RULES FOR THE PROTECTION OF UNDISCLOSED INFORMATION AND ITS RELATIONSHIP TO THE PHARMACEUTICAL INDUSTRY

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Abstract:

The pharmaceutical industry is one of the most important vital industries at the local and global levels due to its close link to human health. International companies have worked to protect their pharmaceutical innovations and inventions, especially undisclosed information, by controlling global markets for pharmaceutical products and achieving more profits, without taking into account the conditions and conditions of developing countries.

Hence, comparative legislation has developed special protection for undisclosed information, including preventing others from violating these secrets and information using dishonest methods and practices through the lawsuit of unfair competition, and the TRIPS Agreement has also set out special rules for the protection of undisclosed information that is obligated to submit to government agencies and concerned authorities to obtain a license to market medicines.

Keywords: *undisclosed information; pharmaceutical industry; TRIPS Agreement; unfair competition lawsuit; criminal protection.*

INTRODUCTION:

Human and animal health has become one of the basic demands of societies and one of the priorities set for governments in most countries of the world, and in order to achieve this, countries have adopted in their health policy systems to combat diseases, by encouraging innovation in the pharmaceutical field to allow the provision of pharmaceutical materials to cover crises and national needs.

Accordingly, the pharmaceutical industry is one of the most important vital industries at the local and global levels because of its close link to human health, as this industry needs to raise huge capital because it depends mainly on continuous research and development, and this explains that the pharmaceutical industry is subject to the control and monopoly of a limited number of multinational companies that have huge capital and superior technological capabilities that are not available in poor countries. The use of undisclosed information by pharmaceutical companies will achieve returns, whether these returns are represented in increasing the company's profits or reducing losses, or attracting new customers to other benefits that accrue to companies operating in the field of medicine according to the nature of the pharmaceutical activity.

Hence, undisclosed information has become capital in every sense of the word in industrially developed countries, as these companies have strengthened the protection of their pharmaceutical innovations and inventions by controlling global markets for pharmaceutical products and achieving more profits, without taking into account the conditions and conditions of developing countries.

Thus, comparative legislation has established special protection for undisclosed information, including preventing others from violating such secrets and information using dishonest methods and practices. In most legislation, it was protected by unfair competition, and the TRIPS Agreement established special rules for the protection of undisclosed information that it is obliged to submit to government agencies and concerned authorities to obtain a licence to market medicines.

Therefore, studying the issue of undisclosed information in the pharmaceutical industry and ways to protect it is of great importance at present due to the remarkable development of this protection through the trend towards enacting special laws to protect this type of information.

Due to the importance of this topic, we find ourselves facing a set of problems: What is meant by undisclosed information? What is the relationship between undisclosed information and the pharmaceutical industry? What are the conditions that must be met in order to protect this information?

Has the Algerian legislature been able to establish special legal mechanisms to protect undisclosed information in the pharmaceutical industry?

The study of this topic has been followed on the analytical method, by exposure to the various legal texts regulating undisclosed information and pharmaceutical products of all kinds, and the legal protection prescribed for this, whether at the national or international levels.

Accordingly, this article was divided into two sections:

The first topic: the nature and conditions of undisclosed drug information

The second topic: the mechanism of protection of undisclosed drug information.

The first topic: the nature and conditions of undisclosed drug information.

Undisclosed information plays an important role in the pharmaceutical industry, because of its great importance in the countries of the world, where it has become one of the most prominent moral elements of industrial and commercial companies, and therefore we will address in this section the relationship of undisclosed information with pharmaceutical products and their legal development (the first requirement), as well as the conditions that must be met to protect undisclosed information (the second requirement).

The first requirement: the relationship of undisclosed information to pharmaceutical products and the evolution of their legal status.

Due to the importance of undisclosed information and its relationship to the pharmaceutical industry, various legislations have tried to define it. Hence, it was necessary to address the definition of the concept of undisclosed information by tracking the legal texts of various international legislations as well as the TRIPS Agreement, in addition to defining the pharmaceutical product because it has a close relationship with undisclosed information.

Subchapter I: The concept of undisclosed information.

Many comparative legislations tried to develop a unified definition of undisclosed information, which falls under business secrecy and has a competitive advantage (1)[1] which led to the difference in legal systems and the word of jurists about launching a unified label for undisclosed information, where many names were used to denote it, as the Uniform American Act of 1979 launched the name of the trade secret (2).

As for the World Trade Organization, it used the term undisclosed information in the international agreements approved by the organization, related to private property, especially the TRIPS Agreement concluded in 1994 (3)[1] which adopted the term secrets in the French edition of this agreement as Information non-divulguées As for the English edition, it has adopted the term undisclosed information according to the literal translation that came in English Undisclosed information.

It is worth mentioning that the TRIPS Agreement did not set a unified definition of undisclosed information, but stipulated in Article 39 of it a number of conditions that must be met in the information in order to receive legal protection, namely that it be confidential and of commercial value (4)[1] as for the Algerian legislation, it did not set a definition of trade secrets, unlike comparative legislation, which requires us to refer to the general rules for its protection, which used the phrase commercial secret in more than one situation Our national legislation, for example, the Algerian legislator explicitly mentioned the term commercial secret in Article 59, last paragraph of Ordinance 03-07 on patents (5)[1] and indirectly mentioned the commercial secret in Article 627 of the Commercial Code about the board of directors of a joint stock company (6), Thus, although the Algerian legislature has made important amendments in line with the TRIPS Agreement, it does not specify the conditions for the identifier to acquire the status of a trade secret.

Hence, we conclude that undisclosed information or trade secrets are information that may be legally protected from being obtained or used by third parties without the consent of its owner, and in a manner contrary to sound business practices, and such information is required to be confidential and of commercial value as a result of its confidentiality, and the owner takes serious measures to maintain its confidentiality.

Subchapter II: The nature of the pharmaceutical or pharmaceutical product.

Due to the importance of pharmaceutical substances, most countries of the world were keen to define their legal concept, in order to determine the legal effects of them, and due to the large number of these substances and the diversity of the purposes allocated to them, they addressed medicines only by defining their limits and interpreting them fundamentally(7), because the pharmaceutical product is broader and more ambiguous than medicine (8).

Hence, the European Union legislation has defined medicine in the regulation on medicinal products permissible for use by humans in its directive No. 27-2004, and in the US legislation in Article 102 of the Federal Food, Drug and Cosmetics Act (9), while the Algerian legislator initiated pharmaceuticals with medicines (10) , which we find at the forefront of the group of substances that fall within the scope of pharmaceuticals, where it is undeniable the need attached to it in the case of a disease report, and because of its importance, the legislator has singled it out with two articles, Article 208 (11) of Law No. 18-11 of July 2, 2018 on health. Article 209 (12) of the same law in which he talks about products similar to medicines.

It should be noted that the Algerian legislator has adopted the broad concept of pharmaceutical substances without distinguishing between the term pharmaceutical substances and pharmaceutical products, despite the difference between them.

Finally, the drug is considered a dangerous product that requires scientific knowledge of high-precision technical pharmaceutical information, so that it can be reached after in-depth prior trials.

Second requirement: conditions for the protection of undisclosed information.

Due to the importance of undisclosed information, specialists in industrial art as well as legal professionals have stipulated conditions to protect this confidential information, these conditions are:

Subchapter I: General Conditions.

The general conditions for non-disclosed information are as follows:

- Confidentiality of information, as confidentiality means withholding what the owner of the information has reached with his own effort and project from the rest of the workers in the field of industrial art itself, or at least it is not easy for them to obtain this information (13).
- The information should be of commercial value
- Take serious and reasonable measures to protect undisclosed information.

Subchapter II: Special Conditions.

Article 39, paragraph 3 of the TRIPS Agreement requires that the confidential data and information that must be submitted to government agencies in order to license the marketing of medicines or agrochemical products must have special conditions, the latter of which are:

- It is mandatory to submit data to the government entity to obtain a license to market medicines.
- Pharmaceutical products contain new chemical entities.
- Make great efforts to access data and information.

Finally, due to the importance of undisclosed information in the field of pharmaceutical products, it can be protected by both civil and penal means.

The second topic: the mechanism of protection of undisclosed drug information.

Comparative legislation establishes special protection for trade secrets or undisclosed information, including preventing others from violating such secrets and information using dishonest methods and practices. In most legislation, it was protected by unfair competition, but the TRIPS Agreement introduced trade secrets as intellectual property and called it undisclosed information, and obligated WTO member States to protect them through the protection regime established in Article 39 of the TRIPS Agreement.

The first requirement: the lawsuit of unfair competition.

Unfair competition rules play a major role in protecting undisclosed information, but filing an unfair competition lawsuit requires a set of conditions set by law. Therefore, in the event of its failure, the owner of the undisclosed information when his confidentiality is violated cannot file an

unfair competition action, but before addressing the conditions for the application of unfair competition, the legal nature of this lawsuit should be addressed.

Subchapter I: The Legal Nature of the Unfair Competition Action.

At the international level, the TRIPS Agreement in Article 39, first paragraph (14)[1] clearly confirmed the protection of undisclosed information through unfair competition rules stipulated in Article 10 bis of the Paris Convention (15)[2]

Accordingly, the protection of undisclosed information focuses on two types of information:

1. Confidential information concerning natural and legal persons and under their legal control (16)[3]
2. Data and other information submitted to the competent government authorities in order to obtain a license to market medicines or agrochemical products (17)[4]

The first paragraph of Article 39 of the Agreement imposed on WTO member States the protection of both types of information by means of the rules set forth in Article 10 bis of the Paris Convention on the Suppression of Unfair Competition, meaning that an assault on any type of information referred to in the second and third paragraphs of Article 39 was an act of unfair competition.

Referring to the text of article 10 bis, paragraph a, above, we find that it stipulates the following: "The States of the Union shall ensure to the nationals of other States of the Union effective protection against unfair competition."

As for the Algerian legislator, he did not regulate the unfair competition lawsuit or its legal basis, but only mentioned some practices that he considered to be illegal practices in Law No. 10-06 of August 15, 2010 amending and supplementing Law No. 04-02 of June 23, 2004 defining the rules applicable to commercial practices (18)[5] the latter providing in article 27 thereof examples of unfair practices.

Subchapter II: Elements of the Unfair Competition Lawsuit.

An unfair competition action shall not be instituted unless there is competition, and the other elements are as follows:

Error: The Paris Convention in Article 10 bis paragraph C (19)[6] provides for acts constituting unfair competition, and the TRIPS Convention refers to the betrayal of confidential information in exchange for commercial bribery.

B. Damage:

No compensation can be claimed under the unfair competition lawsuit unless the acts of unfair competition lead to damage, which is material resulting from the diversion of customers from the plaintiff's products as a result of the infringement by the wrong means carried out by the defendant, or damage to the merchant in his trademarks related to trade, or morally affecting the reputation of the competitor.

Whatever the damage, whether material or moral, present or future, an unfair competition lawsuit can be filed even if the damage is not realized, but is expected to occur in the future, and thus the judge's authority extends to limit the persistence of unfair competition acts that cause damage in the future, in this case the competitor is forced to desist from acts of unfair competition without instructing the plaintiff to prove the damage (20)[7] Where expertise entrusted to people outside the case is often relied upon (21) .

It is worth mentioning that sufficiency with the potential damage to file a lawsuit against unfair competition aims to enable the owner of undisclosed information who violates the confidentiality of his information to resort to the judiciary in order to take precautionary measures to prevent the occurrence of damage in the future, and not only compensate the owner of the undisclosed information for his damage, but also aims to emphasize the perpetrators of unfair competition.

C. Causality:

Causation means the need for a direct relationship between the error committed by the aggressor on the undisclosed information and the damage suffered by the owner of the information, for example, the infringer of commercial or industrial secrets acts that result in damage to the owner's right by causing a decrease or loss of the financial return that the owner would have obtained as a result of his exploitation or use of confidential information, and thus the causal relationship between the aggressor's error as a result of his assault and the damage caused to the owner is

achieved, which is his loss of part or all The financial return resulting from its exploitation of undisclosed information.

It is clear from the above that States are interested in giving special and explicit legal protection to test data, which is the main locus for the development of the pharmaceutical industry as defined by the TRIPS Agreement as a result of the general awareness of the reality and importance of the existence of peremptory legal norms for the protection of such data, as is the case with any other element of industrial property such as patents and industrial designs.

Second requirement: criminal protection of undisclosed information and pharmaceutical products.

Criminal protection of undisclosed information is limited in practice, as the elements of the crime must be proved, which are the existence of a commercial secret, the material element represented in the incident of assault, and criminal intent, and requires the disclosure of the owner of confidential information about it to the investigation and judicial authorities, and the defendant has the right to access it to ensure the right of defense, and this contradicts the interest of the owner of the undisclosed information in maintaining its confidentiality (22) .

Subchapter I: Criminal protection under domestic laws.

The prescribed penalty varies according to its legal qualification, as infringement of undisclosed information may be classified as rape and seizure of something owned by others that requires the imposition of the legally prescribed penalty, and the provisions prescribed for bribery are applied in the event that it is submitted for the purpose of obtaining confidential information without permission from its owner, and the rules of breach of trust are applied to the worker who discloses secrets to others.

Hence, the judiciary considered that the disclosure of a commercial secret is theft as money, and therefore the rules of theft are applied, which was decided by the Criminal Chamber of the French Court of Cassation, which decided that the crime of theft applies in the imposition in which the worker for personal purposes and without the consent of the employer transfers drawings to others for materials manufactured by the employer, which provides criminal protection for confidential information, and the beneficiary of the disclosure of confidential information was considered in bad faith as an accomplice to whom the rules of the accomplice in the crime apply, which it ruled Court of Cassation "if he deliberately assists and participates in the acts prepared and facilitated the commission of the crime by the latter" .

Section II: The position of the Algerian legislator on the protection of undeclared pharmaceutical products.

By analyzing the conditions for the protection of undisclosed information in the field of pharmaceutical products at the level of the TRIPS Agreement and its projection on Algerian law, we note the complete absence of special legal legislation regulating the issue of legal protection of undisclosed information in the field of pharmaceutical products, like many countries, although the legislator, as mentioned above, used the term trade secret in several legal texts, but in fact it is a verbal term only devoid of any regulation that distinguishes it from The most prominent example of this is Ordinance 03-07 on patents, which obliges the judge to take into account the non-disclosure of a commercial secret during a patent dispute (23)[1] but we note that the judge does not have the legal provisions that determine the conditions for acquiring knowledge and information as undisclosed information.

It is worth mentioning that the Algerian legislator did not address the guarantees of the protection of undisclosed information to national and foreign institutions towards the administration as stipulated in Article 39 paragraph of the TRIPS Agreement, as it was limited to the establishment of a national laboratory for the control of pharmaceutical products created by Executive Decree No. 93-140 of June 14, 1993 establishing a national laboratory for the control, organization and operation of pharmaceutical products (24)[1] and Executive Decree No. 92-284 establishing the conditions for the registration of pharmaceutical products. (25).

Hence, we conclude that the absence of legal provisions guaranteeing the rights of pharmaceutical companies leads to their fear of obstacles to disclosing their trade secrets to the national

laboratory for the control of pharmaceutical products in Algeria without any guarantees, and thus affects the reality of public health in Algeria through the licensing of medicines and products whose exact composition is unknown.

CONCLUSION:

From the above, and by addressing the subject of undisclosed information in the pharmaceutical industry, I reached a number of conclusions and recommendations:

1- Results:

- The absence of a comprehensive and comprehensive definition of undisclosed information in the pharmaceutical industry, in addition to the different nomenclature and methods of protection.
- The lack of special legal mechanisms to protect undisclosed information at the level of our national legislation other than the application of general rules, despite the many amendments adopted by the legislator since 2003 with the aim of harmonizing intellectual property rules with the TRIPS Agreement.
- Pharmaceutical products are of particular importance in the TRIPS agreement, with regard to undisclosed information, which is all that is related to confidential data and other information that is required to be submitted to government agencies to obtain a license to market medicines.
- The negative impact of the protection of undisclosed information created by the TRIPS Agreement on developing countries, especially in the pharmaceutical industry, so that developed countries remain the sole exporter of pharmaceutical products.

2- Recommendations:

- The Algerian judiciary adopts an international orientation through the conditions contained in Article 39 of the TRIPS Agreement, considering that Algeria is an observer member of the World Trade Organization as a temporary solution to the legal vacuum related to determining the conditions for acquiring knowledge of the status of undisclosed information until this crucial legal vacuum is remedied.
- More importance should be given to undisclosed information in the pharmaceutical industry, especially since it is closely linked to public health.
- Encouraging national institutions in the pharmaceutical industry, especially in the field of attracting national expertise, and providing an appropriate environment for the stability of these competencies and expertise in Algeria.

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(1) Dominique Dieng, Strategic Intelligence: Guide for research and innovation, Presses Universitaires de Namur, 2014, S.P

(2) Section 4 of Chapter I of the United States Uniform Act of 1979, which amended in 1985, defines trade secrecy as: "Information including structures, models, programs, technical methods and means, which: 1. It shall have a current and possible economic value, as long as it is known only to those persons who obtain its economic value through their work and use, and as long as it is not possible for others to discover or obtain it by lawful means. 2- And be informed by reasonable means according to the circumstances to maintain its confidentiality", Eng. Riyad Ahmed Abdul Ghafour, Legal Protection of Undisclosed Information: A Comparative Study in the Light of Intellectual Property Rights Laws and Conventions and the Provisions of the Civil Code, Anbar University Journal of Legal and Political Sciences, Iraq, Volume 1, Issue Eight, 2013, p. 367.

(3) The TRIPS agreement aims to create in practice a kind of substantive harmonization of the provisions of national legislation by requiring Member States to include the provisions contained in this agreement in their legislation, and to develop detailed regulation aimed at providing the greatest possible effective enforcement of intellectual property rights. In addition, in accordance with the preamble to the TRIPS Agreement, concluded at the end of 1993 and signed in early 1994, this agreement was based on the need to establish new rules and disciplines in a number of areas related to IP, including adequate standards for the existence, scope and use of intellectual property rights, as well as effective means of their implementation.
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(4) Eng. Riyad Ahmed Abdel Ghafour, op. cit., p. 368.

(5)Article 59, last paragraph, of Ordinance No. 03-07 of 19 July 2003 on patents, Official Gazette No. 44 of 23/07/2003 stipulates: "The competent judicial authority shall take into account the legitimate interests of the defendant when adopting any evidence it requests, by not disclosing his industrial and commercial secrets."".

(6)Article 627 of Law No. 15-20 of December 30, 2015, amending and supplementing Ordinance No. 75-59 of September 26, 1975, containing the Commercial Code, Official Gazette No. 71, issued on December 30, 2015, stipulates that: "Those in charge of management and all persons invited to

attend meetings of the Board of Directors shall conceal information of a confidential nature or that is considered to be such."".

(7)Mathieu Guerriaud, Pharmaceutical law, Editions Elsevier Masson S.A.S, France, 2016, p.26

(8) Jean-Claude Beaune, The philosophy of the remedy, Editions Champ Vallon, 1993, p. 38

(9)Drug is defined in European Union legislation as: "1- Any substance or compound of substances that have therapeutic or preventive properties for diseases affecting humans. - Any substance or compound of substances that may be administered to humans for the purpose of restoration, correction or modification of physiological function by means of a therapeutic, prophylactic, metabolic or diagnostic means." U.S. legislation in Section 102 defines medicine as: "Any substance used in the diagnosis, healing, improvement, treatment or prevention of any disease affecting humans or animals. or any substances other than foodstuffs intended to affect the composition or function of the human or animal body." Farhad Saeed Al-Saidi, Parallel Importation and International Exhaustion of Intellectual Rights in International Trade: A Study in the Trade of Patented Pharmaceutical Products, Journal of the College of Law for Legal and Political Sciences, Iraq, Volume III, Issue Ten, 2014, p. 74.

(10) In chapter five of Law No. 18-11 of 2018 on health, the Algerian legislator used the term pharmaceuticals and medical supplies, unlike the French legislator, which combined pharmaceuticals, medical devices and supplies with the French Agency for the Safety of Medicines and Health Materials under one title, "Health materials". Murr Siham, Civil Responsibility of Pharmaceutical Producers and Sellers - A Comparative Study -, PhD Thesis, specializing in private law, Faculty of Law and Political Science, University of Abu Bakr Belkaid, Tlemcen, 2016-2017, p. 41..

(11) Article 208 of Law No. 18-11 of 18 Shawwal 1493 corresponding to July 2, 2018 on health, G.R. No. 46 of 2018 defines medicine as: "Any substance or composition presented as containing therapeutic or preventive properties against human or animal diseases and all substances that may be prescribed to humans or animals for the purpose of carrying out a medical diagnosis or restoring, correcting and modifying their physiological functions."

(12) Article 209 of Law No. 18-11 of 2018 on Health stipulates that: "Medicines are also considered, in particular the following: - Diet feeding products that contain non-food substances that confer beneficial properties for human health. - Persistent products derived from blood. - renal clearance concentrates or peritoneal clearance solutions - Medical gases. They shall be similar in particular: - Physical hygiene and cosmetic products containing toxic substances in quantities and concentrations exceeding those determined by regulation."

(13) Eng. Samah Hussein Ali, Protection of Trade Secrets from Unfair Competition, Journal of Human Sciences, Volume 22, Issue Two, Harizan 2015, p. 879.

(14) Article 39, first paragraph of the TRIPS Agreement states: "1. While ensuring the effective protection of unfair competition as provided for in Article 10 bis of the Paris Convention (1967), member countries shall be obliged to protect confidential information in accordance with paragraph 2, and data provided to Governments or governmental bodies in accordance with the provisions of paragraph 3."

(15) The Paris Convention was concluded in 1883 and revised in Brussels in 1900, in Washington in 1911, in The Hague in 1925, in London in 1934, in Lisbon in 1958, in Stockholm in 1967 and in 1979. Accessed 7/03/2024. https://www.wipo.int/treaties/ar/ip/paris/summary_paris.html.
https://www.wipo.int/treaties/ar/ip/paris/summary_paris.html

(16)Article 39, paragraph 2, of the TRIPS Agreement

(17)Article 39 paragraph 3 of the TRIPS Agreement.

(18) Law No. 10-06 of August 15, 2010 amending and supplementing Law No. 04-02 of June 23, 2004 laying down the rules applicable to commercial practices, Official Gazette No. 46 of August 18, 2010.

(19) Article 10 bis, paragraph (c), stipulates that: "The following shall be prohibited: 1. All acts of a nature that are found by any means whatsoever in confusion with a competitor's establishment, products or industrial or commercial activity. 2 - Allegations contrary to the truth in the practice

of trade, which are of a nature to remove confidence from the establishment, products or industrial or commercial activity of a competitor. 3. Statements or allegations whose use in trade is likely to mislead the public as to the nature, method of manufacture, characteristics, suitability or quantity of the goods..

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(21)Nicole Ferry-Maccario, Marketing law: thwarting the legal aspects of advertising and commercial actions, Editions Person Education, France, 2008, p.16

(22) Eng. Riyad Ahmed Abdel Ghafour, op. cit., p. 389

(23) Article 59, last paragraph of Ordinance 03-07 on patents.

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