

**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:** IP Education, Patent Quality, Pharmaceutical, Examination Procedure, Patent Examiner, Egypt

**1. INTRODUCTION**

One of the most important aims of the patent system is to encourage research and development (R&D) processes to satisfy society's various needs and to provide solutions for its problems in all technological fields.<sup>1</sup> The ultimate

goal is to achieve socioeconomic development. The main functions of the patent system are protection through the grant of exclusive rights, and information through the requirement of disclosure.<sup>2</sup> Both functions should work together to support innovation and this is particularly true for pharmaceutical innovation.

Pharmaceutical patents have special significance. They can be valuable tools to encourage pharmaceutical R&D. The exclusive rights granted to patent holders reward the effort, time and investments put in R&D, and incentivize further research. Public disclosure of patent information is important because information on previous inventions could serve as a starting point for future research.

However, despite the positive role that patents can play in supporting R&D, it is feared that granting too many patents on pharmaceuticals could lead to undesirable outcomes. The most prominent negative effects are, hindering access to medicine and blocking further research.<sup>3</sup> Patents confer monopoly rights on their owners regardless of the possible consequences on human's right in access to medicine. When patients need a particular medication that is solely available from one source, and cannot afford it, this becomes a public health issue.<sup>4</sup> In addition, overprotection of pharmaceutical research results by patent exclusive rights may stifle innovation instead of supporting it. Pharmaceutical innovation is a typical example of sequential innovation which depends to a large extent on previous technologies and research results.<sup>5</sup>

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<sup>1</sup>WIPO, 'Frequently Asked Questions: Patents' <[https://www.wipo.int/patents/en/faq\\_patents.html](https://www.wipo.int/patents/en/faq_patents.html)> accessed 1 May 2019.

<sup>2</sup> WIPO, *WIPO Guide to Using Patent Information* (WIPO 2015) 4.

<sup>3</sup> Carlos M Correa, 'Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing' (2011) South Center Research Paper 41, 3 <[https://www.southcentre.int/wp-content/uploads/2013/05/RP41\\_Pharmaceutical-Innovation\\_EN.pdf](https://www.southcentre.int/wp-content/uploads/2013/05/RP41_Pharmaceutical-Innovation_EN.pdf)> accessed 19 April 2018.

<sup>4</sup> Robert Pearl, 'Why Patent Protection in the Drug Industry is out of Control' (Forbes, 19 January 2017) <<https://www.forbes.com/sites/robertpearl/2017/01/19/why-patent-protection-in-the-drug-industry-is-out-of-control/#e6c702078ca9>> accessed 19 April 2018.

<sup>5</sup> Kyle A Marchini, 'Patents and Innovation in the Pharmaceutical Industry' (2013) 4 Grove City College Journal of Law & Public Policy 47, 49.

The patent system should be efficiently used in the pharmaceutical field to achieve its intended purpose in encouraging innovation while taking into consideration the possible undesirable effects on access to medicine and access to knowledge. It is of utmost importance to devise a patent policy that aims to strike the right balance between patent holders' exclusive rights and public rights. This balance of rights and obligations is an important component of the TRIPS Agreement objectives of protection and enforcement of intellectual property rights (IPRs) in the contribution to the promotion of technological innovation and transfer of technology.<sup>6</sup>

Moreover, countries need to put in place systems which aim to ameliorate the possible negative effects of patents on medicines availability and affordability and on future pharmaceutical R&D. An important principle under the TRIPS Agreement is that World Trade Organization (WTO) members may adopt measures necessary to protect public health, to promote the public interest in sectors of vital importance to socio-economic and technological development, and to prevent the abuse of IPRs.<sup>7</sup>

Although legal control could be exercised to remedy some of the negative effects of excessive patent protection or abuse of patent exclusive rights in the pharmaceutical field, prevention is always better than cure. Patent rights should not be granted in the first place for inventions that do not merit such protection.<sup>8</sup> Creation of unnecessary monopolies must be avoided as much as possible. It is therefore essential to ensure that pharmaceutical patents are of a proper 'quality'.

The issue of patent quality has lately attracted worldwide attention. However, despite the almost universal

agreement on the need to improve the quality of patents, there is much less agreement on what patent quality means. Patent offices bear the primary responsibility in ensuring that patents granted on pharmaceutical inventions are 'good' quality patents.<sup>9</sup>

Linking patent quality to the compliance with the legal requirements for patent protection makes the patent examination process a main determining factor.<sup>10</sup> Patent examination process is performed by patent examiners having technical background and experience in patent search and examination.<sup>11</sup>

Ideally, the examiners would be working according to a set of guidelines formulated in light of a national patent policy. However, in absence of such guidelines or a policy that defines their framework, maintaining high-quality examination procedure and granting high-quality patents would be a difficult task.

This paper highlights the important role that Intellectual Property (IP) education plays in improving the quality of patent examination and granted pharmaceutical patents. This role would be especially prominent when clear policy guidance is not available. In this regard, the experience of the pharmaceutical patent examiners in the Egyptian Patent Office (EGPO) is presented and discussed.

## 2. PATENTS IN THE PHARMACEUTICAL FIELD

It is not disputed that the pharmaceutical industry is one of the most important industries worldwide. It greatly affects human life and the quality of this life. This industry is particularly important for two reasons. The first is social since the provision of affordable high-quality medicines to the patients is a genuine human right. The second

<sup>6</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS 1994) Art 7.

<sup>7</sup> TRIPS 1994, Art 8 (1).

<sup>8</sup> Carlos M Correa and Germán Velásquez, 'Access to Medicines: Experiences with Compulsory Licenses and Government Use – The Case of Hepatitis C' (2019) South Centre Research Paper 85, 14 <[https://www.southcentre.int/wp-content/uploads/2019/04/RP85\\_Access-to-Medicines-Experiences-with-Compulsory-Licenses-and-Government-Use-The-Case-of-Hepatitis-C\\_EN.pdf](https://www.southcentre.int/wp-content/uploads/2019/04/RP85_Access-to-Medicines-Experiences-with-Compulsory-Licenses-and-Government-Use-The-Case-of-Hepatitis-C_EN.pdf)> accessed 30 April 2019.

<sup>9</sup> German Velásquez, 'Guidelines on Patentability and Access to Medicines' (2015) South Center Research Paper 61, 7

<[https://www.southcentre.int/wp-content/uploads/2015/03/RP61\\_Guidelines-on-Patentability-and-A2M\\_EN.pdf](https://www.southcentre.int/wp-content/uploads/2015/03/RP61_Guidelines-on-Patentability-and-A2M_EN.pdf)> accessed 20 January 2018.

<sup>10</sup> WHO, *The Role of Intellectual Property in Local Production in Developing Countries: Opportunities and Challenges* (WHO 2016) 11.

<sup>11</sup> WIPO, 'Alternatives in Patent Search and Examination' Policy Guide (WIPO 2014) 8 <[https://www.wipo.int/edocs/pubdocs/en/wipo\\_pub\\_guide\\_patentsearch.pdf](https://www.wipo.int/edocs/pubdocs/en/wipo_pub_guide_patentsearch.pdf)> accessed 1 May 2019.

reason is economic as this industry can largely contribute to the national economic growth and development.<sup>12</sup>

The pharmaceutical industry is often reported to be one that needs huge financial investments to cover R&D costs.<sup>13</sup> 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.<sup>14</sup>

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 companies with the opportunity to recoup their large R&D investments while protected from the competition of third parties who have not made those investments.<sup>15</sup> Patents reward the effort, time and money put into R&D, and provide incentives for further innovation.<sup>16</sup>

Making the information disclosed in patent documents publicly available is equally important for pharmaceutical R&D. Pharmaceutical innovation relies heavily on the knowledge of preceding innovations and prior research

results.<sup>17</sup> Information on existing inventions and previous R&D outcomes could be the basis for further research.

Effective utilization of the patent system could create an environment conducive to innovation. Such environment is crucial to develop new pharmaceutical products and to improve the existing ones. However, there are often concerns that granting unnecessarily high numbers of patents to protect pharmaceutical R&D results could lead to undesirable consequences. The most prominent negative outcomes in this regard are hindering access to medicines<sup>18</sup> and blocking future research<sup>19</sup>.

A patent empowers its owner to exclude third parties from unauthorized production, use, sale, offering for sale or importation of the patented product. For a pharmaceutical product, that could cause serious problems when, for example, the patent owner sets an exorbitant price for the product, does not make the product available in the market at least in sufficient quantities, or refuses to license the patent despite offering reasonable terms. Such abusive practices might be controlled by drug pricing mechanisms<sup>20</sup>, competition law<sup>21</sup> and patent law<sup>22</sup>. However, the mere fact that a particular person or entity could have significant control over the availability and accessibility of an essential commodity like medicines remains a matter of concern.

Patents do not only allow companies to recoup their R&D costs: they also place the power to control medicine

<sup>12</sup> Dennis A Ostwald, Katharina Zubrzycki, Julian Knippel, 'Research Report: The Economic Footprint of the Pharmaceutical Industry' (International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), WiFor 2015) <[https://www.ifpma.org/wp-content/uploads/2016/02/wifor\\_research-report\\_2015\\_web.pdf](https://www.ifpma.org/wp-content/uploads/2016/02/wifor_research-report_2015_web.pdf)> accessed 5 June 2018.

<sup>13</sup> 'Total Global Pharmaceutical Research and Development (R&D) Spending from 2008 to 2022 (in billion U.S. dollars)' Statista: The Statistics Portal <<https://www.statista.com/statistics/309466/global-r-and-d-expenditure-for-pharmaceuticals/>> accessed 5 June 2018.

<sup>14</sup> Henry Grabowski, 'Patents and New Product Development in the Pharmaceutical and Biotechnology Industries' (2002) Working Paper, Duke University, Department of Economics, 4 <<http://public.econ.duke.edu/Papers/Other/Grabowski/Patents.pdf>> accessed 5 June 2018.

<sup>15</sup> Ellen 't Hoen, 'Analysis: Medicines Patents, Access and Innovation' (Astrid Berner-Rodoreda, Maïke Lukow, Luise Steinwachs Eds, Bread for the World 2016) Analysis 58, 6

<[https://www.brot-fuer-die-welt.de/fileadmin/mediapool/2\\_Downloads/Fachinformationen/Analyse/Analyse\\_58\\_Medicine\\_Patents.pdf](https://www.brot-fuer-die-welt.de/fileadmin/mediapool/2_Downloads/Fachinformationen/Analyse/Analyse_58_Medicine_Patents.pdf)> accessed 19 April 2018.

<sup>16</sup> Grabowski (n 14).

<sup>17</sup> Carlos M Correa, 'Ownership of knowledge — the role of patents in pharmaceutical R&D' (2004) 82(10), Bulletin of the World Health Organization 784, 785.

<sup>18</sup> Carlos M Correa, 'Public Health and Intellectual Property Rights' (2002) 2(3) Global Society Policy, SAGE Publications 261, 262

<<http://journals.sagepub.com/doi/abs/10.1177/1468018102002030201>> accessed 18 February 2018.

<sup>19</sup> Correa, 'Ownership of knowledge' (n 17).

<sup>20</sup> WHO, WIPO, WTO, *Promoting Access to Medical Technologies and Innovation - Intersections between public health, intellectual property and trade* (WHO, WIPO, WTO 2013) 157.

<sup>21</sup> *ibid* 76.

<sup>22</sup> *ibid* 61.

prices in the hands of those companies.<sup>23</sup> In the nineties, millions of AIDS patients in Africa died although antiretroviral medicines were already developed then. Patients did not have access to antiretroviral medicines as they were very expensive and hence not affordable. The pharmaceutical companies that had developed those medicines charged very high prices for them because they were protected by patent exclusive rights.<sup>24</sup>

Pharmaceutical patents can be used to block generic competition.<sup>25</sup> Generic companies usually charge lower prices and thus facilitate access to medicines. In absence of generic competition, for instance, due to strategic patenting of minor modifications, prices would be higher and access to affordable medicines would be blocked.<sup>26</sup>

Overprotection of pharmaceutical research outcomes by patents could impede rather than encourage innovation. While patents are aimed to incentivize their owners to continue innovation, their exclusionary nature could make it difficult for others to do the same. This would block or at least slow down follow-on innovation.<sup>27</sup> When a single medicine is protected by a bundle of patents<sup>28</sup> on the basic molecule, manufacturing processes, various derivatives and physical forms; further R&D on this medicine by third parties would be practically blocked.

Considering the above concerns, the patent system in the pharmaceutical field should strike the right balance between protecting the legitimate interests of innovators and incentivizing innovation on one hand and ensuring that the public at large can benefit from the fruits of this

innovation on the other.<sup>29</sup> In this regard, the strategic adoption and implementation of public health related patent flexibilities in international IP instruments plays a vital role. Pharmaceutical patents should be able to achieve its intended socioeconomic goals with minimum negative effects on access to medicine, generic competition and future innovation. Pharmaceutical patents should be high-quality patents.

### 3. THE CONCEPT OF PATENT QUALITY

There has been an increasing international interest in patent quality. It is seen as an essential component of the patent system that significantly impacts its ability to achieve its intended goals.<sup>30</sup> Therefore, patent quality has been a regular discussion topic in the sessions of the World Intellectual Property Organization (WIPO) Standing Committee on the Law of Patents (SCP).<sup>31</sup> Both developed and developing countries are concerned with the issue and actively engaging in the discussions.<sup>32</sup> However, despite the general agreement on the need to enhance the quality of patents, there is little consensus on the meaning or definition of the term 'patent quality'.

Without a clear and comprehensive definition of what constitutes patent quality, it would be difficult to conduct a fruitful discussion on whether there are patent quality issues and what can be done to fix them. Defining patent quality is a prerequisite to adopting the appropriate measures and policy changes to improve the quality of patents.

<sup>23</sup> Erica Penfold, 'Explainer: the problem drug patents pose for developing countries' (The CONVERSATION, 6 August 2015) <<https://theconversation.com/explainer-the-problem-drug-patents-pose-for-developing-countries-45667>> accessed 4 May 2018.

<sup>24</sup> Hanna Keppler, 'The Untold AIDS Story: How access to antiretroviral drugs was obstructed in Africa' (The EJBM Blog, 1 October 2013) <<https://theejbm.wordpress.com/2013/10/01/the-untold-aids-story-how-access-to-antiretroviral-drugs-was-obstructed-in-africa/>> accessed 11 May 2018.

<sup>25</sup> Correa, 'Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing' (n 3).

<sup>26</sup> Correa, 'Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing' (n 3) 5.

<sup>27</sup> Correa, 'Ownership of knowledge' (n 17) 786.

<sup>28</sup> WIPO Patent Landscape Report on Ritonavir (2011) showed that over than 800 patent have been filed to protect different aspects of Ritonavir (an antiretroviral drug for treatment of HIV infection and AIDS) including its variants, derivatives, combinations, methods of production and use <[http://www.wipo.int/edocs/pubdocs/en/patents/946/wipo\\_pub\\_946.pdf](http://www.wipo.int/edocs/pubdocs/en/patents/946/wipo_pub_946.pdf)> accessed 29 May 2018.

<sup>29</sup> Hoehn (n 15).

<sup>30</sup> WIPO, 'Quality of Patents' <[http://www.wipo.int/patents/en/topics/quality\\_patents.html](http://www.wipo.int/patents/en/topics/quality_patents.html)> accessed 22 January 2018.

<sup>31</sup> *ibid.*

<sup>32</sup> WIPO Secretariat, 'Report on the International Patent System' (SCP/12/3 Rev2, WIPO Standing Committee on the Law of Patents, Twelfth Session, Geneva, June 2008) 56 <[http://www.wipo.int/edocs/mdocs/scp/en/scp\\_12/scp\\_12\\_3\\_rev\\_2.pdf](http://www.wipo.int/edocs/mdocs/scp/en/scp_12/scp_12_3_rev_2.pdf)> accessed 22 January 2018.

There are two important questions to answer with respect to the issue of patent quality: how patent quality could be defined and measured? and why the quality of patents has received much attention lately?

The question of the definition of patent quality could be viewed from a technical, legal or economic perspective, or a combination thereof.<sup>33</sup> From a technical point of view, patent quality reflects the quality of the scientific content or technical information included in the patent application.<sup>34</sup> A high-quality patent would significantly contribute to the body of knowledge in the respective technological field. In this case, patent quality is seen as the quality of the described invention itself.

From a legal perspective, patent quality means validity. A patent of good quality would stand possible invalidation claims. The quality of patents in this regard is dependent on the degree of fulfillment of the legal requirements for patent protection under the respective patent law.

In respect of the economic value, patent quality can be linked to the market value of the patent or the profit it could generate when commercially exploited. The value of the patented technology and the ability of the patent to provide its owner with a competitive edge by excluding other market players are relevant aspects. Patent value could be linked to the quality of the underlying invention or the quality in terms of legal validity. However, at many occasions, patent value and patent quality are considered as two distinct concepts.<sup>35</sup>

Patent quality could have various meanings to different stakeholders. Patent offices, courts, legal experts and patent agents are usually concerned with legal validity.<sup>36</sup> Technology experts and researchers focus on whether the underlying invention involves major technological advancement or minor improvement over the state of the art.<sup>37</sup> Policy makers and macroeconomic experts should link patent quality to the ability of patents to fulfill their main objectives in rewarding and incentivizing innovation while enabling the dissemination and diffusion of technological developments.<sup>38</sup>

Equating the quality of a patent with its legal validity rather than the quality of the underlying invention or its market value is a common approach to patent quality.<sup>39</sup> The quality of patents is often measured in terms of satisfaction of the legal patentability standards. Another approach is to examine how those standards could be applied to ensure the grant of high-quality patents.<sup>40</sup> This requires identifying the parameters against which patent quality could be assessed. In light of those parameters, patent reforms should be more focused on the target of increasing the number of good quality patents rather than just increasing the number of legally valid patents<sup>41</sup>.

At this point, it is necessary to consider the meaning of patent quality from the perspective of patent offices. For this purpose, the ongoing discussions on patent quality in the framework of the WIPO SCP provide a useful insight.<sup>42</sup> Both small offices with limited resources and larger offices with full search and examination capacities are concerned with the quality of the patents they grant.

<sup>33</sup> Alexandra Sklan, 'Patent Quality' (2014) 3(1) *Pharmaceutical Patent Analyst* 17 <<https://www.future-science.com/doi/full/10.4155/ppa.13.74>> accessed 22 January 2018.

<sup>34</sup> Justus Baron, Henry Delcamp 'Patent Quality and Value in Discrete and Cumulative Innovation' Working Paper (2010) CERN WORKING PAPER No. 2010-07, 5 <<https://ssrn.com/abstract=1709999>> accessed 2 May 2019.

<sup>35</sup> R Polk Wagner, 'Understanding Patent-Quality Mechanisms' (2009) 157 *University of Pennsylvania Law Review* 2135, 2139-2140 <<https://ssrn.com/abstract=1452862>> accessed 18 February 2018.

<sup>36</sup> Mariagrazia Squicciarini, Hélène Dernis, Chiara Criscuolo, 'Measuring Patent Quality: Indicators of Technological and Economic Value' (2013) OECD Science, Technology and Industry Working Papers No 2013/03, OECD Publishing, 7

<<http://dx.doi.org/10.1787/5k4522wkwr1r8-en>> accessed 18 May 2018.

<sup>37</sup> *ibid.*

<sup>38</sup> *ibid.*

<sup>39</sup> Bruce Berman, 'The puzzle that is patent quality' (2015) 4 *WIPO Magazine* 16 <[http://www.wipo.int/export/sites/www/wipo\\_magazine/en/pdf/2015/wipo\\_pub\\_121\\_2015\\_04.pdf](http://www.wipo.int/export/sites/www/wipo_magazine/en/pdf/2015/wipo_pub_121_2015_04.pdf)> accessed at 19 April 2018.

<sup>40</sup> Christi J Guerrini, 'Defining Patent Quality' (2014) 82(6) *Fordham Law Review* 3091, 3091 <<https://ir.lawnet.fordham.edu/flr/vol82/iss6/18/>> accessed 04 May 2018.

<sup>41</sup> *ibid.*

<sup>42</sup> WIPO, 'Quality of Patents' (n 30).

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

At the sixteenth SCP session, the delegations of Canada and the United Kingdom proposed a work program on the quality of patents.<sup>45</sup> It indicated that patent offices need to adopt appropriate measures to ensure that the patents they grant meet the standards that achieve the patent system's economic and social policy objectives.<sup>46</sup>

By the eighteenth session, it became clear that WIPO Member States have different definitions and diverse views on what constitutes patent quality.<sup>47</sup> Therefore, the two delegations proposed a questionnaire on quality of patents to explore the various definitions used within national and regional patent offices of Member States.<sup>48</sup>

At the twenty-fourth session, the committee agreed that the Secretariat would circulate a draft questionnaire on the term 'Quality of Patents'.<sup>49</sup> Question 1 dealt with how each office understands the term 'quality of patents'.<sup>50</sup> The responses highlighted two main concepts. One is that the term relates to the quality of the patent itself. The other is that the term is understood in the context of patent grant procedure. Multiple responses referred to both concepts considering them as closely related.<sup>51</sup>

Most responses where patent quality was understood as the quality of the patent itself stated that a high-quality patent shall meet the requirements for patent protection under the applicable law.<sup>52</sup> Those include the three patentability criteria (novelty, inventive step and industrial applicability), sufficiency of disclosure, and claims clarity and conciseness. More specifically, patent quality was linked to the compliance with patentability criteria. According to those responses, patents that meet the patentability criteria have a high presumption of validity and most probably would not be revoked if challenged. This was considered important to create legal certainty both for the patent holder and third parties.<sup>53</sup>

With regard to the quality of the patent grant procedure, it has been seen as the process leading to the desired outcome of patent quality. Many responses indicated factors that would contribute to high-quality grant procedure. The factors included the quality of search and examination process and generated reports, procedure timeliness, availability of skilled and well-trained staff, communication with stakeholders and transparency.<sup>54</sup>

Associating quality with the compliance with statutory requirements of patentability seems appropriate for two reasons.<sup>55</sup> First, the legal patent protection requirements are universal standards for patents. Second, legal validity is the key for legal stability and certainty which are

<sup>43</sup> WIPO Secretariat, 'Report on the International Patent System' (n 32) 54

<sup>44</sup> *ibid.* 55.

<sup>45</sup> WIPO Secretariat, 'Proposal from the Delegations of Canada and the United Kingdom' (SCP/16/5, WIPO Standing Committee on the Law of Patents, Sixteenth Session, Geneva, May 2011) <[http://www.wipo.int/edocs/mdocs/scp/en/scp\\_16/scp\\_16\\_5.pdf](http://www.wipo.int/edocs/mdocs/scp/en/scp_16/scp_16_5.pdf)> accessed 22 January 2018.

<sup>46</sup> *ibid.*

<sup>47</sup> WIPO Secretariat, 'Questionnaire on Quality of Patents: Proposal by the Delegations of Canada and the United Kingdom' (SCP/18/9, WIPO Standing Committee on the Law of Patents, Eighteenth Session, Geneva, May 2012) <[http://www.wipo.int/edocs/mdocs/scp/en/scp\\_18/scp\\_18\\_9.pdf](http://www.wipo.int/edocs/mdocs/scp/en/scp_18/scp_18_9.pdf)><[http://www.wipo.int/edocs/mdocs/scp/en/scp\\_17/scp\\_17\\_8.pdf](http://www.wipo.int/edocs/mdocs/scp/en/scp_17/scp_17_8.pdf)> accessed 22 January 2018.

<sup>48</sup> *ibid.*

<sup>49</sup> WIPO Secretariat, 'Report adopted by the Standing Committee' (SCP/24/6, WIPO Standing Committee on the Law of Patents, Twenty Fourth Session, Geneva, June 2016) 81 <[http://www.wipo.int/edocs/mdocs/mdocs/en/scp\\_24/scp\\_24](http://www.wipo.int/edocs/mdocs/mdocs/en/scp_24/scp_24)

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<sup>50</sup> WIPO Secretariat, 'Updated Responses to the Questionnaire on the Term "Quality of Patents" and Cooperation between Patent Offices in Search and Examination (Part 1)' (SCP/27/4 REV, WIPO Standing Committee on the Law of Patents, Twenty Seventh Session, Geneva, December 2017) <[http://www.wipo.int/edocs/mdocs/scp/en/scp\\_27/scp\\_27\\_4\\_rev.pdf](http://www.wipo.int/edocs/mdocs/scp/en/scp_27/scp_27_4_rev.pdf)> accessed 22 January 2018.

<sup>51</sup> *ibid.*

<sup>52</sup> *ibid.*

<sup>53</sup> *ibid.*

<sup>54</sup> *ibid.*

<sup>55</sup> SONG Hefa, LI Zhenxing, 'Patent Quality and the Measuring Indicator System: Comparison among China Provinces and Key Countries' (2014) 4 <<https://www.semanticscholar.org/paper/Patent-quality-and-the-measuring-indicator-system%3A-Hefa-Zhenxing/7280dae19448d15018320e623c2009aa699746f8>> accessed 22 January 2018.

important for achieving the balance between the rights of the patent owner and the public.<sup>56</sup>

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.<sup>57</sup> This has been accompanied by fears that it might hinder rather than encourage innovation.<sup>58</sup> 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.<sup>59</sup>

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.<sup>60</sup>

There are two main contributing factors to the patent proliferation phenomenon reflected in the grant of high numbers of low-quality patents.<sup>61</sup> First, large companies often follow extensive patenting strategies to sustain market monopoly and block competition from other enterprises especially the Small and Medium Enterprises (SMEs).<sup>62</sup> Second, a number of patent offices around the world apply a relaxed approach for the assessment of patentability criteria.<sup>63</sup>

Low-quality patents have the exact opposite effect to a well-functioning patent system. They create unnecessary monopolies, deter competition and burdensome businesses with high costs in the form of royalties paid to obtain licenses or litigation expenses for invalidation lawsuits.<sup>64</sup> They also negatively impact the scope of public domain. Knowledge which otherwise would be in the public domain will become the private property of patent owners. Access to such knowledge would require obtaining authorization and payment of royalties.<sup>65</sup>

#### 4. QUALITY OF PHARMACEUTICAL PATENTS

Pharmaceutical companies are keen to extensively acquire and enforce patent rights. The main reason they state is that developing new products involves major risks and substantial investments in R&D. However, there are only few patents covering truly new drug molecules.<sup>66</sup> Despite the exponential growth of the number of patents

<sup>56</sup> *ibid.*

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

<sup>58</sup> *ibid.*

<sup>59</sup> 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](https://www.southcentre.int/wp-content/uploads/2014/09/RP52_Tackling-the-Proliferation-of-Patents-rev_EN.pdf)> accessed 20 January 2018.

<sup>60</sup> OECD, 'OECD Science, Technology and Industry Scoreboard 2011: Innovation and Growth in Knowledge Economies' (OECD 2011) 190 <<https://www.oecd-ilibrary.org/science-and-technology/oecd-science-technology-and-industry-scoreboard-2011-sti-scoreboard-2011-en>> accessed 20 April 2018.

<sup>61</sup> Carlos M Correa, 'Beyond 'Patent Quality': Basic Concepts of the Patent System Need to be Reviewed' (2012) Latin America in Movement Online <<https://www.alainet.org/es/node/159796>> accessed 22 January 2018.

<sup>62</sup> *ibid.*

<sup>63</sup> *ibid.*

<sup>64</sup> Guerrini (n 40) 3093.

<sup>65</sup> WIPO Secretariat, 'Opposition Systems' (SCP/14/5, WIPO Standing Committee on the Law of Patents, Fourteenth Session, Geneva, January 2010) 5 <[http://www.wipo.int/edocs/mdocs/scp/en/scp\\_16/scp\\_16\\_ref\\_scp\\_14\\_5.pdf](http://www.wipo.int/edocs/mdocs/scp/en/scp_16/scp_16_ref_scp_14_5.pdf)> accessed 22 January 2018.

<sup>66</sup> Correa, 'Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing' (n 3) 4.

filed and granted in respect of pharmaceuticals,<sup>67</sup> the majority of those patents actually cover simple variations and trivial modifications of existing drug molecules.<sup>68</sup>

Whereas developing new drug molecules would probably involve considerable efforts and entail varying levels of inventiveness, the techniques of making various physical forms and preparations of existing pharmaceutical compounds are often comprised within the general knowledge of a person skilled in the art.<sup>69</sup> Therefore, only few developments of the latter category could be seen as genuinely inventive in the pharmaceutical field in light of the state of the art.<sup>70</sup> In other words, it would be often difficult for such forms and preparations to pass the inventive step test as one of the patentability criteria.

Patent proliferation phenomenon is very prominent and has serious implications in the pharmaceutical field.<sup>71</sup> The core problematic aspect of the proliferation of pharmaceutical patents is the low quality of those patents. According to the OECD composite patent quality index, the quality of pharmaceutical patents filed at the EPO was less than the average and less than the quality of patents in most of the other technological fields.<sup>72</sup> Patent proliferation undermines rather than stimulates innovation and competition.<sup>73</sup>

Various measures could be adopted to address patent proliferation and ameliorate its negative impact on public health and local generic manufacturing capacities.<sup>74</sup> However, the most efficient way is to avoid the grant of such high numbers of low-quality patents rather than trying to minimize their negative effects after being granted. This should ideally happen at the very first place

where patent applications are processed: the patent office.

One of the most important TRIPS flexibilities is the freedom left for WTO members in defining and setting the standards for application of each of the patentability criteria.<sup>75</sup> For example, different countries have different policy choices for the assessment of inventive step. This involves multiple factors such as the degree of progress over prior art and common general knowledge, and the definition of the person skilled in the art.<sup>76</sup>

Countries often apply at least one of two approaches to implement the flexibility on the standards for applying the patentability criteria. The first approach deals with how the patentability criteria are defined in the respective national law and how it is interpreted by case law and practice.<sup>77</sup> An example is Section 3(d) of the Indian Patents Act 1970 (as amended in 2005) which does not consider as an invention the mere discovery of a new form of a known substance unless it provides significant difference in efficacy.

The second approach focuses on how patent examiners apply the patentability criteria. In this respect, and to ensure the quality of granted patents, some patent offices - as in Argentina - issued examination guidelines for patent applications in the pharmaceutical field.<sup>78</sup>

In practice, patent offices in different countries have a range of perspectives on the various aspects involved in assessing the inventive step criterion. This was reflected in the series of studies on inventive step conducted within the framework of the WIPO SCP between 2015 and 2019 and covered, among other topics, the definition of the person skilled in the art, methodologies for inventive step

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<sup>67</sup> Correa, 'Ownership of knowledge' (n 17) 784-785.

<sup>68</sup> Correa, 'Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing' (n 3) 4.

<sup>69</sup> Chandra Mohan SB and others, 'Patents - An Important Tool for Pharmaceutical Industry' (2014) 2(2), *Research and Reviews: Journal of Pharmaceutics and Nanotechnology* 12, 14.

<sup>70</sup> *ibid.*

<sup>71</sup> Correa, 'Tackling the Proliferation of Patents' (n 59) 2-3.

<sup>72</sup> OECD (n 60).

<sup>73</sup> Correa, 'Beyond Patent Quality' (n 61).

<sup>74</sup> Correa, 'Tackling the Proliferation of Patents' (n 59) 3-21.

<sup>75</sup> WHO, *Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health* (WHO 2006) 51.

<sup>76</sup> WHO, WIPO, WTO, *Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property and Trade*. (2nd edn, WHO, WIPO, WTO 2020) 70.

<sup>77</sup> *ibid.* 173.

<sup>78</sup> *ibid.*



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

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.<sup>83</sup> 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.<sup>84</sup> Opting for high standards for patentability requirements would result in patents that are low in quantity but high in quality.<sup>85</sup> By utilizing such pre-grant flexibility, resorting to more cumbersome, lengthy and expensive post-grant flexibilities such as compulsory licensing and invalidation could be avoided.<sup>86</sup> Prevention is always better than cure.

When patent offices apply lax patentability standards, pharmaceutical companies would be encouraged to file high numbers of patent applications on several minor

modifications and trivial developments. The aim of those filings is to extend the length of the exclusivity beyond the 20-years patent protection period, a practice known as 'evergreening'<sup>87</sup>. Although such patents are weak and not likely to withstand invalidation, they could be, and often are, strategically used by their holders to deter generic competition.<sup>88</sup> When generic companies are kept out of the market, drug prices increase and access to medicine is seriously hampered.

High-quality pharmaceutical patents result from high-quality examination procedure. Thus, the most important policy option in respect of the quality of pharmaceutical patents is the choice to apply rigorous standards for the assessment of patentability requirements.<sup>89</sup> This requires a diligent and thorough search and examination process.<sup>90</sup>

The quality of the patent examination procedure, in turn, depends on a number of factors. First of all, a substantive examination system is a prerequisite. Obviously, patent offices that apply formal examination only do not check compliance with the patentability conditions let alone apply high standards to assess them.

Substantive examination requires a sufficient number of qualified patent examiners with solid background in pharmaceutical sciences besides being aware of the latest developments in the field.<sup>91</sup> The examiners need also to

<sup>79</sup> WIPO Secretariat, 'Study on Inventive Step' (SCP/22/3 WIPO Standing Committee on the Law of Patents, Twenty-Second Session, Geneva, July 2015) <[https://www.wipo.int/edocs/mdocs/scp/en/scp\\_22/scp\\_22\\_3.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_22/scp_22_3.pdf)> <[http://www.wipo.int/edocs/mdocs/scp/en/scp\\_12/scp\\_12\\_3\\_rev\\_2.pdf](http://www.wipo.int/edocs/mdocs/scp/en/scp_12/scp_12_3_rev_2.pdf)> accessed 3 April 2021.

<sup>80</sup> WIPO Secretariat, 'Further Study on Inventive Step (PART I)' (SCP/28/4 WIPO Standing Committee on the Law of Patents, Twenty-Eighth Session, Geneva, July 2018) <[https://www.wipo.int/edocs/mdocs/scp/en/scp\\_28/scp\\_28\\_4.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_28/scp_28_4.pdf)> <[http://www.wipo.int/edocs/mdocs/scp/en/scp\\_12/scp\\_12\\_3\\_rev\\_2.pdf](http://www.wipo.int/edocs/mdocs/scp/en/scp_12/scp_12_3_rev_2.pdf)> accessed 3 April 2021.

<sup>81</sup> WIPO Secretariat, 'Further Study on Inventive Step (PART II)' (SCP/29/4 WIPO Standing Committee on the Law of Patents, Twenty-Ninth Session, Geneva, December 2018) <[https://www.wipo.int/edocs/mdocs/scp/en/scp\\_29/scp\\_29\\_4.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_4.pdf)> <[http://www.wipo.int/edocs/mdocs/scp/en/scp\\_12/scp\\_12\\_3\\_rev\\_2.pdf](http://www.wipo.int/edocs/mdocs/scp/en/scp_12/scp_12_3_rev_2.pdf)> accessed 3 April 2021

<sup>82</sup> WIPO Secretariat, 'Further Study on Inventive Step (PART III)' (SCP/30/4, WIPO Standing Committee on the Law of Patents,

Thirtieth Session, Geneva, June 2019) <[https://www.wipo.int/edocs/mdocs/scp/en/scp\\_30/scp\\_30\\_4.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_4.pdf)> <[http://www.wipo.int/edocs/mdocs/scp/en/scp\\_12/scp\\_12\\_3\\_rev\\_2.pdf](http://www.wipo.int/edocs/mdocs/scp/en/scp_12/scp_12_3_rev_2.pdf)> accessed 3 April 2021.

<sup>83</sup> Correa, 'Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing' (n 3) 15-16.

<sup>84</sup> *ibid* 20-21.

<sup>85</sup> Chan Park, Achal Prabhala, Jonathan Berger, 'Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law' (UNDP 2013) 26.

<sup>86</sup> Correa, 'Beyond Patent Quality' (n 61).

<sup>87</sup> WHO, *Public Health, Innovation and Intellectual Property Rights* (n 75) 131.

<sup>88</sup> Correa, 'Ownership of knowledge' (n 17) 784.

<sup>89</sup> Correa, 'Tackling the Proliferation of Patents' (n 59) 3.

<sup>90</sup> *ibid*.

<sup>91</sup> WIPO Secretariat, 'Report on the International Patent System' (n 32) 53.

have a good understanding of the applicable law especially the provisions on patentability requirements.<sup>92</sup>

Another essential requirement for conducting the search is adequate access to a wide range of patent and non-patent databases.<sup>93</sup> It is important also to ensure that specialized and technology specific databases are available.<sup>94</sup> 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 general framework for conducting such procedure. Ideally, there would be a clear national patent policy with certain components addressing the interplay between pharmaceutical patents and areas of public interest.

The patent office would then formulate guidelines for the examination of pharmaceutical patents in light of the national policy and aiming to achieve its objectives. In this ideal situation, patent examination procedure would be conducted in a manner consistent with the guidelines that emanate from the national patent policy.

Adopting pharmaceutical patent examination guidelines is highly important. The guidelines ensure the quality and consistency of the examination procedure. Applying the patentability requirements in the pharmaceutical field involves several issues and cases that are specific to this particular field. Those issues should be dealt with in sufficient details and with practical examples. Therefore, it would be more convenient and preferable to address

such issues in the examination guidelines rather than the provisions of the national patent law.<sup>95</sup>

Recognizing the importance of examination guidelines, the World Health Organization (WHO) in cooperation with the International Centre for Trade and Sustainable Development (ICTSD) and the United Nations Conference on Trade and Development (UNCTAD) supported the development and publication of guidelines for the examination of pharmaceutical patents.<sup>96</sup> The aim was to help patent offices in developing their own guidelines by offering guidance on examination of multiple common categories of pharmaceutical patent claims.<sup>97</sup> As a later follow-up, the United Nations Development Program (UNDP) published guidelines for pharmaceutical patent examination taking into account the developments since the earlier guidelines.<sup>98</sup>

A number of countries have indeed adopted patent laws or policies that define a framework for examination of pharmaceutical patents taking public health implications into consideration. Argentina and India are good examples.<sup>99</sup> Patent offices in those countries conduct rigorous patent examination and apply strict standards to assess the patentability requirements of pharmaceutical patents. They are practically combating the phenomenon of proliferation of low-quality pharmaceutical patents.<sup>100</sup>

Without a clear patent policy or examination guidelines, there would be no guarantee of the quality of the examination procedure or the granted pharmaceutical patents. In absence of defined government policies, it would ultimately be the responsibility of patent offices or courts to develop and implement patent policies.<sup>101</sup> Since

<sup>92</sup> *ibid.*

<sup>93</sup> WIPO, *Guide to Technology Databases* (WIPO 2012) 4.

<sup>94</sup> *ibid.* 5.

<sup>95</sup> Carlos M Correa, *'Integrating Public Health Concerns into Patent Legislation in Developing Countries'* (South Center 2000) 51.

<sup>96</sup> Carlos M Correa, *'Guidelines for the examination of pharmaceutical patents: developing a public health perspective – A Working Paper'* (2007) ICTSD, WHO, UNCTAD <<http://apps.who.int/medicinedocs/en/d/Js21419en/>> accessed 19 January 2018.

<sup>97</sup> Velasquez, *'Guidelines on Patentability and Access to Medicines'* (n 9) 25.

<sup>98</sup> Carlos M Correa, *'Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective'* (UNDP 2016) 4.

<sup>99</sup> *ibid.* 11.

<sup>100</sup> Carlos M Correa, *'Patent Examination and Legal Fictions: How Rights are Created on Feet of Clay'* (2014) South Center Research Paper 58, 6 <[https://www.southcentre.int/wp-content/uploads/2014/12/RP58\\_Patent-Examination-Legal-Fictions-rev2\\_EN.pdf](https://www.southcentre.int/wp-content/uploads/2014/12/RP58_Patent-Examination-Legal-Fictions-rev2_EN.pdf)> accessed 18 May 2018.

<sup>101</sup> Carlos M Correa (Ed), *A Guide to Pharmaceutical Patents*, vol 1 (South Center 2008) xiv.

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.<sup>102</sup>

## 5. IP EDUCATION OF PATENT EXAMINERS AND THE QUALITY OF EXAMINATION 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.<sup>103</sup>

### 5.1 Importance of Legal Education of Patent Examiners

Pharmaceutical examiners have to understand the significance and implications of the quality of the search and examination work they perform and the patents they grant. They should realize their country's right to avail itself of the TRIPS pre-grant flexibility of defining and setting the standards for the patentability criteria. Patent examiners need to have a good grasp of the interpretation of the relevant legal provisions of their national law and the major international instruments, particularly the TRIPS Agreement.

The quality of patent examination can be seen in light of the examiner's ability to take the right decision whether to grant a patent in view of the applicable law and the appropriate standards for patentability requirements. In doing so, the examiner's decisions would be consistent with a court ruling that has involved a comprehensive review of the patent application<sup>104</sup> against law provisions

and their underlying purpose. Patent examiners should not only have sound knowledge and skill in the respective technical field but also knowledge of relevant court rulings and their legal bases.<sup>105</sup>

Based on the above, patent examiners need to receive continued IP education. An increasing number of patent offices are becoming aware of the importance of legally educating their examiners. However, the form, scope and framework of such education or training may differ.

Training activities provided to the EPO examiners include legal and practical expertise. On top of training on how the patentability criteria are applied in practice, they also attend courses on European and international patent law and practice.<sup>106</sup>

The patent branch of the Canadian Intellectual Property Office (CIPO) has created a patent examiner continuous training program.<sup>107</sup> IP related training is seen as the most important covering all the aspects that influence patent examination including jurisprudence. Training activities also cover patent law, appeal decisions and court cases.<sup>108</sup>

One proposal to improve the quality of granted patents from the United States Patents and Trademarks Office (USPTO) was to standardize patent examiners training and qualifications.<sup>109</sup> It is based on the premise that the quality of patent examination could be improved when the examiners are required to undergo both legal and technical training.<sup>110</sup> The proposal requires the examiners to pass the patent bar exam and complete a continuing legal education (CLE). This ensures that the examiner

<sup>102</sup> Velasquez, 'Guidelines on Patentability and Access to Medicines' (n 9) 7.

<sup>103</sup> Fatima Beattie, 'Sharing expertise to boost patent quality' (2013) 5 WIPO Magazine 27 <[http://www.wipo.int/export/sites/www/wipo\\_magazine/en/pdf/2013/wipo\\_pub\\_121\\_2013\\_05.pdf](http://www.wipo.int/export/sites/www/wipo_magazine/en/pdf/2013/wipo_pub_121_2013_05.pdf)> accessed 22 January 2018.

<sup>104</sup> John L King, 'Patent Examination Procedures and Patent Quality' in National Research Council; Wesley M Cohen, Stephen A Merrill (Ed), *Patents in the Knowledge-Based Economy* (The National Academies Press 2003) 56.

<sup>105</sup> *ibid.*

<sup>106</sup> EPO, 'Patent examiner training' <[https://jobs.epo.org/content/Training/?locale=en\\_GB](https://jobs.epo.org/content/Training/?locale=en_GB)> accessed 24 January 2018.

<sup>107</sup> Marc De Vleeschauwer, 'The Canadian Patent Examiner Continuous Training Program' (2014) 39 World Patent Information 73.

<sup>108</sup> *ibid.*

<sup>109</sup> H. Whei Hsueh, 'Standardizing Patent Examiner Training and Qualifications' (Berkeley Technology Law Journal, 11 April 2016) <<http://btli.org/2016/04/standardizing-patent-examiner-training-and-qualifications/>> accessed 19 April 2018.

<sup>110</sup> *ibid.*

understands how patent law provisions are applied and interpreted in a similar manner to patent agents.<sup>111</sup>

The National Center for Industrial Property Information and Training (INPIT) offers training for the Japanese Patent Office (JPO) examiners including highly specialized law courses.<sup>112</sup> IP education is offered to the Korean IP Office (KIPO) examiners including in-depth education on fundamental legislation and intensive training with case studies on patent law and patent litigation.<sup>113</sup>

The National Institute of Management (NIIPM) in India is in charge of examiners' training and education. Some programs aim to provide information on the latest global developments in IP.<sup>114</sup> In 2012, an extensive training program was designed for the newly appointed patent examiners where the topics included introduction to IP, and administrative and constitutional law.<sup>115</sup>

IP knowledge can effectively increase the capacity of patent examiners in understanding and applying the relevant law provisions. In absence of policy guidance or examination guidelines, it would be the examiners' responsibility to evaluate various law interpretations and patentability standards. This is critical for pharmaceutical patent examiners as public interest and socioeconomic considerations strongly influence the choice to adopt the most appropriate interpretations and standards.

## 5.2 The Egyptian Experience in IP Education of Pharmaceutical Patent Examiners<sup>116</sup>

EGPO applies a substantive examination system. A patent application should be examined to ascertain that it satisfies the three patentability criteria and fulfills the requirements of unity of invention and disclosure.<sup>117</sup>

In January 2005, EGPO commenced the examination of patent applications related to pharmaceutical products which were kept -since January 1995- in the 'Mail Box'.<sup>118</sup> There was only a few newly-hired pharmaceutical patent examiners with excellent background in pharmaceutical sciences but very little experience in patent examination. Pharmaceutical patent search and examination requires special skills and various resources which were not, at least adequately, available then. Some training programs were conducted, but they were not very specialized. In addition, access to field specific databases was limited.

Under such circumstances, the examiners had to rely, primarily, on the international search and preliminary examination reports issued by international authorities under the Patent Cooperation Treaty (PCT) system. It was therefore natural that patent examination reports prepared by the Egyptian examiners and issued by EGPO were highly influenced by those reports. In fact, the international reports had significantly contributed to the development and refinement of examination skills of the examiners. They contained rich technical arguments and information on the databases and search fields used.

Also, the pharmaceutical examiners often consulted EPO and USPTO websites to follow examination procedure and final decisions of the corresponding applications. As

<sup>111</sup> *ibid.*

<sup>112</sup> INPIT-JPO, 'Education' <<http://www.inpit.go.jp/english/educate/index.html>> accessed 24 January 2018.

<sup>113</sup> KIPO, 'IP Education of Government Officials' <[http://www.kipo.go.kr/kpo/user.tdf?a=user\\_english.html.html](http://www.kipo.go.kr/kpo/user.tdf?a=user_english.html.html)> accessed 24 January 2018.

<sup>114</sup> Rajiv Gandhi National Institute of Intellectual Property Management <<http://www.ipindia.nic.in/about-us-rg.htm>> accessed 14 June 2018.

<sup>115</sup> Prashant Reddy, 'CGPDTM announces impressive training syllabus for new patent examiners' Spicy IP, 5 January 2012 <<https://spicyip.com/2012/01/cgpdmt-announces-impressive-training.html>> accessed 24 January 2018.

<sup>116</sup> Interviews with the Pharmaceutical Patent Examination Department in EGPO (Cairo, Egypt, May 2018); Eman S Ibrahim,

'Inventive Step in Pharmaceutical Inventions and its Application Standard in Egypt' (Unpublished Advanced Studies Diploma Research Paper, Regional Institute of Intellectual Property, Faculty of Law, Helwan University, Egypt 2012).

<sup>117</sup> Egyptian Law 82 on the Protection of Intellectual Property Rights 2002, Art 16.

<sup>118</sup> Egypt has utilized the flexibility provided for in Art 65(4) of the TRIPS Agreement and postponed the examination of patent applications related to pharmaceutical chemical products filed starting from 1 January 1995. Those applications were kept at what was called "Mail Box". According to Art 43 of the Egyptian Law on Protection of Intellectual Property Rights 82 of 2002, patent applications related to pharmaceutical chemical products which were filed starting from 1 January 1995 were received and maintained pending their examination until 1 January 2005.

much as the Egyptian examiners were learning, their final decisions were also in line with the final decisions for the foreign corresponding applications. Consequently, most of the pharmaceutical patents in EGPO were granted with confidence that their counterparts had already been granted in major patent offices. This was the trend in the first few years after opening the 'Mail Box' in 2005.

As a result, many of the granted pharmaceutical patents covered very broad product claims, various physical forms and minor modifications of known compounds, and second medical uses.<sup>119</sup> The Egyptian examiners did not realize the impact of importing lax patentability standards from the developed world. They could not foresee the serious consequences on public health, medicine affordability and local pharmaceutical industry.

In November 2006, EGPO issued a "Manual of Procedures for Examiners of the Egyptian Patent Office" in accordance with the provisions of the Egyptian Law on the Protection of Intellectual Property Rights 82 of 2002 and the Implementing Regulations. As indicated in its introduction, this manual was largely based on the PCT International Search and Preliminary Examination Guidelines (effective March 2004).<sup>120</sup>

With time, the work in the pharmaceutical department began to take a different form. The number of examiners has increased. They started to accumulate experiences and access specialized databases. Various face-to-face and online courses were co-organized with WIPO and other patent offices. Instead of making individual decisions, the work became more collaborative. The continuous exchange of views and experiences has largely contributed to the consistency of the examination

process and issued reports which became more clear, precise and detailed.<sup>121</sup>

At that point, the examiners started to notice a certain pattern in pharmaceutical patent applications. Despite the ever-increasing numbers of the applications, only a small proportion thereof covered new chemical entities or significant advancements. The vast majority claimed different physical forms, formulations, combinations, methods of manufacture, or second uses of known drugs. They were based on common knowledge and widely used techniques in the pharmaceutical field.

However, the examiners' observations and discussions in this regard were limited. This was because of the lack of awareness of the implications of such a phenomenon let alone the need to take effective steps to deal with it. No policy guidance was available on how to deal with the mentioned cases of pharmaceutical patent claims. In addition, the manual of examination procedure did not deal specifically with any of those cases.

In October 2008, a number of the Egyptian pharmaceutical examiners participated in the workshop "Examination of Pharmaceutical Patent Applications: Developing a Public Health Perspective". The workshop was organized by UNDP and WHO for patent examiners and IP experts from African countries.<sup>122</sup> It involved multiple in-depth technical and legal discussions on the standards for applying patentability requirements, especially the inventive step, to various cases of pharmaceutical patent claims. The discussions also dealt with evergreening of pharmaceutical patents and its impact on medicines availability and affordability and local generic manufacturing in developing countries.<sup>123</sup>

<sup>119</sup> Tahir Amin, 'Granted Pharmaceutical Patents in Egypt Initiative for Medicines, Access and Knowledge (i-Mak) December 2011.

<sup>120</sup> EGPO, 'Manual of Procedures for Examiners of the Egyptian Patent Office' (November 2006).

<sup>121</sup> Interview with Ms Mona S. Farag, Former Head of Pharmaceutical Examination Department in EGPO (Cairo, Egypt, 27 May 2018).

<sup>122</sup> UNDP, WHO, 'Workshop on the Examination of Pharmaceutical Patents: Developing a Public Health Perspective'

Meeting Report, Cape Town - South Africa, 30-31 October 2008 <<http://www.undp.org/content/dam/aplaws/publication/en/publications/hiv-aids/meeting-report-from-undp-and-who-workshop-on-the-examination-of-pharmaceutical-patents-developing-a-public-health-perspective-/Patentability%20criteria%20meeting%20report%20Cape%20Town.pdf>> accessed 22 January 2018.

<sup>123</sup> *ibid.*

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.<sup>124</sup> 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.<sup>125</sup>

In April 2009, UNDP, WHO and ICTSD co-organized another workshop on the Examination of Pharmaceutical Patents from a Public Health Perspective for the benefit of examiners from patent offices in the Arab Region including EGPO.<sup>126</sup> The main objective was to discuss the appropriate guidelines for examining different types of pharmaceutical patent claims, concluding that such guidelines should ensure that public health concerns are considered while examining pharmaceutical patents.<sup>127</sup>

After the two workshops, the pharmaceutical examiners worked together towards a common understanding on the optimum standards for assessing the patentability requirements. As a matter of fact, the twin workshops were the tipping point for a radical improvement in the manner that pharmaceutical patent applications were examined in EGPO. The pharmaceutical examiners decided to adopt high patentability standards, especially regarding the assessment of inventive step. They drafted template paragraphs, covering various categories of pharmaceutical patents, which could be customized and included in patent examination reports.<sup>128</sup> EGPO

pharmaceutical department has informally adopted the Guidelines for Examination of Pharmaceutical Patents developed by WHO, UNCTAD and ICTSD.<sup>129</sup>

Examples of the adopted high standards for patentability criteria include: proper application of absolute novelty requirements and therefore not allowing selection inventions, and requiring a significant and unexpected / non-obvious degree of progress compared to prior art and common general knowledge to meet the inventive step criterion.<sup>130</sup>

Since then, the quality of pharmaceutical examination procedure and issued reports in EGPO has increased.<sup>131</sup> The decisions taken became independent of their foreign counterparts. Reports and decisions of other offices could be used only for general guidance. Only the inventions that involve a significant advancement would be allowed while conventional and trivial modifications would be rejected. The main goal was to ensure that only high-quality pharmaceutical patents are granted.

At this stage, it was clear for the pharmaceutical examiners how adopting the appropriate choice of the patentability standards would impact not only public health but also innovation and competition in the pharmaceutical field. Applying lower standards for assessing patentability could lead to a number of negative consequences. These include incentivizing minor rather than significant innovations resulting in the grant of unnecessarily high numbers of patents on secondary inventions that only block competition without a real innovative impact.<sup>132</sup>

Pharmaceutical companies would not be motivated to spend money, effort and time on developing new chemical entities and truly innovative improvements on existing ones when they could easily obtain secondary

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<sup>124</sup> *ibid.*

<sup>125</sup> Farag (n 121).

<sup>126</sup> UNDP, WHO, ICTSD, 'Examination of Pharmaceutical Patents from a Public Health Perspective' Meeting Report, Cairo - Egypt, 14-15 April 2009 <[https://www.iprsonline.org/ictsdialogues/2009-04-14/2009-04-14\\_desc.html](https://www.iprsonline.org/ictsdialogues/2009-04-14/2009-04-14_desc.html)> accessed 22 January 2018.

<sup>127</sup> *ibid.*

<sup>128</sup> EGPO and Ibrahim (n 116).

<sup>129</sup> Velasquez, 'Guidelines on Patentability and Access to Medicines' (n 9) 28.

<sup>130</sup> EGPO and Ibrahim (n 116).

<sup>131</sup> Farag (n 121).

<sup>132</sup> Hyewon Ahn, *Second Generation Patents in Pharmaceutical Innovation* (Nomos Verlagsgesellschaft MbH 2014) 185 -187.

patents. In other words, low patentability standards would hinder innovation in the pharmaceutical field.<sup>133</sup>

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.<sup>134</sup>

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.<sup>135</sup> 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.<sup>136</sup>

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

The Atazanavir and Sofosbuvir patent applications are great practical examples to demonstrate the significant improvement in the quality of patent examination and granted pharmaceutical patents in Egypt.

Atazanavir is an antiretroviral agent for treatment and prevention of HIV/AIDS. Although the base compound itself was not patented in Egypt, a patent was granted in January 2008 covering its bisulfate salt and a formulation thereof. This patent was a barrier for local production of the medicine in Egypt until its expiry in January 2019.<sup>137</sup>

In 2016, the International Treatment Preparedness Coalition ITPC-MENA requested that this patent be revoked for lack of novelty and inventive step. EGPO examiners issued a report confirming that the patent does not satisfy the patentability criteria.<sup>138</sup> Actually, if the application had been examined any time after mid-2009, it would be rejected by EGPO due to the application of rigorous patentability standards.

ITPC-MENA partnered with other NGOs to initiate court case procedure to revoke the patent in Egypt. However, in 2017 the patent owner announced the extension of its voluntary license on Atazanavir to 12 countries including Egypt. This would reduce the price and facilitate access in Egypt.<sup>139</sup> The Atazanavir patent required a lengthy and costly procedure to ameliorate its negative effects. A lot of money and effort could have been saved if the patent was not granted in the first instance.

Sofosbuvir is an antiviral medication for treatment of hepatitis C virus (HCV). Egypt has the highest prevalence of HCV infection in the world.<sup>140</sup> In 2014, the originator

<sup>133</sup> *ibid* 192.

<sup>134</sup> Interview with Professor Hossam El Saghir, Founder and Director of the Regional Institute of Intellectual Property, Helwan University (Cairo, Egypt, 30 May 2018).

<sup>135</sup> Interview with Mr Adel Oweida, Former Head of the EGPO (Cairo, Egypt, 30 May 2018).

<sup>136</sup> *ibid*.

<sup>137</sup> WHO, *The Role of Intellectual Property in Local Production in Developing Countries* (n 10) 10.

<sup>138</sup> Zakaria, 'A new victory for ITPC-MENA : Bristol-Myers Squibb extends its voluntary license on Atazanavir to Egypt' (International Treatment Preparedness Coalition ITPC-MENA, 25 July 2017) <<https://itpcmena.org/language/en/a-new-victory-for-itpc-mena-bristol-myers-squibb-extends-its-voluntary-license-on-atazanavir-to-egypt/>> accessed 1 February 2018.

<sup>139</sup> *ibid*.

<sup>140</sup> Fatma El Zanaty, Ann Way, 'Egypt Demographic and Health Survey 2008' Ministry of Health, El-Zanaty and Associates, and

company offered to supply the drug to Egypt at a price of US\$ 900 for a 12-week course of treatment which was only about 1% of the price in the United States.<sup>141</sup> In the same year, EGPO rejected a key product by process patent application on Sofosbuvir<sup>142</sup> as it did not meet EGPO strict standards of novelty and inventive step.

Rejecting this patent opened the door for several local companies to sell the drug in Egypt causing a significant price reduction.<sup>143</sup> A 28-day treatment has become available for about US\$ 51 enabling the treatment of hundreds of thousands of patients in Egypt.<sup>144</sup> Moreover, patients from other countries including developed countries are seeking treatment in Egypt.<sup>145</sup> A number of the corresponding granted patents were opposed in various developing and developed countries.<sup>146</sup>

The Atazanavir and Sofosbuvir patents were low-quality pharmaceutical patents. Neither complied with the patentability requirements if applied properly. They did not provide significant contributions over the prior art. However, they would hinder access to medicine and generic competition.

The difference between how the two patent applications were examined in EGPO was mainly due to the difference in the level of IP knowledge of the pharmaceutical patent examiners. IP education has indeed played a pivotal role in improving the quality of the examination procedure and subsequently the quality of the granted patents in the pharmaceutical field.

## 6. CONCLUSION AND A WAY FORWARD

Quality is a key pillar of a well-functioning patent system that is able to achieve positive socioeconomic outcomes. This is especially true in the pharmaceutical field. Patent offices might have different perceptions of patent quality but most of them at least agree that the quality of the examination procedure is a very important factor.

Establishing an efficient patent search and examination system requires substantial skills and resources. Many small limited capacity patent offices, including in Africa and the Arab region, seek technical assistance from larger patent offices which are usually of developed countries. The assistance takes various forms, most often; the provision of training and the sharing of search and examination products and examination manuals.

The advanced infrastructure and technical capabilities of major patent offices usually impress the offices seeking assistance. This builds trust in the quality of search and examination procedure and granted patents in the major offices.<sup>147</sup> It is common to see the examination process in small patent offices performed under the same standards applied in the major offices. Similar reports and final decisions are issued. Practically speaking, the smaller offices become followers of the leader major offices.

This leader-follower approach is problematic. It assumes the examination procedure and granted patents of the leader offices to be always of high quality while this is not necessarily the case. Large patent offices might have their

Macro International (2009) 251-252 <<https://dhsprogram.com/pubs/pdf/fr220/fr220.pdf>> accessed 17 June 2018.

<sup>141</sup> Maggie Fick, Ben Hirschler, 'Gilead offers Egypt new hepatitis C drug at 99 percent discount' (Reuters, 21 March 2014) <<https://www.reuters.com/article/us-hepatitis-egypt-gilead-sciences-idUSBREA2K1VF20140321>> accessed 17 June 2018.

<sup>142</sup> WHO, 'Patent Situation of Key Products for Treatment of Hepatitis C: Sofosbuvir' Working Paper, Updated and revised version June 2016 <[http://www.who.int/phi/implementation/ip\\_trade/sofosbuvir\\_report.pdf?ua=1](http://www.who.int/phi/implementation/ip_trade/sofosbuvir_report.pdf?ua=1)> accessed 1 February 2018.

<sup>143</sup> Germán Velásquez, 'Access to Hepatitis C Treatment: A Global Problem' (2017) South Center Research Paper 77, 23 <[https://www.southcentre.int/wp-content/uploads/2017/05/RP77\\_Access-to-Hepatitis-C-Treatment-A-Global-Problem\\_EN-2.pdf](https://www.southcentre.int/wp-content/uploads/2017/05/RP77_Access-to-Hepatitis-C-Treatment-A-Global-Problem_EN-2.pdf)> accessed 17 June 2018.

<sup>144</sup> WHO, 'Global Report on Access to Hepatitis C Treatment: Focus on Overcoming Barriers' (2016) <<http://www.who.int/iris/handle/10665/250625>> accessed 17 June 2018.

<sup>145</sup> Carmen Paun, 'Another Reason to Visit Egypt: Europe's High Drug Prices' (Politico, 26 April 2018) <<https://www.politico.eu/article/egyptian-holiday-scheme-cashes-in-on-europes-high-drug-prices/>> accessed 17 June 2018.

<sup>146</sup> Patent Opposition Database, 'Sofosbuvir' <<https://www.patentopposition.org/en/drugs/sofosbuvir>> accessed 17 June 2018.

<sup>147</sup> Peter Drahos, 'Trust me: Patent offices in developing countries' Working Paper (Centre for Governance of Knowledge and Development 2007) 17 <[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=102867](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=102867)> accessed 29 May 2018.



own patent quality issues.<sup>148</sup> In addition, there are many differences to be considered such as differences in relevant law provisions, public policies, local capacities, and socioeconomic situations. Importing patentability standards that are unfriendly to the prevailing national conditions must be avoided.<sup>149</sup>

Ensuring high-quality examination in the pharmaceutical field requires an appropriate policy framework and examination guidelines. When they are not available, the role of patent examiners becomes more crucial. They need to be well-equipped with IP knowledge to be able to bridge the policy gap. They should also understand the implications of applying either lax or strict patentability standards for the public interest in their own countries.

The Egyptian experience showed how IP education has significantly changed the attitude of the pharmaceutical examiners towards low-quality patents. It helped them realize that rigorous examination of pharmaceutical patents is the right choice to protect public health.<sup>150</sup> They were able to formulate and implement examination guidelines and enhance the quality of examination and the granted pharmaceutical patents in Egypt.

Many developing countries populations suffer from the negative effects of the increasing numbers of low-quality pharmaceutical patents. Therefore, patent offices in the developing world should follow the example of Egypt and consider IP education as a main component of their examiners' qualifications.

IP education is an effective way to prevent the grant of low-quality patents by improving the quality of the examination procedure. Even when search and examination products of other offices are used, IP

education would enable the examiners to adapt and customize them to suit the locally applied standards.

It would also be advantageous for small patent offices to partner with patent offices in countries having similar socioeconomic conditions and public policies. Particularly important in respect of pharmaceutical patents is the cooperation with offices that have adopted strict patentability standards such as those of Argentina, Egypt and India.<sup>151</sup> Cooperation activities may include training on examination practices and providing guidance on formulating examination guidelines.

IP education increases the capacity of patent examiners to protect public interest by defending against low-quality pharmaceutical patents.

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<sup>148</sup> See Kieren McCarthy, 'Patent quality has fallen, confirm Euro examiners' (The Register, 15 March 2018) <[https://www.theregister.co.uk/2018/03/15/patent\\_quality\\_has\\_fallen\\_confirm\\_euro\\_examiners/](https://www.theregister.co.uk/2018/03/15/patent_quality_has_fallen_confirm_euro_examiners/)> accessed 26 May 2018; Dugie Standeford, 'Despite Ongoing Efforts, USPTO Still Faces Patent Quality Issues' (Intellectual Property Watch, 19 June 2016) <<http://www.ip-watch.org/2016/09/16/despite-ongoing-efforts-uspto-still-faces-patent-quality-issues/>> accessed 26 May 2018.

<sup>149</sup> WHO, *The Role of Intellectual Property in Local Production in Developing Countries* (n 10) 11-12.

<sup>150</sup> Chloé Forette, 'Hepatitis C: Gilead Patent on Sofosbuvir Partially Maintained Following MDM Patent Opposition' (hepCoalition, 5 October 2016) <<http://hepcoalition.org/news/press-releases/article/hepatitis-c-gilead-patent-on-sofosbuvir-partially-maintained-following-mdm>> accessed 19 April 2018.

<sup>151</sup> Correa, 'Patent Examination and Legal Fictions' (n 100) 8.

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