A Model for Enhanced Pharmaceutical Intellectual Property Ecosystem Management in Egypt

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Abstract

This paper investigates the patent examination mechanism at the Egyptian Patent Office (EPO), highlighting its rigorous and effective methodology, particularly through a drug discovery case. This exploratory qualitative study utilized secondary sources and semi-directive interviews to understand the EPO's processes. The examination of a specific drug discovery application at the EPO led to its rejection. This rejection was crucial, as it allowed several local companies to manufacture and sell the drug in Egypt, resulting in a significant price reduction.

The affordability of this medication by local companies stems directly from the EPO's rigorous inventive step standard and the

application of adaptable internal policy guidelines. This stringent requirement ensures that patents are granted only for demonstrably novel technical advancements. This rigorous standard is upheld by the EPO's stringent patent examination process, which is characterized by the expertise and diligence of its patent examiners, their diverse skillset encompassing intellectual property law, pharmacy, and research.

These combined factors enabled the rejection of the initial patent application, thereby fostering generic competition and subsequently driving down drug prices. A notable consequence of the EPO's rejection was the subsequent challenging of the validity of a significant number of related patents in various patent offices across both developed and developing nations.

Beyond the robust examination process, this study highlights a critical challenge within the Egyptian patent system: the discrepancy between a generally sound patent examination process and a notably weak enforcement mechanism. Despite the EPO's strengths in examination, challenges such as slow court proceedings, a limited number of patent cases, a lack of

specialized judicial expertise in patent law, and insufficient awareness among patent holders hinder effective enforcement. This disconnect directly impacts the pharmaceutical sector, potentially deterring pharmaceutical R&D investment and affecting Egypt's attractiveness as a hub for drug innovation.

To address these issues, the paper proposes "A Model for Enhanced Pharmaceutical Intellectual Property (IP) Ecosystem Management in Egypt" that emphasizes the interconnectedness of patent examination, enforcement, harmonization with international standards, and the overall innovation ecosystem for the pharmaceutical sector. This model suggests Intellectual Property protection system management implications, including upgrading examiner qualifications, streamlining examination processes, enhancing knowledge access for examiners, and optimizing recruitment. For enforcement, it recommends improving interagency collaboration, streamlining legal procedures, raising public awareness, and fostering a culture of innovation. Furthermore, it advocates for active participation in

international projects and continuous alignment with global standards for harmonization.

This research underscores that a strong examination arm of a patent system is paramount for public health, preventing undue monopolies and fostering affordability. This study suggests a model that can be examined and applied for its impact on Egyptian IP ecosystem. This research paves the way for further investigation into the internal policies of other patent offices, fostering the exchange of best practices across the global intellectual property landscape. Future research may include different types of data, such as quantitative data, as well as other contexts beyond Egypt.

Keywords: *Ecosystem Management, Egypt, diligence, Examination, Intellectual Property, Inventive step, Patent.*

نموذج لإدارة معززة للنظام البيئي للملكية الفكرية الصيدلانية في مصر

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مستخلص

تتناول هذه الورقة آلية فحص براءات الاختراع في مكتب البراءات المصري، مسلطة الضوء على منهجيتها الصارمة والفعالة، لا سيما من خلال دراسة حالة في اكتشاف الأدوية. استخدمت هذه الدراسة الاستكشافية النوعية مصادر ثانوية ومقابلات شبه موجهة لفهم عمليات مكتب البراءات المصري. أدى فحص طلب إختراع دواء محدد في مكتب البراءات المصري إلى رفضه. كان لهذا الرفض تبعات هامة وعالية التأثير ، حيث سمح للعديد من الشركات المحلية بتصنيع وبيع الدواء في مصر، مما أدي إلي إتاحته بوفرة وبالتالي توفير العلاج لأعداد كبيرة من المرضي في مصر والمنطقة ومكافحة المرض بشكل فعال.

إن القدرة على تحمل تكلفة هذا الدواء من قبل الشركات المحلية تنبع مباشرة من تطبيق معيار الخطوة الابتكارية الصارم لمكتب البراءات المصري وتطبيق المبادئ التوجيهية المرنة للسياسة الداخلية. ويضمن هذا المتطلب الصارم منح براءات الاختراع فقط للابتكارات التقنية التي يمكن إثبات حداثتها. ويتم دعم هذا المعيار

الصارم من خلال عملية الفحص الدقيقة لطلبات براءات الاختراع في مكتب البراءات المصري، وتتميز عملية الفحص الدقيق هذه بخبرة واجتهاد فاحصي البراءات، ومهاراتهم المتنوعة التي تشمل قانون الملكية الفكرية، والصيدلة، والبحث.

مكّنت هذه العوامل مجتمعة من رفض طلب البراءة الأولي، مما عزز المنافسة في الأدوية الجنيسة وبالتالي خفض أسعار الأدوية. وكانت إحدى النتائج الملحوظة لرفض مكتب البراءات المصري هي الطعن اللاحق في صلاحية عدد كبير من البراءات ذات الصلة في مكاتب براءات اختراع مختلفة في كل من الدول المتقدمة والنامية.

بالإضافة إلى عملية الفحص القوية، تسلط هذه الدراسة الضوء على تحدٍ حاسم داخل نظام البراءات المصري: التناقض بين عملية فحص براءات اختراع سليمة بشكل عام وآلية إنفاذ ضعيفة بشكل ملحوظ. على الرغم من نقاط القوة في مكتب البراءات المصري في الفحص، فإن تحديات مثل بطء إجراءات المحاكم، والعدد المحدود من قضايا البراءات، ونقص الخبرة القضائية المتخصصة في قانون البراءات، وعدم كفاية الوعي بين أصحاب البراءات تعيق الإنفاذ الفعال. يؤثر هذا الانفصال بشكل مباشر على قطاع الأدوية، مما قد يثني الاستثمار في البحث والتطوير الصيدلاني ويؤثر على جاذبية مصر كمركز للابتكار الدوائي.

لمعالجة هذه القضايا، تقترح الورقة "نموذجاً لإدارة معززة للنظام البيئي للملكية الفكرية الصيدلانية في مصر" يؤكد على الترابط بين فحص البراءات، والإنفاذ، والتنسيق مع المعايير الدولية، والنظام البيئي العام للابتكار في قطاع الأدوية. يقترح هذا النموذج تداعيات لإدارة نظام حماية الملكية الفكرية، بما في ذلك رفع مؤهلات

الفاحصين، وتبسيط عمليات الفحص، وتعزيز الوصول إلى المعرفة للفاحصين، وتحسين التوظيف.

وبالنسبة للإنفاذ، يوصي البحث الحالي بتحسين التعاون بين الوكالات، وتبسيط الإجراءات القانونية، وزيادة الوعي العام، وتعزيز ثقافة الابتكار. علاوة على ذلك، يدعو البحث إلى المشاركة النشطة في المشاريع الدولية والمواءمة المستمرة مع المعايير العالمية للتنسيق.

تؤكد هذه الدراسة أن الذراع القوية لفحص البراءات في أي نظام براءات أمر بالغ الأهمية للصحة العامة، حيث يمنع الاحتكارات غير المبررة ويعزز القدرة على تحمل التكاليف. وتقترح هذه الدراسة نموذجًا يمكن فحصه وتطبيقه لتأثيره على النظام البيئي للملكية الفكرية المصري. ويمهد البحث أيضا الطريق لمزيد من المراجعة والتحقيق في السياسات الداخلية لمكاتب البراءات الأخرى، مما يعزز تبادل أفضل الممارسات عبر نطاق الملكية الفكرية العالمي. وتوصي هذه الورقة العلمية أن يشمل البحث المستقبلي أنواعًا مختلفة من البيانات، مثل البيانات الكمية، بالإضافة إلى سياقات أخرى تتجاوز مصر.

الكلمات المفتاحية: إدارة النظام البيئي، مصر، الاجتهاد، الفحص، الملكية الفكرية، الخطوة الابتكارية، براءة الاختراع.

1. Introduction

The hepatitis C virus (HCV) has emerged as a major global public health concern since its discovery in 1989, leading to

significant advancements in treatment, including the development of direct-acting antivirals such as sofosbuvir. Sofosbuvir, a breakthrough drug approved by the FDA in 2013, revolutionized HCV therapy due to its high efficacy and tolerability. However, the pharmaceutical patent landscape surrounding sofosbuvir, particularly in developing countries like Egypt, raises critical questions about patent examination mechanisms and their impact on public health access. While patents play a crucial role in incentivizing innovation, concerns persist regarding the quality of patent examination, particularly in relation to incremental pharmaceutical patents that may extend monopolies and hinder generic competition.

This study aims to analyze key factors affecting examination outcomes and their broader impact on Egypt's intellectual property framework and pharmaceutical innovation landscape. It specifically addresses the disconnect between examination standards and enforcement practices, proposing a management model to strengthen Egypt's pharmaceutical IP ecosystem. The central research question guiding this study is: *How do patent*

examiner characteristics and internal policies at the Egyptian Patent Office influence the quality of patent examination outcomes and what are the implications for strengthening Egypt's intellectual property protection system?

2. Literature review

2.1. Sofosbuvir for the treatment of hepatitis C virus infection

Despite being discovered for the first time in 1989 (Choo et al., 1989), the hepatitis C virus (HCV) has only recently come to light as a significant public health concern and cause of illness (Tan et al.,2002). Over the past ten years, oral antivirals that block HCV non-structural viral proteins crucial in viral replication have been made available as well-tolerated and effective therapies that have allowed all infected people to recover (Pol & Lagaye, 2019).

According to Lawitz et al. (2015), HCV can be treated with a limited course of therapy, unlike HIV and other persistent viral illnesses. Michael Sofia, the drug's primary inventor, headed a group at Pharmasset, Inc. that made the discovery of sofosbuvir

in 2007. The chemical, formerly known as PSI-7977 and renamed GS-7977 following Gilead Sciences' acquisition of Pharmasset at the end of 2011, was granted permission by the USAN Council in May 2012 for the non-proprietary name "sofosbuvir." The U.S. Food and Drug Administration (FDA) authorized sofosbuvir in October 2013 for the treatment of chronic HCV infection based on these results. Patients with genotype 1 or 4 HCV were advised to take sofosbuvir plus peginterferon-ribavirin for 12 weeks, patients with genotype 2 HCV were advised to take sofosbuvir plus ribavirin for 12 weeks, and patients with genotype 3 HCV were advised to take sofosbuvir plus ribavirin for 24 weeks. Patients with genotype 1 HCV who are not eligible for interferon should take sofosbuvir + ribavirin for 24 weeks. All dosage guidelines applied to individuals who were also infected with HIV-1.

2.2. Requirements for pharmaceutical patentability

In an era where knowledge assets constitute a primary driver of national economic prosperity, the patent system has established itself as a crucial catalyst for technological advancement and

subsequent economic dynamism. The patent system is studied as an effective policy tool for encouraging innovation (Hou et al., 2022). According to WIPO, Patent is defined as an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem. To secure a patent filing, technical information about the invention must be disclosed to the public in a patent application[1]. A patentable invention must claim a subject matter that is statutorily patentable in the United States, be novel and non-obvious over prior art, and be useful, demonstrating a particular, significant, and credible utility in order to be patentable[2]. In order to ascertain if the invention satisfies the legislative requirements for patentability—namely, novelty, inventive step, and industrial applicability or non-obviousness—a substantive examination is often conducted (Waziri & Gwom, 2021). Whalen (2018) pointed out that, in comparison to their more straightforward peers, patent office examination of applications for inventions

[1] www.wipo.int
[2] https://www.uspto.gov/web/offices/pac/mpep/mpep-9015-appx-l.html#d0e302376

that cross technical boundaries is more time-consuming and involves more back-and-forth.

Thus, a pharmaceutical invention is patentable if it meets the above criteria. Patents for pharmaceutical inventions have been granted in a substantial quantity. The unique place that pharmaceuticals occupy in the market highlights how crucial patent protection is to this industry. A patent is a temporary territorial monopoly right that lasts for a certain amount of time, usually 20 years from the date of filing (Dyer et al.,2023). The original business, which makes significant investments in the invention, elaboration, and development of a new treatment, is the only player on the market until the initial (basic) patent expires, according to the traditional principles of the pharmaceutical industry.

Article 65.2 of the TRIPS[3] agreement states that Egypt and other "developing" nations were exempted from applying the majority of the agreement's requirements until January 1, 2000. To update the 1949 legislation and make sure Egyptian regulations

[3] https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm#:~:text=The%20TRIPS%20Agreement%20is%20a,own%20legal%20system%20and%20practice.

complied with WTO (World Trade Organizations) requirements, a new law (law n° 82)[4] was issued in 2002 regarding the protection of intellectual property rights. Numerous TRIPS agreement flexibilities that are applicable to the public health sector are included.

According to Mándi (2003), within the pharmaceutical sector, patents are extremely important. This industry segment is heavily focused on research. However, the great majority of patents in the pharmaceutical industry relate to novel chemical compounds, formulations, or processes that contain specific chemical constituents.

The types of pharmaceutical patents are as follows: the term "basic patent" refers to the initial patent that was granted following the production and evaluation of the novel active ingredient. "Chemical process patents" receives less attention. What matters most is that the facilities needed to create the novel chemical compound in an amount large enough to support biological testing be made available to a person with the

[4] https://www.fao.org/faolex/results/details/en/c/LEX-FAOC123429/#:~:text=This%20Law%20sets%20forth%20the,undisclosed%20information%20(Book%201).

necessary skills. Industrial scale production of a medication becomes crucial when it hits the market, thus the person who invented it gets to patent all further chemical processes that work for the aforementioned use. Chemical process patents have a delayed expiration date since they are filed several years after the original invention. It frequently happens that the method described and claimed in the basic patent is inappropriate for production on an industrial scale. Regarding "formulation patents", a general overview of the potential methods of administering the novel chemical compounds may be found in the basic patents. Along with certain standard forms of carriers, auxiliary agents, and excipients, conventional methods of administration (oral, rectal, parenteral, etc.) and typical pharmaceutical composition forms (e.g., tablets, capsules, solutions, suspensions, suppositories, injections, etc.) are described. Pharmacopoeias place ever-tougher restrictions on a medication's storability, stability, maximum permitted amount of contamination, and other factors once it is placed on the market. Additionally, new and more advanced dosage formulations are

needed to meet therapeutic needs and commercial considerations. Some more modern formulations are patented later and operate as a barrier to generic competition for a longer period of time, although typical immediate-release tablets or capsules are usually free to be made or marketed after the fundamental patent expires.

The main benefit of these formulation patents is that they can be effectively enforced. These kinds of patents are often distinguished by the inclusion of specific components. Since the generic medication's composition cannot be kept a secret, the formulation patent owner may readily compare the purportedly infringing medication with the patent claims.

When it comes to medications that are essential for maintaining public health, the issues surrounding the patenting of small incremental advancements have particular ramifications. Patents on pharmaceutical products and processes may be used to prevent generic competition from lowering costs and improving access to medications, especially for the underprivileged. This might be the case even in situations when a drug's initial patent has expired, and it is now in the public domain. Patents on well-known compounds

(such as novel doses, formulations, crystal forms, etc.) are frequently deliberately employed to keep rivals out of the market. In other words, pharmaceutical patents can be used to block generic competition. Generic companies usually charge lower prices and thus facilitate access to medicines (Correa, 2011).

According to Velásquez (2017), based on a study by WHO[5], there are 21 different types of patents covering Sofosbuvir. These include two Markush type patents, which have the potential to lead to dozens more, four process patents, nine patents on salts and polymorphs, one patent on the combination of two products, and three patents on the method of usage (i.e., "substance for the HCV treatment"). Patents including a "Markush" claim: very broad claims covering chemical structures that may include a family of thousands or millions of compounds. pharmaceutical patents protect new salts of known active ingredients. Salts are normally formed to increase stability or solubility of the drug.

[5] WHO, Patent situation of key products for treatment of hepatitis C: Sofosbuvir, Geneva, March 2015. https://cdn.who.int/media/docs/default-source/essential-medicines/intellectual-property/sofosbuvir-report.pdf?sfvrsn=5a6c06ea_2

2.3. The patent examination process

According to Schmitt et al. (2023), examining the most relevant previous art for an invention is a laborious manual process that contributes significantly to the analysis of the conditions for patentability. The identification process and the associated extensive patent search are mostly based on traditional techniques, including searches using keywords, citations, or patent classifications (Foglia, 2007; Tseng & Wu, 2008). In addition, it takes time to analyze and compare an invention described in a patent application with related patents in the prior art (Lemley & Sampat, 2012; Marco et al.,2017). This is because patent claims need to be examined with respect to their subject matter and scope of protection. Following filing, an examiner at the patent office looks up previous applications to compare the filed application with its prior art and determines if the invention's claims meet the legal criteria (Lupu et al., 2017; Choudhury et al.,2020). As a result, the ever-growing volume of patent applications influences examination prosecution, and the specific patent examiner has a significant impact on the analysis

conducted by the patent office (Lemley & Sampat, 2012; Righi & Simcoe, 2019; Cockburn et al.,2002).

3. Research Gap

According to Cockburn et al., (2002), In fact, scholars have only just started to build a methodical knowledge of the variations in intellectual property laws between nations and throughout time (Lerner, 2000). Furthermore, there are no published studies of the empirical determinants of patent examiner productivity or of the relationships between the traits of examiners and the performance of the patent rights they issue, with the exception of some preliminary aggregate statistics (Griliches, 1984; 1990).

Although the majority of research on the macro and micro aspects of the examination period—including technical and non-technical characteristics, examiners and applicants—has greatly advanced our knowledge of the trends guiding the patent examination process and system operation, there is still a dearth of studies from the standpoint of policy institutions (Nikzad, 2011; Yang et al. (2024).

According to Dyer et al. (2024), some legal experts contend that "the extent to which patent documents successfully teach the inner workings of cutting-edge technologies is quite limited" (Devlin, 2009), in accordance with Hall and Harhoff (2012). They contend that inventors avoid reading patent disclosures to avoid accusations of wilful infringement (Lemley, 2012), that patent draftees purposefully omit information and create opaque and nonspecific disclosures to avoid disclosing proprietary information (Roin, 2005; Fromer, 2008), and that patent disclosures are frequently "unreadable" (Seymore, 2009). There is currently no research examining the impact of patent examiners on patent disclosure quality or the impact of disclosure quality on future innovation, despite concerns about the quality of patent disclosure in practice and the importance of the disclosure obligation to the patent system's design.

3.1. Research Problem

Despite growing recognition of the critical role patent office’s play in fostering innovation and public access to essential goods, a significant void persists in understanding the empirical

determinants of patent examiner productivity and the impact of examiner characteristics on the quality of issued patent rights. Existing research has largely focused on macro and micro aspects of the examination process, overlooking the crucial perspective of policy institutions and the managerial implications of patent disclosure quality. Concerns about opaque and unreadable patent disclosures, which hinder knowledge dissemination and innovation, remain unaddressed by studies examining the influence of patent examiners on disclosure quality or the subsequent impact of disclosure quality on future innovation. The current study directly addresses this gap by providing an in-depth, qualitative examination of the Egyptian Patent Office's (EPO) examination mechanism, specifically through the lens of a drug discovery case.

This leads to the following research question: *How do patent examiner characteristics and internal policies at the Egyptian Patent Office influence the quality of patent examination outcomes and what are the implications for strengthening Egypt's intellectual property protection system?*

3.2. Research Objective

The primary research objective is to qualitatively describe and analyze the patent examination mechanism at the Egyptian Patent Office (EPO). This study investigates the factors influencing patent examination outcomes, particularly in pharmaceutical cases, and assesses their broader implications for Egypt's intellectual property protection system and pharmaceutical innovation ecosystem. Specifically, it identifies systemic gaps between examination standards and enforcement mechanisms, proposing actionable recommendations through a model to enhance Egypt's pharmaceutical IP ecosystem management.

4. Research Methodology

Utilizing a qualitative approach, this paper examines the Egyptian Patent Office's (EPO) examination of Sofosbuvir, an antiviral medication used in the treatment of Hepatitis C Virus (HCV).

This exploratory research paper is based on in- depth interviews for collecting detail information from the Egyptian Patent Office (EPO) on how examiners worked on the patent application of Sofosbuvir. According to Hannabuss (1996), Wright

(1996), Maxwell (2005) and Sekaran (2007) the in- depth interview is an effective tool in order to get a rich understanding of a new phenomenon, such as examining the impact of patent examiners on patent disclosure quality based on the case of Sofosbuvir in the EPO.

To investigate the efficacy of patent examination at the Egyptian Patent Office, particularly in the case of Sofosbuvir, the authors conducted Six in depth semi-structured interviews with various experts in the field (see Table 1). The interview guide was divided into two primary sections. The first section consisted of open-ended questions centered on the patent examination process, with a specific focus on the Sofosbuvir case. The second section targeted industry experts and Science, Technology and Innovation stakeholders, addressing broader issues related to the Egyptian patent system.

The authors used a purposeful sampling technique in which participants were selected to provide in-depth and detailed information about the phenomenon under investigation (Bhardwaj, 2019). The authors convened a sample comprising

patent examiners with direct experience in the Sofosbuvir file at the Egyptian Patent Office, pharmaceutical industry experts, and specialists in Science, Technology, and Innovation policies to conduct an in-depth analysis of the present case study. All interviews were recorded in order to extract some verbatims. They were also translated from Arabic into English in order to carry out the coding and analysis of the data.

Table 1 - Journal of interviewees

Name	Position
Dr. Mona Yehia	**She was the Head of the Egyptian Patent Office, and currently Vice President of the Egyptian Intellectual Property Authority (EGIPA)**
Dr. Eman Ibrahim	**Senior patent examiner, technical examination at the Egyptian Patent Office**
Dr. Menatalla El Kotamy	**Senior Pharmaceutical Patent Examiner at Egyptian Patent Office. She is currently Executive Secretary to the Chairman at EGIPA**
Dr. Alaa Eldin Adris	**Professor at the Graduate School of Management of Technology at Nile University and Advisory Board Member of Science Technology Innovation (STI) Policy Research Hub.**
Dr. Amr Radwan	**Head of the Research & Innovation Management Department at the Egyptian Academy of Scientific Research & Technology (ASRT)**
Dr. Magdy Elba	**Chairman and CEO, APEX pharma**

The researchers chose to analyze the content manually. As Bardin (1997) explains, content analysis involves a careful

interpretation that balances objective rigor with subjective insight. They began by noting key concepts directly within the interview transcripts. Similar concepts were then grouped together into categories (see Table 2). To support their findings, the authors also included specific examples from the original interviews.

Table 2. Concept Categorization

Categories	concept
IP assessment	Examination, Rigorous, expert, inventive, novelty, patentably assessment, prior art, policy
Pharmaceutical industry	Monopoly, innovation, culture, generic companies, public health
Patent system	Lack, enforcement, harmonization, standards, awareness, court

5. Results and Discussion

5.1. Key Considerations in the Sofosbuvir Patent Examination at the Egyptian Patent Office

In 2014, an originator company sought patent protection for a key Sofosbuvir-related product through the Egyptian Patent Office. Complying with established procedures, they submitted the complete application package to the designated reception desk within the Intellectual Property unit of the Academy of

Scientific Research & Technology (ASRT). After undergoing a preliminary legal review, the application was forwarded to the patent technical examiners for a more in-depth evaluation. Notably, the examiners' team comprises an examiner, a reviewer, and the head of the technical department. This figure shows The Egyptian Patent Office Pharmaceutical Patent Examination Section. The pharmaceutical examination department is the largest within the Egyptian Patent Office.

Based on the analysis of interviews, the patent examination at the Egyptian Patent Office is conducted based on specialization and

the number of experts. Pharmacy is the largest department. The director assigns cases randomly. The process involves legal formalities, administrative procedures, and financial fees. The core of the examination is technical, focusing on reading and searching for keywords, synonyms, chemical structures in various databases, including Egyptian and international ones like PatentScope and Sciencedirect. Patent examiners play a pivotal role in ensuring the quality and consistency of patent decisions. They must have a deep understanding of the subject matter, be able to conduct thorough prior art searches, and apply the relevant legal criteria.

Dr. Mona Yehia, Head of the Egyptian Patent Office, indicated "The Egyptian Patent Office has a rigorous internal quality control process that includes review by examiners, reviewers, internal quality teams, and quality assurance…. This multi-tiered approach aims to ensure the accuracy and consistency of patent examination decisions"

Examiners determined that the molecule lacked novelty based on prior art. They argued that the claimed invention was not

inventive due to the fluorine difference, which made synthesis impractical despite the company's disclosure. The patent application was initially rejected by the examiners. Despite an appeal to the appeals committee, the rejection was upheld. The Egyptian Patent Office ultimately denied the patent, citing the applicant's failure to meet the required standards of novelty and inventive step.

The patent office played a crucial role in promoting generic competition by ensuring that patents are granted only to inventions that are truly novel and involve clear inventive step(s). This helps to prevent anti-competitive practices and encourages the development of affordable generic alternatives.

Dr. Menatalla El Kotamy, Senior Pharmaceutical Patent Examiner at Egyptian Patent Office and she was involved in the examination process of Sofosbuvir, highlighted *"The examination of pharmaceutical patents can be particularly challenging due to the complex nature of the technology involved and the potential impact on public health…. In the case of Sofosbuvir…after the rejection of the Patent,*

negotiations with the Ministry of Health were necessary to ensure an affordable rate for the drug"

Initially, the originator company offered to supply the drug to Egypt at a heavily discounted price of US$900 for a 12-week course. However, the rejection of the patent paved the way for local companies to enter the market, leading to a dramatic price drop. A 28-day treatment became available for as little as US$51, making treatment accessible to hundreds of thousands of Egyptian patients. This price reduction even attracted patients from developed countries seeking more affordable options. The success of this case has prompted challenges to corresponding patents in various countries worldwide. Generic drug manufacturers, such as Pharco and Mercyrl, significantly reduced the price of Sovaldi in Egypt. A new pricing structure was established through the collaborative efforts of the Ministry of Health, the National Committee for the Control of Viral Hepatitis, the Egyptian Patent Office, and the local generic industry. Within a year, the price of a Sovaldi box plummeted from thousands of dollars to less than 2700 Egyptian pounds. The

drug committee further decreased the price to under 900 pounds, well below the global average.

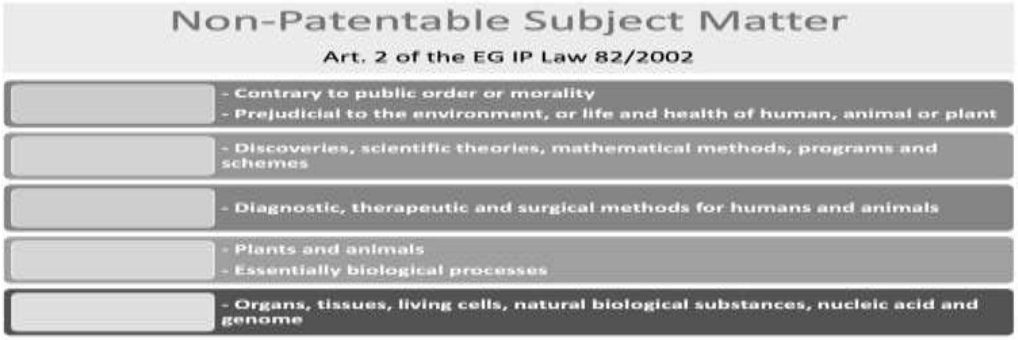
In light of the interview data, the Egyptian Patent Office employs a two-pronged approach to assessing patent applications: novelty and inventiveness. Novelty is determined through rigorous prior art searches, focusing on documents published before the filing date that exhibit identical features. Inventiveness, on the other hand, is evaluated using a less defined framework. The office generally considers a combination of known elements as inventive if it results in a non-obvious outcome. A significant leap, such as stabilizing an unstable compound, is typically viewed as indicative of inventiveness.

Key points emerging from the analysis include the absence of a concrete definition for inventive step, the reliance on a combination approach to assess non-obviousness, and the recognition that simple modifications are often considered obvious improvements. While significant advancements are valued, the assessment process heavily relies on the expertise of patent examiners.

The lack of a clear definition for inventive step introduces subjectivity into the evaluation process. Consequently, patent applications are often assessed on a case-by-case basis, making it challenging to provide consistent and justifiable decisions, especially when dealing with complex technical matters.

According to Article 2(3) of Egyptian law, patents cannot be granted for specific subject matter, including diagnostic, therapeutic, or surgical methods, as well as plants, animals, and genetic material. Article 1 stipulates the core patentability criteria of novelty, inventive step, and industrial applicability. While the law outlines these requirements, it offers limited guidance on determining inventive step.

To address this gap, the pharmaceutical examination department within the Egyptian Patent Office has developed internal policy. However, the ultimate decision regarding inventive step rests with individual examiners, underscoring the role of expert judgment in the evaluation process.



"Any modification, improvement, or addition to a previously patented invention, which meets the criteria of being new, inventive, and industrially applicable" (art. 1) is eligible for a patent, according to the legislation. When it comes to pharmaceuticals, this could involve, for example, developing a novel and creative production method that enhances an existing product or altering a chemical component to alter the way the product functions. Patents on new posologies, combinations, or pharmaceutical compositions, as well as patents on second uses of known goods are not issued in Egypt due to the exclusion of therapeutic procedures and discoveries from article 2(3) and 2(2), respectively.

Dr. Eman Ibrahim, senior patent examiner, technical examination at the Egyptian Patent office, who worked with the team in the

examination of this drug discovery explained this internal policy. According to the internal policy of examiners, minor changes to known compounds or to chemical entities are not patentable, for lack of inventive step and/or because modifications are well known and expected by any person working in the field. This includes crystalline forms, salts, solvates, diasteriomers, enantiomers, minor changes in the chemical structure that changes drug solubility and bio-availability, etc. New dosage forms of known products are also considered not patentable – unless the technique is new and the new form is an inventive way to solve a problem existing with the previous form.

This table (Table 3) presents the Key Considerations in the Sofosbuvir Patent Examination at the Egyptian Patent Office

Key elements	
Rigorous examination process	The Egyptian Patent Office employs a detailed examination process, including thorough literature searches and technical assessments.
Focus on novelty and inventive step	The examiners pay close attention to the novelty and inventive step of the claimed invention.
Internal Policy	The Egyptian Patent Office's pharmaceutical examination department has established an internal policy deeming minor modifications to known compounds unpatentable due to a lack of inventive step.
Challenges in assessing novel molecules	The case highlighted the challenges in assessing the novelty and inventiveness of molecules that are difficult to synthesize
Successful patent rejection	The examiners were able to successfully reject a patent based on their

	findings.
Impact on public health	**The examination process played a crucial role in reducing the cost of generic drugs, benefiting the public.**

According to Kesan and Wang (2020), an inventive concept can be shown when there are additional elements that add limitations that go beyond what is already well-understood, routine, or conventional in the field. Simply adding elements that are already common practice in the industry at a high level is not enough to create an inventive concept.

5.2. Egypt's Patent System: Driving Down Drug Costs, Curing a Nation

Rejecting this patent opened the door for several local companies to manufacture and sell the drug in Egypt causing a significant price reduction. The affordability of the medication by local companies can be attributed to the rigorous patent examination process employed by the Egyptian Patent Office. This process is characterized by the expertise and the level of diligence of the patent examiners, their diverse skillset (encompassing expertise in intellectual property law, pharmacy, and research) and the implementation of adaptable internal policy guidelines. These factors facilitated the rejection of the initial patent application,

thereby enabling generic competition and subsequently leading to lower drug prices. In addition, the validity of a significant portion of the granted patents was contested in patent offices throughout both developed and developing nations.

According to WHO report[6], in little more than ten years, Egypt has successfully made the shift from having one of the highest rates of hepatitis C in the world to one of the lowest, with the prevalence falling from 10% to 0.38%. Starting in 2014 and reinforced in 2018, the President of Egypt launched a nationwide program to eradicate hepatitis C by providing free hepatitis C testing and treatment. More than 60 million people were tested and more than 4.1 million people received treatment as a result of the "100 million seha" (100 million healthy lives) initiative. 99% of those who underwent treatment for hepatitis C were cured, a remarkable success rate made possible in large part by locally produced direct-acting antiviral medications.

[6] https://www.emro.who.int/media/news/egypt-becomes-the-first-country-to-achieve-who-validation-on-the-path-to-elimination-of-hepatitis-c.html#:~:text=Egypt%20has%20successfully%20transitioned%20from,in%20just%20over%20a%20decade.

5.3.Key considerations for the Egyptian Pharmaceutical Industry

Based on the interviews with industry experts and Science, Technology and Innovation (STI) stakeholders, the study reveals a complex interplay of factors influencing the Egyptian pharmaceutical industry. While the global monopoly on medicine poses significant challenges, the role of generic companies and the potential for intervention in patent cases offer opportunities for Egypt to address these issues.

The pharmaceutical industry is dominated by a few developed countries, creating a global monopoly that limits developing countries', including Egypt's, ability to innovate and develop its own drug market. According to the interviewees, this monopoly is often attributed to political factors rather than technological or intellectual limitations. Egypt faces several challenges in the pharmaceutical industry, including:

- **Global monopolies:** The dominance of a few countries in the pharmaceutical sector restricts Egypt's ability to innovate and develop its own drug market.

- **Patent restrictions:** Patent laws can create barriers to entry for generic companies and drive-up drug prices.
- **Multinational company influence:** Multinational companies often exert significant influence over the pharmaceutical industry, shaping policies and practices.

Despite these challenges, Egypt has opportunities to address these issues. For example, the country's ability to intervene in patent cases, as demonstrated with the hepatitis C drug, suggests that it can play a role in challenging monopolies and promoting access to affordable medications.

Dr. Magdy Elba, CEO APEX highlights: "*For generic companies…. These companies have been instrumental in helping Egyptians access affordable healthcare over the past 60 years, particularly as drug prices have risen. Even today, it continues to play a vital role in maintaining market balance, ensuring that a significant portion of the population can receive necessary medications »*

The role of generic companies in providing affordable medications to Egyptians highlights the potential benefits of

alternative approaches to drug development and distribution. While patents can be used to protect intellectual property and incentivize innovation, they can also create monopolies and hinder access to affordable medicines.

According to Dai & Watal (2021), when there's a lot of competition among drug companies, both those that make original medicines and those that make generic versions, it can lower the prices of all drugs. This means that having many different generic companies selling the same drug is important for making medicines more affordable.

5.4. Proposed Model for Enhanced Pharmaceutical Intellectual Property Ecosystem Management in Egypt

Patents are indeed crucial for protecting intellectual property and fostering innovation, particularly within the pharmaceutical industry. They incentivize the substantial investment required for drug discovery and development. However, this study, with its specific focus on the Egyptian patent system and the pharmaceutical sector, highlights that a patent system's theoretical benefits are only realized if its practical application is

robust. Our findings reveal that despite the foundational role of patents, several challenges within Egypt's patent system hinder its effectiveness in supporting pharmaceutical innovation and ensuring broad access to essential medicines.

The core of the issue, as evidenced by the Hepatitis C case, lies in the discrepancy between a generally sound patent examination process and a notably weak enforcement mechanism. While the Egyptian Patent Office is praised for its rigorous patent examination, characterized by the expertise and diligence of its examiners – possessing a diverse skillset encompassing intellectual property law, pharmacy, and research – and adaptable internal policy guidelines (which famously led to the rejection of the key Hepatitis C drug patent, facilitating generic entry), the subsequent enforcement phase presents significant hurdles.

The study highlights several challenges in the Egyptian patent system, including slow examination processes, lack of trust, and weak enforcement. The interviewees highlighted several challenges related to patent enforcement in Egypt. The time it takes for court proceedings and the limited number of patent

cases suggest a weak enforcement system. Additionally, the judicial system may struggle to handle patent cases effectively due to delays and a lack of specialized expertise. This could be attributed to a lack of awareness or reluctance among patent holders to enforce their rights. Furthermore, the interviewees notes that the economic court, responsible for handling intellectual property cases in Egypt, may not have sufficient capacity or expertise to deal with the complexities of patent disputes. This can lead to delays in proceedings and inconsistent judgments (case resolutions or verdicts). Another challenge is the lack of clear and efficient procedures for enforcing patent rights. The process can be time-consuming and costly, discouraging patent holders from pursuing legal action. Additionally, the lack of public awareness about patent rights and enforcement procedures may contribute to the limited number of cases.

Dr. Amr Radwan, Head of Innovation and Research at the ASRT added" *The Egyptian patent office aligns with standard international practices. However, challenges exist, particularly*

in the area of enforcement. The Egyptian Patent Office is qualified and follows good practices in patent examination, but the enforcement mechanisms, involving the economic court and the judicial system, are relatively weak.

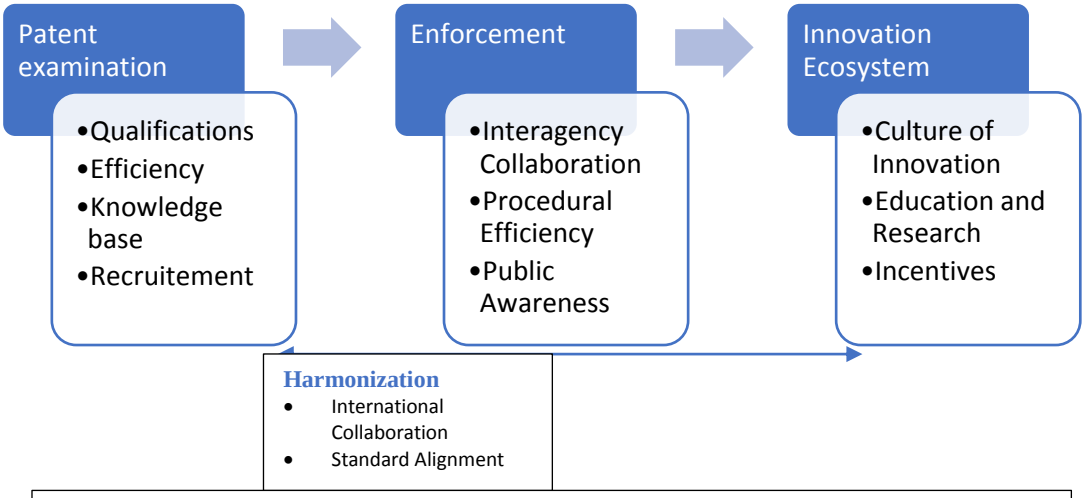
Dr. Alaa Eldin Adris, Professor at the Graduate School of Management of Technology said: *To improve the patent system, it is recommended that law enforcement and economic courts have a better understanding of patent law…. qualified examiners should adhere to tight time schedules and provide clear, concise answers in office actions »*

This disconnect between examination strength and enforcement weakness directly impacts the pharmaceutical sector. While a robust examination process can prevent unjustified monopolies, as seen with the Hepatitis C drug, a weak enforcement mechanism can undermine legitimate patent protection, deterring pharmaceutical R&D investment and potentially affecting the attractiveness of Egypt as a hub for drug innovation. Conversely, effective enforcement ensures that companies investing in novel therapies receive due protection, encouraging

further innovation. The Patent Enforcement Index, as noted by Papageorgiadis & Sofka (2020), underscores this point: strong enforcement directly influences where pharmaceutical companies choose to file patents, impacting investment and access to new medicines.

Based on the study's findings, which highlight a critical disconnect between the strength of patent examination and the weakness of enforcement within Egypt's intellectual property (IP) ecosystem, the authors propose a new model for enhanced pharmaceutical intellectual property ecosystem management in Egypt.

Figure: A Model for Enhanced Pharmaceutical Intellectual Property Ecosystem Management in Egypt developed by the authors



The proposed model developed by the authors emphasizes the interconnectedness of patent examination, enforcement, harmonization, and the innovation ecosystem. For the pharmaceutical sector, this means:

- High-quality and efficient patent grants (through robust examination) are essential for ensuring that only truly novel

and inventive pharmaceutical compounds receive protection. This, as the Hepatitis C case demonstrated, directly impacts drug affordability and patient access by allowing generic competition when patents are justly rejected.

- Effective enforcement creates a secure environment for pharmaceutical intellectual property, encouraging both local and international pharmaceutical companies to invest in R&D and launch new, innovative drugs in Egypt. Without it, even the most rigorously granted patent offers little security.
- Harmonization with international standards ensures that the Egyptian patent system is recognized and respected globally, facilitating cross-border collaborations, foreign direct investment in the pharmaceutical industry, and streamlined drug registration processes.
- A thriving innovation ecosystem, characterized by strong research capabilities (especially in pharmaceutical sciences), a culture of innovation, and a pipeline of skilled inventors, directly feeds the patent examination process with high-quality applications. This, in turn, supports the development

of indigenous pharmaceutical solutions and reduces reliance on imports.

These are the implications for the suggested model that seeks to enhance the pharmaceutical intellectual property ecosystem management in Egypt:

Improving Patent Examination:

- Upgrading examiner qualifications: Given the technical complexity of pharmaceutical patents, it's crucial to ensure examiners possess deep expertise in chemistry, biology, pharmacology, and clinical trial data. This can be achieved through specialized training programs focused on pharmaceutical innovation and regular updates on global drug development trends.
- Streamlining the process: Implementing clear, expedited timeframes for pharmaceutical patent applications, particularly for essential medicines, can accelerate market access. Providing concise office actions focused on substantive issues will reduce back-and-forth and speed up approvals.

- Enhancing knowledge access: Equipping examiners with access to comprehensive global pharmaceutical patent databases, scientific literature, and drug approval information is vital for thorough examination.
- Optimizing recruitment: Attracting patent examiners with backgrounds in pharmaceutical sciences, biochemistry, and related fields is paramount to ensure specialized understanding of drug-related inventions.

Enhancing Enforcement:

- Improving interagency collaboration: Establishing dedicated liaison programs between the Egyptian Patent Office, law enforcement agencies, and the Economic Court to jointly develop specialized training modules on pharmaceutical patent law complexities and enforcement procedures. This directly addresses the current "lack of specialized expertise" in the judicial system.
- Streamlining procedures: Implementing fast-track or specialized tracks within the Economic Court for urgent pharmaceutical patent disputes, such as those involving

essential medicines or potential market entry of generics. This can reduce delays and costs, encouraging legitimate enforcement.

- Raising awareness: Launching targeted public awareness campaigns about patent rights specifically within the pharmaceutical industry to educate both innovators and potential generic manufacturers about their rights and responsibilities.
- Fostering a culture of innovation: Providing specific incentives for local pharmaceutical companies engaging in R&D, and promoting collaboration between academia and industry to build a stronger pipeline of patentable pharmaceutical inventions.

Harmonizing with International Standards:

- Participating in international projects: Actively engaging with global bodies like WIPO and major patent offices (e.g., EPO, USPTO) on initiatives related to pharmaceutical patent examination and enforcement best practices. This ensures

Egypt's system aligns with international norms, crucial for attracting foreign pharmaceutical investment.

- Adopting international standards: Continuously reviewing and adapting Egyptian patent laws and procedures to align with globally recognized standards, particularly those relevant to pharmaceutical product protection and data exclusivity.

The recent establishment of the Egyptian Intellectual Property Authority (EGIPA) offers a pivotal opportunity to significantly strengthen Egypt's patent system. By embracing the proposed model, EGIPA can consolidate its centralized authority to overcome current challenges and effectively drive the implementation strategies outlined within the model.

6. Conclusion and Future Research

This study provides compelling evidence of how rigorous patent examination serves as both a gatekeeper for innovation and a safeguard for public health. Through qualitative analysis of the Egyptian Patent Office's (EPO) examination processes - including secondary research and semi-directive interviews – the authors demonstrated how the rejection of a specific drug patent application

created direct public health benefits. The medication's affordability by local companies results from the EPO's rigorous inventive step standard and adaptable internal policies. This outcome underscores that a strong examination arm of a patent system is paramount for public health, ensuring that patents are granted only for genuinely novel inventions, thereby preventing undue monopolies and fostering affordability. The EPO's decision, grounded in examiners' multidisciplinary expertise (spanning IP law, pharmacy, and research). This study reveals a multiplier effect: the EPO's rejection triggered challenges to related patents globally, demonstrating how robust national examination can influence international pharmaceutical markets.

However, this research uncovers a critical systemic imbalance - while Egypt's examination framework proves effective, enforcement remains hampered by slow judicial processes, limited specialized expertise, and low rights-holder awareness. This disconnect risks undermining pharmaceutical innovation and investment despite strong examination outcomes. To address these challenges, the authors proposed a model for enhanced

pharmaceutical intellectual property ecosystem management in Egypt with key pillars: enhanced examiner training and streamlined procedures; improved interagency coordination and specialized patent courts; public awareness initiatives; and harmonization with global standards. This model offers developing nations a blueprint for balancing IP protection with healthcare access - particularly vital for life-saving medications.

Future research should quantitatively measure this model's implementation impact while exploring its applicability across different technological sectors and jurisdictions. This research paves the way for further investigation into the internal policies of other patent offices, fostering the exchange of best practices across the global intellectual property landscape. The EPO case establishes that when properly resourced and managed, patent offices can significantly advance both innovation and public welfare - a lesson with global relevance in an era of increasing health inequities.

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