewards are lower than its costs, especially if the invention is not -or any more- interesting for the consumers; for example because of the entry of substitutes. In this case, the inventor assumes losses and is led to suspend his patent duration. This is translated by an effective patent lifetime inferior to its legal lifetime **(Van Dijk, 1994)**. Also, in the case of patent infringement, the costs of court and lawyers are very important, especially in the USA, where they apply the contentious procedures. In Europe and Japan, patent holders make appeal rather to opposition procedures which are relatively less costly than contentious procedures but remain expensive also **(Benlakhdar & Foucault, 2004)**.

In addition to high costs, patents do not provide perfect protection from the competitors since the competition is transferred and becomes more acerbic upstream from patent application; this is what we call "*patent race*" **(Le Bas, 2002)**. In this context, patent rights are imperfect since they could not hinder competitors from inventing "*behind*" (related to patent length), "*aside*" (related to patent breadth) or "*above*" (related to patent height) the patent **(Van Dijk, 1994)**.

However, the most important factor that could let patent rights dissuasive to inventors is the case of cumulative innovation. In fact, manufacturing a composite good that requires many patented components could pose problems to the inventor due to the risk of infringing the other patents. In this case, the question that seems obvious is whether reward should be granted to the inventor of the first innovation? Of the second one? Or shared between all the involved inventors? **(Lévêque, 2006).**

Many recent studies reveal that the impact of patent protection on innovation differs among countries and industries and thus it stems from a purely empirical framework which explains the ambiguity inherent to the theoretical analyses.

II.3.3- The Impact of Patents on Innovation: A Brief Review of Literature

Innovations in the southern countries are generally based on the imitation of the northern technologies. Therefore, patent enhancement will lead to a collapse of the innovation rate in developing countries. Basing her research on a gravity econometric model, **Schneider (2005)** confirms empirically this result. The author includes 28 developing countries in a total sample of 47 countries. The analysis reveals that stronger patent rights induce a statistically significant higher innovation rate in developed countries but in developing ones the coefficient associated to patent protection is "negative", confirming that patent enforcement hinders innovation in southern countries. Hence, patent enforcement protects northern firms at the expense of southern ones.

According to **Helpman (1993)**, patent protection has a negative effect even on developed countries. On the basis of a theoretical model, the author assumes that only northern firms are able to innovate and thus they are going to increase their investment in R&D to serve, not only their own markets, but -due to the elimination of imitation in the South- also southern markets. In this case, northern countries will suffer from an "*overinvestment*" **(Helpman, 1993; Fink & Primo-Braga, 1998)** and thus from inflation in production factors, which will lead to a degeneration of the innovation rate in developed countries **(Helpman, 1993; Saggi, 2000; Moschini, 2001)**. However, **Combe & Pfister (2001)** and

Lai (1998) minimize the impact of patents on the prices of production factors showing that in this case, northern firm could make appeal to foreign direct investments in order to benefit from lower production costs. On the basis on this argument, **Combe & Pfister (2001)** confirm the theory of **Helpman (1993)** but only in the short-run, where patents induce market distortions that will be covered by the long-run gains in both developed and developing countries.

Conversely, in reality it seems difficult for developing countries to cover the short-run effects of patent enforcement, even in the long-run, since patent enhancement will hinder the accessibility of southern firm to northern innovations due to the imposed monopoly right and the increase of their prices. In other words, in a context of patent protection, private benefit generally exceeds social benefit.

Globally, the main challenge associated to patent rights is to establish a fair "*balance*" between incentives for innovation and the dissimulation of inventions. Economically, this means that patent protection has to achieve a "*trade-off*" between *dynamic* efficiency and *static* efficiency. The establishment of this trade-off seems difficult to reach, though **(Lévêque & Ménière, 2004)**.

Since the role of patent enhancement differs among countries and industries, it seems more interesting to focus our study on the effects of patent protection on innovation in a particular industry and in a particular country. Our focus is going to be on the pharmaceutical innovation in Tunisia.

III- The Effects of Patent Protection on Pharmaceutical Innovation in Tunisia

We restate that patent rights represent just a factor among many others influencing the activity of innovation. Therefore, we should first study the situation of the Tunisian pharmaceutical industry independently from patent rights (III.1). Second, we will analyze the innovation capabilities in Tunisia by studying the fundamental innovation indicators, especially those in the pharmaceutical industry (III.2). Finally, we will focus the study on the perspectives of patent protection for the pharmaceutical industry in Tunisia before and after the entry into effect of the TRIPs agreement (III.3).

III.1- An Overview on the Tunisian Pharmaceutical Industry

The pharmaceutical industry in Tunisia is led by a strong public sector which has been dynamically developed by the state since the early 1960s. The private sector is also relatively active and represents the main distribution network of pharmaceuticals in Tunisia **(WHO[7], 2003)**.

In 1987, less than 8% of the total pharmaceutical consumption in Tunisia was covered by local production. In the 1990s, we notice a considerable increase of the national contribution in drugs production, achieving 44% in 1999 **(WHO, 2003)**. This increase is explained especially by the expansion of the local production of pharmaceuticals to the private sector. In spite of the development of the private sector, imports of pharmaceuticals are still assured, *exclusively*, by two public establishments: the Central Pharmacy of Tunisia, which imports general pharmaceuticals and the Pasteur Institute of Tunis which has the monopole to import vaccines, serums and allergens[8] (and other biological products) **(WHO, 2003)**. Monopolizing pharmaceutical imports inside the public

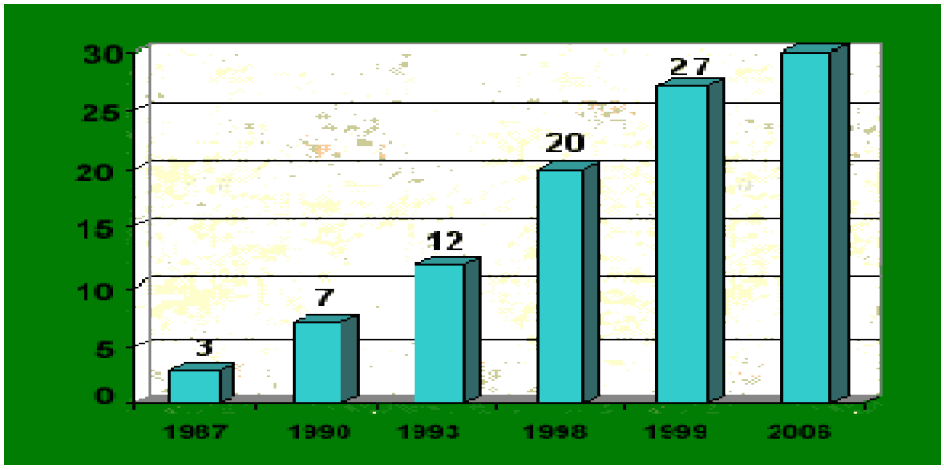
[7] World Health Organization

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

sector stems from an economic policy that aims at a better control of imported products. This measure has been confirmed especially after the discovery of the virus of hepatitis C in a stock of blood imported from France **(WHO, 2003)**.

Recently, the pharmaceutical industry in Tunisia is at a dynamic stage of progress. This is shown by an annual average growth rate of 13% against a world rate set at 7%. In fact, by 2006, 50% of the market needs in pharmaceuticals are covered by the local production. The other 50% are satisfied by imports, especially from France with a part of 70% of total Tunisian pharmaceutical imports **(MPH[9], 2008)**.

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



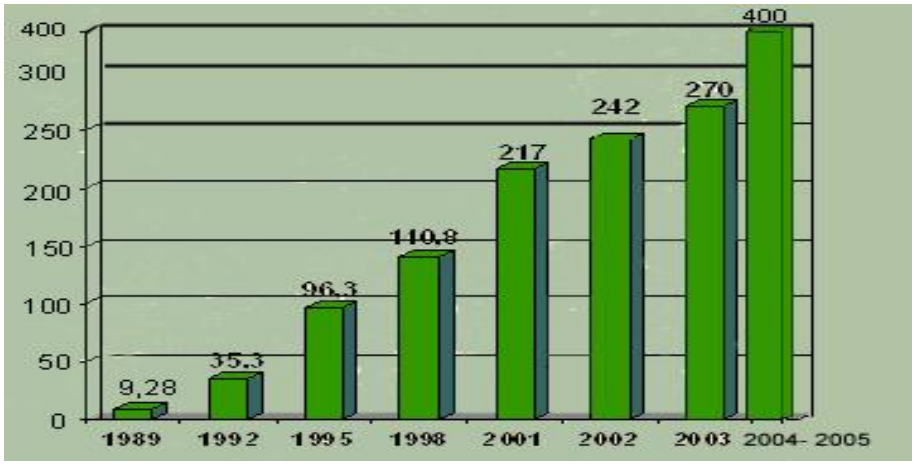
Ministry of Public Health, 2008

As shown in the graph above, the current pharmaceutical industry in Tunisia is represented by 30 pharmaceutical laboratories[10]: two national public firms (SIPHAT and the Pasteur Institute), five foreign subsidiaries of international groups and 23 national private enterprises **(DEC, 2008)**. Among the five foreign subsidiaries, the most important pharmaceutical production units in Tunisia are Pfizer, Sanofi Aventis and Pierre Fabre **(DEC, 2007)**.

The foreign direct investments led by these multinational firms in Tunisia, have notably revivified the Tunisian pharmaceutical industry. The graph below describes the growth trends of the total investment in the pharmaceutical industry in Tunisia which has considerably grown up: from 9,28 million TND in 1989 up to 400 million TND in 2005. This growth is translated by an approximate multiplication by 43 over the last twenty years.

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

[9] Ministry of Public Health of Tunisia
[10] In 2008, the number of pharmaceutical firms in Tunisia still sets up to 30.



Ministry of Public Health, 2008

Lately, public health expenses have significantly grown up in Tunisia; according to the WTO report, they have noted a multiplication by 2,3 over the last decade **(DEC, 2008)**. At the same time, due to the continuous increase of carburant prices worldwide, on the one hand and to the appreciation of the euro on the other, a limited financial resources country such as Tunisia is in front of a big challenge about how to assure the access of Tunisian consumers to essential products, especially those which are vital to preserve public health such as pharmaceuticals. In order to answer to this challenge, the government encourages the development of the industry of generics. Nowadays, generics represent 51% of the local production in Tunisia, while 49% are assured by production of licensed pharmaceuticals **(DEC, 2008)**. The generics based health policy, has drawn the attention of foreign investors to the high potential of the Tunisian pharmaceutical industry in this field. Therefore, several foreign laboratories, which are world experts in generics production, are 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, 2007a)**.

Another explanation for the generics based policy is that the production of generic drugs allows Tunisia not only to control costs and thus health expenses, but also it allows the development of Tunisian pharmaceutical exports. In addition, the Tunisian economic policy encourages the production of generics as an alternative to avoid or at least minimize the dependency (inherent to licenses) towards foreign firms. In fact, in opposition to generics, production 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. This affects as much local consumers (due to the increase of prices) as the state itself (due to a bigger loss of currencies).

ii- The licensee can not export even a part of 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 the retrieve. Therefore, the local production depends always on the owner's strategy and remains thus insecure from the licensee's point of view.

Although generics production presents many advantages for a developing country such as Tunisia, it remains a short-run solution. In other words, a pharmaceutical industry based on production of generics depends on innovation of foreign pharmaceutical laboratories. In these conditions, local firms have to wait until the patent expiry so that they could produce the generic counterpart of the brand name product. The period between the date of the diffusion of the patented drug and the date of patent

expiry could be described as a period of "*inertia*" for the national laboratories and induces dead losses translated by complications, even deaths of patients deprived from drugs against some fatal diseases such as cancer or Aids.

The next paragraph of our paper aims at studying the innovation potential of the Tunisian economy. The question that we are trying to answer at, deals with the reasons that prevent the Tunisian pharmaceutical industry from innovating and thus from developing its own brand name pharmaceuticals.

III.2- The Pharmaceutical Innovation Indicators in Tunisia

To analyze the innovation indicators in Tunisia, we are going to study the inputs (III.2.1), the throughputs (III.2.2) and the outputs (III.2.3) of the activity of innovation. We identify the innovation indicators with reference to the results of the analysis led by **Hertog & Brouwer (2000)**.

III.2.1- The Inputs of Pharmaceutical Innovation in Tunisia

To measure inputs of innovation, we will take into consideration the main key indicators such as R&D expenditures (in % of GDP), tertiary school enrollment, infrastructure equipments (transport, telecommunications …) and statutory incentives (institutions and advantages that assist innovative firms …). All these indicators are studied with reference to the pharmaceutical sector.

III.2.1.1- The Key Inputs of Innovation: Human Resources

The development of the activity of innovation could not take place in the absence of a sufficiently qualified workforce. Since education is considered, according to **Lucas (1988)**, as the main factor of knowledge acquisition and accumulation, it is extremely imperative to study the characteristics of pharmacy education in Tunisia.

The faculty of Monastir is the only pharmacy faculty in Tunisia. Since it has been established in 1975, the number of students has been 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 pharmacy graduate students on the waiting list[11] is continuously increasing due to the market saturation in pharmacies **(MPH, 2008)**.

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

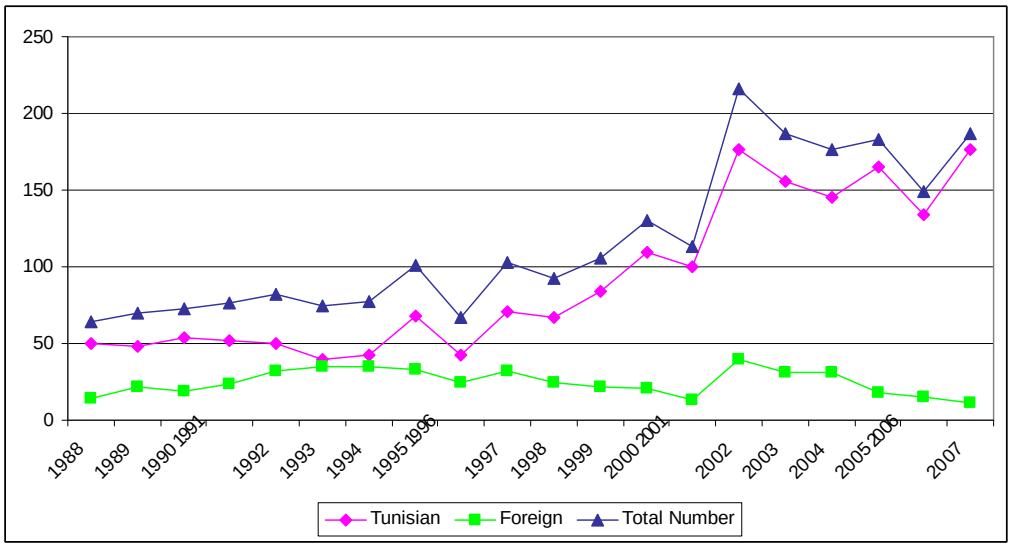
Scholar Year	1987/88	92/93	97/98	99/00	00/01	01/02	02/03	03/04	04/05	05/06	06/07
Students	595	693	852	1144	1220	1281	1280	1270	1364	1399	1436

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

[11] They are waiting for the agreement of the public health ministry that allows them to establish their own pharmacies.

The pharmacy faculty of Monastir is not only the sole pharmacy faculty in Tunisia, but it also gives the best specialized pharmaceutical formation comparing with other pharmacy faculties in the Arab Maghreb Union[12] and the Middle East **(MPH, 2008)**. This is confirmed by the important number of foreign pharmacy students in Tunisia. In fact, this number has risen to 35 in 1997 as well as in 1998 and achieved 40 students in 2002. As shown in the graph below, this number is lately decreasing, though, reaching a number of only 11 students in the scholar year 2006-2007. This number is even lower than the number recorded in 1987-1988 (14 foreign graduated students). Nonetheless, by the current year (2007-2008), the number of foreign pharmacy students has totally upturned the decrease tendency noticed over the past five years, recording 60 foreign students **(MHERST, 2008)**.

Graph -3- Graduate Pharmacy Students (1988-2007)

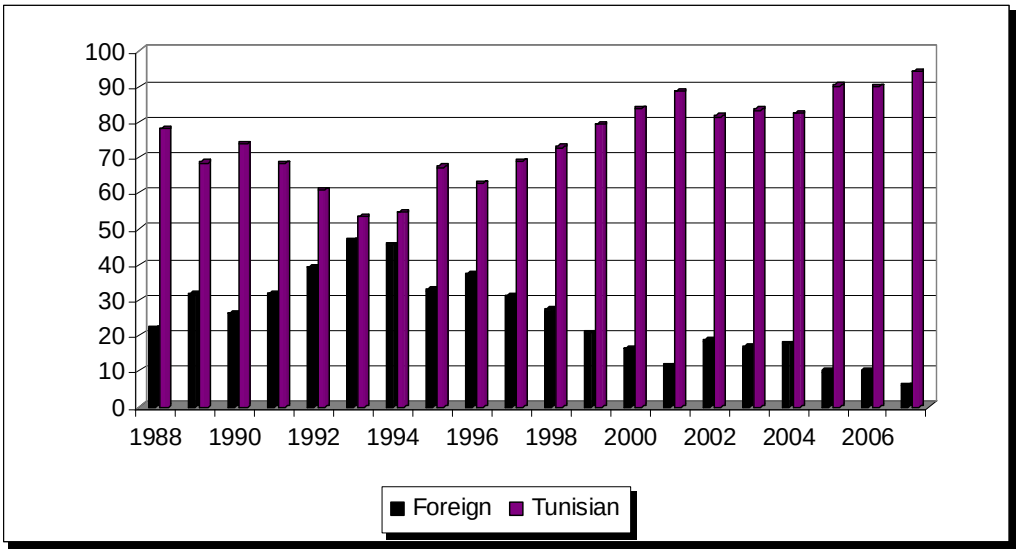


Ministry of Higher Education, Scientific Research and Technology (MHESRT), Tunisia, 2008

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 else 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 by 61% of Tunisian pharmacy students between 2003 and 2007, and a decrease by 35% in the number of foreign students over the same period.

[12] The Arab Maghreb Union includes the five countries of North Africa: Algeria, Libya, Mauritania, Morocco and Tunisia.

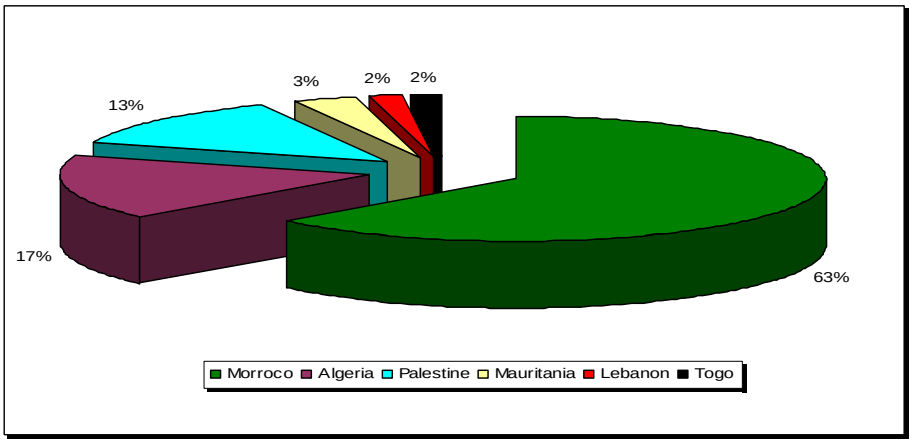
Graph -4- Tunisian and Foreign Pharmacy Students in Tunisia (in %) (1988-2007)



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

Foreign pharmacy students are unequally distributed in terms of nationalities. In fact, during the current scholar year (2007-2008), 60 students from six different African and Middle Eastern countries have been subscribed at the faculty of pharmacy of Monastir. More than half of these students - precisely 63%- are Moroccan. At the second rank, we record ten Algerian students representing 17% of the total number. Third, there are eight Palestinian students subscribed in the pharmacy faculty of Monastir by this year, which correspond to a proportion of 13%. The last 7% is represented by two Mauritanian students (3%), one Lebanese (2%) and one Togolese (2%).

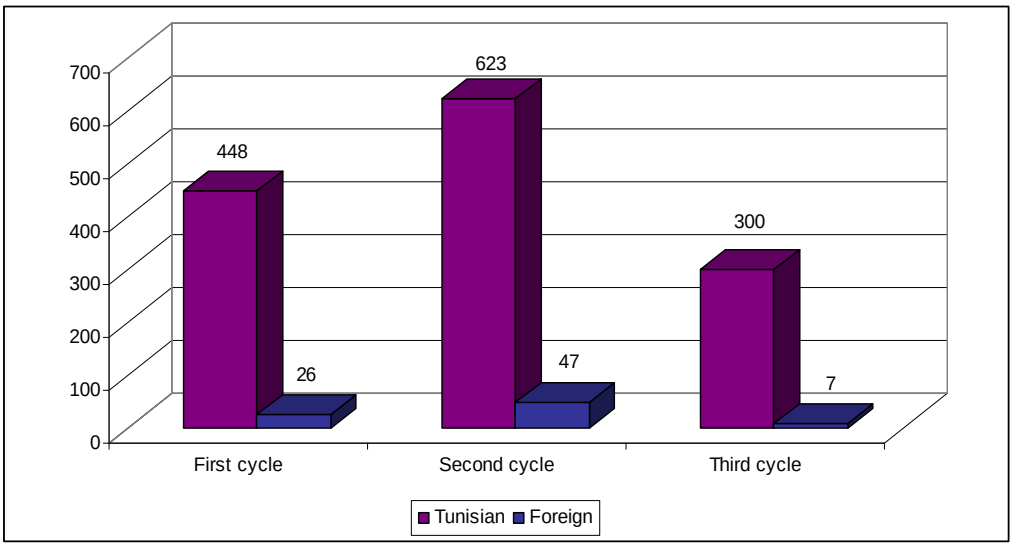
Graph -5- Distribution of Foreign Pharmacy Students in Tunisia by Nationality (2007-2008)



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

Since the establishment of the pharmacy faculty of Monastir, the number of Tunisian pharmacists is constantly increasing (from 1726 in 1990 to 2500 in 2001 and 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.

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)**.

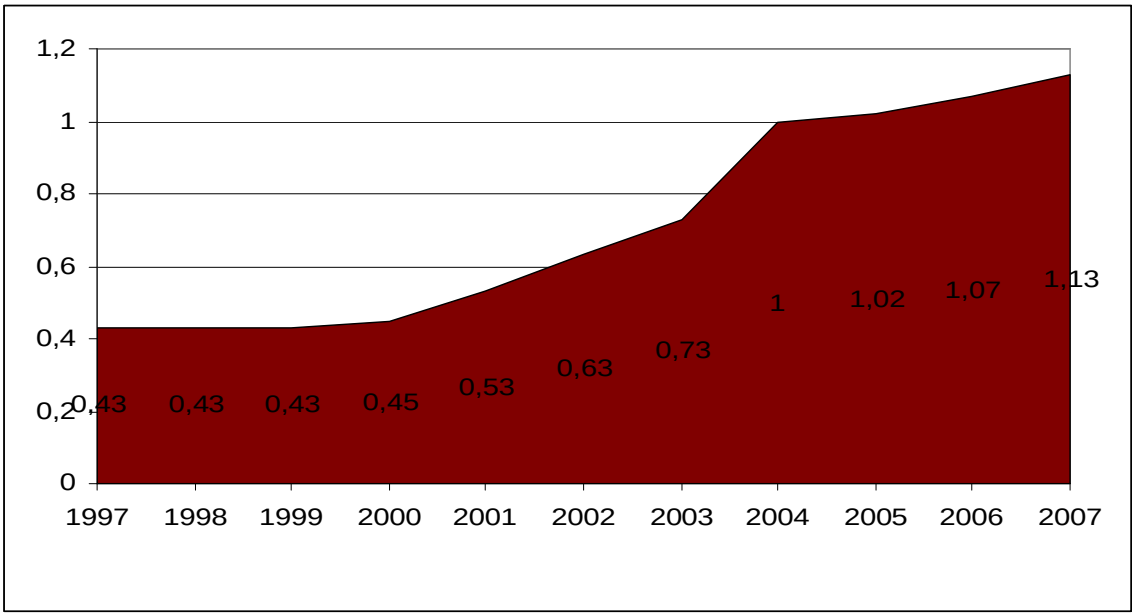
III.2.1.2- Financial Resources

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[13] in Percentage of GDP in Tunisia (1997-2007[14])

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

[14] 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)**.

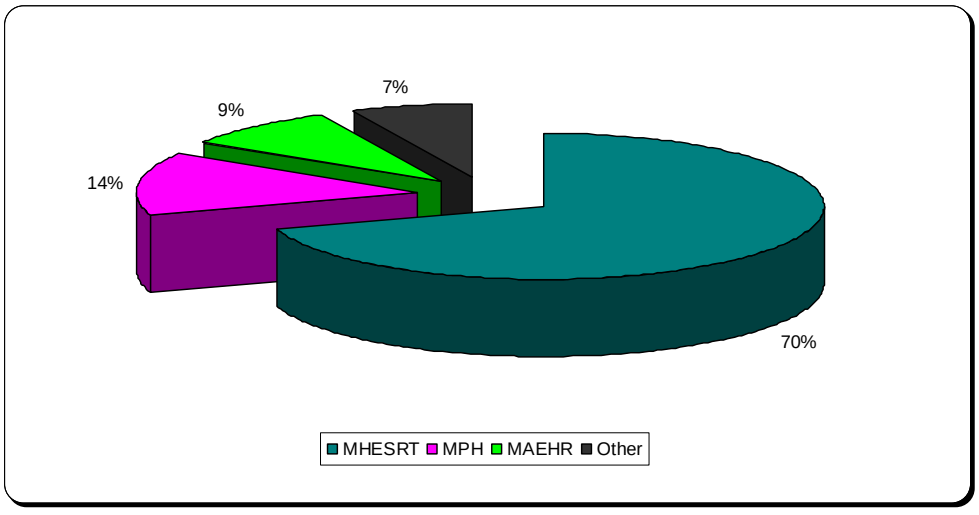


Ministry of Higher Education, Scientific Research and Technology, Tunisia,(MHESRT, 2006b)

As shown in the graph 7, 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 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 are obligated 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 8, 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)

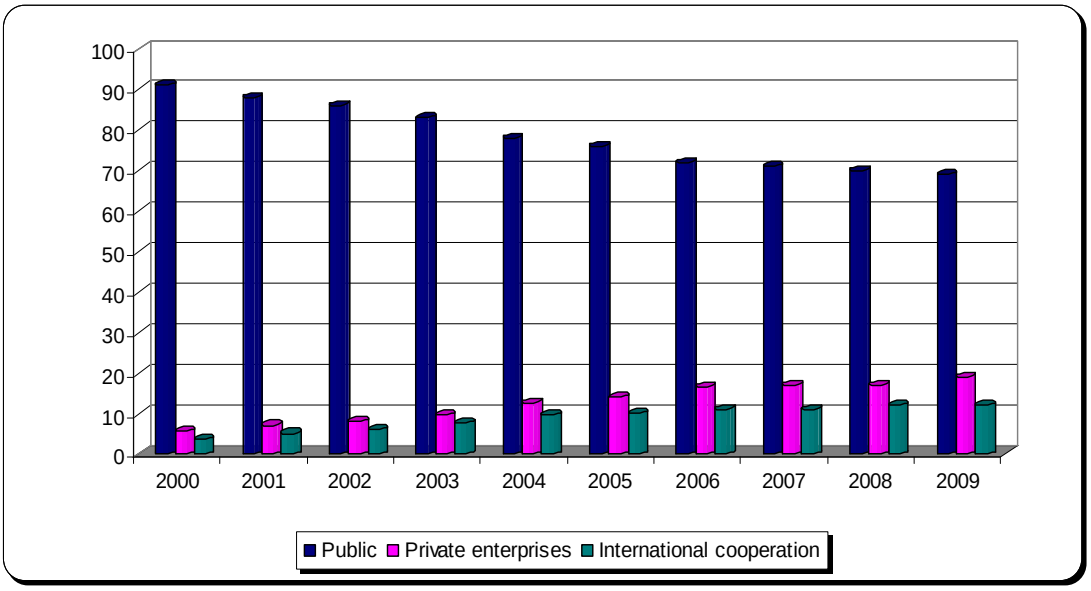


MHERST: Ministry of Higher Education, Scientific Research and Technology;
MPH: Ministry of Public Health;
MAEHR: Ministry of Agriculture, Environment and Hydraulic Resources.

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

We notice that the Tunisian government focuses much more on the academic R&D with a share of 70% of the funding 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 R&D activity, with a part of 91% in 2000 (graph 9). 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 9 describes the distribution of the IERD per financing source.

Graph -9- Distribution of IERD per Financing Source in % (2000-2006[15])



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 local pharmaceutical innovation. Therefore, we can 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, some pharmaceutical multinationals dedicate about 15% of their turnovers to be reinvested 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 …) are generally very expensive. In addition, for security reasons[16], a number of developing countries are deprived of some chemical substances considered as dangerous. Subsequently, we restate that the best pharmaceutical researchers are more willing to immigrate to developed countries. This tendency, called "*brains immigration*", contributes towards a sort of "*impoverishment*" in local human resources and brakes more and more the activity of innovation in developing countries.

III.2.1.3- <u>An overview on the Tunisian Infrastructure</u>

[15] The values from 2007 to 2009 are predicted figures by MHESRT (2006b).
[16] 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.

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: it is at two hours of flight far from Paris, 45 minutes far from Rome, two hours and 35 minutes far from Frankfurt, Brussels and London, three hours far from Cairo and nearly five hours far from Jeddah. Indeed, thanks to its strategic site, Tunisia represents a real platform as much for investment as for trade and production, which facilitates the exchanges in terms of raw materials and products **(MDIC[17], 2008)**.

In the context of logistics, the government assures:

i- A large road network over 19000 km and a highway network over 360 km in 2008[18].
ii- A railway network extended over 2168 km.
iii- 8 commercial ports and 7 international airports[19].

As well as the transport infrastructure, the telecommunication sector seems to record an important development **(MCT[20], 2008)**. In fact, Tunisia disposes of

i- A phone network that allows access to more than 170 countries;

ii- A telecommunications network, which one of the most modern networks in the Mediterranean Basin, composed of seven knots at the national level, equipped with high-speed multi-service switches integrating telephone traffic, Internet traffic and multimedia. This network will be extended into the regions through regional networks adapted and designed to bring closer services to urban areas and to the main sites of activity;

iii- A fully digitalized telephone network covering 100% of the national territory;

iv- There are two mobile telephone network operators: “Tunisie Telecom” and “Tunisiana”;

v- Rural telephony: WLL and MobiRif technology operating according to GSM standard;

vi- Two international gateways; sub-marine cable and digital spatial links;

vii- 11350 public telecommunication centers in all the regions of the country;

Graph -10- Growth Trends in Phone Density per 100 habitants in Tunisia (1992- February 2008)

[17] Ministry of Development and International Cooperation of Tunisia.
[18] These figures are satisfactory relatively to the small area occupied by Tunisia: 163 610 squared kilometers, of which 8,250 are water.
[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 Communication Technologies of Tunisia.

Ministry of Communication Technologies, Tunisia, 2008

viii- An internet network covering all the country, accessible through 12 Internet Service Providers (ISPs) (7 public and 5 private), with an international pass band having a capacity of 750 Mbits/s at the end of 2005;

ix- The use of the new technology "voice over IP";

x- A data transmission network using various technologies (LS, ADSL, Frame Relay, Vsat…);

xi- At the end of 2007 there were: 1,257 million subscribers to the fixed telephone service; 5,681 million subscribers to the mobile telephone service;

xii- The total -cellular and fixed- phone density per 100 habitants was of 4,6 in 1992, has risen to 7,2 in 1997, then to 17,6 in 2002, after that to 68,8 in 2005 to reach almost 100 in 2007 and 102,4 in February 2008 (Graph 10);

All these measures stems from a national policy that aims at improving the society of knowledge in Tunisia in order to guarantee an instant access to information from all over the world and the dissemination of the digital culture within Tunisians. In this purpose and, in addition to the previous measures, the government has put into effect other encouraging processes in order to facilitate the use of technologies:

i- The presidential "family computer program, launched in April 2001, has allowed modest-income families to benefit from specific advantageous modalities. At the end of 2004, the number of computers purchased as part of this program amounted to 42.520;

ii- Tunisian families benefit from a monthly subscription to the Internet with an amount of 10 TND. This amount includes the subscription costs and offers free 15-hours navigation;

iii- The national center of computer for children (CNIPE) and the regional centers of computer for children (CRIPEs) offered training to 88.000 children during the period 2002-2004. Online training and registration services are being established;

iv- A computer center for disabled children, and other spaces intended for this social category, are gradually being created within the CRIPEs. In 2004, they offered training in computer science and multimedia to 1.000 children;

v- The mobile computer laboratory: during the period 2002-2004, 22.400 participants benefited from action of sensitization to computer culture;

vi- The special Internet bus visited, during the period 2002-2004, more than 170 institutions, offering services to more than 10.000 beneficiaries.

All these measures aim at implementing the technology and computer culture within Tunisians and at facilitating the access to information; crucial input for the activity of research and innovation. In addition to these measures, others statutory incentives have been put into effect in order to promote innovation in Tunisia.

III.2.1.4- The Government's Incentives for Innovation

Among the measures taken by the government in order to enhance innovation in Tunisia, the department of scientific research and technology of the MHESRT has organized, since 2003, a sort of cooperation between the local and the Tunisian immigrant researchers. This cooperation amounts to the organization of projects financed by the MHESRT commonly developed by the local and the immigrant researchers. 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)**.

Other encouraging measures taken by the Tunisian government are targeting specifically the pharmaceutical industry in three main corners **(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[21] 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 the tenth of September 1996, the cooperation between pharmaceutical laboratories and the optimisation of production capabilities have been made possible since the authorization to subcontracting between laboratories.

III.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.

[21] Value Added Tax.

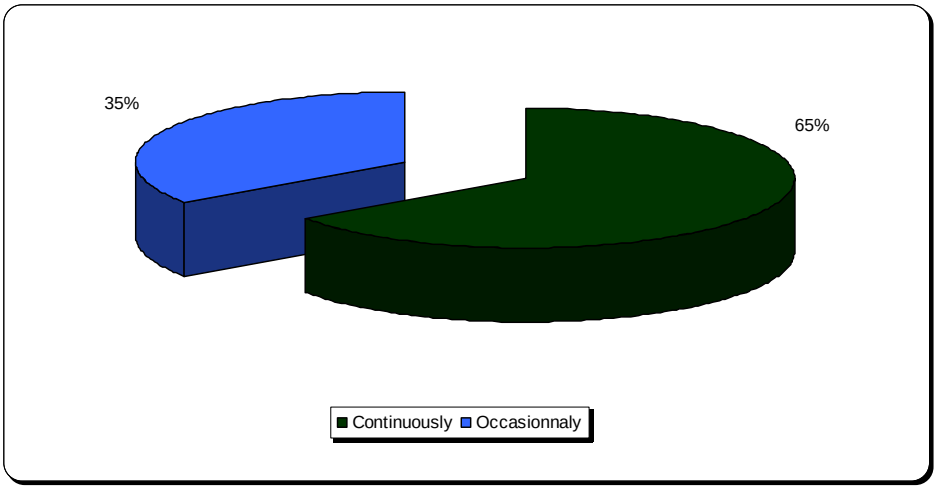
Table -3- Distribution of Enterprises in terms of Activity of R&D (2002-2004)

	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)

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.

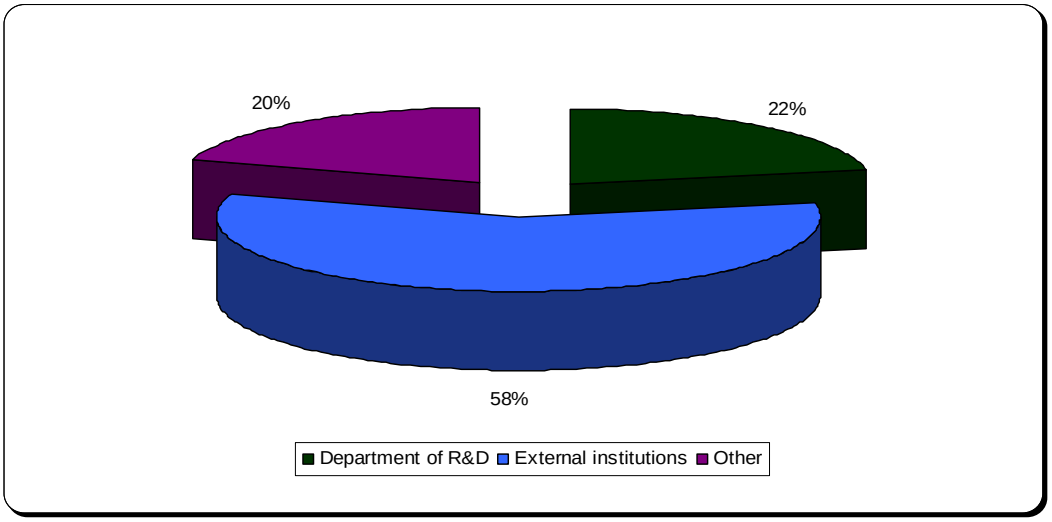
Graph -11- Distribution of Enterprises having an Activity of R&D (2002- 2004)



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

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 -12- The Organisational Structure of R&D within Tunisian 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. These factors have been enumerated by the surveyed firms themselves as follows:

i- The small size of Tunisian enterprises and the Tunisian market are a handicap to the development of a special structure of R&D within firms;

ii- The implementation of a special department of R&D within the firm is very costly, those costs could not be afforded due to the limited financial resources of Tunisian firms;

It is noticed that some 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.

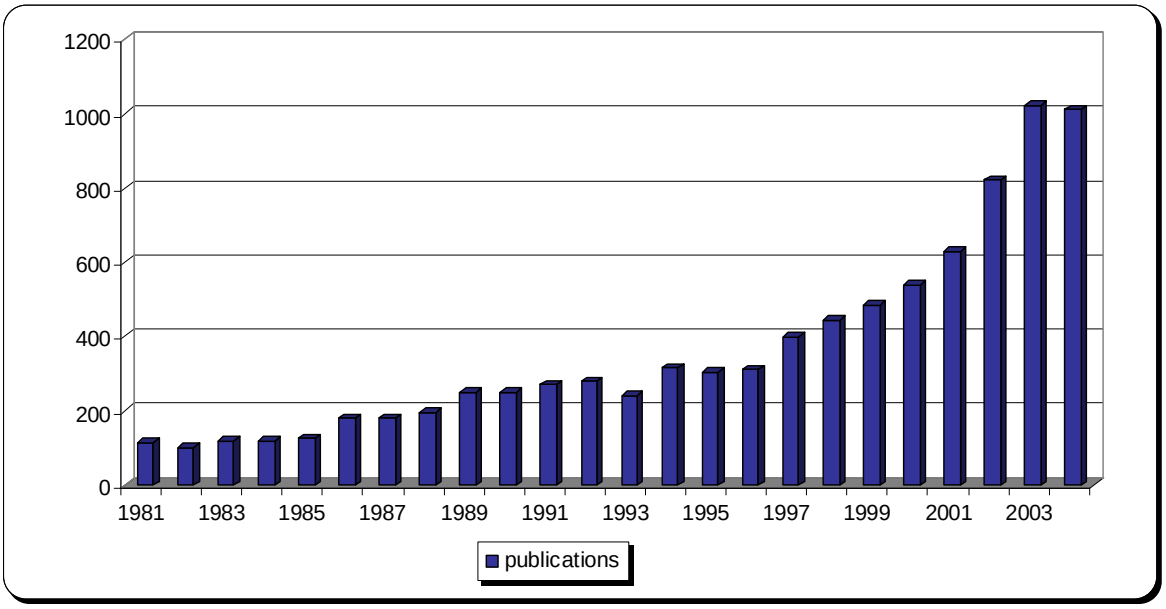
III.2.3- The Outputs of Pharmaceutical Innovation in Tunisia

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 (III.2.3.1) as well as data on pharmaceutical patent applications in Tunisia (III.2.3.2).

III.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.

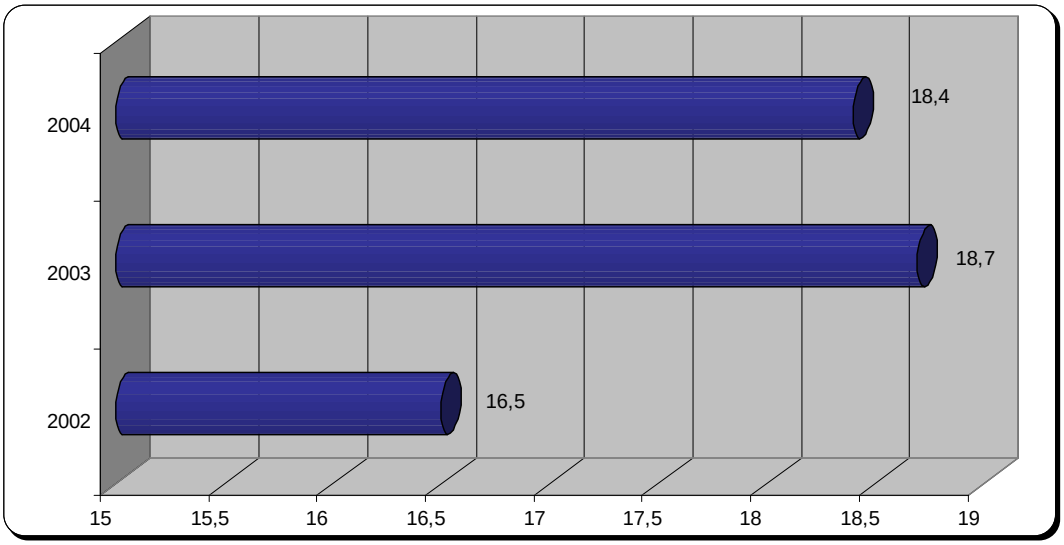
Graph -13- Growth Trends of Scientific Publications in Tunisia (1981- 2004)



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)**. 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 14).

Graph -14- The Share of 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.

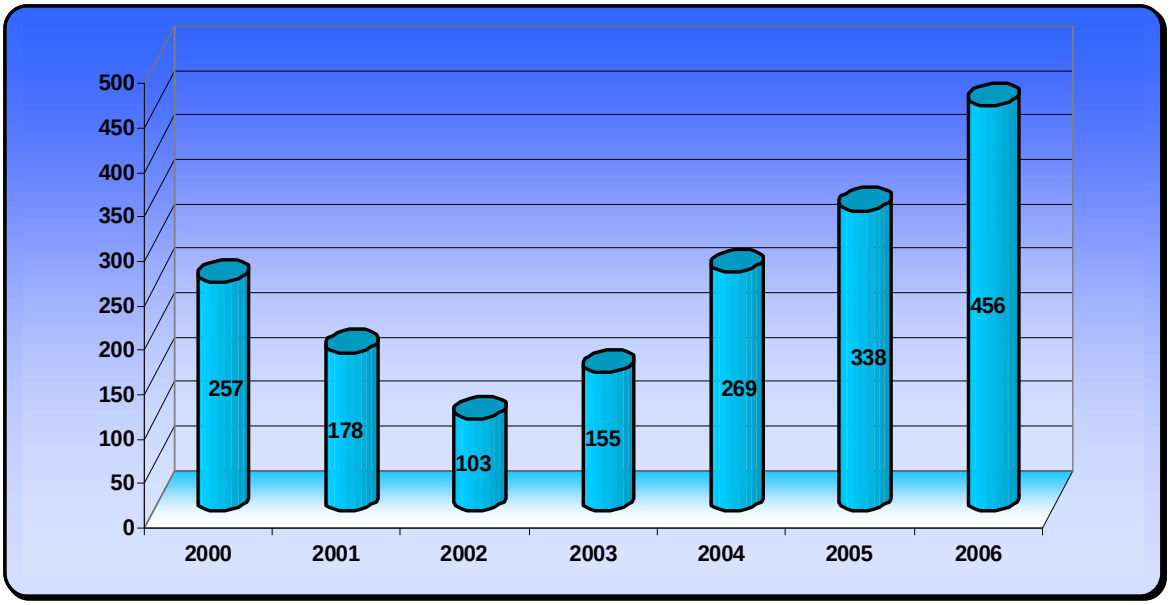
III.2.3.1- Growth Trends in Pharmaceutical Patent Applications in Tunisia

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 graph below (graph 15) shows that the growth trends in patent applications has 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 -15- Patent Applications by Domestic and Foreign Entities in Tunisia (2000- 2006)



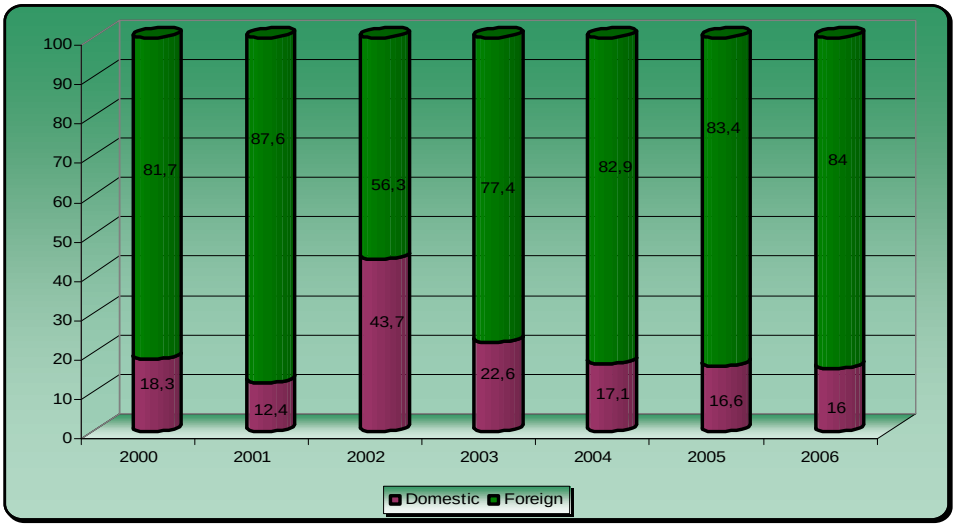
INNORPI, Tunisia, 2008.

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

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

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 2006(graph 16).

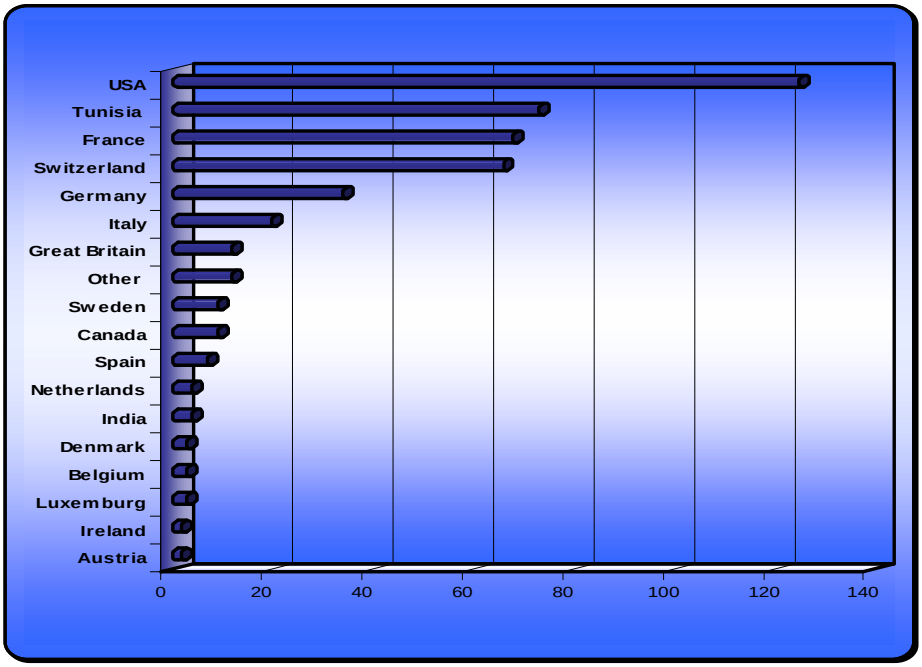
Graph -16- Growth Trends of Patent Applications by Domestic and Foreign Entities in % (2000- 2006)



INNORPI, Tunisia, 2008.

With reference to the graph above, 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).

Graph -17- Distribution of Patent Applications by Nationality (2006)



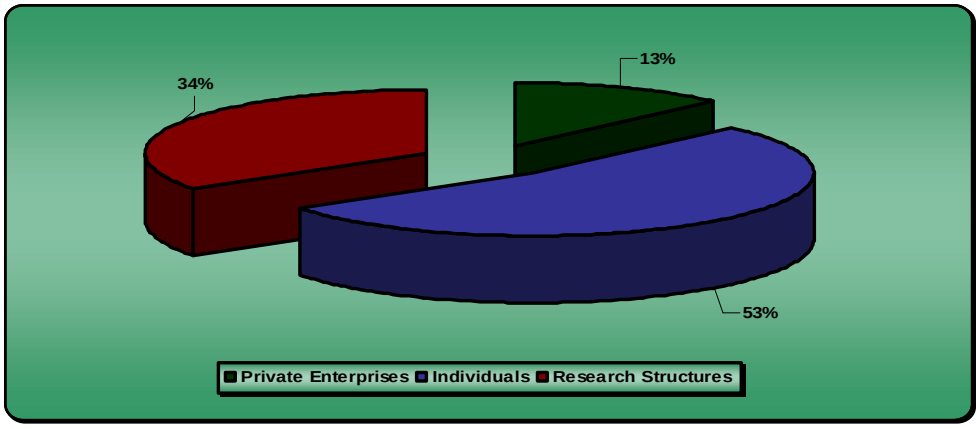
INNORPI, Tunisia, 2008.

According to the graph above (graph 17), it is obvious that Americans 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 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, we notice that the contribution of Tunisians in the activity of innovation remains at a low level, especially among private enterprises. Actually, according to the INNORPI (graph 18), individuals hold the biggest share of patent applications in Tunisia (53%) of 288 patent applications[23] between 2000 and 2006.

Graph -18- Domestic Patent Applications within Different Types of Applicants (Total number 2000 -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.

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. The other 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).

[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.

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.

Again, these figures allow us to confirm that the activity of R&D, especially in the pharmaceutical industry remains at an unsatisfactory level. Therefore, we restate that the low level of innovative activity in Tunisia is explained, on the one hand, by the reduced market size as well as the reduced local firms 'size and, especially, by the lack of financial resources on the other hand. In these conditions, what are the perspectives for the Tunisian pharmaceutical industry in the light of pharmaceutical patent laws?

III.3- Patent Protection in Tunisia: Perspectives for the Local Pharmaceutical Industry

Patent protection in Tunisia has been implemented by laws since 1888 accordingly to the Paris Convention on Industrial Property (1883). According to the decree of December 26, 1888, patentability in all fields of industries has been recognized in Tunisia. However, when the invention deals with food or pharmaceuticals, the decree allows only process patents **(El Kateb, 2005)**. The exclusion of pharmaceuticals from product patentability in Tunisia stems from a health policy that aims at protecting the social welfare by facilitating the access of patients to pharmaceuticals at affordable prices. In fact, patentability of pharmaceuticals provides a monopoly power to laboratories, allowing them to set high prices that developing countries could not afford. In the same framework, the study developed by **Pfister & Mayer (2001)** shows that the increase in prices due to changes in the market structure inherent to patent rights, could even reach 67%. In 2001, only 25% of world population (living in developed countries) have consumed more than 80% of pharmaceuticals. In this context, and according to **Gauvrit (2001)**, there are much more diseases in developing countries but drugs are being much more sold in developed countries.

On the other hand, in the absence of patent protection, private firms would be less likely to invest in pharmaceutical researches. Since developing countries benefit as well from the results of these researches, a reduction of the pharmaceutical innovation in developed countries would affect as much developing countries as developed ones. Actually, **Moschini (2005)** shows that patent protection encourages pharmaceutical innovation also in developing countries. Since patented brand name drugs become more expensive and less accessible to low income people, laboratories in developing countries will be stimulated to invest in pharmaceutical R&D.

Nevertheless, in countries like Tunisia, 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, 2008)**. Therefore, with pharmaceutical patents in Tunisia, brand name drugs are expected to become more expensive and thus the accessibility of low-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 a major problem that inhibit the development of the activity of R&D.

In fact, it requires important funds to engage investment in pharmaceutical R&D, the results inherent to these researches are not always positive, though. For these reasons, it seems more practicable for Tunisia to focus in the short-run on the production of generics and licensed drugs. At the same time,

the government should keep a long-run vision by looking for solutions to overtake the insufficiencies related to innovation in Tunisia. Especially, the government should look for alternatives next to foreign capitals in order to finance local investment in pharmaceutical innovation. In these conditions, patent protection would be susceptible to stimulate innovation in Tunisia, not only by local investors, but also by attracting foreign pharmaceutical laboratories.

IV- Concluding Remarks

Although the pharmaceutical industry in Tunisia is still young, it presents many promising opportunities for local investment. Aware of the exigencies imposed by pharmaceutical multinationals and confident in the reliability of the local human resources, the Tunisian government decides to emphasize on the industry of generics but without abandoning the production of licensed pharmaceuticals.

In this context, Tunisia is obviously trying to consolidate its innovation system but, the results show that it still needs retargeting its goals. Taking the special example of the pharmaceutical industry, the government has to focus also on improving innovation rather than only on the production of generics. Although generics allow the access of Tunisia to lower prices pharmaceuticals, they still represent a short-run "defensive" policy against the continuous increase of brand name medicines. Furthermore, to produce generics, Tunisian pharmaceutical enterprises have to wait until the patent expiry, while to get licenses they have to negotiate with foreign laboratories. It is noticed here that the licensee is always the submissive partner in this kind of negotiations and he is, hence, led to accept the exigencies of the owner of the brand name drug. Therefore, the government has to avoid that kind of problems by encouraging the local pharmaceutical R&D and innovation. This is as much feasible as the government:

- 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[25];
- 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 a real pharmaceutical industry 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. Consequently, Tunisia has to adopt a more "*voluntarist*" national innovation system to create incentives for R&D, especially by calling for foreign resources to finance innovation and by targeting and upgrading more the human resources in order to transform the Tunisian spirit from an "innovation takers" spirit into an "innovation makers" spirit.

[25] We have undergone difficulties to accede to essential databases for the preparation of this paper itself (such as statistics on recent pharmaceutical patent applications).

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