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**PHARMACEUTICAL PATENTS IN THE TRANS-PACIFIC
PARTNERSHIP. THE MORE THINGS CHANGE THE MORE THEY
STAY THE SAME?**

AUTHOR:

D. Rubén CANO PÉREZ

ACADEMIC SUPERVISOR:

DR. D. Manuel DESANTES REAL

ABSTRACT: Life is most value heritage that human beings we have. Pharmaceutical patents play a fundamental roll in the development of people's survival of different countries, which as it is known does not have the same advantage level, extending the lapse of time that the generic medicaments take to be into the market. The Trans-Pacific Partnership Agreement includes this subject in his acquis, therefore we will try to analyse if the global protection changes under the applicable juridical structure umbrella.

RESUMEN: La vida es el patrimonio más valioso que tenemos los seres humanos. Las patentes farmacéuticas juegan un papel fundamental en el desarrollo de la supervivencia de los habitantes de diferentes países, que como bien sabemos no tienen el mismo nivel de avance, alargando el lapso de tiempo que los genéricos tardan en llegar al mercado . El Acuerdo Transpacífico de Cooperación Económica incluye ésta materia entre su acervo, por lo que intentaremos analizar si la protección global cambia bajo el paraguas del marco jurídico vigente.

KEYWORDS: Trans-Pacific Partnership (TPP) – Pharmaceutical Patents – Developing countries – United States (U.S.) – Trade Related Aspects of Intellectual Property Rights (TRIPS).

PALABRAS CLAVE: Acuerdo Transpacífico (TPP) – Patentes farmacéuticas – Países en vías de desarrollo – Estados Unidos (EE. UU.) – Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (ADPIC).

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INTRODUCTION

1. Globalization is the economic, technological, social and cultural process on a world wide scale that consists in the growing communication and independence amongst the different countries. Furthermore, it is the trend of markets and enterprises to spread, achieving a global dimension that exceeds the drawn outlined national borders. In earlier times, the *Bretton Woods Agreements*, established in 1944, the framework for international commerce and finance, created the World Bank, and the International Monetary Fund. Later, the GATT appears, *General Agreement on Tariffs and Trade*, beginning the international relations control. Likewise, 40 years later the implementation of the World Bank and the International Monetary Fund, the negotiation for the origin of World Trade Organisation starts, ending in 1994. In the intermediate years, two significant events take place: the signing of the *North American Free Trade Agreement (NAFTA)*, in 1988; and the *Warsaw Pact*, which was going to put an end to Cold War in 1991, and definitely to give the starting signal to the globalisation after the falling of communism. Since that moment, the integration of local economies translates in market economy, that brings extraordinary progress, but also numerous risks.

2. Ending in 1994, and administered by the World Trade Organization, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) appeared, setting up the minimum standards for the adequate protection of intellectual property rights, as the own TRIPS pointed out. The TRIPS recognized among others, the applicability of the basic principles of GATT 1994, the provision of adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights taking into account differences in national legal systems¹. A point as important as conflictive was at the time the access to essential medicines, which even nowadays is source of many controversies, bringing us to the key aspect of this paper.

3. Starting from the AIDS² in Africa, TRIPS has been subject of several modifications on this topic, in which pharmaceutical patents play a decisive role. From

¹ TRIPS, Part 1, General Provisions and Basic Principles.

² Acquired Immune Deficiency Syndrome

that vision, I will analyse how the “*Agreement of the XXI century*” will change the protection standard of the pharmaceutical patents and consequently, which would be the results for different economies. To do this, in the first part, I will put you in the context, showing out the magnitude of the agreement through the mover reasons of the agreement, and a brief conclusion.

4. As you must know, people don't have the same opportunities to gain access to the pharmaceutical products. TPP implementation in countries that have different development levels, and consequently, don't have the same capacity to access to the medicines could produce that the measurements which could be adapted to developed countries, impede the entry of the drugs to countries with a low development level because of the tardive appearance of the generics. What I will try to do in the second part of this paper is go over the principal steps for the generic drugs to access into the market, highlighting the general and specific regulation, which bring us to the main conflictive points in my opinion according to the *Trans Pacific Partnership*: life cycle of a pharmaceutical product, protection of undisclosed test or other data, and treatment of the generics.

5. Therefore, “*Does the Trans-Pacific Partnership Agreement change, in an extraordinary way, the possibilities for developing countries and least developed countries to access pharmaceutical products?*”

EMERGENCE OF THE TPP

6. Not long ago, was the *Doha's Round* council meeting, in November 2001, Qatar. The aim was to confirm the process of integration, concluding the work started at the *Uruguay's Round*, and trying to promote completely the liberalisation of international trade, definitively, a multilateral trade system. The objective it seemed clear, a system that it could include international trade rules for all countries, for all markets.

7. Perhaps, at the birth's moment of the *Doha Development Program negotiation*, as it is known colloquially, and still previously with the *Uruguay's Round*, no-one had thought in a change of scene. No-one noticed that the states, instead of losing power in a progressive manner, would be gaining it, taking a main roll separately. The slow evolution of the negotiations and the indefinite suspension in 2006, even though it where unblocked at *Bali's Conference* at 2013, produced the proliferation of bilateral, under-regional, and regional agreements across the length and breadth of the world. Two of the most important: The *Trans Pacific Partnership Agreement* (TPP), and the *Transatlantic Trade and Investment Partnership* (TTIP). Consequently, the failure of *Doha's Round*, and the shortage of cooperation structures (specially in Oriental Asia), makes even more important the achievement of stable economic and commercial mechanisms for cooperation that, through the common progress, dissolve inflexibilities³. With that perspective, bearing in mind as much the economic dynamism of Asia, as the geopolitical tensions that in this continent we can observe, we must analyse the dynamic of regional and commercial integration.

³ GRYNSPAN. R., “ El nuevo reequilibrio global”, XXI Reunión Primaria del Círculo de Montevideo, Universidad de Alicante, 16 Octubre 2016.

(vid. <http://circulodemontevideo.org/XXI-Reunion-Plenaria.asp>)

8. Moreover, about what was said before and the universal context, we can affirm that the *Trans-Pacific Partnership Agreement* (TPP), emerge fundamentally of two main events. One the one hand, the weakening of WTO as a guide of prices and good exchange rules, translated in the failure of *Doha's Round*⁴. On the other hand, the impossibility of the *Mechanism of Cooperation Asia Pacific* (APEC) to reach the *Bogor Goals* at 2010.

9. The purpose of the TPP, is to redesign the trade, economical, political and juridical relations, within the nations of Asia-Pacific zone. It is in that moment, where the system breaks down, making place to a structural change of international commerce, that makes us wonder: Where, where are we going? Are we heading to a multilateral structure? Who are the actors, all countries? Or on the contrary, are we on the blocky structure way? If actually, we are heading to a blocky structure, how will it be? Are they going to obey to the historical order (geographic), or they will change their orientation towards geopolitics?⁵ I dare myself to assert, that we are in the second case, blocks which obey to the geopolitical position of countries. It is quite clear, it is not a secret, the transfer of power among north and south, and west and east of the globe of the world, taking place a change of paradigm without precedents. With the unitary system offside, we realize ourselves that the globalisation, at the same time we were thinking was approaching us, is moving us away, fragmenting us. Consequently, we are not facing an era change, but a change of era. Here it is where we can place the main key of the international commerce architecture, which is called “the framework of 21st century” and which could be an inflexion point in the international relationships, as many privates as publics.

⁴ BARTESAGHI, I., “*Efectos del TPP en Asia-Pacífico y Latinoamérica*”, Foreign Affairs Latinoamérica, Vol.15: Num. 3, pp 43-45, México, 2015.
(vid.http://www.observatorioasiapacifico.org/data/OBSERVATORIO.Images/Publication/temp/2015100101511512_Bartesaghi_49.pdf)

⁵ Vid. 3.

THE AGREEMENT'S MAGNITUDE

10. The Trans Pacific Strategic Economic Partnership Agreement (TPP) or simply Trans Pacific Agreement, is a free trade pact among several countries of the Pacific Rim that tackles a variety of subjects. Because of his amplitude, that is reflexed in its 30 chapters; its clandestinity; and the predictable economic repercussion that it is going to have at the relations of this century; it has been as criticized as praised around the world.

Rising and parties

11. Since the 90's decade, Asia has taken a turning point in their trade policy. At 2010, it existed 61 trade agreements concludes, of which 47 where operatives and 25 concerned to the Asia Pacific zone. The origin of the agreement is regional in nature. At 2002, in the bosom of the *Asia-Pacific Economic Cooperation (APEC)*, Los Cabos (Baja California), three countries as Singapore, New Zealand and Chile, began the negotiations with regard to their economic association. The fit had to be later the *Pacific Three Closer Economic Partnership (P3 CEP)*, that only pretended "closer economic relations" between mentioned countries. Later, the pact was formalized at 2003, and it began counting with the interest of other countries like Brunei Darussalam, that will add at 2005, setting the *Trans Pacific Strategic Economic Agreement (P4)*, which was operative at 2006.⁶

12. At 2008, the White House heard about the treaty, and Washington began to see up the pact, handled by George Bush president, U.S. included himself into the negotiations, specially at investments and financial services. Barack Obama, the president-elect at 2009 endorse this decision of turning over the trade centre to the other side of the planet, leaving Europe out borders. Since that moment, U.S. led the negotiations, and the agreements passed to the international first scene, attracting the attention of numerous actors that up to this moment were not being interested. After, all the agreement affairs will be highly confidential. Besides the U.S. inclusion into the

⁶ OROPEZA GARCÍA, A. : «El Acuerdo de Asociación Transpacífico (TPP) ¿Bisagra o confrontación entre el Atlántico y el Pacífico? », p. 13, UNAM, México, D.F., 2013

negotiations, because of motives we will explain posteriorly, the pact changes totally of sphere passing from a simple agreement, that reunite four “non-powerful” economies, to the legal structure which we can appreciate today, treating several subjects in an extraordinary way. Australia, Peru and Viet-Nam, would be included into the negotiations in 2008. Malaysia, was to do later, at October 2010. At the same month, but at 2012, Mexico and Canada would incorporate. For the circle’s closure, in July 2013 would take place the Japan’s inclusion.⁷

Country	Agreement	Inclusion into the TPP negotiations
Singapore	P3 CEP/ P4/ TPP	2002
New Zealand	P3 CEP/ P4/ TPP	2002
Chile	P3 CEP/ P4/ TPP	2002
Brunei Darussalam	P4/ TPP	2005
UU.EE.	TPP	2008
Australia	TPP	2008
Peru	TPP	2008
Viet-Nam	TPP	2008
Malaysia	TPP	2010
México	TPP	2012
Canada	TPP	2012
Japan	TPP	2011

Data source: Compiled on the basis of information provided by Vid. 2.⁸

⁷ Vid. 6.

⁸ Graphic: own production.

What is the Trans-Pacific Economic Cooperation Agreement about?

13. Already analysed the parties of the pact, the subject is divided in two fundamental parts: the tax reduction and the creation of common regulation within the implicated economies. The subjects, regarding the chapters, are as follows:

02.National treatment and market access for goods	16.Competition policy
03.Rules of origin and origin procedures	17.State-owned enterprises and designate monopolies
04.Textiles and apparel	18.Intellectual property
05.Custom administration and trade facilitation	19.Labour
06.Trade remedies	20.Environment
07.Sanitary and phytosanitary measures	21.Cooperation and capacity building
08.Technical barriers to trade	22.Competitiveness and business facilitation
09.Investment	23.Development
10.Cross-border trade in services	24.Small and medium-sized enterprises
11.Financial services	25.Regulatory Coherence
12.Temporary entry for business personal	26.Transparency and anti-corruption
13.Telecommunications	27.Administrative and institutional provisions
14.Electronic commerce	28.Dispute settlement
15. Government procurement	

Data source: Compiled on the basis of information provided by Vid. 2.⁹

⁹ Graphic: own production.

Therefore, it is a formal third generation free trade agreement, who includes goods and services, origin rules, formulas for settlement disputes, sanitary and phytosanitary measures, intellectual property, public works supply and competition policies, as a reduction of more than 18.000 taxes. The TPP, has as a main additional characteristic, the existence of bilateral and sub-regional trade agreements, as well as the intention to keep them. Or what is the same thing, the present agreements will coexist with the TPP as well as 1.2. article of the chapter about initial provisions and general definitions says. Without any aim to be exhaustive, the pact is looking to enclose a general framework for their, each party, intern implementation. Who is not an obstacle for particularities that can emerge imperatively. Of the foreseen on the legal text and having the general context under regard, we can extract that the agreement heads to a future development of opportunities and challenges, as well as a likely union of other economies which operates on this zone reinforcing the regional economies integration and founding a free trade area in the Asia-Pacific zone.

14. With mention to the TPP preamble, we can draw that the parties commit themselves to stablish a regional agreement promoting the economic integration for the trade and investment liberalization, resulting directly the economic increase as well as many welfares. At the same time, the aim is to create new opportunities for the workers and entrepreneurs, contributing to the implementation of the living standards, the consumers' benefits, reducing poverty and promoting sustainable growth. Therefore, the pact searches to reinforce the friendly bows and cooperation among them and the parties' territory people, under the rights, obligations and principles declared at the Marrakesh Agreement, creating the World Trade Organization (WTO). As well, recognizes the parties' right to regulate and resolve with relation to the establishment of a framework and regulation of priorities, to preserve the flexibility, saving the public welfare, the environment, and the existent resources until the moment.

15. However, despite the extraordinary delay of the agreement's object and the numerous benefits that could emerge, the main thing is that reunites 40% good's trade economy. Concretely, 37,5% of world's production. Those twelve countries make 11% world population, which could be translated in 800 million people. Other information is, that it supposes: 23% world exports, 27% imports, 32% incomings of direct foreign investments, and 42% of outputs. In numbers, noting that the benefits could be reduced

at the beginning, from 2025 the TPP track would be a raising of 104 billion dollars per year on social benefits. Here it is the main point, because reuniting a high percentage of the international trade, there are outside, partially, the control of any market unification organism as the WTO is. This is due to two groups under the subject's regard: a) those known as *WTO-plus*, already existing at the WTO, of which there are concluded agreements among three or more WTO members, and his scope can be bigger or smaller than the WTO regulation; and b) those known as *WTO-extra*, which are agreements not regulated by the WTO, but can be developed apart from the organization¹⁰.

16. Consequently, in general, the TPP is an agreement type *WTO-plus*, who goes beyond what WTO's multilateral trade system envisioned. The range of subjects, that is not only largest, but that the reach of integration is stricter and deeper, including, of course: agriculture sector, services liberalization, investment protection, competition policies, consumer's protection, settlement disputes, clauses of workers and environmental protection and stipulations to assure the regulatory coherence between the parties, as well as more protection to the intellectual property (especially pharmaceutical patents).

The TPP and the United States

17. Besides the *Doha's Round* failure and the stagnation of APEC¹¹, as well as the non accomplishment of the *Bogor Goals to 2010*, the agreements takes real importance since the U.S. inclusion into the negotiations. It is clear that facing the passivity, or impossibility of the WTO to fix a uniform market, they had to emerge regional integration agreements. It is here, where the principal economical and political powers play his roll.

18. Thus, the pact is very important under a geopolitical vision, because U.S. search directly moderate the China's power in the Asia-Pacific zone, and consequently, in the

¹⁰ WTO (OMC): Programa de Políticas Comerciales y Gobernanza del Centre for Socio-Economic Development (CSEND), Sesión 29: "*Plurilateralismo o multilateralismo Punto de vista de múltiples colectivos interesados*", INT/SUB/3451, Jakarta, Septiembre de 2015.

¹¹ Asia-Pacific Economic Cooperation.

main environment in which it is envisioned the economic development of 21th century. Revealing is the declaration of Barack Obama, affirming that “*when 95% potential U.S. consumers lives abroad, doesn’t makes sense that China write trade rules*”. The reality is that after the second part of 20th century has been a present power in Oriental Asia and Oceania on: finance, economy, military, transport, political and cultural life affairs. This century faces the apparition of China, no longer as an ideological and systemic rival of bipolarism and Cold War, but as a stronger competitor that U.S. never had. As an increasing power, U.S. search contain China, but trying to benefit of his enormous economic, scientific and political dynamic.¹²

19. Because of that and the high confidentiality a lot of theories had emerged regarding this agreement since the high confidentiality has not allowed the main interested performers in knowing the particularities or the different proposals that were on the table, that is, its advance. The data privacy, like we were noting before, has caused a chain of speculations linked to the U.S. political interests of leading an integration structure of a geopolitical zone that since the Chinese economic exit, has been living a deeper economic and politic transformation. Regarding that treaty from this perspective many doubts arise on whether the parties, or U.S. as the leader of the negotiations, are taking into account the different developments between countries, the institutional capacities, and the political and legal systems of every country being part of the agreement. If it is not like that, it will emerge an extraordinary problem for some of involved countries, because I have to remember that we are facing a *WTO-plus* agreement.

Conclusion

20. All in all, the Trans-Pacific Partnership Agreement, could have several consequences or objectives: a) to create a modern and comprehensive track for the agreements that could take place since now in an international level; b) a deeper promotion of the global integration in the Asia-Pacific zone; c) the consolidation of

¹² PETRI, P., PLUMMER, M., ZHAI, F. «The Trans-Pacific Partnership and Asia-Pacific Integration: *A Quantitative Assessment*», pags 43-46, East-West Center, Honolulu, 2011.

existent trade agreements (around 14 bilateral or regional treaties within the parties at TPP); and d) the TPP would increase, mainly but not only, the U.S. exports to the Asiatic market, because numerous regional agreements excluded that country before.¹³

21. Though TPP in a strict manner is not an APEC initiative, it is considered part of the search of pathfinders to transform this mechanism of intergovernmental conferences, in a true *Free Trade Area at Asia-Pacific* (FTAAP). The TPP, consequently, could be the precursor of FTAAP, and also could be the potential start of a new regional and global regulation system, but with the U.S. in its hearth. Evidence of this is the sign of the declaration in which the *Association of Southeast Asian Nations* (ASEAN) members proclaim a single market in Kuala Lumpur the 22 November 2015. The association is formed by Myanmar, Brunei, Cambodia, Philippines, Indonesia, Laos, Malaysia, Singapore, Thailand and Viet-Nam, with a total of 630 million people, with an economic combined export of 2,6 trillion dollars. Therefore, the TPP should not to be seen as a trade-legal component, but make amply the perspective thinking it will generate multitude of extra contractual consequences to the directly involved parties as well as the other Pacific Rim countries, not to mention with the results that will have in the future for the rest of the international relations.¹⁴ Results that will be materialized also in the sanitary system of the signers' people, in the everyday lives of the individuals pertaining to least developed countries.

¹³ NIÑO PÉREZ, I. : «China ante el Tratado de Asociación Transpacífico (TPP): *Riesgos, alternativas y oportunidades*», pags. 2-5, México, 2013.

¹⁴ Vid. 5

WHEN PUBLIC HEALTH IS ON THE TABLE

22. Health, perhaps, is the most important personal good linked to our own life as human beings and something we have in our heritage, because time is ephemeral and life is finite, and health can't be bought (at least directly). Definitively, here is where the pharmaceutical patent's problem resides. So then, what is the problem? The situation arises from decades ago, if not centuries, where people died if they had not enough resources. Their resources were insufficient to pay the price of certain medicines, so the least developed population, or if we want poorest population, suddenly could not reach these type of products. Governments of developing countries have attempted to improve access to essential medicines by taking various measures, which reduce the price of drugs, but they have faced extreme pressure from developed countries and from the multinational pharmaceutical industry based on the current system of global pharmaceutical patent protection. In accordance with that, the Global Health Observatory (pertaining to the World Health Organization) says, among 1.4 and 1.7 million people died in 2015 due to human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS), which is a consequence of an inability to access to medicines and its limitations. With this pharmaceutical patent system, there has been an attempt to establish a balance, in which after a monopolistic exploitation throughout an extensive time period, the biological product information became public, and allows the "generics" to be introduced into the market. Or as WTO affirms, "*achieve a balance between the social goal in long term to offer incentives for inventions and future creations, and as a short term goal to allow the use of existent inventions and creations*". In this way, simplified, although the market entry is often though, the investment in resources is protected generating new sanitary advantages, and if not protected, they will not be achieved. Obviously, it should be a balance but, are we on balance? Where is balance mentioned? Are twenty years of protection enough for a piece of information (under sanitary and a public interest) that could be vital for a country's population?

23. The greatest disadvantages emerge when there are different countries with different development speeds, generating a higher price of pharmaceutical products in developed countries, and in developing countries with relatively small commercial markets and low levels of disposable income there is very little incentive for

pharmaceutical companies to conduct extensive research and development to create drugs for life-threatening diseases. Here, consequently, to evaluate the regulation we must refer ourselves to the *Trans Pacific Partnership* and the *Doha's Declaration on the TRIPS Agreement and Public Health*¹⁵ which was adopted the 20 November of 2001, with preference as art. 18.6 from TPP asserts. Together with what was said earlier, we must insert this analysis into the juridical segment dedicated to patents within Intellectual Property, among which each party according to article 18.7 undertakes, having ratified: a) *Patent Cooperation Treaty*; b) *Paris Convention for the Protection of Industrial Property*. Likewise, each party is obliged to add (if they are not party already) to: c) *Berne Convention for the Protection of Literary and Artistic Works*; d) *Madrid Protocol concerning the International Registration of Marks*; e) *Budapest Treaty on the International Recognition of the Deposit of microorganisms for the Purposes of Patent Procedure*; f) *Singapore Treaty on the Law of Trademarks*; g) *International Convention for the Protection of New Varieties of Plants (UPOV 1991)*; h) *WIPO Copyright Treaty (WCT)*; i) *WIPO Performances and Phonograms Treaty (WPPT)*. Therefore, we can appreciate that TPP Agreement brings a global, common and legal structure to all signatory countries.

24. Taking into account what was said before, I will try to analyse the damages and benefits of the agreement linked to the pharmaceutical patents that differ between countries and their level of development, and attempt to answer the main question under study: *Does the Trans-Pacific Partnership Agreement change, in an extraordinary way, the possibilities for developing countries and least developed countries to access pharmaceutical products?* To answer this question, I will analyse pharmaceutical patents regulation highlighting which I consider the key points, and pass over the disadvantages of the TPP.

¹⁵ Vid. https://www.wto.org/spanish/tratop_s/trips_s/pharma_ato186_s.htm

PHARMACEUTICAL PATENTS, GLOBAL AND SPECIFIC REGULATION

25. As the TPP defines in art. 18.52, a new pharmaceutical product means a new medicine that doesn't contain or use a chemical entity that has been previously recognised in a party's territory.

26. Patentable subject matter. Under the structure of the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS), the engagements about patentable subject matter set themselves up in article 18.37 of TPP, with the following as main points: 1) patents must be available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step and is capable of industrial application; 2) patents must also be available for inventions claimed as at least one of the following: new uses of a known product; new methods of using a known product; or new processes of using a known product; 3) parties are permitted, should they so desire, to exclude from patentability inventions that may offend *order public* or morality, including to protect human, animal or plant life or health or to avoid serious damage to nature or the environment; and 4) parties are also permitted to exclude: 4.a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; 4.b) and animals other than microorganisms, and essentially biological processes for the production of plants or animal, other than non biological and microbiological processes, and plants. In this topic, compared with TRIPS regulation (art. 27), we can find more than other, one innovation or implementation among all highlighted points. Point 2, which we were talking about, is an extension of the obligations under TRIPS, that although if it is true that the implementation is allowed in some juridical systems, some other parties will have to include this precept, so that could be one *leit-motiv* for international issues. On the other hand, with point 4.b). I don't think that it will suppose any problem as far as most of this regulation is already regarded at UPOV 91¹⁶.

27. Grace period. Here we have another innovation from the TPP regarding TRIPS. Grace period, introduced in article 18.38, makes a novelty for new countries that are

¹⁶ *International Convention for the Protection of New Varieties of Plants. 1991.*

signing the agreement, as are Japan and New Zealand; however, not for countries like Mexico, United States or Canada, that already have this figure in their internal law. In this system, each party shall refuse information provided in public divulgations to determine if one invention is a novelty or has an inventive activity, and also if the public divulgation was: 1) made by the patent applicant or a person that obtains the information in a direct way or indirectly from the applicant; b) or if it took place in the previous months 12 before the application deadline of a party's territory. During this period, it brings the applicants a general immunity to face up likely consequences via "self-disclosure" of the invention before requesting the patent, which is not anticipated in the TRIPS.

28. Patents revocation. Specified in article 18.39, there is not any difference or novelty regarding the rules applied before the TPP, therefore allowing countries to introduce any revocation cause as long as it continues respecting 5th article of the *Paris Convention* and the *TRIPS Agreement*.

29. Exceptions. As well, article 18.40 allows the introduction of likely exceptions, which I don't think it is going to suppose a big controversy, as it doesn't go beyond the standards established up to the moment.

30. Other use without authorization of the right holder. In a similar manner we can analyse article 18.41, whose drafting reiterates directly which article 31 of the *TRIPS Agreement* says. The article considers obligatory licences as part of the general objective of the agreement, which is to settle up a balance among the promotion of access to the existing pharmaceutical products, and promoting investment and development of new medicines. The TRIPS, doesn't have a specific enumeration of causes, but article 31 (in relation with our TPP article) refers to circumstances of national emergency, circumstances of extreme urgency and anticompetitive practices¹⁷. A matter of extraordinary relevance is the "imports under obligatory licences according to the art. 31, f) TRIPS". Those obligatory licences are used mainly to provide for their

¹⁷ ANDERSON, A.: «Global Pharmaceutical Patent Law in Developing Countries- Amending TRIPS to Promote Access for All», The Berkeley Electronic Press, Tulsa, 2006.

internal market, and allow countries to import, generic medicines cheaper with the obligatory licences in case that they are not able to make it by themselves. It includes, as well, measures to prevent the pharmaceutical products flow to inappropriate markets and other rules that receiving governments within the system have to implement to keep all others members informed. To the concern of signer countries of the TPP: Australia, Canada, U.S., Japan, New Zealand announced voluntarily that they will not use this system as an importing member; and Mexico and Singapore declared that they only would use the system as importers when presented by a situation of national emergency or extreme urgency.

31. In relation to the following TPP articles, except article 18.46, there is no extraordinary innovation to the international patent system, regarding patents application, publication (“disclosure”, 18 months until the presentation date or, if given priority, until that earlier date of priority) and to the information that should contains mentioned publication.

32. Patent term adjustment for unreasonable granting authority delays. Article 18.46 introduces a patent term adjustment for unreasonable granting authority delays, which woke up antagonisms. This adjustment, concretized for pharmaceutical products in art. 18.48, provides an extension of the patent protection for unreasonable or unnecessary delays, which we will study afterwards and doesn’t appear in TRIPS neither.

33. Protection for undisclosed test or other data. In addition, it provides, as I will analyse later protection for undisclosed tests or other data.

34. Measures relating to the marketing of certain pharmaceutical products. In article 18.53, without any controversy, the TPP introduces different measurements relative to entry into the market of pharmaceutical products through which parties should establish mechanisms that could solve conflicts that emerge due to the authorization of commercialization in another party’s territory when the person is another than those who made the original application.

DISADVANTAGES OF ITS EMERGENCE. WHY IS THE TPP AGREEMENT BEING CRITICIZED?

35. The Trans Pacific Partnership is criticized because it doesn't protect anymore the economic welfare through the entry of generic medicines, quite the opposite, consolidating neoliberal politics and multinational pharmaceutical interests.

Therefore, we are facing three probable mechanisms or instruments which could extend the patent term, or if we want, a temporal protection of the pharmaceutical components or products, stopping an earlier entry for generics into the market: 1) the extension of patentable subjects' matter; 2) patent term adjustment for unreasonable authority delays in granting; and 3) protection of undisclosed test or other data.

- 1) The article 18.37.2 relative to the extension of patentable subjects' matter to new uses of the known product; new methods for the known product; and new processes use for the known product. In some countries that could be an innovation, but regarding the pharmaceutical patent system of other signer countries, they establish in their own internal patent law term extensions by, mainly, three kind of factors: a) development of new product's indication; b) development of new administration ways; c) development of a likely drug's association. Consequently, this point of view could be in detriment of some countries, but I don't consider it is a relevant measure because even if that could extend the patent's term, it is an inventive activity which justifies the extension.
- 2) The second source of probable issues is article 18.48 concerning to the patent term adjustment for unreasonable authority delays in granting. In this case, the adjustment comes from unjustified delays in the commercial authorization, which would cause the right holder a diminution of the effective patent term.
- 3) Thirdly, article 18.50 relating to the protection of undisclosed tests or other data. This assumption even though it could have an influence on the public availability of information concerning determined drugs, is substantially different of the patent term, as we will explain later.

36. Our TPP establishes that one condition to grant a commercial authorization for a new pharmaceutical product is the presentation of data, tests or evidences which were not divulgated previously according to the security or the efficacy of a product. The party which grants the commercial authorization, accomplished that condition, couldn't

allow to third parties to access to information based on: a) mentioned information; b) commercial authorization granted to the person that presented the information by, at least, five years until the commercial authorization date of the new pharmaceutical product in a party's territory. Something similar is established in case one party takes a valid presentation of a previous authorization of the product from another territory. The same article, in its second paragraph foresees:

- a) It should be established in the mentioned protection, *mutatis mutandis*, for a period never less to three years regarding new clinical information presented being required to support the commercial authorization of a pharmaceutical product previously approved covering a new indication, new formulation or another administration method; or alternately.
- b) Apply as well paragraph 1, *mutatis mutandis*, for a period never less than five years to a new pharmaceutical product that contains a chemical principle that hasn't been approved before by the party. In this case, we are facing a dispositive rule, because one party can protect only tests or other data which were not divulged concerning the security or efficacy relative to a chemical principle that hasn't been approved before.

37. Nevertheless, the polemic doesn't arise simply by its application, but because of its application in countries that have different development levels, and consequently, don't have the same capacity to access to the medicines. This produces that the measurements which could be adapted to developed countries, impede the entry of the drugs to countries with a low development level because of the tardive appearance of the generics. Until the emergence of generics success, there is a great increase of prices because of the monopoly of the owners of the patents, making difficult to the public without economic resources to access the sanitary product. For a better comprehension of the conflictive applicability points established previously, we will analyse the steps to follow starting from the application for the patent until its commercialisation, the pharmaceutical generics treatment, and the distinction among the "protection for undisclosed test or other data" and the patent.

Life cycle of a pharmaceutical product

38. This cycle is normally divided in ten big periods that in several occasions can overlap each other:

- 1) Development period in which, through basic investigation, the aim is to try to find and identify new therapeutic targets.
- 2) The chemical synthesis of new molecules with possibility to patent and its sieving on likely therapeutically targets, where the objective is to be able to select some leader molecules.
- 3) The preclinical development of new drugs, that is the period in which the study of biological activities begins, as many “in vitro” models as in experimental animals; also it is at this moment in which there is an entire consolidation of preclinical documentation. With this documentation, together with the development of the clinical plan (DCP), serves as a base to obtain the authorization, by the regulatory authorities, to start clinical investigation. The international normative that regulates preclinical investigation is described in good laboratory practices (GLP). The results of the preclinical tests can also be used to determinate which is the best pharmaceutical way that could be employed with the new drug during the clinical period. Once preclinical studies are completed, thousands of leading molecules are gradually reduced to a few medicine candidates and put to clinical development. Before starting clinical development periods, it is necessary, on one hand, to introduce all the chemical, preclinical and pharmaceutical knowledge of the candidate drug into a preclinical dossier; and on the other hand, to prepare the DCP describing all the clinical tests that would be experimented on human beings before applying for commercialisation. That dossier, the DCP and the investigation manual will be remitted to the sanitary authorities for evaluation and approval to the start off clinical investigation in human beings, always with known and enough information of the candidate drug.
- 4) Clinical development of new medicines is a period in which the first clinical tests in humans and evaluation of the efficacy and security of the new pharmaceutical product under investigation takes place, but they are also tested for new uses or even new kinds of administration.

- 5) Later, is the period for developing integration of chemical-pharmaceutical –clinical or preclinical- documentation, as well as the registration and authorization by the corresponding agencies that regulate the commercialization of the new drug. Only a few medicines in this period reach this last step of development, previous to commercialisation, called the “registration of new drug”. That documentation called “register dossier” is remitted to the principal sanitary authorities –FDA (U.S), or EMEA and national agencies depending the procedure chosen (Europe). Once the dossier is evaluated by the respective regulatory agencies, in positive cases, we can obtain the authorization for commercialisation and consequently, the approval of the *technical factsheet*, which contains information about the new pharmaceutical product addressed to the sanitary professionals and the *pharmaceutical leaflets*, directed to patients and their families.
- 6) Afterwards, a certain type of documentation is needed and also a certain amount of time to achieve the prices authorization and reimbursements for the new medicine by the national sanitary authorities. If the first major milestone was the authorization of commercialisation and, with it, the technical factsheet and the pharmaceutical leaflet; the authorization of the price and reimbursement is the second biggest step that a drug finds on the path to access to the category of therapeutic innovation. Only those that are considerate as such, reach a superior price than the therapeutic alternatives already commercialized.
- 7) The beginning of the commercialisation of new medicines and their use as a therapeutic alternative, regarding its therapeutic and pharmaco-economic value with respect to the other therapies considered standard.
- 8) The therapeutic maturity of a pharmaceutical product is the period in which the medicine can reach the status of standard therapy.
- 9) The patent expiration term, loss of exclusivity and the entry into the market of the generic products –apart from possible extensions due to the “not disclosure” of data established administratively-.
- 10) Therapeutic obsolescence of the drug¹⁸.

¹⁸ HERNÁNDEZ, G. :”*Tratado de medicina farmacéutica*”, en Editorial Panamericana, Madrid, 2011.

39. Therefore, there are two juridical basic steps in the product cycle of life: patent granting and the authorization for commercialisation.

The patent term, generally, is twenty years, and regarding the TPP, can be implemented by the adjustments that could be made because of unreasonable delays in commercial authorization. Completed this authorization, other protection could start by each government: the protection of the test data or others information, which the administration grant if the applicant proves the validity and efficiency of the patented product. This “secondary” protection, at least five years, can be implemented if the circumstances require it, being overlapped most of times with the patent term, being absorbed or overpassed.

Protection of undisclosed test or other data

40. Unlike patents, protection of undisclosed test or other data awards exclusive rights of commercial nature on registered inventions and, therefore, unfold their effects in the market. Data exclusivity has as a primordial objective as to the existence of secure, effective and quality drugs, being correctly identified with appropriate information.¹⁹ To achieve the protection, among other measurements it is required public intervention, submitting the pharmaceutical products commercialization under sanitary authorization and previous register. Curiously, Public Administration describes as well the criteria that potential applicants must follow in the evaluation process previous to the authorization to the pharmaceutical speciality for checking what can be introduced into the market.²⁰

41. The exclusive data term comes after the authorization of commercialisation even though the patent protection application hasn't been made, as consequence, different fields or spheres of protection are permitted for the inventions. In the United States, the period for data protection is established in twelve years, even though the U.S. parliament is working on an amendment, which could be approved this year, reducing mentioned period to seven years. In short, data exclusivity is a concept only applied to

¹⁹ Informe técnico MSF: “Exclusividad de Datos en los Tratados Internacionales de Comercio: ¿Qué consecuencias tienen para el acceso a los medicamentos?”, 2004.

²⁰ CORREA, C.: “Protección de Datos presentados para el Registro de Productos Farmacéuticos: *Implementación de las Normas del Acuerdo TRIPS*”, South Centre, 2002.

drugs and it is defined as the period that guarantees data security and efficiency generated for the register and authorization of the original product. That data can't be used by other people and no other essentially similar product can be allowed by the authorities. Data exclusivity differs to the patent's right mainly in following aspects of protection. Data exclusivity: a) is not an intellectual property title granted to the inventor; b) is not linked to the patent or depends on it; c) does not give protection to the pharmaceutical principle "per se"; and d) does not prevent that a third person, generating in an independent manner his own secure and efficient innovation, could obtain the commercialization authorization for a similar product.

42. In Europe, data exclusivity is already available through the Directive 2004/27/CE, a period known as the "8+2+1", that is also known as the *Bolar Provision* (born in U.S.).²¹ Hereby, a period of data administrative protection is fixed during eight years in relation with pharmaceutical products, even though authorized generic drugs could not be commercialized until after ten years from the date of the initial medicines authorization²². The above mentioned *Bolar Provision* or regulation exception, which can be established perfectly in some of the TPP signer's territory, is already foreseen in article 30 of TRIPS, which allows the drug producers to use the patented invention to obtain the authorization for commercialisation of this product without the corresponding holder's permission and before the patent's term expires²³. The generic pharmaceutical products could be commercialized as their own version of the original drug as soon as the patent term finishes. That immerge us into the next point.

²¹ VIDAL-QUADRAS, M., SAURI, O.: "Derecho de Patente, Exclusividad de Datos y Comercialización de Genéricos. Uso Experimental y Cláusula Bolar", pags. 131-158, 2008. (Vid:<http://libros-revistas-derecho.vlex.es/vid/exclusividad-genericos-experimental-bolar-450154>).

²² Eight years are about data protection. Ten years are about commercialisation protection or monopoly. Therefore, finished the data protection, eight years, "generic developers" could access to the information to create the generic drugs, but they may not have access to the commercialisation. Hereby, "generic developers" have three years to create their product with data disclosure.

²³ SEGURA, P.: «Incertidumbres sobre patentes químico-farmacéuticas en España», en *Jornadas de estudio y actualización en materia de patentes "Los Lunes de Patentes"*, OEPM, Madrid, 2006. (Vid:http://www.ub.edu/centredopatents/pdf/doc_dilluns_CP/segura_incertidumbrespatriquimfarm.pdf)

Treatment of generic pharmaceutical products.

43. A generic medicine is defined, basically, for being one which presents the same pharmaceutical form, and has an equal qualitative and quantitative composition in pharmacologically active substances to another that is considered the original drug, being a referent medicine and whose security and efficiency profile has been established enough by its continuous clinical use; and in addition, has demonstrated that its therapeutically equivalent to the referent medicine through the required bioequivalence studies.

44. Therefore, and regarding the TPP agreement for the entry into the market generic drugs, we can establish the following limits: a) the pharmaceutical patent of the original product, which has a term of 20 years, adding the adjustments for unreasonable delays that could have existed in the application process for commercialisation. b) and data exclusivity period applicable to the reference medicaments, (5+3) (which pragmatically, really can operate when the patent term has expired).

45. On the other hand, with independence of established periods according to the rules about data exclusivity, the patent has as a principal effect that the generic drug, which uses patented technology, can't enter into the market until the exclusive right had expired. In contrary, it could be object of legal procedures by patent violation. In fact, it normally occurs that in this field a special litigiousness derives from the right's holder interests.

46. Consequently, even if the data exclusivity period is passed, the generic drug will not be able to be sold if it uses a technology which is under patent protection. Likewise, even if the patent protection doesn't exist, it will be not possible to grant an authorization for a generic pharmaceutical product regarding another one, if previously has not passed the perceptive time established by the applicable pharmaceutical regulation.

CONCLUSION. THE MORE THINGS CHANGE THE MORE THEY STAY THE SAME?

47. “*Cambiare tutto per non cambiare nulla?*”²⁴. In this case I’m not using the lampedusian question to refer to the same movement which was criticized by the Italian writer, but it is interesting to analyse if, in all honesty, the *Trans-Pacific Partnership* brings us significant changes in relation with generic products. A report from the UN’s agency over AIDS (UNAIDS) has been reminding us via a communication that, in the Political Declaration about VIH and AIDS of 2011 “approved by unanimity by the General Assembly of United Nations”, the governments reiterated their engagement of making use of the flexible mechanisms foreseen in the TRIPS agreements, headed specifically to promote the access to drugs for people and their commercialization. Likewise, UNAIDS has affirmed, “the governments engaged to guarantee that the provisions about intellectual property rights contents in the trade agreements don’t be opposite to mentioned agreements, as well as the contents in the *Doha’s Declaration about the TRIPS Agreement and Public Health*”²⁵. In spite of it (UNAIDS regretted) several trade agreements which were in negotiation declaring that “it is feared that could conclude the measures called TRIPS in order to implement patentability criteria and terms. These provisions could make it difficult for the generic concurrence and create a rise in drug prices. In the same way, preoccupation exists on the influence that the TPP could have on another future trade agreement”.

48. In this case, we could be facing a modification that harms the generic pharmaceutical products industry, with:

- a) The adjustment established in the treaty for the possible (or probable) delays, as there are low developed countries in which these drugs are not foreseen, something that will produce a delay for the entry of the generic drug into their respective markets.
- b) Another innovation that could harm developing countries is the implementation of patentable subjects settling, which implies that new uses, methods or use process of known products can be patented. Even though, in a similar way, it could have been

²⁴ DI LAMPEDUSA, T: “*Il Gattopardo*”, 1958

²⁵ Vid.:

http://www.unaids.org/sites/default/files/media_asset/JC2260_DOHA+10TRIPS_en_0.pdf

established in some developed countries, is not the same situation for developing countries.

c) Other dark point in the TPP is that in article 18.44 according to the publication of patent application, doesn't introduce the "*best mode*", but I understand that this doesn't imply no bigger problem because all TPP signer countries are already under the TRIPS umbrella and in article 29.1 we can find set this requirement. Consequently, it should be adopted without any problem.

d) With reference to "exclusivity", that at the beginning of the agreement's negotiation was filtered that U.S. wanted to set a 12-year period of data protection, has finally been fixed in the "5+3 mechanism". I don't believe that this last point is going to have great importance, because usually (if not always) every new pharmaceutical product is already protected by a patent, which normally will expire later than data protection which different governments could provide²⁶.

49. Therefore, bearing in mind what I wrote before, I would wish to highlight that this agreement can't be regarded as the beginning of the *apocalypse* for people from developing countries. While it is true that the two new provisions, which I mentioned before, can postpone generic drugs apparition, it is not a situation that changes extraordinarily the previous scenario, which comes mostly from the TRIPS agreement, and when developing countries subscribed it²⁷. In all signer's countries (of the TPP) the pharmaceutical patent was already settled at 20 years, because those countries had already signed TRIPS, and are not being considered (none of the TPP subscribers) as *least developed countries*. So, the provisions for least developed countries that *Doha's Round Declaration of 2001 about TRIPS and Public Health* foresees can't be applied for pharmaceutical products in those countries²⁸.

²⁶ KANTARJIAN, H.: «Strategies that Delay or Prevent the Timely Availability of Affordable Generic Drugs in the United States», American Society of Hematology, New York, 2016.

²⁷ SYKES, A. : «TRIPS, Pharmaceuticals, Developing Countries, and the Doha "*Solution*"», University of Chicago, Chicago, 2001, Working Paper No. 140 (2d series).

²⁸ Least developed countries could have maximum flexibility at least until 2033 according to the *Decision of the Council on the TRIPS Agreement and Public Health, adopted on 6th November 2015* regarding Article 66, Paragraph. No-one of the parties signing the TPP is considered least developed country.
(vid: https://www.wto.org/spanish/news_s/news15_s/trip_06nov15_s.htm).

50. Thus, it is being consolidated (not starting), the diminution of access to knowledge, which produces a significant raise on the price of essential goods and products, as pharmaceutical products or surgeries are. Increasing monopoly of big pharmaceutical enterprises in the market, we can appreciate how the WTO is not acting enough to find the balance between public and private interest again, which could satisfy more efficiently the whole population.

51. For developing countries, for those who are not protected by the WTO with the mentioned provision for least developed countries, the only benefit that I can appreciate is the access to the database of some patents when the patent term has expired. Not beyond at all of the reality, and such a relevant decision, the reasonable position should be: a) increase (not restrict) the access to the knowledge; and b) avoid the patent term extension at the end of its protection.

Hereby, it is confirmed the theory mentioned at the beginning of the TPP analysis, which shows that the situation regarding different level of development in different countries is not a direct consequence of the TPP but the result of the failure by all the international organisms of trying to protect least (or low) developed countries.

52. To conclude, the TPP establishes several measurements that, to the choice of each country, could implement the protection term patents in a different way, and without doubts could contribute to the delay of the generic access to people. What cannot be allowed is the trends which manifest that the starting point of inequality is this treaty. It is result of the little willingness of developed countries to concede some measurements to developing countries and their needs for their own evolution. As well, continuing on this approach but without talking about legislative issues that could present those agreements for the social welfare, we find a large number of “extra-borders” activities, and concretely, the role that lobbies play on it. Those groups of pressure, pharmaceutical in this case, decided to exercise a voracious incidence on the TPP negotiations, pressing the U.S., and as it could be expected in our neoliberal system, pointing out the way to follow for the legal redaction and interpretation. Therefore, in my opinion, the redaction of the TPP (in the big picture but always keeping the mesenteries of the subject under the directives marked by U.S.) hides the pharmaceutical enterprises interests, and their principal representatives, under lobbies. That, in a certain way, broke the balance (which already doesn't exist), among the

public interest and big pharmaceutical enterprises interests, inclined (this hypothetical balance) to the private operators.

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