THE RESPONSIBILITY OF DRUG PRODUCER IN TORT LIABILITY FOR DEFECTS IN ITS PRODUCTS (A COMPARATIVE STUDY)

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ABSTRACT

The risks of scientific development are the relatively recent emergence in the legal system of the producer being responsible for its defective products, and the drug is among these products and with its risks that increase the probability of the damages, it is imposed on the legislator put a special system for liability for the risks of the drug producer. And since drug is one of the important products that aim at human health and safety, in addition to the economic importance of medications and the large funds invested in these industries, expanding the production base of pharmaceutical companies and starting their marketing to global markets. And the fact that the drug is closely related to human health and safety, but in some cases a person is unable to dispense with a drug product that he thinks is in dire need of it to relieve the pain or save his life. The medication is one of the inherently dangerous things that may cause harm to people in their money or their bodies from here attracted the topic of drug producer great attention, and was the subject of a lot of talk especially with regard to defining the concept of the drug and the defective drug, its product, and the obligations imposed on it, and the Iraqi legislator did not care about the subject of the drug and the obligations imposed on its product and did not put a specific definition for it, so we affected the research in this topic And comparing it with the French legislation, the legislation of the United States of America and the Egyptian legislation, to reach the best results.

Keywords: Drug Producer, French Legislation, USA Legislation, Egyptian Legislation, Defective Drug

INTRODUCTION

The medication industry is considered one of the most important industries and the most common and widespread in various countries of the world, and the purpose for this is due to the close connection of drug with the health of human. At a time when a person can dispense with thousands of consumer products, we find that he is unable to dispense with a one drug that he believes he needs to treat from a disease he suffers from. And as a result of that, countries were keen to put in place so-called (Drug Policies) that aim to provide the necessary medicines in abundant quantities and high quality to treat their citizens who need them. In light of the foregoing, many researches and studies have focused on addressing the problems of medication, and legal jurists had a role of these addressing, especially after it was placed on the shoulders of those in responsibility of developing the legislation the task of keeping pace with the tremendous development in the pharmaceutical industry with the corresponding development in the legislative field with the aim of protecting the consumers. This resulted in abundance and several of writings by legal jurists in the medical and pharmacology fields in general. Among the topics of concern was the issue of determine the damages that affect dealers in it, studying the provisions of liability, whether in criminal, civil or disciplinary terms, and what is related to that of determining who is responsible for the damages arise from the practice of these areas. Which entailed examining the responsibility of the hospital, the doctor, the pharmacist, the producer of drug, or the responsibility of all of these combined. It is important know that the search for civil liability for drug producers is gaining more importance for two reasons:

1. Most of the comparative legislations have recently been concerned with updating the provisions relating to the producer liability for harms caused by his defective products in general.
2. The Statistics issued by the World Health Organization stated that the size of defective or fraudulent medication produced by pharmaceutical companies in the world has exceeded 15% of the total global drug market (www.Islam.com).

The aim of the study is to focus on the responsibility of drug producers for the harms caused by their defective pharmaceutical products under the new system approved by much comparative legislation, taking into account that our research in this regard will focus on dealing with the provisions of liability from the contractual point only. The Legal concept of the drug medication is considered one of the most important products that individuals in any society need, and we do not exaggerate in saying that it is one of the most dangerous products to human health, given the harmful side effects it causes In the event of non-commitment for the controls on its use or consumption. Hence, legislation is keen to set controls for the process of its manufacture and circulation, in order to preserve the public health of individuals, and this means that the drug as a product has a specificity that distinguishes it from other products that individuals need, and this specificity appears in its importance and danger at the same time, which prompts those the legislators In various countries, towards the adoption of a strict legal system towards all persons dealing in it, whether doctors, pharmacists, distributors or producers.

The drug goes through successive stages of production until it is put into circulation, starting with a group of chemical research that is conducted by some laboratories of the pharmaceutical companies with the aim of detecting the treatment or preventive elements of certain diseases so that these companies provide adequate support to researchers, whether technically or financially, and then take place after that a series of experiments on some animals with the aim of selecting materials that prove their effectiveness while excluding others that have harmful effects on the human body. After checking the maximum effectiveness and the lowest degree of side effect, the process is trans to the manufacturing stage that begins with mixing the active substances extracted with taste enhancers, so that the drug comes out in the form of tablets, capsules or liquids after proper packaging, and all this is done according to recognized standards determined by the concerned government agencies. And it supervises it to ensure the safety of the drug, until it comes out to the consumer achieving its intended purpose (Radi, 1988).

FIRST TOPIC

Definition of Medication in France

The fifth book of the new legislative regulation of the French Public Health Regulation (CPS) is addressed (Official Gazette (JO), 2002). Publish in March of 2002 defining a drug, as the first paragraph of Article (L 5111-1) defined it as: “Every substance or compound presented as having curative or preventive properties agonist human or animal diseases, as well as every producer that can be submitted to Humans or animals for the purpose of medical examination or to correct or modify their organic functions (Article L .5111-1). The French legislator, through the definition contained in the first paragraph of the article (Article L. 5111-1) referred to, has stipulated two main conditions that are indispensable in the drug: - The first condition - that the drug consists of substances or compounds, and the second condition - that it must be available the properties of treatment or prevention of human or animal diseases. In addition to these two conditions, a third procedural condition stipulated in Article (L5121-8) of the same regulation, which is the necessity of obtaining in advance a license to put the medicinal producer for circulation in the market - which is known in the pharmaceutical community with the license (A.M.M).

The Defective Medication in France

Although the French Public Health Law set a specific definition for a drug, on the other hand, it did not address the concept of a defective that may occur to it. The French legislator in the Public Health Law intended this to avoid repetition of texts, especially since the civil legalization dealt with the conditions of defect necessitating the warranty in general, in addition to its statement of the meaning of the defective producer through its regulation of Law No. 389 of 1998 regarding liability arising from the act of defective producers (TGI Bordeaux, 1987). Where the drug is among the products that fall within the scope of application of the provisions of this law, in what was mentioned in Article (1386-3) of the French Civil Code, which defined the producer within the framework of this responsibility to expressly stipulate that "every movable property, even if it is incorporated into a property including producer extracted from the ground, resulting from livestock, hunting, fishing, and electricity is treated as a producer" (Corr, 1988). And since medicines are among the portables, of course, they are automatically included within this producer (RADP).

The Defect in View of Liability Rules for Doing Defective Products

The concept of defect in the view of the rules of liability for the act of defective products differs from it in the view of the general rules for guaranteeing hidden defects, and this difference appears by referring to what was stipulated in the first paragraph of Article (1386-4) of the French Civil Code, which clarified the meaning of the defective product, as it stipulated 'The product is considered defective if it does not provide the means of safety or security expected of it according to Sharia" (Article 1386-3).

Accordingly, the defect is inflicted on the product in the case in which the protection and safety of the consumer is endangered, so that it becomes harmful or harmful to everyone who uses it. The defect is based here on the idea of the lack of safety or protection expected by Sharia, and does not stop at the unsuitability for use or the absence of the promised quality in the sold product. It is noted that the legally expected lack of safety that the French legislator used to define the defect - according to the new system of producer responsibility - was not new or alien to French legislation, as it was previously used in the Consumer Safety Law issued on July 21, 1983 AD, which was stipulated in Article (L221-1) of the current consumption regulation issued on July 27, 1993 AD (Univ. Du Lille II, 1999).

In view of this legislative term, the defective product is not only the product that is not usable - as is the solution, for example, in laser cylinders related to computers, which may contain programs with viruses that affect the information system of the buyer's device - but the defect may be found in the product according to The new responsibility system despite its validity for use for the purpose for which it was prepared, which is achieved with products that are dangerous by their nature. The defect in its new concept is automatically realized as soon as the safety or security expected from the product is not available, regardless of the identification of the source of this defect.

The Producer of Medication in France

The French civil code was keen through Article (L1286-6) to define the product in general, to state that it is "the manufacturer of the final product, the producer of the raw material, and the manufacturer of a part that is included in the composition of the final product." It also continued the same article in its second paragraph, emphasizing that "it is considered as a producer:

1. Every professional who puts his name, trademark, or any other distinctive mark on the product.
2. Every professional who imports a product into the European Union for the purpose of selling or renting with or without a promise to sell, or any other form of distribution of the product (Art. 1386-4).

Through the defining the producer in the above article, we can abstract some facts, their statement as follows:

First: The French definition is completely identical to what was stated in Article 3 of the European directives on July 25, 1985 AD, from which the French legislator quoted the provisions of the objective responsibility of the producer for the damage caused by his defective products.

Second: This definition is broad and comprehensive, because everyone who contributed to the production process - even if a small amount - was considered responsible for the damage caused by his defective products, whether he was an actual product or just a product in terms of appearance (Art. L 221-1).

Third: The French legislator was interested in emphasizing the quality of professionalism that must be present in the producer in order for it to bear its responsibility in the face of the harmful (Leveneur, 1998). The wisdom is to be strict towards professionals alone and to protect people whose role is limited to conducting experiments and scientific research on some products without seeking to put these products into circulation.

The French jurisprudence concludes from the previous definition by dividing producers into two groups: - the first group includes producers in the strict sense - or as they are called actual producers - and the second group includes other people considered as producers - or producers in terms of appearance as they are often called and on As follows:

A. **The Actual Producer:** It is the one that does not out from one of three person: - The first - the manufacturer of the final product who takes over the supervision and control over the manufacture of his products, and brings the product to the public bearing his name or trademark, and the second - the manufacturer of raw materials that are subsequently subject to the transformation process The industrialist, and the third - is the manufacturer of a part in a product consisting of a group of parts.

B. **The Apparent Product:** We mean everyone who appears in front of consumers with the appearance of the producer, such as the owner of the patent or the owner of the trademark that appears on the products, or the professional importer, in addition to everyone who contributes to the distribution of these products. The wisdom of considering the owner of the patent or the owner of the visible mark as a producer is that the real product may be unknown to consumers, and then the legislator wanted to provide them with protection by referring to the person who presents himself to them as a producer of the commodity. As for the wisdom of considering the importer of the commodity as a producer, it is the facilitation the consumer who is harmed by the product defect, and who, if not for this ruling, would have to sue the actual producer in the country to which he belongs (Article 1386-6).

SECOND TOPIC

Definition of Medication in USA

Through looking at the American legislation, we find that the American legislator deals with the concept of medicine through the Federal Food, Drugs and Cosmetics Act issued on November 21, 1997 (Article L1386-7). After specifying the official authorities concerned with recognizing and registering the drug, the second book of this law in Article (201) included the definition of the drug to stipulate that it is “substances specially prepared for use in the areas of medical diagnosis, treatment, pain relief, healing or prevention of diseases, as well as substances - other than food - intended to affect the structure or functions of the human or animal body" (Larroumet, 1998). We can include some notes on the American legislation for food, drug and cosmetics, as follows:

1. All American legislation showed the provisions on food, drug and cosmetics in one code. Although not subject them all to the provisions of the same. Whether in terms of conditions for granting the required licenses, registration procedures, or in terms of defining places of sale. Or with regard to preservation, storage, packaging or packaging. Even in terms of the penalties imposed in the event of violation of the provisions of each of them (Jamei, 2000).
2. The American legislator used the term "drug" in its broad sense to express medicine, unlike what is the case in France, which deleted the same term, which is in French (Drogue), from the public health law so that it no longer serves the meaning of medicine as it was in the past, but rather is used only on what It is called inferior drugs (Médicament mediocre) or narcotic substances that do not appear to be of legal importance except when the provisions of criminal responsibility are applied (Roosevelt, 1938).
3. American legislation was interested in setting a specific definition for each of the food and cosmetics so that these concepts do not mix with the concept of medicine, and thus it is easy to identify the legal provisions applicable to any of them. The American legislator defines food in Paragraph (F) of Article (201) as "substances used in food or drink for humans or other animals." It also defines cosmetics in Paragraph (I) of the same article as "substances intended for use on the human body to clean it or improve its appearance, including: skin care paints, nail polish, perfumes, hair dyes, toothpastes, deodorants, etc. (Section 201(321)).

The Defective Medication in USA

If we follow the US Federal Food, Drug and Cosmetic Act of 1997, we will find that it was not directly exposed to what is meant by defective drug, but was limited only to stating what is considered adulterated drugs, as stipulated in Article (501) of American law.

A part of American jurisprudence concludes when interpreting the text of Article 501 that the Federal Food, Drug, and Cosmetic Law exposes some cases that combine fraud and defective medication, stressing that the meaning of defect is broader in scope than the meaning of fraud that appears in cases where the product deliberately deceives the consumer in contrast to the defect. Which may result from inadvertent error or negligence? But despite the conclusions of this jurisprudential opinion, the texts of the legislation cannot say that the American legislator has set a specific definition of the defective drug, especially since the responsibility for the act of defective products requires a different concept of the defect that may exist despite the validity of the medicinal product for use (Cooper, 2000).

The Producer Medication in USA

If we look at the legal system in the United States of America, we will find that there is no unified federal law that deals with the provisions of liability arising from the act of products, but in some states there are special laws that lay down a non-detailed regulation of these provisions, although most of them depend on the regulation of the provisions of this responsibility on Common law and related legal precedents as the official source of American law, in addition to some texts contained in the Uniform Commercial Code (FHL, 1941).

According to the American legal system, the person responsible for defective products is not only the producer of the commodity in its final form or the producer of part of its component parts, as well as everyone who sells it, in addition to any person to whom the commodity is transferred from the time it leaves the possession of its product until it reaches the consumer (USFDA, 2002). It is the stage that American jurisprudence calls the "commerce chain movement", as is the case for wholesalers or distributors who may be responsible for defective products despite the absence of any role for them on absolutely in the defects that befall it (Article-501-a-b-c-d). Of course, it is possible that there are several people responsible for the defect that befalls the product, and in this case they are jointly liable in the face of the harmful, with each of them retaining reference to the other, and therefore if the defect affects part of the commodity parts, in this case the responsibility rests with the Both the maker of the defective part and the producer of the entire item in its final form (Phillips, 1998).

In application of the above, on the pharmaceutical product, we will note that the American system is not much different from the situation in France, in terms of expanding the

identification of those responsible for the defects that befall the medication and cause harm to consumers. The producer is according to the definition issued by the American Institute of Law - which is a body of senior jurists in the United States of America entrusted with the arrangement and preparation of some federal legislation, as it was often quoted by the Parliament of the European Union, and in particular when formulating provisions of liability arising from the damages of defective products (Phillips, 1998). He is the manufacturer of the drug in its final form or the primary formulation of the chemicals it contains, or the licensee to offer the drug for sale from the US Food and Drug Administration, as well as the owner of the patent for the drug, and the owner of the trademark that is placed on the drug or any other distinctive mark even if he was not the actual manufacturer. In addition to what has been mentioned, distribution intermediaries and hospitals that dispense medicines to patients in outpatient clinics or to patients residing there.

THIRD TOPIC

Definition of Medication in Iraqi and Egyptian Legislation

If we refer to the comparative legislation, we find that some of them set a definition for the drug in general, while others sufficed with defining the two most prominent forms of the drug, namely: private pharmaceutical preparations and constitutional pharmaceutical preparations (Owen, 2014). The Iraqi legislator did not provide a specific definition of the drug, but rather provided a definition for the special preparations and the constitutional preparations in the Pharmacy Practice Law No. (40) for the year 1970, where the first article of it defined special preparations as: (Preparations or combinations that contain or are described as containing one or more substances of Medical wicker to cure humans or animals from diseases or to prevent them, or used for any other medical purpose, even if it was not expressly declared, and which have already been prepared for sale, offered for sale, or given to the public for external or internal use, or by injection, provided that they are not included in one of the editions of the pharmacopoeia and their official appendices. Among these preparations are liquids and equipment intended for disinfection that is not mentioned in the pharmacopoeia and household insecticides, as well as food products and cosmetics that are used only for medical purposes). The first article of the same law defined the constitutional preparations as: (The medication and compositions mentioned in one of the pharmacopoeias recognized in Iraq).

As for the Egyptian law, Article (58) of the Pharmacy Practice Law No. (127) of 1955 A.D. states that: “In the application of the provisions of this law, special pharmaceutical preparations are considered products and compositions that contain or are described as containing one or more substances with medicinal properties in healing.” Human diseases or their prevention or use for any other purpose, even if it is not explicitly announced when they are prepared for sale and were not included in one of the editions of constitutions and their official appendices. Article 62 of the same law defines constitutional pharmaceutical preparations as: In one of the editions of the pharmacopoeia for which a decision is issued by the Minister of Public Health, as well as constitutional fluids and equipment intended for disinfection).

And if the Egyptian legislator did not put a comprehensive definition that prevents the drug, but it distinguished between pharmaceutical products and cosmetics, through the decision of the Minister of Health regarding the regulation of the circulation of cosmetics, which stipulated that: “A cosmetic product is any substance or any preparation intended for the apparent use of the human body. Such as (the skin of the skin, hair, nails, lips) or the teeth and the mucous membrane of the mouth or the area adjacent to the eye for the purpose of cleaning or protection to maintain it in a good condition or change its appearance or overcome body odor or sweat, and treats medical soap, toothpastes and petals Treating cosmetics, as for colognes, perfumes and air fresheners, they are not treated as cosmetics. Thus, we find that the products to

which the above decision applies are outside the meaning of medicine and are not subject to pharmaceutical monopoly.

Medications are divided into two main categories, in terms of their prescription:

1. Non-prescription medication, which are unsafe and cannot be used without medical supervision.
2. Prescription medications which are safe for human health because they are under the supervision of a specialist (Gaz Pal, 1988).

The first section of the drugs is called over-the-counter-drugs (drugs offered without a prescription). The second is known as Prescription drugs (drugs offered with a prescription). Medication can also be classified according to the type of treatment they perform into topical drugs, hypnotics and anti-allergic drugs, and each drug has three names, the first chemical, the second commercial, and the third a generic name (PPL, 1955). We conclude from the foregoing that the application of the description of the drug to a substance requires the availability of the following elements: - The procedural element, which is the necessity of obtaining a permit from the state before its production. Also, medication is a chemical substance or composition, and medicine is used to prevent or treat diseases suffered by humans or animals.

The Defective Medication in Iraqi and Egyptian Legislation

Our identification of the defective drug in Iraq and Egypt requires that it be presented in a brief manner of what the defect is in the Iraqi and Egyptian laws, and the conditions that must be met in it so that the harmful person can return to the claim of warranty, so we will address the following:

What is the Defect in Iraqi and Egyptian Legislation?

The Iraqi and Egyptian law did not address the defect except by organizing it to guarantee hidden defects in the sales contract (Badr, 2005). The jurisprudence and the judiciary have decided to define what is meant by defect and they are in the process of interpreting and applying this special text to ensure hidden defects, as part of the jurisprudence defines it as “the defect that occurs in a thing in an unusual state in its normal state, as the foundation of construction, cracks in walls, crushing in pots, tools, machines, and decay in grain ...etc."(Ruth, 1996). On the other hand, another aspect defined it as meaning: “The lack of the quality that the seller guaranteed to the buyer is present in the thing sold, and whose failure is considered a scourge of the defect in the normal situation” (Berhan, 2008). As for the Court of Cassation, its rulings have been repeated on the definition of defect as “an emergency scourge that is devoid of the origin of common sense for the thing sold” (Al-Haytham, 2006).

Conditions that Must be Met by the Defect

According to the general rules, the defect that causes the warranty is required to be hidden, effective, and to be present at the time of delivery of the sold item, in addition to being unknown to the buyer, the apparent defects are not guaranteed by the seller, meaning that if the buyer is able in the sales contract to reveal the defect by examining it The sale is done with the care of the usual person, so he is not entitled to recourse against the seller based on the rules of guaranteeing the defect in the sold item. Also, the defect is required to be effective, so that it decreases the value of the thing or its benefit according to the intended purpose, but bearing in mind that the buyer cannot Recourse to the seller if the thing sold does not achieve a special use that is not the usual use, as long as the buyer did not stipulate that private use in the contract (Article-558).

Likewise, one of the most prominent conditions for the defect is that it be present at the time of delivery of the thing sold to the buyer. In the thing sold after delivery, it is not

considered available and is not guaranteed by the seller. Finally, the defect is required to be unknown to the buyer, because the buyer's knowledge of the defect presupposes his satisfaction with the defective sold item, and the seller's knowledge of the defect in the thing sold does not count, as he guarantees the defect whether he is aware of it or is ignorant of it (Mansour). If we want to conclude that a particular drug product has a hidden defect, it is necessary in the first place that there be a sales contract in the relationship between the consumer of the drug and its producer, since the absence of this contractual relationship inevitably leads to the absence of the warranty for the hidden defect, which may happen, for example. In public hospitals where treatment is given to patients free of charge, as well as in cases in which the patient takes free samples of medicine, which the doctor or pharmacist distributes to him, in such cases the consumer of the medicine will have no choice but to refer to the product on the grounds of tort liability (Mamoun, 1998).

The Producer Medication in Iraq and Egypt

Determining what is meant by a drug producer is very important because it will lead to identifying the people responsible for the damage caused by pharmaceutical products in general, as the producer has the burden of compensating consumers for the damage they incur due to the defects of the drug that he produces, and in order to show that we will divide this requirement Into two branches, in the first we talk about defining who is the actual producer?, and in the second we define who is the apparent producer?

Actual Producer

Drug producers can be divided into two groups, the first includes producers in the actual producers, and includes, the final product manufacturer who undertakes supervision and control over the manufacture of his products, the manufacturer of raw materials that are later subject to industrial transformation, and a manufacturer of a part of a product consisting of several parts. The pharmacist who prepares or installs pharmaceutical preparations and preservative factories in containers, packaging or packing. While the second category includes people who are considered to be the producers or the apparent producers, and it includes the patent owner, the owner of the trademark that appears on the product, the professional importer and the distributor of the drug.

First: The Manufacturer of the Final Product who Takes over the Supervision and Control over the Manufacture of his Products

The manufacturer of the final product who undertakes the supervision and control of the manufacture of his products with regard to pharmaceutical products often takes the form of a company, as it is unthinkable for a natural person to produce the drug except in one case, which is the pharmacist who prepares or installs pharmaceutical preparations. By producer, it is meant the one who takes over the thing until it produces its product or the benefit required of it (CC, 1948). The importance of determining what is meant by the product is reflected in the fact that the manufacturer of the drug, Le fabricant du medicament, is the primary cause of harm to drug consumers (Mamoun). If we want to define the concept of the producer in Iraqi law, we find that the Iraqi legislator addressed the definition of local producers in instructions to facilitate the implementation of the provisions of the Law on Protection of Iraqi Products No. (11) of 2010 AD in Article (2), paragraph (1) thereof (Al-Amrousy, 2013). It seems that the Iraqi legislator adopted the method of determining the producer through the industrial means that the person adopts in production (Abdel-Al, 1992). It is also understood from the text of Article Two of the Law of the Central Agency for Inspection and Quality Control No. (54) For the year 1979 that the producer is the natural or legal person who undertakes the process of manufacturing and forming the products in its final form (Muhammad, 1991).

As for the Egyptian law, we find that the Egyptian legislator defined the industrial producer in the General Sales Tax Law No. (11) For the year 1991, where the first article of it stipulated that: "Pharmaceutical establishments, in the application of the provisions of this law, are public or private pharmacies, pharmaceutical factories and drug stores." It turns out to us that the Iraqi legislator did not define the producer in general, so we hope that our Iraqi legislator defines the meaning of the producer in general and takes into account the definition of the producer in the broadest sense to provide the maximum possible protection for consumers, especially for consumers Pharmaceutical products due to their danger and importance at the same time.

Second: Manufacturer of Raw Materials that are Subsequently Subject to Industrial Transformation

The manufacture of a particular drug may require some of the raw materials that are included in its composition, and these raw materials are often extracted from plants, animals or minerals, and these materials are produced by an independent entity called the raw materials manufacturer, meaning the natural or legal person who performs the primary formulations included in The manufacture of a drug, which is subsequently subject to industrial transformation into a drug by the manufacturer of the final product. There are some legislative texts that use the word maker (Shalgami, 2008). It often seeks to limit the responsibility to the range of persons involved in the process of industrial transformation (Transformation) of raw materials on the grounds that the actual field of study of responsibility is industrial products, while other legislation used the term product (Al-Azzawi). It aimed to expand the circle of those responsible for defective products, to also include producers of raw materials that were not subject to industrial transformation (QCL, 1979).

Third: The Manufacturer of a Part of a Product Consisting of Several Parts

The production process may be carried out by one company, then it performs the process of extraction or transformation and then puts its products for circulation in the market, but this situation has become rare at the present time. This situation is in the pharmaceutical production process (Falih, 2010). But in view of industrial progress and international division of labour, some parts of a product may be from the manufacture of another product. In this assumption, the manufacturer must treat a part of a product consisting of several parts as the final product, and thus the same rules applied to the product (Article (67-3)). The producer and the manufacturer should not be confused, as the minimum in the industry assumes an industrial transformation of the part of that product and the parts that have not been industrially transformed are out of the scope of responsibility for defective products (Article, 1386-6). There is no express provision in Iraqi law that extends liability for defective medicine to the manufacturer of a part of a product. As a result of this, some jurisprudence in Iraq went to the view that the consumer should refer to the final product and not to the maker of the parts that make up the product, because this justifies the severity of the final product and its concern for the people who share it. With regard to the drug product in the Egyptian law, it did not allow the consumer to refer to anyone who interferes in the process of manufacturing the drug for the damages that may occur, and therefore the manufacturer is not considered a product of a part of a product consisting of several parts in the Egyptian legislation (Martyr Leaders, 2007).

Fourth: The Pharmacist who Prepares or Installs Pharmaceutical Preparations

The pharmacist's obligation is an obligation to achieve a result represented in providing or selling valid and safe medication that does not pose a danger to the consumer (the patient) who takes them. The drug and the extent of its success in treatment is an obligation to take care (Dr. A martyr's leader). The role of the pharmacist in preparing the drug and preparing it in his

pharmacy has diminished with the scientific progress in the field of medication industry, and it is mostly limited to selling medication (Fatak, 2008). The pharmacist is responsible with the pharmaceutical company as long as he was aware that the medication were not valid, but he nevertheless sold them (Osama, 2005). Article (12-2-3) of the Iraqi Pharmaceutical Profession Law No. (40) for the year 1970 permits pharmacists, pharmacists' assistants and assistants, health staff and students of the College of Pharmacy who are under training to prepare Medicines or packaged (Arafa, 2009). If the drug is prepared in the pharmacy, it is placed in a suitable container, and on its card the name and address of the pharmacy, the name of its owner, the registration number in the medical ticket record book, the name of the drug, the date of preparation, and how to use the drug if it was dispensed without a medical ticket (Majid, 2005). In the event that the prescribed medicine is not available, the pharmacist must inform the patient of the characteristics and dangers of the alternative medicine, even if this medicine is licensed. Also, Article (34) and what follows from the Egyptian Pharmaceutical Profession Law No. (127) of 1955 permitted the pharmacist, the pharmacy director, and the assistant pharmacist, and pharmacy students have to bring medication to the pharmacy according to a medical ticket (Al-Wajeez, 2007). It appears from the foregoing that the pharmacist falls within the concept of the drug product in Iraqi and Egyptian law if his role is focused on the installation or preparation of pharmaceutical preparations. He shall be committed to ensuring safety towards the consumer of medicines unless the doctor himself specifies the materials used in the composition and their quantities.

Fifth: Preservation Factories in Containers, Packaging or Packing

The Iraqi Industrial Investment Law for the Private and Mixed Sectors No. 25 of 1991 showed that packaging works are included in production processes. Therefore, it is possible for factories to be preserved in containers, packaging or packaging by virtue of the producer according to Iraqi law. As for the Egyptian legislator, it extended the scope of responsibility for defective pharmaceutical products to factories for preservation in containers, packaging or packing, according to the text of Article 1 of the General Sales Tax Law No. 11 of 1991, which defined manufacturing as: Converting an organic or inorganic substance by manual or mechanical means or other means to a new product or changing its size, components, nature or type. It is considered manufacturing. Installation of parts of devices, packaging and preservation in boxes, parcels, bottles or any other containers, with the exception of packaging agricultural products as they are. And the packing operations carried out by the retail or retail stores when selling directly to the consumer, as well as the installation of machinery and equipment for construction and building purposes). The drug is considered one of the products that are subject to sales tax, and only samples of imported or locally manufactured drugs are included in the tax exemption (IPP, 1970).

Apparent Producer

First: The Owner of the Patent that Appears on the Product

What is meant by invention is an innovation that did not exist before in all or some aspects, and invention is an action and an effect of the work of the mind and its effects result in something new (Al-Obaidi, 2003). The Iraqi legislator has specified in Article Two of the Patent and Industrial Models Law No. 65 of 1970 the conditions for granting a patent, as it states that: - (Patents are granted based on the provisions of this law for every modern industrially applicable invention that contributes to an innovative step related to either a new industrial product or new industrial methods or a new application of known industrial methods). Contrasted with the text of Article 1 of the Egyptian Intellectual Property Protection Law No. 82 of 2002, which also specified the conditions and foundations for granting a patent, as it stipulated that: "A patent is granted in accordance with the provisions of this law for every invention that is industrially

applicable, that is new and represents a creative step, whether it is The invention is related to new industrial products, or to newly developed industrial methods, or to the application of well-known industrial methods. The patent is also granted independence from every modification, improvement, or addition to an invention for which a patent was previously granted, if it meets the conditions of novelty, creativity and industrial applicability. The grant of the patent is to the owner of the modification or improvement or addition in accordance with the provisions of this law) (Falih, 2000).

The availability of the above conditions (novelty, innovation, applicability) gives an extraordinary advantage to pharmaceutical companies in obtaining new patents or industrial methods developed for drug production. The application of the monopoly rights of the patent in a particular drug leads to the provision of that drug at reasonable prices to its consumers, while the absolute monopoly of the patent leads to a rise in the prices of drugs, especially the new ones (Article 5).

Second: The Owner of the Trademark that Appears on the Product

The trademark has a special importance in the field of medication in general, as it is a fertile field for intense competition between pharmaceutical companies and pharmaceutical products, especially cosmetics, even between similar groups of medication and preparations. A trademark or industrial trademark means every trand or indication that the merchant or manufacturer places on the products he sells or manufactures to distinguish these products from other similar goods (Hassan, 2000). The brand requires some conditions, perhaps the most important of which is that it does not violate public order and morals, especially brands that would mislead the public (Al-Din, 1993). The Iraqi legislator defined the trademark in the amended Trademarks and Geographical Indications Law No. 21 of 1957. The first article states that: “Any sign or group of signs can constitute a trademark through which it is possible to distinguish between the goods of a project from the goods of other projects.” Such as signs, especially words, including personal names, letters, numbers, symbolic shapes and colors, as well as any combination of these signs can be registered as a trademark. If signs are not in themselves capable of distinguishing goods or services, the possibility of registration depends on the distinctive feature gained from use, nor must the sign be visually perceptible in order for it to be eligible for protection as a trademark.

Corresponding to it is the text of Article 63 of the Egyptian Trademark Law No. 83 of 2002, which stipulates that: - (Everything that distinguishes a product - a good or a service - from others, and includes in particular the names that take a distinctive form, signatures, words, letters, numbers, and symbols, drawings, shop addresses, stamps, seals, images, reliefs, and a group of colours that take a special and distinctive form, as well as any combination of these elements if they are used or intended to be used either to distinguish the products of industrial work, agricultural exploitation, or forest exploitation Or for extracts of the land, or any merchandise, or to indicate the performance of one of the services, and in all cases the trademark must be visually perceptible). The difference between the Iraqi and Egyptian legislatures is clear through the above two texts, as the Egyptian legislator requires the visual perception of the trademark, while the Iraqi legislator does not.

Third: The Professional Importer

In view of the seriousness of the issue of importing medication, which as time passes, their harmfulness and spread increase, it was necessary to regulate the importing party (Al-Qalyubi, 2016). Also, the inability of pharmaceutical companies or factories in the Arab countries to provide adequate medicine to their people necessarily leads to their resorting to imports (Samiha). Legislative policies have depended from the beginning on unifying the importer of medication and regulating trade in them, in order to eliminate intermediaries and remove extraneous elements from them, considering their goal as a public service and not

speculation to achieve profits. In Iraq, Law No. 9 of 1983 was issued regarding the General Establishment for drug and Medical Supplies, which aims to provide medication, pharmaceutical chemicals, constitutional and special medical preparations, medical supplies and equipment, and chemicals that are used in the manufacture of drug and poisons, whether by importing them from abroad or making them in Iraq. According to the above-mentioned law relating to the General Pharmaceutical Corporation, the Iraqi corporation is obligated under Article (2-Second-C) to take the necessary measures to import what Iraq needs in terms of medications, chemicals and medical supplies to achieve its purposes set out in Paragraph (First). As for the Egyptian legislator, it issued Law No. 212 of 1960 regarding the trade of drug, chemicals and medical supplies, where the first article of it stipulated the competence of the Supreme Authority for Medicines to import medication, chemicals and medical supplies.

Fourth: The Drug Distributor

Medications stores in Iraq often play the role of a distributor, and the medication store is the link between the producer and the pharmacist. The responsibility of the drug distributor may be raised by subordination to the responsibility of the producer, and his responsibility may be raised independently, because the distributor is committed with the drug producer to provide drugs or medical materials that achieve the health security expected of them by law, and it is a commitment to achieve a result and not take care (Hegazy, 2008). And some jurisprudence in Iraq goes to extend the scope of the producer's responsibility to include the distributor in the event that the identity of the producer is not known with regard to local products, and when the importer is not aware of foreign products (Falih). In Egypt, the responsibility of the distributor is contractual to compensate for the damages if the elements of responsibility are available, such as the distributor’s error that is limited to the limits of his job of storing and distributing the drug, which necessarily includes monitoring the drug, ensuring its packaging and preservation, and sorting out the damaged and expired ones (Salam).

Liability of the Drug Producer in the Tort Range

The tort liability can give the drug consumer some advantages that he does not find if he resorts to a contractual liability lawsuit. For example, the warranty lawsuit in the field of medication defects seems useless, as this lawsuit gives the consumer the right to claim annulment or reduction. The price, which is absolutely useless in the field of harm arising from the medicine, and therefore the victim has no choice but to obtain compensation, which is provided by the general rules in tort liability and perhaps better than those provided by the provisions of contractual liability. In view of our study of the tort liability of the drug producer, we will seek to identify the role played by jurisprudence and the judiciary in order to expand the scope of the drug producer’s tort liability, as detailed below:

Expanding the Idea of Error as a Basis for Drug Producer Responsibility

It is common knowledge that a fault that causes tort liability can be defined as a breach of a legal duty or a deviation in the usual behavior of a distinguished person. On the basis of this, the error of the drug producer is determined as a breach of a legal duty or negligence in the conduct of the drug producer that does not occur from any vigilant producer exposed to the same data and circumstances that surrounded the responsible producer. And the error of the drug producer that leads to the defect of his products is especially evident in the case of the chemical composition of the drug, as the producer is mistaken if he neglects to verify the safety of the elements that go into the manufacture of the drug he produces, or if it is proven that he is not aware and understanding of the nature of the elements he entered in the composition of the drug, which caused The inclusion of elements that would negatively affect the safety of the drug, as well as the product’s error in the conditions of the drug being offered for circulation without

conducting the necessary research and experiments that prove its safety for the prevention or treatment of certain diseases (IGPMAL, 1983).

Here, we cannot fail to emphasize that the producer obtaining the compulsory licenses from the regulatory authorities in the state, such as the Ministry of Health, by offering and marketing the drug does not in any way negate the error of the drug producer if it is proven to be neglected or negligent, as there is no dispute that it is an impossible form to prove. The regulatory bodies in the pharmaceutical field in particular ensure the safety of all packages containing drugs that are offered to consumers, but these control bodies carry out their tasks only on samples of those drugs. But it remains to be emphasized that it is conceivable that the regulatory bodies will share the error with the drug producer, if it is proven that they have failed, for example, in verifying the percentages that make up the chemical components of the drug, which causes wrongly the issuance of licenses to put the drug on the market, or if it authorized the introduction The medicine is in unsafe packages that may interact with chemicals in a way that has a detrimental effect on the safety of the content. Such appearances and others may lead to the existence of a common mistake between the product of the medicine and the parties that authorized its placement in pharmacies for consumers.

Guarding Dangerous Things as a Basis for the Responsibility of the Drug Producer

The industrial revolution that appeared with the early forties of the last century, and the resulting economic and social changes, led to the adoption of civil legislation in most countries of the world of a developed concept of the idea of guarding things as a basis for the responsibility of any person whose guarded dangerous things cause harm to others, and the truth The Iraqi legislator and the Egyptian legislator, in turn, kept pace with these changes, as after the civil law in both legislations organized the responsibility of both the animal guard and the building guard. The responsibility of the guard of dangerous objects in the Iraqi and Egyptian civil law, like the situation in the French civil code, is based on a conclusive presumption that does not accept proof of the contrary, and it is the presumption of error in guarding, which relieves the harmful of the burden of proving the guard's mistake, but it is sufficient for him to prove the interference of the thing under guard in the events damage, and the receiver cannot get rid of this presumption except by proving the foreign cause (Al-Rifai, 1994).

And since the application of the general rules would lead to the absence of liability for the drug producer as a guardian of the formation as soon as the drug is delivered to the consumer, who, upon receipt, becomes the actual guardian of the thing, and therefore he is responsible for the damages that occur to him or to others. For this reason, the French judiciary invented the idea of "fractionation of guard" by establishing a distinction between two types of guarding, namely guarding of use (Gard de comportment) or guarding behavior as some call it. The composition guard (Gard de structure), which is based on the producer or the pharmacist, with its capabilities of supervision, control and follow-up of the internal composition of the drug, is responsible for this composition even after it is delivered to the consumer, who is considered a guard for use only, so that the error of the drug producer is assumed and he must even He gets rid of the responsibility if he proves the fault of the consumer (the use guard) or the existence of the foreign cause. The French jurisprudence initially rejected the idea of dividing the guard set up by the judiciary, but it returned to meet it in many disputes, the most prominent of which was a famous judicial dispute known as the (Oxygene Iiquide) lawsuit (Article, 222). Also, the French judiciary tended in some of its rulings to reject the idea of dividing the guard in the field of medicines and medical products. At the time, we find that it is still highly dependent on it in other fields. In Egypt, part of the Egyptian jurisprudence tends to reject the idea of dividing the guard based on a valid argument to the effect that this innovative type of guarding (the formation guard) would lead to the quality of the guard remaining attached to the product and never separated from it, no matter how far it is related to what he produced.

CONCLUSION

The Iraqi legislator did not consider the manufacturer of raw materials that are subsequently subject to industrial conversion from drug producers, and the Iraqi legislator also did not define the meaning of the producer in general, and did not take in its definition the broad concept of the meaning of the producer to provide the maximum possible protection for consumers. And the Iraqi, Egyptian and French legislators stipulated that the packaging factories be considered by virtue of the producer, and with regard to the Iraqi and Egyptian law, there is no explicit text that the owner of the patent that appears on the product is a producer of it, unlike the French civil legalization, and it is clear from the above that it is necessary to expand the scope of responsibility to include both It contributes to distributing the medicine because it is not possible in some cases to know the identity of the producer or to reach it if its location is known. Therefore, we call on the Iraqi legislator to consider the medication distributor in the same judgment as his producer.

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Article (501-a-b-c-d) of the US Federal Food, Drug, and Cosmetic Act of 1997.

Article (1386-6) it is a manufacturer, although it has a professional title, the manufacturer of a fine product, the manufacturer of a primary material, the manufacturer of a component part.

Art. (L 221-1) Consumption code: "The products and services are sufficient, under normal conditions of use or in other conditions reasonably foreseeable by the professional, to provide security on which they are legitimately extended and not to be carried out santé des persons".

Art. 1386-4. (1) – A product is defective in the sense of being present when it is safe to justify itself without delay.

Article 1386-3 "It is all furniture, but it is incorporated into furniture, and includes products of the sole, the elevator, the chassis and the pedestal. Electricity is considered a product".

Article (L.5111-1) Medium to any substance or composition present as having curative or preventative properties in the treatment of human or animal diseases, wherein any substance or composition which can be administered at any time or at any time to establish a medical diagnostic or to restore, correct or modify their physiological functions by performing a pharmacological, immunological or metabolic action. Not to be regarded as medicaments the dietary products which refer to their composition of chemical or biological substances not constituting all of the same alimony, but the presence of which is specific to each product, according to its own specific requirements test repa.

Article (558) of the amended Iraqi civil code no. 40 of 1951. and Article (447-1) of the Egyptian civil code.

Article (L1386-7) stipulates that: "The location, the environment, the receipt of the credit balance or the credit assimilated to the credit balance, or any other professional supplier is responsible for the lack of security of the product in the very conditions that the product".

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