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Gaps in the Iranian Patenting System: A Barrier to Nanomedicine Commercialization

Payam Mansour Hosseini*, Seyed Reza Hejazi and Abolghasem Arabiun

Entrepreneurship faculty, University of Tehran, Tehran, Iran

Abstract

Nanotechnology is developing rapidly in the world. Nanomedicine as one of the branches of nanotechnology is very important. Getting patents in the field of nanomedicine is significant. The filing of patents plays a very important role in nanomedicine commercialization. In this article, the procedures for getting a patent in Iran and the United States are described. The Turkish patent system has also been described. By comparing the procedures for getting a patent and interviews with experts, gaps in an Iranian patent are discussed. Finally, some reformation options for improving the procedures for getting an Iranian patent in nanomedicine, have been proposed.

Keywords: Iran; Turkey; United States of America (USA); Patent; Commercialization; Nanomedicine

Introduction

The genesis of the concept of nanomedicine sprang from Richard Feynman's historic 1959 lecture and this concept expanded later with Eric Drexler and Freitas [1,2]. Nanomedicine may be defined as the application of nanotechnology to repair, construct and control of human biological systems at the molecular level. Nanomedicine exploits novel properties of nanomaterials and uses nanodevices for detection, prevention, and treatment of diseases [3,4]. Breakthroughs in nanomedicine are expected, as a result of nanotechnology inventions and commercialization of these inventions. The application of nanotechnology to solve problems in nanomedicine and commercialization of new technologies may lead to highly innovative products with novel features [5]. Introduction of new products to market needs successful knowledge, and technology transfer from universities and research laboratories to "high tech" companies, and technology commercialization in these companies. The commercialization of new technologies provides a potential source of income for universities and research organizations, thus promising to reduce their dependency on public funds. In many countries, these institutions encourage their scientist employees to make and disclose inventions, which can then be patented and licensed to commercial firms, and/or to organize spin-off firms [5,6].

Intellectual Property Rights (IPRs) have a vital role in the knowledge and technology transfer, commercialization of new technologies and has led to policy initiatives such as the Bayh-Dole Act in the United States and analogous measures in other countries. Lack of IPRs is a barrier to commercialization in nanomedicine [6,7]. IP means the legal rights. IP indicates: inventions, literary and artistic works, symbols, names and images used in commerce. Industrial property and copyright are two categories of Intellectual property. Industrial property includes patents. A patent is a IPRs granted by an inventor "to exclude others from making, using, offering for sale, selling and importing the invention" for a limited time, in exchange for public disclosure of the invention when the patent is granted [8]. Commercial nanomedicine, however, is at a nascent stage. Patents are already shaping the rapidly evolving field of nanoscience generally and nanomedicine particular. Patents will play a critical role in the success of the global nanomedicine revolution [9]. The filing of patents, a major intellectual property, plays a very important role in nanomedicine commercialization [10]. Influence of patents may be stronger in some industries, such as pharmaceuticals and chemicals, than in others. Patenting system in nanomedicine motivates nanomedicine inventions. This might be caused in part, by the combination of relatively high research intensity in these industries, with the fact that new drugs or chemicals typically are composed of a relatively small number of patentable components [10-14]. Differences in the patenting systems do result in subtle economic differences. For example, the Japanese patenting system is designed in part to promote greater intra-industry knowledge spillovers than the U.S. system [15]. There are several economic impacts of patenting system [16], which can be categorized in these subcategories: (1) the impact of patents on innovation, (2) the impact of patents on the disclosure of inventions, and finally (3) the impact of patents on technology transfer [17]. Another important role of patenting system is to create a market for innovation. Patenting system provide inventors a negotiating tool, with which to license or sell an invention to other firms better positioned to commercialize it. Patenting system is a means of providing a mechanism, through which research laboratories can transfer and commercialize a technology they have developed. Patenting system provides incentives for further development into commercial products. Patenting system provides an infrastructure for commercialization process. An appropriate patenting system plays an important role to increase links between research results and industry especially in high-tech industries [18]. In developing countries, the lack of IPRs and patent protection can affect the mode of technology transfer and technology commercialization. In fact, lack of appropriate patenting system can adversely affect licensing of low cost technologies [19]. On the other side, stronger patenting system and trade secrets are likely to expand exports and improve welfare, if local firms gain a more advanced ability to absorb and implement available international technologies [20]. It is impossible to ignore the role of patents in the nanomedicine field. The

***Corresponding author:** Payam Mansour Hosseini, Entrepreneurship faculty, University of Tehran, P. O. Box 14395-796, Tehran, Iran, Tel: +989123394680; Fax: +982188339098; E-mail: P.m.hosseini@ut.ac.ir

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patent is very important for investors. When investors in nanomedicine companies consider the merits of their investment, patent is the most important item that they review [21].

In the year 2000, Iran was ranked 60th in the world in the field of nanotechnology, but in 2011, the country had advanced to a 12th place. Iran has been granted almost 70 patents in the United States and Europe, and 37% of all patents in 2010 in Iran belonged to the nanotechnology field. Comparing Iranian patent with other countries shows that Iran doesn't have the ideal conditions or the culture of obtaining international patents. Iran needs to work on the culture of granting patents among professors, students and researchers and this process requires time [22].

This research has focused particularly on gaps in Iranian patenting system especially in nanomedicine, which can adversely affect on commercialization of new technologies. Insufficient analysis has been done regarding patenting, as a means of technology transfer and commercialization in Iran. Based on gap analysis in this paper, we suggest some reformation options in Iranian patenting system, for improving development and commercialization of nanomedicine inventions in Iran.

The Patent Cooperation Treaty

The Patent Cooperation Treaty (PCT) is an international patent law treaty, which has been done at Washington on June 19, 1970. It has been amended on September 28, 1979 and modified on February 3, 1984 and October 3, 2001. It provides an integrated procedure for the filing, searching, and examination of applications for the protection of inventions, and for rendering special technical services. A patent application filed under the PCT is called an international application. A PCT application does not itself result in the grant of a patent, since there is no such thing as an "international patent", and the grant of patent is a prerogative of each national or regional authority. The main advantage of PCT is international protection of invention via a single patent application. Under the PCT, an inventor can file a single international patent application in one language with one patent office, in order to simultaneously seek protection for an invention in the PCT member countries [23,24].

Iran has not signed the PCT, and for this purpose an Iranian patent could not be called an international application under the PCT. To get an international application under the PCT in Iran, we would have to go through someone who is a citizen in one of the PCT member countries [25].

Patenting system in Iran

The first Iranian "patent and trademark" law was introduced in 1924. Iran has a long history in patenting. The Iranian patent and trademark office is known as The Administration for The Registration of Industrial Properties (ARIP) in the country, and this administration is a part of "The Registration Office for Companies and Industrial Property" affiliated to "The Registration Organization for Deeds and Properties of Iran (RODP)". The whole system is under the supervision of the Iranian Judiciary System. The Iranian patent system is declaration based. The subject matter will be searched in a database and it can be accessed by the ARIP. Then, the inventor will defend the "scientific validity" through an oral proceeding session, with experts from both the ARIP and Iranian Research Organization of Science and Technology (IROST). In this session, they will decide on whether the subject matter is new or not. If the subject matter is accepted, then payment of the granting fees and publication in the Iranian office journal will be the next steps. Finally, the inventor will grant the patent. This process is shown in Figure 1 [26].

In 2008, the patent law was reformed and the new law entitled "Patent, Industrial design, Trademarks act". Major areas of change in the new law are:

- New law referred to the term "invention".
- There are three pre-requirements; "Novelty", "Inventive step" and "Industrial applicability" for the substantive patentability requirements.
- ARIP will examine the applications.
- Disclosure of the subject matter of the invention by the inventor, will not be considered as novelty destroying.
- Computer software can be patented.
- Application of an invention is defined as its production, import or export, selling, or stocking for later sale, which is only allowable under the consent of the inventor or his representative.

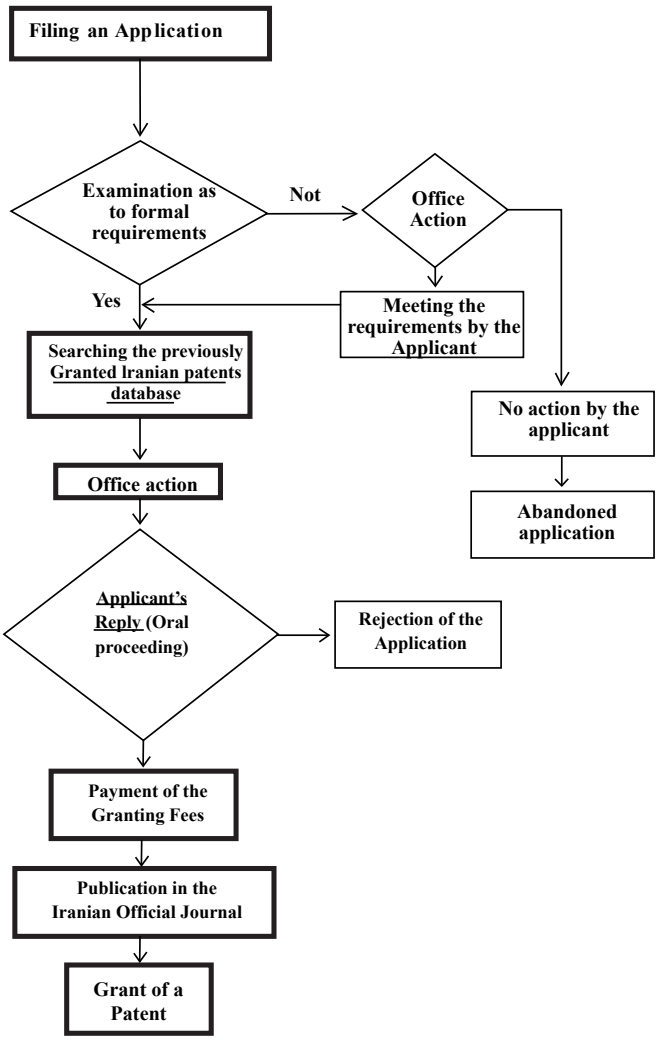

Figure 1: The general procedure for getting an Iranian patent [26].

- The inventor will have the right to be mentioned as such in the patent.
- If the invention is the result of a hire-to-invent doctrine, the economic rights will be granted to the employer unless the contrary is foreseen in the employment agreement.
- The inventor has the right to claim priority, based on a prior filing in any Paris Convention member state.
- The government will have the right to grant a compulsory license under certain conditions.
- The status of enforceability of the patent rights is analyzed under the three sub-categories: Civil remedies, Criminal remedies and Interim and border measures [26,27].

Patenting process overview in the US

The US patenting process has 13 steps which are listed below:

Step 1, Applicant – Has your invention already been patented?

Search the Patent Full-Text and Full-Page Image Databases

- If already patented, end of process
- If not already patented, continue to Step 2

Step 2, Applicant- What type of application are you filing?

Design Patent (ornamental characteristics)

Plant Patent (new variety of asexually reproduced plant)

Utility Patent (most common) (useful process, machine, article of manufacture, composition of matter)

- Step 3, Applicant – Determine Filing Strategy
  - File Globally?

    Need international protection?
  - File in U.S.? – continue to Step 4
- Step 4, Applicant – Which type of Utility Patent Application to file?

  Provisional or

  Nonprovisional
- Step 5, Applicant – Consider expedited examination

  Accelerated Examination Program

  First Action Interview

  Patent Prosecution Highway
- Step 6, Applicant – Who Should File?

  File yourself (Pro Se)

  Use a Registered Attorney or Agent (Recommended)
- Step 7, Applicant – Prepare for electronic filing

  Determine Application processing fees

  Apply for a Customer Number and Digital Certificate
- Step 8, Applicant – Apply for Patent using Electronic Filing System as a Registered e-Filer (Recommended)

  About EFS Web

  Step 9, United States Patent and Trademark Office (USPTO) – USPTO examines application

  Check Application Status

  Allowed?

  Yes, go to Step 12

  No, continue to Step 10
- Step 10, Applicant – Applicant files replies requests for reconsideration, and appeals as necessary
- Step 11, USPTO – If objections and rejection of the examiner are overcome, USPTO sends Notice of Allowance and Fee(s) due
- Step 12, Applicant – Applicant pays the issue fee and the publication fee
  - USPTO Grants Patent

Step 13, Applicant – Maintenance fees due 3 1/2, 7 1/2, and 11 1/2 years after patent grant [28].

The US patent system is totally web-based. It is possible to search through the website, to check if the invention has been patented already or not. It is specified, what the applicant must do to be granted the US patent. The applicant must choose the type of application. The US patent system has a filing strategy which lets the applicant decide, whether they want international protection or not. The international protection provides information on patent programs and agreements dedicated to improving work-sharing and international cooperation between various worldwide IP offices. In the US patent system, there are 2 types of utility patent application to file; Provisional or Nonprovisional. A non-provisional application for a patent includes: (1) a written document which comprises a specification (description and claims); (2) drawings (when necessary); (3) an oath or declaration; and (4) filing, search and examination fees. A provisional application will become abandoned by the operation of law, 12 months from its filing date. The 12 month pendency for a provisional application is not counted toward the 20 year term of a patent, granted on a subsequently filed non-provisional application, which claims benefit of the filing date of the provisional application. The benefits of a provisional patent application are: (1) ease of preparation, (2) lower cost, and (3) the ability to use the term "patent pending", which may have significant marketing advantages. After the examination, the USPTO advises that the applicant contact an attorney, who is experienced because the patent application process is complex. After preparing for electronic filing and applying for a patent, using the Electronic Filing System as a registered e-Filer by the applicant, the USPTO examines the application which can leads to granting a patent [29,30].

Due to burgeoning number of new nanotechnology-related patent applications, filed at the USPTO and continued pressure from industry, the USPTO in August 2004 created a cross-reference classification for nanotechnology, as class 977/Digest1. This class contains 263 subclasses and allows organization of most nanotechnology subject matter in a logical manner. This class is not designed around a topic or technology because nanotechnology is a multi-disciplinary art and prior art is scattered throughout the patent classification system. Issued patents related to nanotechnology using specific keywords, rather than relying on patent classification schemes.

Some challenges facing the USPTO in nanotechnology are:

- Lack of a technology center
- Lack of a classification system
- High attrition rates
- Funding problems
- High patent pendency
- Limited industry-USPTO interaction
- No examiner training or guidelines [31,32].

It should be considered that U.S. patent law has changed last year. Considered the most significant change, the United States is moving from a first-to-invent to a first-to-file system. Some of the most significant changes will come into force in the future. However, other changes will take effect immediately. The immediate changes include:

- Providing an option for prioritized examination
- Banning "tax strategy" patents
- Banning patents directed to human organisms
- Significantly scaling back private "false marking" lawsuits
- Allowing "virtual patent marking" on a website
- Expanding the prior user defense to patent infringement
- Eliminating the "best mode" defense to infringement
- Raising the bar for inter partes reexaminations
- Changing certain patent filing fees
- Limiting the ability to sue multiple infringers in a single lawsuit

Some other changes that will take effect later are:

- Post Grant Review
- Employer Corporation as Applicant
- First to File
- Expanded Definition of Prior Art
- Derivation Proceedings [33,34].

Turkish Patent Institute

Turkey was late in forming a modern patent system for the effective protection of IPRs. Until 24 June 1994, the date on which the Turkish Patent Institute (TPI) was established, the legal system regarding the protection of IPRs provided limited possibilities of registration and was quite outdated, as compared to the developments at the international level. In this regard, becoming a party to the Agreement establishing the World Trade Organization on 1st January 1995, and the beginning of Customs Union with the European Union on 1st January 1996, was some of the most significant incentives for Turkey, in terms of, engaging in legal reforms in the IP field. By those legal reforms, the purpose was not only to integrate with the international regulations, but also to provide an effective IP protection within the country, which is in harmony with the international standards. The Turkish patent system has been affected after the establishment of Turkish Patent Institute, after 1994. For an effective protection of IPRs what is needed is not only amending the law, but also a well-organized patent institute for the execution of the administrative procedures. In order to cover this need, the TPI was established on 24 June 1994, which was the first step towards the formation of a modern patent system in Turkey. One of the most important developments in Turkey, in terms of integration to the international regulations of patent protection, was its participation to the EPC (European Patent Convention). Turkey has become the 20th member of EPC on November 1, 2000. This was an important step, for both the development of the Turkish Patent System and the process of Turkey's integration to the European Union. As for the organizational structure of TPI, it is comprised of seven main organs, namely, the Managing Board, the Advisory Board, the Presidency, the Reexamination and Evaluation Board, the Main Administrative Units, the Auxiliary Service Units and the Consultancy Units. As for the organizational structure of TPI, it is comprised of seven main organs, namely, the Managing Board, the Advisory Board, the Presidency, the Reexamination and Evaluation Board, the Main Administrative Units, the Auxiliary Service Units and the Consultancy Units. After TPI was established on 24 June 1994, until 7 November 1995, the legal background for the effective protection of IPRs in Turkey was formed and in this way, Turkey almost completely harmonized its national law with the international standards. Within such a short period of time, Turkey adopted its national legislation for patents, trademarks, industrial designs and geographical indications, and achieved the necessary legal regulations for Turkey's participation to most of the international agreements, concerning the IP field. After the developments that were attained in 1994 and 1995, TPI continued to work for the proper application of law amendments at home and provided for the effective representation of Turkey in the international arena, with regard to the execution of the participated international agreements. Furthermore, participation to the other significant international agreements concerning the IP field, as well as, further developing the legal and institutional infrastructure necessary for the effective protection of industrial IPRs, were the other developments put forward by TPI since 1995. Since the establishment of TPI in 1994, by conforming to the developments in the world, Turkey properly formed its national legislation for the establishment of a modern and contemporary industrial property system, and considerably progressed towards the achievement of an effective institutionalization within this field [35]. It is obvious by checking the website of TPI that it is well-organized. The website has an administrative and financial autonomy, and its staff employed is specialized at the national and international level. The TPI has a very good hardware and software infrastructure and its national law is harmonized with international standards [36].

Methodology

The data required for gap analysis were collected through process benchmarking and interviews. For analyzing collected data, we investigated the US and Turkey patenting system as a benchmarking results. Then, we interviewed 6 managers of nanomedicine companies in Tehran, of which 1 of them had been granted the US patent. Most of these companies had been granted the Iranian patent. Then, we interviewed 3 inventors who were granted Iranian patent and finally 2 experts of nanotechnology commercialization. After that, we identified gaps differences between the US and the Iranian patenting system. Based on these results, we propose some suggestions for change in the Iranian patenting system. Also, nanomedicine field as a specific field.

Interview results and gap analysis

In this article, we interviewed managers of nanomedicine companies, inventors who were granted an Iranian patent and experts of nanotechnology commercialization, who were familiar with the

process of the Iranian patenting system. The interviews showed that IP is one of the important factors in nanomedicine commercialization in Iran. The nanomedicine commercialization has 3 segments; (1) technology supplier, (2) technology transfer, and (3) receiver of technology. IP has a critical role in technology transfer. Companies need a patent to protect their invention and this is one of the barriers to technology transfer. The limitation of protection of IPRs in Iran is another problem for those who were granted an Iranian patent. Iran is facing a lack of experts in the field of nanomedicine. We identified 6 gaps in classifications in the Iranian patenting system. These 6 gaps classifications are:

(1) Weakness of patent: Since Iran has not signed the PCT; the Iranian patent could not be called an international application. So it shows the weakness of the Iranian patent in contrast to other patents. There are signals of change recently that the Iranian government wants to upgrade the present IP system.

(2) Hardware infrastructure: The ARIP lacks laboratory infrastructures to handle applications. To solve this problem, the ARIP needs to have a dedicated technology center.

(3) Software infrastructure: The ARIP lacks of IT infrastructures and public searching facilities in database of patents. The ARIP does not have an official website and searching for patents is not available. Software tools can make a patent search more efficient and effective.

(4) Process: Long patenting process slows the ability of businesses to bring innovative new products to market. For nanomedicine, commercializing time is very important. Due to the formality checks and oral proceedings, we have the high fatality rate of applications. The ARIP's evaluation is structural judgment versus content judgment, and it usually loses track of evaluating the content of a patent. Also, there is no formal classification scheme for the Iranian nanotechnology patents.

(5) Human resource: The ARIP lacks human resource, especially in nanotechnology. The patent examiners are not expertise and they are not aware of the complexities of nanotechnology. The ARIP needs well-educated human resource for nanotechnology.

(6) Law: In Iran, there is no patent attorney. In Iran, there are some law firms especially in the capital, which claim to provide services but they do not have special technical background. Hence, their services are not as effective as a patent attorney.

Results

Some gaps in the Iranian patenting system make it less attractive to apply for a patent, like limitation of IPRs because Iranian patent is not under the PCT. This issue was one of the most important problems, mentioned by all the interviewees. Applicants from other cities have difficulties because there is only one place in the capital (ARIP) for filing an application, and also for patent infringement (first instance court of Tehran) throughout the country. The ARIP has no official website. The Iranian patenting system does not fully examine the content, so it is without great difficulty to get a patent due to lack of content control, lack of laboratory infrastructures and lack of experts. Recently, motivation to get a patent has been lowered due to some infrastructural problems. Access to Iranian patent information is not possible. There are no searchable databases for the public. The ARIP has a computerized database, but it is only for internal use. It should be noted that this database has some defects, and applications are not classified according to the international classifications. Applications need to be classified. For instance, a classification of nanomedicine technologies and techniques that can be patented is shown (Table 1). It should be considered that the Japanese patent office has formed a unique nanotechnology patent classification.

Discussion

By comparing the patent systems in Iran, Turkey and the US, we can propose resolutions to improve the Iranian patenting system. According to the current law, the first to file a patent application will get the patent. The ARIP does not have an official website and it is not possible to search for patents online. The Iranian patenting system does not provide the international protection, and the ARIP needs to have international cooperation among various worldwide IP Offices so, it shows the weakness of IP in Iran. The Iranian patenting system does not provide a provisional patent, but as it was discussed formerly, maybe the applicant does not need a nonprovisional patent. Iran is facing a lack of laboratory infrastructures in the field of nanomedicine, and having a dedicated technology center in future could be useful. Also, the Iranian patenting system does not include a full substantive

No	Classification	Subcategory	Sub-subcategory
1	Biopharmaceutics	Drug delivery	Drug encapsulation Functional drug carries
		Drug discovery	
2	Implantable materials	Tissue repair and replacement	Implant coating Tissue regeneration scaffolds
		Structural implant materials	Bone repair Bioresorbable materials Smart materials
3	Implantable devices	Assessment and treatment devices	Implantable sensors Implantable medical devices
		Sensory aids	Retina implants Cochlear implants
4	Surgical aids	Operating tools	Smart instrument Surgical robots
5	Diagnostic tools	Genetic testing	Ultrasensitive labeling and detection technologies High throughput arrays and multiple analyses
		Imaging	Nanoparticle labels Imaging devices
6	Understanding basic life processes		

Table 1: Nanomedicine technologies and techniques that can be protected by a United States patent [1].

examination. The Iranian patenting system is more structural judgment based, rather than content judgment based. The long process of getting a patent and formality checks could be shortened. Iran is facing a lack of experts in the field of nanomedicine and the staffs employed are not specialized. Experts should be used during the oral reply process. There is no formal classification scheme for the Iranian nanotechnology patents. Limitation of IPRs is another problem in the Iranian patenting system. Iran is also facing a lack of attorneys, working on patenting.

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