THE IMPACTOF PATENT LINKAGE ON ACCESS TO MEDICINE: THE CURRENT SITUATION IN EGYPT

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ABSTRACT

The pharmaceutical industry is one of the most important and critical industries due to its link to public health. This industry requires huge investments for research and development (R&D) of new drugs for treatment of various diseases. Multinational companies are leaders in this industry as they possess science, money and technology are leaders in this industry. In an effort to recoup investments in R&D multinational companies usually seek not only for higher levels of patent protection but also for extended protection through applying for multiple patents that cover different aspects of the same invention. This is known as "evergreening of patents". The patent linkage system is another example of evergreening by which the regulatory authority links the drug marketing approval to the patent status of the originators. This paper discusses the linkage system in different jurisdictions, and how it affects the entry of generic products into the market. It also discusses the situation in Egypt as a model example for developing countries.

Key words: evergreening, patent linkage, Egypt, generic medicine, developing countries.

1. INTRODUCTION

Patents are one of the most important branches of intellectual property (IP), as it is linked to several industries that rely on technology, and sensitive sectors such as medicine and public health.[1] Patent system gives the inventor the legal protection for his invention so that the he has the right to exclude others from making or using his invention without his consent.[2] This protection is limited, in most countries it extends for 20 years from the filing date of the patent application.[3]

It is well known that developing a new pharmaceutical drug or new chemical entity requires testing the new compounds in assays and animal model.[4] If the preclinical studies ensure that the new compound is safe and effective, it is subjected to clinical studies.[5] Clinical trial phases are steps in research to determine whether the new chemical entity is safe and effective to humane or not.[6]

Companies spend tens to hundreds of millions of dollars to develop a single new chemical entity. Therefore, multinational companies that are leaders in this industry usually seek for higher levels of patent protection.

From the economic point of view, these companies often prefer to perform slight modifications on an old patented molecule and apply for multiple patents that cover different aspects of the same product allowing for an extended patent protection, rather than developing a new compound; this is known as "patent evergreening".[7]

"Patent evergreening" is very common in the pharmaceutical industry and it can take many different forms to extend the term of patent including; applying patent applications for methods of treatment, mechanism of action, isomeric forms, packaging, dosing regimen and screening methods.[8] Patent term extension, data exclusivity and patent linkage systems are other types of patent evergreening.[9]

Patent evergreening is considered a defensive patenting strategy that innovator companies usually follow to create obstacles for generic competitors to enter the market. One of these obstacles is the "patent linkage system" which involves linking drug marketing approval with the originator's drug patent status and refusing marketing approval until the relevant patent expires.[10] In other words, the regulatory

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[1] Mina Mashayekhi, 'Intellectual Property in the World Trade Organization: Turning it into Developing Countries' Real Property' (2010) United Nations Conference on Trade and Development <https://unctad.org/en/Docs/ditctncd20068_en.pdf> accessed 13 May 2019.

[2] Bronwyn H Hall, 'Patents' (2007) Contribution to The New Palgrave: A Dictionary of Economics, second edition <https://eml.berkeley.edu/~bhhall/papers/BHH06_Patents_Palgrave.pdf> accessed 6 May 2019

[3] ibid

[4] Gamal Osman Elhasan, 'Drug Development: Stages of Drug Development' (2015) J Pharmacovigilance <https://www.researchgate.net/publication/281700675_Drug_Development_Stages_of_Drug_Development/download> accessed 6 May 2019.

[5] Vicki L Mahan, 'Clinical Trial Phases' (2014) International Journal of Clinical Medicine <https://file.scirp.org/pdf/IJCM_2014122915372964.pdf> accessed 6 May 2019.

[6] ibid

[7] John R Thomas, 'Patent "Evergreening": Issues of Innovation and Competition' (2010) Congress Research Service <https://www.ipmall.info/sites/default/files/hosted_resources/crs/R40917_091113.pdf> accessed 1 May 2018.

[8] Inderjit Singh Bansal, Deeptymaya Sahu, Gautam Bakshi and Sukhjeet Singh, 'Evergreening – A controversial issue in pharma milieu' (2009) Journal of Intellectual Property Rights <http://indiaenvironmentportal.org.in/files/Evergreening.pdf> accessed 6 May 2019.

[9] Thomas A Faunce and Joel Lexchin, 'Debate 'Linkage' Pharmaceutical Evergreening in Canada and Australia' (2007) Biomed Central <https://www.researchgate.net/publication/6293474_'Linkage'_Pharmaceutical_Evergreening_in_Canada_and_Australia/download> accessed 7 May 2019.

[10] Ravikant Bhardwaj, K D Raju and M Padmavati, 'The Impact of Patent Linkage on Marketing of Generic Drugs' (2013) Journal of Intellectual Property Rights

authority will not allow the generic drug[11] to enter the market if there is a valid originator patent for that drug. As a result, the availability of generic versions of the drug with affordable prices will be delayed.

Patent linkage is considered one of the higher standards of protection negotiated in the post-Trade Related Aspects of Intellectual Property Rights (TRIPS) era known as TRIPS-PLUS commitments, as it goes beyond the minimum standards of the TRIPS agreement.[12] This article discusses the appearance of the patent linkage system in developed countries and how it spread to developing countries. It also sheds light on the effect of this system on access to medicines, with a particular focus on the situation in Egypt and its application in that context.

2. PATENT LINKAGE IN DEVELOPED COUNTRIES

2.1. Patent linkage in US and Canada

The patent system has existed for more than 500 years.[13] By contrast, the patent linkage system developed with the passage of the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman act (1984)) in United States and the Canadian Patent Medicines (Notice of Compliance) Regulations (NOC Regulations).[14]

In the US the Food Drug Administration (FDA) [15] lists the pharmaceutical products and medicinal uses, which are under patent in "Approved Drug Products with Therapeutic Equivalence Evaluations", commonly known as the Orange Book.[16] When a generic company files for approval of an Abbreviated New Drug Application (ANDA), it must certify one of the following four grounds: that the drug is not covered by a valid patent; the patent has already expired; the generic drug will not be released into the market until the expiry of the patent; or the patent is invalid or is not infringed.[17] These grounds are referred to as paragraphs I, II, III and IV certifications.[18] In the first two paragraphs, the FDA grants the approval immediately.[19] In case of paragraph III, the FDA grants approval after the expiration of the patent.[20] Concerning paragraph IV, when there are claims of invalidity or non-infringement, the patent holder is notified and given forty-five days to file an infringement action (under section 271(e)(2)(A) of the US patent linkage system, which held up the approval of generic drug for thirty months.[21] The first generic company that succeeds to invalidate the patent or proves that it is not infringing the patent is given 180 days of generic exclusivity.[22]

Canada is considered the second country that applied the "Patent linkage system" after the US.[23] The linkage regulations in Canada are based on the US patent linkage system with a stay time of 24 months that is shorter than that in the US regulations.[24] Under the regulations of this system, Canada does not allow a generic company to enter the market until it proves that all of the relevant patents have expired.[25] The generic company has to send a Notice of Allegation to the originator claiming non-infringement of the patent. Then, the patent holder will have 45 days to file an application in the Federal court of Canada to prevent Health Canada from

<http://nopr.niscair.res.in/bitstream/123456789/20282/1/JIPR%2018(4)%20316-322.pdf> accessed 1 May 2018.

[11] Generic medicines are the medicine products that are bioequivalent to the originator as they have the same qualitative and quantitative composition of the active substance. They have the same safety and efficacy of the originator but at more affordable prices.

[12] Sandeep K Rathod, 'Patent Linkage and Data Exclusivity: A Look at Some Developments in India' (2011) 8(3) Journal of generic medicines 140-149 <http://journals.sagepub.com/doi/pdf/10.1177/1741134311423461> accessed 4 Jan 2018.

[13] A Samuel Oddi, 'The international Patent System and Third World Development: Reality or Myth?' (1987) Duke Law Journal <https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=3003&context=dlj> accessed 7 May 2019.

[14] Ron A Bouchard, Dan Cahoy, Bengt Domeij, Graham Dutfield, Tom Faunce, Aidan Hollis, Paul Jones, Feroz Ali Khader, Joel Lexchin, Heesob Nam, Juan Luis Serrano, 'Global Pharmaceutical Linkage Regulations:
A Proposed Analytical Framework' (2011) 12 (2) Minnesota Journal of Law Science & Technology 1-44. <https://www.researchgate.net/publication/228416994> accessed 12 May 2018.

[15] The US Food and Drug Administration is a governmental agency responsible for protecting the public health by ensuring the safety, efficacy and security of human and veterinary drugs, biological products and medical devices in US.

[16] US Department of Health and Human Services, 'Approved Drug Products with Therapeutic Equivalence Evaluations' (2019) 39th edition Orange book < https://www.fda.gov/media/71474/download> accessed 7 May 2019.

[17] Judit R Sanjuan, 'Patent – registration linkage' (2006) Consumer project on technology CPTech Discussion Paper <http://www.cptech.org/publications/CPTechDPNo2Linkage.pdf> accessed 14 April 2018.

[18] C Scott Hemphill and Mark A Lemley, 'Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act' (2011) Anti Trust Law Journal <https://law.stanford.edu/publications/earning-exclusivity-generic-drug-incentives-and-the-hatch-waxman-act/> accessed 8 May 2019.

[19] Judit Rius Sanjuan (n 17).

[20] ibid

[21] Brook K Baker, 'Ending Drug Registration Apartheid – Taming Data Exclusivity and Patent Registration Linkage' (2008) American journal of Law and Medicine 303, 307 <http://journals.sagepub.com/doi/pdf/10.1177/009885880803400209> accessed 30 March 2018.

[22] C Scott Hemphile (n 18) 947

[23] Ravikant Bhardwaj (n 3) 318-319 .

[24] Jean F Morin and Melanie B Forcier, 'Pharmaceutical Patent Policy in Developing Countries: Learning from the Canadian Experience' in Guennif S S, Guzman A and Lalitha N (eds),Intellectual Property, Pharmaceuticals and Public Health (SSRN Electronic Journal 2011).

[25] Joel Lexchin and Marc A Gagnon, 'CETA and Intellectual Property: The Debate over Pharmaceutical patents' (2013) CETA Policy Briefs Series < https://carleton.ca/canadaeurope/wp-content/uploads/CETD-Policy-Brief_CETA-and-pharmaceutical-patents_MG_JL.pdf> accessed 8 May 2019.

issuing a Notice of Compliance (NOC) to the generic company for 24 months.[26]

2.2. Patent Linkage in the European Union

Generic medicines play a crucial role in providing high quality and affordable prices throughout the EU.[27] The EU legislation states that granting of marketing authorization should be based solely on quality, safety and efficacy data and not on other criteria.[28] However, generic medicines access to the market in EU faces many obstacles e.g. evergreening tactics.[29] To overcome these obstacles the European Generic Medicine Association (EGA) was actively engaged to the European Commission's follow up initiatives in the pharmaceutical field, to promote generic medicines and increase the access of medicine in affordable prices.[30] As a result, one of the main objectives of EGA was to abandon any pathway that leads to patent linkage which acts as a barrier to generic medicine. This objective was justified by the EU law which stated that "It is not allowed to link marketing authorization to the patent status of the originator reference product".[31] Therefore, the patent linkage system, which is an obstacle to the availability of generic medicines in the pharmaceutical market, is not a part of EU pharmaceutical legislation.[32]

Nevertheless, there are some countries in EU which apply the patent linkage system such as Italy, Hungary, Portugal and Slovak Republic.[33]

In Italy, the patent linkage system has been standing as a barrier in front of the generic medicines.[34] The Industrial – Property Code 2010 stated that "a generic applicant could only start the registration procedure one year before the expiration of any protection on the active substance" which was not conformed to Directive 2001/82/EC. [35] In November 2012 Italy's new "Balduzzi Decree" Article 11 (1) allowed the generic drug manufacturers to register their products even during the patent term of the reference product, but the generic product cannot be classified as a reimbursable drug by the Italian National Healthcare System (SSN) as long as the patent of the reference product is still valid.[36] This is considered a form of patent linkage which delayed the entry of generic medicine into the market.[37]

In Hungary, Article 7(9) of Decree 52/2005 of the Ministry of Health needs the generic manufacturer which is seeking for marketing approval to state that he is not infringing any patent or will market his product after the expiration of the patent of the originator. [38] In case the generic company has the marketing approval the originator company can take legal action against generic company.[39]

2.3. Criticism of the Patent Linkage System

The objective of drug approval-patent linkage system in some countries is to facilitate research and development, and to encourage innovation by providing effective protection system for the patent owner.[40]However, this system gives one sided protection to the patent owner which resulted in abuse of the patent rights.[41]

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[26] Joel Lexchin and Marc A Gagnon, 'CETA and Pharmaceuticals: Impact of the Trade Agreement between Europe and Canada on the Costs of Prescription Drugs' (2014) Lexchin and Gagnon Globalization and Health 10, 13. <https://globalizationandhealth.biomedcentral.com/track/pdf/10.1186/1744-8603-10-30> accessed 17 April 2018.

[27] Alan S,'Generic Medicines: Essential Contributors to the Long-Term Health of Society' (2010) IMS Intelligence Applied <https://www.hup.hr/EasyEdit/UserFiles/Granske_udruge/HUP-UPL/IMS.pdf> accessed 1 June 2018.

[28] ibid

[29] Steven Simeons, 'Sustainable Provision of Generic Medicines in Europe' (2013) Simeons 2 Report <https://pdfs.semanticscholar.org/d0b4/a5ba78141a4cea075a31f1a0e8d5052030ef.pdf> accessed 10 May 2019.

[30] Greg Perry, 'The European Generic Pharmaceutical Market in Review: 2006 and beyond' (2006) Journal of Generic Medicines: The Business Journal for the Generic Medicines Sector <https://journals.sagepub.com/doi/abs/10.1057/palgrave.jgm.4950041> accessed 10 May 2019.

[31] European Generic Medicine Association, 'The EGA'S Thoughts on How to Improve the Legal and Regulatory Framework for Generic and Biosimilar Medicines' (2010) EGA Vision 2015 <https://www.hup.hr/EasyEdit/UserFiles/Granske_udruge/HUP-UPL/EGA_Vision_2015.pdf> accessed 10 May 2019.

[32] Kristof R, Julia P, Andrew B and Stefan B, 'Patent-Related Barriers to Market Entry for Generic Medicines in the European Union: A Review of Weaknesses in the Current European Patent System and their Impact on Market Access of Generic Medicines' (2008) *Journal Of Generic Medicine* 255, 272 <https://www.researchgate.net/publication/31944163_patent-related_barriers_to_market_entry_for_generic_medicines_in_the_european_union_a_review_of_weaknesses_in_the_current_european_patent_system_and_their_impact_on_market_access_of_generic_medicines > accessed 8 May 2019.

[33] Judit R Sanjuan (n 17).

[34] Pieter Dylst, Arnold Vulto and Steven Simoens, 'Analysis of the Italian generic medicines retail market: recommendations to enhance long-term sustainability' (2015) *Expert Review of Pharmacoeconomics & Outcomes Research* <https://www.ncbi.nlm.nih.gov/pubmed/25138241> accessed 10 May 2019.

[35] ibid

[36] Ottavio Sangiorgio, 'Update On The "Balduzzi Law" In Italy And The Reimbursement Linkage Provision' (2015) Simmons & Simmons Elexica <http://www.elexica.com/en/legal-topics/life-sciences-regulatory/02-update-on-the-balduzzi-law-in-italy-and-reimbursement-linkage-provision > accessed 10 May 2019

[37] ibid

[38] Ravikant Bhardwaj, K D Raju and M Padmavati (n10) 318.

[39] ibid

[40] Ki Young Kim, HyunsukJin and Samuel SungMok Lee, 'The Korean Drug Approval- Patent Linkage System: A Comparison with the US Hatch-Waxman Act' (2015) Attorneys at Law <https://www.lexology.com/library/detail.aspx?g=5619213a-4714-4307-8bfd-8e12955841e1> accessed 13 June 2018.

[41] ibid

The United States adopted the patent linkage system to reward pioneer pharmaceutical companies, facilitate the entry of generic medicine into the market, and to produce a kind of competition between generic companies to gain the 180 days of marketing exclusivity.[42] However, due to costly and timely litigations before marketing approval is granted, generics entry to the market is delayed[43], and the high litigations cost may be passed indirectly to the consumer, through increasing the cost of generics. So, what is the value of 180 days of generic exclusivity compared to investment in costly and time-consuming litigation?

Generally, the median time for the regulatory authorities to approve a generic drug is about 4 years, e.g. it is 47 months for the FDA to approve a generic product.[44] As a result, applying patent linkage system which involves refusing generic drug marketing approval until the relevant patent expires, will delay the entry of the generic drug into the market for about four years which are required for the generic drug to be approved by the regulatory authorities.

Therefore, patent linkage system is highly effective in protecting the innovator products from competition with the generics and delaying the entry of generic drugs into the market.[45] Moreover, it extends market monopoly beyond patent protection of the innovator product.[46]

Contrary to the aim of the patent system, the patent linkage system does not encourage innovation, as the pharmaceutical companies often prefer to file follow-on patents evolving from single original patent.[47] This follow-on patents are listed in patent registers in the regulatory authorities to delay generic entry under the patent linkage system.[48]This results in extended monopolies and ultimately delays access to generic medicines at affordable prices.[49]

The negative effect of the patent linkage system on access to generic medicine appears greatly in those countries whose patent office's grant low quality patents, including the United States.[50] In the US, sometimes pharmaceutical companies file additional low-quality patents with the FDA to be registered in the Orange Book, which, according to the US law, grants 30 months stay extending the originator's monopoly.[51]

This problem clearly appears in the case of the FTC v. Bristol Myers Squibb (2003)[52], in which the Federal Trade Commission (FTC) announced that the Bristol-Myers Squibb company has been engaged in a series of anticompetitive acts to prevent or to delay the entry of low-price generic products:[53] two anti-cancer drugs, namely, Taxol and Platinol, and Buspar the anti-anxiety product. Bristol-Myers filed several patents for the three drugs that did not meet the criteria for listing in the orange book.[54]

3. SPREADING OF THE PATENT LINKAGE SYSTEM

The generic entry to the market is affected not only by the patent system but also by the patent linkage regulations that has spread very rapidly in some countries, especially developing countries, after it was limited to the US. The year 2011 is considered the year of the spreading of the patent linkage system on a global level including developing countries through bilateral and multinational free trade agreements (FTAs).[55]

3.1. The Role of FTAs in Spreading the Linkage Regime

Before the TRIPS Agreement, pharmaceutical products were not protected by patent systems in most developing

[42] Molly F M Chen, 'Reconsidering the US Patent System: Lessons From Generics' (2012) Journal of Transitional Law (Note) 1249, 1262. <https://www.vanderbilt.edu/wp-content/uploads/sites/78/Chen-FINAL.pdf> accessed 1 June 2018.

[43] Molly F M Chen, 'Reconsidering the US Patent System: Lessons From Generics' (2012) Journal of Transitional Law (Note) 1249, 1252. <https://www.vanderbilt.edu/wp-content/uploads/sites/78/Chen-FINAL.pdf> accessed 1 June 2018.

[44] GDUFA II: FDA Looks to Speed Up Generic Drug Approval Process < https://www.amplexor.com/zh/resources/news/gdufa-ii-fda-looks-to-speed-up-generic-drug-approval-process.html> accessed 11 May 2019.

[45] Kyung-Bok Son, Ruth Lopert, Deborah Gleeson and Tae-Jin Lee, 'Moderating the impact of patent linkage on access to medicines: lessons from variations in South Korea, Australia, Canada, and the United States' (2018) Son et al. Globalization and Health <https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-018-0423-0> accessed 11 May 2019.

[46] ibid

[47] Ronald A. Bouchard, Dan Cahoy, Bengt Domeij, Graham Dutfield, Tom Faunce, Aidan Hollis, Paul Jones, Feroz A. Khader, Joel Lexchin, Heesob Nam and Juan L. Serrano, 'Structure-Function Analysis of Global Pharmaceutical Linkage Regulations' (2011) Minnesota Journal of Law, Science and technology https://scholarship.law.umn.edu/mjlst/vol12/iss2/3> accessed 11 May 2019.

[48] ibid

[49] Joseph A DiMasi and Laura B Faden, 'Competitiveness in Follow on Drug R &D: A Race or Imitation?' (2011) Nature reviews Drug discovery 23-27 <https://www.ncbi.nlm.nih.gov/pubmed/21151030> accessed 1 June 2018.

[50] Gaétan de Rassenfosse, Adam B. Jaffe and Elizabeth Webster, 'Low-Quality Patents in the Eye of the Beholder: Evidence from Multiple Examiners' (2016) Center for Transformative Innovation Working Paper 1/16 <https://www.swinburne.edu.au/media/swinburneeduau/research/research-centres/cti/working-papers/CTI-Working-Paper-1-16-Low-quality-patents.pdf> accessed 11 May 2019.

[51] Judit R Sanjuan (n 17).

[52] 'FTC Charges Bristol-Myers Squibb with Pattern of Abusing Government Processes to Stifle Generic Drug Competition' (Federal Trade Commission7 March 2003) <https://www.ftc.gov/news-events/press-releases/2003/03/ftc-charges-bristol-myers-squibb-pattern-abusing-government> accessed 13 June 2018.

[53] ibid

[54] ibid

[55] Ron A Bouchard (n 14).

countries.[56] With the adoption of the agreement, all country members were obliged to incorporate the TRIPS requirements into their national legislations. This includes patent protection for all fields of technology without discrimination.

Although TRIPS agreement sets out minimum standards for protection of intellectual property, including patents for pharmaceuticals, it offers some flexibilities to remedy negative effects of patent protection or patent abuse, and decrease the barriers for access to medicine.[57]

The main flexibilities built in TRIPS agreement are: Compulsory license (Article 31)[58], parallel importation (Article 6)[59] and Article 30 of the TRIPS agreement allows the member states to 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.[60]

The Bolar exception is one of these exceptions that is consistent with Article 30 in TRIPS agreement.[61]

Bolar provision compromises between the innovator and generic pharmaceutical manufacturers.[62] As it permits any drug manufacturer to seek regulatory approval while the relevant patent still in force.[63] However, if a generic or biosimilar manufacturer waits until the last day of the expiration of the term of protection of the patent covering the pharmaceutical product, the owner of expired patent will enjoy additional period of protection, until a generic manufacturer obtains market permission from the regulatory authority. During this period expired patent may continue to charge a monopolistic price.[64]

While the developing countries were adapting to the new TRIPS agreement's obligations and trying to get benefits from the TRIPS flexibilities to manage the negative effect of these obligations on access to medicine, a wave of bilateral agreements emerged. These free trade agreements (FTAs) often require higher levels of protection that include TRIPS-PLUS standards that go beyond the TRIPS agreement.[65]

"Patent linkage system" is considered one of the TRIPS-PLUS standards that were rapidly spread through free trade agreements. United States FTAs are considered the first to export such system to other countries like Canada (1993), Mexico (2003), Australia (2005) and some Arab countries like Jordan, Oman and Morocco.[66]

3.2. Patent Linkage in Jordan

The Jordan-United States FTA (2001) was the first free trade agreement between the US and an Arab country.[67] The patent linkage system in this agreement is less aggressive than any linkage system in any other country as it requires notifying the patent owner only.[68] However, other drug regulatory authorities are prohibited from registering generic versions of the medicine until after the patent has expired.

3.3. Patent Linkage in Morocco

The US signed a free trade agreement with Morocco in June 2004 which entered into force in 2006.[69] This agreement included the linkage system in Article 15.10.4. Unlike the Jordanian linkage system, the drug regulatory authority should not authorize the marketing approval of a generic

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[56] P Boulet, J Perriens, F Renaud-Théry, Policy G Velasquez, 'Pharmaceuticals and the WTO TRIPS Agreement: Questions and Answers' (2000) UNAIDS/WHO document <http://apps.who.int/medicinedocs/pdf/whozip18e/whozip18e.pdf> accessed 11 May 2019.

[57] Ellen F. M. 't Hoen, 'TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond' (2003) Economics of AIDS and Access to HIV/AIDS Care <https://www.who.int/intellectualproperty/topics/ip/tHoen.pdf> accessed 11 May 2019.

[58] TRIPS agreement, art 31.

[59] Article 6 of the TRIPS Agreement provides that nothing in the Agreement will be considered to address the subject of exhaustion of IPRs for purposes of dispute settlement. This article didn't oblige the Members to apply certain type of exhaustion however it gives the freedom to the Members to adopt its own policies and rules on the subject of national and international exhaustion.

[60] TRIPS agreement, art 30.

[61] Carlos M Corea, 'The Bolar Exception: Legislative Models and Drafting Options' (2016) The South Center <https://www.southcentre.int/wp-content/uploads/2016/03/RP66_The-Bolar-Exception_EN1.pdf> accessed 11 May 2019.

[62] ibid

[63] Anshul Mittal, 'Patent Linkage in India: Current Scenario and Need for Deliberation' (2010) Journal for Intellectual Property Rights <http://nopr.niscair.res.in/bitstream/123456789/9066/1/JIPR%2015%283%29%20187-196.pdf> accessed 11 May 2019.

[64] Carlos M Corea (n 61) 1-2

[65] Carlos M. Corea, 'Implications of Bilateral Trade Agreements on Access to Medicines' (2006) 84(5) Bulletin of the World Health Organization 399-404 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2627342/> accessed 13 June 2018.

[66] Benjamin P Liu, 'Fighting Poison with Poison? The Chinese Experience with Pharmaceutical Patent Linkage' (2012) Journal Marshall Review Intellectual Property Law 624-630. <https://repository.jmls.edu/cgi/viewcontent.cgi?article=1287&context=ripl> accessed 15 May 2018.

[67] Rohit M, 'All costs, No Benefits: How TRIPS-Plus Intellectual Property Rules in the US-Jordan FTA Affect Access to Medicines' (2007)Oxfam Briefing Paper <https://oxfamilibrary.openrepository.com/.../bp102-all-costs-no-benefits-trips-210307> accessed 20 April 2018.

[68] The agreement between the United States of America and the Hashimite Kingdom of Jordan on the establishment of a free trade area, Article 4.23.b stated that "The patent owner shall be notified of the identity of any third-party requesting marketing approval effective during the term of the patent."

[69] United States–Morocco Free Trade Agreement, U.S.–Morocco, June 15,2004, Article 15.10.4

product until the expiration of the patent term of the originator and should also notify the originator of such an application.[70]

3.4. Patent Linkage in Korea

The Korea-US FTA came into force in 2012 after 6 years of negotiations.[71] The patent linkage system of the Pharmaceutical Affairs Act was revised on 15 March 2015 for the enforcement of the Korea-US FTA.[72] The system comprises: listing of drugs on the Green list (which is equivalent to the Orange Book in the US system); and applicants for generic products must notify patent holders that an application has been submitted to the Ministry of Food and Drug Safety (MFDS) within 30 days from filing this application.[73] When the patent holder receives the notification, he can request a stay of sale of generic drugs.[74] If the request is accepted, sales of generics will be stayed for 9 months.[75] The first generic company that applies for marketing approval and succeeds in challenging the patent will receive 9 months market exclusivity.[76]

The Korean Pharmaceutical industry relies on generic manufacturers.[77] Therefore, it was important for the Korean patent linkage system to facilitate much faster and easier entry of the generic drugs to the market. As a result, the patent linkage system was designed to be more tailored to the situation in Korea as it tried to compensate the delay of the generics by giving them an easier system to obtain generic market exclusivity than that in the US system.[78]

4. PATENT LINKAGE IN SOME DEVELOPING COUNTRIES

4.1. India

"Pharmacy of the developing countries": this is the title that India has gained due to its development of a strong and vibrant generic industry producing safe, effective and affordable generic medicines that have been exported to other developing countries.[79] The generic pharmaceutical products dominate the Indian market and reached up to 90% of the sales.[80]

The Indian government succeeded to make a balance between patent protection and its own generic drug production. Generally, the Indian patent law intended to control evergreening of pharmaceutical patents under section (3d)[81] making use of the TRIPS flexibilities and including Bolar provision in section 107 A and the compulsory license in section 84 (1) of the Patents Act 1970. [82]

India does not apply patent linkage system as it is not a part of drug approval process under the Health ministry or within its patenting process and it cannot be read in the Patents Act 1970.[83] This was assured since the courts have rejected attempts by big pharmaceutical companies to create such system. As an example, the court rejected Bayer's argument against Cipla and confirmed that there is no "patent linkage" regulation in India.[84]

4.2. Brazil

The Brazilian government encourages generic medicines industries in order to provide better access to medicine in affordable prices.[85]

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[70] ibid

[71] Young Sun Cho, HyunsukJin, Yoon and Yang LLC, 'Overview and Implications of the Drug Patent Approval Linkage System in South Korea Regulations' (2014) Practical Law <https://content.next.westlaw.com/Document/I699f6bf2b36911e398db8b09b4f043e0/View/FullText.html?contextData=(sc.Default)&transitionType=Default&firstPage=true&bhcp=1> accessed 10 June 2018.

[72] Yoon Suk Shin, 'Past, present and future of pharmaceutical patents under Korea–US Trade Agreement', (2016) 5(4) Pharmaceutical Patent Analyst <https://www.ncbi.nlm.nih.gov/pubmed/27338849> accessed 10 June 2018.

[73] Young Sun Cho, HyunsukJin, Yoon and Yang LLC (n 66).

[74] Yoon Suk Shin (n 68).

[75] Kyung-Bok Son, Ruth Lopert, Deborah Gleeson and Tae-Jin Lee (n 45) 11

[76] Yoon Suk Shin (n 68)

[77] Ki Young Kim (n 40) 15.

[78] Ki Young Kim (n 40).

[79] SidonieDescheemaeker, 'India, Pharmacy of the Developing World IP, Trade and the Access To Medicine' (2013) JuraFalconisJg<https://www.law.kuleuven.be/apps/jura/public/art/49n3/descheemaeker.pdf> accessed 15 May 2018.

[80] Ravinder Gabble and Jillian Clare Kohler, 'To patent or not to patent? The case of Novartis'cancer drug Glivec in India' (2014) 10(3) Gabble and Kohler Globalization and Health <https://globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-10-3> accessed 20 May 2018 .

[81] Section 3(d) in the Patents Act, 1970 ' the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.'

[82] Aditya Kant, 'Section 3(d): 'New' Indian Perspective', (2009) 14 Journal of Intellectual Property Rights 385-396 https://pdfs.semanticscholar.org/d779/642cc0a5953b4a40c77219458137a7d66a01.pdf accessed 1 September 2018.

[83] Sandeep K Rathod (n 4).

[84] 'Bayer Corporation and Ors V. Cipla, Union of India (UOI) and Ors' (2009) <https://indiancaselaws.wordpress.com/2013/12/14/bayer-corporation-and-ors-vs-union-of-india-uoi-and-ors/> accessed 13 June 2018.

[85] Natalia Arzeno, Rebeca Diaz and Sandra Gonzalez, 'Brazil's Generic Drug Manufacturing Success and the policies that permitted it' (2004) 6.901 Final Project <https://ocw.mit.edu/courses/electrical-engineering-and-computer-science/6-901-inventions-and-patents-fall2005/projects/brazil_gen_drug.pdf> accessed 12 May 2019.

When the TRIPS agreement came into force in 1994, several challenges emerged which threatened the Brazilian's policy of the access to generic medicine at affordable prices especially the country's policy of universal access to AIDS medicines.[86] Therefore, the Brazilian Intellectual Property Law (BIPL) included some of the TRIPS flexibilities that are related to public health such as compulsory licenses, parallel imports, Bolar exception, experimental use and health sector participation in analyzing pharmaceutical patent claims.[87] Moreover, there is no patent linkage system in Brazil according to Law 10,603/2002, art 13 and Industrial Property Law, article 43, VII.[88]

4.3. South Africa

As a member of the WTO, South Africa was obliged to uphold minimum standards of IP protection as mentioned in the TRIPS agreement.[89] South Africa used depository system for granting patents, which requires only correct formalities and paying the required fees to get a patent.[90]

As a result, South Africa gave the opportunity for the pharmaceutical companies to gain multiple patents on an individual product which may be rejected by other countries in the same region.[91] This granting of excessive number of patents resulted in evergreening of monopoly periods and hindrance of access to medicine in affordable prices.

In a comparative study between the number of granted pharmaceutical patents in Argentina, Brazil, Colombia, India and South Africa, it was found that in South Africa 2442 patents were registered in 2008, however, in Argentina 951 pharmaceutical patents were granted in 2000-2007; in Brazil, 278 patents were granted in 2003-2008; in Clombia 439, in 2004-2008 and in India, 2347, in 2005-2008.[92] This study revealed that in South Africa patents are simply registered without sustentative examination and this explains the large number of patents issued in one single year in comparison to other countries which perform substantive examination.[93]

The Patent Act and its regulations as well as the judgments of the Court of the Commissioner of Patents (CCP) are biased to the patent owner.[94]

However, in August 2017, the situation began to change and the department of Trade and Industry published a draft of the IP National Policy.[95] This IP Policy sets out a number of proposals related to the patent law and public health, which encourage substantive search and examination and highlight the flexibilities which are in the Patent Act for example; parallel importation, Bolar provision and compulsory license.[96] Moreover, the South African Medicines and Related Substances Act avoids patent linkage, and it cannot be read in view of the South African's Patent Act.[97]

5. THE SITUATION IN EGYPT

5.1. Pharmaceutical Industry in Egypt

In the early sixties, the pharmaceutical industry in Egypt passed through several stages. Currently Egypt's domestic pharmaceutical industry has flourished, with the presence of about 120 pharmaceutical companies; most of them are generic companies.[98]

Like many other countries, the pharmaceutical products were excluded from patentability before the TRIPS agreement. In January 1995, the agreement on Trade Related Intellectual Property Rights became into force. From this moment member states including Egypt were obliged to adapt their national IP laws to comply with the TRIPS requirements.

The TRIPS agreement gave all countries transitional period to adapt their laws to the minimum standards of the agreement. And it provided the developing countries additional period for five years from 2000 to 2005, for patent protection of the products in areas of technology that had not been protected before the TRIPS agreement, like pharmaceutical products.[99]

This put an obligation on Egypt to protect pharmaceutical products as well as the process using the patent system by

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[86] Gabriela Costa Chaves, Marcela Fogaça Vieira and Renata Reis, 'Access to Medicine and Intellectual Property in Brazil: Reflections and Strategies of civil society' (2008) International Journal of Human Rights 163,167 <http://www.scielo.br/scielo.php?pid=S180664452008000100009&script=sci_arttext&tlng=en> accessed 20 April 2018.

[87] ibid 163-167

[88] Shivam Vashisth, Govind Singh and Arun Nanda, 'A Comparative Study of Regulatory Trends of Pharmaceuticals in Brazil, Russia, India and China (BRIC) countries' (2012) 9 (3) Journal of Generic Medicines <http://journals.sagepub.com/doi/abs/10.1177/1741134312459187> accessed 8 June 2018.

[89] Catherine Tomlinson, John Ashmore, Anele Yawa and Julia Hill, 'Reforming South Africa's procedures for granting patents to improve medicine access' (2015) South African Medical Journal <http://www.scielo.org.za/pdf/samj/v105n9/17.pdf> accessed 12 May 2019.

[90] ibid

[91] ibid

[92] Carlos M Corea, 'Pharmaceutical Innovation Incremental Patenting and Compulsory Licensing' (2011) South Center <http://apps.who.int/medicinedocs/documents/s21395en/s21395en.pdf> accessed 12 May 2019.

[93] ibid

[94] Jonathan Berger and Andrew Rens, 'Innovation and Intellectual Property in South Africa: The Case for Reform' (2018) University of Cape Town Intellectual Property Unit <http://ip-unit.org/wp-content/uploads/2018/05/Innovation-IP-in-SA.pdf> accessed 12 May 2019.

[95] ibid

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[97] Catherine Tomlinson, Yuan Qiong Hu, Julia Hill and Claire Waterhouse (n 89) 16.

[98] Public strategy and government relations specialists, 'Egypt's pharmaceutical sector following bold economic reforms: Challenges and opportunities' (2017) N Gage Consulting <http://www.ngage-consulting.com/downloads/Pharmaceutical_PDF_Final_Version_K_and_A.pdf> accessed 13 June 2018.

[99] World Health Organization, 'Intellectual Property Protection: Impact on Public Health' Access to Medicine (2005) WHO Drug Information

January 2005. This obligation was an alarm to the Egyptian pharmaceutical industry that depends mainly on generic medicines.

Egypt made use of the transitional period and modified its National Legislation to implement the TRIPS agreement and to include TRIPS flexibilities and safeguards to manage the negative effect of the TRIPS obligations on the availability of generic medicines.[100]

Bolar provision in the Egyptian IP law no. 82/2002 article 10/5, is one of the TRIPS flexibilities which stated that "The following shall not be considered as infringements of that right when carried out by third parties: 5- Where a third party proceeds, during the protection period of a product, with its manufacturing, assembly, use or sale, with a view to obtain a marketing license, provided that, the marketing starts after the expiry of such a protection period."[101]

This provision allows the generic producer to obtain the marketing license which usually takes long time even if the patent of the originator product still in force. This gives the opportunity for the generic producer to release its generic product immediately after the expiration of the patent. However, if the generic producer waits until the patent covering a pharmaceutical product has expired, the owner of the expired patent will enjoy extra period of monopoly power, until the generic product obtains market approval from the Ministry of Health (MOH). [102]

Exhaustion is another TRIPS flexibility that limits the rights of the patent holder in controlling the importing, exporting and distribution of the patented product.[103] This flexibility is included in the Egyptian IP law no. 82/2002 Article 10, which states that the patentee's right in excluding others from importing, exporting, using, selling, or distributing the product "shall be exhausted if the patentee marketed or licensed said product to third party/others."[104]

Moreover, article 23 in the Egyptian legislation applies to compulsory licensing under certain circumstances and criteria.[105] Compulsory licensing is a mechanism used by the governments to allow third parties to produce a product that is protected by a valid patent under certain circumstances.[106]

5.2. Patent Linkage in Egypt

Although the Egyptian IP law no.82/2002 does not include a patent linkage provision, some multinational companies are trying to put pressure on the MOH to prevent the registration of the equivalent generic products during the patent term in an attempt to apply the linkage system.[107]

There are some court cases between generic companies and innovators that are still pending. We are waiting for adjudication that ensures that there is no patent linkage system in Egypt and it cannot be read in view of the present law.

5.3. Problems with Patent Linkage in Egypt

Firstly, the role of the patent offices is to register and issue patents[108], while the regulatory authorities are responsible for ensuring safety and efficacy of the pharmaceutical products.[109] Applying the patent linkage system, will make the MOH responsible for detecting patent infringement. This will be problematic, as the MOH lacks the resources and the expertise to assess the validity of the patents whether it is infringed or not.[110]

Secondly, patent rights are private rights; they should be enforced by the right holders not by the government[111] but the patent linkage system will make the MOH responsible for detecting the infringement.[112]

Thirdly, the linkage system will undermine Bolar provision as it will inhibit the registration of generic products before the expiration of the patent of the equivalent originator.[113] As a result, this will delay the entry of the generic products for 2 or 3 years after the expiration of the equivalent patent and will extend the patent protection term.

<https://www.who.int/medicines/areas/policy/AccesstoMedicinesIPP.pdf?ua=1> accessed 12 May 2019.

[100] Mahmoud Diaa, 'Egypt Pharmaceutical Country Profile' (2011) Ministry of Health of Egypt in collaboration with World Health Organization <https://www.who.int/medicines/areas/coordination/Egypt_PSCPNarrativeQuestionnaire_27112011.pdf> accessed 12 May 2019.

[101] Egyptian IP law no. 82/2002, art 10/5.

[102] Carlos M Corea (n 60) 1-2.

[103] Sahar Aziz, 'Linking Intellectual Property Rights in Developing Countries with Research and Development, Technology Transfer, and Foreign Direct Investment Policy: A Case Study of Egypt's Pharmaceutical Industry' (2003) ILSA Journal of International and Comparative Law <https://scholarship.law.tamu.edu/cgi/viewcontent.cgi?article=1121&context=facscholar> accessed 12 May 2019.

[104] Egyptian IP Law no. 82/2002, art 10.

[105] Egyptian IP Law no. 82/2002, art 10

[106] Anshul M,' Patent linkage in India: Current scenario and need for deliberation' (2010) Journal of Intellectual Property Rights 187-196 <http://nopr.niscair.res.in/bitstream/123456789/9066/1/JIPR%2015%283%29%20187-196.pdf> accessed 1 April 2018.

[107] 'Urgent appeal to the Prof. Dr. Prime Minister, Prof. Dr. Minister of Health and Population and Prof. Dr. Minister of Investment' *News Today* (Egypt, 21 December 2013) 2.

[108] Academy of Scientific Research and Technology, 'Egyptian Patent Office' (2017) <http://www.asrt.sci.eg/index.php/asrt-departments/egpo> accessed 12 May 2019.

[109] Erica Lessem, 'An Activist's Guide to Regulatory Issues: Ensuring Fair Evaluation of and Access to Tuberculosis Treatment' (2015) Treatment Action Group <http://www.treatmentactiongroup.org/sites/default/files/201512/TB%20Regulatory%20Guide.pdf>

[110] World Health Organization, 'Briefing Note Access to Medicines' (2006) <http://www.searo.who.int/entity/intellectual_property/data-exclusively-and-others-measures-briefing-note-on-access-to-medicines-who-2006.pdf> access 11 May 2018.

[111] ibid

[112] ibid

[113] Anshul M (n 63) 191.

Fourthly, if a generic medicine is manufactured under a compulsory license, it will not be registered before the expiration of the patent.[114]

6. CONCLUSION

The patent linkage system began in US then spread to other countries through free trade agreements. It varies from country to country. Linkage system strengthens the rights of the patent owners and the abuse of these rights has negative implications on access to generic medicines at affordable prices especially in developing countries.

Egypt as the model example of developing countries in this paper (although it is not a member of any FTAs and does not have a patent linkage provision in the present IP law), is subjected to pressure from the multinational companies to prevent generic medicines from entering the market during the patent term.

By analyzing the current Egyptian IP legislation, it was found that it includes many of the TRIPS flexibilities like Bolar provision and the compulsory licensing which balance the situation between the rights of the patent holder and the rights of the public to access affordable drugs. Therefore, the patent linkage system cannot be read in view of the current law.

Egypt can learn from the Indian experience in which the court final decisions assured that India has no patent linkage system. There are some court cases which are still pending and if the Egyptian courts don't manage to appropriately react to the pending cases in which the originator's companies want to prevent the generics from entering the market, Bolar provision and the compulsory licensing will be undermined, and the generic drugs will be delayed for at least 2 years after the expiration of the equivalent patent. Ultimately, the patients will be the victims of this system as they will not be able to get the more affordable generic medicines until much later.

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