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D. Ángel García Vidal

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ABBREVIATIONS

BSA	Business Software Alliance
CAN	Community of Andean Nations
CBD	Convention on Biological Diversity
CPA	Coalition Provisional Authority
EC	European Community
EEC	European Economic Community
EPC	European Patent Convention
FAO	Food and Agriculture Organization of the United Nations
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
HDI	Human Development Index
ICJ	International Court of Justice
IIPA	International Intellectual Property Alliance
IPC	Intellectual Property Committee
ITC	United States International Trade Commission
MERCOSUR	Mercado Comun del Sur
NAFTA	North American Free Trade Agreement
NSB	National Seed Board
OECD	Organization for Economic Co-operation and Development
PHOSITA	Person Having Ordinary Skill in the Art
STR	Special Trade Representative

TPRG	Trade policy Review Group
TPSC	Trade Policy Staff Committee
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UNCTAD	United Nations Conference on Trade and Development
UNEP	United Nations Environment Programme
UNESCO	United Nations Educational, Scientific and Cultural Organization
UPOV	International Convention for the Protection of New Varieties of Plants
USTR	United States Trade Representative
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

SUMMARY

1. One of the most important international treaties that Iraq is not part of is the TRIPS agreement. Iraq is not one of the members of WTO, but it is in the process and right now is in the list of observer governments. In the same way Iraq is not a member of the most treaties and unions under WIPO except for Paris Convention (1976) and WIPO Convention (1976). However, it is the TRIPS agreement that provides for the wide range of protections of intellectual property rights. Therefore, it is the purpose of this research to analyse all possibilities of implementing the TRIPS agreement, especially in the area of patent by the Iraqi government.

Therefore, the key hypothesis of this research is that Iraq should implement a law that fulfils the requirements of the TRIPS Agreement and at the same time include all the legal flexibilities that help to develop the country with minimum costs and sacrifices. For this reason, the main question that this research asks is whether the CPA Order No. 81 after its dramatical amendments has achieved this goal.

The main objective of this research is to examine and analyse the original Iraqi Patent and Industrial Design Law No. 65 of 1970 (The Patent Laws only) in comparison to the amendments in particular the CPA Order No. 81, then compare these with the provisions of the TRIPS Agreement in order to find out the confirmations and contradictions among them.

The main results achieved are summarized below:

2. TRIPS Agreement is one of the most important agreement which have standardized the intellectual property protection by stating the minimum requirement. There are other international conventions which were established long before the TRIPS Agreement such as Paris and Berne Conventions. Nevertheless, colonial countries exercised pressures and drove their colonies and foreign possessions

into the Berne Convention through its Article 19. Therefore, many least developed and developing countries joined the Berne Convention without their free will, and even the new independent countries that did not have any economic and cultural experience joined the convention based on their colonial countries.

Other developing countries that tried to enact national laws in their own interest were opposed by developed countries and their companies. The reason was that many of the developing countries in their national laws provided for little protection, for example in the area of pharmaceuticals.

Before the TRIPS Agreement, the countries around the world were unhappy about the existing conventions and agreements that regulate intellectual property rights and were trying to amend them. The reason was that the developing countries were always trying for better regulations that allow them to access to foreign technologies and developed countries were condemning them for lacking enforcement mechanism and not being able to sanction the non-compliance countries effectively.

In order for the United States of America to be able to enforce its interest in the new agreement that regulate the intellectual property rights, it chose the GATT forum as it has strong position in the GATT. This was a new step because up to that moment intellectual property rights were looked at as an obstacle to free trade. Within GATT the developed countries could establish a single agreement that incorporate all intellectual property rights. The developing countries did not have a choice except to accept the TRIPS Agreement with the hope to benefit from GATT (WTO) over all.

Nevertheless, the United States of America used its entities such as the Office of the United States Trade Representative (USTR) and the United States International Trade Commission (ITC). These entities provided necessary information to government and enforced the requests of congress and interest groups. USTR has taken many actions under section 301 and special 301 of the Trade Act 1974 such as imposing trade sanctions on foreign countries, impose duties on their goods or threat of using unilateral retaliation if not reforming their intellectual property practices. USTR's pressured developing

countries such as Chile and Indonesia, and also pressured developed countries such as Japan. Another advantage of United States of America that had over other countries during the negotiation process at GATT was continuously receiving information from associations such as International Intellectual Property Alliance (IIPA) and Business Software Alliance (BSA), in which thousands of companies were their member. Accepting high standard of protection refused by the developing countries (in Group Ten) as it was not in their best interests and resisted the GATT forum, but they did not succeed due to economic threatening and political pressures from the United States and eventually the TRIPS Agreement came into existence.

3. The main purposes and objectives of the TRIPS Agreement that can be inferred from the Preamble are; presentation of intellectual property protection in a manner that reduce distortions and impediments to international trade; and recognition of intellectual property rights as private rights so that can be protected against any arbitrary and unjust acts of governments. Creating connection between intellectual property protection and international trade was due to the attempts of the United States and its big corporations so that insert intellectual property protection into the Uruguay round as it is an important principle of the WTO Agreement as well. Though, the Preamble of the TRIPS Agreement has no legal power as any other Articles of the Agreement, nevertheless, it is very useful in clarifying the ambiguity of the Articles and helpful in interpreting them.

Article 1 of the TRIPS Agreement provides for the nature and scope of the Agreement by stating the TRIPS Agreement is not self-executing and the minimum standard of protection provided for have to be given effect by the member countries in their own jurisdictions. The TRIPS Agreement does not state any procedures on how this process to be carried out, therefore this may cause problems for the developing countries as it requires reform in many domestic legislations. Even though the member countries are given freedom to choose the best method of implementation, but they have to prove that it was the best method available at the time. However, the TRIPS Agreement provides for opportunity for the member countries to

implement more extensive protection than what provided for by the Agreement. Article 1 also determines the scope of the TRIPS Agreement by including all categories that are stated in section 1 to 7 of Part II of the TRIPS Agreement within the term of 'intellectual property'.

Article 7 of the TRIPS Agreement states the objectives of the Agreement by emphasizing that the TRIPS Agreement should have positive effects on progressing technological and economic development and social welfare of the developing countries. This was proposed by developing countries so that the TRIPS Agreement should not be in favour of the developing countries only through high standard of protection. If this objective is not achieved the developing countries have right to object the exclusive rights of the right holders. It is also the objective of the TRIPS Agreement that in all types of intellectual property rights the balance of rights and obligations has to be kept, and the interest of the right holders and users have to be balanced. Even though this objective inserted on the request of the developing countries, but nevertheless, the balance between rights and obligations considered superseding objective of the WTO system.

The important principles of the TRIPS Agreement can be found in Article 8. According to this Article member countries are allowed to adopt measures 'to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development'. These measures can be taken from the provisions of the TRIPS Agreement such as exceptions to exclusive rights and compulsory licences, or other measures that have no base in the TRIPS Agreement but consistent with the provisions of the Agreement. Promoting public interest can include many areas and the member countries are allowed to determine their own sectors of vital importance. Therefore, the member countries in general, and the developing countries have great chance of adopting measures that benefit their societies by preventing abuse of intellectual property rights by the right holders, practices which unreasonably restrain trade or practices which have adverse effect on the international transfer of technology.

4. Patent Law No. 61 of 1935 was enacted during the Kingdom of Iraq. However, this law regulated the law of patent in a very basic manner such as having a simple and plain definition of invention that includes mere discovery. Besides that, it excludes some areas from patentability for example pharmaceutical formulations and medicines which made it to the next Law No. 65 of 1970. Law No. 61 of 1935 granted patent to an invention without making any investigation of the usefulness, correctness, truthfulness or correctness of its data or compare the data with the invention that submitted for patent to make sure it matches the invention. The law also stated that the government will not guarantee any of these matters. Even though this law went through a few amendments by law No. 64 of 1940, law No. 27 of 1949 and the last amendment was during the Republic of Iraq by law No. 210 of 1968.

After all these amendments the law No. 61 of 1935 was not up to the standard of protection of intellectual property rights. Therefore, Patent and Industrial Design Law No. 65 of 1970 for the first time enacted during the Republic of Iraq to repeal the law No. 61 of 1935. The new law also has undergone few amendments in order to keep with the international standard of protection. The most important of those amendments were by law No. 28 of 1999 and CPA Order No. 81. The CPA has issued many regulations, memoranda, public notices and orders, in order to rebuild a strong Iraq economically and establish justice after the long run of dictatorship. Through Order No. 81 the CPA has changed the title of the law No. 65 of 1970 to 'Patent, Industrial Design, Undisclosed Information, Integrated Circuits and Plant Variety Law'. This Order has added a few more chapter to the original law including a chapter on 'Protection of New Varieties of Plants'. The Order made 22 amendments on the first chapter (Patent), in which some of them were simple amendments while some other repealed the whole section and replaced them with new ones.

5. The term 'invention' in the original law No. 65 of 1970 and its amendments has gone through some changes. The law defined the invention in section 1.4 as 'every new innovation that industrially exploitable whether relates to new industrial products or innovative

methods and means or both of them together'. This definition included and could be used to identify the major important criteria of patentability because the law did not state the criteria of patentability in other sections of the law. Then the law No. 28 of 1999 added the words of (achieve some specific development). Even though all the traditional criteria of patentability could be found in this definition, but still the CPA Order No. 81 repealed this definition and introduced another one. The new definition contains all the elements of the old one but changed the words. After examining relevant factors, this thesis argues that since the TRIPS Agreement does no define the term 'invention' and it is left for the member countries to define them in the best way that suit their legal system, therefore, one can say that the both of the definitions are in compliance with the requirement of the TRIPS Agreement.

The thesis furthermore examines the original law No. 65 of 1970, in which section 2 states that 'Patents of invention shall be granted according to the provisions of this Law'. However, the CPA Order No. 81 repealed this section and replaced it with new section to include all the criteria of patentability in much clear and similar manner to the TRIPS Agreement. The new section 2 states that 'Patents of invention shall be granted pursuant to the provisions of this Law for each invention that is industrially applicable, novel and involves an inventive step, either concerning new industrial products, new industrial methods, or new application of known industrial methods'. This is clearly an improvement to the Iraqi patent law that eliminate any doubts in non-compliance to the TRIPS Agreement.

6. Exclusion from patentability is another important principle that the TRIPS Agreement which will be another important topic of the thesis to cover. Both subparagraphs of number 2 and 3 of article 27 provide options for the member countries to exclude some areas from patentability. Article 27.2 provides that the member countries may exclude any invention that its exploitation in the territory of a member country goes against *ordre public* and morality. Including these two types of exclusion was based on the proposals by the EEC, Japan and developing countries, because it was common to exclude invention on

these bases by the member countries and other international conventions long before the TRIPS Agreement. However, the TRIPS Agreement does not provide for definition of these terms. In this context, the researcher argues that the member countries are free to determine what situations lead to arise the implementation of these exclusions.

Ordre public can be determined by referring to some situations such as riots and public disorder. Nevertheless, member countries are free to apply the *ordre public* to new situations that do not have prior application and not known at international level. It can be applied if the commercial exploitation of the invention endangers the structure of civil society or simply disharmonize the livelihood of individuals to live in peace and security. The term morality in the TRIPS Agreement is referring to public morality and not individual morality. Article XX(a) of GATT of 1947 under the general exception refers to 'public moral'. Hence, the researcher suggests that if the commercial exploitation of an invention in the territory of a member country caused collective immorality or has negative effect on the morality of the community at large, then that member country is allowed to exclude such invention from patentability.

To compare the above matter with the original Iraqi patent law No. 65 of 1970, section 3.1 provides for exclusions of 'Inventions in which their exploitations cause breaches of public moral or *ordre public* or contradict the public interest'. The term exploitation refers to exploitation in any 'fields of work related to industry, agriculture, profession, and services in broader understanding'. Here in same way of the TRIPS Agreement, the Iraqi patent law provides for exclusion base on public moral and *ordre public*. These exclusions are very important of Iraqi society because of ethnic and religious diversity of Iraq. However, this provision provides for one more base of exclusion which is public interest. Public interest is much wider concept than the *ordre public* and public moral, as it can include these two concepts and more. It has not been used by Article 27.2 of the TRIPS Agreement. Nevertheless, the protection of public interest is allowed under Article 8.1 which allow the member countries to take measures to promote their 'public interest in sectors of vital importance to their

socio-economic and technological development'. Therefore, the researcher suggests that the Iraqi patent law is in compliance with the TRIPS Agreement. From the silence of the CPA Order No. 81 on this issue by not repealing or amending this section it can be inferred that the CPA was of the opinion that this section does not violate the provisions and principles of the TRIPS Agreement.

7. Subsequently, the thesis turns into another relevant topic which is covered by Article 27.3 (a) of the TRIPS Agreement. This provision states that the member countries may exclude from patentability the 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals'. Therefore, methods of treatment of humans and animals are excluded from patentability. This exclusion cannot be extended to products and process that are part of humans and animals treatments. Many countries around the world have excluded such methods and some countries have excluded methods of treatment from patentability base on the lack of industrial applicability. On the other hand, some developed countries such as Australia, New Zealand and United States of America are allowing these methods to be patented as long as they satisfy the criteria of patentability.

In comparison the Iraqi patent law No. 65 of 1970 does not contain any provision in regard of the method of treatment of humans and animals to exclude them from patentability. This silence can be interpreted so that these methods are patentable as a general rule. None of the amendments that passed on added regulation in this regard. The CPA Order No. 81 repealed and amended many provisions of the law No. 65 of 1970 but kept silence on this issue. Maybe it is due to the fact that in the United States of America method of treatment is patentable. Therefore, the CPA in this issue followed the United States patent law rather than using the option of exclusion stated in the TRIPS Agreement, which supposed to enhance the Iraqi patent law to the international standard (TRIPS Agreement).

8. The TRIPS Agreement has been blamed for allowing patenting medicines and drugs which caused rising of prices of medicines beyond capacity of least developed and developing countries. These

countries relying on generic drugs to solve their public health crises but once they joined the TRIPS Agreement they will not be allowed to do so any more, and the problem is that these countries are not able to access patented drugs due to their high prices. The effort of these countries led to the adoption of the Doha Declaration on the TRIPS Agreement and Public Health (14 November 2001). The Doha Declaration addresses the issue of public health and tries to find solutions for the developing countries to solve their public health issues. This declaration emphasizes that the TRIPS Agreement should not prevent member countries from adopting necessary measures to protect their public health and requested the General Council to find a solution for those member countries that cannot benefit from the compulsory licence due to insufficient or no manufacturing capacities in the pharmaceutical sectors. Nevertheless, the CPA Order No. 81 did not add any provision in this regard to help Iraq to have access to inexpensive medicines to support public health in crises, or to take necessary measures to protect Iraqi public health.

9. Next, due to the importance of plants and saving seeds, there are many international conventions and agreements that regulate this issue, such as UPOV Convention, TRIPS Agreement, International Treaty on Plant Genetic Resources for Food and Agriculture and CBD. UPOV Convention is one of the important convention in this area especially after the TRIPS Agreement requested all member countries to protect plant varieties whether through a patent or *sui generis* system.

Interestingly, Article 27.3 (b) of the TRIPS Agreement provides for excluding plants and animals from patentability. Nevertheless, this provision requires that the member countries provide for some form of protection of plant varieties through patent, an effective *sui generis* system or any combination of thereof. This causes problem for the developing countries because many of them never had any form of protection of plant varieties. This protection will have huge impact on their farming practices in the area of saving seeds, genetic diversity and food security. As societies in these countries still farm on the traditional way of saving seeds for next year planting and exchange

good seeds among themselves. Iraq is one of the developing countries that have great fertile land, but due to the uninterrupted wars, majority of its agricultural land and bank seed has been destroyed.

In comparison, the original Iraqi patent law No. 65 of 1970, does not have any regulations pertinent to the protection of animals and plants or excluding them from patentability. nevertheless, after the invasion of Iraq the CPA Order No. 81 added chapter Three*quater* for protection of plant varieties. Most of the provisions of this new chapter have been taken from the UPOV Convention of 1991. For example, the definition of plant varieties is the same definition of the UPOV Convention and all the criteria of registration of plant varieties are same as those of the UPOV Convention which they have to be novel, distinctive, uniform, and stable.

However, in 2013 a new law enacted under the title of 'Registration, Accreditation and Protection of Agricultural Varieties' Law No. 15 of 2013. This new law repealed and replaced chapter Three*quater*.

The CPA Order No. 81 prevented re-using of seeds of protected varieties, however, the new law No. 15 of 2013 introduced new exception which is called 'Optional Exception' which exists under the UPOV Convention, but the CPA Order No. 81 did not introduce it to chapter Three*quater*. The optional exception allows for re-using the seeds of protected varieties that obtained by planting on the farmer's holdings. The new law also included some more exceptions than the CPA Order No. 81 which are on favour of farmers.

10. Article 28 of the TRIPS Agreement states certain rights to the patent holder. However, the rights conferred are in the form of negative rights in which the patent owner has rights to prevent others, for the period of 20 years from the filing date according to Article 33 of the TRIPS Agreement, in cases where the subject matter of the patent is product, from making, using, offering for sale, selling, or importing for these purposes that product, as it is stated in Article 28.1 lit. (a). In cases where the subject matter of the patent is process, as it is stated by Article 28.1 lit. (b), the patent owner has exclusive rights to prevent others to use his process without his consent. Also, when the products

are obtained directly his process he has rights to prevent others from using, offering for sale, selling, or importing for these purposes.

Furthermore, Article 34 has empowered the judicial authorities of the member countries to reverse the burden of proof where there is no enough evidence that the products are manufactured by the patented process. Naturally it is difficult for the patent owner to proof that his patented process is used for manufacturing products that are identical to products that can be manufactured by his process. In these cases, the owner of such identical products has to show that the patented process is not used. Nevertheless, the interest of alleged infringer has to be protected by the courts. Because he may has used different process and want to keep his process secret.

Article 28.2 also has granted the rights to assign, or transfer by succession the patent and to conclude licensing contracts. Even though this article has granted such rights, but it has to be beard in mind that the TRIPS Agreement has allowed the member countries to grant compulsory licence without the consent or against the wishes of the patent owner according to Article 31 and 31*bis*.

As for the Iraqi patent law, section 12 of the original law No. 65 of 1970 referred to rights conferred in a general manner by stating that the patent owner has exclusive right to exploit his invention by all legal means. However, the CPA Order No. 81 repealed this section and replaced with another section that have two subsections very similar to Article 28.1, in which the first subsection dedicated for patented products and the other to patented processes.

11. Even though the patent grants exclusive right to the patent owners, however, countries around the world have set limitations on this exclusive right by providing certain exceptions. In this regard the TRIPS Agreement has provided some exceptions. The first of type of exception can be found in Article 30 of the TRIPS Agreement. This Article gives chance to member countries to provide in their domestic legislations some exceptions to the exclusive rights conferred by a patent. There are some possible exceptions that can be adopted by member countries according to Article 30 of the TRIPS Agreement, such as research and experimentation exception, early working (bolar)

exception, individual prescriptions exception, prior use exception and parallel imports exception.

Last but not least, the TRIPS Agreement also provides for another type of exception which is called compulsory licence. Article 31 provides for this principle under the name of 'other use without authorization of the right holder'. This is involuntarily licence in which the patent holder has no choice because the licence is enforced on him. This licence can be authorized by the governments on the grounds of national emergency, anti-competitive practices, public non-commercial use and dependent patents. However, whenever the member countries have fulfilled the conditions that are stated in Article 31, they can authorize compulsory licence on other grounds as well. However, some of the conditions in Article 31 cannot be fulfilled by the least developed and developing countries due to their underdeveloped technologies. Therefore, after great debate and long process Article 31*bis* came into existence.

Article 31*bis* is the first amendment since the TRIPS Agreement's enforcement. It was amended on 6 December 2005 and entered into force on 23 January 2017. The main purpose of this Article is to allow member countries to have better and easier access to health products through special compulsory licences. Compulsory licence under Article 31 requires that the granting of a compulsory licence has to be predominantly for the supply of domestic market. Therefore, under Article 31 it is not allowed to export majority of products manufactured under the compulsory licence. However, according to the new Article 31*bis* member countries are allowed to grant compulsory licence for the purposes of production of pharmaceutical products and export them to other member countries. Article 31*bis* also prevents the double payment of remuneration to the patent owner by both importing and exporting member countries. In this case only the exporting country is required to pay an adequate remuneration and the importing country is not require paying the remuneration when grants the compulsory licence for the same pharmaceutical products of the exporting country.

The Iraqi patent law No. 65 of 1970 does not provide for any types of exceptions that allowed under Article 30 of the TRIPS

Agreement. Even though the CPA was well aware of the provisions of the TRIPS Agreement but did not add any similar exceptions to the Iraqi patent law. However, the original law No. 65 of 1970 provides some provisions in regard of granting compulsory licence. Nevertheless, all these provisions were amended by the CPA Order No. 81. This order has included almost all the conditions that are stated in the TRIPS Agreement for granting compulsory licence. On the other hand, repealed some flexibilities of compulsory licence that were in favour of Iraq, such as granting compulsory licence when the exploitation corresponds to the needs of Iraq. Thus, the thesis argues that the CPA Order No. 81 also did not add any provisions in regard of granting special compulsory licence for the purpose of pharmaceutical products.

12. It can be concluded that the original law No. 65 of 1970 needs another amendment in order to be incompliance in a better way with the TRIPS Agreement and suits the development of the country and its people. Some of the important recommendations can be summarized as follows.

a) Provision that exclude method of treatment from patentability is existing in laws of many member countries. Therefore, a new provision should be added to this law according to the option established in Article 27.3 (a) of the TRIPS Agreement that can be read as ‘patent shall not be granted in diagnostic, therapeutic and surgical methods for the treatment of humans or animals’. Similar provision is necessary so that the underdeveloped country of Iraq benefit from this exclusion.

b) Furthermore, Article 27.3 (b) of the TRIPS Agreement orders the member countries to provide for protection of plant varieties. In this regard the law No. 15 of 2013 is a sui generis system that provides for protection of plant varieties. However, this law reduced the period of protection and failed to take advantages of the UPOV Convention. For this reason, this thesis recommends an amendment on this law so that be incompliance with the TRIPS Agreement and provide for all the advantages that are stated in the UPOV Convention.

c) The researcher also recommends that another provision should be added to the Iraqi patent law in order to provide for exceptions that allowed under Article 30 of the TRIPS Agreement. The CPA Order No. 81 failed to act in best interest of Iraq and did not include exceptions such as parallel imports, prior use exceptions, individual prescriptions, early working (bolar exception), and research and experimentation exception, which are allowed to be implemented in domestic legislations of the member countries under Article 30.

d) In addition, the original law No. 65 of 1970 does not have any provision similar to Article 34 of the TRIPS Agreement that reverse the burden of proof in cases involve production of identical products of the patented process. Since the CPA Order No. 81 failed to include such provision, therefore, this thesis recommend such provision to be included in the Iraqi patent law so that the patent owners of patented processes enjoy better protection.

e) Lastly, this thesis recommends an amendment to the original patent law No. 65 of 1970 in order to include provisions in order to give effect to Article 31bis of the TRIPS Agreement. According to Article 31bis exporting member countries are allowed to grant a compulsory licence so that majority or all of the productions under such licence be exported to outside the country. The importing member countries of such productions are exempted from paying adequate remuneration to the patent owner while granting compulsory licence to the same products. Subsequently, Iraq as an importing member country that does not have sufficient manufacturing capacities will be able to grant compulsory licences for importing medicines from other member countries that produce such medicines under compulsory licence.

RESUMEN

1. Uno de los tratados internacionales más importantes del que Iraq no forma parte es el Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (ADPIC o TRIPS en sus iniciales inglesas). Iraq no es miembro de la Organización Mundial del Comercio (OMC), pero está en proceso de adhesión y en este momento está en la lista de gobiernos observadores. Del mismo modo, Iraq tampoco es miembro de la mayoría de los tratados y uniones de la OMPI, a excepción del Convenio de París (1976) y del Convenio de la OMPI (1976). Sin embargo, es el acuerdo ADPIC el que brinda una mayor protección de los derechos de propiedad industrial e intelectual.

El objetivo de esta tesis doctoral es analizar todas las posibilidades de implementación del Acuerdo ADPIC por parte del gobierno iraquí, especialmente en el ámbito de las patentes. Por lo tanto, la hipótesis clave de esta investigación es que Iraq debería implementar una ley que cumpla con los requisitos del Acuerdo sobre los ADPIC y, al mismo tiempo, incluir todas las flexibilidades legales que ayuden a desarrollar el país con el mínimo de costes y sacrificios.

El objetivo principal de esta investigación es examinar y analizar la regulación sobre las patentes contenida en la Ley iraquí de Patentes y Diseño Industrial n.º. 65 de 1970, tanto en su versión inicial como en sus modificaciones posteriores [en especial la realizada por la Orden n.º 81 de la Autoridad Provisional de la Coalición (CPA)], y compararla con las disposiciones del Acuerdo sobre los ADPIC a fin de conocer las coincidencias y contradicciones entre estos textos legales.

Se resumen a continuación los principales resultados alcanzados.

2. El Acuerdo sobre los ADPIC es uno de los acuerdos internacionales más importantes de entre los que han estandarizado la

protección de los derechos de propiedad industrial e intelectual exigiendo una tutela mínima. Con anterioridad al Acuerdo ADPIC se concertaron otros tratados internacionales, como las convenciones de París y Berna, a las cuales se sumaron muchos países menos desarrollados y países en vías de desarrollo, a los que faltaba la adecuada experiencia económica y cultural, pero que lo hicieron por la presión de los países coloniales. Así sucedió, por ejemplo, con el Convenio de Berna, al que muchos países se adhirieron por medio de su artículo 19 en contra de su libre voluntad.

En ese contexto, los países en desarrollo que intentaron promulgar leyes nacionales que atendían a sus intereses nacionales se encontraron con la oposición de los países desarrollados y sus empresas, porque estos países en desarrollo ofrecían en sus legislaciones nacionales un reducido nivel de protección de los derechos de propiedad industrial e intelectual, por ejemplo, en el ámbito de los productos farmacéuticos.

En consecuencia, en el período anterior a la celebración del Acuerdo ADPIC, distintos países a lo largo del mundo estaban insatisfechos con los convenios y acuerdos existentes en materia de propiedad industrial e intelectual e intentaron modificarlos. Los países en vías desarrollo pretendían una mejor regulación que le permitiera acceder a tecnologías extranjeras, mientras que los países desarrollados les imputaban una falta de mecanismos de defensa y aplicación de dichos derechos, sin que pudiesen sancionar efectivamente a esos países por no cumplimiento.

Para poder hacer valer sus intereses en el nuevo acuerdo que regula los derechos de propiedad industrial e intelectual, Estados Unidos de América eligió el foro del GATT, donde ya tenía una posición fuerte. Este fue un paso novedoso porque hasta ese momento los derechos de propiedad industrial e intelectual se consideraban un obstáculo para el libre comercio. Dentro del GATT, los países desarrollados pudieron establecer un acuerdo único que incorporase todos los derechos de propiedad industrial e intelectual. Y los países en desarrollo no tuvieron otra opción que aceptar el Acuerdo sobre los ADPIC con la esperanza de beneficiarse del GATT (OMC).

Los Estados Unidos de América utilizaron sus entidades, tales como la Oficina del Representante de Comercio de los Estados Unidos (*Office of the United States Trade Representative*, USTR) y la Comisión de Comercio Internacional (*United States International Trade Commission*, ITC). Estas entidades proporcionaron la información necesaria al gobierno y aplicaron las peticiones del congreso y los grupos de presión. La USTR adoptó distintas medidas en virtud de la sección 301 y 301 de la Ley de Comercio de 1974, como imponer sanciones comerciales a países extranjeros, imponer aranceles a sus productos o amenazar con utilizar represalias unilaterales si no modificaban sus prácticas de propiedad intelectual. Entre los países presionados por la USTR se encuentran países en desarrollo como Chile e Indonesia, y también países desarrollados como Japón. Asimismo, otra ventaja de los Estados Unidos de América durante el proceso de negociación en el GATT fue recibir continuamente información de asociaciones como la Alianza Internacional de la Propiedad Intelectual [*International Intellectual Property Alliance* (IIPA)] y la Alianza de Software Empresarial (*Business Software Alliance*, BSA), integradas por miles de compañías. Finalmente, los países en desarrollo tuvieron que aceptar los altos niveles de protección de la propiedad industrial e intelectual (que inicialmente rechazaron en el Grupo 10), debido a amenazas económicas y presiones políticas de los Estados Unidos, y el Acuerdo sobre los ADPIC se convirtió en una realidad.

3. Los principales propósitos y objetivos del Acuerdo sobre los ADPIC pueden inferirse ya del Preámbulo y son la protección de la propiedad intelectual (término con el que se engloban tanto los derechos de propiedad industrial como los del propiedad intelectual en sentido estricto) de manera que se reduzcan las distorsiones y los obstáculos al comercio internacional; y el reconocimiento de los derechos de propiedad intelectual como derechos privados para que puedan protegerse contra actos arbitrarios e injustos de los gobiernos. La conexión entre la protección de la propiedad intelectual y el comercio internacional se debió a los intentos de los Estados Unidos y sus grandes empresas de insertar la protección de la propiedad

intelectual en la Ronda de Uruguay, ya que también es un principio importante del Acuerdo sobre la OMC. Con todo, aunque es de gran utilidad a los efectos interpretativos, el Preámbulo del Acuerdo sobre los ADPIC no tiene un valor jurídico equiparable al de los artículos del Acuerdo.

El artículo 1 del Acuerdo sobre los ADPIC establece la naturaleza y el alcance de las obligaciones del Acuerdo, disponiendo que no es de aplicación automática y que los miembros respetarán en sus legislaciones el nivel mínimo de protección previsto. El Acuerdo sobre los ADPIC no establece ningún método para que los miembros apliquen sus disposiciones en el marco de su propio sistema y práctica jurídicos, lo que puede causar problemas para los países en desarrollo, cuyas legislaciones nacionales deberán ser reformadas. En todo caso, aunque los países miembros tienen libertad para elegir el mejor método de implementación, deben demostrar que fue el mejor método disponible en ese momento. Por lo demás, el Acuerdo sobre los ADPIC permite que los países miembros implementen una protección más amplia que la prevista en el Acuerdo. El artículo 1 también determina el alcance del Acuerdo sobre los ADPIC al incluir todas las categorías que figuran en las secciones 1 a 7 de la Parte II del Acuerdo sobre los ADPIC dentro del término de «propiedad intelectual».

El artículo 7 del Acuerdo sobre los ADPIC establece los objetivos del Acuerdo al hacer hincapié en que éste deberá tener efectos positivos en la promoción de la innovación tecnológica y el bienestar social y económico de los países en desarrollo. Esta disposición fue propuesta por los países en desarrollo para que el Acuerdo no beneficiase únicamente a los países desarrollados estableciendo un estándar elevado de protección. Si no se logra este objetivo, los países en desarrollo tienen derecho a oponerse a los derechos exclusivos de los titulares de los derechos. Asimismo, otro objetivo del Acuerdo es que en todos los tipos de derechos de propiedad intelectual se mantenga el equilibrio de derechos y obligaciones, equilibrando el interés de los titulares de derechos y los usuarios. Aunque este objetivo también se insertó a petición de los países en desarrollo, el equilibrio entre los derechos y obligaciones es considerado un objetivo general del sistema de la OMC.

Por su parte, los principios del Acuerdo sobre los ADPIC se recogen en su artículo 8. De conformidad con este artículo, los países miembros pueden adoptar medidas «para proteger la salud pública y la nutrición de la población, o para promover el interés público en sectores de importancia vital para su desarrollo socioeconómico y tecnológico». Estas medidas pueden consistir en medidas expresamente recogidas en el Acuerdo sobre los ADPIC, como las excepciones a los derechos exclusivos y las licencias obligatorias, o en otras medidas que no se recogen expresamente en el Acuerdo pero que son coherentes con sus disposiciones. En este sentido, la promoción del interés público puede incluir muchas áreas y los países miembros pueden determinar sus propios sectores de vital importancia. Por lo tanto, los países miembros en general, y los países en desarrollo en particular, tienen grandes posibilidades de adoptar medidas que beneficien a sus sociedades, previniendo el abuso de los derechos de propiedad intelectual por parte de sus titulares, las prácticas que restrinjan injustificadamente el comercio o las prácticas que tienen un efecto negativo en la transferencia internacional de tecnología.

4. La Ley iraquí de Patentes n.º 61 de 1935 se promulgó durante el Reino de Iraq. Sin embargo, esta ley regulaba las patentes de una manera muy básica, hasta el punto de contener una definición de invención que incluía los meros descubrimientos. Además, establecía determinadas prohibiciones de patentabilidad, como las referentes a las fórmulas farmacéuticas y los medicamentos, prohibiciones que llegaron hasta la siguiente Ley n.º 65 de 1970. Por lo demás, de acuerdo con la Ley n.º 61 de 1935 las patentes se concedían sin realizar ningún tipo de examen sobre la utilidad, corrección, veracidad o la exactitud de los datos y sin comparar los datos suministrados con la invención para la que se solicitaba la patente. De hecho, la ley declaraba expresamente que el Gobierno no garantizaba ninguno de estos extremos. Esta ley fue sometida a algunas enmiendas por la ley n.º 64 de 1940 y la ley n.º 27 de 1949. Y la última modificación tuvo lugar durante la República del Iraq por medio la ley n.º 210 de 1968.

Aún después de todas estas enmiendas, la ley n.º 61 de 1935 no estaba a la altura del nivel de protección de los derechos de propiedad

intelectual. Esto hizo que fuese derogada por la Ley de Patentes y Diseño Industrial n.º 65 de 1970, promulgada durante la República del Iraq, nueva ley que también ha sido objeto de algunas modificaciones posteriores para cumplir con el estándar internacional de protección. Los más importantes de esos cambios fueron los realizados por la Ley n.º 28 de 1999 y por la Orden n.º 81 de la Autoridad Provisional de la Coalición (CPA).

La CPA aprobó numerosas reglamentaciones, memorandos, avisos públicos y órdenes para reconstruir económicamente a Iraq y establecer justicia después del largo período de dictadura. A través de la Orden n.º 81, la CPA cambió el título de la ley n.º 65 de 1970, que pasó a denominarse Ley de «patentes, diseño industrial, secreto empresarial, topografías de productos semiconductores y de variedades vegetales». Además, la Orden añadió algunos capítulos nuevos a la ley original, incluido un capítulo sobre «Protección de nuevas variedades vegetales», e hizo 22 enmiendas en el primer capítulo (Patentes), algunas de las cuales fueron simples modificaciones menores mientras que otras implicaron la derogación de secciones y la sustitución por otras nuevas.

5. La definición del término «invención» contenida en la ley original n.º 65 de 1970 y sus enmiendas ha sufrido algunos cambios. La ley definía la invención en la sección 1.4 como «toda innovación nueva susceptible de aplicación industrial, consistente en nuevos productos industriales, métodos o medios innovadores, o en ambos tipos de innovación». Por lo tanto, esta definición incluía y podría utilizarse para identificar los principales requisitos de patentabilidad, porque la ley no los establecía en otras secciones. Posteriormente, la ley n.º 28 de 1999 agregó la referencia a la necesidad de lograr algún desarrollo específico. A pesar de que todos los requisitos tradicionales de patentabilidad se podían encontrar en esta definición, la Orden de CPA n.º 81 derogó dicha definición e introdujo otra que contiene todos los elementos del antiguo texto legal, pero cambiando las palabras utilizadas.

Después de examinar los factores relevantes, en esta tesis sea argumenta que, dado que el Acuerdo sobre los ADPIC no define el

término «invención» y se permite que los países miembros lo definan de la mejor manera que se adapte a su sistema legal, se puede concluir que ambas definiciones respetan en este punto el Acuerdo sobre los ADPIC.

La presente tesis también examina los requisitos de patentabilidad. La ley n.º 65 de 1970, en su versión inicial, establecía en su sección 2 que «las patentes de invención se otorgarán de acuerdo con las disposiciones de esta Ley». Sin embargo, la Orden n.º 81 de la CPA derogó dicha sección y la reemplazó por otra para incluir todos los criterios de patentabilidad de una manera muy clara y similar al Acuerdo sobre los ADPIC. Así, la nueva sección 2 establece que «las patentes de invención se otorgarán de conformidad con las disposiciones de esta Ley para cada invención susceptible de aplicación industrial, novedosa y que implique una actividad inventiva, ya sea en relación con nuevos productos industriales, nuevos métodos industriales o una nueva aplicación de métodos industriales ya conocidos». Se trata, claramente, de una mejora de la ley iraquí de patentes que elimina cualquier duda sobre la coincidencia con lo dispuesto en el Acuerdo sobre los ADPIC.

6. Las exclusiones de patentabilidad constituyen otro de los principios importantes del Acuerdo sobre los ADPIC y es, en consecuencia, otro de los temas examinados con detalle en la presente tesis doctoral.

Los dos subpárrafos de los números 2 y 3 del artículo 27 del Acuerdo permiten que los países miembros establezcan algunas exclusiones de patentabilidad. El artículo 27.2 dispone que los países miembros podrán excluir de la patentabilidad las invenciones cuya explotación comercial en su territorio deba impedirse necesariamente para proteger el orden público o la moralidad. La inclusión de estos dos tipos de exclusión obedeció a las propuestas de la CEE, Japón y los países en desarrollo, porque era común la existencia de este tipo de exclusiones en los países miembros, al amparo de otros convenios internacionales anteriores al Acuerdo sobre los ADPIC. Sin embargo, el Acuerdo sobre los ADPIC no prevé la definición de estos términos. Y en este contexto, en la tesis se argumenta que los países miembros

son libres de determinar qué situaciones conducen a la implementación de estas exclusiones.

Así, el orden público se puede delimitar por referencia a algunas situaciones como disturbios y desordenes públicos. Sin embargo, los países miembros son libres de aplicar el orden público a situaciones nuevas que no tienen aplicación previa y no se conocen a nivel internacional. Así, se puede aplicar si la explotación comercial de la invención pone en peligro la estructura de la sociedad civil o simplemente afecta a las condiciones de las personas para vivir en paz y seguridad.

Por su parte, el término moralidad en el Acuerdo sobre los ADPIC se refiere a la moral pública y no a la moral individual. De hecho, el apartado a) del artículo XX del GATT de 1947 se refiere a la «moral pública». En este sentido, en la tesis se sugiere que, si la explotación comercial de una invención en el territorio de un país miembro provoca inmoralidad colectiva o tiene un efecto negativo sobre la moralidad de la comunidad en general, entonces ese país miembro puede excluir dicha invención de la patentabilidad.

Analizando esta cuestión en la legislación nacional iraquí, se constata que en la ley de patentes iraquí n.º 65 de 1970, la sección 3.1 excluye la patentabilidad de las «invenciones cuya explotación viola la moral o el orden públicos o contradice el interés público». El término explotación se refiere a la explotación en cualquier «campo de trabajo relacionado con la industria, la agricultura, la profesión y los servicios en sentido amplio». En este punto, de la misma manera que el Acuerdo sobre los ADPIC, la ley iraquí de patentes utiliza la moral pública y el orden público como base para la exclusión de la patentabilidad. Y estas exclusiones son muy importantes para la sociedad iraquí debido a la diversidad étnica y religiosa del país. Pero además esta disposición añade un motivo adicional para la exclusión de la patentabilidad, a saber: que la invención sea contraria al interés público, el cual es un concepto mucho más amplio que el de orden público y moral pública, ya que puede incluir más elementos además de esos.

El artículo 27.2 del Acuerdo sobre los ADPIC no alude al «interés público». Sin embargo, la protección del interés público está permitida

por el artículo 8.1, que faculta a los países miembros para tomar medidas para promover su «interés público en sectores de importancia vital para su desarrollo socioeconómico y tecnológico». Por lo tanto, en la tesis se concluye que la ley iraquí de patentes cumple con el Acuerdo sobre los ADPIC. Del silencio de la Orden n.º 81 sobre esta cuestión, al no derogar ni modificar esta sección, se puede inferir que la CPA consideró que esta sección no viola las disposiciones y principios del Acuerdo sobre los ADPIC.

7. Posteriormente, la tesis analiza otro tema relevante, regulado por el artículo 27.3 (a) del Acuerdo sobre los ADPIC; a saber: la posibilidad de excluir la patentabilidad de «los métodos de diagnóstico, terapéuticos y quirúrgicos para el tratamiento de personas o animales»; exclusión que no se puede extender a los productos y procesos que son parte de los tratamientos de humanos y animales.

Muchos países de todo el mundo han excluido tales métodos, algunos basándose en la falta de aplicación industrial. En cambio, otros países desarrollados como Australia, Nueva Zelanda y los Estados Unidos de América permiten que estos métodos sean patentados siempre que satisfagan los criterios de patentabilidad.

Por su parte, la ley de patentes iraquí n.º 65 de 1970 no contiene ninguna disposición excluyendo la patentabilidad de este tipo de métodos, lo cual puede interpretarse en el sentido de que estos métodos son, como regla general, patentables. A este respecto, ninguna de las modificaciones posteriores de la ley introdujo cambios en este punto. La Orden n.º 81 de la CPA derogó y enmendó muchas disposiciones de la ley n.º 65 de 1970, pero guardó silencio sobre este tema. Tal vez se deba al hecho de que en los Estados Unidos de América el método de tratamiento es patentable. Por lo tanto, la CPA en esta cuestión siguió la ley de patentes de los Estados Unidos en lugar de acoger la posibilidad establecida en el Acuerdo ADPIC de excluir la patentabilidad de estos métodos.

8. Una de las críticas que se ha formulado contra el Acuerdo sobre los ADPIC es que permite la concesión de patentes sobre medicamentos, originando el aumento de su precio por encima de la capacidad de los

países menos adelantados y en desarrollo. Estos países dependen de medicamentos genéricos para resolver sus crisis de salud pública, pero una vez que ratifican al Acuerdo sobre los ADPIC ya no pueden hacerlo, y el problema es que estos países no pueden acceder a medicamentos patentados debido a sus altos precios. El esfuerzo de estos países condujo a la adopción de la Declaración de Doha sobre el Acuerdo sobre los ADPIC y la Salud Pública (14 de noviembre de 2001). La Declaración de Doha aborda el problema de la salud pública e intenta encontrar soluciones para que los países en desarrollo resuelvan sus problemas de salud pública. Esta declaración enfatiza que el Acuerdo ADPIC no debe impedir que los países miembros adopten medidas necesarias para proteger su salud pública y en ella se solicita al Consejo General que encuentre una solución para aquellos países miembros que no pueden beneficiarse de la licencia obligatoria debido a capacidades de fabricación insuficientes o inexistentes en el país en el sector farmacéutico.

Sin embargo, la Orden n.º 81 de la CPA no añadió ninguna disposición a este respecto para ayudar a Iraq a tener acceso a medicinas de bajo costo para apoyar la salud pública en crisis o para tomar las medidas necesarias para proteger la salud pública iraquí.

9. Por otra parte, debido a la importancia de las plantas y a la práctica de los agricultores consistente en conservar semillas de su propia producción para proceder a sembrarlas en el siguiente ciclo de cultivo, existen muchos convenios y acuerdos internacionales que regulan esta cuestión, como el Convenio de la UPOV (Convenio internacional para la protección de las obtenciones vegetales, firmado en París el 2 de diciembre de 1961 y posteriormente modificado por las Actas de 10 de noviembre de 1972, 23 de octubre de 1978 y 19 de marzo de 1991), el Acuerdo sobre los ADPIC, el Tratado internacional sobre los recursos fitogenéticos para la alimentación y la agricultura y el Convenio sobre la Diversidad Biológica, hecho en Río de Janeiro el 5 de junio de 1992. El Convenio de la UPOV es uno de los convenios importantes en esta área, especialmente después de que el Acuerdo sobre los ADPIC haya establecido que los Miembros otorgarán protección a todas las obtenciones vegetales mediante patentes,

mediante un sistema eficaz *sui generis* o mediante una combinación de aquéllas y éste.

En efecto, el artículo 27.3 (b) del Acuerdo sobre los ADPIC permite la exclusión de la patentabilidad de las plantas y animales. Sin embargo, esta disposición requiere que los países miembros proporcionen alguna forma de protección a las obtenciones vegetales a través de patentes, un sistema *sui generis* efectivo o cualquier combinación de los mismos. Esto causa un problema para los países en desarrollo, porque muchos de ellos nunca tuvieron ninguna forma de protección de variedades vegetales, y la previsión de la protección tendrá un gran impacto en las prácticas agrícolas de conservación de semillas para proceder a sembrarlas en el siguiente ciclo de cultivo, así como en la diversidad genética y seguridad alimentaria. Porque, en efecto, los agricultores en estos países todavía cultivan en la forma tradicional de guardar semillas para el próximo año, plantando e intercambiando buenas semillas entre ellos. Además, Iraq es uno país en desarrollo que tiene una gran tierra fértil, pero debido a las guerras ininterrumpidas, la mayoría de sus tierras agrícolas y bancos de semillas han sido destruidos.

La ley de patentes iraquí n.º 65 de 1970 no contiene, en su versión inicial, ninguna referencia a la protección de animales y plantas ni a la exclusión de su patentabilidad. Sin embargo, después de la invasión de Iraq, la Orden n.º 81 de la CPA añadió el capítulo *tresquater* para la protección de variedades vegetales. La mayoría de las disposiciones de este nuevo capítulo se tomaron del Convenio de la UPOV de 1991. Por ejemplo, la definición de variedad vegetal es la misma definición del Convenio de la UPOV y todos los requisitos para la protección de las variedades vegetales son los de la UPOV (novedad, distinción, uniformidad y estabilidad).

Sin embargo, en 2013 se promulgó una nueva ley bajo el título de «Ley de Registro, Acreditación y Protección de Variedades Agrícolas», Ley n.º 15 de 2013, que derogó y reemplazó el mencionado capítulo *tresquater*.

La Orden n.º 81 de la CPA impidió la reutilización de semillas de variedades protegidas. Pero la nueva ley n.º 15 de 2013 introdujo la excepción opcional recogida en el Convenio de la UPOV que permite

al agricultor reutilizar las semillas de variedades protegidas obtenidas mediante la plantación en sus explotaciones. Además, la nueva ley también incluyó algunas excepciones más que no figuraban en la Orden n.º 81 de CPA, nuevas excepciones con las que se pretende favorecer a los agricultores.

10. El artículo 28 del Acuerdo sobre los ADPIC se refiere a los derechos conferidos por una patente. Se trata de una serie de facultades negativas en virtud de las cuales el titular de la patente puede impedir a terceros determinadas actuaciones, durante el período de duración de la patente (como mínimo 20 años contados desde la fecha de presentación de la solicitud, según el artículo 33 del Acuerdo). Cuando se trata de una patente de producto, el titular tiene el derecho de impedir que terceros, sin su consentimiento, realicen actos de fabricación, uso, oferta para la venta, venta o importación para estos fines del producto objeto de la patente (art. 28.1 a). Y cuando la patente es de procedimiento, el titular tiene el derecho de impedir que terceros, sin su consentimiento, realicen el acto de utilización del procedimiento y los actos de uso, oferta para la venta, venta o importación para estos fines de, por lo menos, el producto obtenido directamente por medio de dicho procedimiento (art. 28.1 b).

Además, el artículo 34 del Acuerdo ADPIC ha facultado a las autoridades judiciales de los países miembros para invertir la carga de la prueba cuando no hay pruebas suficientes de que los productos han sido fabricados mediante el procedimiento patentado. Naturalmente, es difícil para el titular de la patente probar que su procedimiento patentado se utiliza para fabricar productos que son idénticos a los productos que pueden fabricarse mediante su procedimiento. En estos casos, el propietario de tales productos idénticos debe mostrar que no ha utilizado el procedimiento patentado. Sin embargo, el interés del presunto infractor debe ser protegido por los tribunales. Porque puede haber usado un procedimiento diferente y querer mantenerlo en secreto.

El artículo 28.2 también dispone que los titulares de patentes tendrán el derecho de cederlas o transferirlas por sucesión y de concertar contratos de licencia. No obstante, aunque este artículo ha

otorgado tales derechos, debe tenerse en cuenta que el Acuerdo sobre los ADPIC ha permitido a los países miembros otorgar licencias obligatorias sin el consentimiento o contra los deseos del titular de la patente de conformidad con los artículos 31 y 31 *bis*.

En cuanto a la ley de patentes iraquí, el artículo 12 de la ley n. º 65 de 1970, en su versión inicial, se refería a los derechos conferidos de manera general al establecer que el titular de la patente tiene el derecho exclusivo de explotar su invención por todos los medios legales. Sin embargo, la Orden n.º 81 de la CPA derogó esta sección y la reemplazó por otra que tiene dos subsecciones muy similares al artículo 28.1 del ADPIC, la primera dedicada a las patentes de producto y la segunda a las de procedimiento.

11. A pesar de que la patente otorga derechos exclusivos a su titular, los países de todo el mundo han establecido limitaciones o excepciones a este derecho exclusivo. Y a este respecto, el Acuerdo sobre los ADPIC también prevé algunas excepciones.

El primer tipo de excepciones se recogen en el artículo 30 del Acuerdo, según el cual los miembros podrán prever excepciones limitadas de los derechos exclusivos conferidos por una patente, a condición de que tales excepciones no atenten de manera injustificable contra la explotación normal de la patente ni causen un perjuicio injustificado a los legítimos intereses del titular de la patente, teniendo en cuenta los intereses legítimos de terceros. Encajan aquí excepciones como la excepción de investigación y experimentación, la cláusula Bolar, la excepción referida a la preparación de medicamentos realizada en farmacias extemporáneamente y por unidad de ejecución de una receta médica, la excepción de uso anterior o la excepción de importación paralela.

Por último, pero no menos importante, el Acuerdo sobre los ADPIC también prevé la licencia obligatoria, que constituye otra limitación del derecho de patente. El artículo 31 establece este principio bajo el nombre de «otro uso sin autorización del titular del derecho». Se trata de una licencia que se le impone al titular de la patente y que puede ser establecida por los gobiernos por motivos de emergencia nacional, para poner fin a prácticas anticompetitivas, para

permitir un uso público no comercial, para permitir la explotación de patentes dependientes, o por otros motivos, siempre que los países miembros cumplan las condiciones establecidas en el artículo 31 del ADPIC.

Sin embargo, algunas de las condiciones del artículo 31 no pueden ser cumplidas por los países menos desarrollados y en desarrollo debido a sus tecnologías subdesarrolladas. Por lo tanto, después de un gran debate y un largo proceso, el 6 de diciembre de 2005 se introdujo en el Acuerdo ADPIC un nuevo artículo 31 bis, que entró en vigor el 23 de enero de 2017 y que supuso la primera modificación del Acuerdo. El objetivo principal de este artículo es permitir a los países miembros tener un mejor y más fácil acceso a los productos de salud a través de licencias obligatorias especiales.

La licencia obligatoria a la que se refiere el artículo 31 del ADPIC requiere que la concesión de la licencia obligatoria tenga que ser predominantemente para el suministro del mercado interno, lo cual impide exportar la mayoría de los productos fabricados con la licencia obligatoria. Sin embargo, según el nuevo artículo 31 *bis*, los países miembros pueden otorgar licencias obligatorias para la producción de productos farmacéuticos destinados a ser exportarlos a otros países miembros, lo cual va a permitir la fabricación bajo licencia obligatoria en países desarrollados de fármacos con los que se pretende atender las necesidades de salud pública de los países en desarrollo. Además, el artículo 31 *bis* también impide el doble pago de la remuneración al titular de la patente por parte de los países miembros importadores y exportadores. En este caso, solo el país exportador debe pagar una remuneración adecuada y el país importador no está obligado a pagar la remuneración cuando concede la licencia obligatoria para los mismos productos farmacéuticos del país exportador.

La Ley iraquí de patentes n.º 65 de 1970 no prevé ningún tipo de excepción de las que encajan en el artículo 30 del Acuerdo sobre los ADPIC. Aunque la CPA conocía bien las disposiciones del Acuerdo sobre los ADPIC, no añadió ninguna excepción similar en la ley de patentes iraquí. Sin embargo, la ley iraquí n.º 65 de 1970, en su versión original, proporcionaba algunas disposiciones con respecto a la concesión de licencias obligatorias, disposiciones que fueron

modificadas por la Orden n.º 81 de la CPA, en la que se incluyen casi todas las condiciones que se establecen en el Acuerdo sobre los ADPIC para la concesión de licencias obligatorias. Por otro lado, la citada Orden n. 81 de la CPA también derogó algunas flexibilidades de la licencia obligatoria que favorecían a Iraq, como la concesión de licencias obligatorias cuando la explotación corresponde a las necesidades de Iraq. Por lo tanto, se concluye que la Orden n.º 81 de la CPA tampoco añadió ninguna disposición con respecto a la concesión de una licencia obligatoria especial para los productos farmacéuticos.

12. La conclusión general que se extrae en la tesis es que la ley iraquí n. 65 de 1970 necesita ser modificada para adaptarla plenamente a lo dispuesto en el Acuerdo sobre los ADPIC, así como para adecuarla al desarrollo del país y de su población. Algunas de las principales conclusiones alcanzadas en la tesis se pueden resumir del siguiente modo:

a) Al igual que sucede en la legislación de otros muchos países, debe incluirse en la legislación iraquí una disposición, al amparo del artículo 27.3 (a) del Acuerdo sobre los ADPIC, que disponga que «no se concederán patentes sobre métodos de diagnóstico, terapéuticos y quirúrgicos para el tratamiento de personas o animales». Se necesita una disposición similar para que un país subdesarrollado como es Iraq se beneficie de esta exclusión.

b) El artículo 27.3 (b) del Acuerdo sobre los ADPIC ordena a los países miembros prever la protección de las obtenciones vegetales. Y en este sentido, la ley n.º 15 de 2013 es un sistema *sui generis* que brinda protección a las variedades vegetales. Sin embargo, esta ley redujo el período de protección y no aprovechó las ventajas del Convenio de la UPOV. Por esta razón, en esta tesis se recomienda una modificación de ley para que, a la par que se respeta el Acuerdo sobre los ADPIC, se recojan todas las ventajas que se establecen en el Convenio de la UPOV.

c) El investigador también recomienda que se agregue una disposición a la ley iraquí de patentes para prever las excepciones permitidas en virtud del artículo 30 del Acuerdo sobre los ADPIC. La Orden n.º 81 de la CPA no actuó en interés de Iraq y no incluyó

excepciones como la excepción de importación paralela, la excepción de uso anterior, la excepción referida a la preparación de medicamentos realizada en farmacias extemporáneamente y por unidad de ejecución de una receta médica, la cláusula Bolar o la excepción de investigación y experimentación, que pueden aplicarse en las legislaciones nacionales de los países miembros de conformidad con el artículo 30 del ADPIC.

d) La Ley iraquí de patentes n.º 65 de 1970 no contiene ninguna disposición similar al artículo 34 del Acuerdo sobre los ADPIC que invierta la carga de la prueba en los casos relacionados con la eventual infracción de patentes de procedimiento. Dado que la Orden n.º 81 de la CPA no incluyó dicha disposición, en esta tesis se recomienda que dicha disposición se incluya en la ley de patentes iraquí para que los titulares de patentes de procedimiento gocen de una mejor protección.

e) Por último, esta tesis recomienda modificar la ley iraquí de patentes n.º 65 de 1970 para incluir disposiciones que den efecto al artículo 3 *1bis* del Acuerdo sobre los ADPIC. De conformidad con el artículo 31 *bis*, los países exportadores pueden otorgar licencias obligatorias, de modo que la mayoría o la totalidad de las producciones con esa licencia se exporten fuera del país. Los países miembros importadores de tales producciones están exentos de pagar una remuneración adecuada al titular de la patente mientras otorgan una licencia obligatoria a los mismos productos. En consecuencia, tras esta reforma Iraq, como país miembro importador que carece de capacidad de fabricación suficiente, podrá otorgar licencias obligatorias para importar medicamentos de otros países miembros que producen dichos medicamentos con licencia obligatoria.

1 INTRODUCTION

Iraq, as one of the developing countries, needs to improve its standard in the area of international trade in general, and in the area of intellectual property rights in particular. In order for Iraq to have good relationship with other countries of international community, it has to respect their rights and possessions. This can be achieved through enacting rules and regulations that are in interest of both Iraq and international communities. The original Iraqi Patent and Industrial Design Law No. 65 of 1970 consisted of 54 sections, in which only the first 35 sections were dedicated to patent law and the rest were dedicated to industrial design law. However, four amendments were passed on this law and the most important is by CPA Order No. 81/26 April 2004 which was passed after the invasion of Iraq. The Coalition Provisional Authority lead by USA amended this law intensely by even adding some extra areas and changed the name of the law to (Patents, industrial design, undisclosed information, integrated circuits and plant variety Law). This law intended to enhance the original Law to international standard especially to the TRIPS Agreement as it is stated in the Preamble of the CPA Order No. 81. The reason is that Iraq wanted to join the WTO and currently it is in the accession process. Therefore, one can say that Iraqi patent law is still in the process of developing in order to meet the minimum standard of protection that required by the TRIPS Agreement.

Although Iraq is one of the developing countries that has great natural resources in particular oil, yet, it has the potential to be an agricultural country if the fertile soil utilized properly it can secure food production for its national demand or even more. Iraq was rich in human resources as well, however, due to many consecutive wars with Iran, Kuwait, Coalition States lead by United States of America and currently war with terror, the number of skilled human resources decreased significantly due to death or migration. Therefore, the country needs proper and suitable laws to help to elevate the country

to the status it deserves. A law that help the country to access necessary technology to build a technological country that be able to rely on itself for every type of production including medical products. A technology for rebuilding agricultural sector so that it can secure food production for the need of the whole country instead of relying on importation.

Right now, Iraq is considered to be developing rapidly commercially, therefore, it is necessary to import all kinds of equipment, materials and products without knowing their IP rights and being able to respect these rights. There may be many reasons for this; however, one of the reasons is due to Iraq's nonparticipation in the international conventions and treaties that related to IPR. One of the most important international treaties that Iraq is not part of is the TRIPS agreement. Iraq is not one of the members of WTO, but it is in the process and right now is in the list of observer governments. In the same way Iraq is not a member of the most treaties and unions under WIPO except for Paris Convention (1976) and WIPO Convention (1976). However, it is the TRIPS agreement that provides for the wide range of protections of intellectual property rights. Therefore, it is the purpose of this research to analyse all possibilities of implementing the TRIPS agreement, especially in the area of patent by the Iraqi government.

Therefore, the key hypothesis of this research is that Iraq should implement a law that fulfils the requirements of the TRIPS Agreement and at the same time include all the legal flexibilities that help to develop the country with minimum costs and sacrifices. For this reason, the main question that this research asks is whether the CPA Order No. 81 after its dramatical amendments has achieved this goal.

The TRIPS Agreement is not the first international agreement in the area of intellectual property rights, other international conventions such as the Paris Convention and the Berne Convention existed long before the TRIPS Agreement. However, the developed countries and in particular the United States of America, were not happy with the outcome of these international conventions. Therefore, their effort was to establish a strong international agreement that be able to reduce distortions and impediments to international trades and can take the

member countries accountable of their breaches of the agreement. Nevertheless, the developing countries created their own frontier with the aim of inserting some provisions in their own interest. The enforcement of the TRIPS Agreement should be for the mutual advantages of both producers and users in the same time and balance of rights and obligations should be kept at all the times. Developing countries have right to protect their public health and public interest within the scope of the TRIPS Agreement, as long as the minimum standard which is required by the TRIPS Agreement is implemented.

Patent law is very important for the development of society as it will grant exclusive right to the patent owners. Patent owner will receive exclusive right to use, make and exploit his invention so that gain economic profit. This is an incentive for every inventors and government will guarantee patentee's rights. In return his invention will be disclosed to public to study and research, and even after the expiry of the patent everyone will be able to use the invention for economic benefits as will.

In order for a patent to be granted to an invention, it should have some requirements. Even though the TRIPS Agreement does not define the term invention nevertheless it states the traditional requirements of patentability which they are novelty, inventive step and industrial applicability. Therefore, this research will discuss the requirements of patentability of the original Iraqi patent law No. 65 of 1970 and its amendment of the CPA Order No. 81, in order to see whether the amendment has brought the Iraqi patent law closer to the TRIPS Agreement or not. Whether such amendments were necessary or not.

The TRIPS Agreement provides some exclusions from patentability. This is one of the most important area for the developing countries. Article 27.2 of the TRIPS Agreement provides an option that the member countries can exclude inventions from patentability, if the exploitation of such inventions goes against the principles of *public ordre* and morality. The TRIPS Agreement does not define any such principles and left for member countries to define them and implement them. However, if exploitation of any invention endangers the structure of civil society and its institutions, or negatively affect

the community's immorality then member countries are allowed to exercise its rights under this provision of the TRIPS Agreement and exclude such invention from patentability. therefore, this research will discuss in detail these exclusions and the relevant provisions under the original Iraqi patent law and its amendment by the CPA Order No.81.

The TRIPS Agreement also provides another option for excluding from patentability that relate to method of treatment which they are the diagnostic, therapeutic and surgical methods for treatment of humans or animals. The research will examine this provision in order to find out what can be excluded from patentability. Positions of member countries on this type of exclusion will be analysed even before the existence of this provision and position of those member countries that allow patenting such methods of treatment. Then position of Iraqi patent law and CPA Order will be analysed as well.

Access to medicines and fulfilling the public health needs are always one of the problems of the least developed and developing countries. The sources of these medicines are usually the developed countries and their higher prices has always been problem for poor countries especially with the higher standard of protection of the TRIPS Agreement. Because it will prevent the least developed and developing countries from having access to generic drugs. Notwithstanding, the fact the higher standard of protection will help the pharmaceutical companies to make better profits and in return this encourage them to conduct expensive research and development for discovering new medicines. Eventually, the least developed and developing countries attempt to balance the result of the Uruguay Round, led to the adoption of the Doha Declaration on the TRIPS Agreement and Public Health (14 November 2001). This declaration to acknowledge the problem of these countries and emphasizes that the TRIPS Agreement should not be an obstacle in solving their public health problems. Therefore, this research will discuss the Doha Declaration in detail to find out to what extend it has solved the public health concerns and access to medicines by the member countries, and the Iraqi patent law position will be discussed as well.

The TRIPS Agreement also provides for exclusion from patentability of plants and animals. This is another important area of

exclusion; however, the TRIPS Agreement require from the member countries to provide for the protection of plant varieties. This protection can be through a patent or an effective *sui generis* system or both of them. The research has discussed this area of exclusion in detail with reference to some other important international agreements that have regulated the protection of plant varieties including saving seeds. Iraq has vast area of fertile land that can be used for agriculture. Therefore, providing protection of plant varieties and seeds will affect the farmers significantly. The Iraqi laws in this regard will be examined and analysed with reference to the amendments as well.

The last part of the research will focus on the exceptions to exclusive rights of patent owners in the TRIPS Agreement and Iraqi patent law. The TRIPS Agreement states that member countries have right to provide for limited exceptions to right conferred, without naming any type of exceptions. However, long before the TRIPS Agreement countries around the world were used to limit the exclusive rights of the patent holders by introducing some important exceptions according to their needs. By not naming specific type of exception the TRIPS Agreement offers flexibilities to the member countries to include the exceptions in their domestic law that best serve circumstances. However, the conditions in the TRIPS Agreement have to be abide by the member countries.

Beside the above exception, the TRIPS Agreement provides for another type of exception which names it 'Other Use Without Authorization of the Right Holder', as commonly known as (Compulsory licence). compulsory licence is very powerful tool at the hand of the local authorities to rectify any unbalanced circumstances created due to the exclusive rights of the patent owners. This type of licence imposed on the right holders without their consent. Therefore, the TRIPS Agreement has states a list of conditions and restrictions that have to be followed before any member countries be able to grant a compulsory licence under the TRIPS Agreement. The research will examine and analyse in detail the conditions and circumstances in which this exception can be applied in.

However, due to the strict conditions for applying the compulsory licence, that made many member countries especially the least

developed and developing countries unable to utilise the compulsory licence to supply the needs medicines for themselves. This eventually leads to an amendment to the TRIPS Agreement and introducing special compulsory licence for the purpose supplying pharmaceutical products for the need of the member countries. The research will discuss this new compulsory licence in detail and explain the situations that can be applied on.

The original Iraqi patent law provided for compulsory licence. However, the amendment of the CPA Order No. 81 replaced all the provisions that related to compulsory licence. the research will examine all the provisions of the of the Iraqi patent law before the amendment and after the amendment by the CPA and analyse the weaknesses and advantages that introduced by the CPA Order No. 81.

2 OBJECTIVES

The main objective of this research is to examine and analyse the original Iraqi Patent and Industrial Design Law No. 65 of 1970 (The Patent Laws only) in comparison to the amendments in particular the CPA Order No. 81, then compare these with the provisions of the TRIPS Agreement in order to find out the confirmations and contradictions among them.

Apart from the above main objective, there is a significant number of other objectives as follows:

First: To find out whether the TRIPS Agreement established on bases of fair negotiations and without any coercion from the powerful developed countries and their companies such as big pharmaceutical companies.

Second: Analyse and examine the nature, scope, purposes, objectives and principles of the TRIPS Agreement in order for the member countries (least developed, developing and developed countries, and particularly the Iraqi law makers) have clear vision on how to deal with the TRIPS Agreement and be able to benefit from it.

Third: Examine the historical development of the Iraqi patent law and assess the requirement of patentability under the original Iraqi patent law and its amendments to find out to what extend compatible with the requirement of patentability under the TRIPS Agreement.

Fourth: Analyse the provisions of the TRIPS Agreement that provide for exceptions and exclusion from patentability and compare them to the Iraqi patent law and its amendments made by the CPA Order No. 81 in order to find compatibility among them, and to find out to what extent they have been utilised by the Iraqi patent law.

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3 METHODOLOGY

The thesis methodology is comprised of legal comparative and analytical approaches to all existing significant provisions of the Iraqi patent law before and after amendments among themselves and in comparison, to the provisions of the TRIPS Agreement. The justification for the research analyses is to identify the reasons behind the existence of the TRIPS Agreement and the negotiations that occurred between the developed and developing countries. Analysing the process of standardizing the minimum protection of patent rights before the TRIPS Agreement and tactics used by the each developed and developing countries to gain most out of the TRIPS Agreement and reasons made the developing countries to accept the TRIPS Agreement.

The research compares and analyses the provisions of the original Iraqi patent law with the amendments that followed by the CPA. In this way the research will be able to arrive to conclusion whether the progresses and amendments were made for the benefits of Iraq as a country. For arriving at this conclusion, examining the history of creating the TRIPS Agreement and the provisions of this agreement is necessary. Comparing the original Iraqi patent law and CPA Order No. 81 of the provisions of the TRIPS Agreement will be the best way to find discrepancies among them and a good attempt to make harmonization among them.

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4 RESULTS

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CHAPTER I: TRIPS AGREEMENT AND IRAQI PATENT LEGISLATION

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1 TRIPS HISTORY, BACKGROUND, NEGOTIATION: DEVELOPED AND DEVELOPING COUNTRIES STAND DURING NEGOTIATIONS.

1.1 INTRODUCTION

The agreement of Trade-Related Aspects of Intellectual Property Rights TRIPS (hereinafter the "TRIPS Agreement") is considered as one of the most important and popular agreement on standardizing Intellectual Property Law, as most of the countries in the world are either members or trying and in the process of accession. The TRIPS Agreement is the result of Ministerial Conference in Marrakesh on 15 April 1994, signed by the General Agreement on Tariffs and Trade (hereinafter the "GATT") contracting parties as an annex to the World Trade Organization (hereinafter the "WTO") Agreement.[1]

The process of standardizing intellectual property protection is not new, and its starting point can be traced back to the colonization period.[2] During the colonization period, this process was done by force with the aim of prioritizing the interests of colonial countries. Most of the colonial countries transferred their intellectual property laws into their colonies without their consent. For example, British copy right law applied in Malaysia, Spanish patent law enforced in Philippines and Korean patent law replaced by Japanese patent law.[3]

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1 Nuno Pires de Carvalho, *The TRIPS Regime of Patents and Test Data*, Fourth edition (Alphen aan den Rijn, The Netherlands: Kluwer Law International, 2014), p. 1.

2 Emir Aly Crowne, 'Fishing TRIPS: A Look at the History of the Agreement on Trade-Related Aspects of Intellectual Property', *Creighton International and Comparative Law Journal*, 2 (2011), 77, p. 77.

3 Peter Drahos, 'Developing Countries and International Intellectual Property Standard-Setting', *The Journal of World Intellectual Property*, 5.5 (2002), 765–89, p. 766-67.

These clearly explain that most of the current developing countries had little option of exercising rights over their intellectual property protection standards.

The Paris Convention for the Protection of Industrial Property of March 20, 1883 (hereinafter the Paris Convention) and the Berne Convention for the Protection of Literary and Artistic Works of September 9, 1886 (hereinafter the Berne Convention) long before the TRIPS agreement dealt with the international intellectual property rights. The latter one particularly came to existence as an international convention to protect the interests of exporters. The major colonial countries brought their colonies and foreign possessions into the convention according to Article 19 of the Berne Act. The Article clearly stated that colonial powers has right to act on behalf of their colonies and accede them to the Convention. Most of the current developing and least developing countries dragged into Berne Convention without their freewill and in fact many of them never had a chance of deciding on the setting of intellectual property standards. Even afterwards, some of the newly independent countries were inexperienced economically and culturally that necessitated them to completely rely on their mother countries.[4] In other words they followed the system that chosen by the developed countries and accepted standards that were in the best interest of the developed countries.

Other developing countries that tried to establish some standards for the cause of their own national interests were opposed by the developed countries, because many of them passed national law that gave little protection, for example in the area of pharmaceuticals. These developing countries were not doing something new, in fact they were following the footsteps of current developed states.[5] A study shows that developed countries' members of the Paris Convention excluded from protection some areas that were not in their

[4] Drahos, 'Developing Countries and International Intellectual Property Standard-Setting', pp. 766–67.

[5] Abdulqawi A. Yusuf, 'TRIPS: Background, Principles and General Provisions', in *Intellectual Property and International Trade: The TRIPs Agreement*, ed. by Carlos María Correa and Abdulqawi A. Yusuf, 2nd ed (Austin : Alphen aan den Rijn, Netherlands: Wolters Kluwer Law & Business ; Kluwer Law International, 2008), p. 4.

interest.[6] However, this trend of conflict between developed and developing were not new, because always underdeveloped countries that are in the process of industrialization have given little protection rights in order to reach its goal easily and with minimum cost. It has been admitted by United States Congress that in early stages of development, the United States refused to respect international intellectual property rights because by freely accessing to foreign works could forward its economy and society.[7]

1.2 REASONS BEHIND THE EXISTENCE OF THE TRIPS AGREEMENT

Prior to the existing of the TRIPS Agreement many attempts were made by both developed and developing countries to revise the international standards of intellectual property rights. In many occasions developing countries questioned the international standards of intellectual property rights in particular the Paris Convention and the Berne Convention.[8] These questions were an attempt to modify the regulations so that they will satisfy their needs. As latecomers the developing countries tried to amend and update the conventions so that they have better access to foreign technologies, but they were unsuccessful. On the other hand, these conventions were described as teeth less conventions by developed countries, because they lacked the enforcement mechanisms and could not effectively sanction the non-compliance parties. Dispute under the Paris Convention had to be settle by International Court of Justice (hereinafter the "ICJ") and the decision of the ICJ was not enforceable unless the countries voluntarily cooperated. Both the developed and developing countries pursued different directions with different agendas.[9]

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6 Drahos, 'Developing Countries and International Intellectual Property Standard-Setting', p. 768.

7 Yusuf, p. 4.

8 Drahos, 'Developing Countries and International Intellectual Property Standard-Setting', p. 768.

9 Crowne, pp. 78–79; Srividhya Ragavan, *Patent and Trade Disparities in Developing Countries* (OUP USA, 2012), p. 65.

In the same way the developed countries were unhappy about the international standards protection, as they were aiming for stronger protection and realized that such protection cannot be achieved by World Intellectual Property Organization (hereinafter the "WIPO") and other forums like the United Nations Conference on Trade and Development (hereinafter the "UNCTAD") and the United Nations Educational, Scientific and Cultural Organization (hereinafter the "UNESCO") because its position in these forums is weak and can easily be defeated by developing countries.[10] United States' failed attempts lead to think about shifting to a forum where it is the strongest influential party and can impose its interest without effective opposition. This forum was the GATT forum. This made United States to think again and propose that the issue of intellectual property protection has to be considered as an issue of multilateral trade negotiation.[11] Since developing countries were not sympathetic to the United States intellectual property needs, it had no choice but to create a link between international trade regime and enforcement of intellectual property standards so that be able to stop free riding and 'rebalance the equation'.[12] In fact up to that moment intellectual property rights were looked at as an obstacle to free trade, but due to the United States and United States big businesses, the contracting parties to the GATT meeting in Punta del Este (Uruguay) agreed that in the next round (which is known as Uruguay Round) to include trade related aspects of intellectual property rights as a subject for negotiations.[13] This process was not sudden but it was planned long before Uruguay Round. Some attempts were made during the Tokyo Round on the issue of trade in counterfeit goods which was led by the Levi Strauss Corporation, even though the attempt was unsuccessful to frame the intellectual property rights a trade related issue, but it was

[10] Crowne, p. 79.
[11] Drahos, 'Developing Countries and International Intellectual Property Standard-Setting', p. 769.
[12] Peter Drahos, 'GLOBAL PROPERTY RIGHTS IN INFORMATION: The Story of TRIPS at the GATT', *Prometheus*, 13.1 (1995), 6–19 (p. 8).
[13] Crowne, p. 79.

a good initiation.[14] This followed by creating the Group of Expert on Trade on Counterfeit Goods by contracting parties at their Fourth Session in 1984. The Group was of the opinion that joint action was necessary, but some countries were against producing additional norms and standards and others were of the belief that WIPO was a better forum for dealing with these issues and not GATT.[15] However, there are other reasons that encouraged developed countries to push for GATT. One of the reasons was that they can incorporate all intellectual property rights into a single document and any country wants to benefit from WTO has to ratify this single document (the TRIPS Agreement) as well.[16] Even though the developing countries were aware that TRIPS was a loss but they were of the opinion that joining WTO will be beneficial overall.[17] GATT was considered to be a place where contracts and pacts were freely traded rather than concentration on free trades.[18] Another strong reason that led the developed countries to prefer GATT over WIPO was that the former had a well-established enforcement and dispute settlement mechanisms.[19] Another reason for chosen GATT by United States as a forum for intellectual property was that the GATT's background and dealings with the developing countries was not perfect as supposed to be. The representatives of developing countries were not existed continuously during the process of creating the TRIPS Agreement and during drafting the (Framework of Understanding) and setting the foundations of the final agreement they were left out.[20]

[14] Graham Dutfield, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History*, Globalization and Law (Aldershot, Hampshire, England ; Burlington, VT: Ashgate, 2003), p. 197.
[15] Daniel J. Gervais, *The TRIPS Agreement: Drafting History and Analysis*, 3rd ed (London: Sweet & Maxwell, 2008), pp. 8–9.
[16] Crowne, pp. 79–80.
[17] Dutfield, p. 197.
[18] Drahos, 'GLOBAL PROPERTY RIGHTS IN INFORMATION', p. 13.
[19] Dutfield, p. 199.
[20] Drahos, 'Developing Countries and International Intellectual Property Standard-Setting', p. 770.

1.3 STEPS TAKEN BY DEVELOPED COUNTRIES (UNITED STATES OF AMERICA IN PARTICULAR):

United States government had a great role in the actual existence of the TRIPS Agreement. Alone with all the powers it had could persuade more than 100 countries that they should pay more for the importation of information.[21] The United States government was backing up the interest groups especially those of pharmaceuticals and brand name goods on one side and other various high technology sectors on the other. Fears spread wide that the United States economy was declining and weakening. Base on this pessimism among political elites led the United States government think that this is highly due to intellectual property piracy by other countries.[22] Many American big corporations like IBM, Pfizer and Microsoft which largely relying on intellectual property assets, were worried about losing profits due to piracy.[23] Data collected by the United States International Trade Commission (hereinafter the "ITC") showed that United States corporations losing some US$ 50 billion a year due to weak intellectual property protection abroad.[24] Furthermore, some developing countries were emerging as potential regional economic power such as Brazil and India. While United States looking at their developing as a threat and unfriendly economic rivals.[25] Long before the Punta del Este Ministerial Conference, both of the patent and copyright interest groups were of the opinion that strong and enforceable intellectual property protection is necessary. Patent industries wanted to achieve this through multilateral approach with the aim of globalizing United States standards of intellectual property protection. On the other hand, the copy right industries were concerned more with their level of enforcement. But before the

[21] Drahos, 'GLOBAL PROPERTY RIGHTS IN INFORMATION',p. 7.
[22] Dutfield, p. 199.
[23] Drahos, 'GLOBAL PROPERTY RIGHTS IN INFORMATION', p. 7.
[24] Adronico O Adede, 'Origins and History of the TRIPS Negotiations', in *Trading in Knowledge: Development Perspectives on TRIPS, Trade, and Sustainability*, ed. by Christophe Bellmann, Graham Dutfield, and Ricardo Meléndez-Ortiz (Earthscan, 2003), p. 24.
[25] Drahos, 'GLOBAL PROPERTY RIGHTS IN INFORMATION', p. 7.

Conference both parties agreed that their approaches were complementary.[26]

There are two main entities that had great influence on the United States government decision on preferring strong and high standard of intellectual property rights. The first and most important of these entities is the Office of the United States Trade Representative (hereinafter the "USTR"). USTR was created by Congress and placed in the Executive Office of the President to coordinate trade policy, but in reality, it was a means through which the Congress and interest groups put pressure on the Executive to incorporate their interests in the country's international trade policy. The other entity was the United States ITC. ITC aimed at providing trade expertise to both branches of government (Legislative and Executive) by identifying the effects of imports on US industries and actions necessary to be taken against 'unfair trade practice' including intellectual property piracy. The interests of other developed countries were similar to those of United States. Therefore, it was easy for United States to acquire support of European Union, Japan, Canada and other developed countries. However, before receiving such support, United States through major multinational corporations established Intellectual Property Committee (hereinafter the "IPC") in 1986. IPC did its best to gather supports of European and Japanese governments and businesses. IPC could with help from other local and international business and trade association turn the issue of intellectual property into a trade related issue in a package and eventually developed into the TRIPS agreement. [27] However, developing countries resisted this attempt and United States had to deal with opposition in its own way. Since the United States can be considered as a mastermind of existence of the TRIPS agreement and mostly will be beneficial for the United States, it was the United States that strongly opposed all the resistance. Dealing with sovereign states was not easy for the United States because they had rights under previous international conventions to regulate laws with lower protection from what United States wishes for. Some of these countries were not culturally ready to

[26] Dutfield, p. 201.
[27] Crowne, pp. 81–83.

accept intellectual property and some looked at it as a new form of decolonization or economic imperialism.[28]

As has already been said, one of the main countries that contributed to the existence of TRIPS Agreement and strongly repulsed any resistance against creation of the TRIPS was United States of America. The United States had taken some measures to ensure that nations and in particular developing nations would follow the standards that USA prefers. IPC adopted a strategy of dialogue to divide between the developing countries. In 1988 a delegation from IPC visited newly industrialized countries like Korea, Hong Kong and Singapore, with the intention separate them from India and Brazil by persuading them that their issues and interests are not same as of India and Brazil. The IPC delegation also visited ASEANS with the intention to persuade them that India and Brazil are not suitable countries to represent you as they don't care about investment climate.[29]

The origin of the Office of the United States Trade Representative (USTR) goes back to the time of President Kennedy. During his time and under the Trade Expansion Act of 1962, Congress requested the President to create a Special Representative for Trade Negotiations to conduct United States trade negotiation, which up to that time it was the responsibility of the Department of State.[30] In the beginning the office was called Special Trade Representative (hereinafter the "STR"), but later on according to section 1 (a) of the Reorganization Plan No. 3 of 1979, the office renamed as the Office of the United States Trade Representative (USTR). Reorganization Plan No. 3 of 1979 broadened USTR responsibilities. The primary responsibilities of USTR as stated in Section 1 (b) (1) are developing and coordinating the implementation of United States international trade policy, including commodity matters and direct investment policy and overseeing negotiations with other countries. USTR serve as the principal advisor to the President on international trade policy and on

[28] Drahos, 'GLOBAL PROPERTY RIGHTS IN INFORMATION', p. 9.
[29] Peter Drahos and John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (London: Earthscan, 2002), p. 129.
[30] https://ustr.gov/about-us/history. Seen on 03/11/2016

the impact of other policies of the United States Government on international trade.

Even though there are other committees and groups such as Trade Policy Staff Committee (hereinafter the "TPSC") and Trade policy Review Group (hereinafter the "TPRG"), however it is the USTR that dominates the bureaucratic process and it is all due to USTR's primary responsibility for trade policy formation and implementation. Most of the actions by USTR, among others are under Section 301 of Trade Act 1974 regarding unfair foreign trade practices and Section 182 (which is called special 301 and introduced in 1988 amendments) on intellectual property rights.[31] These new laws were come into existing in order for United States prepare itself for world domination of intellectual property and enforce its own interests by coercing other sovereign states.[32] This is no different from what the British government had done when it had dominant power. For example, when its trade monopoly ended with china, the British government pressured by Lancashire manufacturers, ship owners and other commercial interests to extend the monopoly through whatever means is necessary. Eventually through using military power the monopoly further extended while the Chinese government agreed to more trade agreements. Then after a while further agreement enforced on china, but this time British government aided by the French.[33]

Section 301 is the first section under Title III, Chapter 1 of the Trade Act of 1974. Title III specialised for relief from unfair trade practices and its chapter one dedicated to enforcement of rights of United States and responses to certain foreign trade practices. The first section which is Section 301 titled 'Actions by United States Trade Representative'. Originally Section 301 enacted to give the President the huge flexible power to solve trade disputes and also enhanced the President's authority to impose sanctions unilaterally without observing international obligations. However, currently this responsibility transferred to USTR and it has final decision in cases

[31] Marcus Noland, 'Chasing Phantoms: The Political Economy of USTR', *International Organization*, 51.3 (1997), 365–87 (p. 367).
[32] Drahos, 'GLOBAL PROPERTY RIGHTS IN INFORMATION', p. 9.
[33] Edward Goldsmith, 'The Uruguay Round: Gunboat Diplomacy by Another Name', *Ecologist*, 1990, 202–4 (p. 202-203).

related to section 301 and it has authority of initiating investigations as well.[34]

Section 301 is not directly related to intellectual property rights but gives great power to USTR to take actions, and in fact it is mandatory action when "the rights of the United States under any trade agreement are being denied or an act, policy, or practice of a foreign country (i) violates, or is inconsistent with, the provisions of, or otherwise denies benefits to the United States under, any trade agreement, or (ii) is unjustifiable and burdens or restricts United States commerce".[35] Section 301 specified the authority that USTR has, which in reality is a very broad that includes suspension, withdrawal or prevention of benefits from trade agreements. Furthermore USTR has authority to impose duties or other import restrictions on the goods.[36] Also, USTR has the right to take discretionary action when (1) an act, policy, or practice of a foreign country is unreasonable or discriminatory and burdens or restricts United States commerce, and (2) action by the United States is appropriate.[37] Therefore, USTR has authority to take action and impose trade sanction and punish foreign countries and Section 301 has given United States unilateral power to punish any foreign countries that threaten American interests, whether United States has bilateral or multilateral agreements with these foreign countries or simply their actions considered unreasonable, unjustifiable or discriminatory that restrict or burden the United States trade.[38] Even though section 301 interpreted in such a way as to be applied to all kind of trade practice including trades related to intellectual property. However, to further strengthen the protection of United States intellectual property trades Special 301 added to the Trade Act of 1974 in 1988. Special 301 particularly designed to protect the intellectual property rights.

[34] A. Lynne Puckett and William L. Reynolds, 'Rules, Sanctions and Enforcement under Section 301: At Odds with the WTO?', *The American Journal of International Law*, 90.4 (1996), 675–89 (pp. 676–77).
[35] Section 301 (a)(1)(A) &(B) Trade Act of 1974
[36] Section 301 (c)(1)(A) &(B) Trade Act of 1974
[37] Section 301 (b) Trade Act of 1974
[38] Puckett and Reynolds, p. 675.

The title of special 301 (section 182) of Trade Act of 1974 reads as "Identification of Countries That Deny Adequate Protection, Or Market Access, For Intellectual Property Rights". The main purpose of the Special 301 as can be understood from the title is to promote the adequate and effective protection of intellectual property rights in foreign countries. This can be achieved by Special 301 (section 182) through using a foreseeable threat of unilateral retaliation by the United States to induce trading partners to reform their intellectual property practices.[39] This retaliation was the result of the reality as stated by the United States International Trade Commission that in 1986 alone United States companies lost between $43 and $61 billion due to the piracy practices abroad. The President and the Congress were firmly committed and ready to do everything to adequately protect intellectual property rights through international trade negotiations and revisions to the United States trade laws.[40] Protecting the United States businesses and interests and satisfying the policies of both the president and the Congress were the reasons of enacting and designing the Special 301 in its current form. Base on this determination, Special 301 requires the USTR that within 30 days after submission of a report of (National Trade Estimate) to the President, the Committee on Finance of the Senate, and appropriate committees of the House of Representative,[41] to identify those foreign countries that 'deny adequate and effective protection of intellectual property rights, or deny fair and equitable market access to United States persons that rely upon intellectual property protection'.[42] Furthermore USTR can identify some foreign countries as 'priority foreign countries'. However, some stipulations are stated in Special 301 (section 182 of the Trade Act 1974) in those countries in order USTR be able to list as priority foreign countries, such as if they 'have the most onerous or egregious acts, policies, or practices that (i) deny adequate and effective intellectual property rights, or (ii) deny fair and equitable market access to United States persons that relay upon

[39] Judith H. Bello and Alan F. Holmer, 'Special 301: Its Requirements, Implementation, and Significance', *Fordham International Law Journal*, 13 (1989), 259 (p. 259).
[40] Bello and Holmer, p. 260.
[41] Section 181(b)(1) Trade Act of 1974.
[42] Special 301(Section 182) (a)(1)(A) & (B) Trade Act of 1974.

intellectual property protections.[43] Special 301 does not stop here but further authorised USTR to put any states in priority foreign countries 'whose acts, policies or practices described in subparagraph (A) have the greatest adverse impact (actual or potential) on the relevant United States products, and that are not (i) entering into good faith negotiations, or (ii) making significant progress in bilateral or multilateral negotiations, to provide adequate and effective protection of intellectual property rights'.[44]

Special 301 enacted exclusively to protect the intellectual property rights of United States companies and businesses in foreign countries. It gives a great authority to USTR to investigate in a very short time, much faster than investigation conducted according to normal section 301.[45] USTR admitted that Special 301 has great impact on changing acts and policies of intellectual property rights of foreign countries. For example, during 1989, People's Republic of China and Taiwan committed and agreed to amend their copyright laws that bring them into line with what is acceptable intellectual property rights according to the United States. Colombia also changes its policy regarding permission problems of motion picture and Saudi Arabia enacted a new patent law entirely. USTR also admitted that both Chile and Indonesia yield to the proposed patent law amendments or anew patent law including increased protection for pharmaceuticals. But still USTR was not satisfied and believed that during Uruguay Round none of the United States trading partner happy with the intellectual property standards proposed by U.S.[46]

USTR did not stop by targeting developing countries only, but rather USTR used section 301 to put pressure on a developed country such as Japan in order to direct its intellectual property protection standards to the same of those of United States. Japanese market in United States was blooming and creating bad image to the United States economic capabilities. Therefore, public was made to understand that it is the United States ideas and knowledge that have

[43] Special 301(Section 182) (b)(1)(A) Trade Act of 1974
[44] Special 301(Section 182) (b)(1)(B) & (C) Trade Act of 1974
[45] Bello and Holmer, p. 263.
[46] Bello and Holmer, pp. 265–66.

been stolen by the Japanese.[47] Eventually, the United States government worked on this point and in 1984 the United States trade officials put pressure on Japan's Ministry of International Trade and Industry to give up its proposals for a *sui generis* form of protection for computer software.[48] This may be the reasons why Japan stayed away from targeting developing countries bilaterally in intellectual property issues.[49]

Even though section 301 and special 301 had a great role in assisting USTR in performing its task, but without reports and data from intellectual property lobbies such as International Intellectual Property Alliance (hereinafter the "IIPA") and Business Software Alliance (hereinafter the "BSA"), USTR could not perform its duty. Thousands of companies are gathered to create these associations and they were active in countries all over the world and continuously feeding information to USTR. With the help of all these big corporations, USTR was capable of persuading ample number of countries, majority of them were developing countries, to enact or amend their intellectual property laws so that satisfy United States needs.[50]

This clearly helped and put United States in advantageous position comparing to other countries while negotiating and submitting its idea at GATT. But this was not enough as some developed countries priority was not inclusion of intellectual property into the trade domain, i.e. to be part of GATT. Therefore, United States had to do its best to influence its alliance within the developed countries and started with the most distinct group which was Quad group. Quad group was one of the essential groups which had great influence on TRIPS negotiations. Quad consisted of the United States, the European Community (hereinafter the "EC"), Japan and Canada. Sometimes the group extended to include Switzerland and Australia,

[47] Drahos, 'GLOBAL PROPERTY RIGHTS IN INFORMATION', p. 8.
[48] Drahos, 'Developing Countries and International Intellectual Property Standard-Setting', p. 773.
[49] Crowne, p. 85.
[50] Drahos, 'GLOBAL PROPERTY RIGHTS IN INFORMATION', pp. 10–12.

or some other countries, depended on the issues discussed, which then called Quad Plus.[51]

The intellectual Property Committee (IPC) had a great task of persuading the member states of Quad to have consensus plan and strategy while entering negotiation during GATT meetings and eventually overcome resistance that comes from the developing countries. United States was well prepared and informed. All the United States intellectual property associations and committees were continuously advising the negotiation delegation. The United States negotiators in comparison to other countries negotiators had gained an advanced expertise during bilateral and North American Free Trade Agreement (hereinafter the "NAFTA"). Even it was the first time for the GATT Secretariat to deal with the intellectual property and above all it was a surprise topic to be discussed in the round and other countries were unprepared as it was last minute inclusion,[52] and considered as a very small issue in an overloaded busy agenda of the Uruguay Round, and it was not certain whether such a controversial issue will make it to the end of the round.[53]

However, it cannot simply accept the notion that developing countries surrender to United States will without any resistance. In fact, some developing countries resisted on the issue of intellectual property. Both Brazil and India introduced their own proposals but after they were evaluated by United States associations and business organizations and passed their opinions to other developed countries, they were criticised and rejected. [54]

1.4 DEVELOPING COUNTRIES PERSPECTIVE TO THE TRIPS AGREEMENT AND ITS SHAPING

Developing countries were targeted by developed countries and especially by United States in all of the bilateral, regional and consequently at international level (GATT/WTO). United States did its best to enforce its intellectual property terms through section 301

[51] Crowne, p. 90.
[52] Drahos, 'GLOBAL PROPERTY RIGHTS IN INFORMATION', pp. 12–15.
[53] Adede, p. 25.
[54] Drahos, 'GLOBAL PROPERTY RIGHTS IN INFORMATION', pp. 12–15.

and special 301 of Trade Act 1974. USTR through its power greatly influenced and directed the agreements to satisfy United States businesses and government. Started with the bilateral agreements, then to regional agreements and finally at GATT. This process considered to be an economic coercion and the only effective way to enforce other states to comply with United States intellectual property objectives. The process was supported and assisted by multinational corporations and believed that it's the necessary coercion to limit the theft of United States technology and profits.[55] Transnational corporations already controlling almost every aspect of trade in the world and through the GATT they wanted to control other areas as well.[56] But in the same time developing countries had different opinions regarding intellectual property rights and standards.

Distinction between developed, developing and least-developing countries is necessary while discussing the TRIPS agreement. The agreement has given some privileges to developing and least developing countries. [57] For example, Article 65, 66 and 67 of part VI of the TRIPS agreement which regulate the transitional arrangements, clearly mentioned the developed, developing and least-developed countries, and assigned some privileges and duties on them. Therefore, in order for countries to benefit from these privileges, they have to be categorized in the developing or least-developing countries. Even though the WTO does not have an official list of separating countries based on their developments because WTO does not have any definition of what constitute the developed, developing and least-developing countries. Therefore, every country can claim to be a developing country so that benefit from the privileges, however, this claim can be contested by other members. [58]

There are many factors that can be looked at in order to identify the developing and least-developing countries. Even though every country does continuously develop from one state to another. But as a

[55] Drahos, 'GLOBAL PROPERTY RIGHTS IN INFORMATION', p. 16.
[56] Goldsmith, pp. 203–4.
[57] 'WTO | Development - Who Are the Developing Countries in the WTO?' <https://www.wto.org/english/tratop_e/devel_e/d1who_e.htm> [accessed 7 February 2017].
[58] 'WTO | Development - Who Are the Developing Countries in the WTO?'

general rule those countries with limited economic and social developments are considered to be within the list of developing or least-developing countries.[59]

There are other specific indications which can be relied upon in determining the development status of a country. For example United Nations Development Programme has a Human Development Index (hereinafter the "HDI"), that rely on some factors such as Demography, Education, Environmental Sustainability, Gender, Health, Human Security, Income/Composition of Resources, Inequality, Mobility and Communication, Poverty, Trade and Financial Flows, Work, Employment and Vulnerability.[60] The World Bank also stated long list of indications in order to categorize countries which they are Agriculture & Rural Development, Aid Effectiveness, Climate Change, Economy & Growth, Education, Energy & Mining, Environment, External Debt, Financial Sector, Gender, Health, Infrastructure, Poverty, Private Sector, Public Sector, Science & Technology, Social, Development, Social Protection & Labour, Trade and Urban Development.[61]

However, United Nations' Development Policy and Analysis Division uses three main criteria of income, human assets and economic vulnerability, while making recommendations on the inclusion and graduation of eligible countries from the list of least developed countries.[62] Therefore when a country claims to be a developing or least developing country can rely on these organizations and their factors and indications to prove its claim.

Almost all developed countries in European continent and even the United States used patent in the past mainly as a means to encourage local development and industrialization. The enactment of patent law and its amendments were always done in the light of

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[59] Ragavan, pp. 1–2.

[60] 'Human Development Data (1980-2015) | Human Development Reports' <http://hdr.undp.org/en/data> [accessed 12 February 2017].

[61] 'The World Bank Indicators | Data' <http://data.worldbank.org/indicator> [accessed 12 February 2017].

[62] 'LDC Identification Criteria & Indicators | Development Policy & Analysis Division', *Development Policy & Analysis Division | Dept of Economic & Social Affairs | United Nations*, 2010 <https://www.un.org/development/desa/dpad/least-developed-country-category/ldc-criteria.html> [accessed 12 February 2017].

national economic and social issues. In the same way the developing countries such as India and Brazil wished and successfully followed the same footstep in order to enhance their local industrializations and solve their shortcoming especially in the area of health care. Introducing patent to the area of trade was for the first time experienced by WTO (GATT) in order to enhance trade. This will be great if simultaneously enhance local industrialization and address local issues. Another factor that elevated and standardized the patent in the developed countries was time. The patent regimes that they are practicing today were the process of progressing through time, for example patent regime is the United States took almost 300 years to be standardized. Enforcing new standard of patent regime for under developed countries within a short frame of time will not always correlate with national development questions.[63]

Although majority of countries were of the opinion that intellectual property protections are necessary for promotion of further innovation, but they differ on what, how and how much to protect. Developing countries of the opinion that variation to intellectual property law is fundamental for them to stay on the path of development.[64] Due to the economic crises and social situations, for example both India and Brazil are suffering from poverty and a high incidence of AIDS,[65] the developing countries in Group Ten could not accept all the conditions set forth by developed countries and therefore resisted the GATT forum, but United States through its policy of economic threatening and political pressure managed to conclude the agreement.[66]

During the TRIPS negotiations many groups were established which some consisted only the developed countries such as Quad Group or only the developing countries such as Andea Group and others a mixture of the developed and developing countries such as the 10+10 Group and Group 11. The most important groups were those groups that included developed countries such as the United

[63] Ragavan, pp. 25–27.
[64] Ragavan, p. 64.
[65] Ragavan, p. 61.
[66] Crowne, p. 83.

States, the European Community, Japan and Canada. The TRIPS agreement was the product of the opinions and proposals of those groups that consists these developed countries rather than those groups that included the developing countries. Least developing countries were ignored and not included in any important groups.[67]

The group of 'Friends of Intellectual Property' was another important group that formed during Punta del Este and its main purpose was to make sure that intellectual property considered as a trade related issue. Once the Quad members agreed on an issue and reached consensus, Friends Group was used as a path to take the consensus forward further. Friends Group was a medium of exercising negotiation among developed countries. Negotiators learned from each other and developed the idea of what to expect from negotiations and what to be negotiated. This led to build a consensus among developed countries on intellectual property so that be able to control any resistance that comes from developing countries.[68]

From January 27 to July 31 of 1986 the Preparatory committee met formally in nine meetings. A group of ten developing countries that consist of India, Brazil, Argentina, Cuba, Egypt, Nicaragua, Nigeria, Peru, Tanzania and Yugoslavia, which they were led by India and Brazil, insist that comprehensive code on intellectual property should not be discussed within GATT. These countries firmly insisted that subjects of trade in services, intellectual property rights and investment should not be addressed.[69]

In May 1990 another group of developing countries that included Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Tanzania, Uruguay, Pakistan and Zimbabwe started to actively participate in the negotiation process of the TRIPS Agreement by submitting their own detailed proposal. In their proposal they wanted to emphasize on procedures and remedies against trade in counterfeit and pirated goods, in the same time tried to

[67] Drahos, 'Developing Countries and International Intellectual Property Standard-Setting', pp. 771–72.
[68] Drahos and Braithwaite, pp. 128–29.
[69] Drahos and Braithwaite, p. 133; A. Jane Bradley, 'Intellectual Property Rights, Investment, and Trade in Services in the Uruguay Round: Laying the Foundations', *Stanford Journal of International Law*, 23 (1987), 57 (p. 81).

minimize the high standards of intellectual property rights that developed countries were demanding. The developing countries were also focused on the importance of public policy objectives on national intellectual property rights and respect and safeguard national legal system and traditions on intellectual property rights in light of different level of development of each country.[70]

These countries complained a lot because many comprehensive and extensive proposals on intellectual property rights submitted by developed countries. Many other documents also submitted by GATT Secretariat and WIPO that related to connection between GATT norms and intellectual property, intellectual property treaties and international standards. India and Brazil as leading countries were put on priority watch list and others placed in watch list. Despite all these pressures India and Brazil continued on their objections throughout the negotiation process. They believed each country is in a different state of development and as a sovereign state should be given a freedom of setting minimum standards of intellectual property accordingly. In fact, the developing country negotiators in an attempt to create a strong front line of resistance had met in February 1989 in the resort of Talloires in France. The developing countries knew that they cannot individually face the pressures from the developed countries and in particular the United States. However, since there was no enough cooperation among the developing countries and India as a leading country failed to attend informal Third World Group meeting in April 1989, the alliance falls apart. Not to forget that the developing countries were each individually targeted by the United States through its sections of 301 and special 301, and bilateral treaties, especially Brazil. United States multinational corporations heavily presented in Brazil and by targeting and imposing sanctions on wide range of Brazilian goods, showed how United States private sectors serious about their goals in reaching the standards of intellectual property rights they desire. Also, the GATT Secretariat continuously pressured the developing countries through the Green Room process. Group discussion in the Green Room grew smaller and key countries were participated and exchange consultations. This made the developing

[70] Adede, p. 28.

countries negotiators call the process the Black Room consultations. Eventually, by 1990 onwards the discussions and negotiations were focused on how far the final draft of TRIPS agreement deviate from the original proposal submitted in 1988 by Pfizer, IBM, DuPont and other members of the international business community. Then the battle on the language of the TRIPS agreement starts as every country wanted the language to be construed in the way that describe the deals favours by the country. If a particular issue is not in their favour, the negotiators try to construct the article in an ambiguous language so that to be able to open a backdoor exit and be able to run away from responsibility of that particular issue. But it was a difficult task for negotiators as they all entangled in a complex web of relationships. Every negotiator was considered insider for some groups and outsider for others. Furthermore, some negotiators were fulfilling the wish of their countries, which they have other ambitions. For example, South Korea did not support India and Brazil fully because South Korea was trying to join the Organization for Economic Co-operation and Development (hereinafter the "OECD") and finally in 1996 became a member.[71]

1.5 CONCLUSION

From the historical perspective and negotiation process of creating the TRIPS Agreement, it can be concluded that the TRIPS Agreement as an international agreement did not come into existence for the benefits of all countries equally. During the process many coercion mechanisms implemented by developed countries and in particular the United States of America. The developing countries were aware of this fact but accepted the agreement partially because they did not have any choice but submit to the will of developed and industrialized countries, and also hoping to gain some advantages from joining the WTO.

[71] Drahos and Braithwaite, pp. 133–40.

2 NATURE, SCOPE, OBJECTIVES AND PRINCIPLES OF THE TRIPS AGREEMENT

2.1 INTRODUCTION

The TRIPS Agreement like many other international conventions and agreements established for certain purpose and has its own specific nature and scope of obligations, objectives and principles. In order to understand the nature, purposes, scopes, objectives and principles of the TRIPS Agreement, one has to look at the provisions and articles of the TRIPS Agreement as they create obligations upon the member countries to implement them. Even though there is one particular provision in the TRIPS Agreement that dedicated for clarifying the objectives of the Agreement, but still there is a debate in regard to what is the main objective of the TRIPS Agreement. Critics believe that the main objective of the TRIPS Agreement is to enhance the protection of intellectual property, however this is considered as a common misunderstanding by Nuno Pires de Carvalho. NP de Carvalho believes that "the main - if not the only - objective of the TRIPS Agreement as well as that of the whole WTO Agreement is to promote free international trade".[72] Principle of an agreement is considered to be a central part of the system by being the spirit of the whole agreement and represent the different rules that create one single agreement. If not for the principles of the TRIPS Agreement the social, environmental and economic aims of the WTO and TRIPS Agreement may be jeopardised by the scope of the intellectual

[72] Nuno Pires de Carvalho, *The TRIPS Regime of Patents and Test Data*, Fourth edition (Alphen aan den Rijn, The Netherlands: Kluwer Law International, 2014), p. 46.

property rights.[73] In this part the objectives and principles of the TRIPS Agreement will be discussed after looking at the purpose, nature and scope of the obligations of the Agreement.

2.2 PURPOSE, NATURE AND SCOPE OF THE TRIPS AGREEMENT

The TRIPS Agreement states minimum standard of intellectual property rights through rules and principles in order to ensure protection of the rights. It is considered to be the most comprehensive agreement in the international level compare to other agreement in the area of intellectual property rights.[74] The scope of such rights defined through the articles of the agreement by conferring rights to the title holders. Rights in the TRIPS Agreement considered to be negative rights in the sense that it is required from others not to deal with the protected subject matters without permission from the right holders.[75]

2.2.1 Purposes and Objectives of the TRIPS Agreement According to the Preamble

There are two main purposes and objectives that can be deduced from the Preamble which are consistent with the foundation of the WTO. First; presenting the intellectual property protection in a better way that reduce distortions and impediments to international trade. And second; recognition of intellectual property rights as private rights which can be protected against any arbitrary and unjust acts of governments.[76]

It is not necessary that all international agreements and conventions relating to intellectual property have a preamble, for example some of those agreements tabled by the United States of America and the European Community. Before 1990 having Preamble

[73] Rodrigues Jr and Edson Beas, *The General Exception Clauses of the TRIPS Agreement: Promoting Sustainable Development* (Cambridge, U.K.: Cambridge University Press, 2015), pp. 44–45.
[74] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 32.
[75] Carlos María Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*, Oxford Commentaries on International Law (Oxford ; New York: Oxford University Press, 2007), p. 7.
[76] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 39.

in the current form was not considered to be useful.[77] The Preamble does not have same legal power as those of the Articles and it is not considered to be creating specific rights and obligations. However, it can be referred to while interpreting the provisions of the TRIPS Agreement.[78] Not all the Article of the TRIPS Agreement are clear enough to avoid interpretation. Some of the articles may carry more than one meaning and can be interpreted in more than one ways, therefore the Preamble can be referred to in many interpretative contexts.[79]

The TRIPS Agreement in the first sentence of the Preamble states that members '*Desiring* to reduce distortions and impediments to international trade' and this is directly connected to the intellectual property when the next part of the paragraph of the Preamble states that 'taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade'. This proves that according to the TRIPS Agreement there is a strong connection between intellectual property rights and international trade. The existence of such connection was due to the attempts by the United States of America and United States' big corporations to include the trade-related aspects of intellectual property rights as one part of negotiation in the Uruguay Trade Round which was launched by Ministerial Declaration in 1986.[80] Despite the efforts of developing countries or less developed countries to stop this attempt but still made it to the Uruguay Round. Even though some analysts are of the opinion that the TRIPS Agreement was discussed in wrong place as it is not about the free trade but rather creating new domestic rules and

[77] Peter-Tobias Stoll, Jan Busche, and Katrin Arend, *WTO: Trade-Related Aspects of Intellectual Property Rights* (BRILL, 2009), p. 65.

[78] Stoll, Busche, and Arend, p. 67.

[79] *Resource Book on TRIPS and Development*, ed. by United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development (Cambridge; New York: Cambridge University Press, 2005), p. 10.

[80] Drahos, 'Developing Countries and International Intellectual Property Standard-Setting', p. 769.

regulations, and legal regimes.[81] However, by relating intellectual property rights to free trades, the TRIPS Agreement is recognizing the same purpose that stated in the Preamble of the WTO Agreement 'substantial reduction of tariffs and other barriers to trade and to the elimination of discriminatory treatment in international trade relations'. It was the same interest that the GATT of 1947 was founded on, which was 'liberalization of international trade'.[82] Trade in this context refer to both areas of trade of the WTO which they are trade in goods and in services.[83]

The TRIPS Agreement is part of the WTO (GATT) and therefore it is concentrated only on those parts of intellectual property rights that their protections considered to be distortions and barrier to trade. Those areas that the parties to the GATT considered were trade related aspects of intellectual property rights such as copyright and trade related parts, with some other areas of industrial property that have independent Articles within the TRIPS Agreement which are; trademarks, geographical indications, industrial designs, patents, and layout designs (topographies) of integrated circuits. Some other areas that related to industrial protection but not given an independent Articles but joint with other areas, and they are protection of undisclosed information and plant varieties. Protection of undisclosed information though mentioned in Section 7 of Part II of the TRIPS Agreement but in Article 39.1 of the TRIPS Agreement it is stated that undisclosed information is merely to give 'effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention (1967)'. Plant varieties also mentioned in Article 27.3 (b) within Section 5 of Part II of the TRIPS Agreement which dedicated for patents. According to the said article plant varieties shall be protected by the member countries through patent or an effective *sui generis* system as an alternative patent protection or *sui generis*

[81] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 3.

[82] Paul Katzenberger and Annette Kur, 'TRIPS and Intellectual Property', in *From GATT to TRIPs: The Agreement on Trade-Related Aspects of Intellectual Property Rights*, ed. by Friedrich-Karl Beier and Gerhard Schricker, IIC Studies, v. 18 (Weinheim; New York: VCH, 1996), pp. 2–3.

[83] Stoll, Busche, and Arend, p. 66.

system can be combined with patent protection.[84] Therefore, it becomes clear that the reason behind the words of the first paragraph of the Preamble of the TRIPS Agreement that international trade considered as an important element in the TRIPS Agreement and concentration will be on those intellectual property rights that their measures and procedures of enforcement will not lead to barrier to international trade.

The first paragraph of the Preamble did not neglect the requirement in which the TRIPS Agreement established for essentially, in the first paragraph of the Preamble while concentrating on trade the members should take 'into account the need to promote effective and adequate protection of intellectual property rights'. This is an acknowledgement that effective and adequate protection of intellectual property rights is necessary in every individual country in order to have free international trade with reduced distortions and impediments. In case these effective and adequate protection is absent, then it is believed that distortions and impediments subsequently occur in international trade and achievements of individuals and corporates will be abused as well, while investments will lead astray. Therefore, it is not the high standard of intellectual property right or its effective and adequate protection that threatens the international trade, but the abuse of such rights will do. This is an opinion that harmonization of strong intellectual property protection is necessary and should be an important objective of the TRIPS Agreement. Other abuses of intellectual property rights can be found in other places in the TRIPS Agreement such as Article 8.2 and Article 40. Article 8.2 states that it is necessary to prevent any abuse of intellectual property rights by right holders through needed measures by the TRIPS Agreement member countries. Such measures can be adopted 'to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology'. Article 40 of the TRIPS Agreement concentrates on anti-competitive practices that relate to intellectual property rights. Therefore, any abuse in practice of intellectual property rights that have adverse effect on competition

[84] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 33.

in the relevant market can be dealt with by the member countries in their legislation.[85]

As Article 31.1 of the Vienna Convention in regard of interpretation of treaties stated that 'A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose', therefore the Preamble serves as a purpose of interpretation since the Preamble identifies the object and purpose of the TRIPS Agreement. This further strengthened by the Doha Declaration on the TRIPS Agreement and public health,[86] as in paragraph 5 (a) states that the provisions of the TRIPS Agreement shall be read with the purpose and object of the TRIPS Agreement and especially objectives and principles. This clearly refers to the Preamble and Articles of 7 and 8 of the TRIPS Agreement. Even though its believed that the provisions of the TRIPS Agreement cannot be further broadened or narrowed in the light of the Preamble and Article 7 and 8, because any alterations would mean a new negotiation on what have already agreed on.[87]

2.2.2 Need for New Rules and Disciplines

The second paragraph of the Preamble is concerned with passing new rules and disciplines that are needed to accomplish the objectives of the first paragraph. In the second paragraph five subparagraphs numbered in which the new rules and disciplines should be regulated for accordingly. The first one is Subparagraph (a) that states 'the applicability of the basic principles of GATT 1994 and of relevant international intellectual property agreements or conventions'. There are some important principles in the GATT 1994 which they are national treatment, most favoured nation, transparency and sovereignty,[88] which the TRIPS Agreement needs to abide by. Since

[85] Katzenberger and Kur, p. 5-7.

[86] 'WT/MIN(01)/DEC/2 -WTO | Ministerial Conferences - Doha 4th Ministerial - Declaration on the TRIPS Agreement and Public Health - Adopted 14 November 2001', 2001 <https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> [accessed 22 December 2017].

[87] Carvalho, *The TRIPS Regime of Patents and Test Data*, pp. 37–38.

[88] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 5; Stoll, Busche, and Arend, p. 68.

the TRIPS Agreement is integral part of the GATT/WTO, therefore it's understandable that comply with the GATT's principles. In many situations the Panels and Appellate Body have referred to the principles and previous GATT jurisprudence in cases of the TRIPS Agreement.[89] Nonetheless, the question to what extent the GATT principles apply in the TRIPS Agreement is not clear yet, though these principles should not undermine the TRIPS Agreement. However, subparagraph (a) goes further than the GATT principles and requires the integrity to the applicability of other intellectual property agreements and conventions, such as Berne Convention,[90] Paris Convention and the Washington Treaty.[91]

In subparagraph (b) new rules and disciplines should be regulated concerning 'the provision of adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights'. The requirement of adequate standards and principles is necessary in order to balance the protection rights of the right holders and the interest of public and users in general. It was not the intention of the negotiators to impose highly standards form of protections, but it was the adequate standards and principles that are enough to achieve the objective of the TRIPS Agreement as stated in the first paragraph of the Preamble, which is to reduce distortions and impediments of international trade.[92] Then what constitutes adequate standards and principles is a matter of opinion, as what may be an adequate standards and principles for the developed countries many not be the same for less developed countries, and this may change through times as well. The developed countries have changed their standard of protection through times and during their development stages. However, the TRIPS Agreement states minimum standard of protection and requires from the member countries to incorporate these minimum standards that put forth in the Agreement into their national legal system. This has been considered as the highly criticised

[89] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 6.
[90] Stoll, Busche, and Arend, pp. 68–69.
[91] Gervais, p. 155.
[92] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, pp. 10–11.

aspect of the TRIPS Agreement because 'one size does not fit all' notwithstanding some limited period of transition given by part VI of the TRIPS Agreement.[93]

Subparagraph (c) emphasis on 'the enforcement of trade-related intellectual property rights, taking into account differences in national legal systems'. The Preamble wanted to stress on another important point as well which is the element of enforcement of the TRIPS Agreement that cannot be found in the previous conventions on intellectual property rights. This was one of the important point that United States of America and other developed countries emphasised on during the negotiation because according to them the previous conventions such as Paris Convention and Berne Convention lacked effective binding enforcement method to deal with non-compliance member countries. For this reason, these conventions were called teeth less convention by the developed countries.[94] However, the second part of this subparagraph added an important element to the enforcement measure which is considering the differences in national legal systems. This brings flexibility to the enforcement measure.[95] Because this gives an opportunity to the member countries as to how implement the obligations required by the TRIPS Agreement.[96]

In fact, subparagraphs (d) and (e) mention two important and necessary points to the developed and developing countries respectively. Developed countries were supporting the high standards of minimum protection and enforcement provisions, therefore in the case of any disputes arising from non-compliance should be resolved according to the multilateral procedures of the WTO.[97] Article 64 of the TRIPS Agreement states that 'The provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the

[93] Correa, *Trade Related Aspects of Intellectual Property Rights*, pp. 7–8.
[94] Crowne, p. 78.
[95] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 11.
[96] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 9.
[97] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 9.

settlement of disputes under this Agreement except as otherwise specifically provided herein'.

Since the provisions of the TRIPS Agreement require very extensive legislative and administrative measures that are above the capacity of less developed countries, hence, it provides for transitional arrangements in subparagraph (e) to help those countries in order to be able to implement the minimum standard protections of the TRIPS Agreement. In two occasions the transitional period extended. The first time was on 27 June 2002 when the Council for the TRIPS Agreement extended the transitional period until 2016 for least developed country members in regard pharmaceutical products. The second time was on 19 November 2005 in the same way the transitional period was extended for least developed countries until 1 July 2013 in regard the applicability of the whole TRIPS Agreement.[98]

There are four more paragraphs in the Preamble that recognize important points, such as dealing of international trade in counterfeit in paragraph three, as this was the wishes of United States of America with the support of EC. Then, the Preamble recognizes the intellectual property rights as private rights in the fourth paragraph. This was included in order to reaffirm that the matters of intellectual property rights should be left for private parties to deal with, though the TRIPS Agreement in some occasion allowed the interference of states particularly in cases of criminal sanction or balancing the public rights and rights of intellectual property right holders.[99] The importance of this paragraph is that it gives rights holders to take burden of their rights and be able to defend their rights without necessity of states interference and taken action of *ex officio*.[100]

The fifth paragraph recognizes an important element which is 'Recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives'. Implementation of high standard of intellectual property rights may cause great changes to the national systems and policies especially to the less developed

[98] Stoll, Busche, and Arend, p. 70.
[99] Gervais, p. 156.
[100] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 10.

countries. In this regard the Preamble recognizes some flexibilities and taking into account the public policy objective of national systems.[101] However, others considered this to be more restrictive than what applied in many countries, because the public policy objectives here limited to 'national systems for the protection of intellectual property' and not national systems of other areas that may be affected by the high standard protection.[102]

The sixth paragraph recognizes another important element of maximum flexibility for the least developed country members. This allows the TRIPS Agreement provisions interpreted more flexible in favour of least developed countries. In the contract law usually, the terms of an agreement are interpreted in the interest of the weaker party when circumstances warrant it. This kind of maximum flexibility are permitted in the implementation of domestic laws and regulation when it serves a sound and viable technological base as required the by the sixth paragraph.[103]

The seventh paragraph emphasizes on the importance of reducing tensions and resolving dispute settlement through multilateral procedures. This was emphasized on the request of the developing countries in order to prevent the developed countries from taken bilateral threats and enforcement measure.[104] Because it is common that developed countries use bilateral agreement in order to impose their conditions on the developing countries. For example, United States of America has done these many times through bilateral agreements and using section 301 of the United States Trade Act as a weapon against the targeted countries by the USTR to impose what United States think a fair practice of intellectual property rights and in case of failure of the bilateral agreement imposing sanction is the next

[101] Gervais, pp. 156–57.
[102] Correa, *Trade Related Aspects of Intellectual Property Rights*, pp. 12–13.
[103] Gervais, p. 157.
[104] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 11.

step by the United States of America. Currently this practice called TRIPS-PLUS.[105]

The last paragraph of the Preamble desires to establish the relationship between the WTO and the WIPO and other relevant international organizations. Originally the developing countries were resisting the idea of adopting intellectual property rights within the GATT forum, because WIPO as part of the United Nation is best organization that specialist in the intellectual property rights and not the GATT. However, this attempt was not successful, then it was requested that the WIPO should be fully associated in activities of fields related to intellectual property in the GATT forum. But at the end WIPO served as an observer and help the negotiation parties during the process of creating the TRIPS Agreement. In 1995 a cooperation agreement between WIPO and WTO signed and the outcome was stated in Article 63.2 of the TRIPS Agreement which is the common registry for notifying laws and regulations. Even though the Preamble mentions WIPO by name but does not disregard the role of any other relevant international organizations that regulate intellectual property rights such as UNESCO.[106]

2.2.3 Nature and Scope of Obligations

Article 1 of the TRIPS Agreement mentions nature and scope of obligation of the TRIPS Agreement which consists of three clauses. The first sentence of Article 1.1 obligates all member countries to give effect to the provisions of the TRIPS Agreement through laws and regulations. This means that the TRIPS Agreement is not self-executing, and the minimum standards provided for in the TRIPS Agreement have to be given effect by the member countries within their jurisdictions,[107] because there are differences between international rights and obligations and their direct applicability. In order for international agreements to have domestic validity and apply directly, must not include and have any conditions such as

[105] Peter Drahos, 'Bits and Bips Bilateralism in Intellectual Property', *The Journal of World Intellectual Property*, 4.6 (2001), 791–808 (pp. 791–92).
[106] Correa, *Trade Related Aspects of Intellectual Property Rights*, pp. 15–18.
[107] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 22.

requirement of implementation through domestic legislations as it is the case of the TRIPS Agreement. Some influential market players such as United States of America, the European Community and Japan did not accept direct applicability of WTO Agreements and this led to other countries to follow the same system. Even though some other Member countries such as Australia and Spain accepted direct applicability of some provisions of the TRIPS Agreement. Other countries if in principles do not accept the direct applicability, then has to be done though domestic legislations.[108]

The TRIPS Agreement does not state any procedures on how the process of effective implementation carry out by the member countries for the fact that some provisions can be applied directly as Article 31 and others only stating minimum standards or offer choices between two options as Article 34.1. The important element in the first sentence of Article 1.1 of the TRIPS Agreement is that provisions of the agreement has to be given an effect that can really operate and not only transposing the provisions into national laws and regulations.[109] It does require, however, from the member countries to change their national laws and regulations and any other administrative procedures that are necessary to give effect to the provisions of the TRIPS Agreement and reasonable measure have to be taken in order to ensure consistency between national legislations and the TRIPS Agreement.[110] This makes the implementation of the TRIPS Agreement very difficult especially for the developing countries because the implementation requires reform in many domestic legislations, if not all of them, that relate to intellectual property laws in a very short period of time.[111]

The second sentence of Article 1.1 of the TRIPS Agreement gives opportunity to member countries to implement more extensive protection than the minimum standard which is required in the TRIPS Agreement. For example, Article 33 states that the period of protection of patent shall not be less than 20 years from the filing date

[108] Stoll, Busche, and Arend, pp. 78–80.
[109] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 72.
[110] Gervais, p. 163.
[111] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 24.

of the application. Therefore, member countries are allowed to increase and extend this period. This leads to creating TRIPS plus measure which can be implemented through national public policy and unilaterally or through bilateral and regional agreements. Since the TRIPS Agreement does not prevent TRIPS plus measures by the member countries, some developed countries such as the United States of America, the European Union and European Free Trade Association have signed numerous free trade agreements with developing countries especially in the area of patents.[112]

As of mid-2017 the WTO has received 659 notifications of 'Regional Trade Agreements' and 445 of them are in force.[113] For example, the Community of Andean Nations (hereinafter the "CAN") and the Mercado Comun del Sur (hereinafter the "MERCOSUR"), which have been notified to the TRIPS Council. And examples of bilateral trade agreements are United States-Jordan and United States-Chile.[114] This negative form 'Members may but shall not be obliged' was originally the idea of United States and European Community which leads to implementing TRIPS plus measures in their own interest.[115]

In the other hand, however, the second part of the second sentence of Article 1.1 requires that any implementation of more extensive protection should not contravene the provisions of the TRIPS Agreement. In other words, implementation of any TRIPS plus laws and regulation has to be consistent with actual regulations stipulated in the TRIPS Agreement. Strictly reading the words of Article 1.1 may lead to the believe that the TRIPS Agreement does not favour of

[112] Carvalho, *The TRIPS Regime of Patents and Test Data*, pp. 73–74.

[113] Grosse Ruse-Khan and Henning Majid, 'FROM TRIPS TO FTAs AND BACK: RE-CONCEPTUALISING THE ROLE OF A MULTILATERAL IP FRAMEWORK IN A TRIPS-PLUS WORLD', *Forthcoming, Netherlands Yearbook of International Law; Max Planck Institute for Innovation and Competition Research Paper No. 18-02; University of Cambridge Faculty of Law Research Paper No. 3/2018*, 2018, p. 7 <https://doi.org/10.17863/CAM.17577>.

[114] David Vivas-Eugui, 'Regional and Bilateral Agreements and a TRIPS-plus World: The Free Trade Area of the Americas (FTAA)', *Quaker United Nations Office (QUNO), Geneva*, pp. 6–7 <https://www.wto.org/english/tratop_e/region_e/sem_nov03_e/vivas_eugui_paper_e.pdf>.

[115] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 24.

creating TRIPS plus measures through enforcing member countries to implement TRIPS plus measures in their national laws. Nevertheless, while reading Article 1.1 in conjunction with Article 71.2, it becomes clear that multilateral agreements are permitted by the TRIPS Agreement that contains higher standards of protection.[116]

The last sentence of Article 1.1 of the TRIPS Agreement provides flexibility to member countries in regard to method of implementations as it states that 'Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice'. Member countries are free to choose an appropriate method; however, this can be challenged by other member countries in front of a dispute settlement panel or the Appellate Body which they can review whether it was the best appropriate method within the legal system and practice of the member country in question. Then it is the duty of the member country to show that it was the best and most suitable appropriate method that was reasonably available and chosen in a good faith.[117]

Article 1.2 of the TRIPS Agreement determines the scope of the TRIPS Agreement and defines what the term 'intellectual property' refers to. Article 1.2 states that all subject of Sections 1 to 7 of Part II of the TRIPS Agreement are categorized as intellectual property. Those sections are titled according to their type of intellectual properties, which they are Copy Right and Related Rights, Trademarks, Geographical Indications, Industrial Designs, Patents, Layout-Designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information and Control of Anti-Competitive Practices in Contractual Licences. This is the limitation of the scope of the TRIPS Agreement to these categories only and limiting the subject matter scope of intellectual property as well. Even within each headings of Section 1 to 7 of Part II there may be other subject matters that traditionally not considered to be within the headings, such as *sui generis* plant variety protection under section 5 on patents. However, since the categories of sections 1 to 7 of Part II are not precise enough

[116] Carvalho, *The TRIPS Regime of Patents and Test Data*, pp. 73–74.
[117] Gervais, p. 164.

and under Article 1.1 the member countries are free to choose the method of protection of the subject matters. Therefore, it will be left to the member countries to give the subject matters a title, and what title will be considered as an intellectual property and to determine the scope of intellectual property according to their own legal system.[118]

2.2.4 Eligibility for Protection under the TRIPS Agreement

According to Article 1.3 of the TRIPS Agreement nationals of other member countries and custom territories should be given same treatment as their own nationals, whether it be a natural or legal person as stated in footnote number one of Article 1.3. This is the same as the principle of non-discrimination in the traditional trade-based system, which according to this principle foreign national must not be given less favourable than its own nationals.[119] The footnote number one further states that even a natural or legal person 'who have a real and effective industrial or commercial establishment in that customs territory' will be treated as nationals of member countries of the WTO. The meaning of the word 'nationals' is not defined in the TRIPS Agreement; therefore, it has to be interpreted in the way that accords with the public international laws. In addition to that the intellectual property rights are considered private rights as provided for by the Preamble of the TRIPS Agreement, therefore such private rights can be owned by States or any part or agency of the States as long as they hold those intellectual property rights that covered by the TRIPS Agreement.[120] Furthermore, the TRIPS Agreement in the second sentence of Article 1.3 states that nationals of Member countries of other international conventions that regulate intellectual property rights will be considered as nationals of member countries of the TRIPS Agreements and will get benefit from the disciplines of the TRIPS Agreement.[121] The international conventions that listed in this

[118] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, pp. 44–47.
[119] Gervais, p. 168.
[120] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 42.
[121] Stoll, Busche, and Arend, p. 86.

provision are the Paris Convention (1967), the Berne Convention (1971), the Rome Convention and the Treaty on Intellectual property in Respect of Integrated Circuits. It can be concluded that the word 'nationals' has been given very wide meaning in order to protect intellectual property rights as private rights of very wide ranges of persons, whether at international or domestic levels, or natural or legal persons as long as they hold intellectual property rights in those areas mentioned in the TRIPS Agreement.

2.3 OBJECTIVES OF THE TRIPS AGREEMENT

The TRIPS Agreement contain one article which is titled the 'Objectives' (Article 7 of the TRIPS Agreement) and ordinarily should represent the objectives of the whole Agreement. The content of the Article was proposed by twelve developing countries to the Uruguay Round Negotiating Group, however, the original proposal was under the title 'Article 2 Principles' of the Anell Draft.[122] Paragraphs 1 and 3 of the original proposal of Article 2 of the Anell Draft summarised into Article 7 of the TRIPS Agreement. Main purpose for the insertion of Article 7 of the TRIPS Agreement was the concerns of the developing countries that the TRIPS Agreement and in particular the standard protections of patents should be in a manner to have positive effect on advancing their technological and economic development, and social welfare.[123] The developing countries were worried that the objectives of the TRIPS agreement are directed only toward the strong protection of the intellectual property rights by developed countries.[124] To the developing countries the wordings of Article 7 of the TRIPS Agreement will balance between rights and obligations and their interests will be taking into account, even though

[122] During the negotiations on the standard of intellectual property protection between the developed and less developed countries, a draft prepared by the GATT Secretariat and Chairman Anell in order to bring their opinion closer to each other on the matter, the draft is known as Anell Draft. See Peter K. Yu, 'The Objectives and Principles of the Trips Agreement', *Houston Law Review*, 46 (2009), 979–1046 (p. 990).

[123] Carvalho, *The TRIPS Regime of Patents and Test Data*, pp. 164–65.

[124] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 119.

it's mainly concentrated on technology related intellectual property rights.[125] However, the majority of the developed countries' proposals were mainly concentrated on general statement of intent and do not coincide with the spirit of the Articles of the TRIPS Agreement. Nevertheless, articles of the TRIPS (including Articles 7 and 8) should be given greater importance during implementations and interpretations.[126]

Even though the heading of Article 7 particularly states 'Objectives' but the objectives of the TRIPS Agreement cannot be limited to Article 7 alone, but rather has to be read with Article 8 and the Preamble of the Agreement. For this reason, some scholars such as NP de Carvalho are of the opinion that Article 7 is misplaced as it's more accurately related to Patent. Therefore, it should have placed in Section 5 (Patents) of the Part II or in the Preamble with the Paragraphs 5 and 6 (development objectives).[127] Article 7 can strongly be associated with Patent because the wordings of the Article which has some phrases such as 'technological innovation', 'technological knowledge', and the word 'technology'. All these words indicating that the developing countries were mostly concerned with the Patents and its impact on their countries.[128]

Even though the wordings of the Article 7 start with 'The protection and enforcement of intellectual property' but since it's linked with technical innovation, therefore it applies to those provisions of intellectual property rights that involve technical innovations only. This means that Article 7 only applies to patents and trade secrets as in wider sense may involve technical innovation and knowledge even though they cannot be patented. Other areas of intellectual property rights such as copyrights and related rights, trademarks, geographical indications and industrial designs cannot be placed under the umbrella of Article 7 as titled the objectives of the TRIPS Agreement. However, it can be argued that the phrase of

[125] Stoll, Busche, and Arend, p. 180.
[126] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 124.
[127] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 165.
[128] Stoll, Busche, and Arend, p. 181.

'promotion of technical innovation' is very wide and not necessarily limited to the area of patentable inventions. Technical invention is considered as only one early stage of the innovation. The innovation process may lead to enhancement of existing or creation of new product or service, even though it may not include every area of intellectual property.[129]

Other commentators also are of the opinion that the last two phrases of Article 7 of the TRIPS Agreement that read 'in a manner conducive to social and economic welfare' and 'to a balance of rights and obligations' have emphasis on wider areas and can apply almost to all types of intellectual property rights. Developing countries gave up on resisting insertion of protection and enforcement of high standards of intellectual property rights in the GATT, which apparently all were in favour of developed countries. However, the developing countries wanted to make sure that in return the high standard of protection, especially in the area of Patent, has some advantage on their social, economic and technological development.[130]

This idea of creating link between intellectual property rights' protection and their promotion of social and economic and technological development that exist in Article 7, with other ideas in the Preamble and Article 8 are originally taken or inspired by those of the Draft International Code of Conduct on the Transfer of Technology which was negotiated under the umbrella of UNCTAD but never became an international instrument.[131] The wording of Article 7 and 8 (objectives and principles) cannot be found in other intellectual property international instruments such as Paris Convention and Berne Convention.[132] This becomes clear that this idea is not new and the developing countries always wanted some benefits in exchange for their compliance to the high standards of

[129] Stoll, Busche, and Arend, p. 181.
[130] Yu, pp. 1000–1001.
[131] Yusuf, p. 10.
[132] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 119.

protection of intellectual property rights and they wanted this to be presented in an international instrument.

2.3.1 Balance Between Rights and Obligation of Intellectual Property Holder

According to the last part of Article 7, developing countries have the right to object the exclusive rights of the right holders if failed to use their innovation actively to benefit the social and economic welfare of the country or failed to perform their obligations while enjoying their rights. However, the developing countries have to be careful in balancing between intellectual property right holders' interests in form of fair returning of compensation for their innovations and those of the users and public in general. The reason is that if the balance tilted towards the interest of users and public, the inventors are not spending much efforts of time and money in their innovations and this counterproductive process will not be in favour of the developing countries and their public.[133]

It is also well established that enforcement and protection of intellectual property rights has a higher purpose of benefiting society as a whole and not just protecting the interests of specific individual or group rights. Article 7 of the TRIPS Agreement clearly stated that 'the protection and enforcement of intellectual property rights should contribute…to the mutual advantage of producers and users of technological knowledge', which means that the protection and enforcement should have equal impact and benefit to both of the users and producers. All the privileges that contributed to the individuals and groups were with the purpose of providing further benefits to society in general. This apply to both developed and developing societies, but specifically in less developed societies as they are considered mostly users of technology and not producers of technology. Even though Article 7 of the TRIPS Agreement requested and supported by less developed countries, but it fits the spirit of the

[133] Gervais, pp. 203–4.

WTO, as balancing between rights and obligations considered superseding objective of the WTO system.[134]

Even in the previous Intellectual Property conventions (for example Article 5A of the Paris Convention) the principle of balance of rights and obligations existed between the governments on behalf of public interests and intellectual property right holders' interests.[135] This will help the interpreters of the TRIPS Agreement and assist courts as well. Usually courts are interested in reasons behind creating particular intellectual property rights by national legislators, and in this regard, courts can rely on Article 7 that the TRIPS Agreement intended to keep balance between interests of right holders and society in general. TRIPS negotiators never wanted to abandon the interests of user of intellectual property assets and by keeping this balance a harmonized atmosphere will be created that promote both social and economic welfare.[136]

GATT's approach in Intellectual property rights which apparent in the TRIPS agreement is permissive approach rather than prescriptive approach, in which GATT gives wide freedom to member countries to adopt regulations which best suits their unique situation with the condition that these regulations should not be inconsistent with GATT and their application be far from discriminatory and arbitrary manner. Permissive approach to Intellectual Property norms comes from the stand that GATT believes intellectual property rights may cause trade barriers. This is a special treatment of Intellectual Property rights by GATT as the normal approach by GATT to achieve trade liberalization was prescriptive approach.[137]

[134] Yu, pp. 104–8.

[135] Rajan Dhanjee and Laurence Boisson de Chazournes, 'Trade Related Aspects of Intellectual Property Rights (Trips): Objectives, Approaches and Basic Principles of the GATT and of Intellectual Property Conventions', *Journal of World Trade*, 24.5 (1990), 5–15 (p. 10).

[136] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 126.

[137] Dhanjee and de Chazournes, p. 6.

2.4 PRINCIPLES OF THE TRIPS AGREEMENT

Article 8 of the TRIPS Agreement allocated for specifying the principles of the TRIPS Agreement. The origin of Article 8 can be traced back to the Anell Draft. In Anell Draft a group of developing countries suggested some principles under Article 2 of the B text of the Draft. B text is part of the Draft that suggested and supported by developing countries. Clause 2 and 4 of Article 2 of the Draft made it to the TRIPS Agreement as Article 8 and titled Principles.[138]. Article 8 of the TRIPS Agreement consists of two paragraphs. Article 8.1 gives great powers to member countries in adopting 'measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development'. However, Article 2 of the B text contained two extra measures which they were to protect public morality and national security, but they did not make it to Article 8. Yet still these measures can be found within the other Articles of the TRIPS Agreement. Article 27.2 allows members countries to prevent patenting inventions if they believe such prevention is necessary to protect *ordre public* and morality, and in the same way Article 73 provides for security exceptions.[139]

As we have seen before while discussing Article 7 of the TRIPS Agreement, NP de Carvalho believes that Article 8 does not set any new principles and exceptions. The important public policies and exceptions are already regulated in other articles of the agreement, such as exhaustion, compulsory licences, and exclusions from patentability or registrability. According to NP de Carvalho, Article 8 cannot set any new exception or limitation to the rights conferred in the TRIPS agreement. However, Article 8 simply offers exceptions and limitations to the use of the rights and not on the rights. This Article shows how the process of concession of the TRIPS Agreement was managed and cleared some doubts that the developing countries

[138] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, pp. 122–23.

[139] Yu, p. 1010.

had, that they will not be able to adopt measures to stop the effect of some of the intellectual property rights on their most important areas of public health, nutrition and matters of vital socio-economic importance. Hence, Article 8 allows the adoption of some measures by member countries with the condition that such measures are consistent with the provisions of the TRIPS Agreement.[140] These measures can be intellectual property rights measures that naturally allowed by the TRIPS agreement for example exceptions to exclusive rights (Article 30), compulsory licences (Articles 31 and 31*bis*) and the disclosure to the public of test data (39.3), or other measures like marketing approval and price control of medicines, which is considered as a non-intellectual property rights measures as stated by Correa.[141] Carlos M. Correa gave an example of Canada that as one of the developed country put prices of drugs under permanent examination. This practice is common in many developing and developed countries including many European countries as well.[142]

The process of such measures can be taken while the member countries 'formulating or amending their laws and regulations'. If the term 'measures' alone existed in the provision, then it could include any rules and decision whether from national authorities or from courts. However, since it is stated and encompassed with the terms of 'in formulating or amending their laws and regulations', therefore it refers only to 'binding legislative measures'.[143]

Originally the developing countries proposed this provision that had the words of intellectual property rights to the national laws and regulations, however later on it was omitted to include any national laws and regulations without been limited to laws and regulations related to intellectual property rights. It has to be an official published law or regulation; if the measure is stated in an administrative practice then it will not be justified under the TRIPS Agreement.[144]

However, when it comes to measures by Members to promote public interest, it is not necessary that those measures in future will

[140] Carvalho, *The TRIPS Regime of Patents and Test Data*, pp. 193–94.
[141] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 104.
[142] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 104 Footnote 60.
[143] Stoll, Busche, and Arend, p. 192.
[144] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 195.

achieve their goals, but it's enough to show that the measure taken is suitable for that particular situation. Public interest has a wider concept than the *ordre public* of the Article 27.2. The term 'public interest' is considered to be more subjective than that of the '*ordre public*' and cannot be measured by any other objective tests. When interest of public and an individual collides and face each other, the individual should relinquish his rights in favour of that of public, as it will benefit the society and common good as a whole.[145]

Public interest is a domestic issue which covers anything that affects the interest of public in general. It cannot be contested by other Members with their own view because every country has its own priorities and interests base on circumstances of the country in question. The word 'sector' also has a wide meaning which can include any type of sector of economic activities with different sizes even it may include small enterprises. The phrase 'vital importance to their socio-economic and technological development' may seem to limit the scope of the provision, but what constitute an important sector is for the Member state to determine within its socio-economic and technological development. Furthermore, the phrase 'socio-economic and technological development' is broad enough to include any type of activities in different sectors, not limited to matters related to economic or technology, but social matters are included as well as long as considered socially important.[146]

Economies of developing countries like Brazil, China, India, and South Africa are complex due to their rapid development and cannot be compared to that of the European countries and United States of America. Sectors of vital importance in China, for example, are very different compare to other countries. China may prefer stronger intellectual property protection in some specific areas such as entertainment, software, semiconductors and certain areas of biotechnology. However, in other areas like pharmaceutical, chemicals, fertilizers, seeds and foodstuff that China heavily relies on due to its massive population for the purpose of agriculture and public

[145] Yu, p. 1011.
[146] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 105.

health, therefore, in these areas China does not want and resist increasing intellectual property protections.[147]

On the other hand, despite the fact that the origin of this provision is from B text of the Anell Draft that included the opinion of the developing countries, yet, the current Article 8.1 of the TRIPS Agreement contains two phrases that limit the benefits of this provision for the developing countries. These phrases in fact were added by the developed countries. The first one is the phrase of 'adopt measures necessary' which allow the member countries to adopt only those measures that are necessary and not what they consider necessary. In fact, this phrase has affected the abilities of the developing countries to adopt any measures which they consider necessary. The second phrase that further limit the flexibilities of this Article is the requirement that the measures to be 'consistent with the provisions of this Agreement'. Unaware and inexperience of the developing countries were the cause of adding these phrases by the developed countries during the negotiation process. However, even if the developing countries were aware of the side effect of these phrases, the belief is that they would not be able to stop the modification due to the political pressures of the developed countries.[148]

However, this should also be addressed in the light of Article 7 and the Preamble, in other words, in the light of the balance of rights and obligations, and the social and economic account.[149] When a measure taken by a developing country and found out that the measure is inconsistent with one particular standard would not automatically be rejected, because it's the consistency of the measure with the overall of the TRIPS Agreement should be taken into account.[150] Correa is of the believe that paragraph four of the Doha Declaration on the TRIPS Agreement and Public Health of 2001,[151] can be understood that when

[147] Yu, p. 1013.
[148] Yu, pp. 1013–15.
[149] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 104.
[150] Yu, p. 1014.
[151] 'WT/MIN(01)/DEC/2 -WTO | Ministerial Conferences - Doha 4th Ministerial - Declaration on the TRIPS Agreement and Public Health - Adopted 14 November 2001', Paragraph 4 We agree that the TRIPS Agreement does not and should not prevent

there is a conflict between intellectual property rights and rights to protect public health or to promote access to medicines for all, intellectual property rights should not be a hindrance to arrive to that objective.[152]

2.4.1 Appropriate Measures to be Taken by Member Countries

Again, while NP de Carvalho analysing this provision, he stated that this provision does not add any principles to the TRIPS Agreement even though the Article named and titled Principles. It merely states some conditions that can be taken by member states to prevent anticompetitive and abuse practices.[153] Others believe that Article 8.2 is only having a historical and symbolical effects and only shows what the developing countries were trying to emphasize during the negotiations.[154] The structure and content of this provision is very close to the previous one, as they both provide for measures that can be taken by member countries and they also require the consistency and necessity as well, though the word necessary is not used in this provision but the word ‘’needed’ is used.[155] In many places the TRIPS Agreement used the concept of necessity before one member country be able to use measures to limit the intellectual property rights or depart from obligations stated in the Agreement. The terms are used include ‘necessary, unnecessarily, need and needed’, however these terms are synonymous and considered to be requiring same level of precaution before a measure to be implemented.[156]

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members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose’.

[152] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 105.

[153] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 213.

[154] Yu, p. 1017.

[155] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 214; Yu, p. 1016.

[156] For more detail see Carvalho, *The TRIPS Regime of Patents and Test Data*, pp. 113–17.

Article 8.2 states that member countries are allowed to use appropriate measures that may be needed in order to prevent three types of practices by the right holders which they are: 1- abuse of intellectual property rights, 2- resort to practices which unreasonably restrain trade, 3- adversely affect the international transfer of technology. Even though the provision provides that the measures has to be within these practices but did not stipulate their content or their doctrinal structure.[157] Therefore, it is open to member countries to choose their regulations in order to deal with these practices.

2.4.1.1 Abuse of Intellectual Property Rights by the Right Holders:

As a general rule there is no absolute rights as can be understood from the Latin maxim of '*summum jus summa injuria*' which means 'extreme justice is extreme injustice'.[158] This means that every right should be practiced within limited sphere which rights of society and third party be respected.[159] The word abuse has not been defined in the TRIPS Agreement. Therefore, to find the meaning of the word abuse, or practices that include within the meaning of the word, some option are exists for member countries. As a basic rule no practices that are allowed under the TRIPS Agreement can be considered an abuse practice. The abuse may refer to, not using the intellectual property rights actively or the patent does not work properly. Others connect the word abuse with competition law only and do not see it to have wider meaning. This opinion is based on the interpretation of Article 40.2 of the TRIPS Agreement which regulates 'Control of Anti-Competitive Practices in Contractual Licences'. This provision states that 'Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market',

[157] Stoll, Busche, and Arend, p. 203.
[158] 'Summum Jus Summa Injuria Law and Legal Definition | USLegal, Inc.' <https://definitions.uslegal.com/s/summum-jus-summa-injuria/> [accessed 11 December 2017].
[159] Rodrigues Jr and Edson Beas, p. 36.

however what can be noticed here is that the word abuse connected with practices or conditions that have adverse effect on competition. However, this is not the case of Article 8.2, therefore, the word 'abuse' used here is not limited to anti-competitive practices. Although all anti-competitive practices considered an abuse of intellectual property rights, there are other abuses that cannot be categorized within the scope of anti-competitive practices. For that reason, the abuse in this context may refer but not limited to: misuse of intellectual property, 'tying agreements, the presupposing of licence fees after the expiry of the intellectual property right in question, package licences, the charging of licence fees calculated on the total turnover of the licence holder and the infringement of non-competition clauses'.[160] However, other scholars are of the opinion that Article 40 does provide for the elements that exist in this provision and its somewhat redundant.[161]

2.4.1.2 Practices which Unreasonably Restrain Trade

This phrase commonly interpreted as anti-competitive practices and categorised under the competition law. Among those who look at it this way is Professor Correa. For this reason, he advises the developing countries to regulate competition rules that best suits their circumstances. The member countries of the WTO are not required to have a competition policy and most of the developing countries either don't have competition policies or they have weak competition policy. Nevertheless, such policies have great impact on intellectual property rights in developed countries. Therefore, such policies are considered as an important aid to legal framework of intellectual property rights. Some of the anti-competitive practices that may need an effective control by the developing countries are 'predatory pricing, collusive tendering and tied purchases and sales'.[162] Measures regarding anti-competitive practices can be regulated within intellectual property right's laws, even though this form is not desirable, or as an

[160] Stoll, Busche, and Arend, pp. 199–201.
[161] Yu, p. 1017.
[162] Correa, *Trade Related Aspects of Intellectual Property Rights*, pp. 111–12.

independent legislation. In both cases the competition law should be an active part of legal frame work of the intellectual property system.[163]

The notion of restrains to trade in this provision according to some scholars goes beyond competition law. It is true that restrain of competition is one of the principle ways of a restraint of trade, but the provision does not lay any limitation to competition forms of restraint. Therefore, member countries are allowed to adopt measures to prevent any form of trade restraints which occurs as a consequence of using or even existing an intellectual property rights by the right holders. However, it should be beared in mind that the practices by the right holders have to be unreasonably restraint trades, because some practices are carried out in order to facilitate the prolific use of the intellectual property rights. This means the member countries have to create a balance between the unreasonableness with extend benefits that has on the intellectual property protection. [164]

2.4.1.3 Practices which have Adverse Effect on the International Transfer of Technology

This is an independent form of measure which member countries are allowed to take in order to stop any practices by the intellectual property right holders which have adverse effect on the international transfer of technology. International transfer of technology was one of the concerns of the developing countries during all stages of negotiation of the TRIPS Agreement especially against one-sided restriction by right holders.[165] This phrase of the provision like the ones before it, as discussed in previous sections, does not limited to control of anti-competitive practices in contractual licences of Article 40. Member countries are allowed to regulate laws for transfer of technology such as technology pricing. However, still intellectual property right holders have freedom of transferring their own

[163] Gervais, p. 211.
[164] Stoll, Busche, and Arend, pp. 201–2.
[165] Stoll, Busche, and Arend, p. 202.

technology because in principle they can refuse such transfer but still this issue can be solved through compulsory licence.[166]

2.5 CONCLUSION

The Preamble, nature and scope of obligation (Article 1), objectives (Article 7) and principles (Article 8) of the TRIPS Agreement show the facts of the reality of struggles and negotiations among developed and developing countries in order to achieve most out of the TRIPS Agreement for their own favours and in the same time present some important elements of the TRIPS Agreement. The TRIPS Agreement in these provisions formalized the idea of connection between international trade and intellectual property rights and introduced those intellectual property rights that affect international trades and tries to reduce distortions and impediments to them. In the meantime, the Preamble introduced some flexibilities in favour of the developing countries such as 'taking into account differences in national legal system' while the obligations of the TRIPS Agreement implemented. Also, the Preamble recognizes the necessity of transitional arrangements or consideration of public policy objectives especially development and technological objectives.

Article 1 of the TRIPS Agreement opened the door for TRIPS plus measures which has been enforced by developed countries on developing countries though bilateral or regional agreements. In the same time Article 1 gives freedom of determining method of implementation of the TRISP Agreement by member countries which give some flexibilities that benefit especially the less developed countries. Article 7 is on the objectives of the TRIPS Agreement that emphasizes on issues attracted by the developing countries such promotion of technological innovation, transfer of technology, balance of rights and obligations and giving priority to social and economic welfare of the member countries.

Last but not least, Article 8, which is supported by the developing countries as well, presents the important principles of the TRIPS

[166] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 112.

Agreement such as protection of public health and nutrition, and promotion of public interest which should be set into priority during introducing TRIPS Agreement into local laws, and prevention of abuse of intellectual property rights.

3 HISTORY OF IRAQI PATENT LAW AND ITS AMENDMENTS

3.1 INTRODUCTION

The current state of Iraq was established by the Great Britain by merging three provinces of Mosul, Baghdad and Basraha which once they were part of the Ottoman Empire. The new political entity created as one nation consists of many different ethnic and religious groups who were inhabiting these provinces for thousands of years.

The first entry of British Army was in 1914 and by 1918 all the three provinces were jointed, and a provisional government was established. In March 1921 Churchill presided a conference in Cairo and nominated Faysal I who was son of the Sharif Husayn bin Ali as King of Iraq with one condition that a plebiscite to be held in order to confirm the nomination. After the plebiscite, in August 1923 Faysal I was formally crowned.[167]

As a Kingdom Iraq enacted the first patent law according to the Law No. 61 of 1935 on Patents.[168] However, through a revolution the political system of Iraq changed, and the monarch overthrown by Abd al-Karim Qasim and established the Republic of Iraq in July 1958.[169]

In the latest constitution of Iraq which was passed by the Parliament after the invasion of Iraq by United States of America and its Coalition Partners defined the political system of Iraq. The Permanent Constitution of Iraq was promulgated in 2005 which is considered as the highest law of the country. Article 1 defined The

[167] 'Iraq - The Governorship of Midhat Paşa | History - Geography', *Encyclopedia Britannica* <https://www.britannica.com/place/Iraq/The-governorship-of-Midhat-Pasa> [accessed 14 January 2018].

[168] 'Iraq: Law No. 61 of 1935 on Patents' <http://www.wipo.int/wipolex/en/details.jsp?id=10549> [accessed 14 January 2018].

[169] Charles Tripp, *A History of Iraq*, 3rd ed (Cambridge, UK ; New York: Cambridge University Press, 2007), p. xiii.

Republic of Iraq, stating that 'The Republic of Iraq is a single federal, independent and fully sovereign state in which the system of government is republican, representative, parliamentary, and democratic, and this Constitution is a guarantor of the unity of Iraq'.

After the change of political system from monarchy to republic, in 1970 the first patent law during the Republic enacted under the title of (Patent and Industrial Design) Law No. 65 of 1970,[170] and replaced the old patent law of monarchy reign Law No. 61 of 1935. The Law No. 65 of 1970 followed by some instructions, regulations and amendments. The most important amendments were through 'Law No. 28 of 1999 First Amendment to Law No. 65 of 1970 on Patents and Industrial Designs',[171] and Coalition Provisional Authority (CPA) Order No. 81 of Patent, Industrial Design, Undisclosed Information, Integrated Circuits and Plant Variety Law "CPA/ORD/26 April 2004/81".[172]

3.2 PATENT LAW NO. 61 OF 1935 AND ITS AMENDMENTS

Patent Law No. 61 of 1935 was a simple and basic law which was enacted in a time that invention and industrial development cannot be compared to those of current time. The judicial system and capability of government in handling and protecting the intellectual property rights was at minimal level. For example, in this law the word invention under section one defined as 'producing new thing (matter) through information or creating new method and medium for producing knowing things or creating new method and medium for producing new result in industrial area and that include discovery or just improving in the mentioned areas'.[173]

[170] 'Law No. 65 of 1970 on Patent and Industrial Designs' <http://www.wipo.int/wipolex/en/text.jsp?file_id=238400> [accessed 10 October 2017].

[171] 'Iraq: Law No. 28 of 1999 First Amendment to Law No. 65 of 1970 on Patents and Industrial Designs' <http://www.wipo.int/wipolex/en/details.jsp?id=10515> [accessed 17 January 2018].

[172] 'Order No. 81 Patent, Industrial Design, Undisclosed Information, Integrated Circuits and Plant Variety Law.' <http://www.wipo.int/wipolex/en/text.jsp?file_id=181090> [accessed 10 October 2017].

[173] 'Iraq: Law No. 61 of 1935 on Patents', Section 1.

However, despite the low expectation of outcome of inventions, even in this law some important areas were excluded from patentability which they were considered vital matters for needs of society in general which they were pharmaceutical formulations, medicines, and methods used in financial and banking matters.[174] All these exclusions made it to the Law of Patent and Industrial Design No. 65 of 1970.

Under this law (Patent Law No. 61 of 1935) period of protection was only 15 years from the filing date, which is considered short period by the current standard and without making any differentiating among types of inventions. On the other hand, if the patent registered outside Iraq, then period of protection would have been same as period of protection of that foreign country with the condition that the granted period of protection does not exceed 15 years.[175] This means that the law accepted shorter period of protection from foreign countries but did not recognize protection longer than 15 years of other countries.

It is also stated under section 21 that the patent will be revoked in three circumstances: (A) if the invention was not new, it was granted contrary to this law or any other laws, granted by fraud or due to infringement of rights of others; (B) the subject of the patent breaches public security and its contrary to morality and ethics; and (C) the presented information about the invention is not sufficiently explaining the subject or essence of the invention or method of application not included in a complete and precise manner.[176]

Patent Law No. 61 of 1935 clearly stated in section 14 that patent will be granted by the registrar according to the provisions of this law without making any investigation to the usefulness, correctness, truthfulness or correctness of its data or compare it with the invention that submitted for patent to make sure it matches the invention, and government will not guarantee any of these matters.[177] Certainly, with rules and regulations like this no government in the world will be able

[174] 'Iraq: Law No. 61 of 1935 on Patents', Section 4.
[175] 'Iraq: Law No. 61 of 1935 on Patents', Section 7.
[176] 'Iraq: Law No. 61 of 1935 on Patents', Section 21.1.
[177] 'Iraq: Law No. 61 of 1935 on Patents', Section 14.

to protect intellectual property rights of inventors and right holders in a proper way. This certainly will not guarantee the safety of ideas and inventions from stealing and copying by others. Even though section 23 provides for penalties in forms of imprisonment for not more than two years or financial penalty and fine not exceeding one thousand Iraqi Dinar for those who intentionally deceive, attempt, assist, or encourage of doing any of the following acts; (A) manufacture or the method of producing which is the subject of the granted patent is violating the rights of the original right holder; (B) import, sale, store for the purpose of selling or display for selling any manufactured product that produced in violation to the rights of the rights holder; (C) publish in an announcement, plate (board), stamp or cover that a certain thing (invention) was granted a patent but in reality no patent was granted or the period of patent has expired or the patent was already revoked.[178]

From the outset, Patent Law No. 61 of 1935 had undergone three amendments prior to its replacement by Patent and Industrial Design Law No. 65 of 1970. All these amendments show that the Iraqi Government, since its establishment, had tried to provide a patent law that best serves the interest of both Iraqi people in general and the interest of intellectual property right holders.

The first amendment was passed by Law No. 64 of 1940 which is titled as 'Amendment to Law No. 61 of 1935 on Patents'.[179] In this amendment two provisions were added to section 22 which is about the revocation of patent and all the rights that attached to that patent. The original section 22 under subsection 1 provided three situations that causes the revocation of the patent; (A) if fees were not paid on stipulated time; (B) if the patent holder, without legitimate reasons, did not put the invention into work in Iraq within two years of granting the patent; (C) if the patent holder brought a foreign product similar to the one that he was granted patent for. However, under subsection 2 one exception is provided for the above situations, which

[178] 'Iraq: Law No. 61 of 1935 on Patents', Section 23.

[179] 'Law No. 64 of 1940 Amendment to Law No. 61 of 1935 on Patents' <http://www.iraqld.iq/LoadLawBook.aspx?page=1&SC=&BookID=2005> [accessed 16 January 2018].

is the absence of sufficient facilities to industrialize the invention or establish a trade base on the invention inside Iraq. But still the inventor has to publish the invention to public. In addition to this exception, the amendment provided for another two exceptions; (A) in case of section 22.1 (A) if the unpaid fee on stipulated time was due to war; (B) in case of subsection 2, if patent holder or his representative could not publish the invention to public or industrialize and put to work the invention was due to war. These exceptions show that the amendment to the Patent Law No. 61 of 1935 was in favour of the right holders and protecting their rights in better way.

Another amendment was followed in 1949 by Law No. 27 of 1949 Second Amendment to Law No. 61 of 1935 on Patents.[180] This amendment added another section that include 2 subsections to Patent Law No. 61 of 1935 and according to the new provisions, new patent shall not be granted after expiration period of the patent. In another word, after expiration of 15 years there will be no extension. According to the second provision, after revocation of patent according to sections 21 and 22, new patent shall not be granted to the invention in which it was subject of the revoked patent.

The last amendment was during the Republic by the Law No. 210 of 1968 Amendment to Law No. 61 of 1935 on Patents.[181] This amendment converted the provision of section 14 into section 14.1 and added section 14.2 and 14.3 as well. According to subsection 2 the registrar has authority to reject a patent application, transfer its ownership, amendment or renew it and eras it from the register if found to be contrary to public interest. Subsection 3 gives right of appeal to the right holder to the Minister of Economic of the decision of the registrar within 30 days, and both party has right to appeal to the Council of Ministers and the decision of the Council will be final.

This amendment is clearly in favour of public in which the interest of public is considered to be higher to the interest of the right

[180] 'Law No. 27 of 1949 Second Amendment to Law No. 61 of 1935 on Patents' <http://www.iraqld.iq/LoadLawBook.aspx?page=1&SC=&BookID=3302> [accessed 16 January 2018].

[181] 'Law No. 210 of 1968 Amendment to Law No. 61 of 1935 on Patents' <http://www.iraqld.iq/LoadLawBook.aspx?page=1&SC=&BookID=24416> [accessed 16 January 2018].

holders. Right to appeal can be considered as an improvement, but not to Minister and Council of Ministers because their decisions are tamed by nature because they are executive branch of government in the same way of registrar. Therefore, their decisions will be biased toward the right holders and they cannot be considered partial. However, the perfect place to acquire justice are courts as they are exercising judiciary which have judicial power to decide the cases between the registrars and the right holders.

3.3 PATENT AND INDUSTRIAL DESIGN LAW NO. 65 OF 1970 AND ITS AMENDMENTS

Law No. 61 of 1935 was considered to be an outdated law and was necessary to be replaced by a new law in order for the Republic of Iraq be able to trade with industrialized and developed countries and benefit from their technologies and be able to protect the intellectual property rights of the inventors and right holders in a better way. This can be noticed as explained at the end of the Patent and Industrial Design Law No. 65 of 1970 which repealed the Patent Law No. 61 of 1935, a paragraph written without having any section number and titled (Mandating Reasons) which states reasons for replacing the old patent law. Under the Mandating Reasons, it is stated that due to the economic, industrial and social development of the country that makes Patent Law No. 61 of 1935 unable to respond to them in a proper way, and for insuring the protection of intellectual property and encouraging the inventors and widening the relationship with developed countries this law has been enacted. Law No. 65 of 1970 on Patent and Industrial Design repealed the Law No. 61 of 1935 on Patents along with all its amendments and regulations (systems) issued thereunder.[182]

Law No. 65 of 1970 has also undergone four amendments which two of them are minor amendments and the other two are considered major amendments. The first amendment was through 'Law No. 28 of 1999 First Amendment to Law No. 65 of 1970 on Patents and

[182] 'Law No. 65 of 1970 on Patent and Industrial Designs', Section 52.

Industrial Designs'.[183] This first amendment includes 13 sections out of which the first 12 sections are amendments to the original law No. 65 of 1970, and the last section simply dedicated for the date of enforcement which from date of publishing it in the official Gazette, and it include place of writing it down which is Baghdad. Out of these 12 amendments some of them are minor amendments such as changing one word, or one single subsection and others are major amendments by changing the whole section, such as section 1, 5, 9, 13, 29 and 51.

The first amendment of Law No. 28 of 1999 is considered a huge amendment to the original law. However, the second amendment which is implemented according to 'Law No. 5 of 2002 Second Amendment to Law No. 65 of 1970 on Patents and Industrial Designs',[184] has amended only one section. The second amendment law includes two sections only and the second section dedicated to enforcement date which is from publishing it in the official Gazette. The amendment in the first section is about section 22 of the original law and replacing it with new section that includes six subsections. The original section 22 is about inventions that relate to military and defence system in which the registrar has to inform ministry of defence. After the amendment section 22 includes more detail on this matter and requests forming a special committee that include representatives from ministry of defence, military industrialization corporation and security services.

The third amendment can be considered as a major amendment because it changes the nature and scope of the original law of Law No. 65 of 1970 on Patents and Industrial Designs. This amendment occurred after the invasion of Iraq by the United States of America and its Coalition Partners in 2003 and was made through the Coalition Provisional Authority (CPA) Order No. 81 of Patent, Industrial

[183] 'Iraq: Law No. 28 of 1999 First Amendment to Law No. 65 of 1970 on Patents and Industrial Designs' <http://www.wipo.int/wipolex/en/details.jsp?id=10515> [accessed 17 January 2018].

[184] 'Iraq: Law No. 5 of 2002 Second Amendment to Law No. 65 of 1970 on Patents and Industrial Designs' <http://www.wipo.int/wipolex/en/details.jsp?id=10347> [accessed 17 January 2018].

Design, Undisclosed Information, Integrated Circuits and Plant Variety Law 'CPA/ORD/26 April 2004/81'.

Shortly after the invasion of Iraq, the Coalition Provisional Authority (hereinafter the "CPA") was established in order to govern the country. On May 6, 2003 Lewis Paul Bremer III named as the new director of the CPA, and on May 12 officially took the office. Paul Bremer had held many positions in the United States governments before taking such position in Iraq, such as assistant to Secretaries of State Henry Kissinger and Alexander Haig, ambassador to the Netherlands, managing director of Kissinger Associates and Homeland Security Advisor Board. On June 28, 2004 the CPA ruling ended and Paul Bremer handed the authority to the Iraqi provisional government.[185]

Paul Bremer during his directorship and presidency of the CPA expected to rebuild a strong Iraq economically and bring justice after long run of dictatorship. One of his major work was de-Ba'athification program through removing all the Ba'ath party members from their ruling authority and prevent them from taking public position ever again. In his capacity as chief administrator of the CPA he also created the Iraqi Special Tribunal for Crimes against Humanity (Special Tribunal) for trying against genocide, crimes against humanity and war crimes. He established a property claims commission, a central criminal court and a new Iraqi army and civil defence corps.[186] He also issued a series of regulations, orders, memoranda and public notices. In his first regulation which named as Coalition Provisional Authority Regulation No. 1, he stated that all the laws that were in force before the occupation will continue to be in force unless they contradict the regulations and orders issued by the CPA and until they will be suspended or replaced by the CPA or by legislation of any other Iraqi democratic institutions. In section 3 of the same Regulation No. 1, it is stated that the regulations and orders issued by the CPA will remain enforce unless 'repealed by the

[185] 'L. Paul Bremer III | American Statesman', *Encyclopedia Britannica* <https://www.britannica.com/biography/L-Paul-Bremer-III> [accessed 18 January 2018].

[186] Eric Stover, Hanny Megally, and Hania Mufti, 'Bremer's "Gordian Knot": Transitional Justice and the US Occupation of Iraq', *Human Rights Quarterly*, 27.3 (2005), 830–57 (pp. 832–33).

Administrator or superseded by legislation issued by democratic institutions of Iraq', it further stated that 'Regulations and Orders issued by the Administrator shall take precedence over all other laws and publications to the extent such other laws and publications are inconsistent'.[187]

The preamble of the CPA Order No. 81 clearly stated that the economy of Iraq needs to be changed and modernized in order to benefit the whole people of Iraq. For that reason, one of the big change to be occurred is by changing the Iraqi intellectual property system because the Iraqi Patent and Industrial Design Law No. 65 of 1970 and other related laws does not meet the international standard of protection. It further stated that its necessary to have fair, efficient and predictable environment for protection of right holder's interests and privileges whether be a company, lender, entrepreneurs. It also refers to the necessity of improving people's life condition, technical skills and fighting unemployment. It is the interest of the Iraqi Governing Council to join the World Trade Organization (WTO) therefore its necessary to adopt modern intellectual property standards. Also based on the report of Secretary General to the Security Council of July 17, 2003, the Preamble states that it is necessary to change the economic system from 'non-transparent centrally planned economy to a free market economy characterized by sustainable economic growth through the establishment of a dynamic private sector, and the need to enact institutional and legal reforms to give it effect'.[188]

Therefore, Paul Bremer gave the right to himself to amend the original Patent and Industrial Design Law No. 65 of 1970 through Coalition Provisional Authority Order No. 81 of Patent, Industrial Design, Undisclosed Information, Integrated Circuits and Plant

[187] 'Coalition Provisional Authority Regulation Number 1', 2003, p. Section 2 <http://govinfo.library.unt.edu/cpa-iraq/regulations/20030516_CPAREG_1_The_Coalition_Provisional_Authority_.pdf> [accessed 18 January 2018]; Sean D. Murphy, 'Coalition Laws and Transition Arrangements during Occupation of Iraq', *The American Journal of International Law*, 98.3 (2004), 601–6 (p. 602) <https://doi.org/10.2307/3181659>.

[188] 'Order No. 81 Patent, Industrial Design, Undisclosed Information, Integrated Circuits and Plant Variety Law.', The Preamble <http://www.wipo.int/wipolex/en/text.jsp?file_id=181090> [accessed 10 October 2017].

Variety Law "CPA/ORD/26 April 2004/81".[189] Order No. 81 of the CPA made 79 amendments to the Law NO. 65 of 1970, out of which the first 22 amendments were on Chapter One 'Patent' with the first amendment dedicated to changing the name of the whole law to 'Patent, Industrial Design, Undisclosed Information, Integrated Circuits and Plant Variety Law'. The rest of the amendments from number 2 to 22 dedicated to amendments of the patent part of the original law No. 65 of 1970. The Order No. 81 of CPA added some new parts to the original law No. 65 of 1970 as well, such as chapter Three*bis* which titled 'Protection of Undisclosed Information', chapter Three*ter* with the title of 'Protection of Integrated Circuits', and chapter Three*quater* for the 'Protection of New Varieties of Plants'.

However, on 12 May 2013 a new law was enacted under the name of Registration, Accreditation and Protection of Agricultural Varieties Law No. 15 of 2013 in which repealed chapter Three*quater* for the Protection of New Varieties of Plants. Under this law, section 18 states that 'Repeal section 51 to 79 of the CPA Order No. 81 of 2004 of Law Patent, Industrial Design, Undisclosed Information, Integrated Circuits and Plant Variety Law'.[190] Though this is a mistake by the new Law No. 15 of 2013, because CPA had authority to promulgate Order No.81 according to the laws and usages of war and Resolution 1483 and 1511 (2003) of the Security Council,[191] therefore an amendment to the original law becomes part of the law. In its capacity, the CPA amended some parts and added some new chapter to Law No. 65 of 1970, therefore, the section 18 of Law 15 of 2013 should have written as follows 'Repeal chapter Three*quater* including all sections thereunder of the Patent, Industrial Design, Undisclosed Information, Integrated Circuits and Plant Variety Law No. 65 of 1970 Amended', without any necessity of referring to the CPA Order No.

[189] 'Order No. 81 Patent, Industrial Design, Undisclosed Information, Integrated Circuits and Plant Variety Law.'

[190] 'Law No. 15 of 2013 on Registration, Release and Protection of Agricultural Varieties', Section 18 <http://www.iraq-lg-law.org/ar/webfm_send/1447> [accessed 8 October 2017].

[191] 'United Nations Official Document - Resolution 1511 (2003) - Adopted by the Security Council at Its 4844th Meeting, on 16 October 2003' <http://www.un.org/en/ga/search/view_doc.asp?symbol=S/RES/1511(2003)> [accessed 20 January 2018].

81. This fault can be noticed in Patent, Industrial Design, Undisclosed Information, Integrated Circuits and Plant Variety Law No. 65 of 1970 Amended, under chapter Three*quater* by referring to the sections of the CPA Order No. 81.

Lastly and for the fourth time Law No. 65 of 1970 on Patent, Industrial Design, Undisclosed Information, Integrated Circuits and Plant Variety Law was amended through Law No. 58 of 2015.[192] However, the Fourth Amendment did not change much from Law No. 65 of 1970, because it includes only one minor amendment in Section 1 which changes the definition of The Ministry from Minister of Industry to Minister of Planning, and by this amendment all the powers and authorities in the Law No. 65 of 1970 will be shifted from the Minister of Industry to the Ministry of Planning. This was the third time that the definition of 'The Ministry' was amended. The first time it was repealed by Law No. 28 of 1999 First Amendment, which replaced the word Minister of Economy by The Secretariat and defined to mean 'Secretariat for the Council of Ministers', then the second time this definition repealed by the CPA Order No. 81 and the word Minister added again and to be defined as the Minister of Industrial.

3.4 CONCLUSION

Since the establishment of the first government in the Kingdom of Iraq, patent law was enacted as part of encouraging inventions in the Kingdom. However, the Patent Law No. 61 of 1935 was unpretentiously drafted, and its definition of invention was wide enough to include even a simple improvement or a discovery. In this law it was clearly stated that the government could not make any investigation in the nature of the invention or its data, whether it is useful invention or not. It can be perceived that newly established country in the Middle East like Iraq a century ago, had little resources

[192] 'Law No. 58 of 2015 Fourth Amendment to Law 65 of 1970 on Patent, Industrial Design, Undisclosed Information, Integrated Circuits and Plant Variety - (Qanun altaedil alrrabie liqanun bira'at alaikhtirae walnamadhij alsinaeiat walmelwmat ghyr almufasih eanha waldawayir almutakamilat wal'asnaf alnabatiat raqm (65) lisanat 1970)' <http://ar.parliament.iq.> [accessed 20 January 2018].

to do all these enquiries, but no legislature should regulate such provisions and support executive branch of government from escaping its responsibilities. Even though this Law had subsequently seen a number of amendments but could not attain international standards, therefore, it was a right step to be replaced by the Republic of Iraq and enact Patent and Industrial Design Law No. 65 of 1970 instead.

Patent and Industrial Design Law No. 65 of 1970, also has undergone four amendments. The most important amendments were the first amendment through Law No. 28 of 1999, and the third amendment through CPA Order No. 81. The first amendment included 13 sections and amended some sections with little alterations and repealed some other sections and replaced them with new sections. On the other hand, the CPA Order No. 81 which was introduced after the invasion of Iraq by the United States of America and its Coalition Partners in 2003, altered the Law No. 65 of 19790 with the intention of elevate the law to the international standard of protection.

CPA Order No. 81 changed the title of the Patent and Industrial Design Law No. 65 of 1970 to 'Patent, Industrial Design, Undisclosed Information, Integrated Circuits and Plant Variety Law'. Amended many sections and added some new chapters to the law. However, on 12 May 2013 a new law was enacted to and replaced chapter Three*quater* (Plant Variety) of the amended law No. 65 of 1970.

CHAPTER II: PATENTABLE SUBJECT MATTER IN THE TRIPS AGREEMENT AND IRAQI PATENT LAW

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1 INVENTIONS, CRITERIA OF PATENTABILITY AND SUFFICIENT DESCRIPTION

1.1 INTRODUCTION

Patent is a binding contract between the patentee and the public in general. According to this agreement the inventor will receive exclusive rights for certain period of time in order to benefit from his invention. The society will benefit from the invention as well by receiving new ideas and after the protection period expired, everyone in the society has right to benefit from the invention economically as well.

In this part the terms of patent, invention and criteria of patentability and sufficient discretion will be analysed and examined according to the TRIPS Agreement and Iraqi patent law No. 65 of 1970 with reference to the amendments, especially the first amendment of law No. 28 of 1999 and the CPA Order No. 81. These amendments have repealed those sections that relate to criteria of patentability and introduced new sections. However, not all the core elements of these terms have changed, nevertheless, the amendments have tried to enhance the standard of protection and present clarity.

1.2 PATENT AND INVENTION UNDER THE IRAQI PATENT LAWS

1.2.1 Patent

The original term of patent derived from the words of Letters Patent, which means ‘open letter’. It is called open letter because the letter is not closed but it meant to be seen by public once sealed by the king or administrator to show that the holder of the letter is granted a certain offices of state or granted a dignities or any other privileges

including monopoly rights in inventions.[193] The word patent originally came from the Latin word of *patere* (to be open) and the first time as a system was practiced in Venice in the fifteenth century and later on officially regularized in the Venetian Senate's 1474 Act. The Act referred to some essential features that modern patent law relies on. For example, the Act identifies special Office and Board in which new and ingenious device to be registered, in condition that the device previously was not made in the Commonwealth. The device has to be put into practicable work, then forbade everybody else from making such device without consent and license from the author for the period of ten years. Also provided for punishment in case of infringement which was payment of one hundred ductas to the author and the device has to be destroyed.[194]

In England this kind of practice was considered new compare to the Venetian Senate's 1474 Act but had a long history of practice in England and the English Crown as they granted many such monopoly rights. However, this practice was easy to be abused and in fact abused during the reign of Elizabeth I and James I, therefore Parliament enacted the Statute of Monopoly, in order to prevent any such abuses. The Statute of Monopoly authorise the issuance of letter patent, even though the Statute forbade the monopolistic grants by the English Crown[195].

Patent is considered the strongest of all the other intellectual property rights, because it is a binding contract between the inventor and the public in general. The patentees will receive limited period of exclusive rights to use, make and exploit their inventions, in return the inventions will be published, and all the information will be disclosed, and then will be available for everyone to study and research on them in order to develop them further. However, the patent rights and monopoly rights will not be given easily but after a thorough

[193] Thomas Terrell and others, *Terrell on the Law of Patents*, 16th ed (London: Sweet & Maxwell, 2006), p. 1.

[194] Robert P. Merges, Peter S. Menell, and Mark A. Lemley, *Intellectual Property in the New Technological Age, Sixth Edition*, 6 edition (Austin: Wolters Kluwer Law & Business; New York: Aspen Publishers, 2012), pp. 125–26.

[195] Martin Adelman, Randall Rader, and John Thomas, *Cases and Materials on Patent Law*, Third Edition (Thomson/West, 2009), p. 9.

examinations and compliance with strict conditions that must be met. This kind of strictness in examination and granted extensive power makes the patents the strongest rights.[196] Since it is an industrialised bargain, the government will make sure through protection of the inventors' rights that they will be able to commercialise their invention and make money out of their ideas and inventions. For this reason, sometimes the patent is called industrial property which involve technological inventions that can be used in manufacturing or commercial operations, including machines (new machines or advancing the existing machines), processes, or other aspects of technological inventions.[197] After the protection period expires the public be able to benefit from the disclosure of the new technology and innovation, because they will be part of the public domain and freely available for everyone to study, use and utilize them.

The original Iraqi Patent and Industrial Design Law No. 65 of 1970, in its section 1.8 defines patent as 'a certificate of registration of the invention', even though section 1 in whole repealed by first amendment Law No. 28 of 1999, but the definition of patent stayed in same section 1.8 and without altering the definition. CPA Order No. 81 did not change this definition and therefore remain as it is since the first Patent Law during the Republic of Iraq.

1.2.2 Invention

Understanding the concept of invention in modern patent law is very new which can be traced back to eighteenth century. In modern legal system there is difference between invention as an idea and its embodiment and has been accepted as an important patent doctrine.[198]

The term invention in Iraqi Patent Laws has gone through some changes since the Law No. 61 of 1935. In this law the word invention under section one defined as 'producing new thing (matter) through

[196] Catherine Colston, *Principles of Intellectual Property Law*, Principles of Law Series (London: Cavendish Publ, 1999), p. 37.
[197] Christopher May and Susan K. Sell, *Intellectual Property Rights: A Critical History*, Ipolitics (Boulder, Colo: Lynne Rienner Publishers, 2006), p. 8.
[198] Alain Pottage and Brad Sherman, *Figures of Invention: A History of Modern Patent Law* (Oxford [England]; New York: Oxford University Press, 2010), pp. 1–2.

information or creating new method and medium for producing knowing things or creating new method and medium for producing new result in industrial area and that include discovery or just improving in the mentioned areas'.[199] This definition shows that the word invention had been given the simplest definition because according to this definition even discoveries were considered to be within the sphere of an invention. According to the basic principle of patent laws 'discovery' is not patentable. This is because 'A "discovery" is commonly considered to mean the mere recognition of what already exists; it is the finding of casual relationships, properties on phenomena that objectively existed in nature'.[200]

One of the important step was taken by the Law No. 65 of 1970 in which the term invention in section 1.4 defined is to remove the discoveries from the definition. This law defined the invention as 'every new innovation that industrially exploitable whether relates to new industrial products or innovative methods and means or both of them together'. In the first amendment Law No. 28 of 1999 this subsection was amended by adding an extra sentence at the end of the subsection to be red as 'every new innovation that industrially exploitable whether relates to new industrial products or innovative methods and means or both of them together or achieve some specific development in order to be outside of traditional framework'.

The definition of invention of the original Law No. 65 of 1970 and including its additional part by the Law No. 28 of 1999 have some important elements. Firstly, it has to be a new innovation, secondly, industrially exploitable, and third, relates to new industrial products or innovative methods and means or both of them, or achieve some specific development. The last part (achieve some specific development) is the new element which added by Law No. 28 of 1999 that broaden the concept of invention in the way that even if the new innovation which industrially exploitable does not relate to new industrial products or methods, still can be considered invention if

[199] 'Iraq: Law No. 61 of 1935 on Patents', Section 1.

[200] Carlos María Correa, 'Implementing the Trips Agreement in the Patents Field', *The Journal of World Intellectual Property*, 1.1 (1998), 75–99 (p. 77) <https://doi.org/10.1111/j.1747-1796.1998.tb00004.x>.

achieve some specific development in order to be outside the traditional circle.

However, the CPA Order No. 81 amended the whole subsection and introduced a new definition of the term invention as it is 'Any innovative idea, in any of the fields of technology, which relates to a product or a manufacturing process, or both, and practically solves a specific problem in any of those fields'. The CPA Order No. 81 presented some of the elements and criterion of the term invention in a clear and more precise form. It exchanged the words of 'new innovation' to 'innovative idea', 'industrially exploitable' to 'field of technology', and 'achieve some specific development' to 'practically solves a specific problem in any of those fields'. Even though exchanged the words of 'relates to new industrial products or innovative methods and means or both of them' to 'relates to a product or a manufacturing process, or both' but both phrases imply introduce same conditions. As for the rest will be discussed further in the next section.

On the other hand, the TRIPS Agreement does not define the term invention, even though in Article 27.1 clearly states that 'patents shall be available for any inventions'. This will leave the member countries to define the term invention in such a way that best suits their legal systems. The dominant trend of the member countries is to avoid defining the term 'invention', because this will give them 'a certain degree of flexibilities in a changing scientific and technological context'. Most of the countries simply stating the traditional criteria of patentability, in which they are (novelty, inventive step and industrial applicability).[201] However, reference to the word invention has to be done in a good face and subject to method of interpretation of the Vienna Convention.[202]

[201] Correa, 'Implementing the Trips Agreement in the Patents Field', p. 77.
[202] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 272.

1.3 CRITERIA OF PATENTABILITY UNDER THE IRAQI PATENT LAWS AND TRIPS AGREEMENT

Criteria of patentability under the Iraqi patent laws has gone through some changes. The original Patent and Industrial Design Law No. 65 of 1970 provided for some criteria, and later on the first amendment of Law No. 28 of 1999 added some changes. Finally, the CPA Order No. 81 changed some of these criteria. In this section, the general criteria of patentability of the Iraqi Patent laws will be analysed and compared to those of the TRIPS Agreement.

While section 1.4 of the original law No. 65 of 1970 defined the term invention, it provides some important elements which can be considered as bases and criteria for granting the patent, because nowhere else in the Law No. 65 of 1970 any formal criteria are mentioned which can be used as bases of patentability. Section 2 of the original Law No. 65 of 1970, however, simply stated that 'Patents of invention shall be granted according to the provisions of this Law', without referring to any criteria of patentability.

1.3.1 New invention and Novelty

The invention will be considered new and novel if it is bestowed upon the public by the inventor for the first time. However, if the invention was taken or created based on the information and knowledge that was available in public domain, then the inventor did not offer anything to society and his invention cannot be considered new and novel.[203]

The term new invention was used in section 1.4 of the original law No. 65 of 1970 without determining what is meant by new. However, section 4 stated two situations in which invention cannot be considered new, therefore except for these two situations, every invention would have considered to be new invention. This means that Iraq has taken restrictive view as to what shall be considered novel

[203] Sean B. Seymore, 'RETHINKING NOVELTY IN PATENT LAW', *Duke Law Journal*, 60.4 (2011), 919–76 (p. 930).

and what kind of disclosure affect the criterion of novelty[204]. From both of the provisions of section 4.1[205] and 4.2[206], it can be observed that the Iraqi Legislature gave general ruling to the term 'New' and restricted novelty to the period of 50 years prior to the patent application date. Therefore, any invention that has been practically utilised and available for public to benefit from products of the invention, prior to the date of the application for patent, then that invention considered part of the prior art and cannot be patented because it lacks the novelty criterion. Here the priority is given to first to file. Even after the amendment by the CPA Order No. 81, priority stayed same. May be this is due to the fact the United States of America in 2011 amended the US Patent Act and changed the priority date from first to invent to first to file.[207] However, in Germany the priority is given to first to invent, the original principle was first to file, however this was changed due to the reform in 1936 and replaced by first to invent principle.[208] Even though first to file system is considered more efficient and less costly to settle a conflict. In the other hand first to invent system is more just and fair, because the patent will be given to the person who invented it first.[209]

Also, even if the invention not utilised but publicized in such a way that an expert of the field who is a 'person having ordinary skill in the art (hereinafter the "PHOSITA")'[210] can exploit such invention

[204] Nabeel Mahdi Althabhawi and Zinatul Ashiqin Zainol, 'Patentable Novelty in Nanotechnology Inventions: A Legal Study in Iraq and Malaysia', *NanoEthics*, 7.2 (2013), 121–33 (p. 123).

[205] 'Law No. 65 of 1970 on Patent and Industrial Designs', Section 4.1 (If the invention, in the 50 years prior to the date of the application for a patent, has been publicly worked out in or outside Iraq, or if the description or drawing of the invention has been publicized in periodicals within Iraq or outside it in such a clear way that enables experts to exploit).

[206] 'Law No. 65 of 1970 on Patent and Industrial Designs', Section 4.2 (If, in the 50 years prior to the date of the application for a patent, letters patent had been granted to the invention or part thereof to a person other than the inventor or to whom the rights of the invention have been assigned, or that others had already applied for the same patent, or part thereof).

[207] Althabhawi and Zainol, p. 126.

[208] *Patent Law: A Handbook on European and German Patent Law*, ed. by Maximilian Wilhelm Haedicke and Henrik Timmann (München: C.H. Beck, 2014), p. 8.

[209] Gervais, p. 338.

[210] Jonathan J. Darrow, 'The Neglected Dimension of Patent Law's PHOSITA Standard', *Harvard Journal of Law & Technology*, 23.1 (2009), 227–58 (p. 227).

into a practical use, then the invention will not be considered as new invention and cannot be granted a patent. However, if the subject matter of the invention has been kept secret, then the next invention in the same area will be considered novel and the new inventor has right to apply for patent as the subject matter invented without relying on previous work or publicised information. But according to the United States Patent system, secret information considered as part of the broader class of prior art, even though it was kept secret from public.[211] However, if an invention was granted a patent or applied for a patent by others, then will not be considered a new invention. Same principle can be found in Article 87-89 of the European Patent Convention (hereinafter the "EPC"). Even prior use by the applicant or his predecessor (own publication) also can be considered that it has become part of the state of art. If the information has reached the public through written or oral sources, I will become part of the state of art. Because technical teaching can be described orally, through a presentation, lecture, speech … etc. However, only that part of the information will become start of art which has been disclosed.[212] This means that if another person applied for patenting the same invention or part of it just one day before the new applicant, then the new applicant's invention will not be considered new. It does not matter whether all these situations have occurred in Iraq or outside Iraq, because section 4 covers inventions whether be inside Iraq or abroad.

However, section 4 did not refer to verbal disclosure in any way. Therefore, if the oral information regarding the subject matter of the invention is spread out within community, it will not bar the invention from the patentability and the invention will be considered new and novel. On the contrary, in United States of America, both forms of disclosure whether oral or written will prevent next invention from the element of novelty. Though if oral disclosure has occurred outside the territory of the United States, then such disclosure will not bar the patentability of the subject matter. But this will not apply to written disclosure, as like rest of the world if written disclosure has occurred inside or outside of the United States, then it will prevent the

[211] Althabhawi and Zainol, p. 125.
[212] Haedicke and Timmann, pp. 141–45.

patentability of the invention on the basis of novelty. However, the form of disclosure should not be matter as much as whether the information has become part of public domain or not.[213]

The amendment by the CPA Order No. 81 was considered one of the major amendments as it added, suspended and amended many provisions of the Original Law No. 65 of 1970. The order amended the definition of the Invention and in the new definition the words 'every new innovation' replaced by 'any innovative idea'. However, the CPA Order No. 81 amended section 2 as well by adding some more elements and criteria, which states 'Patents of invention shall be granted pursuant to the provisions of this Law for each invention that is industrially applicable, novel and involves an inventive step, either concerning new industrial products, new industrial methods, or new application of known industrial methods'. This new section can be seen as positive amendment which states the requirement of patentability since it states three criteria of patentability which are internationally known and considered to be standard requirements. These criteria are: new (novelty), inventiveness (involves an inventive step and non-obvious) and industrial applicability (useful) and these are the same criteria which is required by the TRIPS Agreement in Article 27.1[214].

The CPA Order No. 81 also amended section 4 of the Patent and Industrial Design Law No. 65 of 1970. First the Order changed the numerical of both subsections of 4.1 and 4.2 to subsections 4.a and 4.b. This is a small technical amendment and does not affect the content of the Law and it is unnecessary change. Then it deleted the condition of 50 years period in both subsections. Which in fact it will bring more legal sense to the subsections, because limiting novelty of the inventions to 50 years prior to the date of the application for a patent has no logical basis, as to what logic the inventions of 60 years prior to the date of the application have not became public knowledge and part of public domain but the inventions of past 50 years have become part of public domain. The only logic that one may think of is that the legislatures were trying to give another chance to inventors to

[213] Althabhawi and Zainol, p. 123.
[214] Gervais, p. 338.

use the old information and produce something out of it, but still more provisions should had been included to make this encouragement workable in a way that did not affect the legal rights of the owners of the original idea and those of their predecessors. However, in general time should not matter but the important element is whether the information has been available within the community or not, therefore by deleting the period restriction, the CPA Order improved the original law.

Furthermore, the CPA Order No. 81 added another provision to section 4,[215] of the Law No. 65 of 1970 which is an exception to the previous subsection in which if the disclosure of the information is the applicant himself or his predecessor by an action taken in the last twelve months before the filing date or priority date, or the disclosure occurred due to an abuse by third parties, then such disclosure will not bar the element of novelty of the invention. Similar provision can be found in the patent acts of other countries, for example in The Patents Act 1977 (as amended up to and including 28 January 2018) of the United Kingdom[216], in section 2(4) states the same situations and included extras. The United Kingdom Patents Act is very detailed act and states all the elements patentability in great detail, and in section 2 novelty criterion regulated in a satisfactory manner. In section 2(4) states that disclosure of subject matter of the patent in six months before filing date of the application will not bar the novelty of the invention in these situations; disclosure occurred due to the obtaining information unlawfully or in breach of confidence or displayed at an international exhibition.

[215] 'Order No. 81 Patent, Industrial Design, Undisclosed Information, Integrated Circuits And Plant Variety Law.' Number 7, which can be found also in 'Law No. 65 of 1970 on Patent, Industrial Design, Undisclosed Information, Integrated Circuits And Plant Variety (Amended).' Section 4.c 'Notwithstanding subparagraphs (a) and (b), the disclosure of the invention to the public shall not be taken into account if it occurred twelve months before the filing date of the application or its priority date, if any, and it occurred by actions taken by the applicant or applicant's predecessor or due to an abuse by third parties against the applicant or predecessor' < http://www.iraq-lg-law.org/ar/content/ [accessed 10 October 2017].

[216] Expert Participation, 'Patents Act 1977', Section 4 <https://www.legislation.gov.uk/ukpga/1977/37/contents> [accessed 28 January 2018].

1.3.2 Inventiveness (involves an inventive step and non-obvious)

The primary evidence as to what constitute an inventive step is the opinion of a person having ordinary skill and expert as to whether the invention is obvious or not and determining such task will 'involve questions of fact and degree' as well.[217] This is what the United Kingdom Patent Act 1977 confirmed in section 3 by stating 'An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art'. The same regulation and interpretation exists in section 103 of the United States Code 35 Patents, as the question would be whether there is a difference between the subject matter and the prior art by a person who have ordinary skill in the art.

However, there is an overlapping between the term invention and its criteria of non-obviousness because there is no obvious invention, but there can be a degree of inventiveness. For this reason, some has suggested that the provision of patentability in the patent laws should be read a 'patents shall be available for any invention provided that it is new, involves a sufficient inventive step and is useful'. Also, it is a fact that both novelty and inventive step has to be determined through comparison with the prior art.[218]

The Iraqi original Patent and Industrial Design Law No. 65 of 1970 does not provide for criteria of patentability in a proper form as has been explained previously. However, after the first amendment by Law No. 28 of 1999 the definition of invention in section 1.4 provided for as 'every new innovation that industrially exploitable whether relates to new industrial products or innovative methods and means or both of them together or achieve some specific development in order to be outside of traditional framework'. From this definition it can be asserted that by the term of 'new innovation' the legislature wanted to make sure that the invention must have some innovation in it. The last sentence of the definition which was added by the first amendment

[217] Terrell and others, pp. 242–43.
[218] Carvalho, *The TRIPS Regime of Patents and Test Data*, pp. 257–58.

make this objective more perceivable by pointing out that even if the invention is not totally new still can be patented if the invention has added at least some specific development and addition so that it be outside of traditional framework and circle. If the innovation is outside the traditional framework, then the invention has added something which cannot be found in the prior art. This process can be done by comparing the new subject matter to the whole of the prior art. But the law failed to mention in a direct manner that it is in the perspective of the person with normal skill and expertise that the new innovation has been achieved is new to the prior art. Because in section 18 of the original Patent and Industrial Design Law No. 65 of 1970 it is stated that: 'The Directorate examine the application and its annexes to check the following: 1. The application is submitted in accordance with section 16 of this Law. 2. The specification and drawing illustrate (demonstrate) the invention in a manner that allows the owners (employers) of the industry (field) to implement it. 3. The innovative elements that the concerned person seeks to protect, should be mentioned in the application in a clear and specific manner'. Section 16 of the original law also requires that the application for a patent should include the detail description of the invention and its new elements. Therefore section 18 wants to make sure that the directorate will check for these matters in order the owners and employers of the industry in that particular field be able to implement them. However, Instruction No. 1 of 1990 on implementing Law No. 65 of 1970 in section 1.1, and Regulation No. 3 of 2001 on the classification of Patents and Industrial Designs in section 2(a), state that 'the invention will be considered innovative if it does not look obvious (self-evident) to an expert person while taking into consideration technical development prior to the application'.[219]

Indirectly sections 18 and 16 require the invention to have new and innovative element in order to be granted a patent and be protected. In the other hand, Instruction No. 1of 1990 on

[219] 'Iraq: Instructions No. 1 of 1990 Implementing Law No. 65 of 1970 on Patents, Industrial Designs', Section 1.1 <http://www.wipo.int/wipolex/en/details.jsp?id=10511> [accessed 10 February 2018]; 'Iraq: Regulation No. 3 of 2001 on the Classification of Patents and Industrial Designs', Section 2(a) <http://www.wipo.int/wipolex/en/details.jsp?id=10546> [accessed 14 February 2018].

implementing Law No. 65 of 1970 and Regulation No. 3 of 2001 on the classification of Patents and Industrial Designs clearly stated the new invention should have an inventive step. According to section 1.1 of the instruction and section 2(a) of the regulation if the new invention appeared obvious and self-evident to a person skilled in the art, then the invention will not be considered innovative. And base on section 1.4 of the Law No. 65 of 1970 an invention has considered to be a 'new innovation'. Consequently, an invention according to Patent and Industrial Design Law No. 65 of 1970, has to include an inventive step in order to be accepted within the definition of invention.

However, the CPA Order 81 amended section 18.2 in order to clear some uncertainties. Section 18.2 as amended by the Order states 'That the specification and drawing disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.' The wordings of this subsection are very close to that of section 16.2 as amended. The difference is that section 16 demands applicant for a patent to comply with certain conditions and section 18 demands the Central Organization for Standardization and Quality Control[220] to make sure the condition has been fulfilled. Both of the subsections require the content of the application for patent disclose and include enough clear and complete information so that can be carried out by a person skilled in the art. And as for the inventiveness and non-obviousness of the invention, the CPA Order No. 81 when amended section 2 clearly states that the invention in order to be patentable should involve an inventive step. Therefore, the new Law after all the amendments clearly and undoubtedly include the criterion of inventiveness, by requiring that every invention should involve an inventive step to a person skilled in the art by comparing to the prior art. This is a positive development by enhancing the patent law of Iraq to the international standard and clearing some ambiguous provisions of the original Law No. 65 of 1970 which did not state the

[220] Section 1.3 the definition of The Directorate: Directorate of registration and monitoring public companies (enterprises) of the original Law No. 65 of 1970 repealed by the first amendment of Law No. 28 of 1999 and replaced by The Central: The Central Organization for Standardization and Quality Control. And in section 2 of the Law No. 28 of 1999 states that the word (The Central) replace the word (The Directorate) wherever mention in the Law.

requirements of patentability in an obvious way compare to patent laws of developed countries.

Article 27.1 of the TRIPS Agreement states that the subject matter has to involve an inventive step in order to be patented. In the other hand, the TRIPS Agreement in footnote 5 gives option to the member countries to choose between the terms of 'inventive step' and 'non-obvious'. Therefore, according the TRIPS Agreement the condition of inventiveness will be fulfilled if the subject matter of the invention is not obvious to the skilled person in the art while considering the technical knowledge and the state of the art.[221] This shows that the non-obviousness is synonymous with the term inventive step as explained by the footnote 5 of the TRIPS Agreement. Out of these two terms the CPA Order No. 81 chose the term inventive step and it is still enforce as part of the Iraqi patent law because it is perfectly fulfilling this requirement of the TRIPS Agreement.

1.3.3 Industrial Applicability (Usefulness)

The general rule is that patent shall not be given to an abstract idea even if will lead to an economic revolution. That is why many countries in their national statutes require the invention to have industrial applicability in order to be patented.[222] Article 1(4) of the Paris Convention provides some example of industrial patents such as 'patents of importation, patents of improvement, patents and certificates of addition, etc'.[223]

As to what invention can be covered within the range of 'capable of industrial application' is left for the countries to decide according to their interest. Some has used this term in broader meaning and applied to every invention which can be used in any sort of industry, while others defined the term more specifically such as those invention that can be used in a manufacturing process or produce material

[221] Stoll, Busche, and Arend, p. 484.
[222] Carvalho, *The TRIPS Regime of Patents and Test Data*, pp. 261–62.
[223] 'WIPO-Administered Treaties: Paris Convention for the Protection of Industrial Property', Article 1(4) <http://www.wipo.int/treaties/en/text.jsp> [accessed 2 February 2018].

products.[224] Therefore, generally in order for an invention to be patented it has to be used in industrial fields including agriculture.[225] This principle can be found in Article 57 of the EPC as it states that 'An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture'.

The Iraqi original Patent and Industrial Design Law No. 65 of 1970, in section 1.4 while defined the word invention and stated the criteria of industrial applicability for patentable invention, that every innovation should 'industrially exploitable whether relates to new industrial products or innovative methods and means or both of them together'. The words of 'industrially exploitable' used by the original law have the same meaning as 'industrially applicable'. The law goes further by illustrating the areas in which the invention can relate to which are new industrial products or innovative methods and means or relate to both products and methods in the same time. Since nowhere else in the law the word industrial is defined, therefore the meaning of industrial can be taken in a broader meaning to include any kind of industry including the agriculture whether be an industrial product or method. This kind of understanding can be seen in section 1.2 of the Instruction No. 1 of 1990 on implementing Law No. 65 of 1970 and section 2(b) of Regulation No. 3 of 2001 on the classification of Patents and Industrial Designs, as they state that 'the invention will be considered industrially applicable if it can be applied or used in any fields of work related to industry, agriculture, profession, and services in broader understanding'.[226]

After the first amendment by Law No. 28 of 1999 an extra phrase added to the definition which was 'or achieve some specific development in order to be outside of traditional framework', this made the meaning of 'industrially exploitable' much broader. With

[224] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 278.

[225] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 361.

[226] 'Iraq: Instructions No. 1 of 1990 Implementing Law No. 65 of 1970 on Patents, Industrial Designs', Section1.2; 'Iraq: Regulation No. 3 of 2001 on the Classification of Patents and Industrial Designs', Section 2(b).

this extra phrase it is not necessary that the industrially exploitable innovation relate to whole new product or method but will suffice to add a specific development so that alter the invention to be differentiated from the previous inventions.

However, the CPA Order No. 81 amended section 1.4 (definition of invention) and section 2 (granting of patent). In both of these amendments the criterion of 'industrial applicability' has changed. In section 1.4 the term 'industrially exploitable' has been replaced with 'in any of the field of technology'. The amendment goes further by stating that the innovation has to relate to a product or manufacturing process or both, this part is almost same as the original Law No. 65 of 1970 requirement but with playing around with the words. For example, the word 'new industrial product' changed to just a 'product', and 'manufacturing process' replaced the word of 'innovative methods and means'. These all referring to industrial and technological innovation which can be seen in the TRIPS Agreement.

However, the last sentence of the original law which was added by the Law No. 28 of 1999 totally changed to 'and practically solves a specific problem in any of those fields' which this becomes part of the 'a product or a manufacturing process or both' and not an independent element, because of the word 'and' instead of 'or' as it was used in the definition of invention of the original law. The definition of invention according to the CPA Order No. 81 is mostly relate to technological invention, because in the case of the original law, the word industrial was used which may carry wider meaning. But this may be due to that fact that the CPA Order No. 81 widened section 2 of the original law to include all the criteria of the patentability in the same format of all the laws and regulations of the developed countries. Section 2 which is amended by the CPA Order No. 81 clearly stated the invention in order to be patented should be 'industrially applicable' whether 'concerning the new industrial products, new industrial methods, or new application of known industrial methods'. Article 1(3) of the Paris Convention[227] gave the widest definition to what should include within the meaning of industrial property by stating that 'Industrial

[227] 'WIPO-Administered Treaties: Paris Convention for the Protection of Industrial Property', Article 1(3) <http://www.wipo.int/treaties/en/text.jsp> [accessed 2 February 2018].

property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour'.

CPA Order No. 81 when amended section 1.4 introduce another sentence which is 'in any of the fields of technology', this part has been taken from 'in all fields of technology' of the TRIPS Agreement. This means that the range of patentability can be extended to all fields of technology, including pharmaceuticals[228] which in many countries were excluded from patentability including Iraq. In the original Law No. 65 of 1970, section 3 which state the situations and areas in which patent shall not be granted and in section 3.2 stated the 'medical and pharmaceutical formulations'. Nevertheless, CPA Order No. 81 suspended section 3.2, in order to clear any doubts whether pharmaceutical products and methods included within the scope of fields of technology and prevent Iraq from excluding such inventions from patentability.

The TRIPS Agreement require the invention to be capable of industrial application. And in footnote 5 states that the term 'capable of industrial application' is synonymous with the term of 'useful'. However, the term 'useful' seems to be broader than the industrial capability. Because there are some inventions which are not applicable industrially but still offer some benefits to society and humanity. For example, United States of America allows purely experimental invention to be patented, which cannot be used in industry, such as methods of doing business. Because United States uses the term utility, therefore it is not necessary all inventions have technical effect in order to be patented. But since the TRIPS Agreement provides for minimum standard, member countries are allowed to implement higher standard than what required by the TRIPS Agreement,

[228] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 356.

therefore this practice of United States is justifiable.[229] As long as the invention can be proved to be useful for a particular purpose.[230]

1.4 SUFFICIENT DESCRIPTION AND DISCLOSURE UNDER IRAQI PATENT LAW AND TRIPS AGREEMENT

According to section 16.1 of the original Law No. 65 of 1970 that the application for the patent should be submitted to the registrar and should not include more than one invention. In section 16.2 it is stated that the application shall include a detailed description of the invention and the method of its exploitation so that it can be executable. The description shall include the new elements that the applicant (inventor) request to be protected in a clear manner and shall be accompanied by the drawing of the invention.

The CPA Order No. 81 amended section 16.2 and added 16.2*bis*. Section 16.2 as amended states that the invention should be disclosed in a sufficiently clear manner and complete so that can be carried out by a person skilled in the art. In fact, this amendment by the CPA Order is exactly similar to the first part of Article 29.1 of the TRIPS Agreement. Article 29.1 of the TRIPS Agreement also demand member countries to require from the applicant for a patent to 'disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art'. Since Iraq desires to join the WTO and by extension to TRIPS Agreement, the amendment by the CPA Order No. 81 brings the Iraqi patent law aligned with TRIPS Agreement and a step closer to fulfil the accession requirements. During the negotiation period of the TRIPS Agreement the developing countries wanted the patentee to be enforced to bring the patented invention into work, but the attempt was rejected by the industrialized countries. In the same way the developing countries proposed of using 'person versed in the technical field' instead of 'person skilled in the art' but it was turned down.[231]

[229] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 361.
[230] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 262.
[231] Stoll, Busche, and Arend, p. 522.

The developing countries were trying to take every chance to focus on the technical field as it was what they were looking for to gain out of the TRIPS Agreement.

However, the second part of Article 29.1 of the TRIPS Agreement which is an optional request in which the member countries 'may require the applicant to indicate the best mode for carrying out the invention known to the inventor', this part cannot be seen in the amendment by the CPA Order. Even though the words of 'sufficiently clear and complete' gives the sense of very high disclosure of the invention. In such a way that it is not just enough for the person skilled in the art to understand but rather he will be able, based on his skill and the clear and complete disclosure, to carry out the invention without going through the reverse engineering. However, the member countries may request from the inventor to reveal what was the best mode for carrying out the invention. This was not mandated by the TRIPS Agreement because there may not necessarily the specific technicalities have been developed for carrying out the invention at the time of filing the application, or the best mode may change after filing the application[232]. However, some areas such as biotechnological invention which by nature cannot be described properly enough, therefore member countries are allowed to ask for deposit of such material to assist written description, or other methods that can help third parties understand them properly. And the indicating the best mode for carrying out the invention will certainly help in using the invention after expiry date of the patent or during the lifetime of the patent in case of compulsory licence.[233] Certainly, this optional provision is very useful for developing countries which always trying to get benefit from foreign technology and be able to use them locally through the patentees directly or indirectly through compulsory licences. Nevertheless, the CPA Order No. 81 decided not to include such provision into the Iraqi patent law through its amendments, which in fact having such provision enhance the Iraqi patent law by benefiting from foreign technology to the maximum extend. In fact, surprisingly same provision can be found in the United

[232] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 366 and 369.
[233] Correa, *Trade Related Aspects of Intellectual Property Rights*, pp. 301–2.

States of American's patent law as it states, in section 35 U.S.C. 112 Specification, that 'shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention'.[234]

Section 16.2bis which is added by the CPA Order 81 provides that 'An applicant for a patent shall provide information concerning the applicant's corresponding foreign applications and grants'. The exact same provision can be found in the TRIPS Agreement as well but as an optional provision in which member countries are allowed to include it in their local laws or opt it out. However, having such provision will help the developing countries as they have limited human resources and infrastructure, therefore this provision will facilitate their examination and decision in regard of the application by contacting foreign patent offices and coordinate as to their process of examinations and decisions.[235]

This shows that the CPA Order No. 81 has included some good provisions for Iraq as a developing country and to bring up the regulation standard to that of the international communities and TRIPS Agreement. But failed in some situations to include provisions like second part of Article 29.1, which would have been very helpful for Iraqi patent law, especially Iraq could have benefited from such provisions in regard to the foreign technological invention which they want to apply for patent in Iraq, and it is part of international standard and TRIPS Agreement also provided for as an optional provision.

1.5 CONCLUSION

In the definition of the term invention and criteria of patentability, the CPA Order No. 81 had altered the original law No. 65 of 1970 to a great extent. Since TRIPS Agreement does not provide for definition of invention, therefore it has been left for member countries to define the term in their best interest. However, CPA Order No. 81 changes the definition to include every kind of technical invention. As for the requirement of new invention, the CPA Order No. 81 has improved

[234] 'United States Code Title 35 - Patents', p. Section 112 (a) <https://www.uspto.gov/web/offices/pac/mpep/mpep-9015-appx-l.html#d0e302824912> [accessed 30 January 2018].
[235] Stoll, Busche, and Arend, p. 527.

both section of 1.4 and 2 by clearly presenting and requesting that the invention has to be new and novel in order to be patentable. It has also improved the Iraqi patent law so that it could reach the same level of that of international communities and TRIPS Agreement. However, failed to include optional requirement of the TRIPS Agreement in Article 29.1 of requesting the inventor to reveal the best mode for carrying out the invention.

The CPA Order No. 81 enhanced the original law by clearing the doubt and ambiguity of the criterion that the invention should 'involve an inventive step', as its required by the TRIPS Agreement. Because the original law did not mention the inventive step requirement in an obvious way. Since it is the one of the essential and important criteria of patentability in the modern patent system, therefore the amendment in this regard by the CPA Order No. 81 is positive improvement.

The CPA Order No. 81 has successfully aligned the 'industrial applicability' requirement with that of the TRIPS Agreement like the previous two requirements. Choosing the 'industrial applicability' instead of 'usefulness', will be much better for Iraq as a developing country that want to receive all technology to develop itself as the term usefulness is much wider and allows patenting of broader fields. However, the CPA Order No. 81 by asserting 'in any of the fields of technology' and suspending the exception of 'medical and pharmaceutical formulation', has burdened Iraq to a responsibility which is not obliged to take while still not a WTO member. This step is not in favour of Iraq because it has not yet recovered from the severe aftereffect of the invasion and still in war with terror. Many Iraqi people still living in shelter and not have access to basic living requirements including medicine. Therefore, this amendment can be considered as a premature move by the CPA and the Iraqi interest was not in mind while the original law amended as much as trying to higher the standard of intellectual property protection to that of the TRIPS Agreement.

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2 EXCLUSIONS FROM PATENTABILITY

2.1 INTRODUCTION

Article 27.1 of the TRIPS Agreement generalized granting patent for all types of inventions in all the fields of technology without excluding any areas and without discrimination as to the place of invention. However, Article 27.2 and 27.3 of the TRIPS Agreement limited the first provision by excluding some types of invention from patentability. For example, Article 27.2 gives freedom and choice to member countries to exclude from patentability of invention if the commercial exploitation of such invention in the territory of a member country goes against *ordre public* and morality. Hence, this chapter discusses Article 27.2 of the TRIPS Agreement first, then will be followed by the position of Iraqi patent law.

Similarly, Article 27.3 provides for two different types of exclusions which are also optional for member countries to implement or not. The first type is related to methods of treatment of humans or animals whether be a diagnostic, therapeutic and surgical. In this chapter detail of this provision is discussed with reference to those countries that provide for protection of method of treatment through patent such as United States of America, New Zealand and Australia. Then the position of Iraqi patent law and its amendments will be discussed. The second part of Article 27.3 provides for exclusions from patentability of plants and animal. However, this provision requests the member countries to provide for protection whether be in a form of patent or *sui generis* system or combination of both of them. Due to the significance of this provision, it will not be discussed in this chapter, but will be analysed in a broader context independently in the next chapter.

Lastly, this chapter will examine the access to medicines and public health. Due to importance of this topic, this chapter will focus on the Doha Declaration on the TRIPS Agreement and Public Health as well. Some of the paragraphs of the Doha Declaration deal with flexibilities and options of the member countries to handle their domestic issues concerning public health. The position of developing countries and how they can access to medicines to fulfil their public needs will be discussed. Then the position of Iraqi patent law and its amendments will be discussed.

2.2 *ORDRE PUBLIC* AND MORALITY

2.2.1 *Ordre public* and Morality Under TRIPS Agreement

Article 27.2 of the TRIPS Agreement allows member countries to exclude inventions from patentability if the commercial exploitation of the inventions endanger *ordre public* and morality in territory of the country concerned.[236] This is based on the proposals submitted by (the European Economic Community (hereinafter the "EEC"),[237] Japan[238] and developing countries[239]).[240] The concept of *ordre public* and morality is not new as many countries used these concepts to prevent inventions from patenting long time even before the TRIPS Agreement was born. For example, in the United States of America, these concepts referred to in 1817 as 'frivolous or injurious to the well-being, good policy, or sound morals of a society'. In European countries' laws and many other civil law countries the practice of exclusion from patentability similar to the wordings of Article 27.2 of

[236] Article 27.2 of the TRIPS Agreement states that 'Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law'.

[237] 'GATT Document No. MTN.GNG/NG11/W/68 of 29 March 1990', 1990 <https://docs.wto.org/gattdocs/q/UR/GNGNG11/W68.PDF> [accessed 22 April 2018].

[238] 'GATT Document No. MTN.GNG/NG11/W/74 of 15 May 1990', 1990 <https://docs.wto.org/gattdocs/q/UR/GNGNG11/W74.PDF> [accessed 22 April 2018].

[239] 'GATT Document No. MTN.GNG/NG11/W/71 of 14 May 1990', 1990 <https://docs.wto.org/gattdocs/q/UR/GNGNG11/W71.PDF> [accessed 22 April 2018].

[240] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 287.

the TRIPS Agreement, were provided for. Such as Article 53(a)[241] of the European Patent Convention.[242]

The notion of '*ordre public*' is taken from the French word of public order and it is used because it gives much narrower meaning than the English notions of 'public order' and 'public interest'. The European Patent Office has related *ordre public* to cases such as riots and public disorder, or those inventions that leads to criminal or offensive behaviour. Every invention has to be taken individually in order to be decided whether it is against *ordre public*. However, since there are no exact cases and situations that can be limited to *ordre public*, therefore, member countries are free to apply the *ordre public* to those situations that have no prior cases nor well known at international level. This in fact gives a flexibility to member countries to evaluate their conditions and decide on those principles if are breached will tantamount breaching *ordre public*.[243] *Ordre public* can be related to public policy, which is directly affecting the institutions of a particular society. Without such *ordre public*, society will tear apart, and the structure of civil society will be endangered.[244] It is also related to the notion of security, whether collective or individual, such as physical damage or anything can put the normal life of society in general into risk, or simply disharmonize the livelihood of individuals to live in peace and security.[245]

In the same way of the *ordre public*, the term morality is not defined in the TRIPS Agreement. Likewise, a unanimous definition of the term morality was not achieved so far at the international law.[246]

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[241] European Patent Office, 'The European Patent Convention', Article 53. European patents shall not be granted in respect of: (a) inventions the commercial exploitation of which would be contrary to "*ordre public*" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States. <http://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar53.html> [accessed 13 February 2018].

[242] *Resource Book on TRIPS and Development*, ed. by United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development (Cambridge; New York: Cambridge University Press, 2005), p. 376.

[243] Correa, *Trade Related Aspects of Intellectual Property Rights*, pp. 287–88.

[244] Gervais, p. 343.

[245] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 312.

[246] Stoll, Busche, and Arend, p. 493.

However, Article XX(a) of GATT of 1947[247] which appeared also in GATT of 1994 was dedicated for the 'General Exceptions' in which 'public morals' which was considered as one of the bases of excluding invention from patentability. Here, the law clearly states that its public morals and not individual morals or private morals that leads to exceptions.[248] Therefore, if the commercial exploitation of the invention in the territory of a member country caused collective immorality or has negative effect on the morality of the community at large, then this member country is allowed to exclude such invention from patentability.

Though originally there is a jurisprudential debate as the positivist school of law believes that law should be based on logic and reason only without considering morality. On the other hand, the school of natural law believes that law should reflect the morals of society.[249] In line with this principle, the majority of countries in the world considered morality in regulating their laws. For this reason, the draftsmen of TRIPS Agreement and GATT were cogitating on this principle. That is why we can clearly see that the TRIPS Agreement did not ignore the issue of morality in intellectual property protection. Furthermore, what constitutes a morality is dependent on the understanding of a country or cultural group to a particular conduct. Because some conducts and behaviours are considered normal and correct in some countries and societies, while in some other societies and countries the same conducts and behaviours are seen utterly different. Hence, the evaluation has to be done on case by case basis. In this regard religious, social and moral values of every society have to be considered. Therefore, in evaluating the outcome of industrial exploitation of an invention, whether it will affect the morality of the society, it has to be looked at from the realizations of fair and

[247] 'The General Agreement on Tariffs and Trade (GATT 1947)' <https://www.wto.org/english/docs_e/legal_e/gatt47_02_e.htm#articleXX> [accessed 12 February 2018].

[248] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 312 (Footnote 712).

[249] Kathleen Liddell, 'Immorality and Patents: The Exclusion of Inventions Contrary to *Ordre public* and Morality', in *New Frontiers in the Philosophy of Intellectual Property*, ed. by Annabelle Lever, University of Cambridge Faculty of Law Research Paper No. 55/2016 (Rochester, NY: Cambridge University Press, 2012), p. 12 <https://papers.ssrn.com/abstract=2865820> [accessed 15 February 2018].

reasonable persons. Needless to mention that the principle of good faith has to be observed as well.[250]

Article 27.2 of the TRIPS Agreement includes the term 'necessary' and this looked at as requirement from the member countries. It has to be proven that it is necessary to exclude the invention from patentability because its commercial exploitation endangers the *ordre public* and morality of the member country. This needs to be shown that there is a real connection between the safeguarding of the *ordre public* and morality and the outcome of the measure that has been taken by the member country.[251] The member country also has to prove that other measures were not available that are consistent with the principles of the WTO, in order to be taken by them to protect *ordre public* and morality. This means that the member country has to use this measure as the last resort, after ensuring that there was no other justifiable and reasonable alternative that is less consistent with the WTO.[252]

To elaborate more on *ordre public*, Article 27.2 of the TRIPS Agreement provides some examples that may be considered as a basis for *ordre public* and morality which they are protection of 'human, animal or plant life or health or to avoid serious prejudice to the environment'. However, *ordre public* and morality are not limited to these situations or cases related to these situations. But still the focus is on the commercial exploitation of the invention and not the invention itself. The TRIPS Agreement allows member countries to exclude from patentability the invention that its commercial exploitation goes against the principles of *ordre public*. Therefore, if the invention is not applied in the member country, then the member country cannot exclude its patentability. The TRIPS Agreement clearly states that such exploitation has to be practically occurred in specific territory of the member country. In other words, the invention has to be industrially applied and exploited in territory of a particular

[250] Stoll, Busche, and Arend, pp. 493–94.
[251] Stoll, Busche, and Arend, pp. 494-95.
[252] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 378.

member country, and then this member country will be allowed to exclude its patentability base on the principles of *ordre public*.

The last proviso of Article 27.2 states that it's not allowed for a member country to exclude patentability merely because the industrial exploitation of the invention is prohibited by domestic law. Therefore, in order for any invention to be excluded from patentability has to be based on real grounds as mentioned in Article 27.2.[253] This is influenced by Article 4*quater* of the Paris Convention for the Protection of Industrial Property, in which the Article states that 'The grant of a patent shall not be refused and a patent shall not be invalidated on the ground that the sale of the patented product or of a product obtained by means of a patented process is subject to restrictions or limitations resulting from the domestic law'.[254] According to this Article of the Paris Convention restrictions and limitations by domestic laws and regulations that are not part of the patent system, should not be imported into the system.[255] However, Article 27.2 of the TRIPS Agreement goes further than sale of products or products itself, by generalizing the concept of exclusion to every kind of commercial exploitations that the right holder obtained by the TRIPS Agreement. Since commercial exploitation is not defined in the TRIPS Agreement, therefore, one can apply the definition of The Panel in the case of *Canada-Pharmaceutical Patents*, which states that exploitation include every commercial activity that the patent holder performing on his patent in order to gain economic benefits.[256]

[253] Carlos María Correa, 'Patent Rights', in *Intellectual Property and International Trade: The TRIPS Agreement*, ed. by Carlos María Correa and Abdulqawi A. Yusuf, 2nd ed (Austin: Alphen aan den Rijn, Netherlands: Wolters Kluwer Law & Business; Kluwer Law International, 2008), p. 231.

[254] 'WIPO-Administered Treaties: Paris Convention for the Protection of Industrial Property'.

[255] Sam Ricketson, *The Paris Convention for the Protection of Industrial Property: A Commentary* (Oxford: Oxford University Press, 2015), p. 390.

[256] Canada – patent protection of pharmaceutical products - Report of the panel, WT/DS114/R ON 17 MARCH 2000, para. 7.54 <https://www.wto.org/english/tratop_e/dispu_e/7428d.pdf>.

2.2.2 *Ordre public* and Morality Under Iraqi Patent Law

Section 3 of the Patent and Industrial Designs Law No. 65 of 1970 states that 'Patent shall not be granted in the following circumstances; 1. Inventions in which their exploitations cause breaches of public moral or *ordre public* or contradict the public interest'. Here the law clearly refers to the exploitation of an invention. In fact, the Law No. 65 of 1970 is different from Article 27.2 of the TRIPS Agreement because the word commercial does not exist within section 3.1 of the Law No. 65 of 1970. However, the explanation in section 1.2 of the Instruction No. 1 of 1990 on implementing Law No. 65 of 1970 and Regulation No. 3 of 2001 on the classification of Patents and Industrial Designs in section 2(b), made it clear that the word exploitation or industrial exploitation (application) 'can be applied or used in any fields of work related to industry, agriculture, profession, and services in broader understanding'.[257] Therefore, the term exploitation has general meaning and can be referred to any kind of commercial use, in which the patent holder uses his patent to gain benefits.

When it comes to the issue of morality, under the Iraqi Patent Law the word public moral is used, hence, clearly eliminate any doubts that may arise whether morality is meant to be public or individual moral as in the case of Article 27.2 of the TRIPS Agreement as has been discussed in the previous section.

Iraq is one of the most multicultural and socially diverse countries in the Middle East. Therefore, the meaning of the term public moral needs to carry the broadest sense as much possible. Because what is moral according to Iraqi Muslims may not be the same for Iraqi Christians, Yazidis or Sabians (Mandaean) or other minority religions, and vice versa. Iraq has some ethnics as well, apart from Arab, such as

[257] 'Iraq: Instructions No. 1 of 1990 Implementing Law No. 65 of 1970 on Patents, Industrial Designs', Section 1.2 <http://www.wipo.int/wipolex/en/details.jsp?id=10511> [accessed 10 February 2018]; 'Iraq: Regulation No. 3 of 2001 on the Classification of Patents and Industrial Designs', Section 2(b) <http://www.wipo.int/wipolex/en/details.jsp?id=10546> [accessed 14 February 2018] 'the invention will be considered industrially applicable if it can be applied or used in any fields of work related to industry, agriculture, profession, and services in broader understanding'.

Kurds which is the second largest population, and other ethnic minorities like Assyrians, Syriac, Turkmen, Armenian and Yazidi which is considered as a different ethnic as well. With all this diversity, it will be difficult to define public morality in Iraq, because each of these religious and ethnic groups are living in separate areas. Even though in the big cities such as Baghdad, all these groups can be found creating one big community with shared perspective of morals. However, one can find a village or a group of villages, or even a city that have only one of these religious or ethnic groups. That is why in the early beginning the Iraqi patent law referred to public moral and still it's a big task to define exact conducts of public moral in Iraq. After all, in the end, balance has to be created between public and individual interests. And every moral in question should be evaluated by a reasonable person in a good faith.

Section 3 of the Patent and Industrial Designs Law No. 65 of 1970 refers to two more reasons beside public morality, which member countries can exclude patentability of an invention base on them which they are '*ordre public* and public interest'. If the exploitation of an invention breaches *ordre public* or contradict public interest, then Iraq is allowed to refuse patenting such invention no matter how innovative and novel it is. As for the term '*ordre public*', it has same meaning as and will cover all those areas that covered by the TRIPS Agreement. However, the Law No. 65 of 1970 does not refer to 'protect human, animal or plant life or health or to avoid serious prejudice to the environment' and CPA Order No. 81 also did not amend this subsection, therefore it is enforced as it is without referring to 'protect human, animal or plant life or health or to avoid serious prejudice to the environment'. Nevertheless, as it is explained previously these are simply some examples and the words '*ordre public* and morality' cannot be limited to these issues only. However, the Law No. 65 of 1970 has an extra term which is 'public interest'. Public interest is very general term which can include the above issues and more. Because if its limited and can only be invoked in the most serious issues of public order such as 'where a genuine and sufficiently serious threat is posed to one of the fundamental interests

of society',[258] then why public interest mentioned in the same subsection with *ordre public*.

Public interest can be invoked when if the exploitation of the invention goes against the interest of the public. However, the same precautions of *ordre public* and morality has to be taken into consideration while invoking the issue of public interest, such as weighing and balancing all the factors.[259]

Lastly, the question then will be whether section 3.1 of the Law No. 65 of 1970 comply with the TRIPS Agreement. Despite the CPA Order No. 81 ordered with the intention to bring intellectual property law of Iraq up to the international standard and joining Iraq to WTO (TRIPS Agreement) was in mind while the CPA Order No. 81 was regulated.[260] Therefore, by not adding or deleting any words in this subsection, one can conclude that the CPA was of the opinion that this subsection was in fact is in compliance with the TRIPS Agreement. Nevertheless, the extra term 'public interest' is wide enough to include *ordre public* and public morals, and other areas. As Nicolas F. Diebold, while analysing the public order and public morals, states that all the exceptions under Article XIV of General Agreement on Trade in Services (hereinafter the "GATS") and Article XX GATT are public interests which can be used member countries to justify their actions.[261] Therefore, the term 'public interest' is an extra exception that cannot be found in Article 27.2 of the TRIPS Agreement. Nevertheless, under Article 8.1 of the TRIPS Agreement, member countries are allowed to take measures to promote their 'public interest in sectors of vital importance to their socio-economic and

[258] 'General Agreement on Trade in Services GATS', Article XIV Footnote 5 <https://www.wto.org/english/docs_e/legal_e/26-gats_01_e.htm#fnt-5> [accessed 15 February 2018].

[259] Nicolas F. Diebold, 'The Morals and Order Exceptions in WTO Law: Balancing the Toothless Tiger and the Undermining Mole', *Journal of International Economic Law*, 11.1 (2008), 43–74 (p. 44) <https://doi.org/10.1093/jiel/jgm036>.

[260] 'Order No. 81 Patent, Industrial Design, Undisclosed Information, Integrated Circuits And Plant Variety Law.', Preamble <http://www.wipo.int/wipolex/en/text.jsp?file_id=181090> [accessed 10 October 2017].

[261] Diebold, p. 46.

technological development'.[262] Therefore, it can be concluded that section 3.1 of the Law No. 65 of 1970 is in compliance with the provisions of the TRIPS Agreement by following the general principles that stated in Article 8.1.

2.3 DIAGNOSTIC, THERAPEUTIC AND SURGICAL METHODS FOR THE TREATMENT OF HUMANS OR ANIMALS

2.3.1 Diagnostic, therapeutic and surgical methods for the treatment of humans or animals under the TRIPS Agreement

Article 27.3[263] of the TRIPS Agreement provides for some exclusions from patentability by member countries, such as (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals, (b) plants and animal. Even though in subparagraph (b) member countries required to provide protection of plant varieties in form of a patent system or an effective *sui generis* system or both.

Based on the developing countries' proposal, Article 27.3(a) introduced a provision that relate to medical care. However, the proposal by the developing countries[264] were much wider than what is stated in this provision. The exception in this clause is limited to those

[262] Article 8.1 of the TRIPS Agreement states that 'Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement'.

[263] Article 27.3 of the TRIPS Agreement states that 'Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.'

[264] 'GATT Document No. MTN.GNG/NG11/W/71 of 14 May 1990' PART II, Article 4 (1) stated the exceptions and in subparagraph (iv) stated that the 'methods of medical treatment for humans or animals' as one of the exceptions.

categories that are mentioned.[265] This provision is dealing with methods of treatment of humans and animals, which cannot be used for excluding products and process that are part of human and animal treatments. Therefore, only those methods that are used in medical treatment of humans and animals can be excluded from patentability.[266] Other methods which are not used for animal treatment, such as those methods used for enhancing the quality of animal meat or used for enhancing other beneficial properties of animals, cannot be excluded from patentability according to Article 27.3(a). Likewise, cosmetic methods are not subject to this provision because they are not considered to be an essentially importance for public health and are not under ethical scrutiny, unlike other methods of treatment.[267]

This provision is limited to diagnostic, therapeutic and surgical methods that are used in treating humans or animals. Many countries around the world exclude these methods from patentability. Even though some of them do not have included specifically in their laws but still exclude them on the base of lack of industrial applicability.[268] However, under TRIPS Agreement these methods excluded from patentability as an exception and not on lack of patentability requirements.[269] And TRIPS Agreement does not enforce member countries to implement this provision because it is an optional provision. However, a country like United Kingdom clearly in The Patents Act of 1977 in section 4A of Methods of treatment or diagnosis, states that '(1) A patent shall not be granted for the invention of- (a) a method of treatment of the human or animal body by surgery or therapy, or (b) a method of diagnosis practised on the human or animal body'.[270] Similar provisions can be found in other

[265] Gervais, p. 350.
[266] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 384.
[267] Stoll, Busche, and Arend, p. 499.
[268] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 292.
[269] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 320.
[270] 'Patents Act 1977' Section 4A, <https://www.legislation.gov.uk/ukpga/1977/37/contents> [accessed 28 January 2018].

international conventions, for example in European Patent Convention (EPC 1973) in both Article of 52(4) and 53(c).[271]

Nevertheless, in some developed countries like Australia, New Zealand and United States of America these methods are patentable if they satisfy the criteria of patentability. In United States of America, the criterion of utility is used instead of industrial applicability, hence the scope of patentability is broader in such a way that methods of treatment can be patented. Though in 1996 the United States Patent law (United States Code Title 35 - Patents) was amended[272] to give immunity to medical practitioners from infringement suits for using patented surgical procedures.[273] In New Zealand, the method of treatment of humans and animals are patented. However, the patentability of these methods is not unlimited. There is an exception to this type of patents. If the method used to surgery on humans or to treat or prevent diseases in humans, then the method will not be patented. On the other hand, patentability of these methods in Australia are much broader. The general position in Australia is that the methods of medical treatment are patentable.[274]

Granting patents to methods of treatment are rare in countries where they allow patenting such methods. A possible reason behind this may be the difficulties in enforcing such patents. It is very problematic for patent owners to check and monitor activities of a

[271] 'The European Patent Convention'. Article 52(4) 'Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.' and Article 53(c) 'methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods'

[272] Section 287 (c) (1) 'With respect to a medical practitioner' s performance of a medical activity that constitutes an infringement under section 271 (a) or (b), the provisions of sections 281, 283, 284, and 285shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity', 'United States Code Title 35 - Patents'.

[273] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 384.

[274] Anna Feros, 'Patentability of Methods of Medical Treatment', *European Intellectual Property Review (EIPR)*, 23.2 (2001), 79 (p. 84).

large number of doctors and surgeons while practicing and applying these methods in their own private offices whereas strict privacy rules apply between them and patients.[275]

Reasons for excluding these methods may be different from one country to another but generally can be related to ethical and moral issues in the developed countries.[276] However, most of the developing countries are excluding methods of treatment on the basis of necessity of their countries to have such methods available for free.[277] Some other justifications for not patenting these methods may include; First, Patients may be denied to have access to a method of treatment while no other alternative is available; Second, The right holder may refuse the patented method; Third, Compulsory licence may not be the right toll to make the patented information available for all; Fourth, Patenting these methods will prevent flow of ideas between scientists and medical profession; Fifth, Conflicts of interest between the doctor and patient if the doctor is the right holder of the patented method of treatment; Lastly, Disclosure of patient's record for the purpose of royalty payment by the patentee.[278]

However, generally it is an accepted idea among the profession that such invention should be dealt with by peer review and other colleagues be able to benefit from the invention. Such practices are considered to be part of professional ethics; therefore, these methods are not dealt with by the patent office. However, Nuno Pires de Carvalho compares these methods to culinary recipes and believes that both of them are generally not patented because their exact application will depend on individual skills. He believes that even if cooking recipes can be patented, but usually are not applied for. Because the application of the recipes depend on a skilled cook and his reward will be through becoming popular chef and gains through having more

[275] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 387.
[276] Gervais, p. 350.
[277] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 384.
[278] Feros, pp. 84–85.

clients and put higher prices on his menu. In the same way the skilled doctor or surgeon will be able to apply the methods. Also, such methods have very limited markets because they are usually applied on very limited cases. Therefore, rewards can be received by applying them skilfully and gain professional prestige.[279]

Generally, Article 27.3(a) of the TRIPS Agreement does not affect patentability of equipment and instruments that will be used for executing these methods that are mentioned in the provision. But in case these methods can be performed without using the patented apparatus and instruments, then according to Article 27.3(a) the user has to get permission from the right holder of such apparatus in order to execute such methods. Nevertheless, the governments have other options to bypass the permission of the rights holder of this apparatus such as compulsory licences, because such apparatus made the non-patented methods a de facto monopolization.[280] Even though one may argue that pharmaceutical products are considered methods of treatment for humans and animals, then according to Article 27.3(a) can be excluded from patentability. Because patent claims relating to a particular substance that can be used for medical treatment and therapeutic methods are almost same without any real difference between them. In both situations a medical activity is going to be applied for a patent.[281] However, Article 70.8[282] of the TRIPS

[279] Carvalho, *The TRIPS Regime of Patents and Test Data*, pp. 319–20.
[280] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 292.
[281] Bengt Domeij, *Pharmaceutical Patents in Europe* (Stockholm: Kluwer Law International / Norstedts Juridik, 2000), p. 178.
[282] Article 70.8 of the TRIPS Agreement states that 'Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:
(a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;
(b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and
(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance

Agreement clearly stated that member countries have to provide patent protection for pharmaceutical and agricultural chemical products.[283]

2.3.2 Iraq's Patent Law Position to Diagnostic, therapeutic and surgical methods for the treatment of humans or animals

The Patent and Industrial Design Law No. 65 of 1970 does not contain any provision to regulate protection of diagnostic, therapeutic and surgical methods for the treatment of humans or animals or to exclude such methods from patentability. The only provision in regard of patenting medical activity is section 3.2 which stated that patent shall not be granted to medical and pharmaceutical formulations, and without stating any rules in regard of methods of treatment of humans and animals. Since the law is silent about patenting methods of treatment, therefore, it can be considered that these methods are patentable.

The most important amendments to the Law No. 65 of 1970, were passed through Law No. 28 of 1999 and CPA Order No. 81. However, none of these two amendments touch the issue of patenting or excluding from patentability the methods of treatment of humans or animals. Surprisingly both of them suspended section 3.2 of the Law No. 65 of 1970 which excluded medical and pharmaceutical formulations from patentability. In addition to that, the amendment Law No. 28 of 1999 may be justified as to why does not have added (or remained silent) any regulation with respect to methods of treatment. The reason was that this amendment was passed in 1999 before the invasion of Iraq and there was no intention from Iraqi

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with Article33of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b)'

[283] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 386.

government to join WTO as Iraq was under sanction by United Nations Security Council Resolution 661 of 6 August 1990.[284]

However, the CPA Order No. 81 was passed after the invasion of Iraq, and in the preamble of the Order, it clearly states that 'Recognizing the demonstrated interest of the Iraqi Governing Council for Iraq to become a full member in the international trading system, known as the World Trade Organization, and the desirability of adopting modern intellectual property standards'. Therefore, there is no excuse for the CPA not to pass any regulation regarding the methods of treatment of humans and animals. Does this silence from the CPA is because United States of America is allowing patentability of methods of treatment of humans and animals? However, since this issue is debatable even in United States to the extent that the law in this regard was amended in 1996 to provide immunity to medical practitioner or a related health care entity against any suits that arises from using patented surgical procedures.[285] Therefore, the CPA should have considered this issue more carefully and added a provision similar to Article 27.3 (a) of the TRIPS Agreement, because the CPA and the United States Government created some 'cells' for reforming Iraqi Commercial Law. Each of these cells chaired by a senior United States National Security Council and included representatives of several United States agencies such as Department of Commerce, Defense, State, and the Treasury. Then for deciding on every matter, the CPA coordinated with the governing Council in Iraq, Iraqi ministries, and the Iraqi civil society groups and coalition partners as well.[286] Hence, surely the CPA was aware how less developed Iraq is and what will benefit the country in future especially in the area of intellectual property rights. All the amendments to the intellectual property rights (laws on trademarks, patents and copyrights) were passed by the CPA with help of attorneys for the United States Patent and Trademark Office, as they worked closely together. Therefore, the

[284] 'United Nations Official Document -Security Council Resolutions - 1990' <http://www.un.org/Docs/scres/1990/scres90.htm> [accessed 22 February 2018].
[285] 'United States Code Title 35 - Patents', Section 287 (c) (1).
[286] Theodore W. Kassinger and Dylan J. Williams, 'Commercial Law Reform Issues in the Reconstruction of Iraq', *Georgia Journal of International and Comparative Law*, 33 (2004), 217 (pp. 219–20).

CPA was well aware of the WTO and its agreements such as TRIPS Agreement.[287]

Since this provision added basis on the proposal of the developing countries and Iraq as one of the developing countries have great necessity for provision like this to help develop its medical profession and infrastructure. In addition to that, excluding methods of treatment from patentability is also popular in developed countries and international convention as well. Likewise, many countries around the world are preventing methods of medical treatment to be patented, including countries from European community, Asia, Africa, North America, South America and Central America.[288] Therefore, the CPA by being well aware of the TRIPS Agreement and Iraqi situation, should have added a provision to section 3 of the Law No. 65 of 1970 to 'exclude from patentability: diagnostic, therapeutic and surgical methods for the treatment of humans or animals' as stated by Article 27.3(a) of the TRIPS Agreement.

2.4 ACCESS TO MEDICINES AND PUBLIC HEALTH

2.4.1 General Considerations

Usually prices of health-related materials and pharmaceuticals are very high and the excuse for such high prices is the cost of their research and development. Therefore, if level of protection of intellectual property rights of pharmaceuticals and other health related materials and equipment increase, this will automatically increase their prices on the national market as well. The sources of these formulations and materials are the developed countries. However, public health sectors and normal people in less developed countries are economically under pressure and cannot cope with such higher prices. Thus, any increase of intellectual property protection of health materials will directly affect general population of the developing countries. However, Abbott and Correa argued that some developing

[287] Kassinger and Williams, p. 224.

[288] O. Mitnovetski and D. Nicol, 'Are Patents for Methods of Medical Treatment Contrary to the *Ordre public* and Morality or "generally Inconvenient"?', *Journal of Medical Ethics*, 30.5 (2004), 470–75 (p. 470) <https://doi.org/10.1136/jme.2002.000786>.

countries like Saudi Arabia that have high level of petroleum revenues, increasing intellectual property protection of pharmaceuticals and other health related materials may not affect the country's public health sector. [289]

The countries spending on drugs within the public health sector are in different situations. For example, the developed countries expenditures on drugs is around 10 to 20 percent of total health spending, while this percentage goes much higher up to 50 percent in the least developed countries. The problem is that the TRIPS Agreement does not make any distinction between the lifesaving products such as pharmaceutical products and any other merchandises or commodities.[290]

The TRIPS Agreement has been blamed for preventing countries from accessing to inexpensive copies of patented medicines (generic drugs) and raising prices of medicines through patent monopolies. The higher cost of patented drugs was the reason of inaccessibility of AIDS treatment in the developing and least developed countries and subsequently thousands of people lost their lives in Africa.[291]

Pharmaceutical enterprises claiming that strong patent protection of their products will lead to good incomes that automatically encourage them to conduct expensive research and development. On the other hand, lesser standards of protection will lead to low income streams and lower incentives to invent. According to this argument, the higher the standard of protection and the higher cost of payment by consumers will eventually benefit the society by encouraging pharmaceutical companies to do long term researches and developments. However, it has been argued by the developing

[289] Frederick M. Abbott and Carlos María Correa, *World Trade Organization Accession Agreements: Intellectual Property Issues* (Rochester, NY: Social Science Research Network, 30 May 2007), p. 28 <http://papers.ssrn.com/abstract=1915338> [accessed 23 February 2016].

[290] Maria Auxiliadora Oliveira and others, 'Has the Implementation of the TRIPS Agreement in Latin America and the Caribbean Produced Intellectual Property Legislation That Favours Public Health?', *Bulletin of the World Health Organization*, 82.11 (2004), 815–21 (p. 816).

[291] Haochen Sun, 'The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health', *European Journal of International Law*, 15.1 (2004), 123–50 (p. 124) <https://doi.org/10.1093/ejil/15.1.123>.

countries that in cases of crises of diseases like HIV/AIDS, long term research and development will not benefit the patents while they are dead. As for other diseases if the price of medicines and other products are very high, then only limited numbers of individuals will be able to buy them. The rest of the public in developing and least developed countries will not be able to buy them in the first place. Therefore, the pharmaceutical enterprises will not be able to receive incomes that guarantee their survivals.[292]

However, the profits of pharmaceutical companies are very low in developing countries as it represents only 5 to 7 percent of total profit of the companies since 90 percent of their sales are within the territory of the developed countries. Therefore, it will not be a huge loss to the pharmaceutical companies to reduce their profit percentage in the developing countries. Rather they should look at it as a humanitarian assistance by giving up portion of their profit. Another general argument for unreasonably higher prices of pharmaceutical products and medicines is the cost of research and development. However, data shows that only 10 to 20 percent of pharmaceutical companies' budgets are spent on research and development. The substantial amount of their expenses is spent on advertising and promotion, and other administrative expenditures. Nonetheless, after all these expenses their profits and earnings are very high.[293]

One may wonder why the developing countries rely on generic drugs. One of the main reasons may be due to the response of developed countries to public health crises in the developing countries as has been described as poor. Even when the World Bank and International Monetary Fund interfere to help, their aid will not be so much beneficial because their help will be in the form of loans and not grants. The loan has to be paid back eventually with addition to interest. Hence, overall this aid will weaken the economic development of developing and least developed countries. In some cases, also, while a country refused to comply or delay

[292] Frederick M. Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO', *Journal of International Economic Law*, 5.2 (2002), 469–505 (pp. 472–73) <https://doi.org/10.1093/jiel/5.2.469>.
[293] Abbott and Correa, p. 28.

implementation of health reform legislation, such as the Republic of South Africa, received threating of imposing trade and economic sanctions. Therefore, in crises situations, developing countries cannot rely on developed countries or international community to response to their problems. The developing and least developed countries must prepare themselves to respond to any public health crises. The principal self-help and solutions for them may be the generic drugs that are patented by pharmaceutical enterprises.[294]

The drug prices vary substantially between patented drugs and off-patent drugs, especially when there is more than one company produces the drugs. For example, in the United States, the price of off-patent drugs will reduce by 60 percent, however, when the same drug produced by ten companies the price falls to 25 percent of the wholesale price of the original patented drug.[295]

2.4.2 The Doha Declaration on the TRIPS Agreement and Public Health

Even after the enforcement of the TRIPS Agreement, the developing and least developed countries did not stop from their attempt to protect and advance their essential interests. They understood that by working together and creating coalition, they will be able to protect themselves from being outplayed by the EU-US block. The result of their attempt was the adoption of the Doha Declaration on the TRIPS Agreement and Public Health (14 November 2001) (hereinafter the "Doha Declaration").[296] This is the clear signal that the developing countries want to remedy the unbalanced result of the Uruguay Round.[297] However, it cannot be said that the Doha Declaration will resolve all concerns of the

[294] Abbott, p. 471 and 473-474.
[295] Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO', p. 472.
[296] 'WT/MIN(01)/DEC/2 -WTO | Ministerial Conferences - Doha 4th Ministerial - Declaration on the TRIPS Agreement and Public Health - Adopted 14 November 2001'.
[297] Sun, p. 135.

developing countries in regard to medicines and TRIPS Agreement, but still it is a significant improvement.[298]

Initially the Doha Declaration negotiated by member countries of the WTO through TRIPS council which made recommendations to the General Council and finally to report submitted to the Ministerial Conference. Since the Ministerial Conference has 'the authority to take on decisions on all matters under any of the Multilateral Trade Agreement'.[299] Therefore, it can be said that the Doha Declaration is the result of WTO decision making framework.[300] In this capacity, the Doha Declaration has legal effect on the WTO bodies, especially the Dispute Settlement Body and the Council for TRIPS Agreement as well as all the member countries. The Doha Declaration represents a political statement that the developing and least developed countries rely on in the area of public health in order to have access to medicines without fear of legal battle. The Doha Declaration interprets the TRIPS Agreement, instructs the council for TRIPS Agreement and decide on transitional provisions of the TRIPS Agreement.[301]

The Doha Declaration generally addresses the issues of public health and not limited to some specific issues as the developed countries wanted to, such as AIDS. Nevertheless, it finally implemented the style that mostly mirrors the drafts of the developing

[298] Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO', p. 469.

[299] 'WTO | WTO Analytical Index: Guide to WTO Law and Practice - Marrakesh Agreement Establishing the World Trade Organization' Article IV (1) ' There shall be a Ministerial Conference composed of representatives of all the Members, which shall meet at least once every two years. The Ministerial Conference shall carry out the functions of the WTO and take actions necessary to this effect. The Ministerial Conference shall have the authority to take decisions on all matters under any of the Multilateral Trade Agreements, if so requested by a Member, in accordance with the specific requirements for decision making in this Agreement and in the relevant Multilateral Trade Agreement.' <https://www.wto.org/english/res_e/booksp_e/analytic_index_e/wto_agree_02_e.htm#articleIVB2> [accessed 27 February 2018].

[300] James T. Gathii, 'The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention of the Law of Treaties', *Harvard Journal of Law & Technology*, 15.2 (2002), 291 (p. 300).

[301] Carlos María Correa, 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health', *World Health Organization*, 2002, p. 42 <http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf> [accessed 28 February 2018].

countries. The core point of the draft of the developing countries was the notion of that 'nothing in the TRIPS Agreement shall prevent Member from taking measures to protect public health'.[302] The Doha Declaration introduced a major alteration that is not in favour of the pharmaceutical companies. Because the developing countries are allowed to break patent protections for every kind of illnesses that became the national health issue and includes variety of illness such as cancer, diabetes, asthma, and etc.[303] Generally, the Doha Declaration modified TRIPS Agreement to the extent that member countries are allowed to have greater diversity in dealing with importation of pharmaceutical products.[304]

The Doha Declaration consists of 7 paragraphs and the first three paragraphs are considered to be preambles and the rest of paragraphs are considered to be the operative paragraphs.[305] In the first paragraph of the Doha Declaration it is stated that 'We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics'.[306] The ministers clearly admitted that there is massive public health problem affecting the developing and least developing countries and some examples are stated. However, these are just some examples of illnesses that were recognised as the major issues during the Doha Ministerial Conference. Because as it is clear from the end of the sentence, it mentions 'other epidemics', which can be related to any other major health issues that might face developing and least developed countries in future.

The second paragraph of the Doha Declaration states that 'We stress the need for the WTO Agreement on Trade-Related Aspects of

[302] Sun, p. 135.
[303] Steve Charnovitz, 'The Legal Status of the Doha Declarations', *Journal of International Economic Law*, 5 (2002), 207 (p. 207).
[304] Alexander James Stack, *International Patent Law: Cooperation, Harmonization, and an Institutional Analysis of WIPO and the WTO* (Edward Elgar, 2011), p. 88.
[305] Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO', p. 490.
[306] 'WT/MIN(01)/DEC/2 -WTO | Ministerial Conferences - Doha 4th Ministerial - Declaration on the TRIPS Agreement and Public Health - Adopted 14 November 2001', para. 1.

Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems'.[307] This paragraph emphasizes that the TRIPS Agreement should not be an obstacle in solving issues related to public health concerns by being part of the bigger action whether at national or international level in order to solve the addressed issues. This might be addressed to some of the WTO members which they dismissed the participation of an important organization such as World Health Organization in formal meeting while discussing the issues of accessing to medicines. Thus, one can see that this paragraph obliquely recognizes the role of the World Health Organization in preventing and treatment of diseases.[308]

The third paragraph of the Doha Declaration states that 'We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices'.[309] This paragraph attempts to reconcile between the position of developed and developing countries by addressing their concerns in one paragraph. In the first sentence of the paragraph the opinion of the developed countries stressed on by indicating that indeed the intellectual property protection is promoting the development of new medicines. This came after the developing countries presented their doubts that high standard of intellectual property protection does not encourage research and development of pharmaceutical drugs that particularly relevant to them. The second sentence in an inadequate and weak manner admits that higher standard of intellectual property protection will have negative consequences in which increase the price of patented drugs. This automatically will affect the poor people in the developing and least developed countries by having difficulty in accessing such medicines. This paragraph acknowledges two contradicting opinions. In one side

[307] 'WT/MIN(01)/DEC/2 -WTO | Ministerial Conferences - Doha 4th Ministerial - Declaration on the TRIPS Agreement and Public Health - Adopted 14 November 2001', para. 2.

[308] Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO', p. 491.

[309] 'WT/MIN(01)/DEC/2 -WTO | Ministerial Conferences - Doha 4th Ministerial - Declaration on the TRIPS Agreement and Public Health - Adopted 14 November 2001', para. 3.

it acknowledges the importance of intellectual property protection for research and development of drugs while in the other side it admits this is actually a concern and have negative effect on their prices.[310] However, this is considered as a big political victory for the developing and least developed countries that they achieved consensus among all member countries that patent protections have impact on drug prices. By nature, the patent system encourages the right holder to put higher prices on patented materials than those off patented or normal products that are subject to competitive market.[311]

The fourth Paragraph of the Doha Declaration is an important one as it states that:

'We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose'.[312]

This paragraph was one of the most controversial provisions of the Doha Declaration and gone through intensive negotiations because the target of the developing countries was to acquire recognition that the TRIPS Agreement should not be interpreted to prevent member countries to adopt measures that are necessary to protect public health. However, the developed countries and pharmaceutical companies used pressure and opposed the attempt of the developing countries. The developing countries wanted to emphasize on some measures and flexibilities such as compulsory licence and parallel importation to

[310] Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO', p. 491.

[311] Correa, 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health', p. 7.

[312] 'WT/MIN(01)/DEC/2 -WTO | Ministerial Conferences - Doha 4th Ministerial - Declaration on the TRIPS Agreement and Public Health - Adopted 14 November 2001', paragraph 4.

enhance public health protection. However, the developed countries were of the opinion that reference of public health in Article 8 of the TRIPS Agreement should only be applied in consistency with other provisions of the TRIPS Agreement. They argued that TRIPS Agreement cannot be seen as a barrier of public health's protection and provisions of the TRIPS Agreement should not be undermined. Furthermore, the European Union countries are of the opinion that the TRIPS Agreement should not be blamed for the health crises that exist within the territory of the developing and least developed countries and at the same time it should not be a barrier in combating the health crises of the developing countries. The European Union's position was more understandable to the situation of the developing countries and was ready to negotiate concerns on the interpretation of the provisions of the TRIPS Agreement.[313]

One of the important points of paragraph four is that it started with the term of 'we agree', which represents the Doha Declaration as an agreement by the member countries. And since it is decided by the member countries of the WTO, therefore, this agreement can have interpretative authority of the TRIPS Agreement according to Article 31.3[314] of the Vienna Convention on the Law of Treaties of 1969. According to Article 31.3 of the Vienna Convention, in the process of interpretation of any treaty or application of its provisions, the subsequent agreement among members of the treaty shall be taken into account. Not just agreement between members but any subsequent practice or any relevant rules of international law has to be taken into consideration.[315] Therefore, the Doha Declaration in

[313] Correa, 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health', pp. 9–10.

[314] *Vienna Convention on the Law of Treaties*, 1969, Article 31.3 There shall be taken into account, together with the context:

(a) Any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions;

(b) Any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation;

(c) Any relevant rules of international law applicable in the relations between the parties.

<https://treaties.un.org/doc/publication/unts/volume%201155/volume-1155-i-18232-english.pdf> [accessed 22 December 2017].

[315] Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO', p. 491.

paragraph four emphasizes that this declaration is an agreement and shall be taken into account in the process of interpretation of the TRIPS Agreement or in the process of implementation of the provisions of the TRIPS Agreement.

In the first sentence of paragraph four, the Doha Declaration emphasizes that the TRIPS Agreement does not prevent the member countries to take measures in order to protect public health and should not be interpreted as such. This indicates that a conflict may arise between intellectual property rights protection and measures to protect public health. Therefore, in such case when a conflict exists between the intellectual property rights and public health, the acts of intellectual protection should not be an obstacle in front of member countries to take necessary measures to protect public health. This can be read with Article 8.1[316] of the TRIPS Agreement which allows member countries to adopt measures necessary to protect public health, and this provision provides for a proviso that such measure have to be consistent with the provisions of the TRIPS Agreement. However, when combining Article 8.1 with paragraph four, it can be argued that member countries may be able to derogate from some obligations under the TRIPS Agreement if it is necessary to protect public health.[317]

The second sentence of paragraph four confirms commitment of member countries to the TRIPS Agreement and guides panels and the Appellate Body on how to interpret the provisions of the TRIPS Agreement on issues relating to public health, as it states, ‘we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all’. Therefore, when there is ambiguity, or more than one interpretation is possible in a case, the panel or the Appellate Body should choose the

[316] Article 8.1 of the TRIPS Agreement ‘. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement’

[317] Correa, ‘Implications of the Doha Declaration on the TRIPS Agreement and Public Health’, p. 11.

interpretation that is supportive the member countries' right to protect public health and particularly to access to medicines.[318]

In the second part of paragraph four, the Doha Declaration emphasizes on another important point which is flexibilities in the TRIPS Agreement. This part as states in the Doha Declaration that 'In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose', affirms that the member countries have full right to benefit from all the flexibilities available in the TRIPS Agreement in all the areas and especially in the area of protection of public health and taking necessary measures in this regard.

Developing countries and least developed countries also can take advantage of Article 8 of the TRIPS Agreement in order to optimize the protection of their public health. This can be achieved by taking advantage of all the flexibilities and safeguards and incorporate them into their legislation. This eventually makes them have better access to medicines.[319] This was confirmed by the former WTO Director-General Mike Moore, during the discussion of the Doha Declaration, as he stated that this meeting is an opportunity for member countries to feel that they have right to use the flexibilities in the TRIPS Agreement such as parallel imports and compulsory licensing.[320]

Paragraph five of the Doha Declaration includes four subparagraphs. In subparagraph 5 (a) it states that 'In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles'. Here, the Declaration emphasizes on customary rules of interpretation according to Article 31 of the Vienna Convention as has been discussed within the content of previous paragraph four. It also refers to Article 7 and 8 of the TRIPS Agreement by stating that each provision of the TRIPS Agreement should be read with its objectives and principles, as they are the titles

[318] Correa, 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health', pp. 11–12.
[319] Oliveira and others, pp. 816–17.
[320] Sun, p. 135.

of Article 7 and 8 of the TRIPS Agreement. This indicates that these Articles are more than preamble Articles and has to be referred for the interpretative purposes.[321] This clearly has political impact beside its legal impact, as combining customary rules of interpretation of public international law and objectives and principles of the TRIPS Agreement. Therefore, the member countries have the right to take all measures necessary to protect their public health while implementing the TRIPS Agreement.[322]

Subparagraph 5.b. states that 'Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted'. This subparagraph affirms rights of the member countries to use compulsory licence as one of the main legal instrument to limit the exclusive rights of the patent owner in order to fulfil their public policy objectives including supply of medicines according to domestic needs. Article 31 of the TRIPS Agreement provides for compulsory licence, but this Article states some conditions that has to be followed such as it has to be determined case by case, prior negotiation, remuneration … etc. Article 31 states some possible grounds which can be used for granting compulsory licence, such as national emergency, public non-commercial use, and anti-competitive. Nevertheless, these grounds are not exhaustive, as member countries are free to stipulate other grounds as well. This subparagraph of 5.b. just reaffirm that member countries have rights of using compulsory licences to fulfil their public health needs and meet other objectives as well.[323]

Subparagraph 5.c. of the Doha Declaration states that 'Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a

[321] Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO', p. 493.
[322] Carmen Otero Garcia-Castrillon, 'An Approach to the WTO Ministerial Declaration on the TRIPS Agreement and Public Health', *Journal of International Economic Law*, 5.1 (2002), 212 (p. 214).
[323] Correa, 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health', p. 15.

national emergency or other circumstances of extreme urgency'. This subparagraph gives explicit freedom to member countries to determine what constitute a national emergency or other circumstances of extreme urgency. This is to allow them, to grant compulsory licence according to their own circumstances. Combining this subparagraph with the previous one is helping the member countries to deal with public health more freely without fear of legal battle from the pharmaceutical industries.[324]

The last subparagraph of 5.d. states that 'The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4'. This is the clearest evidence and unequivocal recognition that member countries of the TRIPS Agreement have right to allow parallel importation (exhaustion of intellectual property rights) of medicines. When a product has been put onto market by the patent holder, then the buyers have right to sale and transfer, and subsequently the patent holder's right to stop such action by buyers is extinguished and exhausted by his first sale. In the same way when the patented product is licensed whether voluntarily or involuntarily through a compulsory licence, and the licensee put the product onto the market, it has the same consequences as though the patent holder has put the product onto market. There are two provisions in the TRIPS Agreement which allow the principle of exhaustion and parallel importation, which they are Article 6 and 31 lit. (f). Article 6[325] states that exhaustion is not subject to dispute settlement without defining the term of exhaustion. This indicates that member countries are permitted to define this principle according to reasonableness and needs. They may define in such a way that exhaustion occur by first sale through a licensee in the same manner as it happens by first sale through a patent holder.

[324] Sun, p. 138.

[325] TRIPS Agreement, Article 6 states that 'For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights'.

Article 31 lit. (f)[326] also states that the compulsory licence should be granted predominantly for fulfilling the needs of domestic market. Hence, the non-predominant portion can be exported by the licensee and imported by another without the consent of the patent holder.[327]

This subparagraph gives an opportunity to those member countries that want to legitimately apply for an international exhaustion principle according to the TRIPS Agreement. However, such member countries should incorporate such permissions in their domestic legislations in order be able to benefit from this flexibility or others that allowed under the TRIPS Agreement and confirmed by the Doha Declaration. Such flexibilities do not automatically become part of the laws of member countries, hence the member countries will not be protected from legal actions of the patent holders. This is unfortunate fact that most of developing countries' patent laws have not used (or partially used) these flexibility in their favour which clearly allowed by the TRIPS Agreement.[328]

Paragraph six of the Doha Declaration states that 'We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002'.[329] This paragraph acknowledges the fact that some member countries are uncapable of utilising the compulsory licence as an effective tool to handle their public health crises because of insufficient or no manufacturing capacities. At the same time these member countries cannot import sufficient quantities of generic medicines from other member countries that used the compulsory licence to produce medicines. This is due to the restriction imposed by Article 31 lit. (f)

[326] TRIPS Agreement, Article 31 lit. (f) states that 'any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use'.
[327] Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO', p. 495.
[328] Correa, 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health', p. 18.
[329] 'WT/MIN(01)/DEC/2 -WTO | Ministerial Conferences - Doha 4th Ministerial - Declaration on the TRIPS Agreement and Public Health - Adopted 14 November 2001', Paragraph 6.

that compulsory licence should be granted in order to supply predominantly the requirement of domestic market of the member country that granted such licence. Though non-predominant portion can be exported but the amount may not be sufficient as many developing countries may want to import such products in large quantities to meet their needs. Therefore, those member countries with manufacturing capacities such as India, the United Kingdom and United States of America, are able to grant compulsory licence and produce the quantities they need for their public health crises. On the other hand, those countries that do not have sufficient manufacturing capacities to produce medicines will not be able benefit from compulsory licence, even though they have massive health crises such as AIDS in the African countries. In fact, this is the problem of most of the developing countries for the fact that production capacities of pharmaceutical products in the world is unbalanced.[330]

Some developing countries have limited capacity to produce certain types of medicines, but not all types that are necessary for their public health. However, in general the developing countries have not used the compulsory licence as a tool to solve their health care problems. This may be due to some reasons; first, increasing incidence of patent protection is a recent phenomenon by the TRIPS Agreement; second, developing countries facing strong opposition from developed countries and their big pharmaceutical companies to use the compulsory licences, and such opposition require strong political commitment from the developing countries part; third, some developing countries have concern over reaction of foreign direct investors; forth, it is better for companies and enterprises in developing countries to deal directly with foreign patent holders than compete against them through compulsory licences; finally, granting and implementing compulsory licences require some prior conditions that relate to administrative, financial, and technical capacities, which are usually absent in developing countries.[331]

[330] Correa, 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health', p. 19.
[331] Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO', pp. 498–99.

Out of this concern the Doha Declaration in the second sentence of paragraph six instructed the TRIPS Council to find a solution and report back to the General Council before the end of 2002 as a matter of urgency. Base on this, a legal situation had to be found so as to enable the member countries to authorize compulsory licensing for export.[332] This is clear that the Doha Declaration left this problem unresolved and passed the responsibilities onto the Council to find a solution. Looking for solution for the problem in the paragraph 6 was not easy. It took almost two years of negotiations among member countries in order to arrive at a solution that satisfies both of the industrialised and developing countries. At the end, and after a compromise from both sides a solution achieved and adopted as a decision of the General Council.[333] The decision titled 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' of August 30th, 2003.[334]

This Decision was considered as a significant step in respond to the problem initiated by paragraph 6. According to paragraph 11 of the Decision of 30 August 2003, the TRIPS Council has to prepare an amendment to the TRIPS Agreement that replace the provisions of the Decision by the end of 2003. The amendment was finalized and proposed to be adopted by the member countries under the title of 'Amendment of the TRIPS Agreement' Decision of 6 December 2005.[335] Article 31*bis* and the Annex of the TRIPS Agreement, which

[332] Bartelt Sandra, 'Compulsory Licences Pursuant to Trips Article 31 in the Light of the Doha Declaration on the Trips Agreement and Public Health', *The Journal of World Intellectual Property*, 6.2 (2005), 283–310 (p. 296) <https://doi.org/10.1111/j.1747-1796.2003.tb00202.x>.

[333] Frederick M. Abbott and Rudolf V. Van Puymbroeck, *Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision* (World Bank Publications, 2005), p. 9 <http://siteresources.worldbank.org/INTSAREGTOPHIVAIDS/Resources/DohaGuideJune22005.pdf>.

[334] 'WT/L/540 - WTO | Intellectual Property (TRIPS) - Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' <https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm> [accessed 7 April 2018].

[335] 'WTO | Intellectual Property (TRIPS) - Amendment of the TRIPS Agreement - Decision of 6 December 2005' <https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm> [accessed 7 April 2018].

were the content of the Decision of December 2005 are almost identical to the wording of the provisions of the Decision of August 2003.[336] The amendment includes waiver of two important provisions of Article 31 which are an obstacle of transporting medicines produced under compulsory licence to those developing countries with insufficient or no manufacturing capacities. First, exporting member countries are relinquished from the obligation that they have to produce medicines under the compulsory licence predominantly for their domestic market. Second, importing member countries of medicines produced under compulsory licence are relinquished from responsibilities of paying remuneration to the right holder.[337] These are an important and significant improvement in favour of the developing countries in order to fulfil their needs through acquiring enough medicines for their public health crises.

The last paragraph of the Doha Declaration, which is paragraph seven which states that

> 'We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2. We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement'.[338]

[336] Stoll, Busche, and Arend, p. 584.
[337] Abbott and Puymbroeck, p. 9.
[338] 'WT/MIN(01)/DEC/2 -WTO | Ministerial Conferences - Doha 4th Ministerial - Declaration on the TRIPS Agreement and Public Health - Adopted 14 November 2001', Paragraph 7.

The least developed countries have repeatedly complained that the developed countries are not doing their part of the deal within the TRIPS Agreement which is transfer of technology as required by Article 66.2.[339] This article of the TRIPS Agreement requires from the developed countries do their best in motivating and encouraging their domestic enterprises and institutions for the purpose of transferring technology to least developed countries so that they be able to build a viable technological base for themselves. Paragraph 7 in the first sentence reaffirm this obligation of the developed countries that imposed by the TRIPS Agreement. Besides this, a Working Group[340] under the umbrella of the General Council established in order to make recommendation to help easy transfer of technology to least developed countries and examine the relationship between trade and transfer of technology.[341]

The second sentence of paragraph seven provides for extension of transitional period for the least developed countries. The extension period is in regard of section 5 (Patents) and 7 (Protection of Undisclosed Information) and in relation to pharmaceutical products only and until 1 January 2016. Though this date is passed right now, however, it was a great opportunity for the least developed countries to take the advantage of this period because it was an extension over the period which is provided for by Article 66.1 of the TRIPS Agreement. The least developed countries did not have to follow the procedures stated in Article 66.1 in order to benefit from this new

[339] TRIPS Agreement, Article 66.2 states that 'Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base'.

[340] 'WT/MIN(01)/DEC/1 Ministerial Conference - Fourth Session - Doha, 9-14 November 2001 - Ministerial Declaration - 20 November 2001' Paragraph 37 states that 'We agree to an examination, in a Working Group under the auspices of the General Council, of the relationship between trade and transfer of technology, and of any possible recommendations on steps that might be taken within the mandate of the WTO to increase flows of technology to developing countries. The General Council shall report to the Fifth Session of the Ministerial Conference on progress in the examination' <https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=37246&CurrentCatalogueIdIndex=0&FullTextSearch=> [accessed 11 April 2018].

[341] Sun, pp. 138–39.

extension. As this extension is without prejudice to other rights that provided for under Article 66.1, therefore, the least developed countries still had rights to apply for extra transitional period for other matters under Article 66.1.[342]

2.4.3 Access to Medicine and Iraqi Patent Law

The original Iraqi Patent and Industrial Designs Law No. 65 of 1970 clearly excluded patentability of medicines. Section 3.2 states that patent shall not be granted in the cases of medical and pharmaceutical formulations. Therefore, according to this subsection, Iraq did not give intellectual property right to protect medicines and drugs. In this situation Iraq was having access to all medicines whether to buy generic drugs or produce medicines by public company to fulfil the needs of the people without having permission from right owners. According to this subsection even if Iraq was not in public health crises such as having epidemics in the country, companies and enterprises were allowed to import and export any types of drugs without fear of facing legal action by the right holders.

However, the exclusion of medical and pharmaceutical formulations from patentability did not last, as it was repealed by both of the major amendment that passed over the original Law No. 65 of 1970. First the Law No. 28 of 1999 in section 3 states that 'subsection (2) of section 3 of the Law is repealed'. Then for second time the same subsection repealed by the CPA Order No. 81. The CPA Order No. 81 in Article 6 states that 'Article 3.2 is suspended'. The CPA Order No. 81 refers to the provisions of the Law No. 65 of 1970 as Articles and not sections. It is unclear why the Order No. 81 suspended this subsection from the original Law No. 65 of 1970 while it was repealed by the amendment Law No. 28 of 1999. The only logical explanation has to be that the CPA was not aware of existing amendment Law No. 28 of 1999, otherwise, suspending a repealed subsection will not add any legal value to the original Law No. 65 of 1970.

[342] Correa, 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health', p. 38.

Neither of the amendments of Law No. 28 of 1999 nor the CPA Order No. 81 added any new provisions to substitute such suspension. Many countries have included some sort of exceptions of patenting medicines. For example, Law No. 9.279 of May 14, 1996 (Law on Industrial Property) of Brazil in section 43 states some exception to exclusive rights of the titleholder and in subsection III states that 'to the preparation of a medicine in accordance with a medical prescription for individual cases, carried out by a qualified professional, as well as to the medicine so prepared'.[343] Also Indian Patent Act 1970 in section 47 provided that patent shall be granted with subject to certain condition and in subsection (4) states:

'in the case of a patent in respect of any medicine or drug, the medicine or drug may be imported by the Government for the purpose merely of its own use or for distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the Government or any other dispensary, hospital or other medical institution which the Central Government may, having regard to the public service that such dispensary, hospital or medical institution renders, specify in this behalf by notification in the Official Gazette'.[344]

These examples show that member countries[345] of the WTO and TRIPS Agreement are included in their laws exceptions to exclusive rights of patenting medicines whether be in a simple way in case of Brazil or in a more advance way as in case of idea in which the exception may benefit the country in many situations. Therefore, the CPA Order No. 81 should have taken advantage of the Doha Declaration by including a new provision in regard of access to medicines and drugs to benefit the public health of Iraq. Excluding pharmaceutical and medical formulations from patentability may be

[343] 'Brazil: Law No. 9.279 of May 14, 1996 (Law on Industrial Property)', Section 43.III <http://www.wipo.int/wipolex/en/text.jsp> [accessed 6 March 2018].

[344] 'Indian Patent Act 1970 (Updated till 23 June 2017)' Section 47 (4) <http://www.ipindia.nic.in/writereaddata/Portal/IPOAct/1_113_1_The_Patents_Act_1970_-_Updated_till_23_June_2017.pdf> [accessed 6 March 2018].

[345] List of Exceptions of Other Countries Can be Found Here 'Exceptions and Limitations of the Rights - Certain Aspects of National /Regional Patent Laws' <http://www.wipo.int/export/sites/www/scp/en/national_laws/exceptions.pdf This can be found in http://www.wipo.int/scp/en/annex_ii.html> [accessed 6 March 2018].

very extreme for current position of Iraq which intends to join the WTO and TRIPS Agreement. But taken into consideration of Iraqi situation as a developing country that still in war with terror, the CPA Order No. 81 should have included a provision so as to enable Iraq to handle public health crises whenever arise.

2.5 CONCLUSION

Ordre public and morality are two important principles that were introduced to TRIPS Agreement in Article 27.2. Though, meaning of these terms can be taken from laws of other countries such as United States of America and France or other international institutions such as European Patent Office, but neither terms defined by the TRIPS Agreement. This gives flexibility to member countries to apply these terms in their own situations and decide on each case individually. Some examples are provided by the TRIPS Agreement that can be used as basis for using *ordre public* and morality by member countries to protect them such as 'human, animal or plant life or health or to avoid serious prejudice to the environment'. However, these are just samples and *ordre public* and morality can be extended to other areas if necessity requires that. In Patent and Industrial Designs Law No. 65 of 1970 these concepts are used in a wider context to include public moral, *ordre public* (public policy) and public interest. Clearly these terms cover wider areas due to diversity in ethnic, cultural and religious sects of Iraq. Therefore, these exclusions can be taken advantage of by Iraq since none of the amendments altered them.

Article 27.3 (a) introduced another important and optional exclusion from patentability which is diagnostic, therapeutic and surgical methods of treatment of humans and animals. Excluding these methods from patentability is very popular around the world and even some countries exclude them on the base of lack of industrial applicability. However, this provision cannot be found in the Law No. 65 of 1970. Despite the importance of this exclusion due to the health crises in Iraq, the amendments that passed on the Law did not add any similar provision. Latest amendment was through CPA Order No. 81. The CPA was well aware of the provisions of the TRIPS Agreement,

and in the same time the CPA was running Iraq, therefore, through its full knowledge of the situation should have added a provision to the Law No. 65 of 1970 similar to Article 27.3 (a) of the TRIPS Agreement.

Access to medicines and protection of public health is an important issue to the developing and least developed countries. Due to the vital of this issue the Doha Declaration on the TRIPS Agreement and Public health was adopted in Ministerial Conference in 2001. Even though this declaration did not solve all the problems of the developing and least developed countries, but it mirrored their interest to a great extent. The Doha Declaration gives a great opportunity to these countries to have access to medicine to solve their public health issues in any epidemic cases without fear of facing legal battle from big pharmaceutical companies and developed countries. The reason is that the Doha Declaration clearly admits the fact that strong intellectual property rights will increases prices of medicines. Furthermore, the declaration stresses that the TRIPS Agreement should be interpreted and implemented in a manner to fulfil the needs of the member countries to protect their public health and have access to medicines. Though the Law No. 65 of 1970 excluded pharmaceutical and medical formulations from patentability, but this exclusion suspended by both of the amendments of Law No. 28 of 1999 and CPA Order No. 81. In return both amendments were silent as how the country resolves the epidemic crises and how the country access to medicines in such crises. They should have introduced a provision in this regard like most of the developing countries have such as Brazil and India.

3 SAVING SEED, PLANTS AND PLANT VARIETIES UNDER TRIPS AGREEMENT AND IRAQI PATENT LAW

3.1 INTRODUCTION

Saving seed can be defined as 'the practice of saving seed yield from one harvest for future crop use'. Also, the Brown Bag Sale has been explained as it 'occurs when farmers purchase seed from seed companies, plant the seed in their own field, harvest the crop, and then sell the reproduced seed to other farmers for them to plant as crop-seed on their own farms'.[346] Traditionally farmers in both developed and developing countries replanted, exchanged or sold seed from previous year production. However, under the patent system farmers are not allowed to sell grown seed as its common especially in the developed countries that crops annual purchase is a rule. But this practice still rare in the developing countries, instead of informal reuse, exchange or sell is a normal practice.[347]

There are some international treaties and organizations that govern the patents of plants and seeds. The important ones are The International Convention for the Protection of New Varieties of Plants (hereinafter the "UPOV Convention") (Act of 1991), The World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) (1995), The World

[346] Kelly T. Crosby, 'The United States and Iraq: Plant Patent Protection and Saving Seed', *Washington University Global Studies Law Review*, 9.3 (2010), 511–34 (p. 511).

[347] *Commission on Intellectual Property Rights Final Report, Integrating Intellectual Property Rights and Development Policy* (London, September 2002), p. 58 <http://www.iprcommission.org/graphic/documents/final_report.htm> [accessed 21 September 2017].

Intellectual Property Organization (WIPO), International Treaty on Plant Genetic Resources for Food and Agriculture by Food and Agricultural Organization of the United Nations (hereinafter the "Plant Treaty") (2001),[348] and The Convention on Biological Diversity (hereinafter the "CBD"). Out of these international treaties, Iraq is a member of WIPO,[349] and most recently on accessed and became one of the contracting parties of the Treaty on 27 November 2017.[350] and is currently in the process of conceding TRIPS Agreement as well. The process of accession of Iraq to the TRIPS Agreement first initiated on 13 December 2004 and the working party met again for the second time in April 2008.[351]

Iraqi patent law is still in the process of evolution and not finalized yet. The first patent law in the Republic of Iraq was passed under the title of (The Patent Law and Industrial Design) Law No. 65 of 1970, which subsequently undergone many amendments. The first amendment was by Law No. 28 of 1999 and the second amendment implemented by Law No. 5 of 2002. However, after the invasion of Iraq by United States of America and Coalition partners, the Coalition Provisional Authority (CPA) under the ruler of Paul Bremer rewrote some of the laws of Iraq especially in the areas related to trade in general including the patent law. The CPA introduced the Order 81/26 on April 2004 under the title of (Patents, industrial design, undisclosed information, integrated circuits and plant variety Law).[352] Then, this title became the new amended title to the Law No. 65 of 1970 (The Patent Law and Industrial Design) and introduced 22 amendments to the patent section. Order 81/26 also made some amendments in regard

[348] Crosby, pp. 514–22.

[349] 'Information by Country: Iraq' <http://www.wipo.int/members/en/details.jsp?country_id=81> [accessed 31 July 2017].

[350] 'International Treaty on Plant Genetic Resources for Food and Agriculture, Official List of Contracting Parties Elaborated by the Legal Office of FAO' <http://www.fao.org/fileadmin/user_upload/legal/docs/033s-e.pdf> [accessed 13 November 2017].

[351] 'WTO | Accession Status: Iraq' <https://www.wto.org/english/thewto_e/acc_e/a1_iraq_e.htm#status> [accessed 26 July 2017].

[352] English version can be accessed through 'Order No. 81 Patent, Industrial Design, Undisclosed Information, Integrated Circuits And Plant Variety Law.' <http://www.wipo.int/wipolex/ar/text.jsp?file_id=181090> [accessed 26 July 2017].

to plant variety by adding chapter Three*quater* of Protection of New Plant Varieties which consists of 28 Articles. However, the Law No. 65 of 1970 amended in 2013 and chapter Three*quater* removed entirely and was replaced by a new law under the name of Law No. 15 of 2013 on Registration, Accreditation and Protection of Agricultural Varieties.[353] The study will examine amendments in intellectual property laws of Iraq on saving seeds (plant varieties) whether they are compatible with international treaties or there are further steps necessary to take.

3.2 INTERNATIONAL TREATIES THAT REGULATE THE PROTECTION OF VARIETIES AND PLANTS BY MEANS OF INDUSTRIAL PROPERTY RIGHTS

3.2.1 The World Intellectual Property Organization

WIPO as an international organization always tried to create an international patent system and to provide some minimum protection standards. However, as an agent of United Nations, the influence of developing countries on WIPO has been great. The developing countries were continuously tried to increase the standard of transfer of technology in one hand, but when it comes to the scope of patentable subject matters, WIPO has not been favoured for the inclusion of plant varieties.[354] The Paris Convention in which Iraq is a member country does not have any provision regarding the plant varieties.[355] However, in Patent Law Treaty,[356] which was passed by WIPO 'with the aim of harmonizing and streamlining formal procedures with respect to national and regional patent applications

[353] 'Law No. 15 of 2013 on Registration, Accreditation and Protection of Agricultural Varieties' <http://www.iraq-lg-law.org/ar/webfm_send/1447> [accessed 8 October 2017].
[354] David S. Tilford, 'Saving the Blueprints: The International Legal Regime for Plant Resources', *Case Western Reserve Journal of International Law*, 30 (1998), 373 (pp. 405–6).
[355] *Implications of the Trips Agreement on Treaties Administered by WIPO*, ed. by Organización Mundial da Propiedade Intelectual (Xenebra) (Genève: WIPO, 1997), p. 48.
[356] 'Patent Law Treaty' <http://www.wipo.int/wipolex/en/details.jsp?id=12642> [accessed 31 July 2017].

and patents and making such procedures more user friendly',[357] Article 3 (1) (a) states that the provisions of Patent Law Treaty 'shall apply to national and regional applications for patents for invention and for patents of addition'. In the Explanatory Notes on The Patent Law Treaty and Regulations Under The Patent Law Treaty, which are prepared by the International Bureau of the WIPO stated that if a plant is the result of a genetic engineering, then application for patents of such plants are allowed under the Patent Treaty Law.[358] Even though Iraq is a member state of WIPO, but Iraq is not a contracting party to the Patent Treaty Law,[359] therefore, not bound by the provisions of the Patent Treaty Law.

3.2.2 International Treaty on Plant Genetic Resources for Food and Agriculture by Food and Agricultural Organization of the United Nations (Plant Treaty)

The origin of the Plant Treaty goes back to the voluntary International Undertaking on the Plant Genetic Resources adopted by the Commission on Genetic Resources for Food and Agriculture in 1983. The international Undertaking's objective was to 'make plant genetic resources available for plant breeding, recognizing that they were a "heritage of mankind" and available to all'.[360] Later on in 1996 the Global Plan of Action at the Leipzig International Technical Conference on Plant Genetic Resources adopted. All these works then adopted by the Commission on Genetic Resources for Food and Agriculture in 2001 as a legally binding international treaty and

[357] 'Patent Law Treaty (PLT)' <http://www.wipo.int/treaties/en/ip/plt/> [accessed 31 July 2017].

[358] 'Explanatory Notes on The Patent Law Treaty And Regulations Under The Patent Law Treaty', para. 3.03 <http://www.wipo.int/export/sites/www/treaties/en/ip/plt/pdf/plt_notes_pubxex.pdf> [accessed 31 July 2017].

[359] 'Patent Law Treaty (Geneva, 2000) Contracting Party Status on July 15, 2017' <http://www.wipo.int/export/sites/www/treaties/en/documents/pdf/plt.pdf> [accessed 31 July 2017].

[360] Charles Lawson, 'Implementing Farmers' Rights: Finding Meaning and Purpose for the International Treaty on Plant Genetic Resources for Food and Agriculture Commitments?', *European Intellectual Property Review (EIPR)*, 37.7 (2015), 442–54 (p. 443).

entered into force on 29 June 2004. [361] The objectives of the Plant Teary as stated in Article 1 are 'the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use'. Farmers' rights were considered key element during the adoption in 2001 of the Plant Treaty and entering into force of the Treaty in 2004.[362] Article 9 of the Plant Treaty dedicated to the Farmers' Rights and recognizes and justifies the rights that farmers have due to the 'enormous contribution that the local and indigenous communities and farmers of all regions of the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world.' [363] The Plant Treaty further stated that nothing in Article 9 under Farmers' Rights shall be interpreted in such a way as to limit the farmers' rights to save, use, exchange and sell farm-saved/propagating materials.[364] It is clear that the Treaty doesn't want any contracting party to limit the farmers' rights which help and develop plant genetic resources as a production basis of foods and agriculture. However, it has to be taken into account that FAO does not address all the rights of the farmers, for example the rights of those farmers in regard of those plant varieties commercialised from their farm germ plasm.[365] The Plant Treaty also does not provide for intellectual property rights.[366] Currently Iraq is one of the contracting parties as accessed the Treaty on 29 August 2014 and entered into force on 27 November 2014.[367] The entry into force of the Treaty is

[361] 'Overview | International Treaty on Plant Genetic Resources for Food and Agriculture | Food and Agriculture Organization of the United Nations' <http://www.fao.org/plant-treaty/overview/en/> [accessed 13 November 2017].
[362] Lawson, p. 442.
[363] *International Treaty on Plant Genetic Resources for Food and Agriculture*, 2004, Article 9.1 <http://www.fao.org/3/a-i0510e.pdf> [accessed 14 November 2017].
[364] *International Treaty on Plant Genetic Resources for Food and Agriculture*, Article 9.3.
[365] Michael Blakeney, 'Protection of Plant Varieties and Farmers' Rights', *European Intellectual Property Review (EIPR)*, 24.1 (2002), 9–19 (p. 12).
[366] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 353.
[367] 'International Treaty on Plant Genetic Resources for Food and Agriculture, Official List of Contracting Parties Elaborated by the Legal Office of FAO'.

one year after the last amendment of the Law No. 65 of 1970 in 2013 and enacting Law No. 15 of 2013 on Registration, Accreditation and Protection of Agricultural Varieties.

However, as stated in the preamble of the Plant Treaty that 'Affirming that nothing in this Treaty shall be interpreted as implying in any way a change in the rights and obligations of the Contracting Parties under other international agreements; Understanding that the above recital is not intended to create a hierarchy between this Treaty and other international agreements'. The language of the preamble is clear enough that contracting parties cannot escape any obligations they have under other international agreements, even though they have joined them later than the Plant Treaty.[368] This means that even if Iraq in the future will join the TRIPS Agreement, yet it still has to comply with the high standard of intellectual property rights that the TRIPS Agreement provided for, especially in the area of patent and breeders' rights, even though Iraq is one of the contracting parties of the Pant Treaty.

3.2.3 Convention on Biological Diversity (CBD)

The United Nations Environment Programme (hereinafter "UNEP") responded to the wide spread acknowledgment of importance of biological diversity to present and future generations, and to threats to species and ecosystems caused by human activities, by establishing some Ad Hoc Working Groups that started from 1988 to 1991, and by 1992 they agreed on the final version of the text which they have provided, and the CBD came into existence. The Ad Hoc Working Group while discussing the creation of a legal text, they had to take into consideration 'the need to share costs and benefits between developed and developing countries as well as ways and means to support innovation by local people.'[369] The CBD is an attempt for creating an international regulation for the purpose of conservation and utilization of biological resources. The CBD

[368] Lawson, p. 447.
[369] 'History of the Convention on Biological Diversity, Introduction' <https://www.cbd.int/history/> [accessed 18 November 2017].

recognizing that the genetic resources and crop diversities are centred in less developed countries. However, the language of the CBD is considered vague language because the CBD tried to satisfy the needs of all. For that reason, the CBD contains provisions for the protection of Intellectual Property rights, transfer of technology, and accesses to genetic resources and results and benefits that arise from biotechnologies, which should all be based on mutually greed terms by both developed and developing countries. These are the outcome of the political deal that brought the CBD into existence.[370]

Genetic resources are defined as 'genetic materials of actual or potential value' which refers to any 'any material of plant, animal, microbiological or other origin containing functional units if heredity' as defined by Article 2 of the CBD. Therefore, seeds, cuttings and even DNA of the plants are all covered within the scope of the CBD. In principle the CBD is a convention mainly concerned with the farmers' rights. Hence many developing countries tried to incorporate as many provisions as possible into the TRIPS Agreement. Because TRIPS Agreement is part of the package of WTO and any country (whether it is a developed or less developed) wishes to join the WTO has to incorporate the TRIPS Agreement and comply with all its provisions. As some developed countries like the United States of America not ratified the CBD. The important provisions of the CBD that of the farmers' rights inserted into the TRIPS Agreement are only those apparent in Article 27 of the TRIPS Agreement which is related to patents and in particular Article 27 (3) which every member country has to provide some sort of protection of plant varieties whether through a patent or *sui generis* system or both. [371] Enforcement of other provisions of the CBD through the TRIPS Agreement is opposed by some developed countries such as United States of America, Japan and Switzerland.[372]

[370] Blakeney, 'Protection of Plant Varieties and Farmers' Rights', p. 14.
[371] Blakeney, 'Protection of Plant Varieties and Farmers' Rights', pp. 14–15.
[372] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 398.

Iraq has acceded to the CBD in 2009.[373] However, implementation of the CBD has considered by some policy makers and members of civil society to cause some conflicts with implementation of the TRIPS Agreement when in future Iraq becomes party to the TRIPS Agreement. According to them in the TRIPS Agreement interest of private commerce is placed above the interest of public and reduced other objectives of public policy.[374] On the contrary to that opinion some others are of the belief that contracting parties can implement both of the CBD and TRIPS Agreement without any conflict and in fact it is what expected from them to do. Since this is the normal principle of international law that countries are members of different bilateral and multilateral agreements and they are in fact implementing all these agreements in the same time, in a manner that does not cause any conflict and they considered to perform their obligations.[375]

3.2.4 The International Convention for the Protection of New Varieties of Plants (UPOV Convention) (Act of 1991)

The UPOV Convention was first drafted in 1961 and came into force in 1968 when the United Kingdom, the Netherlands and Germany, as first countries ratified the UPOV Convention. The UPOV Convention has undergone three revisions in 1972, 1978 and 1991.[376] These revisions were not in favour of seed users and farmers but were in favour of the corporate breeders. Initially the UPOV Convention of 1991 had limited members, but after the TRIPS Agreement obliged that every member country should have an intellectual property rights for the protection of plant varieties, and also through the trade agreements between some developed and non-

[373] 'Convention on Biological Diversity, Iraq - Country Profiles' <https://www.cbd.int/countries/default.shtml?country=iq> [accessed 21 November 2017].
[374] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, pp. 404–5.
[375] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 350.
[376] 'UPOV Lex' <http://www.upov.int/upovlex/en/upov_convention.html> [accessed 21 November 2017].

industrial less developed countries, members of the UPOV Convention has increased.[377]

The UPOV Convention is considered as a *sui generis* form of intellectual property protection[378] that includes the rights of plant breeders and intellectual property rights of plant varieties.[379] Even though Article 27 (3) (b) of the TRIPS Agreement only mentioned the word '*sui generis* ' without anything about the UPOV Convention, however majority member countries of the TRIPS Agreement, while implementing the requirement of having intellectual property protection of plant varieties, they incorporate the UPOV Convention into their legal system.[380]

Although the rights of the farmers and seed savers after every revision of the UPOV Convention were narrowed and the rights of the corporate breeders strengthened further.[381] After every revision, duration of protection increased as well. In the previous Act of 1978 the duration of protection was 18 for trees and vines, and 15 for other plants. However, in the current UPOV Convention of 1991 the minimum duration of protection as stated in Article 19 is 25 years for trees and vines, and 20 years for other plants from the date of granting protection. However, the UPOV Convention of 1991 provides for some exceptions to the Breeder's right, which some of them categorised as compulsory exceptions under Article 15 (1) and the other as optional exception which provided in Article 15 (2) of Act 1991 of the UPOV Convention. The optional exception is new and

[377] 'GRAIN — UPOV 91 and Other Seed Laws: A Basic Primer on How Companies Intend to Control and Monopolise Seeds', 2015, p. 4 <https://www.grain.org/article/entries/5314-upov-91-and-other-seed-laws-a-basic-primer-on-how-companies-intend-to-control-and-monopolise-seeds> [accessed 21 November 2017].

[378] Rolf Jördens, 'Progress of Plant Variety Protection Based on the International Convention for the Protection of New Varieties of Plants (UPOV Convention)', *World Patent Information*, 27.3 (2005), 232–43 (p. 232) <https://doi.org/10.1016/j.wpi.2005.03.004>.

[379] Pratibha Brahmi and Vijaya Chaudhary, 'Protection of Plant Varieties: Systems across Countries', *Plant Genetic Resources*, 9.3 (2011), 392–403 (p. 392) <https://doi.org/10.1017/S1479262111000037>.

[380] Jördens, p. 239.

[381] 'GRAIN — UPOV 91 and Other Seed Laws: A Basic Primer on How Companies Intend to Control and Monopolise Seeds', p. 4.

allows farmers to save seeds under certain conditions in such a way that interest of the breeder is not undermined.[382]

3.2.4.1 Compulsory Exception

Article 15 (1) of the UPOV Convention of 1991 provided some compulsory exception and the first of such exceptions is 'acts done privately and for non-commercial purposes.' This means that the act has to be done for private purposes and at the same time for non-commercial purposes. If one of these two elements is not available the exception does not apply. For example, if seeds of protected variety are saved by a farmer in his own farm but used for commercial purposes, then the exception does not apply and authorisation from the breeder is required. However, if the same seeds are to be used in his own gardens without sharing them with others or the farmer use the production of the protected seeds only for consumption by himself, his families and those dependents on him for living such as subsistence farming, then these acts will fall within the scope of Article 15 (1) (i) in which breeder's authorisation is not required.[383]

The second compulsory exception is provided for under Article 15 (1) (ii) are 'acts done for experimental purposes'. This simply includes all acts done by any one for the experimental purposes, and it's called 'research exemption'[384]. The third and last compulsory exceptions to the breeder's right is 'acts done for the purpose of breeding other varieties' unless it is 'essentially derived from the protected varieties, not clearly distinguishable from the protected variety or its production requires the repeated use of the protected variety', as stated in Article 14(5). The second part of the third compulsory exception is 'acts referred to in Article 14 (1) to (4) in respect of such other varieties', which they are (multiplication,

[382] Jördens, p. 235.

[383] *Explanatory Notes on Exceptions to The Breeder's Right Under the 1991 Act of the UPOV Convention*, 22 October 2009, p. 5 <http://www.upov.int/edocs/expndocs/en/upov_exn_exc.pdf> [accessed 21 November 2017].

[384] David J. Jefferson, Alex B. Camacho, and Cecilia L. Chi-Ham, 'Towards a Balanced Regime of Intellectual Property Rights for Agricultural Innovations', *Journal of Intellectual Property Rights*, 19 (2014), 395–403 (p. 398).

conditioning, offering, marketing, etc). The third compulsory exception also called 'breeder's exemption'.[385]

3.2.4.2 Optional Exception

The UPOV Convention of 1991 named Article 15 (2) an optional exception, and also the text of the provision with the phrase of 'each Contracting Party may' clearly suggests that it is an optional provision. Therefore, the contracting parties have choice to implement it or not, and if decided to adopt the optional exception, then farmers are allowed to use the product (seed) of their harvest for propagating purposes. However, the product has to be obtained by planting on their own holding (Article 15 (2)). The Diplomatic Conference of 1991 of the UPOV Convention limited the saving seed practice to those seeds that only considered as a common practice on the land of the Contracting Party. In the Diplomatic Conference was of the opinion that this provision cannot be presented as a 'farmer's privilege' and cannot be extended to areas of agricultural or horticultural production in which replanting saving seeds are not common practice. This means that other areas in which the production of the harvest is not used for replanting as a common practice such as production of fruits, ornamentals and vegetables, cannot be covered by the optional exception of the UPOV Convention.[386]

The phrase of 'within reasonable limits and subject to the safeguard of the legitimate interests of the breeder' is a requirement that all member countries have to take into consideration while implementing the optional exception. Even though inclusion of the optional exception into the UPOC Convention of 1991 is recognition of saving seed practice by some countries, but the process has to be applied on a crop by crop basis according to the member country in such a way that does not prejudice the legitimate interests of the

[385] Max Thiele-Wittig and Paul Claus, 'Plant Variety protection—A Fascinating Subject', *World Patent Information*, 25.3 (2003), 243–50 (p. 246) <https://doi.org/10.1016/S0172-2190(03)00074-7>; *Explanatory Notes on Exceptions to The Breeder's Right Under the 1991 Act of the UPOV Convention*, p. 6.

[386] *Explanatory Notes on Exceptions to The Breeder's Right Under the 1991 Act of the UPOV Convention*, pp. 8–9.

breeder and does not weaken the objectives and incentives that provided by the UPOV Convention.[387] The purpose of all these exceptions in general is creating a balance between rewarding innovations in plant varieties and use of these protected innovations for benefits of society as a whole.[388] This will certainly depend on each member state individually and during implementing this provision the concerned member state has to consider all relevant factors in order to arrive to such balanced legislation of plant variety protection. Iraq currently is not one of the Members of UPOV, however when expressed an interest of becoming Member of UPOV and participate in the sessions of the Council, Iraq accepted by the Office of the Union to be an observer of the Council of the UPOV.[389]

3.2.5 Saving Seeds under TRIPS Agreement

TRIPS Agreement is considered unique in nature as it includes minimum standard of patentable objects. Before TRIPS Agreement patent principles regulated by Paris Convention, as it allowed states liberally to exclude from patentability. Article 27 of the TRIPS Agreement is considered one of the important Articles of the TRIPS Agreement as it regulates the patent. The subject of patent is a commercial subject and highly affecting the livelihood of all the members and in particular the less developed countries. In general, Article 27 of the agreement requires the Member countries to grant patent if the conditions of paragraph 1 met and not lawfully excluded from patentability according to paragraphs 2 and 3 of Article 27. Even though Article 27 should provide for minimum standard of protection rights but paragraph 1 stated that 'patents shall be available for any inventions, whether products or processes', which is considered as a

[387] Rolf Jördens and Peter Button, 'Effective System of Plant Variety Protection in Responding to Challenges of a Changing World: UPOV Perspective', *Journal of Intellectual Property Rights*, 16 (2011), 74–83 (p. 77).
[388] Jefferson, Camacho, and Chi-Ham, p. 398.
[389] 'UPOV Observers' <http://www.upov.int/members/en/observers.html> [accessed 25 November 2017]; 'Rules Governing the Granting of Observer Status to States, Intergovernmental Organizations and International Non-Governmental Organizations in UPOV Bodies' <http://www.upov.int/edocs/infdocs/en/upov_inf_19.pdf> [accessed 25 November 2017].

very high standard of protection. This part of paragraph 1 directed to the developing countries as it was practice of many of them to exclude patentability of many areas though the general conditions of being 'new, involve an inventive step and are capable of industrial application' were available. Therefore, developing countries should provide for patents for all the areas unless it's provided for exclusions under paragraphs of 2 and 3.[390]

The generality of Article 27.1 of the TRIPS Agreement caused some disagreement among member countries. One of the controversial areas that includes in Article 27.1 is biotechnology related inventions. TRIPS Agreement does not provide any rules to regulate biotechnology related inventions. However, Article 27.3 (b) which is an exception clause stated that the members are allowed to exclude from patentability plants and animals. Also, Article 27.2 provides for very general exceptions on the ground of *ordre public* and morality, which can be relied on in cases where members could not avoid patentability on bases of Article 27.3.[391]

3.2.5.1 Article 27.3 (b) of the TRIPS Agreement

The provision of Article 27.3 (b) is a complex provision and it reflects the position of most of the developing countries and some developed countries as well. The developing countries during the time of Uruguay Round (during the negotiation of the TRIPS Agreement) were not experienced enough to evaluate any provisions related to the field of biotechnology. Furthermore, some developed countries such as Canada was reluctant to submit to full patentability according to Article 27.3 (b), as there was a debate at national level whether to accept the patentability of higher life forms. Therefore, during the Uruguay Round Canada was reluctant to accept the patentability of higher life forms in Article 27.3 (b).[392] Since the TRIPS Agreement has come into existence the differences among developed countries reduced but not eliminated as to what should be patented and excluded

[390] Stoll, Busche, and Arend, pp. 470–71.
[391] Stoll, Busche, and Arend, pp. 481–82.
[392] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 322.

from patentability. In the United States of America plant varieties and animal races are subject to protection while in Europe they are not.[393] The origin of patentability of living things is relatively new in developed countries, as it traces back to 1930s in the United States of America and as for the plant varieties and breeders' rights it started to exist in second half of the twentieth century.[394]

Article 27.3 (b) allows the patentability of micro-organism, micro-biological processes for the production of plants and animals, and non-biological processes for the productions of plants and animals. However, members are allowed to exclude from patentability 'whole animal (including, obviously, human beings), animal varieties and parts of animals (including parts of human beings); whole plants and plant varieties (provided an alternative system of protection is provided) and parts of plants; and essentially biological process.'[395] Article 27.3 (b) gives some flexibilities for protection of plant varieties, however, the provision enforces the member countries to provide some form of protection through patent or any form of *sui generis* . This causes problems to the developing countries as most of them never have any form of protection to the plant varieties and this caused concern for them as any form of protection will have huge impact on their farming practices especially in the area of seed saving and exchanging, genetic diversity and food security. For that reason, during the negotiations most of the developing countries backed up by European Community countries rejected the proposal forwarded by the United States, Japan, the Nordic countries and Switzerland. They proposed that plants and living organisms to be widely covered and protected by patent. [396]

A question may arise here: what is Plant variety? Since the TRIPS Agreement does not provide a definition for it. However, in order to

[393] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 388.

[394] *Commission on Intellectual Property Rights Final Report, Integrating Intellectual Property Rights and Development Policy*, p. 58.

[395] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 323.

[396] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 390-391.

understand what Plant Variety is, one can look at other conventions such as the UPOV convention and also more clear definition can be found in a ruling of European Patent Office in 1995 of (Greenpeace v Plant Genetic Systems NV) by refereeing to the UPOV Convention as well. The Technical Board of Appeal of the European Patent Office in the Reasons for the Decision stated that plant varieties as a concept refers to:

'any plant grouping within a single botanical taxon of the lowest-known rank which, irrespective of whether it would be eligible for protection under the UPOV Convention, is characterised by at least one single transmissible characteristic distinguishing it from other plant groupings and which is sufficiently homogeneous and stable in its relevant characteristics'[397]

Even though Article 27.3 (b) permits member countries to exclude from patentability plant varieties including hybrids, plant cells, seeds and other plant materials, but they should provide some type of protection through patents, *sui generis* or a combination of both. Under this provision it is stated that the *sui generis* has to be an effective *sui generis* system in protecting the plant varieties, therefore the content and scope of the system is left to the discretion of the member countries to choose. Again, this flexibilities and choices is due to the disagreement among the industrialized countries, as in USA, Japan and Australia patenting of plant varieties were allowed but this is not the case in Europe.[398]

3.2.5.2 Sui generis System

The system of *sui generis* for protecting the plant varieties is not new. During 1920s and 1930s some countries introduced a protection system different from patent protection for the purpose of breeders' rights and called it *sui generis* system. Breeders' rights also rely on

[397] European Patent Office, 'T 0356/93 (Plant Cells) of 21.2.1995', para. 23 <https://www.epo.org/law-practice/case-law-appeals/recent/t930356ex1.html> [accessed 3 October 2017].

[398] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 392-394.

features such as new, distinct, uniform and stable in order to protect the plant varieties. Under the breeders' rights the specific and existing plant variety will be protected and allows the farmers to re-use the seeds obtained by their own and the protected variety can be used in extra breeding without permission from the title holder and this called the (Breeders' exemption). The *sui generis* system spread around world and adopted by many countries especially when the UPOV Convention adopted during 1960s.[399] The UPOV Convention described as an inbuilt balance which not only allows farmers to save seeds for future uses, but farmers allowed to use new varieties a couple of times on his own farm for the purpose of multiplication. The UPOV Convention is very useful for the researchers as it allows the protected varieties to be used for new selections.[400] Article 15 (1) (ii) of the UPOV Convention of 1991 is dedicated for one of the compulsory exceptions to the Breeder's Right, in which stated that breeder's right shall not extend to 'acts done for experimental purposes'.

Although the developed countries possess most of the industrial technologies in the area of biotechnology, the vast majority of the biodiversity exists in the developing countries, which can be considered as the source of current developments. However, only the developing countries mostly affected (negatively) by the strong patent system. Usually developing countries' fears arise when the patent or any intellectual property right system prevent small scale and medium scale farmers and breeders from re-using the saved seeds as their traditional practice in developing countries. Also relying on small numbers of protected seeds may eliminate the varieties of existing seeds and affect the biodiversity of the land. Patenting some types of genes and plant varieties that are necessary for surviving some

[399] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, pp. 394–95.

[400] Koffi Dogbevi, *The Sui Generis System of Plant Variety Protection Under the TRIPS Agreement: An Empty Promise for Developing Countries* (Rochester, NY: Social Science Research Network, 1 April 2017), p. 30 <https://papers.ssrn.com/abstract=2961801> [accessed 21 November 2017].

developing countries, reduce the chances of further research and breeding when necessity required doing so.[401]

3.3 SAVING SEED UNDER INTELLECTUAL PROPERTY LAWS OF IRAQ

3.3.1 Law No. 50 of 2012 on Seeds and Seed Tubers

The Iraqi government recognized the importance of seed to the country since 1927, the year in which legislation was passed by in order to enhance the production of cotton through improved seed. The latest attempt by Saddam's Regime was in 1995 when National Seed Board (hereinafter the "NSB") was established and chaired by the Ministry of Agriculture. Under the NSB many research centres established for the purpose of seed production and supply among others.[402] The current governing system which is considered a democratic system of government tries its best to align its laws with international laws. Therefore it has passed some laws such as Law No. 50 of 2012 on Seeds and Seed Tubers, which is a new attempt to organize and encourage seed production in both public and private sectors.[403] Under this law, section 2 states the aims of the Law and in subsection two states that the second aim of this law is to 'guarantee the registration, accreditation and protection of new agricultural varieties that bred by researcher of Republic of Iraq, including those varieties that previously registered and accredited, and to provide enough quantities to be given to farmers in suitable times, prices and locations, and to ensure special procedures to authenticate the seeds and related matters'. The Law guarantees the registration, accreditation and protection of new agricultural varieties bred by Iraqi researchers including those varieties that previously registered and

[401] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 410.

[402] Awas Issa Abbas, *Focus on Seed Programs The Seed Industry in Iraq* (WANA Seed Netwok, 2001), pp. 2–3 <https://www.seedquest.com/statistics/pdf/Iraq2001.pdf> [accessed 7 October 2017].

[403] Law No. 50 of 2012 on Seeds and Seed Tubers, sec. 2 (1) <http://extwprlegs1.fao.org/docs/pdf/irq145545.pdf> [accessed 8 October 2017].

accredited. Section 2 of the Law states the aim of the Law which primarily emphasizes on the varieties and seeds bred by Iraqi researchers and breeders without reference to varieties propagated outside Iraq as stated in Section 2.

However, chapter five of the Law deals with Trade of Seeds and Seed Tubers, consists of sections of 18 to 30, regulate trade and exchange of seeds and seed tubers that are produced, imported or exported. These sections give rights to producers, importers and exporters of seeds and seed tubers to apply for licence to produce, import or export seeds and seed tubers. This clearly gives rights of foreign and outside seeds and seed tubers to be registered, accredited and protected by Iraqi government. In the final step, the National Seed Board after getting recommendation from the competent authority[404] will grant approval to licence and can be renewed every three years.[405] This shows that this law encourages exchange of seeds and seed tubers and allow introducing foreign seeds into Iraqi market, without stating the protection duration. However, there are some conditions that have to be met before granting the licence of importing and releasing foreign seeds into Iraq. Section 18 of the Law No. 50 of 2012 on Seeds and Seed Tubers, states that application has to be made to the competent authority to get a licence, and sample has to be submitted for lab inspection before NSB grants permission. There is a book guidance of official varieties that all accredited and registered varieties recorded in order to be qualified to the program of seed authentication (verification).[406] The importer and imported foreign seeds and seed tubers has to comply with the conditions stated by the law No. 50 of 2012. For example, the importer should have a valid licence in order to import. The type, varieties and country of origin has to be fixed on the licence or permission papers that issued from official authority that recognized by the competent authority. The importer has to notify the NSB on any genetic alteration and the nature of the alteration. The imported seeds and seed tubers should

[404] The Competent Authority is defined by sec. 1 (14) of the Law No. 50 of 2012 on Seeds and Seed Tubers, as General Commission for Seed Inspection and Authentication.
[405] 'Law No. 50 of 2012 on Seeds and Seed Tubers', sec. 20 (1).
[406] 'Law No. 50 of 2012 on Seeds and Seed Tubers', sec. 8.

have been tested by the International Seed Testing Association (hereinafter the 'ISTA') or other international testing rules that verify the seeds authentication according to the laws of the country of origin, however, the system of authentication of the country of origin has been recognized by the Ministry (Ministry of Agriculture).[407] Also, the imported seeds and seed tubers have to be from varieties available and relied on in Iraq. Even though the Minister of Agriculture has authority in emergency situations and on suggestion by the NSB to allow the importation of limited seeds for limited period from varieties that are not relied nor accredited in Iraq but has been accredited in the country of origin with the condition that has similar agricultural environment to Iraq. If these conditions are not met the imported seeds and seed tubers have to be returned or destroyed, with exception to small quantities that can be kept for research purposes.[408]

The Law No. 50 of 2012 on Seeds and Seed Tubers regulate and encourage trades of local and foreign seeds. However, it does not protect the seeds and seed varieties in the sense of intellectual property protections that exist within patents and other *sui generis* systems. Therefore, it cannot be considered as an active *sui generis* system that required by Article 27.3 (b) of the TRIPS agreement.

3.3.2 The Intellectual Property Legislations

3.3.2.1 The situation before the Coalition Invasion

According to the document published by the Food and Agriculture Organization of the United Nations (hereinafter the "FAO") in 2015, Iraq as a whole is going through series of political, infrastructural and economic crises. These crises affected many areas of Iraqis' livelihoods including the agricultural sector and food production. After the 2003 invasion, FAO realised the disasters that happened to Iraq's bank seed, therefore started helping government in rebuilding seed industry.[409] Focusing on Iraq's agriculture is essential

[407] 'Law No. 50 of 2012 on Seeds and Seed Tubers', sec. 1 (1).
[408] 'Law No. 50 of 2012 on Seeds and Seed Tubers', secs 24–27.
[409] FAO, 'Iraq and FAO, Advancing Agricultural Technologies for Food Security and Resilience' (FAO, 2015), pp. 1–2 <www.fao.org/3/a-au080e.pdf>.

for the Iraqi people as it is one thing that they can always rely on in this uncertainty of the political future of the country. Flourishing the agricultural sector will always be a good answer to address the food security.[410]

Historically, Iraq is considered as a land of agriculture by virtue of the rivers of Tigris and Euphrates and their tributaries. This fertile soil made Iraq cradle land of some of the oldest great civilizations, and 'Iraq is an important primary and secondary centre of domestication for many crops such as wheat, barley, lentil, chickpea and medics… Cereal production occupies about 95% of the arable land.'[411] However, the original un-amended Patent Law which was introduced in 1970 (Law No. 65 of 1970) did not contain any rules to regulate the plant varieties. To illustrate that, section 3 of this law was allocated to subject matters or areas which cannot be patented did not contain any regulations in regard to livings whether animals, plants or anything related to them. This shows that before the invasion of Iraq, the Iraqi Government did not want to patent any living matters or process in this regard. Even after the 2003 invasion when CPA Order No. 81/26 April 2004 was introduced by the CPA (which amended the first Patent law of 1970), yet section 3 does not contain any regulation in this regard. However, the CPA Order No. 81 inserted a new chapter for protecting the plant varieties. After the invasion ended and after a few set of elections, the new parliament and the new government decided that the chapter for plant varieties protection should be repealed and replaced by a new Law No. 15 of 2013 on Registration, Accreditation and Protection of Agricultural Varieties.

3.3.2.2 The amendments of the CPA Order No. 81

CPA took upon itself the responsibilities to rebuild Iraq in every way including the legal system. The CPA administrator L. Paul Bremer III, through a series of Orders introduced many new rules and regulations to many areas of Iraqi Laws, including the intellectual property laws of Iraq. Through these changes the CPA wanted to

[410] Crosby, p. 527.
[411] Abbas, p. 1.

elevate the position of Iraq to the required international standard both economically and politically.[412] One of the Orders was the Order No. 81 of the CPA which added chapter Three*quater* (consists of 28 Articles) of Protection of New Plant Varieties and revolutionised the intellectual property protection as it is the first of kind in Iraq's Intellectual Property Laws. In its preamble the Order stated that the CPA to enhance the economic condition of the people of Iraq through important changes to the Iraqi intellectual property system. One of the significant changes was an addition and for the first time explicitly new plant varieties (livings) protected with a specific duration of time and the law provides punishment for its infringement. Article 1of the Order defined the word variety as:

> 'Any plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a breeder's right are fully met, can be defined by the expression of the characteristics resulting from a given genotype or combination of genotypes, distinguished from any other plant grouping by the expression of at least one of the said characteristics and considered as a unit with regard to its suitability for being propagated unchanged'[413]

However, when comparing this definition with the one provided by the UPOV Convention of 1991 in its Article 1 (vi) it shows that both of the definitions are same. This means that the Order copied the definition of variety from the UPOV Convention word by word. When it comes to the criteria of registration, the Order required the same criteria as those of the UPOV Convention of 1991. The plant variety has to be novel, distinctive, uniform and stable, in order to be registered and protected by the Order.[414]

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[412] Elizabeth Mirza Al-Dajani, 'Post Saddam Restructuring of Intellectual Property Rights in Iraq Through a Case Study of Current Intellectual Property Practices in Lebanon, Egypt, and Jordan.', *The John Marshall Review of Intellectual Property Law*, 6.2 (2007), 250–71 (pp. 250–51).

[413] 'Order No. 81 Patent, Industrial Design, Undisclosed Information, Integrated Circuits and Plant Variety Law.', Article 1 <http://www.wipo.int/wipolex/en/text.jsp?file_id=181090> [accessed 10 October 2017].

[414] 'Order No. 81 Patent, Industrial Design, Undisclosed Information, Integrated Circuits and Plant Variety Law.', Chapter Threequarter, Article 4.

3.3.2.2.1 *Novelty:*

The criterion of novelty as requested by the Order require that the variety propagating and harvesting has not being sold or transferred with the consent of the breeder for more than one year inside Iraq and for more than four years outside Iraq, but six years outside Iraq if related to trees and vines, at the date of filing the registration or at the date of priority provided for in Article 8 (A) of chapter three*quater*. According to Article 8 (A) of chapter three*quater* the applicant permitted to apply for right of priority within twelve months following the first registration. This right of priority is valid in all member countries of the WTO or other international agreement in this area in which Iraq is a member. This right of priority is also taken from Article 11 of the UPOV Convention of 1991. However, as mentioned earlier the fact is that Iraq up to this moment is not a member country of WTO. Thus, there was no reason for CPA to grand this favour to an organization (Member States) that cannot return back the favour in the same way. This was particularly right when Iraq was under occupation and was in need of favour from developed and even stabled developing countries.

3.3.2.2.2 *Distinctness:*

The requirement of distinctness of the variety is considered as a second criterion for granting protection to the new variety by Article 4 (B) of the Order. The new variety has to be clearly distinguishable from any other variety which considered a common knowledge. Any variety has been applied for granting intellectual property protection or for entering in the Register, will be considered as common knowledge if this process occurred before filing the application for new variety.[415] This article again is the exactly worded as written in Article 7 of the UPOV Convention of 1991 and has the same criterion of distinctness.

[415] 'Order No. 81 Patent, Industrial Design, Undisclosed Information, Integrated Circuits And Plant Variety Law.', chap. Threequater, 4 (B).

3.3.2.2.3 *Uniformity:*

The third criterion for a variety to be considered as a new variety is uniformity. Article 4 (C) of the Order requires the new variety has possessed adequate uniformity in its relevant characteristics. The Order stated that new variety acquire the uniformity criterion 'if it is uniform subject to the variation that may be expected from the particular features of its propagation'.

3.3.2.2.4 *Stability:*

The fourth requirement of new variety is stability as stated by Article 4 (D) of the Order. The stability acquired when the relevant characteristics of the new variety remain unchanged after repeated propagation or in the case of a particular cycle of propagation, at the end of each such cycle. The third and fourth criteria are also taken from the Articles of 8 and 9 of the UPOV Convention of 1991.

Another important element from the Order which is exactly taken from the UPOV Convention of 1991 is the duration of the breeder's right. Article 17 of chapter three*quater* of the Order stated that duration for protecting the new variety shall be twenty years from the date of filing the application. However, the protection period of trees and vines shall be twenty-five years.

3.3.2.3 The Law No. 15 of 2013

Sui generis system has a strong point in which provides for rights of both breeders and farmers in well balanced and equitable system. The Order also provides for the rights of breeder as it is stated in the UPOV Convention of 1991. However, one of the crucial area for every country is the farmer's right, especially for the developing countries. The UPOV Convention of 1991 provides some exceptions to the breeder's right in uses of new and protected variety for private and non-commercial purposes, experimental purposes and breeding other varieties with some exceptions. Another important exception to the breeder's right which is in favour of farmers in the way that developing countries, those countries in which their economy heavily

rely on small farmers can benefit from this optional exception as stated by the UPOV Convention of 1991:

> '[Optional exception] Notwithstanding Article14, each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety or a variety covered by Article14 (5)(a)(i) or (ii).'[416]

This exception was not taken into consideration by the CPA in Iraq while they had seen the situation of the fields and seed bank of Iraq which was destroyed by the invasion war.[417] Contrary to that the Order completely prohibited the farmers from 're-using seeds of protected varieties or any varieties mentioned in items 1 and 2 of paragraph (C) of Article 14 of this Chapter.'[418] This provision was in fact taken from the United States of American Patent Act, as the courts in USA interpreted the Act in companies' interest and prevent farmers from saving, reuse, or resale protected seeds.[419] This shows that in some situations the Order failed to follow the UPOV Convention of 1991 and regulate laws that are in best interest of Iraqi farmers.

It is worth mentioning that the Law No. 15 of 2013 on Registration, Accreditation and Protection of Agricultural Varieties replaced the CPA Order No. 81 and regulated the protection of new varieties in different way. The Law No. 15 of 2013 consists of 20 sections only and without giving details on some issues. The criteria of protection of new varieties stated in section 3 are without dedicating any special subsection to each criterion and without

[416] 'International Convention For The Protection Of New Varieties Of Plants. Act of 1991', Article 12 (2) <http://www.upov.int/export/sites/upov/upovlex/en/conventions/1991/pdf/act1991.pdf> [accessed 9 October 2017].

[417] Elizabeth Finkel, 'Scientists Seek Easier Access to Seed Banks', *Science*, 324.5933 (2009), 1376–1376 (p. 1376) <https://doi.org/10.1126/science.324_1376>.

[418] 'Order No. 81 Patent, Industrial Design, Undisclosed Information, Integrated Circuits and Plant Variety Law.', Chapter Threequater, Article 15 (B).

[419] Crosby, p. 511.

defining them. Section 3 (3) of the Law stated that new variety, hybrid or progeny in order to be registered or accredited should have the stability, uniformity, distinctiveness characteristics, and have high genetic value and agricultural addition or new industrial application. These criteria should have been explained and defined as any other important legal terms. Every important legal term needs to be clarified in order to avoid misinterpretations. The rest of the section which consists of nine subsections is merely technical requirements for registration and accreditation.

Apart from that the Law No. 15 of 2013 provides for the breeder's rights in detail as well. However, the Law provides extra exception than the one provided by the Order. Section 12 (1) of the law states that the breeder's right shall not include acts by individual or companies whether private or public, or other public-sector bodies for personal un-commercial purposes or for experimental purposes or for breeding another new variety or hybrid. Section 16 (1) authorising minister on recommendation from the committee[420] to grant licence to others with the permission of the breeder of using the protected variety, hybrid or progeny if public interest required that. In this case the breeder will be awarded equitable monetary compensation in which the financial value of the licence has been taken into consideration by the neutral committee established for this purpose. Section 14 also reduced the protection period of the variety, hybrid or progeny to ten years from the date of filing the application, except varieties of trees and vines that shall be protected for twenty years.

3.4 CONCLUSION:

After the invasion of Iraq, the bank seed and seeds reserved in other ways were affected severely by the war and the invasion. War affected human resources as well, especially the scientists who migrated to outside of Iraq either because of poverty, unemployment or fear on their own lives. There was no need in what so ever to enact law for protection of biological varieties to the level of that of

[420] Section 1 (1) defined The Committee as the national committee for registration, accreditation, and protection of agricultural varieties.

developed countries as the CPA did. It becomes clear that the new Law is not regulated in such a better way than the Order was but provides for licences and shorter period of protection. However, by replacing the Order, it shows that the current Iraqi government believes that it is not yet in a situation and condition to enact a law equivalent to the international conventions but tries to fulfil the requirements of TRIPS Agreement by providing a protection to plant varieties in a form of *sui generis* system. Iraq should amend the Law No. 15 of 2013 so that get benefit from other international laws that Iraq recently became party such as International Treaty on Plant Genetic Resources for Food and Agriculture by Food and Agricultural Organization of the United Nations. Also comply in better way to international laws by increasing the duration of protection and best serve the interests of the Iraqi community by taking the advantage of the rights of saving seeds given to farmers by the UPOV Convention.

CHAPTER III: RIGHTS CONFERRED AND EXCEPTIONS TO PATENT RIGHTS IN THE TRIPS AGREEMENT AND IRAQI PATENT LAW

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1 PATENT AND RIGHTS CONFERRED

1.1 INTRODUCTION

The basic principle of granting patent is that the patent owner should have certain rights over his patented invention whether be a product or a process. In this regard the TRIPS Agreement has included special provision that confers certain rights to the patent owner. In this section the Article 28 of the TRIPS Agreement will be analysed in detail in order to find out the rights that are conferred to the patent owners. Article 33 and 34 of the TRIPS Agreement will also be analysed that regulate terms of protection and special circumstances of reversing burden of proof in cases that relate to process patents.

In line with this analysis, this section will turn into analysing the Iraq's position on how patent and rights conferred by the original law No. 65 of 1970 with reference to amendments especially the first amendment law No. 28 of 1999 and CPA Order No. 81. The relevant sections of the law and its amendments will be compared to the provisions of the TRIPS Agreement in order to find out the degree of compliance.

1.2 RIGHTS CONFERRED ACCORDING TO THE TRIPS AGREEMENT

The basic principle of the patent rights is to exclude others from exploiting the patented invention and to say 'no' to others. This means that patent is emphasizing on excluding others rather than the right to use by the patent owner, as the right to use emerges from economic freedom.[421] Therefore, the exclusivity confers negative rights, which is a legal tool in the hand of the patent owner to prevent others from utilising and performing some specific acts in regard of the invention,

[421] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 356.

rather than positive rights which gives the patent owner rights over his products and processes. The principle of exclusivity is inherent to patent grants, which allows the title holder to enjoy the invention exclusively in order to obtain economic gains during the lifetime of the patent which is 20 years from the filing date.[422]

Article 33 of the TRIPS Agreement[423] provides the minimum protection period of 20 years from the filing date and not from the grant of the patent. Therefore, member countries are not under obligation to provide for minimum effective protection, as there may be some lost of time between filing date and granting date of the patent, due to delay in examination process or marketing approval.[424]

Article 28.1 of the TRIPS Agreement states that 'A patent shall confer on its owner the following exclusive rights:', and states two situations according to the subject matter of the patent whether be a product or process. The content of Article 28.1 was inspired by Article 19 of the draft Patent Law Treaty as it was existed in 1990, as it was contained the standards that were considered common in industrialised nations.[425]

1.2.1 Where the subject matter of a patent is a product.

Article 28.1 lit. (a) of the TRIPS Agreement states that 'where the subject matter of a patent is a product' the patent owner has exclusive rights 'to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product'. The enumeration of acts that are mentioned in Article 28 in which the patent owner has power to prevent others is exhaustive, therefore, should be narrowly interpreted.[426] Footnote 6 of the TRIPS Agreement which provides elaboration on this point states that 'This right, like all other rights

[422] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 414.
[423] Article 33 of the TRIPS Agreement states that 'The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date'.
[424] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 343.
[425] Gervais, p. 374.
[426] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 296.

conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6'.

The definition of these terms in Article 28 have not been elaborated by the TRIPS Agreement, therefore, they have to be defined by the member countries according to their legal systems and practices, in accordance of Article 1.1 of the TRIPS Agreement.[427] The terms 'offering for sale' and 'selling' are legal terms and their meaning have to coincide with the system of the member country in their use according to civil or commercial law of the member country.[428]

The term 'making' literally refers to 'constructing, framing, creating, from parts or other substances'. However, if a different process was used in making the same product then the patent rights have not been infringed and it does not matter whether large or small quantities are produced. Since this provision does not elaborate on what include within the term of making, therefore, special consideration has to be given for acts of repair or modification of patented product. Nevertheless, the infringement in these cases will depend on the extent of such acts and the circumstances of the case.[429]

Recent developments have allowed some exception within the scope of Article 31*bis* of the TRIPS Agreement, in which manufacturing and making for purpose of exporting is not considered infringement if the conditions of compulsory licence under Article 31*bis* are met. Also, some member countries have considered some acts of making not infringement of exclusive rights within the meaning of Article 28.1 lit. (a) such as 'preparation in a pharmacy or by a medical doctor, of a medicine in accordance with a medical

[427] Article 1.1 of the TRIPS Agreement states that 'Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.'

[428] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 356.

[429] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 419.

prescription and for individual use',[430] within the scope of Article 30 of the TRIPS Agreement.

The term 'using' here refers to using in the commercial transaction. Using product for private or domestic purposes will not infringe the rights of the patent holder. Some uses have been considered not infringing the rights of the patent holders within the scope of Article 30, such as for the purpose of scientific research and experiment or uses under voluntary or compulsory licences.[431]

Evidently, uses of patented product which marketed by the patent owner or with his consent whether be domestically or internationally (exhaustion of rights has to be considered) will not be within the range of exclusive rights of the patent owner. The patent owner may prevent those uses that 'include for example activities of commercialization but not entailing sale, like renting, leasing or sales demonstrations'.[432]

Nevertheless, mere position or display of the patented product is within the scope of 'using' of the provision. On the other hand, utilization of patented products as parts of vehicles, aircraft or vessel, may be covered by this provision and the right holder has right to prevent such uses. Even though many countries have provided for exception in this case in accordance of Article 5*ter* of the Paris Convention.[433]

Article 5*ter* of the Paris Convention[434] provides for exception of patented devices that forming part of vessels, aircraft or land vehicles, as from the title of the Article. This is the only exception that deals

[430] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 296.

[431] Michael Blakeney, *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPs Agreement*, Intellectual Property in Practice (London: Sweet & Maxwell, 1996), p. 87.

[432] Stoll, Busche, and Arend, pp. 515–16.

[433] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 297.

[434] Article 5*ter* of the Paris Convention states that 'In any country of the Union the following shall not be considered as infringements of the rights of a patentee: 1. the use on board vessels of other countries of the Union of devices forming the subject of his patent in the body of the vessel, in the machinery, tackle, gear and other accessories, when such vessels temporarily or accidentally enter the waters of the said country, provided that such devices are used there exclusively for the needs of the vessel; 2. the use of devices forming the subject of the patent in the construction or operation of aircraft or land vehicles of other countries of the Union, or of accessories of such aircraft or land vehicles, when those aircraft or land vehicles temporarily or accidentally enter the said country'.

with infringement of patents. This exception was added on the basis of the French proposal at the Hague Revision of Conference in 1925 and stayed as it is since then. The main purpose of this exception is to limit the rights of the patent owner to protect the freedom of transport for the interest of public from the exclusive rights of the patent owner that may cause prejudice.

The term 'offering for sale', this include any activity with the aim of selling the patented product such as commercialization of the product. This has been differentiated from the term 'selling' in the provision because some member countries such as United States of America offering for sale is not considered an offence and there is no penalty for such act.[435] Also, offers to licence or lease will not be covered by this right, as it is explicitly states that include only offering for sale.[436]

The term 'selling' has to be interpreted narrower than the term of 'commercializing'. Because the patent owner has rights to prevent others from sale or resale of the infringing products only, and not those products that legitimately available in market whether the patent owner has put it in market, or available in market through a voluntarily or compulsory licences.[437]

The term 'importing' is very general which empowers the patent owner to prevent others from importing his patented product in all circumstances even if for non-commercial purposes or for free.[438] Nevertheless, the principle of exhaustion of rights under Article 6 has to be taken into consideration, as required by Footnote 6, while implementing the exclusive right to import. However, Article 31*bis* of the TRIPS Agreement, has recently provided for some exceptions under special compulsory licence for the purpose importing pharmaceutical products.

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[435] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 420.
[436] Stoll, Busche, and Arend, p. 516.
[437] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 297.
[438] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 420.

1.2.2 Where the subject matter of a patent is a process

Article 28.1 lit. (b) states that 'where the subject matter of a patent is a process' the patent owner has exclusive right 'to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process'.

Here according to the first part of the provision the patent owner has right to prevent the others from using his process to make products, and the process here refers to the method of making the product. Though in some member countries such as the United States of America beside the method of making, also method of use of the product can be protected if it is not suggested by the prior art, but Article 28.1 lit. (b) does not provide for such protection.[439]

According to the second part of Article 28.1 lit. (b) the protection is not limited to the process but rather extended to the acts of using, offering for sale, selling and importing of products that obtained directly by the patented process. This is an extra step that was not available in the majority of the member countries at the time of adoption of the TRIPS Agreement.[440] Almost all the developing countries did not protect the direct product of the patented process. On the other hand, in developed countries such as Germany this type of protection was provided for since 1891.[441] Article 5*quater* of the Paris Convention,[442] also provides that when a member of the Union provides protection to the production of the patented process, then this

[439] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 420.
[440] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 298.
[441] Stoll, Busche, and Arend, p. 517.
[442] Article 5*quater* of the Paris Convention states that 'When a product is imported into a country of the Union where there exists a patent protecting a process of manufacture of the said product, the patentee shall have all the rights, with regard to the imported product, that are accorded to him by the legislation of the country of importation, on the basis of the process patent, with respect to products manufactured in that country'

protection has to be extended to the imported products that have been made abroad by that process.[443]

Nevertheless, Article 28.1 lit. (b) is protecting those products that directly obtained by the protected process. The reason is that there are many products that can be obtained from different processes, therefore, simply proving that the product can be obtained by the protected process is not enough to be covered by this provision. In order to be covered by this protection, evidence has to be produced that the patented process was used in making the product. Though the term 'at least' indicates that the member countries may, but not under obligation, extend the protection to similar products that are not manufactured by the patented process.[444]

Differentiating between processes that make same product is important, because in the chemical sector similar products can be obtained through different processes. Therefore, in order for the extended protection apply to the products, it has to be proved that it was manufactured by the patented process. However, sometimes it is complicated, as the process of making the product involves some steps and not all these steps are patented. In this case in order for the product to be protected it has to be proved that no material or important steps outside the patented process were use in manufacturing the product.[445]

Article 34 of the TRIPS Agreement[446] is dedicated for burden of proof in cases (of civil proceedings) that concern the process patents,

[443] Ricketson, pp. 415–16.

[444] Correa, *Trade Related Aspects of Intellectual Property Rights*, pp. 298–99.

[445] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 421.

[446] Article 34 of the TRIPS Agreement states that '1. For the purposes of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process: (a) if the product obtained by the patented process is new; (b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable

where direct evidence of using the patented process in manufacturing is not available. Contrary to the normal standard of rules of evidence, Article 34.1 allows the judicial authority to reverse the procedural principles and put the burden of proof on the infringer to demonstrate that the patented process is not infringed.[447] This is based on the '*probatio diabolica'*, as it is very difficult for the patent owner of the process to prove that his patented process was used by the infringer to manufacture the products that are similar to the products that can be produced by his patented process, except in cases that he can access the process that made similar products.[448]

There are some conditions that have to be met in order for the judicial authority of the member countries to reverse the burden of proof. It has to be proved that the product is similar and identical to the product that can be produced by the patented process. Then, the member country has to implement a *prima facie* presumption that the product obtained by the patented process in two situations as states in Article 34.1 '(a) if the product obtained by the patented process is new, or (b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used'. Therefore, it has to be shown that the product for the first time manufactured by the patented process and such product is new, and that the patent owner has to show that he has taken every necessary step in his capacity to determine what process was used but was unsuccessful. The term 'substantial likelihood' has been defined as 'a

through reasonable efforts to determine the process actually used. 2. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the condition referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled. 3. In the adduction of proof to the contrary, the legitimate interests of defendants in protecting their manufacturing and business secrets shall be taken into account'.

[447] Gervais, pp. 408–9.

[448] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, pp. 496–97.

strong possibility based on the facts of the case and the available evidence'.[449]

Paragraph 2 of Article 34 of the TRIPS Agreement emphasizes that the member countries are free to reverse the burden of proof in only one of the above situations. These two cases exist because of disagreement between the European Commission and the United States of America. During the negotiation of the TRIPS Agreement, the European Commission preferred reversing burden of proof only in the first situation, while the United States of America favoured the second option.[450]

Paragraph 3 of Article 34 of the TRIPS Agreement is an effort to protect the interest of the alleged infringer by protecting his process in confidentiality, because there is a chance that the product manufactured by a different process than the patented process. Therefore, the alleged infringer has right to keep his process secret and the member countries have to take this into consideration while revering the burden of proof. This can be done by appointing an expert as a mediator, who has to keep the received information of the alleged infringer as confidential and during the court proceedings he can only disclose whether the process is the patented process or not.[451]

1.2.3 Rights to assign, transfer and licence

Article 28.2 of the TRIPS Agreement states that 'Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts'. This indicates that patents are assignable without any limitation, and they are transferable by succession as well. Nevertheless, the right of member countries of registration of the assignment and transfer are not precluded by this provision. The right of registration is within the power of member countries in order to protect the rights of third parties from the effects of the process of assignment and transfer.[452]

[449] Gervais, p. 409.
[450] Gervais, p. 409.
[451] Stoll, Busche, and Arend, p. 613.
[452] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 299.

This provision also confers the right to conclude licensing contracts. Therefore, the patent owner has rights to enter into agreements for the purpose of licencing the patent. However, this provision does not refer to cases in which the member countries are allowed to grant compulsory licence without or against the consent of the patent owner. According to Article 31 and 31bis of the TRIPS Agreement, member countries are allowed to grant compulsory licence. Therefore, the rights of the patent owner to conclude licensing contracts does not prevent the rights of the member countries of the TRIPS Agreement to impose the compulsory licence according to Article 31 and 31*bis*.[453]

According to Article 28.2 the patent owner has rights to grant licence and stipulate conditions of such contracts. Nevertheless, this provision does not prevent the member countries to practice their rights according to Article 40.2 of the TRIPS Agreement.[454] Thus, member countries have rights to insert in their domestic legislations licensing practices and conditions in order to control abuses of licensing agreements.[455]

1.3 IRAQ'S POSITION TO PATENT AND RIGHTS CONFERRED

Once patent granted, the right holder has legal monopoly over his invention and outcome of his invention whether be a process or a product. Section 12 of the original Patent and Industrial Designs Law No. 65 of 1970 clearly states that 'the patent shall confer upon owner of the invention exclusive right to exploit the invention by all legal means'. This is a direct grant of monopoly right to the inventor to use

[453] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 422.

[454] Article 40.2 of the TRIPS Agreement states that 'Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grant back conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.'

[455] Correa, *Trade Related Aspects of Intellectual Property Rights*, p. 300.

his invention whether be a process or product in all possible ways that law allows it. Nevertheless, this Section was amended by the CPA Order No. 81. Section 12 after the amended has two subsections,[456] one specified for patented product and the other for industrial process.

Section 12 lit. (a) provides that the patent shall prevent any person from using the patented product without licence whether for the purpose of making, exploiting, using, offering for sale, selling or importing that product. In the same way Section 12 lit. (b) states that no one allowed without authorisation of the patent owner to use the patented process or any product directly made by the patented process, offering for sale, selling, or importing the product. Noticeably, the amended Section 12 is more detailed because it has been taken from provisions of the TRIPS Agreement. These two subsections are almost the same as Article 28. 1. lits. (a) and (b).

However, Article 28 of the TRIPS Agreement has another provision which states that 'Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts'. However, the CPA Order No. 81 did not state this provision with the other two subparagraphs. Yet, in the original patent law No. 65 of 1970 some references can be found in Section 25 which has not been amended since then. Section 25 states that 'It is permissible to utilize the patent in all legal means possible, and to transfer its ownership including all rights attached to it through a succession. The patent right cannot be used against others except after its registration by the registrar, and the utilisation, mortgaging and transfer of its ownership will be announced accordingly'. However, over all the CPA Order No. 81 improved the exclusivity right of the patent owner by monopolising some specific acts which can be

[456] 'Order No. 81 Patent, Industrial Design, Undisclosed Information, Integrated Circuits And Plant Variety Law.' Section 12 amended to read as ' "A patent shall grant its owner the following rights: a) Where the subject of the patent is a product, the right to prevent any person who has not obtained the owner's authorization from making, exploiting, using, offering for sale, selling or importing that product. b) Where the subject of the patent is an industrial process, the rights to prevent any person who has not obtained the owner's authorization from using the process or the product directly made by the process, offering for sale, selling or importing the product.'<http://www.wipo.int/wipolex/en/text.jsp?file_id=181090> [accessed 10 October 2017].

performed by the patent owner, compare to the general statement of the original patent law No. 65 of 1970.

In neither the original Iraqi patent law No. 65 of 1970 nor the amendments that followed including the CPA Order No. 81, include any provision that regulate the burden of proof similar to Article 34 of the TRIPS Agreement. As it has been explained before, it is very difficult for the patent owner to prove whether his patented process was used to produce similar product that can be manufactured by his process. For this reason, Article 34 authorised the member countries to reverse the burden of proof and request the alleged infringer to prove that different process was used. CPA Order No. 81 should have added similar provision in order the owner of patented process enjoy better protection.

Section 13 of the original Law No. 65 of 1970 consisted of two paragraphs that regulate the protection period of patents. In the first paragraph it states that 'the protection period of patent is 15 years from the date of applying for patent or from the date of completion of documentations, and annually will be renewed by paying the fee as required by law'. The second paragraph was dedicated for protection of foreign patents within the territory of Iraq. As it is stated that 'the protection period of patents that have been registered outside Iraq will be the exact period that were granted in the foreign country, but the registration period inside Iraq shall not exceed 15 years, and the certified copy should be placed with the registration office and renewed annually according to the above paragraph'.

Nevertheless, this section repealed by the first amendment Law No. 28 of 1999 and replaced by new provision which stated that 'protection period is 20 years starts from the date of applying for patent, except for patents of medical and pharmaceutical formulations in which the protection period will be 10 years and can be extended twice for the period of 5 years each time, and all required documents have to be completed within 6 months from the application date, and annually will be renewed by paying the fee as required by law'. This clearly can be considered as a progress to the previous section by extending the protection period from 15 years to 20 years. However, provided for protection of medical and pharmaceutical formulations

which is not provided for by the TRIPS Agreement as the minimum protection period required by Article 33 of the TRIPS Agreement is 20 years from the filing date without any reference to medicines.

For this reason, the CPA Order No. 81 has tried to correct this situation and brings the Iraqi patent law in compliance with the TRIPS Agreement, by repealed section 13 for the second time and replace it with new provision as states that 'The term of duration of the patent shall not end before the expiration of a period of twenty years for registration under the provisions of this Law as from the date of the filing of the application for registration under the provisions of this Law.'

1.4 CONCLUSION

From Article 28 of the TRIPS Agreement it can be concluded that the nature of rights conferred to the patent owner is negative rights that exclude others from utilising the patented invention whether be a product or process for a certain period. Article 33 states that the patent owner has rights to exclude others from utilising his patented invention for at least 20 years from the filing date. Article 28.1 lits. (a) and (b) confer rights to exclude others from making, using, offering for sale, selling or importing patented products or products directly manufactured by patented process, and also prevent third parties to use the patented process without authorisation of the patented owner. The patent owner also has the right to assign, transfer and to conclude licensing contracts. Article 34 of the TRIPS Agreement provides for reverse of burden of proof in cases where similar products of patented process have been manufactured. In these cases, it is very difficult for the owner of the patented process to prove that the products are not manufactured by his patented process, therefore, the judicial authority of the member countries has the right to order the alleged infringer to prove that his products are not manufactured by the patented process. Nevertheless, his interests of keeping his process as a secret have to be considered by the member countries.

Section 12 of the original Iraqi patent law No. 65 of 1970 provided for rights conferred but the provision did not separate the patented product from patented process and did not mention anything

about the products that are directly manufactured by the patented process. Therefore, the CPA Order No. 81 rightfully repealed this section and replaced by another that provides for the rights conferred in detail and similar to Article 28.1 lits. (a) and (b) of the TRIPS Agreement. However, Article 28.2 is not included in the amendment of the CPA Order No. 81, therefore, for the purpose of more clarity and better compliance with the TRIPS Agreement, it should have added such provision within section 12, instead of section 25. The patent law No. 65 of 1970 lacks provision similar to Article 34 of the TRIPS Agreement that provide for reverse of burden of proof, and all the amendments did not touch this issue. CPA Oder should have added this provision to the law No. 65 of 1970 in order the owner of the patented process enjoy better protection.

2 EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS IN THE TRIPS AGREEMENT AND IRAQI PATENT LAW

2.1 INTRODUCTION

Intellectual property rights in general and in particular the protection of patent rights have expanded the power of exclusive rights of the patent holder to the extent that the developing countries could not hide their concerns. The concerns mostly are about the high standard of protection of individual interests of the patent holder over the interests of society, especially those related to public health and consumer protection.[457]

Normally patent offers exclusive rights in which others are not allowed to use patent holders' inventions without their authorization. Patent offers an important market benefit to the patent holder through monopoly. However, patent laws around the world have limited these exclusive rights of use in some circumstances and they call it 'exceptions to exclusive rights'. The purposes of these exceptions vary, they may be for non-commercial (such as private use and scientific research) or commercial use. They also can serve as the purpose of encouraging competitions or avoiding barriers to future scientific experiments.[458]

[457] Carlos María Correa, *Intellectual Property Rights And The Use of Compulsory Licenses: Options for Developing Countries* (South Centre, October 1999), p. 1 <https://www.iatp.org/files/Intellectual_Property_Rights_and_the_Use_of_Co.pdf> [accessed 21 March 2018].

[458] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 430.

This chapter discusses the exceptions that the TRIPS Agreement provides pursuant to its Article 30. This Article states the conditions and criteria that has to be followed when a member country needs to put exceptions to the rights conferred by the TRIPS Agreement which is exclusive rights of the patent holders. These criteria are going to be analysed and discussed in detail. There are many different exceptions, but since Article 30 does not mention any exception by name, therefore, this chapter will analyse some possible exceptions that can be categorised under the umbrella of this Article.

Next, the TRIPS Agreement provides for another exception that limits the exclusive rights of the patent holders, which is called 'compulsory licence'. To clarify that, Article 31 provides for some unexclusive grounds of grating the compulsory licence and conditions that have to be followed by a member country so that to grant compulsory licence or as Article 31 refers to it as 'other use without authorization of the right holder'. This chapter will also analyse all the subparagraphs of Article 31 in detail in order to examine their effects on granting compulsory licence and how to be applied by the member countries.

This chapter will further discuss and analyse Article 31*bis* of the TRIPS Agreement, as it is newly added Article to the Agreement that provides further limitation to the exclusive rights of the patent holder. Article 31*bis* provides for a particular compulsory licence in regard of pharmaceutical products. This Article will be discussed and analysed in detail with reference to the Annex of the TRIPS Agreement, and how can be applied in order to enable member countries to use it so that their public health needs are fulfilled.

The last section of this chapter will be dedicated for discussing and analysing the exceptions and limitations to the exclusive rights of the patent owner that provided by the Iraqi Patent and Industrial Designs Law No. 65 of 1970. In the first-place the position of the Iraqi patent law before the amendment will be discussed and analysed. Then, the amendments passed by the CPA Order No. 81 will be analysed while comparing to the original law before amendment and its suitability and improvements will also be analysed.

2.2 EXCEPTIONS TO RIGHTS CONFERRED UNDER THE TRIPS AGREEMENT (ARTICLE 30)

Article 30 of the TRIPS Agreement under the title of 'Exceptions to Rights Conferred', states that 'Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties'.

Different countries adopted different exceptions to exclusive rights of the patent holder. Some of the long established exceptions that are used by the countries all over the world at the time of negotiations of the TRIPS Agreement are; private and non-commercial use, experimental and scientific use, prior use, extemporaneous preparation of a medicine in a pharmacy, foreign vessels, aircraft or land vehicles, international civil aviation (chicago), regulatory review (bolar)[459], exhaustion of patent rights (national exhaustion and regional or international exhaustion),[460] and parallel imports (importation of products from a country where the product legally marketed). During the negotiation some of these exceptions proposed by developing countries to be included in the TRIPS Agreement, but it was rejected by the developed countries. The developed countries proposed a general language similar to that of Article 9 (2) of the Berne Convention, without stating any specific acts that could be exempted.[461]

[459] Named after a United States case of 'Roche Products, Inc. Appellant, v. Bolar Pharmaceutical Co., Inc., Appellee, 733 F.2d 858 (Fed. Cir. 1984)', *Justia Law* <https://law.justia.com/cases/federal/appellate-courts/F2/733/858/459501/> [accessed 11 March 2018].

[460] Christopher Garrison, *Exceptions to Patent Rights in Developing Countries* 'United Nations Conference on Trade and Development (UNCTAD), International Centre for Trade and Sustainable Development (ICTSD)*'* (International Centre for Trade and Sustainable Development (ICTSD), 2006), pp. 2–15.

[461] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 431-432.

Some other developed countries including the United States supported the idea that the member countries should have the right to restrict exclusive rights of the patent holder through compulsory licence only. However, at the end the TRIPS Agreement adopted the general formulation without stating any particular exceptions. This shows that there was a difference between the developed and developing countries, and even among the developed countries as well, which finally gave birth to Article 30 out of compromise. Article 30 is very similar to Article 9.2 of the Berne Convention. Article 9.2[462] of the Berne Convention has become a model for some other Article of the TRIPS Agreement such as Article 13 (Limitations and Exceptions to Copyright and Related Rights), Article 17 (Exceptions to Trademarks), and Article 26.2 (Protection of Industrial Designs).[463]

Nuno Pires de Carvalho is of the opinion that this article should be considered as a deviation from the general rule of the TRIPS Agreement that patent rights are exclusive. The general rule is stated in Article 28[464] of the TRIPS Agreement that the patent holder has exclusive right whether to protect the product or process of his invention and prevent other benefits from the invention without his consent. Therefore, Article 30 is an exception to the general rule and always should be dealt with in an exceptional way and its language

[462] 'WIPO-Administered Treaties: Berne Convention for the Protection of Literary and Artistic Works' Article 9 Right of Reproduction: 2. Possible Exceptions 'It shall be a matter for legislation in the countries of the Union to permit the reproduction of such works in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author.' <http://www.wipo.int/treaties/en/text.jsp> [accessed 11 March 2018].

[463] Stoll, Busche, and Arend, pp. 536–37.

[464] Article 28 of the TRIPS Agreement, Right Conferred 1. A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

with a restrictive manner. For de Carvalho, this Article is introduced in order to create a balance between rights and obligations as required by Article 7 of the TRIPS Agreement. Out of this member countries are not allowed to request further derogation from the general rule of exclusive rights of Article 28.[465]

However, others are of the opinion that member countries have more freedom while adopting the exceptions under Article 30 into their domestic patent legislation, especially in determining what act can be permitted with the nature and extent of the permitted act.[466]

2.2.1 The Criteria for the Application of Article 30

The moment TRIPS Agreement adopted by a member country, all the exceptions to the exclusive rights of the patent holder that exist under the domestic laws and future regulations in this regard have to be coincided with the tests and provisos of Article 30.[467] There are three criteria that should be met in order for exceptions successfully implemented under Article 30. The WTO Panel in *Canada-Pharmaceutical Patents*,[468] intensively analysed and interpreted the scope of exceptions under Article 30. Therefore, in analysing and discussing terms of this Article, the opinion of the Panel cannot be ignored and will be an important source of interpretation.[469] In the case of *Canada-Pharmaceutical Patents* it was held by the Panel that there are three criteria in Article 30 that have to be met in order for the

[465] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 377.
[466] Stoll, Busche, and Arend, p. 537.
[467] Garrison, p. 19.
[468] 'WTO | Dispute Settlement - the Disputes - DS114 Canada-Pharmaceutical Patents' ' On 19 December 1997, the EC requested consultations with Canada in respect of the alleged lack of protection of inventions by Canada in the area of pharmaceuticals under the relevant provisions of the Canadian implementing legislation, in particular the Patent Act. The EC alleged that Canada's legislation is not compatible with its obligations under the TRIPS Agreement, because it does not provide for the full protection of patented pharmaceutical inventions for the entire duration of the term of protection envisaged by Articles 27.1, 28 and 33 of the TRIPS Agreement. ' <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm> [accessed 3 May 2018].
[469] Rodrigues Jr and Edson Beas, p. 90.

member countries be able to adopt the exception. The criteria are; firstly, the exception must be limited, secondly, the exception does not unreasonably conflict with a normal exploitation of the patent, and thirdly, do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.[470]

Each criterion should be looked as related to each other and interpreted accordingly. However, each carries different meaning and must be complied to each of them separately. The Panel further explained that if an exception complies with the first condition but still there is chance to fail with other two conditions, or complies with the first two conditions, may still fail with the third conditions. Therefore, in order for an exception under Article 30 of the TRIPS Agreement to be permitted to limit the exclusive rights of the patent holder has to fulfil all the three conditions that are required by the Article.[471] The first condition is of a legal nature, while the other two conditions are related to economic influence of the exception.[472]

2.2.1.1 The Limited Exception

For the definition of 'limited' the Panel in the case of *Canada-Pharmaceutical Patents* referred to the interpretation of European Communities. According to the EC the word 'limited' can be described by words such as 'narrow, small, minor, insignificant or restricted'.[473] These words actually relate to measurement. Therefore, it can be said that this condition refers to some sort of quantification.[474] The Panel agreed with the opinion of the EC to give the word 'limited' a narrow connotation instead of broad meaning cited by the Canada. Even the Panel admitted that the word 'limited' may carry both of the narrow and broad meaning but in this context

[470] *Canada – Patent Protection of Pharmaceutical Products - Report of the Panel*, WT/DS114/R ON 17 MARCH 2000.
[471] *Canada – Patent Protection of Pharmaceutical Products - Report of the Panel*, WT/DS114/R ON 17 MARCH 2000, Paragraph 7.21.
[472] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 379.
[473] *Canada – Patent Protection of Pharmaceutical Products - Report of the Panel*, WT/DS114/R ON 17 MARCH 2000, Paragraph 7.28.
[474] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 379.

while combined with the word 'exception', it connotes a narrow meaning. The reason is that the word exception also refers to a limited derogation. Therefore, the phrase 'limited exception' connotes a narrow exception. An example is given by the Panel to explain the meaning of 'limited' which is 'a mail train taking only a limited number of passengers'.[475] Also the Panel was of the opinion that 'limited exception' can be determined by the extension of curtailment of the patent owner's rights and that has to be a small diminution of such rights.[476]

However, the Panel report in the case of *Canada-Pharmaceutical Patents* does not create any binding precedents and this report was not subject to appeal. Therefore, future panels and Appellate Body may change their mind in this regard and adopt the broader meaning that was proposed by Canada.[477]

2.2.1.2 The Exception Does Not Unreasonably Conflict with A Normal Exploitation

This condition requires that the exception does not unreasonably conflict with a normal exploitation of the patent. Therefore, it has to be determined what is unreasonable in particular circumstances and in what situation does it conflict with the normal exploitation of the patent.[478] The Panel in the case of *Canada-Pharmaceutical Patents* did not define the terms of unreasonable and conflict. Therefore, the member countries have flexibility in determining what does unreasonably conflict mean. However, the Doha Declaration on the TRIPS Agreement and Public Health states that in accordance with the customary rules of interpretation of public international law, the

[475] *Canada – Patent Protection of Pharmaceutical Products - Report of the Panel*, WT/DS114/R ON 17 MARCH 2000, Paragraph 7.30.
[476] *Canada – Patent Protection of Pharmaceutical Products - Report of the Panel*, WT/DS114/R ON 17 MARCH 2000, Paragraph 7.32.
[477] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 434.
[478] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 434.

provisions of the TRIPS Agreement have to be interpreted in the light of the objectives and principles of the TRIPS Agreement. Therefore, the provisions of the TRIPS Agreement including Article 30, should be interpreted according to the principles of Articles 7 and 8. Hence, the protection of intellectual property rights should be best presented so that public and society's interests are protected, not only the interest of individual rights. This is how all the developing countries look at the principles of Article 7 and 8.[479]

In order to find out whether the regulated exception unreasonably conflicts with normal exploitation of the patent, not only the regulated exception has to be examined, but also its application has to be examined as well.[480]

In the case of *Canada-Pharmaceutical Patents* both parties (Canada and EC) were of the opinion that the word 'exploitation' refers to the extraction of commercial value whether by working the patent, licensing the patent to others, or selling the patent rights to others. However, they disagree on the meaning of 'normal'.[481] Yet, the Panel held that the word 'normal defines the kind of commercial activity Article 30 seeks to protect'. Because the word 'normal' in dictionary defined to be something 'regular, usual, typical, ordinary, conventional'. Therefore, the Panel concluded that the normal exploitation by any patent owner is the right to exclude all forms of competition that may reduce the economic benefit expected to be gained through a monopoly rights granted by the patent.[482]

However, Nuno Pires de Carvalho is of the opinion that the Panel has errored because according to him exclusive right of the patent holder excludes the illegal competition only. It is usual in market that the patented products face competition from other patented products or even un-patented products. Therefore, 'normal exploitation' should not be linked with competition. According to NP de Carvalho 'normal

[479] Stoll, Busche, and Arend, pp. 541–42.
[480] Stoll, Busche, and Arend, p. 542.
[481] *Canada – Patent Protection of Pharmaceutical Products - Report of the Panel*, WT/DS114/R ON 17 MARCH 2000, Paragraph 7.51.
[482] *Canada – Patent Protection of Pharmaceutical Products - Report of the Panel*, WT/DS114/R ON 17 MARCH 2000, Paragraph 7.55.

exploitation' is the type of exploitation that follows the general standards and objectives of the law.[483]

2.2.1.3 The Exception Do Not Unreasonably Prejudice the Legitimate Interests of the Patent Owner, Taking Account of the Legitimate Interests of Third Parties

The last requirement and condition of Article 30 of the TRIPS Agreement is that the regulated exception by the member countries should not unreasonably prejudice the legitimate interest of the patent owner and in the same time the legitimate interest of third parties has to be taken into consideration. Even though this condition is complicated as it requires proving a negative action, but still the member countries that asserted the exception have the burden of proof on them. Because no one can know whether legitimate interest of the patent owner is prejudiced or not until knowing what legitimate interest the patent owner claims. The same logic applies to the legitimate interest of the third parties. Because it is difficult to apprehend the legitimate interest of the third parties without determining the legitimate interest of the patent owner.[484]

In order to find out the real meaning of 'legitimate interest' the Panel in the case of *Canada-Pharmaceutical Patents*, first tried to find out the literal meaning of the word 'legitimate' in normal dictionary in which the Panel stated that 'The word "legitimate" is commonly defined as follows: (a) Conformable to, sanctioned or authorized by, law or principle: lawful; justifiable; proper; (b) Normal, regular, conformable to a recognized standard type'. Base on this, the Panel rejected the proposal by the EC that the 'legitimate interest' refers to 'legal interest'.[485] However, the Panel preferred to look at 'legitimate interest' in this context as 'a normative claim calling for protection of interests that are "justifiable" in the sense that they are supported by

[483] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 380.
[484] *Canada – Patent Protection of Pharmaceutical Products - Report of the Panel*, WT/DS114/R ON 17 MARCH 2000, Paragraph 7.60.
[485] *Canada – Patent Protection of Pharmaceutical Products - Report of the Panel*, WT/DS114/R ON 17 MARCH 2000, Paragraph 7.68.

relevant public policies or other social norms'.[486] In this sense 'legitimate interest' is much broader than the 'legal interest'.[487]

However, a problem may arise in dealing with legitimate interest of the patent owner and that of the third parties. The underlying public policy may be equal in regard of protection of intellectual property rights of private entity in return for creating the invention and transferring it to society for the benefit of all. Nevertheless, the legitimate interest of patent owner and legitimate interest of third parties are different. Normally the legitimate interest of the patent owner is to exclude others (third parties) from utilization of the invention or prevent competitors from competing his invention in order to gain maximum economic profit. On the other hand, may be the legitimate interest of the third parties to be able to utilize the invention without getting the authorization from the patent owner.[488] However, as has been mentioned before, Article 30 should be interpreted in the light of Articles 7 and 8 which are on objectives and principles respectively. Accordingly, member countries have to keep balance between protecting the rights of patent owners and social and economic welfare of society. In order to solve the conflict of interests, it is best to introduce an exception that best keep the balance of rights and obligations.

2.2.2 Exceptions That Can Be Categorised Under Article 30

According to Article 30, member countries have rights to introduce exception with some conditions as discussed in previous section. However, providing exceptions under this Article is optional and not mandatory. Therefore, member countries have rights to introduce one or more exceptions according to their needs and ability to fulfil the conditions. There are some exceptions that are adopted in

[486] *Canada – Patent Protection of Pharmaceutical Products - Report of the Panel*, WT/DS114/R ON 17 MARCH 2000, Paragraph 7.69.
[487] *Canada – Patent Protection of Pharmaceutical Products - Report of the Panel*, WT/DS114/R ON 17 MARCH 2000, Paragraph 7.71.
[488] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 382.

the legislations of many member countries.[489] Here are some of those permitted exception:

2.2.2.1 Research and Experimentation Exception

One of the exceptions that are widely used by the international community and one of the most popular one is research use and experimentation. Even though the scope of applicability of this exception may vary from one-member country to another, but they usually allow the use of the patented invention for the purpose of scientific experiments without needs of authorisation of the patent holder. The widely use of this exception shows that there is an international agreement that the development of scientific research and technology should not be monopolized by the patent holders.[490] The exemptions can include those researches and experiments that are performed on the patented inventions with the intention of commercial purposes. For example, to improve the patented invention, for the purpose of evaluation of the patented invention so that request a licence, or simply to check whether the patented invention really works, and the patent granted is valid.[491] The Panel in the case of *Canada-Pharmaceutical Patents* while analysing the term of 'legitimate interest' states that 'under the policy of the patent laws, both society and the scientist have a "legitimate interest" in using the patent disclosure to support the advance of science and technology'. The public policy purpose of granting patent is to facilitate the transfer and advancement of knowledge in the area of patent. Therefore, if granting patent is for the purpose of preventing others from experimental use, then this will go also against the requirement of disclosure to the public. Nevertheless, at the end the Panel did not

[489] Stoll, Busche, and Arend, p. 547.
[490] Rodrigues Jr and Edson Beas, p. 180.
[491] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 437.

decide whether adopting this exception by the member countries falls within the terms of Article 30.[492]

2.2.2.2 Early Working, Regulatory Review or Bolar Exception

This is another important exception that can be allowed under Article 30. Even though this exception is new compared to the use of other exception, but it was known at the time of negotiations of the TRIPS Agreement. This exception is useful in the area of pharmaceutical products. Granting patent to a new medicine requires a very difficult and long process of tests, trials and collecting data in order to prove that the medicines are safe and effective.[493] Nevertheless, under this exception the manufacturers of generic drugs are allowed to use and test the invention during the protection period without requirement to apply to get authorisation from the patent owner. The logic behind this exception is that the products of generic drugs be available to consumers to buy the moment the patent expires.[494] This is in the benefit of members of society to get medicines at lower prices.[495]

This exception has been named as 'Bolar Exception' after the United States case of 'Roche Products Inc. v. Bolar Pharmaceutical Co.' (Fed. Cir. 1984). The subject matter and core issue of this case was early working on patented drugs. Even though the outcome of the case was negative, in the sense that the Court of Appeals for the Federal Circuit did not allow the early work on the patented drug.[496] However, this case became the reason that the United States Patent Act was amended in order to include such exception in Section 217.e

[492] *Canada – Patent Protection of Pharmaceutical Products - Report of the Panel*, WT/DS114/R ON 17 MARCH 2000, Paragraph 7.69.
[493] Garrison, p. 13.
[494] Stoll, Busche, and Arend, p. 548.
[495] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 438.
[496] 'Roche Products, Inc. Appellant, v. Bolar Pharmaceutical Co., Inc., Appellee, 733 F.2d 858 (Fed. Cir. 1984)'.

(1).[497] Then many countries around the world included this exception into their legislations, among them countries of the European Unions. Some of these countries are Canada, Australia, Argentina, France, England, Israel and Thailand.[498]

European Directive 2001/83/EC of the European parliament and of the Council of 6 November 2001 on the community code relating to Medicinal products for human use, in Article 10.6 states that 'Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products'.[499] Article 27 (d) of the Notices From European Union Institutions, Bodies, Offices and Agencies states that the rights conferred by a patent shall not extend to 'the acts allowed pursuant to Article 13(6) of Directive 2001/82/EC (1) or Article 10(6) of Directive 2001/83/EC (2) in respect of any patent covering the product within the meaning of either of those Directives'.[500] Therefore, the bolar exception officially considered as an exception to the exclusive rights of the patent owners.

The Panel in the case of *Canada-Pharmaceutical Patents* referred to this exception as regulatory review and confirmed that this type of exception is consistent with Article 30 of the TRIPS Agreement.[501] There can be no conflict with Article 30, since this exception allows the marketing of generic drugs only after expiry of the protection period of the patent.[502]

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[497] 'United States Code Title 35 - Patents'.

[498] Stoll, Busche, and Arend, p. 549.

[499] 'Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use, Official Journal L – 311, 28/11/2004, P. 67 – 128 as Amended by Directive 2002/98/EC, 2004/24/EC and 2004/27/EC' <http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004481.pdf> [accessed 3 May 2018].

[500] 'Notices from European Union Institutions, Bodies, Offices and Agencies' <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:175:0001:0040:EN:PDF> [accessed 3 May 2018].

[501] *Canada – Patent Protection of Pharmaceutical Products - Report of the Panel*, WT/DS114/R ON 17 MARCH 2000, Paragraphs 7.47, 7.50, 7.59, 7.73, 7.83 and 7.84.

[502] Stoll, Busche, and Arend, p. 550.

2.2.2.3 Individual Prescriptions Exception

Nowadays many member countries have included this exception in their legislation in which manual preparation of medicines and medical products in a pharmacy by pharmacists or by a medical professional and doctors are allowed on the request of individual prescription.[503] This exception is limited to individual cases; therefore, manufacturing of large quantities are not allowed.[504] In the case of *Canada-Pharmaceutical Patents*, the Panel held that a pharmacist is allowed to use a patented pharmaceutical invention while preparing and dispensing a medical compound. The Panel listed some countries that have this exception in their legislations.[505]

2.2.2.4 Prior Use Exception

It is normal that more than one research centres or institutions carrying out research on the same issue and trying to reach solution to the same problem. It is possible that a third party independently has been carrying out actions and activities that relates to the invention but in secret. That is why usually the research centres are in race to invent first and apply for patent as soon as possible. Once patent granted, the patent owner has right of monopoly and prevent others from using his invention without prior authorization. However, its well-recognized principle that it is also not fair to prevent third parties to complete their work that they have started before the patent was granted. Similarly, prior users are allowed to continue manufacture whatever

[503] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 438.

[504] Stoll, Busche, and Arend, p. 550.

[505] *Canada – Patent Protection of Pharmaceutical Products - Report of the Panel*, WT/DS114/R ON 17 MARCH 2000, p. Paragraph 4.17 and Footnote 76 'Provision for the dispensing pharmacist's exception is made in ten of the 15 EU member States (Belgium, Denmark, France, Germany, Greece, Ireland, Luxembourg, Netherlands, Sweden and the United Kingdom) as well as the Czech Republic, Hungary, Iceland, Norway, the Slovak Republic and Slovenia '. Also in the Spanish Patent Law 24/2015, Article 61.1 (d) states that patent rights do not extend to preparation of medicines made in pharmacies extemporaneously and by unit in execution of a medical prescription or to the acts related to the medicines thus prepared.

they were producing. Therefore, the right of protection of the patent owner should be limited in this regard.[506] This right of prior use does not create any direct legal relationship between the patent holder and the prior user. It only asserts the rights of the *bona fide* use of invention by third parties before filing the patent and granting the patent.[507]

In the WIPO draft treaty for harmonization of patent law prior use was recognized as a legitimate ground of exception. Some member countries of the European Patent Convention recognized the prior use as an exception such as Section 64 of the United Kingdom Patents Act 1977.[508] Since this exception under the United Kingdom Patents Act 1977 has been considered to be consistent with the European Patent Convention, therefore, it has to be considered to be compatible with the TRIPS Agreement as well.[509]

2.2.2.5 Parallel Imports

The term of 'Parallel Imports' has been defined as 'Products imported into a country without the authorization of the right holder in that country, which have been put on the market in another country by that person or with his consent (Article 6)'. According to Article 6 of the TRIPS Agreement,[510] when a state or a group of states regulating the principle of exhaustion (international exhaustion) in their domestic legislations, the patent owner losses the exclusive rights of importation of the protected products and parallel importation is authorised within the states.[511]

[506] Garrison, p. 5.
[507] Stoll, Busche, and Arend, p. 551.
[508] 'Patents Act 1977', p. Section.
[509] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 438.
[510] Article 6 of the TRIPS Agreement under the title of Exhaustion states that 'For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights'.
[511] Oliveira and others, p. 816.

Insertion of international exhaustion under Article 6 was the wish of the developing countries in order to permit parallel imports, so that their consumers are able to access to products at lower prices. However, this idea was not accepted by the developed countries. Nevertheless, eventually Article 6 adopted a liberal view in which the member countries are at liberty to adopt the most suitable system according to their needs whether be a national or international exhaustion. On other hand, the developed countries have rights under Article 6 to adopt national exhaustion so that they prevent access by other countries to import patented products.[512] The reason is that according to national exhaustion only exclusive right to use, offer for sale and sell are extinguished. The logic is that the patent owner has gained full benefit from his patent rights when he has made the first sale of a particular product. However, other exclusive rights of making and importing of that particular product are still within the exclusive rights of the patent holder.[513]

This concept has great economic benefits, because the same product can be sold at a much lower price in one country than others.[514] This is due to differences in economic growth and development of the countries. Least developed countries have much lower GDP per capita income; hence price of products is much lower than developed countries. Another fact that affect the price of product is that in least developed and developing countries the cost of production is much lower and standard of living is much lower than developed countries. If the price of products to be equal in developed and least developed countries, then rate of sale and gain of profit will be much lesser in the least developed countries. That is why once the patent holder imported or licenced for his products to be imported to a least developed country, then he has to agree to sell the products in

[512] Ana Maria Pacon, 'What Will TRIPs Do for Developing Countries?', in *From GATT to TRIPs: The Agreement on Trade-Related Aspects of Intellectual Property Rights*, ed. by Friedrich-Karl Beier and Gerhard Schricker, IIC Studies, v. 18 (Weinheim; New York: VCH, 1996), pp. 329–56 (p. 337).

[513] Christopher J. Clugston, 'International Exhaustion, Parallel Imports, and the Conflict between the Patent and Copyright Laws of the United States', *Beijing Law Review*, 04.03 (2013), 95 (p. 95) <https://doi.org/10.4236/blr.2013.43012>.

[514] Stoll, Busche, and Arend, p. 551.

lower prices in that country. Then other countries can benefit from this reduction prices and buy it through a parallel importation.

Article 30 of the TRIPS Agreement also, in principle, has enough flexibility to allow derogation to the exclusive rights to import in cases where the patented product legally commercialised or imported in a foreign country. According to Article 28 of the TRIPS Agreement the exclusive right of importing patented products is belong to the patent owner. Article 28.1 states that patent owner has some exclusive rights and in lit. (a) states that 'where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;'. However, an explanation is given in the footnote 6 that right of importation of products like all the other rights are subject to exhaustion as it states that 'This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6'.[515]

2.3 Other Use Without Authorization of the Right Holder (Compulsory Licence)

Developed countries in general do not have problem with the high standard of protection of patent rights. This is due to their historical backgrounds and experiences with patent rights. Their solid traditions and laws in the area of competition and consumer protections are well legislated. In contrast, this type of high standard of protection that exists in the TRIPS Agreement is new to the least developed and developing countries. They are unprepared and unable to deal with the high standard of protection. This high standard of protection directly affects the general population which they have lower income. The majority of people have problem in accessing the patented products which some of them may be necessary for their livelihood, such as

[515] Stoll, Busche, and Arend, pp. 551–52; United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 439.

medicines. That is why the use of compulsory licences for the developing countries is receiving growing attention.[516]

Compulsory licences are tools created for keeping balances between patent holder's rights and need of society for the patented product, and usually it is operated where the balance is tilted toward the interest of society over the interest of patent holder. Compulsory licence can be defined as 'involuntary contract[s] between a willing buyer and an unwilling seller imposed and enforced by the state'.[517] For this reason the compulsory licences are considered to be very powerful rights granted to authorities, therefore, it has to be used extremely carefully, otherwise they will cause great injustice. Thus, compulsory licences are restricting the legal rights of the patent owners unwillingly by authorising third parties to commercialise the patented products by making, using, and selling them.[518]

Compulsory licence limiting the exclusive rights of the patent owners. The basic principle of granting patent is that the patent holder should enjoy some exclusive rights and should have monopoly over his invention, to sell, produce, make, use and import in the best way of his wish to gain economic benefit in return for his creative activity. However, once the compulsory licence enforced on him without his permission, it is considered to be a direct interference with his 'private power' that he has due to his patent. Thus, this process of compulsory licence discourages others to invest in research and development and may kill desires of creating and inventing new products.[519] Therefore, it has to be used carefully in order to keep balance between interests of both patent owner and general public.

Nowadays many developing countries have adopted the principle of compulsory licence in their domestic laws. Those countries that recently provided for compulsory licence stated a comprehensive list

[516] Correa, *Intellectual Property Rights And The Use of Compulsory Licenses: Options for Developing Countries*, p. 1.
[517] Srividhya Ragavan and Raj Davé, 'Frand and Compulsory Licenses: Analysis and Comparison', 2015, 9-3 to 9-12 (p. 9–8). Available at: https://scholarship.law.tamu.edu/facscholar/726.
[518] Jamie Feldman, 'Compulsory Licenses: The Dangers behind the Current Practice', *Journal of International Business and Law*, 8 (2009), 137 (p. 137).
[519] Stoll, Busche, and Arend, p. 557 and Footnote 9.

of reasons that may cause granting compulsory licence. However, generally compulsory licence is granted for lack or insufficiently working, and to remedy the situations that occur due to anti-competitive practices. It is usually granted for the sake of public interest in cases of emergency or governmental use. The World Health Organization stated that the compulsory licence can also be granted in cases of abuse of patents in order to reduce the price of medicine so that be people be able to buy it.[520]

2.3.1 Historical Background

For the first time in history the concept of compulsory licence was introduced in the United Kingdome through the Statute of Monopolies in 1623. Then the same concept was introduced by other countries during nineteenth century so that apply it on their local patented inventions. Prior to the application of the principle of compulsory licence in some countries such as France, the drastic measure of forfeiture for non-working was applied. Then it was replaced by compulsory licence which can be considered to be more just than the forfeiture.[521]

However, for the first time under patent act the concept of compulsory licence was introduced under United Kingdom's Patent, Designs and Trade Marks Act 1883. Section 22 of the Act empowered the Board of Trade to order the grant of a compulsory licence where: '(a) The patent is not being worked in the United Kingdom; or (b) The reasonable requirements of the public with respect to the invention cannot be supplied; or (c) Any person is prevented from working or using to the best advantage an invention of which he is possessed'.[522] The content of this Section became the base for the United Kingdom's subsequent adopted patent acts of 1902, 1907, 1919, 1949 and 1977,

[520] Carlos María Correa, *Integrating Public Health Concerns Into Patent Legislation In Developing Countries* (Geneva: South Centre, 2000), p. 94.
[521] Correa, *Intellectual Property Rights And The Use of Compulsory Licenses: Options for Developing Countries*, p. 3.
[522] Great Britain, *The Patents, Designs, and Trade Marks Act, 1883 (46 & 47 Vict. C. 57) with the Rules and ...* (Stevens and Sons, 1884), Section 22 <http://archive.org/details/patentsdesignsa01britgoog>.

beside other regulations.[523] This provision had influenced the patent acts of other countries. To the extent that having compulsory licence provision in the patent law around the world became a typical feature. As of the beginning of the 1990s recognition of this principle by countries reach one hundred countries. Furthermore, it had great role in developing international conventions as well, such as Paris Convention for the Protection of Industrial Property (the Paris Convention).[524]

The Paris Convention as one of the leading conventions in the area of patents, provides for compulsory licence in order to 'prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work', as states in Article 5. A. (2). This provision deals with compulsory licence only in order to prevent abuses that resulted from the exercises of the exclusive rights of the patent owner. The word abuse is not elaborated here except for cases of 'failure to work'.[525]

The Paris Convention does not allow granting compulsory licence in the early period of granting the patent, but applicant to compulsory licence has to wait three to four years before he is allowed to apply for the licence. At the same time, this Convention does not provide for any limitation on the granting of the licence and does not provide for compensation. These reasons contributed the negotiation of having compulsory licence in the TRIPS Agreement.[526]

2.3.2 Compulsory Licence and Article 31 of the TRIPS Agreement

Article 31 of the TRIPS Agreement regulated an important principle which is granting the so-called compulsory licence. However, the terms of compulsory licence, non-voluntary licence,

[523] Terrell and others, pp. 432–36.
[524] Correa, *Intellectual Property Rights And The Use of Compulsory Licenses: Options for Developing Countries*, pp. 3–4.
[525] Ricketson, p. 403.
[526] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 463.

licences of right or obligatory licence are not used in the TRIPS Agreement. Instead, Article 31 refers to this principle as 'other use without authorization of the right holder'.[527] Therefore, it is permissible that member countries use any terms they prefer as long as it indicates of other use of subject matter of a patent without authorization of the right holder, it is considered to be a compulsory licence.[528]

The term compulsory licence was not used in the TRIPS Agreement because many member countries of the GATT did not use this term. In many of those counties, already the governments were allowed to use private property for the benefit of public without authorisation of the owner as long as the just compensation is provided for. Another reason is that the word 'licence' indicates of having voluntary permission from the right holder but in fact the granting of compulsory licence is enforced on the right owner of the subject matter of the patent without having any choice of refusal through a governmental authority whether be an executive branch or judicial branch. In the case of compulsory licence, the right holder is not part of the deal, because he refused licencing others to use his invention. He is a third party to a negotiation between the authority that grants the compulsory licence and an entity that granted the authority to utilise the invention. Therefore, one can argue that using the word 'licence' in this situation is misleading.[529]

Footnote 7 of the TRIPS Agreement further illustrates the meaning of 'other use' by stating that it 'refers to use other than that allowed under Article 30'. This is in order to distinguish between 'limited exceptions' that are allowed under Article 30 with three conditions (have been discussed in previous Section in detail) and compulsory licence under Article 31. Article 30 may provide for limited exceptions through legislation that have general effect on parties involved. On the other hand, Article 31 directly affect interests of an individual right holder and authorised party. Article 31 states the procedures that the member countries should follow when granting a

[527] Stoll, Busche, and Arend, p. 556.
[528] Gervais, p. 390.
[529] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 387, Footnote 890.

licence and it include some terms that should be embodied in the licence. These procedures and terms may vary from one compulsory licence to another depend on the context in which the licence granted. Even so, it does not specify or limit the grounds for granting the compulsory licence.[530]

Since Article 31 does not provide for specific grounds of granting the compulsory licence and it was left for the member countries to decide. Nevertheless, the member countries can find some grounds in the provisions of the Article. The only ground mentioned specifically is semiconductor technology in Article 31 (c). Nevertheless, within Article 31 references can be found to some grounds, albeit these grounds are not exhausted, such grounds are national emergency, anti-competitive practices, public non-commercial use and dependent patents.[531]

For using other grounds, the member countries can use interpretation of Article 8 of the TRIPS Agreement, in which gives the member countries some options, such as in Article 8.1 to 'adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development'. Also, based on Article 8.2 the member countries have the choice to provide measures in their laws and regulations that are 'Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology'. Combination of these provisions of Article 8 with Article 31, they provide great deal of flexibilities to member countries to grant compulsory licence on grounds of their choice. However, it has to be taken into consideration that the member countries are not allowed to grant compulsory licence on frivolous grounds or on no grounds.[532]

[530] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 462.
[531] Blakeney, *Trade Related Aspects of Intellectual Property Rights*, p. 90.
[532] Stoll, Busche, and Arend, p. 566.

Article 31 of the TRIPS Agreement states two types of 'other use' as it states in the introductory note 'Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government'. Therefore, it allows to grant compulsory licence, firstly for use by the government and secondly for use by third parties authorized by the government. However, Article 31 states a list of conditions that have to be followed by the member countries as a guideline before implementing the compulsory licence.[533]

2.3.2.1 Individual Merits

The first principle that must be followed in order to grant a compulsory licence is that it has to be granted on a case by case basis.[534] This principle can be found in Article 31 lit. (a) which states that 'authorization of such use shall be considered on its individual merits'. This clearly prevents member countries to approve granting compulsory licence in advance, such as for patents in a specified field of technology or involving certain patentees.[535] This provision states so that member countries do not provide 'blanket licensing clause' in their national laws in order to grant compulsory licence automatically in some areas. It is allowed that a member country to legislate that an area of health and nutrition area considered as inherently public interest, but such law should not lead to automatic compulsory licenses.[536] Rather the compulsory licence has to be applied exceptionally, therefore, every individual application for granting such licence should be dealt with separately and considered duly.[537]

[533] Sara M. Ford, 'Compulsory Licensing Provisions under the TRIPs Agreement: Balancing Pills and Patents', *American University of International Law Review*, 15 (1999), 941 (p. 959).
[534] Gervais, p. 391.
[535] Blakeney, *Trade Related Aspects of Intellectual Property Rights*, p. 91.
[536] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 399.
[537] Stoll, Busche, and Arend, p. 567.

2.3.2.2 Prior Negotiations and protection of the right holder

Article 31 lit. (b) of the TRIPS Agreement[538] states some important conditions and principles that member countries have to follow before granting compulsory licence. First, it requires that the proposed user whether be a government or third parties have contacted the right holder to negotiate acquiring the voluntary licence before applying for compulsory licence. This means that the TRIPS Agreement prefer voluntary licence. Nevertheless, this Article is flexible because it requires that the negotiation has to be carried on reasonable terms within reasonable period of times. The word 'reasonable' is not defined in the Article, therefore, its left for the member countries to decide. Generally, the negotiation is around the amount of royalty that has to be paid to the patent owner. The royalty amount may differ base on many things, such as on the number of products made or sold, or base on the licensee's net income, or it can be a fixed amount at periodic intervals. Nonetheless, the royalty payment differs from one industry to another, and sometimes within the same industry the royalty payment may be different from one technology to another. However, the negotiation may include other elements such as, duration of the licence terms, additional technology, grant-back, tying arrangements and export restrictions.[539] The condition of 'reasonable commercial terms and reasonable period of time' has to be complied by the prospective licensee.[540]

[538] TRIPS Agreement, Article 31 lit. (b) states that 'such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly'

[539] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, pp. 469–70.

[540] Stoll, Busche, and Arend, p. 568.

Next, Article 31 lit. (b) in its second sentence provided for three exceptions to prior negotiation. This means that the member countries are allowed not to follow the previous requirement of prior negotiation 'in case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use'. These terms are very general, and they may carry a variety of interpretation. What constitute emergency has not been defined in the TRIPS Agreement, therefore it is left for member countries to decide. The member countries can in their legislations and through official decrees name situations and circumstances that may constitute an emergency. However, when one look at the second waiver of the prior negotiation 'other circumstances of extreme urgency', which provide for much wider flexibility for the member countries, it becomes clear that declaring urgency does not need official declaration of national emergency. Though the word 'extreme' is used here that refers to the ultimate urgency, but there isn't any general rule that can be used to differentiate between extreme urgency and moderate urgency.[541]

The next exception that does not require prior negotiation is 'public non-commercial use'. This term is much wider than the emergency and extreme urgency use, because it does not require any emergency or extreme circumstances. Therefore, the member countries have right to use this exception whenever they desire to serve their citizens. This exception is very important for the developing and least developed countries, as it allows them to avoid costly patents that serve public interests especially those related to public health care. The significance of this exception can be noticed in Article 31 lit. (b) fourth sentence as it does not require advance notification of the patent owner prior to use.[542]

However, meaning of both of the words of 'public' and 'non-commercial' to be taken into consideration and defined in good faith. The word public normally refers to government and official authority

[541] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 471.

[542] E. Richard Gold and Danial K. Lam, 'Balancing Trade in Patents: Public Non-Commercial Use and Compulsory Licensing', *The Journal of World Intellectual Property*, 6.1 (2003), 5–31 (pp. 8–9) <https://doi.org/10.1111/j.1747-1796.2003.tb00192.x>.

that carry the activity of using the patent invention. The word public also in this context gives the meaning that the patent invention should be used for public benefits. Thus, in order to invoke this exception, the subject matter of the patent should be used by official authority and for the benefit of the public. As of the word of 'non-commercial', it should be understood as to mean 'not for profit'. Therefore, the patent invention should not be used for gaining profits as it is usually done by commercial enterprises and it should be used for public institutions such as a public hospital that does not run for the purpose of economic gain.[543]

Third, the third sentence of Article 31 lit. (b) states that in cases of national emergency or extreme urgency the government is under obligation to inform the patent owner as soon as reasonably practicable. Even though in these two circumstances the prior negotiation is waived but nevertheless the licensee bears the parallel obligation to give notification to the patent owner of the granting the compulsory licence. However, the time of notification is not determined but the term of 'reasonably practicable' is used. This gives flexibility and ample time to the licensee to inform the patent owner, and it is not necessary to be prior to the grant of the licence.[544]

In the fourth sentence of Article 31 lit (b), it is stated that public non-commercial use is not under obligation to notify the patent owner as it is the case for national emergency and extreme urgency. The fourth sentence reads as 'In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly'. This sentence indicates that the governments or contractors has to notify the patent owner only if they know or have reasonable grounds to know that the subject matter of the licence is patented. It further instructs that the user whether the government or

[543] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 471.

[544] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 472.

the contractor is not under obligation to do a patent search to find out whether the subject matter of the licence is patented or not.[545] It cannot be presumed that the government or the contractor knew that the invention was patented, and public knowledge presumption is not acceptable here. The patent owner is the one has to prove that the licensee had knowledge of the existence of the patent. The government can also benefit from the domestic legislations which can provide for use of privately owned inventions without authorisation. In fact, such legislations are allowed under Article 44.2 of the TRIPS Agreement,[546] which allow governments to use such invention with the condition of just remuneration according to Article 31 lit. (h).[547]

2.3.2.3 The Scope and Duration of the Compulsory licence

Article 31 lit. (c) of the TRIPS Agreement clearly stated the scope and duration of the compulsory licence as it states that 'the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive'.

In the first part this provision limits the scope and duration of a licence to the purpose of which it was authorised.[548] This imply that the grant of compulsory licence should not be unrestricted to any field of application, but rather it has to be limited for the purpose it was granted for. For example, if a compulsory licence granted for some parts of military aircraft, then the same patented parts cannot be used for civil aircrafts. In the same way the duration of the licence has to be

[545] Gervais, p. 392.
[546] Article 44.2 of the TRIPS Agreement states that 'Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31.In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available'.
[547] Stoll, Busche, and Arend, p. 570.
[548] Blakeney, *Trade Related Aspects of Intellectual Property Rights*, p. 92.

limited as well. Nevertheless, this does not mean that the compulsory licence has to be given to a certain period only, but the licence duration has to be long enough to fulfil the purpose it was granted for. Or else, Article 31 will not fulfil the purpose it was designed for.[549]

Article 31 does not limit the grounds for which the compulsory licence can be applied, instead it states conditions that should be followed when the compulsory licence is granted. Even though this provision can be seen as encouraging granting of compulsory licence, but it has been argued by Nuno Pires de Carvalho that the conditions set by Article 31 with the intention of protecting the private rights of the patent holders.[550] Thus Article 31 lit. (b) restricts the purpose (grounds) of granting compulsory licence in regard of semi-conductor technology which shall be only for the purpose of public non-commercial use or remedy anti-competitive practices.[551]

2.3.2.4 Non-exclusivity

Article 31 lit. (d) clearly states that 'such use shall be non-exclusive'. This means that the granting of a compulsory licence to a particular patented invention does not exclude the patent owner from using his product. The patent owner still has the right to commercialise his invention and licensing it to third parties. This is to make sure that granting compulsory licence is not first choice of the licensee and this also encourage voluntary licensing.

According to this provision the patent owner has rights to compete with the licensee whether directly by himself or license the invention to third parties. The patent owner is under no obligation to share his commercial strategy with the licensee. This eventually create a commercial risk for the licensee, as exploitation of the patented invention necessitate good amount of investment. This eventually leads to decrease of application of granting compulsory licence. However, the purpose of Article 31 'is not to facilitate granting

[549] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, pp. 472-73.
[550] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 411.
[551] Stoll, Busche, and Arend, p. 571.

compulsory licences, but rather to submit them to conditions of predictability and legal security'.[552]

2.3.2.5 Non-assignment

Article 31 lit. (e) of the TRIPS Agreement states that 'such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use'. This is to ensure that the licensee does not obtain a stronger position than what the compulsory licence has already granted him. The licensee is not allowed to create a trading system for the compulsory licence that was granted to him.[553]

Looking at this subparagraph, one question may arise as to whether it allows sub-licensing or not as Article 5. A. (4) of the Paris Convention[554] clearly states that sub-licensing is not allowed under compulsory licences. However, Article 31 lit. (e) of the TRIPS Agreement does not mention the word sub-licensing. Nevertheless, in this regard the compulsory licence can be compared to voluntary licence. As in voluntary licence when the licence is non-exclusive, the licensee does not have authority to sub-licence the patent. In the same way Article 31 lit. (d) clearly states that the compulsory licence has to be non-exclusive, and subsequently it cannot be sub-licensed again. Thus, it was not necessary for Article 31 lit. (e) state again that sub-licencing is not allowed as it is the case with Article 5. A. (4) of the Paris Convention.[555]

Exception has been given to the goodwill, which does not constitute any tangible assets of the subject matter of the compulsory licence. This in fact create a flexibility against the non-assignment. Thus, according to part of the Article 31 lit. (e), if the entire assets of

[552] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 413.
[553] Stoll, Busche, and Arend, pp. 572–73.
[554] Paris Convention for the Protection of Industrial Property in Article 5 A. (4) states that 'Such a compulsory license shall be non–exclusive and shall not be transferable, even in the form of the grant of a sub–license, except with that part of the enterprise or goodwill which exploits such license.'
[555] Carvalho, *The TRIPS Regime of Patents and Test Data*, pp. 414–15.

the compulsory licence is in the form of goodwill, then it can be assigned and transferred as part of the market transaction.[556]

2.3.2.6 Predominantly for The Supply of The Domestic Market

Article 31 lit. (f) of the TRIPS Agreement states that 'any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use'. This means that the compulsory licence should be 'predominantly' used for the domestic market. This indicate that the intention of the granting such licence should be for fulfilling the domestic market and not for exporting. Even though the term 'predominantly' may carry the meaning that small part of the subject matter of the compulsory licence can be exported but should not exceed more than fifty percent of the total production. Prior to the existence of the TRIPS Agreement, many countries legislated the principle of compulsory licence with the intention of exporting it to foreign markets. The Paris Convention did not prevent such practices. However, once the TRIPS Agreement implemented such practice should not be allowed. Because the principle of compulsory licence under Article 31 is considered as an exception to the general rule of exclusive rights of the patent owner, therefore, it should be kept as an exception. Thus, this subparagraph is introducing another limitation to the Paris Union Members that are member of the WTO (TRIPS Agreement) in the same time.[557]

This subparagraph, according to the previous argument, prevents a country that have no technological capabilities to produce under the patented invention, to be able to buy such products for lesser money from another country that produce them under compulsory licence.[558] For this reason, some other authors claim that if the intention of a

[556] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 473.

[557] Carvalho, *The TRIPS Regime of Patents and Test Data*, pp. 415–16; United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 474.

[558] Bartelt Sandra, p. 284.

member country of granting the compulsory licence is principally to fulfil the need of domestic market, then it has complied with the term 'predominantly'.[559] Thus it does not make any different how many percentage of the compulsory licence's products will be exported to foreign market.

However, under Article 31 lit. (k) when the compulsory licence granted by judicial or administrative process of a member country to remedy an anti-competitive practice, then that member country is not obliged to comply with Article 31 lit. (f). In another word, in this situation the member country is allowed to export majority of the products to foreign market.[560]

Furthermore, recent developments have added some more exceptions to this subparagraph. At the Doha Ministerial Conference in 2001, the Doha Declaration on the TRIPS Agreement and Public Health was adopted. On the recommendation of Paragraph 6 of the Doha Declaration[561] which was intended to create a path to the member countries so that they can easily access to medicines.[562] Eventually this followed by a Decision of the General Council of 30 August 2003. Part of this decision became Article 31*bis* and other became an Annex to the TRIPS Agreement. This was adopted by the General Council under the name of Amendment of the TRIPS Agreement (Decision of 6 December 2005)[563] and submitted to the member countries in order to be accepted.[564] Article 31*bis* 1 provides an exception to Article 31 lit. (f) when the products in question are pharmaceutical products.[565]

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[559] Stoll, Busche, and Arend, p. 574.
[560] Stoll, Busche, and Arend, p. 573.
[561] Declaration on the TRIPS Agreement and Public Health, Paragraph 6 states 'We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.''WT/MIN(01)/DEC/2 -WTO | Ministerial Conferences - Doha 4th Ministerial - Declaration on the TRIPS Agreement and Public Health - Adopted 14 November 2001'.
[562] Abbott and Puymbroeck, p. v.
[563] 'WTO | Intellectual Property (TRIPS) - Amendment of the TRIPS Agreement - Decision of 6 December 2005'.
[564] Gervais, pp. 396–97.
[565] Stoll, Busche, and Arend, p. 581 and 584.

2.3.2.7 Termination

Article 31 lit. (g) of the TRIPS Agreement states that 'authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances'. This subparagraph provides for termination of the compulsory licence while the legitimate interest of the licensee is not prejudiced and gives authority that the licence be reviewed by the competent authority.[566]

This subparagraph requires that the compulsory licence formally be terminated by the authority (executive or judicial) after taking all circumstances into consideration. Automatic termination is not allowed in this situation though the situations that causes its grant disappear, because it create a great risk to the licensee and this will cause injustice.[567] Some mechanism can be adopted in order to terminate the compulsory licence in such a way that the legitimate interest of the licensee is adequately protected. For example, in the terms of granting the compulsory licence a sufficient time can be stipulated so that the licensee recover the costs he has spent and earn reasonable profit. Also, during the normal period of the compulsory licence, it cannot be terminated so that to protect the licensee's interest. However, if the patent holder requested such termination, then he has to compensate the licensee for rest of the licence's value and in the same time he has to fulfil the needs of the market instead of the licensee.[568] Therefore, in deciding to terminate the compulsory licence balance has to be kept between the legitimate interest of the licensee and that of the patent owner.[569]

[566] Blakeney, *Trade Related Aspects of Intellectual Property Rights*, p. 92.
[567] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 458.
[568] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 475.
[569] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 457.

When a member country legislates rules of compulsory licence into their laws, it has to be bear in mind to include some mechanism in order the patent owner be able to petition for a review to prove that the circumstance lead to granting the licence are not existence anymore and are unlikely to recur, as stated by this subparagraph. Nonetheless, the licensee has the right to appeal and present its own justification and evidence so that the licence be continued or renewed.[570]

2.3.2.8 Adequate Remuneration

Article 31 lit. (h) of the TRIPS Agreement states that 'the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization'. This is an improvement by the TRIPS Agreement as the Paris Convention does not provide for any regulations as to adequate compensation of the patent owner, whether the licensee is a government or private party.[571] This is because TRIPS Agreement in its preamble[572] has considered intellectual property rights as private rights, hence any acquiring of such rights should be adequately compensated.[573]

During the negotiation process in Brussels, the negotiators were hesitating whether to choose the term 'adequate' as it was proposed by the United States of America, or 'fair and equitable' which was supported by several members. This subparagraph is considered to be one of the most controversial provisions of the TRIPS Agreement.[574] However, this subparagraph does not illustrate the meaning of 'adequate remuneration'. Nevertheless, one can get a hint of the meaning of this term by looking at Article 44 and 45 of the TRIPS

[570] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 475.
[571] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 475.
[572] TRIPS Agreement, the Preamble in its fourth paragraph states that 'Recognizing that intellectual property rights are private rights'
[573] Stoll, Busche, and Arend, p. 575.
[574] Gervais, pp. 393–94.

Agreement. Article 44 provides for injunctions, but the second paragraph[575] states that when the use is by government or third parties authorised by government, then the only remedy is the one provided by subparagraph (h) Article 31 instead of damage according to Article 45[576]. Since the judicial authority is the one which has to assess the adequate damage and in the above cases the adequate damage is replaced by adequate remuneration, therefore, the same criteria can be used to assess the 'adequate remuneration'. Which can be determined in the same way as damage, by calculating the amount that the patent owner would have made if he was the one utilising the patented invention instead of the licensee.[577]

Adequate remuneration is different from one case to another according to their circumstances as it is stated in the subparagraph. Therefore, adequate remuneration cannot be standardized in which a uniform fee to be paid by the compulsory licensee in the same sector of industry. A uniform and average fee can be taken into consideration and used only as one of the factors of determining the adequate remuneration. Also, when trying to determine the adequate remuneration, the subparagraph requires that the economic value of the authorization has to be taken into account. But the provision is unclear whether it refer to the economic value according to the

[575] Article 44.2 of the TRIPS Agreement states that 'Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31.In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available'.

[576] Article 45 of the TRIPS Agreement states '1. The judicial authorities shall have the authority to order the infringer to pay the right holder damages adequate to compensate for the injury the right holder has suffered because of an infringement of that person's intellectual property right by an infringer who knowingly, or with reasonable grounds to know, engaged in infringing activity. 2. The judicial authorities shall also have the authority to order the infringer to pay the right holder expenses, which may include appropriate attorney's fees. In appropriate cases, Members may authorize the judicial authorities to order recovery of profits and/or payment of pre-established damages even where the infringer did not knowingly, or with reasonable grounds to know, engage in infringing activity'.

[577] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 458.

patentee or the licensee. Economic value according to the authorization of the patentee would be the fee that he asks for licencing his patented invention in a voluntary licence. On the other hand, according the licensee the economic value of the compulsory licence would be the potential profit that the licensee is expecting.[578] Therefore, member countries are free to select factors that may determine the adequate remuneration, but they have to be careful because if they enforce inadequate remuneration, then they will violate Article 31 lit. (h).[579]

2.3.2.9 Judicial Review

Article 31 in both subparagraphs of (i) and (j) provides for judicial review or independent review by a distinct higher authority in that member country. However, in the first subparagraph of (i) it is states that 'the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member', which is requesting review of a decision of granting compulsory licence. This refers to legal validity of the decision only, without dealing with any other interlocutory issues. On the other hand, subparagraph (j) states that 'any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member', which is requesting review of a decision relating to the remuneration. Here the review is not limited to validity of the decision, but all other decisions that have influence the decision should be reviewed. Beside the amount of the remuneration, other issues such as methods of payment, currency, liquidity and insurance can be subject to review.[580]

Due to the fact that the legal systems of the member countries are different from one another, therefore, these subparagraphs are only stating general terms and give some discretion during

[578] Stoll, Busche, and Arend, p. 576.
[579] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 459.
[580] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 460.

implementations. Both of the subparagraphs state that the review can be carried out by the judicial review, which is clear enough by the patentee and the licensee to follow the procedures. However, the second part which is an independent review by a distinct higher authority in that member country, is not clear enough as the subparagraphs do not define the nature of that authority. But the word 'independent' means that the reviewing person or body should not be under control the authority that granted the licence or determined the remuneration. The term 'distinct' indicates that there should be adequate separation between the person or body reviewing and the one granting or determining the remuneration in function even though they are under same agency. This is reinforcing the idea of independent review. The term 'higher authority' refers to the notion that the reviewing authority should be higher in raking and level than the one granted the licence or determined the remuneration, so that be out of their influence in making the decision.[581] This option of 'independent review by a distinct higher authority' was added to these subparagraphs by Australia during the negotiations.[582] This seems to be a good choice as usually the judicial process may consume very long time and cost a lot, however, the process of administrative review is faster and less costly. If the procedures laid down in this provision followed carefully, the decision will be as just as the one reviewed by judicial authority.

2.3.2.10 Remedies for Anticompetitive practices

Anti-competitive practice was one of the main concerns of TRIPS Agreement negotiators, which had increased due to the monopolies arise from the exclusive rights granted to patent owners by the intellectual property rights. Other articles and provisions of the TRIPS Agreement has allowed member countries to take measures and control such practices, such as Article 8.1 and 40 of the TRIPS

[581] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, pp. 477–78.
[582] Stoll, Busche, and Arend, p. 576.

Agreement.[583] Beside these provisions, also Article 31 lit. (k) states that 'Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur'.

This provision gives authority to member countries to bypass the conditions in Article 31 lits. (b) and (f), which are notifying and prior negotiation with the patent owner, and the licence should be predominantly used for supplying the domestic market, when the compulsory licence granted in order 'to remedy a practice determined after judicial or administrative process to be anti-competitive'. However, in this situation the government should not deprive the patent owner from receiving adequate remuneration, nevertheless this situation can be taken into consideration while determining the adequate remuneration. This provision can be interpreted as allowing the national authorities to reduce the remuneration or even a 'royalty free' licence. The final sentence gives further authority to the member countries' competent authority to refuse termination of the compulsory licence if and when the anti-competitive conditions which led to granting the licence are likely to recur.[584]

2.3.2.11 Dependent Patents

Article 31 lit. (l) of the TRIPS Agreement,[585] provides for three more conditions beside other conditions of this Article, in cases that

[583] Blakeney, *Trade Related Aspects of Intellectual Property Rights*, p. 92.

[584] Stoll, Busche, and Arend, p. 577; United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development, and UNCTAD-ICTSD Project on IPRs and Sustainable Development, p. 479.

[585] Article 31 lit. (l) of the TRIPS Agreement states that 'where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

concern the dependent patents. The dependent patent (second patent) is a patented invention which cannot be worked without exploiting the original patent (first patent). Generally, the dependent patent owner requests a voluntary licence over the original patent. However, if it is not granted, the dependent patent owner may apply for authorisation of using the original patent through a compulsory licence.[586]

In Article 31 lit. (l) of the TRIPS Agreement it is stated that when compulsory licence granted in order to permit the second patent which cannot be exploited without infringing the first patent, three additional conditions has to be followed.

Firstly; it is required that the second patent involve an important technical advancement, and such technical advancement should have considerable economic significance. However, the term 'economic significance' is not precise concept and may carry many interpretations. It is possible that the second patent have technically advanced the original patent but may have little application with great economic significance and vice versa.[587] Determining important technical advancement of an invention is matter of subjective judgment that carry a wide range of discretion.[588] However, this condition introduced by the TRIPS Agreement because some countries had very generous policy in granting compulsory licence in these cases. Therefore, it was introduced in order to limit granting such licences only after following this stringent condition.[589]

Secondly, the first patent owner, shall be given a cross-licence on reasonable terms so that to be able to benefit from the invention of the

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(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and
(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent'.

[586] Anonymous, 'Genes and Ingenuity: Gene Patenting and Human Health (ALRC Report 99), 27. Compulsory Licensing, Dependent Patents', 2010 <https://www.alrc.gov.au/publications/27-compulsory-licensing/dependent-patents> [accessed 5 April 2018].
[587] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 471.
[588] Stoll, Busche, and Arend, p. 578.
[589] Gervais, p. 394.

second patent. This condition stipulated here in order to keep balance and both patent owners benefit from each other's inventions and not one of them only. However, it is required that there should be a negotiation process on reasonable terms. This indicate there the cross-licence will not be without compensation. It is presumed that the first patent owner already received adequate compensation after the compulsory licence granted to the second patent owner. Therefore, when the first patent owner acquires the cross-licence, it is logic that he should compensate the second patent owner as well. Or the economic value of both patented inventions can be evaluated and the most valuable receive an adequate compensation.[590]

The final and third condition is related to non-assignability of the first patent except with the assignment of the second patent. However, the condition of non-assignment already covered by Article 31 lit. (e). Therefore, one can perceive that the third condition of Article 31 lit. (l) replacing Article 31 lit. (e), with one addition which is the exception of non-assignability to the second patent only. For this reason, it has been suggested by Nuno Pires de Carvalho, that this condition should read as 'the compulsory licence granted under subparagraph (l) shall be assigned only with the patent that enjoys such use'.[591]

2.4 ARTICLE 31BIS AND COMPULSORY LICENCE FOR PUBLIC HEALTH

Article 31*bis* is the first amendment to the TRIPS Agreement. It was amended by the General Council's Decision of 6 December 2005,[592] and submitted to member countries to be accepted. However, in order for any amendment to take effect, two thirds of the member countries have to accept it. Paragraph 3 of Article X of the WTO Agreement states that an amendment 'shall take effect for the

[590] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 471; Stoll, Busche, and Arend, p. 578.
[591] Carvalho, *The TRIPS Regime of Patents and Test Data*, p. 472; Stoll, Busche, and Arend, p. 578.
[592] 'WTO | Intellectual Property (TRIPS) - Amendment of the TRIPS Agreement - Decision of 6 December 2005'.

Members that have accepted them upon acceptance by two thirds of the Members and thereafter for each other Member upon acceptance by it'.[593] For this reason the amendment entered into force only on 23 January 2017. Beside Article 31*bis*, the amendment also inserted an Annex and Appendix to the TRIPS Agreement. Basically, the provisions that inserted through this amendment are to give a legal basis to the member countries to be able to grant special compulsory licences in regard of producing and exporting generic medicines to those member countries that don't have domestic capabilities to produce such medicines sufficiently enough to fulfil the domestic needs.[594]

However, the original idea of having a special Article in the TRIPS Agreement in regard of compulsory licence for health products emerged from the Paragraph 6 of the Doha Declaration.[595] This paragraph admits that some member countries have insufficient or no manufacturing capacities thus cannot effectively use the compulsory licence tools to produce medicines. Therefore, the TRIPS Council should find a solution as soon as possible and report back to the General Council by the end of 2002. For this purpose, TRIPS Council conducted several meetings, and some solutions discussed, such as amendment to Article 31 lit. (f) in a manner to allow for granting compulsory licence for the purpose of exporting only.[596] Meetings took place throughout 2002 and 2003 and the final compromised agreement by the member countries within the TRIPS Council

[593] 'WTO | Legal Texts - Uruguay Round Agreement - Marrakesh Agreement Establishing the World Trade Organization' <https://www.wto.org/english/docs_e/legal_e/04-wto_e.htm#articleX> [accessed 8 April 2018].

[594] 'WTO | Intellectual Property (TRIPS) - (as Amended on 23 January 2017)' <https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm> [accessed 7 April 2018].

[595] 'WT/MIN(01)/DEC/2 -WTO | Ministerial Conferences - Doha 4th Ministerial - Declaration on the TRIPS Agreement and Public Health - Adopted 14 November 2001', Paragraph 6 states that ' We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002''.

[596] Peter Rott, 'The Doha Declaration: Good News for Public Health?', *Intellectual Property Quarterly*, 3 (2003), 284–311 (p. 295).

submitted to the General Council of the WTO and endorsed as 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health'[597] on 30 August 2003.[598] Eventually this adopted and presented as an amendment of the TRIPS Agreement by the decision of the General Council on 6 December 2005, and finally took effect as part of the TRIPS Agreement's Article 31*bis*, Annex and Appendix on 23 January 2017.

The first paragraph of Article 31*bis* states that 'The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement'. This paragraph is almost identical to paragraph 2 of the Decision of the General Council which was prepared under the title of 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' on 30 August 2003'.[599]

This paragraph exempted an exporting member country from obligation stated under Article 31 lit. (f), which is granting a compulsory licence predominantly for the supply of domestic market. Therefore, exporting members are allowed to grant a compulsory licence so that majority or all of the productions under such licence be exported to outside the country. Even though this provision does not clarify which member countries can be an exporting country, but in

[597] 'WT/L/540 - WTO | Intellectual Property (TRIPS) - Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health'.

[598] Duncan Matthews, 'WTO Decision on Implementation of Paragraph 6 of The Doha Declaration on The TRIPS Agreement and Public Health: A Solution To The Access To Essential Medicines Problem?', *Journal of International Economic Law*, 7.1 (2004), 73–107 (p. 9) <https://doi.org/10.1093/jiel/7.1.73>.

[599] 'WT/L/540 - WTO | Intellectual Property (TRIPS) - Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health', Paragraph 2 ' The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph'.

the Annex to the TRIPS Agreement under paragraph 1 lit. (c)[600] all member countries are eligible to be an export member country.[601] However, Article 31*bis* 1 states that the exporting country must under the compulsory licence produce and export pharmaceutical products and exporting them to an eligible importing member.

'Pharmaceutical product' is defined by the paragraph 1 lit. (a) of the Annex of the TRIPS Agreement.[602] The pharmaceutical products are not limited to medicines, but they can be any patented products, or any products produced in the patented process within the pharmaceutical sector. Paragraph 1 lit. (a) of the Annex also states that it includes any 'active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included'. Therefore, it may include vaccines as well because normally they are produced by pharmaceutical sectors as other medicines.[603] It can include other patented products such pharmaceutical salts, isomers, polymorphs, combinations, manufacturing processes, etc, as long as these pharmaceutical products are required to be patented in the exporting countries.[604]

'Eligible importing member' is also defined in the paragraph 1 lit. (b) of the Annex.[605] All the least developed countries are

[600] Paragraph 1 lit. (c) of the Annex to the TRIPS Agreement states that '"exporting Member" means a Member using the system to produce pharmaceutical products for, and export them to, an eligible importing Member'

[601] Stoll, Busche, and Arend, p. 585.

[602] Paragraph 1 lit. (a) of the Annex of the TRIPS Agreement states that '"pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2). It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included'.

[603] Vandoren Paul and Eeckhaute Jean Charles, 'The Wto Decision on Paragraph 6 of the Doha Declaration on the Trips Agreement and Public Health', *The Journal of World Intellectual Property*, 6.6 (2005), 779–93 (p. 784) <https://doi.org/10.1111/j.1747-1796.2003.tb00242.x>.

[604] Carlos María Correa, 'Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health', *World Health Organization*, 2004, p. 9 <http://bases.bireme.br/cgi-bin/wxislind.exe/iah/online/?IsisScript=iah/iah.xis&src=google&base=REPIDISCA&lang=p&nextAction=lnk&exprSearch=181527&indexSearch=ID> [accessed 10 April 2018].

[605] Paragraph 1 lit. (b) of the Annex of the TRIPS Agreement states that '"eligible importing Member" means any least-developed country Member, and any other Member that has

automatically eligible importing members without performing any obligations.[606] Nevertheless, all the other member countries of the TRIPS Agreement whether be a developing or developed countries, can be categorised as the eligible member countries as long as they inform the TRIPS Council that they are using the system in whole or partially. This notification can be done at any time. The system can be used only for national emergency, other circumstances of urgency or in case of non-commercial use or for all of them, as it is stated by this paragraph of the Annex. This notification is just routine procedures and only for the purpose of transparency.[607] As the footnote 1 of the Annex clarifies that this notification does not need to be approved by a WTO body in order for the member to use the system.

This paragraph of the Annex further states that some member countries have decided not to use this system as importing member and in footnote 3 the name of these members are mentioned which they are 'Australia, Canada, the European Communities with, for the purposes of Article 31*bis* and this Annex, its member States, Iceland, Japan, New Zealand, Norway, Switzerland, and the United States'. The Annex states also that some other member countries (names of these countries are not mentioned in the Annex) are decided to use the system only in cases of national emergency and other circumstances of extreme urgency.

The last part of Article 31*bis* 1, states that paragraph 2 of the Annex has to be taken into consideration while applying Article 31*bis* 1. Paragraph 2 lit. (a) of the Annex states three conditions that have to

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made a notification to the Council for TRIPS of its intention to use the system set out in Article 31*bis* and this Annex ("system") as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system as importing Members and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency'.

606 Correa, 'Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health', p. 15.

607 Frederick M. Abbott, 'The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health', *American Journal of International Law*, 99.2 (2005), 317–58 (p. 345) <https://doi.org/10.2307/1562501>.

be followed by eligible importing member while making a notification to the TRIPS Council. First, name and quantities of the product(s) has to be specifies. Second, the least developed countries are presumed to have no manufacturing capacities. However, other eligible importing members have to prove that they have no manufacturing capacities, or they have insufficient capacities in the pharmaceutical sector to produce the products that they are intending to import, according to the Appendix to the Annex of the TRIPS Agreement. Third, if the pharmaceutical product is patented in its territory, the member country has to state in its notification, that it has granted or intending to grant compulsory licence to that product according to Article 31 and 31*bis* of the TRIPS Agreement and provisions of the Annex.

Paragraph 2 lit (b) and (c) of the Annex states four obligations on the exporting member countries when they grant a compulsory licence for the purpose of exporting. Firstly, according to paragraph 2 lit. (b) (i) of the Annex, it has to produce only the amount necessary in order to meet the needs of eligible importing member country and has to import all of the amount to that member country only. Secondly, according to paragraph 2 lit. (b) (ii) of the Annex, the products have to be labelled through a special packaging, colouring or any other way so that easily be differentiated in order not to have significant impact on the price of the product elsewhere or prevent transferring them to different market. Thirdly, according to paragraph 2 lit. (b) (iii) of the Annex, before transferring the products, in the website of the licensee or WTO website, information about the quantities and special features of the product should be posted. Lastly, according to paragraph 2 lit. (c) of the Annex, the exporting member should notify the TRIPS Council about the transaction including, the conditions of the licence and its duration, name and address of the licensee, type of the product and its quantities, information about the importing member country, and other details that posted on the website, according to previous requirement.

Even though, these requirements suggest that a compulsory licence for the purpose of export should be granted for a limited quantity, however, there is nothing to prevent the exporting country in a single compulsory licence export to more than one country. In fact,

several importing countries can arrange among themselves for importing same pharmaceutical products in one exporting country in order to obtain much suitable prices.[608]

The second paragraph of Article 31*bis* of the TRIPS Agreement[609] states some important regulation in regard of payment of adequate remuneration to the patent holder. Previously according to Article 31 lit. (h) of the TRIPS Agreement when both importing and exporting countries grant a compulsory licence, both of them should have paid an adequate remuneration to the patent owner. However, under Article 31*bis* 2 prevents this double payment when both importing and exporting granting compulsory licence for the same pharmaceutical products. This paragraph provides that in such cases only the exporting country is required to pay the adequate remuneration according to the patent owner taking into account economic value and circumstances of the importing country. This is considered to be a reasonable solution to prevent double payment of remuneration and this will not lead to any difficulties.[610] In order for the importing member country to be exempted from payment of the remuneration is that the importing country grant compulsory licence corresponds to similar licence in the exporting member and the exporting member has paid the remuneration.[611]

The third paragraph of Article 31*bis* of the TRIPS Agreement,[612] provides for another important exemption to the principle of Article

[608] Correa, 'Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health', p. 25.

[609] Article 31*bis* 2 of the TRIPS Agreement states that 'Where a compulsory licence is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement, adequate remuneration pursuant to Article 31(h) shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member'.

[610] Frederick M. Abbott and Jerome H. Reichman, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions', *Journal of International Economic Law*, 10.4 (2007), 921–87 (p. 944) <https://doi.org/10.1093/jiel/jgm040>.

[611] Stoll, Busche, and Arend, p. 588.

[612] Article 31*bis* 3 of the TRIPS Agreement states that 'With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local

31 lit. (f) in regard of granting compulsory licence predominantly for supplying the domestic market. Article 31*bis* 3 allows for re-export of imported pharmaceutical products.[613] However, this waiver applies when the member countries of the TRIPS Agreement are least developed and developing countries that they are members of the same regional trade agreement. Furthermore, the member countries of that regional trade agreement are at least half of them are from the list of United Nations least developed countries. Therefore, this condition only applies on the African regional groupings, as it was their specific request, nevertheless during negotiations some other member countries showed interest.[614]

The main advantage of this exemption which created by Article 31*bis* 3 is that it applies to all the member countries of the regional trade agreement and notification to the TRIPS Council is not necessary whenever an exportation is made. However, this provision does not allow the same exporter to supply to all or some of the member countries of the same regional trade agreement, but rather the waiver is in regard of re-exporting from the importing member country of the trade agreement to other members.[615] Nevertheless, the last sentence of this provision provides for the principle of territoriality as it states that 'It is understood that this will not prejudice the territorial nature of the patent rights in question'. Therefore, according to this principle when the pharmaceutical

production of, pharmaceutical products: where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least-developed countries, the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question'.

613 Abbott and Reichman, pp. 944–45.

614 Vandoren Paul and Eeckhaute Jean Charles, p. 790.

615 Correa, 'Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health', p. 25.

product is patented in an importing member country, such patent is valid and has legal effect only in that member country. It is independent from any other patent granted for the same product in other member countries. Thus, a compulsory licence granted for a patent in one-member country does not have any effect on another patent granted for the same product in other member countries. This principle of territoriality obliges every member wishes to import from the original exporter or from another importing member country, it has to apply for compulsory licence.[616]

The purpose of this waiver as stated by both Article 31*bis* 3 and paragraph 5 of the Annex, is to promote economies of scale as it was an existing concern during the negotiation on the Decision of 30 August 2003, especially for the developing countries.[617] Therefore, paragraph 5 of the Annex states that this kind of exporting and importing should be promoted. Further this paragraph provides that the developed member countries should take responsibility to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement and also with other intergovernmental organization.[618]

Paragraph four of Article 31*bis* of the TRIPS Agreement states that 'Members shall not challenge any measures taken in conformity with the provisions of this Article and the Annex to this Agreement under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994'. This paragraph expressly prevents nonviolation nullification or impairment under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.[619] Therefore, member countries are not allowed to bring

[616] Vandoren Paul and Eeckhaute Jean Charles, p. 790.
[617] Stoll, Busche, and Arend, p. 588.
[618] Article 67 of the TRIPS Agreement, under the title 'Technical Cooperation' states that 'In order to facilitate the implementation of this Agreement, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members. Such cooperation shall include assistance in the preparation of laws and regulations on the protection and enforcement of intellectual property rights as well as on the prevention of their abuse, and shall include support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel'.
[619] 'WTO | Disputes - Dispute Settlement CBT - Legal Basis for a Dispute - Types of Complaints and Required Allegations in GATT 1994 - Article XXIII of GATT 1994 Subparagraph 1 Lits (B) and (C). 'If any contracting party should consider that any benefit

actions under these two subparagraphs which relates to dispute settlement in cases of nonviolation and situation. This prohibition is important because it will bring substantial insecurity to those countries that are ready to use the system.[620]

The last paragraph is Article 31*bis* 5 of the TRIPS Agreement which states that 'This Article and the Annex to this Agreement are without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2), and to their interpretation. They are also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the provisions of Article 31(f)'.

In the first sentence this provision confirms that Article 31*bis* and the Annex do not interfere with the rights, flexibilities and obligations of the member countries under the TRIPS Agreement and the Doha Declaration the TRIPS Agreement and Public Health. However, Article 31*bis* 5 reaffirms the exceptions that provided by this Article under paragraphs of Article 31*bis* 1 and 3, which they are exceptions to obligations under Article 31 lits. (f) and (h).[621] Therefore, during implementation of this provision the member countries still can benefit from the flexibilities and limitations to the principle of exclusivity of rights of the patent owner. In the same time, implementation of this provision should not permit the member

accruing to it directly or indirectly under this Agreement is being nullified or impaired or that the attainment of any objective of the Agreement is being impeded as the result of, (b) the application by another contracting party of any measure, whether or not it conflicts with the provisions of this Agreement, or (c) the existence of any other situation'.' <https://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c4s2p1_e.htm> [accessed 14 April 2018].

620 Abbott and Reichman, p. 945.

621 Article 31 lits. (f) and (h) of the TRIPS Agreement, '(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use; (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization'.

countries to escape from the obligations provided for in the TRIPS Agreement and Doha Declaration.

The EC Regulation No. 816/2006 also provides for compulsory licence for the purpose of manufacturing pharmaceuticals and exporting them to countries with public health issues. This regulation is considered to be an action by the EU in order to solve public health problems especially in the least developed and developing countries that do not have access to safe and affordable medicines. Nevertheless, even the developed countries that informed the WTO about their intention to import such medicines, can be eligible to benefit from this scheme.[622]

The term 'their interpretation' refers to the interpretation of the TRIPS Agreement and Doha Declaration. Paragraph 5 lit. (a) of the Doha Declaration,[623] states while interpreting the provisions of the TRIPS Agreement according to Article 31 of the Vienna Convention, the objectives and principles of the TRIPS Agreement have to be taken into consideration. Those objectives and principles stated in Article 7 and 8 of the TRIPS Agreement with other principles that are laid down in the Preamble and Part I of the TRIPS Agreement.[624]

The last sentence of Article 31*bis* 5 of the TRIPS Agreement emphasizes that Article 31*bis* and the Annex shall not affect the rights of the member countries to export pharmaceutical products in which produced under compulsory licence and fulfilled the requirement of Article 31 lit. (f). Basically, Article 31 lit. (f) requires the member countries to grant the compulsory licence predominantly for supplying the domestic market. Therefore, the non-predominant portion can be exported to another member country.[625]

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[622] 'Regulation (EC) No. 816/2006 - Export of Generic Medicines to Developing Countries: Compulsory Licences' <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=LEGISSUM:l21172&from=ES> [accessed 4 May 2018].

[623] 'WT/MIN(01)/DEC/2 -WTO | Ministerial Conferences - Doha 4th Ministerial - Declaration on the TRIPS Agreement and Public Health - Adopted 14 November 2001', 'In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles'.

[624] Stoll, Busche, and Arend, p. 590.

[625] Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO', p. 495.

2.5 IRAQ'S POSITION TO COMPULSORY LICENCE

One of the important principles of patent is granting exclusive right to the patent owner. However, countries around the world specify some circumstances in which they limit the exclusive right of the patent owner. These limitations are called exceptions as it is stated in Article 30 of the TRIPS Agreement as 'Exceptions to Rights Conferred'. Different countries have stated different exceptions, however, in the previous part some examples have been discussed that can be allowed under Article 30 of the TRIPS Agreement, such as Research and Experimentation Exception, Early Working, Regulatory Review or Bolar Exception, Individual Prescriptions Exception, Prior Use Exception and Parallel Imports. However, the patent law No. 65 of 1970 does not state any such exceptions and neither the CPA Order No. 81. The CPA was well aware of the provisions of the TRIPS Agreement, therefore, should have taken advantage of Article 30 of the TRIPS Agreement and included some of these exceptions in the amendment. As these exceptions are important for the fulfilment of the needs of society and its development.

2.5.1 Compulsory Licence Under the Original Law No. 65 of 1970

There is another type of exception which limit the exclusive rights of the patent owners, which is called compulsory licence exception. However, this exception has to be applied for and granted by executive or judicial authority. The Iraqi patent law No. 65 of 1970 provides regulation in regard of compulsory licence in sections of 27, 28 and 29.[626] Nevertheless, all these Section were amended by CPA Order No. 81.[627] However, before the amendment Section 27 was consisted of two provisions. In the first provision the patent owner was required to inform the Registrar of the exploitation date of the invention within 30 days of the commencement of the exploitation. The second provision provided for three circumstances in which the

[626] 'Law No. 65 of 1970 on Patent and Industrial Designs'.
[627] 'Order No. 81 Patent, Industrial Design, Undisclosed Information, Integrated Circuits And Plant Variety Law.'

Registrar authorised to grant compulsory licence to whom applied for it. According to this provision the Registrar was the executive authority that empowered to grant compulsory licences in the following circumstances. First, if the right holder did not exploit the invention in Iraq within three years of granting the patent. Second, if the exploitation by the patent owner did not correspond to the needs of the country. Three, if the patent owner stopped exploiting the invention for at least two years. However, the provision stated a condition on the applicant that he should be able to exploit the invention in a serious manner. The provision also stated that the patent owner has legal right to apply in the registry in order to receiving an adequate remuneration within ninety days of granting the compulsory licence. This suggest that if the patent owner did not apply for remuneration within specified period he will loss his legal right to receive remuneration. The provision also provided that the patent owner has right appeal against the decision of the Registrar before the Minister within thirty days of receiving notification of the grant of the compulsory licence, and the decision of the Minister is final and irreversible. According to Section 1.1 of the original patent law No. 65 of 1970 the Minister is Minister of Industry.

Section 28 of the original patent law No. 65 of 1970 before the amendment provided for another circumstance in which the compulsory licence can be granted accordingly. In this case compulsory licence can be granted to a dependent patent. Section 28 stated that when the exploitation of the patented invention (second patent/dependent patent) has great industrial significance and its exploitation require using another previously patented invention (first patent), then the Registrar has the authority to grant compulsory licence to the second patent owner. However, the provision of this Article required that the second patent owner approached the first patent owner to obtain voluntarily licence on reasonable conditions and the first patent owner refused to grant him the voluntarily licence. According to this provision what constitute reasonable conditions in this context can be determined by the Registrar.

Section 28 provided for granting compulsory licence in the vice versa situation as well. In circumstances when the first patent is a

dependent patent, and it has great importance that requires using subsequent patented invention (second patent). In the same condition the first patent owner has to request voluntarily licence from the second patent owner on reasonable conditions. If his request is refused, then the Registrar will be allowed to grant compulsory licence. In both circumstances adequate remuneration should be provided according to the stipulations stated in Section 27.

Section 29 of the original law No. 65 of 1970 stated that 'the Registrar may revoke the patent granted and anyone who has interest may request the Registrar to revoke it if the invention was not exploited in Iraq within two years of granting the compulsory licence'. This Section obviously did not make any sense as to why the patent would be revoked if the invention was not exploited during granting the compulsory licence. But Iraqi legislature spotted the mistake and amended this Section through the Law No. 28 of 1999 First Amendment to Law No. 65 of 1970.[628] Therefore, Section 29 to be read as 'the Registrar may revoke the compulsory licence granted and anyone who has interest may request the Registrar to revoke it if the invention was not exploited in Iraq within two years of granting the compulsory licence'.

In all the previous circumstances of granting compulsory licences according to Section 27 and 28, the Registrar was authorised to revoke the compulsory licence pursuant to Section 29. According to Section 29 everyone who had an interest could request for revocation of the compulsory licence if the invention was not exploited in Iraq within two years of granting the compulsory licence.

2.5.2 Compulsory Licence After the Amendment made by the CPA Order No. 81.

The CPA Order No. 81 amended all the three sections that regulated the compulsory licence under the Iraqi patent law No. 65 of 1970. The amended Section 27 consists of three paragraphs in which they provide for different circumstances in which the compulsory

[628] 'Iraq: Law No. 28 of 1999 First Amendment to Law No. 65 of 1970 on Patents and Industrial Designs'.

licence can be provided for exclusively. First, Section 27. A. states that when the use of the subject matter of the patent necessary for national defence or emergency or for non-commercial public good. In these circumstances the compulsory licence can be granted to states authorities or third parties. The only condition stated in the paragraph A. is that the patentee has to be notified as soon as possible. Circumstances referred in this paragraph are close to Article 31 lit. (b) of the TRIPS Agreement. In the TRIPS Agreement the terms of 'national emergency or other circumstances of extreme urgency or in cases of public non-commercial use' are used. The term emergency in Section 27. A clearly refers to national emergency, which obviously include necessities in circumstances of national defences. Therefore, it was not necessary to include this circumstance within Section 27. A.

On the other hand, the original patent law No. 65 of 1970 before the amendments, in its Section 30 stated that the Minister may issue an order to confiscate (expropriate) the ownership of the invention if public interest of the country or national defence requires it. This expropriation includes all rights gained through the patent. Nevertheless, Section 30 provided for adequate remuneration and right to appeal to the President of the Republic of Iraq. However, this Section has nothing to do with compulsory licence, because in compulsory licence the patent owner is not deprived totally from his right over the invention, it is simply an authorisation of using his invention without his consent. Meanwhile, according to this section, the patent owner permanently loses right over the invention and not allowed to exploit it any more. Hence the CPA Order No. 81 amended Section 30 to be read as 'The Registrar's compulsory license decision shall be appealable to the Minister within 60 days of its notification'. Therefore, it seems that the CPA wanted to replace this total deprivation of the rights of the patent owner to granting licence over the invention without his consent in circumstances of necessity for national defence. However, it would have been more beneficial for Iraq, if the CPA had copied the three circumstances of Article 31 lit. (b) of the TRIPS Agreement 'national emergency or other circumstances of extreme urgency or in cases of public non-commercial use'. The term 'other circumstances of extreme urgency'

would have been much more beneficial instead of national defence, as will include wider range of circumstances that can be determined by Iraq to grant compulsory licence.

Next, Section 27. B. 1 provides for another circumstance in which the Registrar can grant a compulsory licence; that is if the patent owner does not exploit the invention or exploits insufficiently. However, some durations have been stipulated before the compulsory licence granted. Either four years have passed from the application date or three years from granting date, and the applied date is the one that elapses later. Therefore, the Registrar cannot grant licence even though the invention has not been exploited unless the latest date of these two periods has elapsed. The Section has authorised the registrar to extend this period if found out that reasons beyond control of the patent owner, prevented him to exploit the invention.

The new amended Section 27. B. 1 has restricted granting compulsory licence compared to the old Section 27. In the old Section 27. 2 compulsory licence could be granted in three situations related to exploitation. Firstly, patented invention was not exploited within three years of granting the licence. Secondly, exploitation did not correspond to the needs of Iraq. Thirdly, stopped exploitation at any time for two years. However, the new Section 27. B. 1 removed the second and third circumstances and extended the period of the first one. This is clearly being in the benefit of patent owners, and while considered as a great disadvantage for a developing country like Iraq, because having variety of options to grant compulsory licence certainly help the country to fulfil its needs of products and technologies in considerable low prices. Furthermore, according to the new Section 27. B. 2 any importation of subject matter of the patent to Iraq will be considered an exploitation of the patent.

The last circumstance of granting compulsory licence according to Section 27. C. is to remedy unfair competition. This is a new circumstance that was not existed in the original Iraqi patent law. Therefore, it benefits the country to balance between exclusive right of the patent owner and fair competition. This provision is inspired by Article 31 lit. (k) of the TRIPS Agreement. However, it is failed to

include all the exceptions that stated in Article 31 lit. (k) such as exception to prior negotiation and notification.

Section 28 of the original patent law before amendment provided compulsory licence in cases of dependent patents. However, this type of compulsory licence is removed after the amendment by the CPA Order No. 81. The current section 28 provides for conditions and requirements of granting compulsory licence. The conditions are, A. Each application shall be considered on its merits, B. Prior negotiation on reasonable remuneration and conditions failed during a reasonable period of time between the parties, C. 'The scope and duration of the license shall be limited to the purpose for which it is granted. If the license application relates to semiconductor technology, then it shall only be granted for non-commercial public good or to rectify practices deemed by the competent judicial or administrative authority to be anticompetitive', D. Shall not be exclusive, E, shall not be assignable, F. should be for meeting the demand of the domestic market except in cases of anticompetitive, and G. patent owner shall receive equitable remuneration.

All these conditions can be found in Article 31 of the TRIPS Agreement, some of them rephrased and others exactly copied. However, some conditions such as judicial review of the licence was not included within Section 28, instead an independent section was added which is Section 30*bis* that states 'The Registrar's compulsory license decision shall be appealable to the Minister within 60 days of its notification'. But this section does not include judicial review of adequate remuneration as it is the case in Article 31 lit. (j) of the TRIPS Agreement. Also, the CPA Order No. 81 did not include in its amendment any special provisions in regard of 'Remedies for Anticompetitive practices' like Article 31 lit. (k) and 'Dependent Patent' like Article 31 lit. (l). Since the CPA Order No. 81 was ordered to inline the Iraqi patent law with the TRIPS Agreement, it should have included all the conditions and paragraphs of Article 31 of the TRIPS Agreement, including compulsory licence in cases of dependent patents.

Section 29 also amended to read as 'The Registrar may cancel the compulsory license *sua sponte* or on the strength of an application

from the patentee if the reasons for its grant lapsed. This license cancellation shall, however, preserve the rights of those involved in the compulsory license'. This restricts the right to apply for cancelation to patent owners only. In the old Section 29 whoever had an interest in the licence could apply for revocation if it was not exploited within two years of granting it. However, in the new section, the patent owner has to apply for cancellation and state that the reasons for its grant are no longer exist.

The CPA Order No. 81 did not add any special regulation in regard of compulsory licence for medical products and drugs. The Doha Declaration on the TRIPS Agreement and Public Health (14 November 2001),[629] in paragraph 6 states that solution has to be found in regard of problem of the public health that the developing countries facing. Then the General Council of the WTO endorsed a solution under the title of 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health'[630] on 30 August 2003, on which eventually becomes Article 31*bis* and the Annex of the TRIPS Agreement. Therefore, since the CPA amended the Iraqi patent law No. 65 of 1970, should have taken some points from these attempts of the TRIPS Council to include special regulation in regard of compulsory licences for medicines, because Iraq as one of the developing countries cannot produce and obtain enough medicines to fulfil the needs of the country. Even though the CPA Order No. 81 has improved and aligned the Iraqi patent law closer to the TRIPS Agreement but could have done better.

2.6 CONCLUSION

The TRIPS Agreement has provided for exceptions and limitation to the exclusive rights of the patent owners. These exceptions can be found mainly in three Articles of the TRIPS Agreement. The first is Article 30 which is titled 'Exceptions to Rights Conferred'. Iraq as one of the developing countries can benefit from the exception

[629] 'WT/MIN(01)/DEC/2 -WTO | Ministerial Conferences - Doha 4th Ministerial - Declaration on the TRIPS Agreement and Public Health - Adopted 14 November 2001'.
[630] 'WT/L/540 - WTO | Intellectual Property (TRIPS) - Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health'.

provided under Article 30 if it becomes member of the TRIPS Agreement. Member countries have right to determine the type of exception to implement that best serve the needs of their countries. Options are not restricted whether be for a non-commercial purpose or for commercial purpose because Article 30 does not mention any exception by name and it is left for member countries to decide. For example, it can be for private use, experimental and scientific use, prior use, extemporaneous preparation of a medicine in a pharmacy, regulatory review ("bolar"), individual prescriptions, exhaustion of patent rights (national exhaustion and regional or international exhaustion), and parallel imports (importation of products from a country where the product legally marketed). However, Article 30 states some conditions that have to be followed. Once these conditions fulfilled then the member countries have the right to choose the exceptions that satisfy their requirements without fear of legal actions from the patent owners.

The original Iraqi patent law No. 65 of 19790 does not include any exceptions that have been allowed under Article 30 even though Iraq is still not a member of the TRIPS Agreement. Series of amendments have passed on this law including the major one by the CPA Order No. 81. Nonetheless, none of them inserted any provision that provide for exceptions which legally allowed under Article 30 of the TRIPS Agreement. The majority of the blame is on the CPA Order No. 81 because it was regulated with the intention of preparing Iraq to join the WTO in which include the TRIPS Agreement. The CPA was well aware of the situation of Iraq after the invasion and the detailed provisions of the TRIPS Agreement as well. Therefore, the CPA should have included some of the above exceptions to boost Iraq's economy for rebuilding again after the invasion.

Another important exception is the so-called compulsory licence, which is provided by the TRIPS Agreement and calls it 'Other use Without Authorization of the Right Holder'. Article 31 and 31*bis* provide for compulsory licence with substantial detail. Article 31 allows compulsory licence to be granted in cases of 'national emergency or other circumstances of extreme urgency or in cases of public non-commercial use', 'to correct anti-competitive practices'

and dependent patent. However, Article 31 states some condition and requirements that have to be followed by the member countries before being able to grant compulsory licence. Since some of these conditions have made obstacles for the developing and least developed countries that have insufficient or no manufacturing capacities so that be able to use compulsory licence to produce and access important products for their needs especially in the area of public health.

In order to rectify this situation, the TRIPS Agreement was amended and Article 31*bis* with an Annex and Appendix were inserted. These newly added provisions provide for easy access to medicines by allowing member countries export and import medicines produced under compulsory licence. The provisions also provide for some exceptions to the conditions that are stated in Article 31 lits. (f) and (h).

The original patent law No. 65 of 1970 provided for compulsory licence in a limited number of situations such as, if the invention was not exploited within three years of granting the licence, exploitation did not correspond to the needs of Iraq, stopped exploitation at any time for two years and dependent patent. However, the CPA Order No. 81 repealed all these situations except for not exploiting within three from granting the licence or four years from the application date. The CPA Order No. 81 provides for some new exception but not for all the situations and cases that are stated in the TRIPS Agreement, especially in relation to medical products. Therefore, the CPA Order No. 81 should have included all the exceptions available in the TRIPS Agreement if they had really taken the best interest of Iraqi public and private sectors.

5 CONCLUSION

In the first section of chapter one it has been established that the TRIPS Agreement is one of the most significant international agreement that regulates the intellectual property rights. Most of the countries around the world are either became members or are in the process of becoming member to the TRIPS Agreement. However, before this agreement many other agreements have existed that regulate the intellectual property rights such as Paris Convention and Berne Convention. Most of the developed and developing countries were unsatisfied with them. Developing countries were unsatisfied because originally these conventions were endorsed and agreed upon by the developed countries, and the developing countries could not find their interest in them. On the other hand, some developed countries were unsatisfied because they could not sanction the non-compliance parties properly.

Eventually, due to the efforts and pressures from the United States of America and its big businesses the intellectual property rights issues inserted into the GATT (WTO) and TRIPS Agreement came into existence. Both of the United States Trade Representative (USTR), Intellectual Property Committee (IPC) and United States International Trade Commission (ITC) played great roles in enforcing the United States' legislative and executive to persuade countries around the world for creating the TRIPS Agreement. Some of the attempts were through dialogue and other through threat of unilateral retaliation and imposing trade sanctions.

The least developed and developing countries were all aware of the fact that the TRIPS Agreement is going to be in favour of the developed countries. They were aware of that fact and also that these developed countries used the patent as a tool for encouraging domestic development and industrialization. Now the developed countries are well industrialized, and they need high standard of protection of intellectual property rights. Nonetheless, the least developed countries

and developing countries accepted the TRIPS Agreement with few privileges and benefits for them, but with the hope that they will be getting some advantages of receiving technologies while joining the WTO as whole.

II

In section two the researcher established that in the TRIPS Agreement international trade is connected to the intellectual property rights and by not having effective and adequate protection of intellectual property rights by member countries will negatively affect the free international trade by causing impediments and distortions. To avoid this situation the negotiators of the TRIPS Agreement intended to regulate adequate standards and principles, not to impose highly standard form of protection. However, these principles have to be given effect through domestic legislations of member countries, as the TRIPS Agreement is not self-executing. The TRIPS Agreement, however, does not specify how these principles should be implemented, but rather the method of implementation is left for member countries to choose according to their own legal system and practice.

Even though the TRIPS Agreement provisions are considered to be high standard of protection for the developing countries. However, Article 7 will take the interest of the developing countries into account and establishes a balance between rights and obligations. The content of this Article which is titled objectives, were taken from the proposals of the developing countries, so that the TRIPS Agreement will not operate only in the interest of the developed countries. This Article reflects on the interests of the developing countries in which concentrated on promotion of technical innovation in such a manner that conducive to social and economic welfare. This requirement of the developing countries is not something new because it can be found in other international conventions such as Paris Convention and Berne Convention. Therefore, they wanted this to be fixed in the TRIPS Agreement in exchange of their compliance to the high standards of protection of intellectual property rights that exists in the TRIPS

Agreement. Otherwise, the developing countries have legal rights to object to the exclusive rights that granted by the Agreement.

It can be concluded from the first part of Article 8 that the member countries have the right to take measures necessary to protect their public health, nutrition and other public interest of vital socio-economic importance. These measures can be taken from the TRIPS Agreement such as the exceptions and limitations or the member countries can take measures not stated within the TRIPS Agreement such as marketing approval and price control of medicines. Therefore, these measures are not limited to intellectual property rights' measures but can include measures from any national laws and regulations that have been officially published as laws and regulations.

The second provision of Article 8 provides for further measures by the member countries that help them to prevent or stop the right holders from using their exclusive rights abusively. The word 'abuse' used in this provision is not limited to anti-competitive practices but can include any type of abuse that infringe the rights of third party and society in general. Furthermore, the member countries are allowed to adopt measures to prevent the right holder to use their intellectual property rights if such use caused any form of trade restraints. In addition to the abovementioned, this provision empowers the member countries especially the developing countries to achieve their aim of receiving technology in return of compliance with the high standard of protection. The provision states that if the right holders' practices have adverse effect on the international transfer of technology to the member country, then this member country has right to adopt measures to prevent such practices.

III

In section three the history of Iraqi patent law and its amendments were examined and analysed with references to important terms such as patent and invention. Next, the criteria of patentability in both Iraqi patent law and TRIPS Agreement have been discussed and examined. The Iraqi patent law was passed through some stages since establishment of Iraq as a country in 1920s. During the Monarchy period, Iraq enacted its first patent law, which was Law No. 61 of

1935 on Patents. This law amended few times until finally repealed by Patent and Industrial Design Law No. 65 of 1970 during the republic era because it was considered to be an outdated law. Law No. 65 of 1970 has also undergone four amendments, in which only two of them have made significant amendments, which they are first amendment by Law No. 28 of 1999 and third amendment by CPA Order No. 81.

IV

In section one of chapter two the definition of the term 'invention' was discussed, in which under Law No. 61 of 1935 the term had a simple definition i.e. considered discovery as invention that can be patentable. However, this term was changed from such a simple definition to a more modern definition by Law No. 65 of 1970, and even further developed by the amendment under Law No. 28 of 1999. Nevertheless, this definition was repealed and replaced by another one which was introduced by the amendment provided by the CPA Order No. 81. Even though the latest definition is included with the precise criteria of patentability, but the TRIPS Agreement does not define the term 'invention' as it is left for member countries to define according to their own legal systems.

All the criteria of patentability could be found within the definition of the term 'invention' in the Law No. 65 of 1970 before the amendment by the CPA Order No. 81. However, after the amendment the same criteria can be found in the definition, and the CPA Order No. 81 also specified another section for including all the criteria of patentability that are mentioned in the TRIPS Agreement. This way the CPA Order NO. 81 has improved the Iraqi patent law by clearly and precisely introduced the criteria of patentability.

V

In section two and three it has been established that the member countries of the TRIPS Agreement are allowed to exclude some areas from patentability. Therefore, according to the TRIPS Agreement

right of granting patent is limited base on some principles. Article 27.2 states that if the commercial exploitation of an invention endanger *ordre public* and morality. None of these terms are defined by the TRIPS Agreement, which is in favour of the member countries to define them according to their domestic understanding. However, generally speaking any invention jeopardises the structure of civil society and institutions of the society, then will be excluded from patentability base on breaching *ordre public* and morality.

Interestingly, section 3.1 of the Iraqi patent law No. 65 of 1970 provides that if exploitation of an invention breaches the principle of *ordre public*, public moral and public interest, will be excluded from patentability. All the amendments including the CPA Order No. 81 did not amend this provision. Therefore, this provision is in compliance with the TRIPS Agreement even though the term public interest is not mentioned in Article 27.2 of the TRIPS Agreement, but member countries are allowed to protect their public interest according to Article 8 of the TRIPS Agreement.

Article 27.3 (a) of the TRIPS Agreement also provides for another important exclusion from patentability which is 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals'. This provision is optional provision as all the exclusion provisions in the TRIPS Agreement are optional. Therefore, some member countries do not exclude method of treatment form patentability such as Australia, New Zealand and United States of America. Nonetheless, majority of member countries are excluding method of treatment from patentability.

It is noticeable that such provision cannot be found in the Iraqi patent law No. 65 of 1970 and none of the amendments added any provision in this regard. Since Iraq is one of the developing countries and in need of exclusion from patentability as much as possible to cope with the current situation that Iraq is going through sectarian wars and war with terror. Iraq is underdeveloped country in many areas especially in the areas that related to medicines and method of treatments. Therefore, this thesis is recommending adding a provision similar to that of the TRIPS Agreement to the Law No. 65 of 1970 in section 3.2 to be read as 'patent shall not be granted in diagnostic,

therapeutic and surgical methods for the treatment of humans or animals'.

Furthermore, the Doha Declaration on the TRIPS Agreement and Public Health admitted that there is massive public health problem that affects the developing counties. In this regard the ministers, through the Doha Declaration emphasized that the TRIPS Agreement should not be an obstacle in solving the public health issues of the developing countries but instead should be part of the solution. In addition, the it has been admitted that high standard of protection is having negative impact on drug prices. Therefore, the provisions of the TRIPS Agreement should be interpreted in a manner supportive to member countries to protect their public health and access medicines through flexibilities that available within the TRIPS Agreement. Doha Declaration further stated that the member countries should have right to determine ground of granting compulsory licence in this regard and determine what constitutes the national emergency and other circumstances of emergency.

The original Iraqi patent law No. 65 of 1970 had a provision that excluded medical and pharmaceutical formulations from patentability. However, this provision repealed and suspended by both amendments of No. 28 of 1999 and CPA Order No. 81 without substituting it with another provision related to access to medicine. The CPA Order No. 81 ordered in 2004 which is 3 years after endorsement of the Doha Declaration, therefore the CPA Order No. 81 should have taken advantage of the Doha Declaration and added a new provision to make easy for Iraq to access to medicines for needs of the public health, like other member countries have done it. This shows that the CPA Order No. 81 was legislated within the intention of solving the problems of Iraqi people. Therefore, the law No. 65 of 1970 should be amended in this regard to include some situations that Iraq can access medicines without authorisation of the patent holders as an exception to their exclusive rights, such as in cases of 'preparation of a medicine in accordance with a medical prescription for individual cases, carried out by a qualified professional, as well as to the medicine so prepared'.

VI

Article 27.3 (b) of the TRIPS Agreement excludes from patentability of plants and animals, however, it requires that member countries to provide for protection of plant varieties through a patent or an effective *sui generis* system or a combination of both of them. The original Iraqi patent law No. 65 of 1970 does not have any regulation in this regard. However, the CPA Order No. 81 added a new chapter for the protection of plant varieties. All the essential provisions of this chapter such as the definition of plant varieties and requirement of registration and protection, have been taken from the UPOV Convention of 1991. However, the CPA Order No. 81 failed to take the optional exception from the UPOV Convention of 1991 which gives limited right of re-using seed. But instead in this regard the CPA Order No. 81 has followed the United States of America's style of prohibiting saving, re-suing or resale protected seed. This showed that the CPA Order No. 81 was not regulated in best interest of Iraq, as the CPA was well aware of the bad situation of Iraqi fields and seed bank.

However, Law No. 15 of 2013 on Registration, Accreditation and Protection of Agricultural Varieties has replaced the CPA Order No. 81. The new law regulated the protection of new varieties in different way and provides for breeder's rights and in the same time provides for some extra exceptions than the CPA Order No. 81. Nevertheless, Law No. 15 of 2013 reduced the period of protection. Therefore, this thesis recommends this law to be amended so that Iraq can have a better *sui generis* system for protection of plant varieties that comply with the TRIPS Agreement and in the same time take advantage of the UPOV Convention that offered better rights to farmers in regard of saving seeds.

VII

In section one of chapter three, it has been concluded that Article 28 of the TRIPS Agreement has conferred certain exclusive rights to the patent owners in a form of negative rights. Some of these rights

are over the patented products, patented processes and direct products of patented processes, and other rights are related to rights to assign, transfer by succession and conclude licensing contracts. Nevertheless, these exclusive rights are subject to some exceptions that referred to in Articles of 30, 31 and 31*bis* the TRIPS Agreement. The TRIPS Agreement in Article 34 also provides for reversing the burden of proof in civil proceeding of cases involve identical products of the patented process.

The original Iraqi patent law No. 65 of 1970 referred to these rights in section 12 in a general term that the patent owner has exclusive right to exploit the invention by all legal means. However, the CPA Order NO. 81 repealed this section and replaced with the new one while it failed to follow the Article 28 of the TRIPS Agreement by not stating the rights to assign, transfer and concluding licensing contracts. Even though section 25 of the original law No. 65 of 1970 states some of them but not similar to the TRIPS Agreement especially in the rights to conclude licensing contracts. Therefore, this thesis recommends that an amendment in section 12 in order to include all the exclusive rights that are stated by the TRIPS Agreement will be necessary. Since the original Iraqi patent law does not contain any provision similar to Article 34 of the TRIPS Agreement, and none of the amendments including the CPA Order No. 81 added any similar provision, therefore, this thesis also recommends that similar provision should be inserted to the Iraqi patent law so that the patent owners enjoy better protection.

VIII

Section two was dedicated to the exceptions to exclusive rights of patent owners. It has been concluded that Article 30 of the TRIPS Agreement can be used to grant many types of exceptions to the exclusive rights of the patent owners by following the criteria in Article 30. There are three general criteria, the exception must be limited, the exception should not unreasonably conflict with a normal exploitation of the patent, and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the

legitimate interests of third parties. Therefore, the member countries are allowed to place exceptions to exclusive rights as long as they follow the criteria.

Next this section has discussed and analysed the compulsory licence. compulsory licence is another important tool that keeps balance between patent owner's rights and need of society for patented products, through limiting the exclusive rights of the patent owners. Article 31 of the TRIPS Agreement provides for 'other use without authorization of the right holder', and the term 'other use' refers to other exceptions to the exclusive rights of the patent holders than what allowed under Article 30. Grounds of granting compulsory licence is left for the member countries to determine according to their circumstances. Nevertheless, some conditions and requirements are stated in other for member countries to follow before granting the compulsory licence either to government or third parties authorised by government.

The thesis has discussed in detail these conditions and requirements and concluded despite the importance of the compulsory licence exception to the member countries so that use it for fulfilling their needs, however, some of the conditions have created obstacles in front of least developed and developing countries to use this exception. Article 31 lit. (f) is one of the major obstacles for the least developed and developing countries, as it requires the compulsory licence should be granted predominantly for the supply of the domestic market. The fact is that many of those countries do not possess enough technology to produce most of the patented products locally. This eventually lead to amendment of the TRIPS Agreement and Article 31bis was added.

Article 31*bis* submitted to member countries to be accepted by the General Council on 6 December 2005 and entered into force only on 23 January 2017 in addition to an Annex and Appendix. This article was added to remedy the obstacles that Article 31 caused to the least developed and developing countries. Therefore, Article 31bis permits the member countries to grant compulsory licence so that majority of the pharmaceutical products under the licence can be exported to other member countries. Furthermore, Article 31*bis* exempts the importing

member country from adequate remuneration. This thesis has concluded that this Article can help the member countries to fulfil their needs of medicines for their public health.

Following the above discussion, the thesis has discussed and analysed the position of Iraqi patent law to exception to exclusive rights of the patent owners. In fact, neither the original law No. 65 of 1970 nor the CPA Order No. 81 contain any regulations allowing exceptions within the scope of Article 30 of the TRIPS Agreement. Since the CPA Order No. 81 ordered with the intention of inline the Iraqi intellectual property laws with that of the TRIPS Agreement, and if the CPA acted in favour of Iraq should have included some important exceptions that are allowed with the scope of Article 30 such as parallel imports.

Nevertheless, the original law No. 65 of 1970 provided for compulsory licence in a few cases such as, if the right holder did not exploit the invention in Iraq within three years of granting the patent, if the exploitation by the patent owner did not correspond to the needs of the country, if the patent owner stopped exploiting the invention for at least two years and in cases of dependent patent. However, the CPA Order No. 81 amended all the provisions that related to compulsory licence by extending the period of not exploiting the invention in Iraq in the first situation and removing all the other three situations, even though compulsory licence in cases of dependent patent is provided for by the TRIPS Agreement. The CPA Order No. 81 added some new provisions to the Law No. 65 of 1970 in regard of compulsory licence that have taken them from Article 31 of the TRIPS Agreement. In this the CPA Order NO. 81 has brought the original law closer to the TRIPS Agreement but failed to mention any circumstances that stated in Article 31bis of the TRIPS Agreement.

Last but not least, Article 31*bis* took effect only in 2017 but the Doha Declaration and Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health took place between 2001 and 2003, therefore, the CPA was well aware of the problem of developing countries in regard of supplying medicines for their public health crises. For this reason, the CPA should have added the exceptions in Article 31*bis*, which basically has been taken from

provisions of the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. Again, in this regard the CPA did not acted in interest of Iraq. Therefore, this thesis recommends that all the exceptions to exclusive rights of the patent holders exist within the TRIPS Agreement should be implemented by the Iraqi patent law so that be able to fulfil the needs of Iraq.

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