Ethiopia's Accession to World Trade Organization (WTO): The Need to Reform Ethiopian Patent Law to Facilitate Access to Medicine

Abstract

As a country dealing with a pending WTO accession procedures, Ethiopia is required / expected to go through different legal reforms in order to have WTO-compliant domestic laws. Inter alia, the country specifically needs to review its intellectual property laws to provide a protection for intellectual properties as envisaged under the rule of WTO. However, adopting WTO-compliant rules to protect intellectual property, especially patent, exhibits a cross-road of patent protection and access to patented invention such as pharmaceuticals. It is logical to think that strong patent protection highly challenges an eased public access to the patented invention since the very nature of patent provides a stronger exclusive right to the right holder. To systematically deal with the issue of balancing patent protection to right holders and access to medicine to the public, different countries successfully reformed their laws to facilitate access to medicine while still adhering to WTO's rules on patent. Thus, scrutinizing areas of reforms under Ethiopian patent law, in order to facilitate access to medicine before joining WTO, would help the country to adopt WTO-compliant rules which exhaustively addresses / exploits all exceptions, flexibilities and legal loopholes available to facilitate access to medicine.

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PART I

Introductory Remarks

Before rushing into examining or establishing the details of Ethiopian patent law with regard to its role on facilitating access to pharmaceuticals, it would be helpful to shortly point out the relationship between patent and access to patented innovations in general. Lately, literatures seem to show / define that intellectual properties, especially patentable innovations, and public demand to access patented inventions, as two competing interest ("Monopoly" and "Access") which hinges on a balance.[1]

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[1] I. Barpujari, "Facilitating Access or Monopoly: Patent Pools at the Interface of Patent and Competition Regimes," Journal of Intellectual Property Rights., vol .15, (September 2010), pp 345-356

The competition between monopoly and access to medicine could be well understood by examining the nature of patent protection. On one hand, patent protection provides an exclusive right for the inventor or owner of an invention to exclude others from making, using, selling or in any way commercially exploiting his / her patent protected invention.[2] Such exclusive right gives a stronger power for the innovator or patent owner to have a monopoly over making, distributing, selling or lending etc. of the invention. Because of this monopoly, in the country where the patent is protected, everyone will be deprived of exercising those exclusive rights granted under patent protection for the innovator / patent owner.

On the other hand, the issue of "Access" is a competing public interest which challenges the monopoly of patent right. It is natural to expect that the public to have an interest on at least using the inventions created. Simply put, the public wants access to those inventions which patent right offers a stronger monopoly on usage, selling, lending etc.

Ergo, looking at the above nature of patent protection and the interest of the public, one could have the audacity to consider patent protection system as a competition between monopoly and access.

Protection for Pharmaceuticals: TRIPS[3] Vs Ethiopian Law

TRIPS, under Section 5 - article 27 (Patentable Subject Matter) denotes that patent protection shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involves an inventive step and are capable of industrial application.[4] As many other products of invention, Pharmaceuticals or medicines are / could be patentable subject matter under TRIPS agreement. In other words, inventions of medicines or medical process could get protection of patent law as long as they fulfil the requirements provided.[5]

[2] Sven Bostyn and Nicolas Petit, "Patent = Monopoly – a legal fiction", December 2013, http://www.4ipcouncil.com/application/files/7014/3325/2653/Patent_Monopoly_-_Legal_Fiction_-_Bostyn_and_Petit_-_4iPcouncil.pdf Last accessed Oct, 2017

[3] Trade Related Intellectual property, (hereinafter abbreviated as "TRIPS").

[4] Agreement on Trade-Related Aspect of Intellectual Property Rights, 1995, art. 27(1), Section 5.

[5] Ibid.

In 1995 the Transitional Government of Ethiopia introduced a proclamation, "A Proclamation Concerning Inventions, Minor Inventions and Industrial Designs",[6] to protect domestic inventions which are believed to help the technological advancement of the country and to facilitate transfer of foreign technologies. This proclamation defines patent as "a title granted to protect invention; the invention may relate to product or process"[7]; it would be crucial to know what exactly the proclamation meant by "invention". Fortunately, the word "invention" is defined under the proclamation as "an idea of an inventor which permits in practice the solution to a specific problem in the field of technology".[8] From the above two definitions given by the proclamation for the word "patent" and "invention", one can understand that Ethiopian legal system offers patent protection for domestic inventions which solves specific problems in the field of technology. Despite such general protection, the proclamation provided exceptions for patent protection right; the proclamation listed out non-patentable inventions.[9] Fortunately or unfortunately the proclamation exempted products which can be used for treatment of humans or animal body by surgery or therapy, as well as diagnostic methods practiced on human or animal body.[10] Contrary speaking, it seems that the law impliedly mentioned patent protection for medical products / medicines. Since the proclamation don't list pharmaceutical products under the list of non-patentable inventions.

Therefore, looking at the stipulations of TRIPS agreement and the promotion No. 123/1995 of Ethiopia, one can say that both the agreement and the proclamation protect pharmaceutical products / medicines.

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[6] A Proclamation Concerning Inventions, Minor Inventions and Industrial Designs, 1995, proc. No. 123, **Neg. Gaz,** Year 5, no. 25.

[7] Id., Article 2(5).

[8] Id., Article 2(3).

[9] Id. Article 4(1) (e-f): Non-patentable Inventions; (a): Inventions contrary to public health or morality, (b): plant or animal varieties essentially biological processes for the production of plants and animals, (c) : schemes, rules or methods for playing games of performing commercial and industrial activities and computer program, (d): discoveries, scientific theories and mathematical methods, (e): methods of treatment of the human or animal body by surgery or therapy, as well as diagnostic methods practiced on the human or animal body, (f): works not protected by copy right

[10] Id., Article 4(2)

PART II

Patent and Access to Medicine: *vis-à-vis* the Existing TRIPS Flexibilities

The Baffling Cross Road: Patent and Access to Medicine

As discussed under Part I of this article, patent offers for inventors / patent right owners an exclusive right against the public to use and benefit from economic exploitation of the protected right. Article 33 of TRIPS agreement obliges states to protect an invention which gets patent protection for a maximum of twenty years. This right gives for patent right holder a strong exclusive right which might be considered as strong government permitting economic monopoly in the market where the invention is protected. In effect, the patent right holder will have a right to decide when, how, how many products etc. to offer to the public including the price of his invention. Using the monopoly protected by patent protection the patent right holder could exercise his right in ways he/she deems fit; despite its serious impact on the public. This issue becomes a serious debate when it comes to pharmaceutical products which highly relates to well-being of human kinds and potentially a lucrative business for inventors / patent right holders, especially in in times of serious disease outbreak.

Though governments are duty bound to protect patent rights, they are also required by various international treaties and customary laws such as UDHR[11] to facilitate adequate health service. Strict application of patent right would result a total denial of access to the public at large even for those medicines which are or would be detrimental to the survival of human beings. On such cases governments may stand on a baffling cross road of either protecting patent rights or granting access to the public to save lives against patent protected medicines.

The extreme choice of protecting patent rights or public interest to access to patented invention, especially, medicines would have a direct effect of abrogating the protection given for either of the two interests. Thus, it would be better to find a

[11] Universal Declaration of Human Rights, 1948, Art. 25.

solution which could strike a balance between the above discussed two competing interests.

For WTO member countries, TRIPS provides some flexibility which could help to strike a fair balance between patent right and access to medicine. The flexibilities are discussed as follows.

PART III

TRIPS Flexibilities to Facilitate Access to Medicine

Even though TRIPS agreement provides mandatory rules and obligations to be complied with, the agreement leaves different rooms by which member states get a right to provide their own standards and requirements which still adheres to the fundamental obligations the agreement mentions.[12] These flexibilities are considered as an effective tool to facilitate access to affordable medicine if implemented in domestic law through wise legal and policy reforms.[13] Countries like Brazil, India and South Africa used these flexibilities in their reformed TRIPS-compliant intellectual property laws to successfully strike a balance between the need to protect patent rights for pharmaceuticals and public demand to access to medicine.[14]

In order to examine areas where Ethiopian patent law needs a reform, if any, to facilitate access to medicine, it would be wise to explore TRIPS flexibilities which could play a significant role on this regard. The flexibilities under TRIPS agreement are discussed as follows.

A. Defining / Providing Criteria for Patentability

Despite stating that any inventions, whether product or process, in all fields of technology are protected under patent law (provided that they are new, involve inventive step and capable of industrial application[15]), the agreement failed or intentionally left to member states to define what constitutes:

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[12] Carlos M. Correa, "Intellectual property rights and public health: the general context and main trips compliant flexibilities", Intellectual property and access to medicines: papers and perspectives, World Health Organization, P. 20.

[13] Id., pp. 11 – 20.

[14] M. Monirul Azam, "The Experiences of Trips -Compliant Patent Law Reforms in Brazil, India, and South Africa and Lessons for Bangladesh", Akron Intellectual Property Journal, pp. 61 – 99.

[15] Id., Footnote 4, art. 27

- ♣ Inventions

Since what exactly is considered as an "invention" is not defined under the agreement, member states are free to define what constitutes an invention which is protected and a mere "discovery" which is not protected. Therefore member states could use strict line to differentiate mere discoveries from invention; in order not to grant patent protection for some discoveries which may not be considered as invention. On pharmaceutical sector this would help states to prohibit patent right protection for discoveries which couldn't be considered as invention.

- ♣ New (Novelty Standard)

Novelty standard requires the invention to be new in order to get patent protection. However, what constitutes "new invention" is left for member states to define. Therefore, considering their policies, economic advantage and especially its effect of facilitating access to medicine, member states could define novelty as "local novelty" (standard which grants patent protection if the medicine produced is new / hasn't been known in the local market) or "Universal Novelty" (standard which grants patent protection if the medicine produced has not been known universally). Logically speaking, universal novelty requirement helps to facilitate access to medicine because the medicine produced might have been already known / registered in other country; in such a case the medicine might be considered as not new to the world and gets no patent protection. On the other hand if a country follows local novelty standard, there might be a higher chance for the medicine to be considered as "new" because, despite being known to the rest of the world, it might not have entered to the market / known in the country where patent registration is being requested. This narrows access to the medicine because as long as it is new for the market of the country where registration requested, it might get protection despite even being an old fashioned or outdated invention in other countries. Therefore, member states have a right to choose from either of the two novelty standards considering their interest on facilitating access to medicine.

- ♣ Inventive step (Non-obviousness)

Patent protection requires inventors to bring an inventive step to their work in order to invent non-obvious invention. Without involving such steps of innovation, the chance of getting patent protection would be very low. Questions such as, what "constitute

inventive step?" or "what should inventive step involve?" is left to be answered by legislations of member states. This flexibility would help states to have strict laws and standards which require inclusion of significant inventive step to get patent protection rather than simply registering inventions which involve no inventive step or minor and insignificant improvement which contributed very less to consider the medicine produced as "new." Therefore, drafting domestic laws wisely on this regard denies persons who want to get patent protection / monopoly by merely adding insignificant changes on their works.

B. Compulsory License

Compulsory Licensing could be defined as "granting of a license by a government to use a patent without the patent-holder's permission".[16] Under article 31 of TRIPS agreement and "Doha Declaration on The TRIPS agreement and public health"[17] the right to use compulsory license is mentioned as one of the flexibilities recognized under TRIPS system as a tool to facilitate access to medicine.[18] Member states could use compulsory license by subjecting patent-protected medicine to be manifested domestically or imported from abroad without the consent of the patent right holder.[19] Since compulsory licensing gives power to member states to import or domestically manufacture reverse-engineered medicines from the already patented medicine in a domestic market by fulfilling procedural requirements attached to exercising compulsory license.[20]

[16] Sara M. Ford, "Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents", American University International Law Review, vol. 15 , Issue 4, p. 945

[17] Declaration on the TRIPS Agreement and Public health, 2001, Ministerial Conference Fourth Session Doha, 9 – 14.

[18] Ibid.

[19] M. Khor, "Patent, Compulsory License and Access to Medicine: some recent experiences", Intellectual property and access to medicines: papers and perspectives, World Health Organization, P. 87 - 88.

[20] TRIPS agreement, Art. 31 states that: compulsory license could be exercised when;
(a), the government or company authorized should have been unable to get voluntary licensing despite efforts made to get the license on reasonable commercial terms;
(b), when compulsory license sis issued, adequate compensation must be given to the patent holder;
(c), Compulsory license should mainly aim at supplying to the domestic market;
Etc.

Even though, requirements are attached in order to use compulsory license, member states are given the freedom to freely determine grounds upon which such license should be granted.[21]

National emergency, public interest, public health, insufficient exploitation by patent right holder, compulsory license as a punishment for anti-competitive act of patent right holder etc. could be legitimate ground to grant compulsory license against a patent protected medicine. Since there is no exhaustive list of ground, member states could freely determine when and why to grant compulsory license. This highly helps states to exercise a limitative power against the strong monopoly of the patent right holder. Legal reforms of countries such as Brazil and India could be cited as an exemplary effective usage of compulsory licensing flexibility which indeed facilitated access to medicine.[22]

C. Parallel Import

Article 6 of TRIPS agreement is commonly cited as a provision which paves a way for member states to import patent protected goods from abroad without the consent of patent right holder.[23] This free importation right is known as "parallel importation", the import and resale in a country, without the consent of the patent holder, of a patented product that has been legitimately put on the market of the exporting country under a parallel patent".[24] Simply put, parallel importation helps countries to import medicines which are cheaper in international market as compared to the locally existing medicine. This highly discourages domestically monopolized and expensive medicine by patent right holders since member states could easily import the same medicine which is being sold in other country where the medicine is patent protected. Cheaper parallel import would play a positive role on facilitating easier access to medicine with cheap price as compared to expensive but similar medicines. Wise exercising of parallel importation flexibility would threaten local pharmaceutical companies; in effect leading them

[21] Ibid. footnote 17.
[22] Id. Footnote 14, pp. 61 – 99.
[23] Lonias Ndlovu, "Access to Medicines under the World Trade Organization Trips Agreement: A Comparative Study of Select SADC Countries", University of South Africa, 2014, p.143.
[24] Id., P.144.

to reasonable price reduction which may help them to compete or stay in the market viably.

Therefore, using such flexible right of importation, member states could provide an affordable medicine for the public at large.

D. Exceptions to Patent Right

Fulfilling requirement s mentioned on article 30 of TRIPS agreement, member states are free to provide exceptions to exclusive patent rights granted. Experimental and research exception (use of invention to understand and study the innovation for scientific purposes), exception of non-commercial private use, exception of usage for education / teaching the innovation, and *Bolar* / early working / exception (conducting research and experimentation for immediate permission of marketing generic medicines as soon as expiry of patent protection; (this results a serious competition against the previous patented medicine and its generic equivalent) could be cited as examples of exceptional flexibilities under TRIPS system.[25]

Using these exceptional flexibilities could help member states to access usage or resale of the patented medicine without serious challenge form the patent right holder. Therefore, to facilitate access to medicine and to develop researching activities, member states could use the above mentioned exceptions.

E. Pre-Grant / Post-Grant Opposition

Since patent right offers a strong protection for patent right holder, it would be logical to grant this right following strict standard of evaluation. The standard or process of evaluation could also give a chance to those persons who want to oppose registration of patent before or after registry.[26] Grounds such as lack of novelty, lack of inventive step and industrial application, personal claims

[25] Id., Footnote 14.
[26] Ibid.

(contractual or non-contractual dispute) and usage of protected indigenous knowledge etc. could be used as grounds for pre-grant or post-grant opposition.[27] Wider pre-grant and post-grant objection grounds would help to scrutinize novelty of the innovation to be protected and to minimize or avoid the risk of protecting works which may not fulfil a relatively inventive step which may be considered as not enough to give an exclusive patent right against the interest of the public at large to access the medicine.

Therefore, looking at the above discussed TRIPS flexibilities, one could argue that despite the burdensome looking obligations of the agreement, TRIPS also offers a room to exercise a sovereign power to facilitate access to medicine while still protecting patent rights.

F. **Article 31bis (TRIPS amendment on Article 31(f))**

Article 31 of TRIPS agreement is all about providing exceptional right to member states to use patent against the permission of patent right holder, by governments / third parties authorized by government.[28] Such right is commonly cited as "compulsory license". This article articulates detailed rules attached to compulsory license right as preconditions. Among this preconditions, article 31(f) states that compulsory license shall only be authorized predominantly for the supply of domestic market of the member authorizing such use. This specific article vaguely requires member states to use compulsory license predominantly for domestic purpose rather than exportation.

However, the requirement of article 31(f) has been criticized for being a challenge to countries with no or limited capacity in the pharmaceutical sector as they claim that this article denies an opportunity for such countries to import those pharmaceuticals from member states who could produce and export the pharmaceuticals through compulsory license.[29]

Therefore, considering the above mentioned critics, WTO introduced TRIPS amendment on article 31(f). The exceptions added to article 31(f) by the amendment (article 31bis) aimed to address the above critics as follows.

Article 31bis reads as follows:

[27] Ibid.
[28] Agreement on Trade-Related Aspect of Intellectual Property Rights, 1995, art. 31, Section 5.
[29] Pre-amble of Declaration On The Trips Agreement And Public Health, Adopted on 14 November 2001

1. ***"****The obligations of an exporting Member under Article* ***31(f)*** *shall not apply with respect to the grant by it of a compulsory license to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement".*

Looking at the above articulation one can deduce that the amended article allows (1), countries to get access to (import when needed) pharmaceuticals produced or imported under compulsory license in other countries, and (2), export of such pharmaceuticals to the market of other developing or least-developed countries which are parties to a regional trade agreement that share the health problem in question.

Article 31bis came into picture because of two major concerns: (1), article 31(f) of TRIPS prohibits member states from permitting compulsory license to import pharmaceuticals, (2) the same article prohibit exportation on pharmaceuticals produced under compulsory licensing.

Article 31bis rectified the above two problems by (1), allowing countries to grant compulsory license to import a particular drug, (2), to allow exporting countries to export generic drugs to a country that has issued a compulsory license.

To sum up, article 31bis appeared to rescue countries with insufficient or no manufacturing capacity who couldn't use, domestically, their compulsory license right effectively, by allowing such countries to allow compulsory license to import generic drugs. It also legalizes exportation of generic drugs to a country which allowed importation of generic drug through compulsory license. These two amendments paves ways for least developed countries to import generic drugs through compulsory license without being limited to use such right because of their poor economic or technological

capacity to manufacture drugs domestically. The more least-developed and developing countries are allowed to import generic drugs, the more they could address their countries public health concerns; including access to get affordable medicine.

PART IV

The Need to Reform Ethiopian Law to Facilitate Access to Medicine

If Ethiopia still pursues the effort to join to WTO, it will be inevitable for the country to go through some legal reforms in order to have, at least, TRIPS-compliant Intellectual property law or maybe, TRIPS-*plus* (higher / more burdensome obligations than TRIPS). Thus, it would be logical to look into patent related laws which might need a reform in order to facilitate access to medicine for the public by using flexibilities TRIPS agreement offers. Areas of reforms might include:

A. Defining / Providing Criteria for Patentability

- Ethiopian patent law[30] provides requirements for a given invention to get patent protection. The proclamation provides a definition for "invention" and universal novelty standard to acquire patent protection.[31] However, the proclamation failed to clearly state that minor or insignificant changes made on an invention shall not be protected as an "invention". Having clear stand on this regard discourages persons who want to benefit from strong patent protection by merely adding insignificant changes to already existing invention (also known as "ever-greening"). Ergo, it would be wise to include exclusion of minor or insignificant changes on invention as non-patentable invention.
- The proclamation failed to give a power to an independent examination body of expert / qualified organization to strictly examine whether adequate innovative steps are followed, whether the medicine meets novelty standard, and whether patent protection benefits or harms the public. Based on the results of the above examination, the examining body or qualified

[30] Id., Footnote 6.
[31] Id., Art. 2(1) and 3(2).

organization should recommend the concerned commission to grant or decline applications made for patent. This measure helps to follow strict patentability criteria to grant patent only to those medicines which are new and whose patent protection doesn't preclude access to medicine.

B. Compulsory License

Compulsory license system under the promotion no.123/1995 of Ethiopia confines itself to very narrow grounds which justifies compulsory license; (only to cases where access to patented prior or later inventions are detrimental to effective use of a given invention and only on cases where the patent right holder fails to use his invention three years after patent grant or four years after filing application to registration. However, considering the flexibilities under TRIPS system, Ethiopian patent law should widen grounds for compulsory license; for instance: public health, public interest, national emergency, extreme urgency, insufficient exploitation / usage of patent right domestically, anti-competitive act of the patent right holder, etc. could be used as additional grounds for compulsory license. Looking at the experience of countries like Brazil and India, who facilitated access to medicine by having strong compulsory license system with plenty of grounds, Ethiopian law on this regard could benefit from compulsory license system with various grounds for application to get this license. Government should also get a right to exercise compulsory license by itself as long as it fulfils the requirements attached to get such license. Ergo, it seems that the current law needs a serious reform on this regard.

C. Parallel Import

It is very hard to find an article which deals with parallel importation flexibility under Ethiopia patent law. Since parallel importation flexibility plays a significant role on helping the government or private investors who want to import cheaper generic medicine on which the country heavily relies on[32], the law on this regard could have included rules on parallel importation as TRIPS flexibility envisaged. Thus, Ethiopian patent law should include parallel importation of cheap generic medicines to the

[32] Fikremarkos Merso, "Ethiopia's Accession to the WTO: Does it imply anything on Access to Affordable Medicines?", Faculty of Law of Addis Ababa University, Series in Business Law, vol. 2 (2008)

public and in effect, discouraging expensive medicines which have patent protection in the country.

D. Exceptions to Patent Right

Even though, proclamation no. 123/1995 provided exceptions to patent right (acts done for non-commercial use, usage for research and examination etc.), other exceptions such as usage for education, *Bolar* exception (access to knowledge, research and usage of the protected medicine before immediate permission of marketing generic medicines as soon as expiry of patent protection) etc.

E. Pre-Grant Opposition

Ethiopia's patent law failed to clearly provide rules for pre-grant opposition of a certain application. It would be helpful if the law is reformed to give an opportunity for interested parties to oppose patent protection before grant. Lack of novelty, lack of inventive step and industrial application, personal claims and usage of protected indigenous knowledge etc. could be used as grounds for pre-grant or post-grant opposition. Such opposition rights would facilitate access to medicine by challenging protection of medicines which are not worth protecting under in the eyes of patentability, public order, morality etc.

F. Duty / Obligation of Patent Right Holder

Besides being required to work his / her invention in Ethiopia[33], patent right holders may be obliged not to engage in anti-competitive trading activities which directly or indirectly narrows public access to an affordable medicine. Thus, strong competition consumer protection laws and enforcement could be part of the legal reform in order to facilitate access to medicine by prohibiting anti-competitive trade practice.

G. Government Use

The existing patent law failed to give a wider room for the government to exercise or use patented medicine without the consent of patent right holder during extreme urgency or national emergency etc. The government could exercise this exceptional right when:

[33] Id., Footnote 6, Art. Art. 27 (1) & (2)

- ♣ Patent is granted with exception that the government can import generic medicines to the public or private enterprises for non-commercial and commercial use;
- ♣ Government authorizes a domestic or foreign generic medicine producing companies to produce generic medicines of the protected medicine by paying a royalty to the patent right holder;
- ♣ Government acquires full ownership of the patent right by paying compensation

Including such stipulations which gives power to the government could help the government to use by itself or by assigning third parties / agents / to effectively use the exceptional power granted against the patent right holder in order to facilitate access to affordable medicine.

H. **Article 31bis (TRIPS amendment on Article 31(f))**

Since the current patent law is not amended to accommodate change / amendments adopted by TRIPS system to facilitate access to medicine, specifically, with regard to effectively exploiting compulsory licensing system avoiding hurdles which challenges doing so, Ethiopian patent law could benefit from amending its rules to include TRIPS rules of Article 31bis which paves the way for: (1) countries to grant compulsory license to import a particular drug, (2), to allow exporting countries to export generic drugs to a country that has issued a compulsory license.

PART V

Conclusion

As compared to the continuing debate over the right to access to medicine vis-à-vis paten right protection for pharmaceuticals and the rules of Doha Declaration on the TRIPS agreement and public health[34], the 1995 transitional period patent law of Ethiopia[35], failed to effectively address / include all TRIPS flexibilities which could be used as a safety valve to counter balance the overwhelming monopoly patent right

[34] Id., Footnote 17.
[35] Id. Footnote 6.

creates on access to pharmaceuticals. Despite the inclusion of sketchy rules on compulsory license with narrow grounds, narrow exceptions / limitations, relatively weak patentability threshold which don't exclude "ever greening"[36] (attempt to get protection by simply showing insignificant change on existing invention), lack of specific duty on patent right holder to refrain from anti-competitive behavior, relaxed rule against patent right holders who don't exploit their invention without any economic rationale etc. are some of the problems of the existing Ethiopian patent law which failed to harvest the fruits of TRIPS flexibilities utterly. Ergo, it appears so crucial for Ethiopia, a least developed country, to use any flexibility available under TRIPS legal system in order to facilitate eased access to affordable medicine while still adhering to fundamental rules of TRIPS.

Recommendation

Having in mind TRIPS flexibilities and lack of Ethiopian patent law to effectively exercise the flexibilities to facilitate access to medicine, the following legal reforms are recommended.

- Introducing strict / high patentability threshold which discourages attempts of ever greening and grant patent right protection for those inventions which exhibit significant novelty considering universal novelty;
- Ethiopian patent law could benefit from introducing a system of examining patentability of pharmaceuticals by independent body / organization of expert on the area, who could professionally examine the novelty of the invention and check whether the public interest to access to medicine will be better off or worse of the requested patent protection;
- The legal system should introduce a robust compulsory licensee system with various grounds to use patented medicine without the consent of the patent right holder; the wider grounds of compulsory license are, the wider right for the government or third parties to facilitate access to medicine through compulsory license. Compulsory license should also be used as a tool to discourage the act of using patent merely to block usage / importation by

[36] Id. Footnote, 14, p.77.

others acts of abuse of exclusive patent right. Compulsory license system could also help on discouraging the act of excessive pricing, unreasonable terms of contractual license or any other acts which may hamper industrial development;

- The compulsory license system for in action (failure of the patent right holder to work the invention domestically three or four years after patent right protection and filing, respectively) under Ethiopian patent law, could lead patent right holders to freely refrain from working their inventions for three or four years and later on they could justify their inaction giving plenty excuses because the proclamation paves a way for patent right holders to justify their in action by raising "legitimate reasons". Therefore, the law should be reformed to control such technical ways getting patent protection without working the inventions domestically by giving excuses. Narrow or exhaustive list of "legitimate reasons" must be mentioned under the law to regulate abuse.
- Ethiopian compulsory license could also benefit from giving a partial exclusive right for the new license by limiting the exclusive right of the patent right holder (limiting the number of voluntary license the patent right holder could offer could be used as a systematic tool for such purpose);
- Access to medicine could also be easily facilitated if the legal reform includes parallel importation right; the right to import generic medicines without the consent of the patent right holder in order to provide cheap medicine for the public and create a business competition (leading to reduction of price by patent right holder) in domestic market
- Interested parties should also be given pre-grant opposition right on specific grounds to challenge the would be patent protection. Such opposition could help the public to challenge patent protection for inventions which shows insignificant change / novelty or applicability in the field of technology. The more medicines are not protected, the more access to medicine will be facilitated;

- The patent law could facilitate access to medicine and transfer of knowledge if *Bolar* exception (requiring patent right holder to submit documents and work process of his invention for research purpose and eventually immediate sell in the market as soon as the patent protection expires). This exception will easily exhibit and transfer knowledge and help introduction / sell of the patented medicine as soon as its protection expires; in effect creating a competitive market between the expired patent right holder and new sellers of the same medicine;
- Government use exception should be provided to give wider right for the government to purchase / temporarily use patent rights by paying compensation;
- The country's patent could reap the benefit of TRIPS flexibility related to TRIPS article 31bis amendment since this amendment avoided vague and cumbersome requirements attached to compulsory licensing. Ergo, amending Ethiopian patent law to embrace this advantageous amendment, seems a right choice to facilitate access to medicine through using TRIPS flexibilities effectively.

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