The legal Protection of Ethiopia Traditional Medicines and Patent System

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CHAPTER ONE

THE CONCEPT OF PATENT AND TRADITIONAL MEDICINES WITH THEIR LEGAL AND HISTORICAL DEVELOPMENTS.

1.1 patent as a general concept

The term patent has made its root in Latin WORDS," LITERARE PATENTES" that were taken to mean open letters patent (Literate patents) are letters addressed by the soveign to all whom these presents shall come, reciting the grant of some dignity, office, monopoly franchise, or other privilege to the patentee. They are not sealed up but are left open (hence the term 'patent') and are recorded in the patent rolls in the record office.

In time, the right control various sectors of the market become a royal privilege. Granted by the monarch in return for various benefits. These carly monopolies were not concerned with invention, but with commerce.

However, unlike in the when patent and multi lateral implications. Patent in its modern sense of applications is being used only in two ways; the first refers to the rights and privilege conferred up on the inventor while the second directly refers to the document issued by the governmental authorities 8. It is also possible to observe and understand this situation form more or less similar definitions given below.

A patent may not obtained if the subject matter of the patent would be obvious to a person having

Ordinary skin in the field. To be patent able the device must be use full. And must consist of some new ideal or principal not known before. It must be a discovery as distinguished from mechanical skill or knowledge. The device may be a process, a machine, an article of manufacture, or a composition of matters.

On the same manner, in our patent system, a patent is the title granted to protect invention, which may be related to product or process. An invention on the same manner, in our patent system, a patent is

the title granted to protect invention, which may be related to a product or process. An invention is technical solution to a specie problem in the field of technology, hence all invention is patent able if it new, involve an inventive step and industrially applicable.

Therefore, when we conceder the above definitions except with the wording differences they have similar of patentee in their main constituent elements. All they imply patent is granted right derived law. It is the result of the legislative function of the national government.

1.1.1 purpose of having a patent system

Having a patent system for a country has many advantages; the following are some of its advantages.

First a patent system provides an incentive to invent by possibility of reward to the inventor and those who support him.

Second, and comparative to the first a patent system stimulates the investment of addition capital needed for the further development and marketing of the invention.

Third, by affording protection a patent system encourages early public disclosure of technological information.

Fourth, a patent system promotes the beneficial exchange of products. Therefore having a patent system is important for encouraging the development of technologies and innovation by making patent grant public documents. By disclosing the invention to the public about the new invention and its uses. So that the disclosure has enabled later inventors to build up further inventions on the base of the developed earlier patentees.

1.1.2 AN ECONOMIC REVIEW OF THE PATENT SYSTEM

When we look the need of patent system from another economic point of view, particularly concerning –patent owner relationship, there are some group of economics that says the consumers are worse of by the patent system. Because the consumers could have the fruits of this technical progress with out paying any toll charges.

Hence, with the help of the patent system the intention make it possible to produce more or better products than could have been produced with out them, therefore, what ever the consumers pay to the

patent owner is only a part of the increase in real come that is engendered by the patent induced inventions.

1.2 The concept of Traditional Medicines and related concepts

1.2.1 Definition of Traditional medicine

In 1976 a group of experts from the African region met under the auspices of the world heath organization (WHO) for African and defined traditional medicines as follows.

"… It is the sum of total knowledge and practices whether applicable or not. Used in diagnosis prevention and elimination of physical mental or social in balance and relying exclusively on practical experience and observation handed down from generation to generation, whether verbally or in writing"

"Traditional medicine might also be considered as a solid amalgamation of dynamic medicine know-how and ancestral experience."

Further more, traditional medicine refers to health practices, approaches, knowledge and beliefs incorporating plant, primal and mineral based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination to treat, diagnose and prevent illnesses or maintain well being.

1.3 The concept of Traditional Medicines in Ethiopia

The practice of traditional medicines in Ethiopia consists of the use of herbs, spiritually healing holy water, and bone setting, and miner surgical procedures. These practices vary in their form, procedure, and content according to the local, customs, and are very widely practiced.

Traditional medicine in Ethiopia related with culture that used us a means of health treatment mechanism for the society, which existed before modern biomedicine has been practiced.

Likewise Ethiopia traditional medicine is the knowledge and a practice comes from generation to generation by oral or in writing for preventing and eliminating physical, mental and social imbalance.

1.3.1 Historical development of Traditional medicine in Ethiopia

The beginning of traditional medicines in Ethiopia is not accurately known, particularly in its recorded form perhaps dates back to several centuries ago. Historian estimate that Ethiopia traditional pharmacopeias may have existed as early as the fifteenth century. How ever, the earliest known text of Ethiopian traditional remedies is perhaps the gees "Metsehaf Fews' wrote around the middle of the seventieth century.

1.3.2 The respective legal development of Ethiopia

The patent of TM in Ethiopia was legalized by the proclamation of 1942, authoring traditional healers to practice non-dangerous indigenous traditional system. That reinforced by yet another proclamation issued in 1948, which encouraged not only the practice of safe therapeutics, but also the voluntary of traditional healers with the ministry of health.

The recent proclamation NO, 218/2000 enacted to repel the medical practitioners registration proclamation NO; 100/1948.its preamble says that it is found necessary to repeal the medical practitioners registration proclamation. Then there is no legislation enacted concerning traditional medicine and its practitioners.

1.3.3 Review of the 1942 and 1948 medical practitioners proclamation

Article 8 of proclamation NO 1942 say," Nothing contained in this proclamation shall construed so as to prohibit or prevent the practice of system of therapeutics according to indigenous method in such practice. "Provided that nothing in this article shall be construed to authorize any person to practice any indigenous system of therapeutics, which is dangerous to life.

On the same manner, pursuant to article 3 of the 1948 medical practitioners registration sub-article (a) says, No person shall carry on the profession or business of medical practitioner un less he holds a license granted under section 5 of this proclamation.

Provided that nothing in this section shall be construed to authorize any person to practice any system of therapeutics expect amongst the local community to which he belongs, or to practice any such system, which is dangerous or injurious to health or life.

That means, the only reservation on the traditional healers (practitioners) were not to practice any such system, rather on dangerous, or injurious herbal medicines to health of life, even they did not have a license.

1.3.4 Application and granting of license under the 1948 proclamation

Pursuant to article 4(a) of this proclamation, application for license to practice, as medical practitioner shall make to the minister… and shall accompany by the fee prescribed. Then, Pursuant to sub (b) of the same article, the minister shall submit the application and the documents attached there to the board that shall express its opinions in a written to the minister.

Accordingly, on the basis of article 5 (a) the minister may on the recommendation of the bored (the general advisory bored of health), grant the application if he is satisfied the applicant

1. Is of good character
2. Is qualified to carry on his profession.
3. Is an Ethiopian citizen or has received permission to remain in the empire.

The license shall only entitle the holder there of to carry on the profession (which is specified in the license). And profession of every person to whom a license granted or whose license cancelled or suspended under this proclamation.

1.4 The need of encouraging Ethiopian traditional medicines & its treatment

The main purpose of encouraging ETM and its treatment is the following basic reason:-

A. Traditional medicine is part of popular culture, with 80 of population using it for various medical complications
B. A traditional medicine is less costly than modern medicine and from time to time the price of modern-medicines becomes so expensive.
C. Because of the increasing rate of the increasing rate population the in adequate of providing modern medicine, makes the utilization of TM very necessary.
D. There are countries that we can share their experience that they attain a huge health care system by utilizing TM.

E. Utilization of traditional medicine considered as one way of making a progress towards self-reliance.
F. Traditional medicine and its treatment is highly contribute for the development of modern medical as it did in the past especially on diseases that does not yet got its cure.
G. ETM can be the symbol of our national knowledge resources heritage.

A good case for non-obviousness can be made if an invention yields surprisingly unexpected results. Events occurring years after the invention was made can influence the determination of non-obviousness is a requirement for obtaining a patent. An invention is non obvious fit would be viewed as an unexpected or surprising development by some one skilled in the technology of the particular field.

CHAPTER TWO

PATENETABLE INVENTIONS AND ITS REQUIREMENTS

2.1 Persons Entitled to patents

The right to a patent shall belong to the inventor. An inventor is any person who has invented or discovered any new of useful art. Machine, or composition of matters or any new or useful improvement therefore is recognized as an inventor in the United States.

But here, it is important to differentiate between the original and the first inventor and the one who first or reduces his invention to a fixed, positive and practical form.

2.2 Statutory Requirements for a patent right

One of the requisites of patent ability is that the alleged invention must be new or novel the novelty in order that an invention may be protected by a patent is that it must posse statutory newness, to be patent able subject matter of the patent must be new in the inventor was the first to accomplish that result in substantially way he did.

2.3. Utility (Industrial applicability and its nature)

For the purpose patent " Utility" means among other things the capacity to perform the function intended by the invention or to operate according to the inventive concept and accomplish the purpose claimed by the inventor or to operate according to the inventive concept and accomplish the purpose of the invention or to achieve the objective there of.

Under the authorities such as collision V dean the court defined term "useful" as follows.

"An invention is useful, as that term is used in the statute….if it capable of being beneficially used for the purpose for which it was designated …. Or, as sometimes stated. If it will operate to perform the functions and its is not count ray to law, moral principles, or public "policy.

Therefore to possess utility, the invention must be capable of producing a result, and that result must be a good result.

So generally to posses patent able utility an invention must be capable of producing a result, with must be good capable so applied affaires as to prove advantageous in the ordinary pursuits of life.

2.4. Non-Obviousness (Inventive step)

The term “inventive step” or non-obviousness refers to the distance between the prior art and the clamed invention and whether the technical improvement over prior art is sufficiently improvement to warrant the grant of a patent.

2.4.1 Useful points in determining non-obviousness

This means, in other word, if the combinations of elements yields that any one skilled in the art obviously colludes predict the invention fails for lack of non-obviousness. The sum is merely that of the parts. But if a different or unexpected result is obtained by the combination it frequently is described as synergistic.

Secondary consideration

One secondary consideration is that of commercial success. If a product is immediately successful and sells like wild fire, that will be some evidence the product’s non-obviousness. The assumption is that an obvious invention would have been developed and marketed sooner.

Another secondary consideration is the long felt-but unfulfilled-needed doctrine. If a need had been felt in a field but had not been satisfied, that is considered some evidence that an invention is not obvious. Again, the assumption is that an obvious invention would be developed earlier.

2.4.2 Non-obviousness and novelty

Non-obviousness and novelty intersect because of the similarity of some of the factual questions involved in both inquires.

Even though both novelty and non-obviousness involve a survey of the prior art, novelty only considers prior with respect to substantial identity and its inquiry is in to be entire prior art, that means the search is quite narrow, whereas, non-obviousness considers the prior art with respect to what the next obvious step in the inventive process would have been and the search is relatively narrow limited to only pertinent and an a logs art, but the test is much broader.

CHAPTER THREE

PATENT PROTECTION FOR TRADITIONAL MEDICINES COMOARATIVE PERSPECTIVE

3.1. The Socio-Economic Importance of Patent Protection for Traditional Medicines(TM)

Even though its is possible to protect TM by other IPR systems like trade mark and trade secrete, the writer of this paper is focusing on the patent protection of TM. This is because from the very objective of the patent systems countries provides a patent protection for any inventions weather product or process, in all fields of technology if they are new, involve an inventive state and are capable of industrial application. Hence, it is important to look first what is the socio-economic importance of TM.

As ZHANG QINGKUI, director general the pharmaceutical and biological invention examination department at the Chinese intellectual property office said that.

"Promoting drugs IPR protection can encourage innovation and research on new drugs strengthen supervision over medicines regulate the market and ensure the peoples safety"

What we can understand from this is that the IPR protection of TM has a lot of importance. That means, if we provide IPR protection for TM that fulfils the required requirements, further innovation and research based on that protected drugs would be made, and the society will also benefited by using that new drug.

On the same manner, since the IPR protection needs prior examination and investigation. The people's safety with no problem protected from its negative side effects. Regarding traditional medicine and international trade, now a day's trade in traditional medical products is growing. As increasingly important outlet or use for international medicine falls under the rubric of "complementary ", "alternative ", or "non conventional "medicine.

As an outcome of the Uruguay Round negotiations, many developing and least developed countries have accepted the obligation under the Trips agreement to establish huge standards of intellectual property protection are means of promoting tree trade.

It may be argued that biodiversity, and the traditional knowledge associated with using it in a sustainable manner, are a comparative advantage of those countries that are biodiversity which enabling them to participate more effectively in global markets and thus rise above current of poverty and deprivation.

This is an example of how protection of traditional knowledge at the national and the international levels seen as a potentiality powerful tool for advantage the integration of least developed countries in to the global economy.

Intellectual property, however, is not only about properly. It is also about recognition of and respect for the contributions of identifiable human creators.

From this perspective, intellectual property has a very important role to play in protecting the dignity of holders of traditional knowledge and by conferring property right in relation to such knowledge giving those holders a degree of control of its use by others.

The very important aspect of traditional knowledge that justifies for its legal protection as the agreement of WIPO members is that, it is traditional only to the extent that its creation and use part of the electoral traditional of communities. Traditional does not necessarily mean that the knowledge is ancient.

Moreover, traditional knowledge is developing, broadening its scope and created every day. It is evolving as a respect a response of individuals and communities to the challenges posted by their social environment. In its users, traditional knowledge is also contemporary knowledge.

However, in order to protect traditional medicine (TK) by the existing intellectual property mechanisms, which intended to function in a trade related context, may not fully respond to the essentially cultural nature of traditional knowledge. This is because traditional knowledge not produced systematically, but in accordance with the individual or collective creators 'response to and interaction with their cultural environment.

In addition, traditional knowledge, as representative of cultural values, generally held collectively. Further more, most traditional knowledge is transmitted orally from generation to generation, and remains largely undocumented.

So generally, traditional medicines as a sub set of traditional knowledge shares the attitude and rules of WIPO in TK.

Hence, the WIPO over all objectives and on going work disclosed, the effective use of intellectual property mechanism for the protection of traditional medicines is very important. This is because,

1. For interaction of holders of traditional knowledge or (healers of TM) pose to the international community by and through WTO (TRIPS)
2. For the protection of their property rights, traditional healers give a degree of control of its use by others.
3. IPR protection of such knowledge is available means of promoting a sense of national cohesion and identity.

3.2 WTO (TRIPS) Patent Rules On Medicines

Pursuant to article 27-1 Trips agreement, countries are obliged to provide patent protection for any inventions, whether products or processes in all field of technology. If they are new, involve an inventive step and are capable of industrial application. How ever, there is variation of the national level among WTO members as to what they consider an invention that is new or that involves an "inventive step" for granting patent protection.

Such various are, of course, bounded by the basic rule of treaty interpretation that given provision be interpreted reasonably. More over provisions of the TRIPS agreement should be interpreted so as be consistent with other obligations for example that found in article 27-1 to provide patent protection in all fields of technology.

Regarding the applicability of intellectual property protection to traditional medicine by the TRIPs agreement, there has been a great deal of discussion about the protection of traditional knowledge, including traditional medicine through the intellectual property system.

The protection of traditional knowledge including traditional medical knowledge arises under Article 8(s) of the convention of a biological diversity.

"Contracting parties shall as for as possible and appropriate subject to their national legislation. Respect, preserve and practice of indigenous and local community".

3.3 Traditional knowledge Digital Library

A traditional knowledge digital library being compiled to document century's old healing remedies, formula, compounds and medicine treatments in order to prevent patenting of ancient indigenous practices and techniques.

Holders of traditional knowledge have identified patents had been granted for inventions that did not satisfy the rest of "novelty" because of prior traditional knowledge related disclosure. Some of the patent later invalidated due to the knowledge related disclosures that are against the patent right.

The most efficient use of such traditional knowledge related disclosures and the patent system is, to make such discloser available to patent examines of prevent such patent from issuing in the first place.

The need to improve documentation of traditional knowledge for use by patent offices as part of the "prior art "up on which their examination of patent application is based widely accepted. Indeed in recent to the WTO TRIPS council, the government of Brazil stated that it.

Considers that documentation of tradition knowledge would have the clear benefits of providing documentation for patent offices to determine prior art and check against patent claims that are filed with out the consent of the holders of traditional knowledge. Regarding these different members / of the WTO/ such as Switzerland, India and the United states have already agreed on the usefulness of documenting traditional knowledge.

Furthermore, the WTO standing committee on information technology has agreed to incorporate traditional knowledge in a digital library. How ever, merely making such information available in digital from is not sufficient to ensure that it is regularly used by patent examining authorities.

Technical standards will have to be agreed up regarding international exchange of traditional medicines documentation with in existing intellectual property information system for the search of prior art. More over, though will have given to inclusion of classes, subclasses, groups of sub groups for traditional medicine so that traditional medicine based patent can be systematically searched.

CHAPTER FOUR

THE LEGAL PROTECTION OF ETM AND THE PATENT SYSTEM OF ETHIOPIA

4.1 Challenges on the Patent Protection of ETHIOPIAN Traditional Medicine

In the existing IPR system of Ethiopia there is no specific legislation concerning on the protection of traditional medicine. For this there are different reasons can be raised as p problem or challenges?

First, the main problem is the nature of the traditional medicine itself. Meaning most TK (including TM) is transferring from generation to generation as a common heritage and held collectively. Hence, it will affect the novelty requirement of patent ability, as it anticipated in the priority date for patent protection.

Secondly, in Ethiopia there is not clear that differentiate traditional healers from lay persons that use TM for personal consumption. Meaning if there is no clear demarcation like Chinese and Indians who provides a distinction point on their legislation who are traditional healer and who are not, it is difficult for providing patent (IPR) protection for all person who seeks protection.

That means mostly, TK (including TM) are transferred orally from generation to generation. Therefore, it is difficult to have tangible reference in case of patent examination.

So generally, according to their observation there is practical and conceptual problem for the IPR (particularly patent protection) for Ethiopian tradition medicines (the interview questionnaire is attached on the appendix of the paper).

On the other hand, the group of healers says, they do have the knowledge about IPR protection. Particularly patent and copy right protection. Concerning patent protection for ETM, they said they tried to get a patent protection for their new drug invention but they fear that there is no confidence. That means they have not confidence on the patent system existing today, since there is no specific law and mechanism on the protection of ETM.

Finally, the other challenges for the patent protection of Ethiopia traditional medicine is that the absence of required qualification of the patent examiners in the patent department of ELPO.

That means, in order to investigate whether one TM invention fulfils the requirement of patent ability. Particularly inventive step and practical applicability the examiners should have same knowledge on medicine and related field. However, this mechanism does not created in our patent system for examination of new invention or traditional medicines of Ethiopia.

4.2 The Socio-Economic Importance of Patent Protection of ETM

Patent protection for invention in Ethiopia traditional medicine, is not the only means of protection. Meaning, there can be other mechanisms like trade mark or trade secret protection but due to the nature of patent that is designed protect new inventions, it is preferred than other protection of ETM like the Chinese dose.

The knowledge of medicines plants is a framework for continued creativity and innovation renewable source of wealth both as an economic asset and as cultural inheritance.

Whereas the existing Ethiopia intellectual property law particularly our patent law does not give much emphasis for this indigenous national potential inventions, which is Ethiopian traditional medicine.

So generally, in order to promote and encourage local inventions with regard to Ethiopian traditional medicine to develop seal drug industries through inventions and to participate in the existing drug international trade, patent protection for TM healers is very important.

4.3 The Ethiopian Patent Law and the Patent Protection of ETM

When we look our patent proclamation 123/1995 on invention minor inventions and industrial designs regarding the patent ability of TM, there is no specific prohibition, as far as they are new, involves an incentive step and is industrially applicable.

So generally, this provision disclose is that except for methods for treatment of the human or animal or animal body by surgery, therapy or diagnostic methods, products used for any of the methods for treatment of the human or animals, TM or herbal drugs can be patented.

What the writer of this paper is saying is that, the requirements of patent ability are indirectly excluding traditional medicine from patent ability.

4.4 ETM and Utility Model Certificate

On obviousness is not required in case of utility model certificate. Hence, compared to patent, utility model is a simple inexpensive and fast method of protecting inventions.

On the same manner, pursuant to article 39 (1) of the proclamation, the novelty requirement is flexible, as the oral disclosure does not destroy its novelty it clearly says a minor invention shall not considered new if at the time of filing it has already been described in, printed publication made available to the public or has already been used in Ethiopia.

The main objective of this research is to identify problems related to protection of TK and to develop intellectual property rights policy and guideline for traditional medicine protection.

Conclusion and Recommendation

Conclusion

Patent is legal title granted its holders the exclusive rights to make use of an invention for limited area and time by stopping other, among other things, making using or using or serving it with out authorization.

Having a patent system provides an incentive to invent by offering the possibility of reward to the inventor and those who support him. By affording protection a patent system encourages early public disclosure of technological information. Some of which might otherwise be kept secret. Since disclosure provides a basis for further advances in the invention involved.

Further more, a patent system promotes the beneficial exchange of products, service and technological information across national boundaries by providing protection for individual property of foreign nationals.

Traditional medicines is the sum total of knowledge and practices whether applicable or not, used in diagnosis, prevention and elimination of physical mental or social in imbalance and observation handed down from generation to generation, whether verbally or in writing.

Traditional medicine is a subject of traditional knowledge. Its protection and sharing of benefits has been under debate at both the international and domestic level for decades.

This is because there is no authoritative threat-base definition exists for either “traditional knowledge” or its subject “traditional medicine” for the purpose of their protection.

The concept of traditional medicine in Ethiopia is inferred from the practice which consists of the use of herbs, spiritual healing, and holy water, bone-setting and minor.

Surgical procedures, these practices vary in their form procedure, and content accordingly to the local, customs, and are very widely practiced.

The beginning of traditional medicine in Ethiopia is not accurately known, particularly in its recorded form perhaps it dates back to several centuries ago. Historians estimate that Ethiopian traditional pharmacopeias may have existed as early as the fifteenth century. How ever, the earliest known text of

Ethiopian traditional remedies is perhaps the geez “Meshafe Fews” written around the middle of eh seventeenth century.

The practice of TM in Ethiopia was legalized by the proclamation of 1942, authorizing traditional healers to practice non-dangerous indigenous traditional system. This was reinforced by yet another proclamation issued in 1948, which encouraged not only the practice of safe therapeutics, but also the voluntary registration of traditional healers with ministry of health.

There are four aspects (elements) of traditional medicine and its use that should be considered in connection with question about its that is, traditional medicine may be both ancient and contemporary, traditional medical knowledge may be codified (written or non-codified (oral), traditional medicine may involve products pr process, traditional medicinal products are increasingly traded internationally and are therefore, of increasing economic significance.

Our patent law on this regard follows the first file that is the right to a patent shall belong to the people who field the first application.

Despite the difference in the mechanism of examination, search procedure and other minor differences, internationally there well- accepted patent ability requirement. That is novelty, inventive step and industrial applicability.

Therefore, their need, a conducive and encouraging IPR system for this indigenous traditional knowledge, particularly patent protection for ETM healers.

This is because, firstly traditional medicine is part of popular culture with 90(80) of the population using it for various medical complications.

Secondly, traditional medicines are less costly than modern biomedicine, and from time to time the price of modern biomedicine becomes so expensive.

Further more, utilization of traditional medicine is considered as one way of making a progress towards self-reliance.

The most efficient use of such traditional knowledge related disclosures and the patent system is to make such disclosures available to patent examiners so as to prevent such patents from issuing in the first place.

Documentation of this data base traditional knowledge would have the clear benefit of providing documentation for patent offices of determine prior art and check against patent claims that are filed without the consent of the holders of traditional knowledge.

On the other hand, by a close reading of our patent proclamation 123/1995 and the council of ministers regulation No. 12/1997 invention, minor invention and industrial designs council our patent law does not give much emphasis on the patent.

Protection of ETM, that means the existing patent ability requirements, particularly the inventive step is not considering ETM.

There is no specific legislation for classifying one new drug invention is obvious or non-obvious by our patent system. This is because as we saw the content of traditional medicine is very wide in its scope. It consists of herbs, spiritual healing, and holy water, bone-setting and minor surgical procedures.

Therefore, the question which traditional medicine is protected who can examine that means, the qualification of the examiners and the mechanism of testing inventive step and other patent ability requirement are not clearly discussed by our patent proclamation.

However, our patent proclamation and regulation does not specifically provides which type of Ethiopian traditional medicine is protected, how the patent office or the commission undertake a substantive examination of drug invention, needs further clarifications.

Concerning Ethiopian traditional medicine and utility model certificate, even though UMC is relativity conducive for the protection of ETM than a patent, it has its own problems.

First, UMC is granted for a minor innovation without the need of inventive step requirement and there is not substantial examination is required.

Therefore, even though UMC is a simple, inexpensive and fast method of protecting minor invention, because of the above short coming the writer of the paper does not recommend UMC is the best way for the protection of ETM.

Recommendation

Therefore, what should we do for creating conducive patent system in the patent protection of Ethiopian traditional medicines.

- The main and the first thing that must be done with regard to ETM patent protection are preparing a national policy. Since policies are the backbone for enacting further legislation and also helps to coordinate ETM to the national health system.

This national policy should be made on the Ethiopian traditional medicine and intellectual property rights protection that takes into consideration the socio-economic and culture importance of IPR protection of ETM to the whole society and also for individual and joint practitioners of ETM as such.

Regarding this our constitution says under article 51(3) the federal government shall establish and implement national standards and basic policy criteria for public health, as well as for the protection and preservation of culture and historical legacies.

- Secondary like the Indians *"honey bee database"* that involves documentation, experimental and dissemination of indigenous knowledge including TM, we also should have to create this kind of mechanisms for preserving and patenting ancient indigenous traditional medical practices and knowledge which have not inventive step.

This is very important for the patent examiners in case of patent application of TM. Since at least they got a reference to be inferred the alleged invention is obvious or non-obvious or whether or not patent ability requirements are fulfilled.

However, in order to do this, the involvement and the positive willingness of Ethiopia traditional medicine healers are very important. That is through their Ethiopian national traditional medicine practitioners association, for giving information as the knowledge is on their hand.

On the same manner, the ESTC particularly the Ethiopian intellectual property office expected to involve, make research and give educative on the general.

Awareness of the IPR protection of ETM and the importance of this digital traditional knowledge library mechanism obviously the government particularly the legislator and the executive body should participate and support these activities like the Indians government does.

Thirdly, concerning the patent ability requirements of Ethiopian traditional medicine, we should follow the practice and experience of china with a minor modification for making suitable to our socio-economic and cultural make up.

Generally, Ethiopia should share the Chinese and the Indians patent protection system for traditional (herbal) medicine. Since most of their populations are beneficiaries of traditional medicines (like Ethiopia) and are government of both countries are providing a patent protection system for traditional medicines and its healers with specific and conducive patent system. As r result of their experience we can learn a lot from them.

Concerning the high costs of filing patent application fee as one obstacle to the acquisition of patents by most practitioners of TM two solutions are proposed.

Firstly, the Ethiopian patent proclamation should exempts or minimizes the amount of application and renewal fee Ethiopian traditional medical healers, if they come to apply for new drug invention, since this is one form of encouraging them for invention and coming confidentially to the office for application.

Secondly, collective failing of patent application by traditional healers associations on behalf of individual or groups of informal innovators should be developed.

This is because; it is easier to give financial and legal assistance under the umbrella of the association and collectively rather than for each (individual) ETM healers.

On the other hand in our legal system there are no clear points that differentiate healers from laypersons who use TM for personal consumption.

Hence, like our commercial code in article 5 that provides a demarcation for traders (who are traders and who are not), the legislator should also provide a clear point who are traditional healers in Ethiopian context and who are not. This is because it makes the process of patent protection for ETM very simple and fast.

- Concerning Ethiopian traditional medicine and utility model certificate, even though UMC is a sample, inexpensive and fast method of protecting minor invention, because it lacks international patent able standards, that are inventive step and substantial examination and also it is short term of protection, it is not the best way for the protection of ETM. Hence ,we

should strength our patent protection, which is conducive and encouraging for ETM indigenous new drug invention.

There fore, when we read in conjugation of article 51(13) and (19) of the FDRE constitution, we can conclude that the legislator has a duty to establish Ethiopian tradition knowledge in general, and Ethiopian traditional medicine in particular, protection and preservation mechanism though a patent system. Since ETM are our cultural and historical legacies.

On the same manner, Ethiopia is a party to the convention on biological diversity (CBD), it is expected to translate the basic provisions of the CBD in to domestic law. Since, pursuant to article 8 (j) of the CBD stipulates that the innovations and practices of indigenous and local communities should be respected, preserved and maintained.

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- Traditional medicines and its healing and controlling draft regulation (1998)
- The civil code of the empire of Ethiopian.NEG.GAZ proc.No 165 (1960)
- The FDRE constitution. NEG.GAZ, proc No 165 (1960)
- The commercial code of the empire of Ethiopia,NEG.GAZ PROC.No 3 (1960)

APPENDIX

Interview

With Mekele health center Health Office Expert (w/ro kiros Haylu)

1. Is it possible to protect Ethiopian traditional medicines by our existing paten system? So what pre conditions should be fulfilled?
2. Is their any problem (challenge) for the patent protection of Ethiopian traditional medicines? If any, what should be done for solving these problems?
3. Do you believe the existing patent ability requirements that are novelty, inventive step and industrial applicability take in to consideration new drug inventions of Ethiopian traditional medicines?
4. Did the office tray for the enactment of a specific law regarding the IPR (particularly patent protection) Ethiopian traditional medicines?
5. How do you see the necessity of national police measures for patent protection of Ethiopian traditional medicines? What efforts do you made regarding this?
6. Did any Ethiopian traditional medical healers come at the office seeking a patent protection for their any herbal drug protected by patent in our patent system?
7. Generally what must be done for the patent protection of Ethiopian?

Interview

With Traditional Medical Healers in Mekele city

1. Do you know about intellectual property in general and patent protection for new drug invention in particular and the patent ability requirements?
2. Do you know about the existence of Ethiopian intellectual property office and patent proclamation for protecting new inventions?
3. If you know, do you triad to get patent protection for your new drug invention by going to the office?
4. Concerning patent protection some people say ETM does not fulfill the patent ability requirements that is novelty, inventive step, and industrial application because it simply transferred from generation to generation how you do see this?
5. Do you have any new herbal invention (ETM), which can be protected by patent?
6. What do you expect from the government, Ethiopia intellectual property office or other organ for having a patent protection for new Ethiopian traditional medicines invention?
7. What efforts did the association made for the patent protection of Ethiopian traditional medicines collectively or individual and what is the objective of the association? (asked only for the association)