THE ROLE OF INTELLECTUAL PROPERTY EDUCATION IN ENHANCING THE QUALITY OF PHARMACEUTICAL PATENTS: THE EGYPTIAN EXPERIENCE

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ABSTRACT

Patents in the pharmaceutical field are of special significance. They could support innovation and incentivize research and development. However, there are often concerns that they could also hinder access to medicine. Therefore, pharmaceutical patents should be of high quality in terms of their ability to achieve their intended socioeconomic goals with limited negative impact. Despite the international interest in patent quality and the wide agreement on the need to improve it, there is much less agreement on what patent quality is. Patent quality can be closely linked to the compliance with the legal requirements for patent protection. Therefore, the quality of patent examination procedure has a great influence on patent quality. In absence of a clear patent policy or patent examination guidelines, it would be difficult to ensure the quality of the examination procedure and the granted patents in the pharmaceutical field. The role of intellectual property (IP) education of patent examiners in bridging this gap and enhancing the quality of patent examination procedure is examined. For this purpose, the Egyptian experience is presented and analyzed. IP education helps patent examiners to realize the impact of the quality of the work they perform and the patents they grant in their society. IP education ultimately contributes to enhancing the quality of patents granted in the pharmaceutical field.

Keywords:

[4] Robert Pearl, 'Why Patent Protection in the Drug Industry is out of Control' (Forbes, 19 January 2017) <

reason is economic as this industry can largely contribute to the national economic growth and development.[12]

The pharmaceutical industry is often reported to be one that needs huge financial investments to cover R&D costs.[13] Developing a new pharmaceutical product takes considerable time and effort, requires large investments and involves major risks. The process includes multiple stages; from the initial discovery and experimentation, through clinical testing and regulatory approval, to the final product development and launch into the market.[14]

The patent system has a very special significance in the pharmaceutical field. Both protection and information functions of the patent system work towards supporting innovation and ensuring the continuity of R&D activities.

A patent confers on its owner the right to exclude others from commercially exploiting the invention without the owner's authorization. Patents provide pharmaceutical

Small offices might not have the required infrastructure and well-trained examiners to conduct comprehensive search and examination.[43] Large offices with sufficient capabilities may have problems due to the pressure of increasing backlogs of unexamined applications.[44]

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important for achieving the balance between the rights of the patent owner and the public.[56]

While the legal requirements for patent protection are universal, their respective definitions and standards of application vary according to the law and practice in each country. Those requirements are usually assessed during patent examination in patent offices.

Low-quality examination procedure would negatively impact the quality of the granted patents. Patent examination could be considered of low quality when the legal patentability requirements are not adequately and comprehensively assessed by patent examiners. This could happen due to various reasons such as lack of the necessary resources, an insufficient number of qualified examiners, increased workload and backlogs, or even worse, a patent policy that encourages the grant of high numbers of patents regardless of their quality.

This leads to the question of why patent quality has surfaced as a topic that attracted worldwide attention in recent years. There has been a tremendous increase in patent filing and granting activities since the 1980s.[57] This has been accompanied by fears that it might hinder rather than encourage innovation.[58] While patents might create an environment supportive for innovation, the number of granted patents in a particular country or region cannot be used as a direct and reliable measure of the innovation level in that country or region.[59]

The OECD composite patent quality index based on patents filed at the European Patent Office (EPO) suggests that the increase in numbers of patent filings observed over the past two decades was accompanied by an average 20% decrease in patent quality.[60]

There are two main contributing factors to the patent proliferation phenomenon reflected in the grant of high numbers of low-quality patents.[61] First, large companies often follow extensive patenting strategies to sustain market monopoly and block competition from other

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[56] ibid.

[57] 'Proliferation of Patents' The Innovation Policy Platform <http://www.innovationpolicyplatform.org/www.innovationpolicyplatform.org/content/proliferation-patents/index.html> accessed 5 April 2021.

[58] ibid.

[59] Carlos M Correa, 'Tackling the Proliferation of Patents: How to Avoid Undue Limitations to Competition and The Public Domain' (2014) South Center Research Paper 52, 1 <https://www.southcentre.int/wp-content/uploads/2014/09/RP52_Tackling-the-Proliferation-of-Patents-rev_EN.pdf> accessed 20 January 2018.

[60] OECD, 'OECD Science, Technology and Industry Scoreboard 2011: Innovation and Growth in Knowledge Economies' (OECD 2011) 190 <https://www.oecd-ilibrary.org/science-and-

evaluation and the level of the inventive step[79]; common general knowledge: its combination with the state of the art[80], secondary indicia and problem invention[81]; and inventive step for inventions in the field of organic and inorganic chemistry, including pharmaceutical application.[82]

Deciding on the appropriate level of patentability standards, particularly for the inventive step, involves multiple considerations: how to encourage innovation as an important goal for an effective patent system, how to avoid negative consequences on public health and access to medicines, and how to promote competition in the pharmaceutical market and build local pharmaceutical manufacturing capacity.[83] All these considerations have to be studied in light of the respective national context.

Countries can choose to apply rigorous standards for the assessment of patentability conditions to avoid granting patents on inventions that do not merit the protection.[84] Opting for high standards for patentability requirements would result in patents that are low in quantity but high in quality.[85] By utilizing such pre-grant flexibility, resorting

have a good understanding of the applicable law especially the provisions on patentability requirements.[92]

Another essential requirement for conducting the search is adequate access to a wide range of patent and non-patent databases.[93] It is important also to ensure that specialized and technology specific databases are available.[94] Other complementary yet influential factors include specialized training programs and access to search and examination products of other patent offices.

For optimum interaction between all of the mentioned factors, they need to be applied in light of a clear vision to the purpose of the patent examination procedure and a

patent offices are the first stop for patent examination, they have to take the initiative to develop patent policies that support and do not run counter to health policies.[102]

5. IP EDUCATION OF PATENT EXAMINERS AND THE QUALITY OF EXAMNATION PROCEDURE AND PHARMACEUTICAL PATENTS

Patent examiners are the first line of defense against the grant of low-quality patents. They are responsible for conducting high-quality patent search and examination. To efficiently perform this duty, they should be equipped not only with specialized technical knowledge in their respective technical fields but also with an in-depth understanding of the applicable law.[103]

5.1 Importance of Legal Education of Patent Examiners

Pharmaceutical examiners have to understand the

much as the Egyptian examiners were learning, their final

The workshop was a great success. EGPO examiners were actively engaged sharing their experience and concerns. One important lesson to learn was on how to examine pharmaceutical patents taking public health objectives into consideration. According to the workshop report, the examiners have come to realize how the work they perform and the decisions they take could impact access to medicine, conceding that due to the special nature of their jobs they are responsible as guardians of public health.[124] The delegates returned to EGPO and started internal discussions on choosing the most appropriate standards for applying the patentability requirements in respect of pharmaceutical patents. [125]

patents. In other words, low patentability standards would hinder innovation in the pharmaceutical field.[133]

EGPO pharmaceutical examiners realized the positive impact of IP education on their work. Most of them attended multiple courses and pursued their studies in the field of IP. Currently, most of the pharmaceutical examiners in EGPO hold an Advanced Studies Diploma or LLM in IP laws. Most of their IP Diploma research papers dealt with various aspects of the relationship between IPRs and pharmaceuticals.[134]

In 2013, EGPO pharmaceutical department established an internal quality team to review the applications to be granted. This team is independent of the general quality committee reviewing samples of accepted and rejected applications in all technological fields.[135] The aim was to ensure the consistency of the examination procedure and that all the granted pharmaceutical patents are in compliance with the applied high patentability standards.

Today, EGPO pharmaceutical examiners exchange their experience with other patent offices through training programs and workshops on applying high patentability standards for pharmaceutical patents. In addition, about 30% of the trainers in the National IP Academy of Egypt are pharmaceutical patent examiners.[136]

What has happened with EGPO pharmaceutical patent examiners between 2005 and today is mainly due to IP education. Pharmaceutical examiners realized the impact of their daily work on issues of public concern. Their perspective has changed influencing their choice of the examination standards they should apply. This affected their practice and inspired them to formulate their own examination guidelines. In absence of external policy guidance, IP education has enabled EGPO pharmaceutical examiners to develop an internal policy that governs how pharmaceutical patents should be examined.

5.2.1 The Atazanavir and Sofosbuvir Cases in Egypt

[133] ibid 192.
[134] Interview with Professor Hossam El Saghir, Founder and Director of the Regional Institute of Intellectual Property, Helwan University (Cairo, Egypt, 30 May 2018).
[135] Interview with Mr Adel Oweida, Former Head of the EGPO (Cairo, Egypt, 30 May 2018).
[136] ibid.
[137] WHO, *The Role of Intellectual Property in Local Production in Developing Countries* (n 10) 10.

<https://theejbm.wordpress.com/2013/10/01/the-untold-aids-story-how-access-to-antiretroviral-drugs-was-obstructed-in-africa/> accessed 11 May 2018

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