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Access to pharmaceutical products: Algerian law as a model

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Abstract: The pharmaceutical industry is actively involved in all phases of development, but its greatest contribution is translating and applying knowledge to develop products. Beginning with the inventive idea until the exploitation of the patent for an invention. Thus, the clinical trials required to obtain marketing authorization are largely funded by different sectors. In this context, the idea of public health is imposed, being one of the priorities to be protected.

Keywords: Industry; inventions; international treaties; patents; public health.

I. INTRODUCTION:

The right to health protection guarantees access to care, and the principle of equal access complements this right with a notion of redistribution of health resources.

The legislation of several countries satisfies all the requirements implied by these two principles. The fact remains that in practice, those excluded from the right to care and inequalities are worsening, due to the very evolution of the health system towards ever more technicality and ever more demanding lifestyles and work methods. Thus, the state of health of populations presents serious inequalities, with those who are poorly treated being increasingly poorly treated (Jean Paul MARKUS 2019, 40).

Moreover, in 2016, the governments of 31 O.E.C.D. countries for which data exist have together allocated about 53 billion USD to R&D in the field of health (an area broader than pharmaceuticals).

This figure is an underestimate of total government support because it excludes most tax incentives as well as funds allocated to higher education and public enterprises. At the same time, the pharmaceutical industry has spent some US$101 billion on R&D in the various O.E.C.D. countries (O.E.C.D. 2019, 03).

Beyond personal disaster and human drama, diseases and epidemics with pernicious effects have become a global priority that is demographic, economic, social, moral and security related.

Because of their devastating scale and impact, they constitute a global crisis and one of the most formidable challenges to human life and dignity as well as to the effective exercise of human rights, jeopardize social and economic development worldwide and affect society at all levels - national, local, family and individual (A/RES/S-26/2).

In the face of this situation, the following problem arises: What is the extent of the texts related to Algeria's access to pharmaceutical products?

In order to answer this problem, the research objectives are closely linked to a legal perspective which is necessary at the international level and also at the level of internal legislations. Also, to master the tools of healthy competition on the market, allowing the exploitation of pharmaceutical products.

Thus, we rely on the descriptive method of certain texts, in addition to the analytical method, in order to study the context of the legislator's position and the effectiveness of the texts.

Consequently, the study proposes to analyze the following axes: First the influence of international texts(I), then the reality and the scope of internal texts, based on patents for inventions, being the instrument for the protection of pharmaceutical inventions(II), and finally the possibility of exploiting pharmaceutical products on the market, while going through a series of procedures before being able to access these products and make them available in society(III).

I: -International influence :

The treaties administered by the World Intellectual Property Organization and the World Trade Organization(I-1) have taken a strong interest in the subject of medicines, and have even seen reforms in the provisions affecting public health(I-2).

I-1. The protection of public health by international treaties :

The protection of public health is becoming increasingly important. It is emerging as a guideline in the conclusion of international agreements in the medical field.

This imperative of public health protection may lead to less favourable conditions for patent holders. A balance between access to medicines has been established to encourage research and development of medicines under the legal framework of pharmaceutical patents.

There are two types of international legal protection for pharmaceutical patents, mainly the Paris Convention for the Protection of Industrial Property (P.U.C, 1883) and the Patent Cooperation Treaty (P.C.T, 1970), which implies a single registration in order to benefit from protection in several countries chosen by the inventor. Both texts are administered by the World Intellectual Property Organization (W.I.P.O, 1966).

At the same time, there is strict international legal protection, represented by the Agreement on Trade-Related Aspects of Intellectual Property Law (T.R.I.P.S, 1994), patent law is governed by articles 27 to 34.

The T.R.I.P.S. agreement takes into account the importance of public health protection and provides flexibility in access to medicines in situations of national emergency. Until the Doha Declaration in 2001, the W.T.O. affirmed the importance of health protection in order to promote access to medicines.

The W.T.O. is well aware that access to medicines is an important aspect of public health. These provisions have been a guideline for Member States, which have transposed them into their national laws (Thai CUONG 2016, 14)**.**

The Doha Declaration recognized the seriousness of public health problems, and underlined the need for the agreement on T.R.I.P.S. to be an instrument at the service of public health.

It reiterated four essential points: The importance of public health, the possibility for Member States to take measures to protect it, the possibility and the duty to interpret and implement the T.R.I.P.S.in a way that is favorable to public health, and the need to promote technology transfer.

Specifically, the declaration affirmed that the agreement should not "prevent members from taking public health measures," that it should be "interpreted and implemented in a manner supportive of the right of W.T.O members to protect public health and, in particular, to promote access to medicines.

I-2. The reform of the T.R.I.P.S. agreement:

Several legal solutions can be implemented in order to make effective the cohabitation between the protection of pharmaceutical invention and the protection of public health.

The promotion of a new system for regulating pharmaceutical inventions that is independent of the basic patent system could be a considerable step forward in the process of rebalancing the interests at stake.

This new system should introduce a specific interpretation of the patent rules for the protection of pharmaceutical invention.

This specific interpretation would consist in framing the implementation and interpretation of the provisions of the T.R.I.P.S. agreement relating to pharmaceutical inventions in such a way that it is more favourable to the protection of public health.

This requires member states to review the objectives of the T.R.I.P.S. agreement and to recognize, in the same way as patent holders, the right of users of products derived from pharmaceutical inventions.

The reform of the provisions of the T.R.I.P.S. agreement cannot be based exclusively on the implementation of new legal measures; the integration of alternative solutions to the patent system could make public health protection more effective.

In addition, the search for coherence between health, intellectual property and trade in order to find solutions regarding access to medicines (Pascal LAMY, 2013).

Thus, the possibility of authorizing uses of the subject matter of a patent without the authorization of the right holder, meaning the granting of compulsory licenses (Article 31, T.R.I.P.S.).

This latter flexibility seemed the most promising for access to medicines in developing countries, as it gave states a great deal of latitude in determining the grounds for granting compulsory licences.

However, Article 31 of the agreement, under "f", contained a significant legal pitfall. It stated that compulsory licences should be reserved "predominantly" for the supply of consumers in producer countries.

As a result, there was concern that only countries with a minimum level of pharmaceutical production and technological capacity would be able to take advantage of the compulsory licensing mechanism.

This difficulty was highlighted at the Fourth W.T.O Ministerial Conference held in Doha, Qatar, from November 9 to 14, 2001. At the end of this meeting, a "Declaration on the W.T.O Agreement on T.R.I.P.S and Public Health" was adopted, paragraph 6 of which stated: "[...] W.T.O members with insufficient or no manufacturing capacity in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the W.T.O Agreement on T.R.I.P.S.".

As for the scope of the products covered by the decision is very broad and goes even further than just pharmaceuticals, as it extends to "pharmaceutical products", as defined by Article 1 of the General Council Decision of August 30, 2003, implementing paragraph 6 of the Doha Declaration on the T.R.I.P.S. and public health, such as :

"Any patented product, or product manufactured by a patented process, of the pharmaceutical sector needed to address public health problems as recognized in paragraph 1 of the Declaration. It is understood that it would include the active ingredients necessary for the manufacture of the product and the diagnostic kits necessary for its use".

The decision specifies that the active ingredients necessary for the manufacture of the product and the diagnostic kits necessary for its use are included in this definition.

With regard to the diseases potentially concerned, the decision refers to public health problems as recognized in paragraph 1 of the "Declaration on the Agreement on T.R.I.P.S. and Public Health", meaning those that affect many developing and least developed countries, in particular problems resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. (Constance CHERON 2009, 74)

Finally, the "plasticity" of developing countries, in other words their capacity to adapt to the international context and, particularly, at the national level, their capacity to integrate a certain protection of pharmaceutical technologies while meeting their urgent needs for medicines, is really put to the test: "Developing States are forced to apply the agreement in all its rigor on their territory under penalty of all kinds of political or trade sanctions". (Botoy ELANGI 2007, 483)

II: Patenting: The instrument for protecting pharmaceutical inventions

In order to be able to protect inventions in the pharmaceutical field, the Algerian legislator, influenced by international treaties, has reserved for these inventions a legal protection by patents, which requires first of all the satisfaction of the conditions of patentability(II-1), then the conditions necessary for the grant of the patent, starting with the filing(II-2)

II-1. Conditions of patentability :

The patent is at the same time a legal instrument of industrial and social policy. It is above all a choice of governments to make it an instrument for the promotion of public health within the limits of the means at their disposal.

The patent is unquestionably an instrument that allows a certain degree of industrialization in a given sector, when it is supported by an adapted policy and sufficient funds.

At the national level, the patent system should be considered not only in the context of industrial and trade policies, but also in the context of public health.

Therefore, as a legal instrument, patents on pharmaceutical products and processes "must be administered impartially, so as to protect the interests of the patent holder while safeguarding the fundamental principles of promoting public health. (W.H.O 2002, 41).

According to the former text on patents for inventions in Algeria, specifically article 08 of Executive Decree 93-17, pharmaceutical products could in no case benefit from the granting of a patent for invention. Contrary to the current situation, when the provisions of the previous article disappeared in the last text on patents, the ordinance 03-07. (Article 07 , Ordinance n° 03-07).

Thus, for the validity of a pharmaceutical patent, both substantive and formal requirements must be met.

For the substantive conditions, inventions that are new, that result from an inventive step and that are susceptible of industrial application can be protected by a patent . (Article 03 , ordinance 03-07)

Also, according to Article 07 of the Ordinance 03-07: "Are not considered as inventions:.... - methods of treatment of the human or animal body by surgery or therapy as well as diagnostic methods;...".

For novelty, countries have to determine whether the patent granted on the compound covers the drug precursor, and to what extent claims on certain compounds should also cover the corresponding drug precursors.

In the UK, for example, sales of hetacillin, a ketone adduct of ampicillin that was immediately hydrolyzed in the body as ampicillin, were found to infringe ampicillin patent rights because it was "ampicillin in disguise".

In this situation, the difficulty lies mainly in the freedom left to states to choose whether or not to bring drug precursors into the patentable field.

The provisions on the patentability of medicines will have to regulate the rules relating to the claim to the patentable pharmaceutical subject matter, so as to limit the patent race and allow for the patentability of products whose therapeutic contribution is effectively certain.(Ozoua BRIDJI 2013, 37).

Concerning inventiveness, it should be emphasized that the patentability of a process by "analogy" consists in the patentability of processes that are not fundamentally new.

However, some countries allow their patentability as long as the resulting chemical product is new and has novel properties.

The notion of novel property is all the more vague since it does not guarantee the therapeutic contribution of the chemical product Carlos. (CORREA, 2001)

As for the possibility of industrial application, the process is considered to be a method in motion, "the invention relates to a process when it consists in the implementation of means according to a succession of stages or steps to be carried out in a determined order and under particular conditions (in terms of time, temperature, pressure, etc.) in order to obtain a result which will be either a product or an immaterial effect.

The process can be abstract (like an operating process, a program) or concrete (like a heat treatment conferring certain properties to an alloy). (Jean Luc PIOTRAUT 2010, 170)

In addition to the above conditions, the Algerian National Institute of Industrial Property (I.N.A.P.I.) (Executive decree N°98 – 68) also requires that the product must be of a specific form in order to benefit from a pharmaceutical patent.

This reinforcement of rights would then benefit multinational firms more than national companies. The major deficiency related to the very function of the I.N.A.P.I., lies in the fact that it accepts all patent applications concerning pharmaceutical products without taking into consideration all the issues related to public health.

In other words, the I.N.A.P.I. does not distinguish between patents concerning essential drugs, considered to be of public utility, and those considered to be non-essential. (Abdelkader HAMADI 2017, 104).

II-2. Conditions related to deposits

The procedures begin with the filing of an application (Article 20, odinance03-07).

After this stage, the competent service verifies whether the application meets the requirements relating to the formalities of filing by examining the application (Article 27, ordinance 03-07), the grant (Article 31, ordinance 03-07), and finally the publication. For this, the competent service publishes the patent in an official bulletin of patents (B.O.P.I) (Article 32, ordinance 03-07).

Within the framework of these procedures, it is of extreme importance to underline the paradox between the articles of the same text (Ordinance 03-07).

From the moment we find articles from 27 to 30 under the examination section, we find in parallel article 31, which stipulates that: "Patents for inventions are granted without any prior examination at the risk and peril of the applicants and without any guarantee".

The paradox underlined must be removed from practice, by the exclusion of article 31 that has arisen, particularly when it concerns a patent related to human health, more precisely, a pharmaceutical patent.

Closely related to the latter, we recall the position of the Algerian legislator regarding compulsory licensing.

According to the provisions of article 49 of ordinance 03-07: "A compulsory licence may be granted at any time by the minister in charge of industrial property to a state service or to a third party designated by the minister, for a patent application or for a patent of invention, in the following cases:

... (1) Where it is in the public interest, in particular ... health ..., and in particular where the fixing of prices for patented pharmaceutical products which are excessive or discriminatory in relation to average market prices is in the public interest ...".

A legal situation in conformity with international provisions, indirectly imposed by the 2001 Doha Declaration, administered by the W.T.O.

Even if Algeria is not yet a member country of the W.T.O., we note a clear and direct resumption of the legal provisions of this international organization, in the subject of Algerian patents related to public health.

III - Administrative procedures

Following the grant of the patent, another series of procedures is required, allowing the exploitation of the drug in the commercial field(III-1), followed by a registration decision, which represents a means of control and delivery at the same time(III-2).

III-1. The commercialization of the drug :

The pharmaceutical industry is at a high level of quality assurance in the development, manufacturing and control of products. A marketing authorization system ensures that marketed medicines have been evaluated by a competent authority, ensuring their compliance with the standards in force in terms of safety, efficacy and quality.

The quality during the large-scale production of a pharmaceutical product must be rigorously identical to the quality of the drug tested in the laboratory and for which a "D.E", registration decision has been obtained (AFSSAPS, official bulletin N° 2011 /8 bis).

Knowing that the Algerian legislation is very much inspired by the European legislation, indeed to be able to manufacture and / or market a drug on the national territory the granting of a decision of registration "D.E" similar to the A.M.M. with the competent authorities is imperative in accordance with Art 174, 175 and 176 of Law 08-13.

The central commission for the nomenclature of pharmaceutical products intended for human medicine is responsible for giving opinions or making proposals to the Minister of Health on the establishment of the

nomenclature of pharmaceutical products intended for human medicine and the modifications to be made for the periodic updating of this nomenclature.

It pronounces, in particular, on the effectiveness and improvement of the therapeutic properties of medicines and this in order to protect the health of the population (Art 02, Decree n° 80-142).

Firstly, pharmaceutical products must have a corporate name, which can take two forms:

-Either a trade name, in terms of law, a trademark (Ordinance n° 03-06). Which is the sign affixed to the product to distinguish it (Article 02, Ordinance 03-06). Thus, the registration of the trademark is mandatory, because in case of non-registration, one is faced with the offence of non-registration of the trademark (Art 33, Ordinance 03-06).

-Either the International Common Name, as adopted by the World Health Organization, followed by the name of the manufacturer.

When the special name is a trade name, the International Common Name must appear in visible characters immediately below the trade name.

The trade name shall be chosen so as to avoid confusion with other pharmaceutical products and shall not be misleading as to the qualities or properties of the speciality (Article 03, Executive Decree No. 92-284).

In the same context, the form of the product is essential; therefore the primary and secondary packaging must comply with the specifications.

The European Directive 2001/83/EC establishing a Community code relating to medicinal products for human use specifies the different types of packaging items:

- Primary packaging: the container or any other form of packaging that is in direct contact with the active ingredient or bulk product.

-Secondary packaging: are the articles that are not in direct contact with the product such as the articles ensuring the packaging of the manufactured product and which together constitute the finished product. Finally,

-Tertiary packaging or outer packaging: the packaging in which the primary packaging is placed).

Within this framework, and in accordance with standard I.S.O 11615, the I.S.O. has published technical specification I.S.O./T.S. 16791 which aims in particular to guarantee "the right medicine to the right patient" and which therefore provides for the adoption of bar codes to secure medication.

Figures show that by adopting measures to reduce the rate of adverse reactions, even in the European Union alone, more than 750,000 medical errors, sometimes with serious consequences, could be avoided each year, saving 3.2 million hospital days and preventing 260,000 permanent disabilities and 95,000 deaths per year.

I.S.O. standards on drug identification are becoming increasingly popular, and governments are now requiring them to be applied in a growing number of countries.

Concerned parties share the view that they will become the reference model for drug information at the global level. (Garry LAMBERT 2016)

III-2. The registration decision: a means of control and delivery

The registration decision is presented in accordance with Article 06 of Decree 92-284, which provides and regulates the information that the document must contain.

It is granted by the Minister of Health after the opinion of the National Nomenclature Commission.

The documentary, analytical, pharmacological, pharmacotechnical, microbiological and toxicological evaluation is entrusted according to article 14 of decree N°92-284 to the national laboratory for the

control of pharmaceutical products "L.N.C.P.P." whose conclusions will be transmitted to the Minister of Health (Directorate of Pharmacy).

For this purpose, the national laboratory for the control of pharmaceutical products was designated for the first time as a collaborating center of the W.T.O. for the conformity of medicines (C.E.C.O.M.E.D.) in 2003, with the missions of pharmaceutical training on the one hand and expertise and quality control of medicines on the other hand. It was redesignated as such in 2005, and in 2009.

This laboratory is in charge of the study of the scientific files of pharmaceutical products submitted for registration, the monitoring of the safety, efficacy and quality of marketed pharmaceutical products. (Article 04, Executive Decree 93-140)

A manufacturing system ensures that authorized medicinal products are only produced by licensed producers whose activities are subject to regular inspections by the competent authorities. (A.F.S.S.A.P.S., official bulletin N° 2011 /8 bis).

This is why, in Algeria, the national laboratory for the control of pharmaceutical products is considered as a reference laboratory in terms of drug control, it carries out the systematic control of all batches of imported drugs, and the validation of the control laboratories that any drug manufacturer in Algeria must have in order to have the power to release each batch produced.

Also, the technical committee of registration (C.T.E.) plays a decisive role in this sequence, in the sense that pharmaceutical products intended for marketing are first subject to registration and carry an D.C.I.

The C.T.E. was created in 1998 by ministerial decree, within which the submission price is studied for its therapeutic and economic interest. It is composed of the Director of Pharmacy, Deputy Director of Registration, Director General of the L.N.C.P.P., Coordinator of Clinical Experts, Coordinator of Analytical Experts, Coordinator of the Price Committee and four (04) medical experts.

In the absence of a drug regulatory institution, namely a national drug agency, the institutional authority dealing with the decision to grant a certificate of free sale (C.L.V.) is issued for a specific period, renewable on the basis of a technical and scientific file, by this technical registration committee (C.T.E.). This committee is usually made up of representatives of the Ministry of Health (Director of Pharmacy), doctors, pharmacists, health inspector and public purchasing office. (Abdelkader HAMADI 2017, 104).

Thus, the registration decision is issued for a period of five years, renewable for five-year periods. (Article08, Executive Decree 92-284).

-Study and evaluation of the scientific and technical file,

-Physico-chemical and, where appropriate, microbiological and biological tests,

-Pharmacological and toxicological tests,

-Clinical tests.(Article 12, Executive Decree 92-284).

Obviously, the work of the scientific expert accompanies the entire life cycle of the drug. His opinion is essential during the creation of the drug substance, he has the obligation to carry out a study on the benefit/risk ratio before any marketing authorization of the drugs.

The expert has a dual role, on the one hand he must create and develop the knowledge necessary for the decision.

On the other hand, he must help to produce standards and methodologies for the interpretation of the available data; these data make it possible to detect risks from the outset. The expert thus participates directly, through this function, in the exercise of the decision; he shapes the "funnel" of political choice. (Chahnez ANTRI-BOUZAR 2017, 18)

II. CONCLUSION :

As a consequence of the current health crisis, it has been necessary to study certain texts, particularly those that are marred by criticism, as well as other texts, which have been introduced by the Algerian legislator, in order to guarantee access to medicines.

As such, this guarantee is of an international nature, provided for in international requirements, through the maintenance of public health following the use of compulsory licenses granted to developing countries, with a view to making the public interest prevail over the private interest.

The same position was adopted by the Algerian legislator in the text on inventions.

However, the nature of these inventions related to pharmaceutical products has obliged the Algerian legislator to require precise procedures subsequent to obtaining a patent, in order to ensure the efficacy and safety of the products, before they are put on the market.

In the end, access to medicines is far from being a remote issue, compared to its magnitude, which remains a considerable challenge to be met.

In this sense, a number of factors must be taken into account: the right to health, the pursuit of the general interest, the availability of pharmaceutical products, the duality of competition and innovation.

Of course, this competitiveness must adapt to a sustainable market, often bypassing a human emergency, without threatening the origin of its existence.

As a result of such situations, a profound change of direction is required, according to the following recommendations:

- The financing of pharmaceutical R&D (research and development) imposes a complementarity that results from diversified sources in the State.

Emanating from direct budget allocations, research grants and the financing of public research institutions and higher education establishments.

-To include the emergency situation related to public health in Algerian texts, notably the modification of article 49 of the 03-07 ordinance, so as to include the cases of the emergency situation, thus easily implying certain consequent situations, as well as the current health situation related to Covid.

-Amend article 31 of the 03-07 ordinance, and currently remove it from the scope of practice, in order to avoid the paradox between the text of this article, which stipulates that the granting of patents for inventions is carried out without any prior examination at the risk and peril of the applicants and without any guarantee, and articles 27 to 30 under the section "examination", which set out a chain of procedures concerning the examination.

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