المعهد القومى للملكية الفكرية
The National Institute of Intellectual Property
Helwan University, Egypt

# المجلة العلمية للملكية الفكرية وإدارة الابتكار

دورية نصف سنوية محكمة يصدرها

## المعهد القومي للملكية الفكرية

جامعة حلوان

العدد الرابع
يوليو ٢٠٢١

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- ترسل البحوث إلى محكمين متخصصين وتحكم بسرية تامة.
- في حالة قبول البحث للنشر، يلتزم الباحث بتعديله ليتناسب مع مقترحات المحكمين، وأسلوب النشر بالمجلة.

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**جامعة حلوان - ٤ شارع كمال الدين صلاح - أمام السفارة الأمريكية بالقاهرة -جاردن سيتى**
**ص.ب: ١١٤٦١ جاردن سيتي**
**ت: ٠٢٠٢ ٢٥٤٨١٠٥٠ + محمول: ٠٢٠١٠٠٠٣٠٠٥٤٨ + ف: ٠٢٠٢ ٢٧٩٤٩٢٣٠ +**
http://www.helwan.edu.eg/niip/
ymgad@niip.edu.eg

# The Appropriateness of Patents Legislations for Attaining Sustainable Development in Egypt

**Dina Raafat Mohamed Tawfeek Mostafa**

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## Abstract

This study aims to overview the appropriateness and adequacy of the present Egyptian patent legislations for attaining sustainable development in Egypt as a developing country. In view of the commercial strategies recently employed by large companies from the developed countries to prolong their products, it became urgently needed to revise Egyptian provisions pertaining the protection of patents and reevaluate the conditions and criteria of patentability.

Recently, so-called "evergreening" practices are being made by the large companies, especially, pharmaceutical and biotechnological companies. Through these evergreening practices those large companies seek patent protection for modified forms of base compound, medical uses of a known chemical compound, combinations of known chemical compounds, particular formulations (tablets, topical forms), dosage regimens, and processes, among others – what is otherwise referred to in the literature as "secondary patents".

These practices are made by exploiting ambiguities in regulatory provisions, such as absence of specified criteria for inventive step. These practices limit competition from generic drug national companies and this in turn, can keep medicine prices high and affects the national innovation, which consequently affects the development in Egypt. As a result, the objective of patent laws to promote innovation is defeated and, instead, the patent laws are just used for protecting monopoly.

## Introduction

The term "sustainable development", at economic level, can be defined basically as an approach to economic planning whereby attempts are made to foster the economic prosperity of a country while preserving the resources for the utilization by the future generations[١] In Line with the strategic plan for achieving sustainable development, Egypt aims at maintaining the balance between developing competitive and diversified economy on the one hand and improving the quality of life of the Egyptian citizens and improving their standard of living on the other. At the economic level, said balance is reflected to reality by attracting foreign investments along with supporting the national startups and expanding investments in research and development.

Intellectual property rights generally and in particular patents play a major role in the fields of public health and biotechnology which are also the key factors in sustainable development [٢]. In the line with national strategy for achieving sustainable development, it is the role of policy makers to revise the patent system in Egypt taking into accounts the global economic environment and the commercial strategies employed by the large companies from developed countries by exploiting ambiguities in regulatory provisions of the patent system.

In recent decades, biotechnology, in particular, molecular biology and genetic engineering play a crucial role in developing extraordinary achievements in many fields. One of the most

[١] Lukose, Lisa P. "Sustainable development and intellectual property". The ٣rd International Conference of Multidisciplinary Approaches on UN Sustainable Development Goals UNSDGs, Bangkok, Thailand, ٢٠١٨, p.٦٧.
[٢] [٢] *Ibid,* p٦٨.

important fields is the pharmaceutical industry such as vaccines and biopharmaceuticals[١]. The interference of biotechnology in the pharmaceutical industry is very apparent as statistics reveals that ١٩٠ biotech companies were acquired by large pharmaceutical companies in the last three decades, at a cost of US$ ٣٩٣,٣ billion[٢]. Due to the direct effect of patenting biopharmaceuticals on public health from the one hand and the national economy on the other, presence of clear standards of patentability is necessary.

## The impact of Strategic Patenting on both developing and developed countries

Recently, statistics reveal that the number of new breakthrough medicines is decreasing[٣, ٤], whereas the number of inventions that contain modifications of existing drugs is increasing, i.e., pharmaceutical companies have been increasingly focusing their research on incremental development of drug, follow-on innovation, rather than on breakthrough innovation[٥]. Follow-on innovations are innovations that are dependent upon modifications made to primary inventions such as new therapeutic uses of previously disclosed compounds, new formulations or routes of, dosage regimens,

[١] Possas, Cristina. et.al. "Innovation and intellectual property issues in the decades of vaccines: A Brazilian perspective". Intellectual property issues in Biotechnology, edited by Singh, Harikesh B., Jha, Alok., Keswani, Chetan, CAB International, ٢٠١٦, pp. ١٨١-١٩٢.

[٢] Evens, R. and Kaitin, K. "The evolution of biotechnology and its impact on health care". Journal of HEALTH AFFAIRS, ٢٠١٥, vol.٣٤, No.٢ pp. ٢١٠-٢١٩.

[٣] Pammolli F, Magazzini L, Riccaboni M. "The productivity crisis in pharmaceutical R&D". Nature Reviews Drug Discovery., vol.١٠, No.٦,٢٠١١, P. ٤٢٨-٤٣٨.

[٤] Scannell, JW., Blanckley, A., Boldon, H., Warrington, B. "Diagnosing the decline in pharmaceutical R&D efficiency". Nature Reviews Drug Discovery, Vol. ١١, No.٣, ٢٠١٢, P.١٩١-٢٠٠.

[٥] IMAK (٢٠١٨) Overpatented, overpriced: how excessive pharmaceutical patenting is extending monopolies and driving up drug prices.

combination products, and the like[١].The current conflict amongst scholars is about whether follow-on inventions are worthy of patent protection. Some arguments allege that the value of follow-on innovations is comparable to or might exceed that of primary innovation[٢], while other arguments alleged that follow-on patents are poor quality patent and just used for evergreening primary patents and preventing the timely entry of generic competition, which may harm public health[٣].Evergreening practices are strategic use of patent system, where pharmaceutical companies extend patent protection beyond the basic patent term for as long as possible, by filing secondary patents for protecting incremental development of drug which may provide no or little therapeutic effect[٤]. Each of such patents would typically have a later expiration date, which effectively extends a period of market exclusivity beyond the expiration of a basic patent. Moreover, most of those secondary patents are used as sleeping patents not for commercialising but for constructing denser web of patents used as strategy in order to create legal and commercial uncertainty for generics in relation to the possibility of their market entry[٥]. From the side of the developing countries, strategic patenting impairs follow-on innovation of national generic companies and blocking them from competition, which affects the national economy on the one hand and affects the public health on the other.Strategic patenting does not only concern the policy makers

[١] Holman, Christopher M., Minssen, Timo., Solovy, "Patentability Standards for Follow-On Pharmaceutical Innovation", Biotechnology Law Report, Vol.٣٧ No.٣, Mary Ann Liebert, Inc.,٢٠١٨ , p.١٣٢

[٢] Ibid. P.١٣٤

[٣] Carlos M. Correa, Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective, UNDP (٢٠١٥). P٦

[٤] Burdon, Michael. and Sloper, Kristie."The art of using secondary patents to improve protection".International Journal of Medical Marketing. Vol. ٣, No.٣,٢٠٠٣, P. ٢٢٧

[٥] Gurgula, O. "Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?". *IIC, Vol.* ٥١, ٢٠٢٠, pp.١٠٦٢–١٠٨٥.

in developing countries, but also this issue is raised even in the most developed countries. Although, in developed countries like USA and that of the European Union the patent laws are too lenient to check ever-greening practices[١]. There is now a general trend in the United States and Europe to overview that excessive patenting in the pharmaceutical industry is extending monopolies and driving up drug prices[٢]. In this regard, a report issued by IMAK analyzing twelve best selling drugs in the United States finds out that there are hundreds of patent applications filed by large pharmaceutical companies to extend their monopolies far beyond the twenty years of protection and block the competition from the generic companies, according to that report. There are ١٢٥ patent applications filed and ٧١ granted per drug. Prices have increased by ٦٨٪ since ٢٠١٢[٣].

**Deficiency of technical conditions in the Egyptian Patent Act**

According to the Egyptian plan for attaining sustainable development, one strategy for fostering development is focusing on production of generics and collaborative research in order to create further knowledge that will allow Egypt to shift from pure generic producers into innovators of new drugs. Therefore, the provisions of the Egyptian patent system should be revised in order to be in line with national economic strategies and to bridge the gaps through which large pharmaceutical exploit those commercial strategies[٤].

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[١] Kumar, A., Nanda, A. "Ever-greening in Pharmaceuticals: Strategies, Consequences and Provisions for Prevention in USA, EU, India and Other Countries". Journal of Pharmaceutical Regulatory Affairs, Vol.٦, issue ١, ٢٠١٧, pp.١-٦

[٢] IMAK (٢٠١٨) *Op. Cit.*

[٣] *Ibid*

[٤] Sustainable Development Strategy: Egypt vision ٢٠٣٠. Ministry of Planning and Economic Development | mped.gov.eg..

The area of the inventive step in the Egyptian patent legal provisions is vague. There are no criteria for defining inventive step, approach to follow in deciding the inventive step of an invention, or even official guidelines. According to the Egyptian patent act, for the invention to be granted a patent, the invention shall be novel, inventive and industrially applicable. Further, a patent shall be granted independently for every modification or improvement or addition to a previously patented invention, which meets the criteria of being new, inventive and industrially applicable[١٧١]. The Egyptian patent act just sets the minimum standards of patentability given by TRIPS agreement. Such minimum standards of patentability are not compliant with Egyptian national need.

**Different Standards for determining inventive step (non-obviousness) around the world:**

Trips agreement allows parties to set the criteria of inventive step according to their own national needs. Legal systems of developed countries, such as United States and countries of European Union adopt somehow low standards for determining inventive step which could be demonstrated through the numbers of secondary patents granted for follow- on inventions, especially in the pharmaceutical products and processes[٢]. Nevertheless, there are clear approaches and guidelines for determining inventive step in those legal systems, where the patent's examination process and the results

[١] Egypt. , Intellectual property act no. ٨٢ of ٢٠٠٢, part ١, patents and Utility models. Article١.
[٢] IMAK (٢٠١٨) *op. cit.*

thereof reflect the vision of those countries in encouraging follow-on innovation.

In the United States, the inventive step (non-obviousness) of the invention is governed by section ١٠٣ of the patent act of ١٩٥٢. According to this section, the invention is considered inventive or nonobvious when the differences between the subject matter of the patent application and the prior art have not been obvious at the time the invention was made to the skilled person in the art[١]. In the pharmaceutical follow-on innovation, examining non-obviousness is basing on unpredictability, where the dominating principle is that as a desired quality of a specific solid form such as salt,

enantiomer, etc. cannot be predicted. Such follow-on inventions are the result of trial and error and therefore those inventions considered inventive[٢].

European Patent Office explains that the term 'obvious' means that the claimed invention does not go beyond the normal progress of technology but merely follows plainly or logically from the prior art, i.e. something which does not involve the exercise of any skill or ability beyond that to be expected of the person skilled in the art[٣]. In drug industry, the efficacy, efficiency, safety or side effects of a compound could be established only through experiments and testing, even that is known that compound has such properties that make it useful in treating certain diseases. According to that

[١] Nelson, Amy. "Obviousness or Inventive Step as Applied to Nucleic Acid Molecules: A Global Perspective". North Carolina Journal of Law & Technology, vol.٦, issue ١,٢٠٠٤. P.٣-٦.

[٢] Gurgula, O. "The ''obvious to try'' method of addressing strategic patenting: how developing countries can utilise patent law to facilitate access to medicines". The South Centre, Policy Brief, No.٥٩, ٢٠١٩, pp.٢-٣.

[٣] Nelson, Amy. ٢٠٠٤, *op. cit.*, pp.١٥-٢٠

approach, the first part asses that whether it is obvious to try a particular route or method through the teaching of the disclosure of the prior art in the manner that the skilled person will be motivated to try it. The second part of the test whether there is a reasonable expectation of success, in light of the prior art, which means that the skilled person while trying this method or route also expects that it will succeed, hence the outcome will be obvious[١].

## India as a model of developing country of high standards of inventive step

India adopted legislation and policies for examining patent applications relating to pharmaceutical products and processes accounts for public health considerations. In view of evergreening practices made by foreign pharmaceutical companies, India has amended its own patent system, paying a special attention to the provisions in relation to pharmaceutical inventions. In the patent (Amendment) Act ٢٠٠٥, a clause (d) is added to section ٣ with respect to the technical conditions of patentability. Clause (d) stipulate that 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[٢].The Indian legislator

[١] Lemley, Mark A. "Expecting the Unexpected", Notre Dame L. Rev., vol. ٩٢, No.٣ (٢٠١٧) pp. ١٣٦٩-١٣٩٤.

[٢] Rainforth, George." How do the Jurisdictions of India, Canada and the United Kingdom Interpret the Inventive Step Requirement for Follow-on Pharmaceutical Innovation". (Master thesis), The university of British Columbia, The Faculty of graduate and postdoctoral studies, ٢٠٢٠, pp.٥-٨

further added an explanation for the purposes of clause (d), giving examples for some of non-inventive products, such as 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[١].

With consideration that some scholars argue that clause (d) of section ٣ of the amended Indian act is problematic as it charges the patent office with making a determination of enhanced efficacy, rather than letting healthcare providers, patients, and third party payers assess whether the new formulation provides sufficient additional benefit to justify any additional cost[٢]. Nevertheless, as a result, the patent legislations in the India becomes a reflection of the country' strategy in protecting its national generic companies' interests on the one hand and protecting the public health by maintaining generic medications of affordable prices on the other hand.

## Conclusion

It is worth considering focusing on production of generics and collaborative research in order to create further knowledge that will allow Egypt to shift from pure generic producers into innovators of new drugs. This paper, therefore, argues that provisions of the patent legal system should be revised, with regard to the technical

[١] *Ibid.*
[٢] Holman, Christopher M., Minssen, Timo., Solovy, ٢٠١٨. *Op.Cit.* p.١٤٠

conditions, in particular, with respect to the pharmaceutical inventions.

Nevertheless, Persons in the field of patents can easily notice that, in the recent ١٠ years, the examination process in the Egyptian patent office is inspired by some legislations and guidelines from other developing countries such as India. With respect to pharmaceutical patents application, there is an examining approach that adopts high standards in deciding the inventive step. However, this examining approach is not supported by the Egyptian patent legal system or any official guidelines. The problem here is that deciding the inventive step of an invention seems to be personal point of view dependent upon the examiner's opinion solely. Moreover, the absence of official guideline for examining technical conditions affects the harmony and uniformity of the decisions issued from the Egyptian patent office and triggers a conflict, in particular, in case that the applicant granted a patent for the same invention in one of the developed countries that adopt low conditions of inventive step, such as United States. The situation here became arguments in opposite to arguments. The inventor companies submit their arguments and comparative studies, in order to prove the inventive step from their own point of view on the one hand, and the examiners reply with their arguments rejecting the inventive step of that invention. As a result before the judge, where there are not clear provisions or official guidelines, some of those follow-on inventions may be accepted and others may be rejected. There is no uniformity. Moreover, there is still a likelihood of dominating the Egyptian market by the drugs of foreign companies and blocking national

generic companies from competition and even blocking national follow- on innovation.

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