PATENT PROTECTION AND PUBLIC HEALTH PROMOTION IN TANZANIA

Nuru Benjamin Komba[*] *& Chacha Mairo*[**]

Abstract

Intellectual property rights refer to intangible rights that are conferred to a person for the protection of his intellectual creation. One of the subsets of intellectual property is patent, which deals with protection of inventions. This article aims at critically analysing the relationship between patent protection and promotion of public health. The article begins by discussing the international legal framework on patent protection and their position on the promotion of public health. Further, the article analyses the measures to be taken by developing countries so as to promote public health in their countries and at the same time ensuring patent protection. An analysis of the Tanzanian legal framework on patent protection and the efforts taken to promote public health follows thereafter. Ultimately, the article draws a conclusion and provides recommendations on what should be done by developing countries so as to effectively promote public health.

Keywords: Intellectual Property, Patent Protection, Public Health, Developing Countries.

[*] Nuru Benjamin Komba, LL. B (Hons), UDSM; PGDLP (LST); LL.M Candidate (UDSM), Tutorial Assistant, University of Dar es Salaam, School of Law. *banjaminnuru94@gmail.com*

[**] Chacha Mairo, LL. B (Hons), UDSM; PGDLP (LST); LL.M Candidate (UDSM), Tutorial Assistant, University of Dar es Salaam, School of Law. *mairochch@gmail.com*

1. INTRODUCTION

Patents refer to the intangible rights that are granted by the government to an inventor for the protection of his invention. The World Intellectual Property Organization (WIPO) defines patent as a document issued by a government office, upon application, describing an invention and creating a legal situation in which the patented invention can normally be exploited with the patent owner's authorization.[1] Innovation is a "social welfare good" that has value both for producers (inventors) and consumers, to expand their choices and improve their general wellbeing, for instance through improvements in health care.[2] Patent protection is credited with a number of functions but the most celebrated one is the incentive function. That means, with patent protection the inventor is being rewarded for coming up with his invention by conferring him economic rights which enable him to recoup the expenses that were incurred by him in making such an invention. In the absence of the incentive function, there would be less innovations than society desires, therefore in return for the inventions, the society grants a time-limited monopoly on new inventions.[3]

The granted time-limited monopoly to a patent holder makes one to have control over the production, supply, distribution and even price by virtue of exclusivity. However, this may have a negative impact when it comes to the promotion of public health by ensuring easy access to essential medicines, vaccines, medical equipment and

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1 WIPO, "WIPO Intellectual Property Handbook", (2nd Edn.), WIPO Publication No. 489 (E), WIPO, 2004, at p.17.

2 Abbott, F. M., "First Report (Final) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation", 1(4), *Journal of International Economic Law*, 1998, p. 607, at p. 613.

3 Commission on Intellectual Property Rights, Innovation and Public Health, *Public Health, Innovation and Intellectual Property Rights*, Geneva, WHO, 2006, at p. 19.

machines. For example, in order to recover the expenses incurred in coming up with an invention, the patent holder for pharmaceutical products may set high prices for medicines. These high prices may not be easily afforded by a lower-income person. Medicine prices in developing countries are often above the production costs.[4] In order to safeguard the interest of the public, a country may override patents in order to promote public health objectives, one of them could be access to medicines.

In the health sector, denial of affordable access to treatment or pharmaceuticals can have death consequences. In this situation, conditions such as price that determine access to medicine are critical especially for the low-income segments of the population.[5] According to the World Health Organization (WHO) Report of 1998, a large part of the world population still lacks access to essential medicines, and a good example is the poorest parts of Africa where over 50 per cent of the population lack that access.[6] An estimated 1.5 billion people are not expected to survive to the age of 60 and more than 880 million people lack access to health care.[7] Again, according to the United Nations Programme on HIV and AIDS (UNAIDS) Report of 1998, the world has more than 33 million HIV positive people and 95 per cent of them live in developing countries and most of them cannot afford the necessary drugs.[8]

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4 WHO, *Intellectual Property Protection: Impact on Public Health*, 19(3), *WHO Drug Information*, 2005, at p. 236.

5 Correa, C., *Integrating Public Health Concerns into Patent Legislation in Developing Countries*, Geneva, South Centre, 2000, at p. 2.

6 *Ibid*, at p. 6.

7 United Nations Development Programme, *Human Development Report*, New York, Oxford University Press, 1999, at p. 4.

8 Correa, C., *Integrating Public Health Concerns into Patent Legislation in Developing Countries,* Geneva, South Centre, 2000, at p.7.

2. INTERNATIONAL LEGAL FRAMEWORK ON PATENT PROTECTION

This part provides an analysis of the international legal instruments that address the aspect of patent protection as well as their position regarding the promotion of public health. The part discusses the link between the exclusive nature of patent rights to an inventor as provided for in international legal instruments and justification for limitation of such rights, precisely on public health considerations.

2.1 Agreement on Trade Related Aspects of Intellectual Property Rights, (TRIPs Agreement) 1994

TRIPs Agreement is an international agreement under the World Trade Organisation (WTO), an international organization that deals with the rules of trade. In joining the WTO, members adhere to various agreements regulating trade and their related aspects, TRIPs Agreement being one of them. TRIPs Agreement establishes minimum standards for a set of intellectual property rights that WTO members' institutions through national legislation should adhere to. Under this agreement members are required to make patents available for any invention in all fields of technology without discrimination.[9] This is aimed at ensuring that, intellectual creations of the inventor are recognized and protected as an incentive function.

Despite this recognition of patent protection, TRIPs Agreement on the other side allows member countries to refuse the grant of patent protection in order to protect *ordre public* or morality, including

[9] Article 27(1), Agreement on Trade Related Aspect of Intellectual property Rights, 1994.

protection of human life and health.[10] The purpose of this provision is to ensure that sufficient medicines are available in generic forms in a competitive market, which has a positive impact on prices. The TRIPs Agreement also enumerates a number of things that may be excluded from patentability such as diagnostic and therapeutic methods of treatment of humans or animals.[11] The objective of this provision is to maintain a broad public domain for the promotion of access to affordable health products through both importation and local pharmaceutical production of high quality generic medicines.[12]

With patent protection, TRIPs Agreement highlights a number of rights that are to be conferred to the patent holder such as the right to prevent others from exploiting the patented invention by manufacturing, selling, or exporting it.[13] The conferred rights, however are not absolute because member countries are allowed to provide exceptions to those rights so long as the exceptions do not conflict with the normal exploitation of such inventions.[14] From this position, member states to the Agreement, including developing countries are given a room to impose exceptions to the conferred rights, so as to meet different aims one of them being promoting public health.

TRIPs Agreement further allows a degree of flexibility and sufficient room for countries, especially developing countries to accommodate their own patent and intellectual property systems and developmental needs.[15] This provision is used by developing

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10 Article 27(2), i*bid*.
11 Article 27(3), *ibid*.
12 EAC, *Regional Intellectual Property Policy on the Utilization of Public Health-related WTO-TRIPs flexibilities and Approximation of National Intellectual Property Legislation*, Arusha, EAC, 2013, at p.14.
13 Article 28, Agreement on Trade Related Aspect of Intellectual property Rights, 1994.
14 Article 30, *ibid*.
15 Article 66(1), *ibid*.

countries to enact patent laws that are perfectly applicable to them so as to meet different purposes like promoting public health.

2.2 Doha Declaration on TRIPs Agreement and Public Health (Doha Declaration), 2001

This Declaration was adopted by WTO members in 2001. It was adopted for the purpose of clarifying the ambiguities between the need for governments to apply the principles of public health and the terms of the TRIPs Agreement. This was done following the growing concerns that patent rules might restrict access to affordable medicines for populations in developing countries, in their efforts to control diseases of public health importance such as HIV, tuberculosis and malaria.[16] The Declaration recognizes the gravity of the public health problems affecting many developing and least developed countries[17] and that is why it focuses more on the flexibilities that these countries are accorded with under the TRIPs Agreement. This focus is crucial since it is these flexibilities which guarantee the balance between the exclusive patent rights and the interests of the public, consumers and competitors.[18]

Doha Declaration recognizes that intellectual property protection is important for the development of new medicines and its effects on prices.[19] The Declaration further refers to several aspects of TRIPs Agreement. They include, the right to grant compulsory licenses and freedom to determine the grounds upon which the licenses can be granted, the right to determine what constitutes a national

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16 WHO, *Intellectual Property Protection: Impact on Public Health*, 19(3), *WHO Drug Information*, 2005, at p. 236.

17 Paragraph 1 of the Doha Declaration.

18 UNAIDS, *Doha +10 TRIPS Flexibilities and Access to Antiretroviral Therapy: Lessons from the Past, Opportunities for the Future*, Geneva: UNAIDS, 2011, at p. 7.

19 Paragraph 3 of the Doha Declaration.

emergency and circumstances of extreme urgency.[20] Doha Declaration states that, TRIPs Agreement does not and should not prevent members from taking measures to protect public health.[21]

Member countries are urged by the Doha Declaration to use the available flexibilities under the TRIPs Agreement, for the promotion of public health. This should be done through ensuring easy access by the public to essential medicines. Members are also allowed to refuse granting or enforcing patents on pharmaceuticals and protection of undisclosed data.[22]

3. MEASURES TO BE TAKEN BY DEVELOPING COUNTRIES IN PROMOTING PUBLIC HEALTH

Innovation is a social welfare good hence, a country should strive to protect patents. This is because, the society desires at all times to have as many innovations as possible. However, in granting such protection the respective country must also ensure that the society is not deprived of any public interest that arises out of those innovations. In implementing the second obligation, the government of the respective country must take aboard several key issues when drafting or implementing its intellectual property laws so as to promote public health. These key issues are succinctly discussed below:

3.1 Parallel Importation (Exhaustion Principle)

This is the importation without the patent holder's authorization of a patented product that is marketed in another country either by the

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20 Paragraph 5(b) and 5(c), *ibid*.
21 Paragraph 4, *ibid*.
22 Paragraph 7, *ibid*.

patent holder's or without the patent holder's authorization.[23] Under this principle, once a patent holder sells the patented product in an open market, he cannot prohibit any subsequent resale of that product. This is because, the rights in respect of that market have been exhausted by the selling of the product.

This principle is amongst the key issues to be considered by a country so as to promote public health. The reason behind is that, many patented products are sold at different prices in different markets. Parallel importation thus enables the importation of the patented products at a lower price since there are substantial price differences between the same pharmaceutical products sold in different markets. Hence, a state can use this principle as a tool for enabling access to affordable medicines.[24]

It is important to note that, parallel importation of patented products produced abroad is allowed upon meeting two requirements. That is, the patented products should be produced with the authorization of the domestic patent owner and the products should be subsequently sold without any clear notice of restriction by the owner.[25] This rule applies regardless of the existence of any patent rights in the exporting country.

Parallel importation works efficiently and effectively when countries adopt an "international exhaustion" regime. The regime allows the importation of patented products marketed anywhere in the world. The TRIPs Agreement leaves member countries with mandate to

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23 WHO, *Intellectual Property Protection: Impact on Public Health*, 19 (3) *WHO Drug Information*, 2005, at p. 240.

24 *Ibid*, at p. 240.

25 Heath, C., *Parallel Imports and International Trade*, Munich, Max Plank Institute for Foreign and International Patent, Copyright and Competition Law, at p. 3.

decide on the issue of exhaustion.[26] This flexibility can therefore be used by developing countries to adopt an international regime on exhaustion principle so as to promote public health.

3.2 Compulsory Licenses

Under a compulsory license, a competent government authority is allowed to license to a third party or a government agency the use of a patented product without the consent of the patent holder. A compulsory license can be used to authorize the importation, production and sale of a generic version of a patented product before relevant patents expire. A country may authorize the production of drugs in order to deal with a national emergency and the supply of the generic version of the medicine at a lower price and a greater quantity.[27]

The TRIPs Agreement lays down a number of conditions for the grant of a compulsory license such as seeking the patent holder's consent before the grant, and remunerating the patent holder.[28] However, in the event of addressing a national emergency or other circumstances of extreme urgency, those conditions are waived in order to hasten the process. As another condition, TRIPs Agreement[29] requires the granted compulsory license to be used for the domestic market only and not for the export market. The WTO General Council Decision of 2003[30] provided for a compulsory license exclusively for export whereby a manufacturing country was allowed to export generic versions of patented pharmaceutical products to a country with no or little manufacturing

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26 Article 6 of TRIPs Agreement.

27 Guennif, S., *One Size Fits All but which one? From TRIPs Agreement to "TRIPs Plus" agreements: Intellectual Property Rights Regime and Access to Medicines in Developing Countries*, France, 2007, at p. 4.

28 Article 31 of the TRIPs Agreement.

29 Article 31(f), *ibid*.

30 The decision concerned the implementation of Paragraph 6 of the Doha Declaration.

capacity of its own under a compulsory license issued primarily for export purposes.[31]

On the other hand, the Doha Declaration, 2001 gives flexibility to the countries to determine the grounds upon which a compulsory license can be granted and to determine what amounts to a national emergency or other circumstances of extreme urgency. This provision therefore gives a room for the developing countries to provide for the situations under which the government can grant compulsory license, and that may include the protection of public health. Developing countries in promoting public health must therefore include the issue of compulsory license in their patent laws. Normally, compulsory licenses are listed as exceptions to the rights conferred to the patent holder.

3.3 A "bolar" provision (regulatory review exception)

Bolar provision is a provision which allows the testing and regulatory approval of generic versions of a medicine before the patents related to it expire. This provision allows a potential competitor to use the patented invention, to undertake acts which are necessary for obtaining regulatory approval and registration of a generic product. The registration is made before the expiry of the patent term with the patent owner's permission.[32] By this provision, generic manufacturers are allowed to start marketing their products immediately upon the expiry of relevant patents.[33]

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31 The Decision was reflected in the amendment to the TRIPs Agreement in the form of Article 31*bis*, which came into effect in January 2017.

32 UNAIDS, *Doha +10 TRIPS Flexibilities and Access to Antiretroviral Therapy: Lessons from the Past, Opportunities for the Future*, Geneva, UNAIDS, 2011, at p. 8.

33 WHO Regional Office for South-East Asia, *Public Health Protection in Patent Laws: Selected Provisions*, UHC Technical Brief, WHO, 2017, at p. 2.

This provision is normally incorporated in the domestic laws under the rights conferred by the patent and/or the exceptions to the rights conferred. If this provision is not incorporated in domestic patent laws, then generic manufacturers may only start the process of testing and registering their products after the end of the patent term. This will be time consuming and consequently, there will be a delay in the actual marketing of generic medicines.

3.4 Exercising the "least developed countries exemptions"

The least developed countries exemptions are the "2021 and 2033 transition periods". Under these exemptions, WTO member countries that are least developed enjoy the two transition periods under the TRIPs Agreement, 1994 and Doha Declaration, 2001. Firstly, developing countries enjoy a transition period not to apply the provisions of the TRIPs Agreement except Articles 3, 4 and 5 for a period of ten years from the date of application. Secondly, developing countries have a right to refuse the granting and/or enforcement of patents on pharmaceuticals and protection of undisclosed data until 1st January 2033. This transition period grants more time to the developing countries to fine tune their intellectual property regime according to their needs.

The TRIPs Agreement, provides for the transition periods which are available to the least developed countries[34] while paragraph 7 of the Doha Declaration gives flexibility to those countries to refuse to grant and/or enforce patents on pharmaceuticals and protection of undisclosed data.

These transition periods and exemptions should effectively be used by developing countries in their domestic patent laws so as to promote public health. Least developed countries benefit from

[34] Articles 65(2) and 66, of TRIPs Agreement.

these transition periods in two main ways. One, they can obtain medicines at generic prices since no patents on pharmaceuticals are granted and two, by not granting patent on pharmaceuticals as they can trigger the development of a generic industry to supply low-cost medicines.[35] Under domestic patent laws, these transitions and exemptions are often stated under matters excluded from patentability.

3.5 Incorporating an "anti-ever greening" clause

The term "ever greening" describes patenting strategies that are normally intended to extend patent protection over the same compound. Under this situation, companies file and obtain patents, subsequent to the original patent, on other aspects of the same compound or on formulations of the original compound that do not have incremental therapeutic value but which are deemed patentable under some patent laws.[36]

These additional patents that are granted on aspects of the same compound of the original compound tend to delay the marketing of generic versions of products. Consequently, this negatively affects public health because generic versions of medicines will not enter into the market when the patent term expires. A good example can be seen from the patenting of a similar but different dosage form, like the use of capsules rather than tablets.

In drafting or revising their patent laws, it is important for the developing countries to consider ever greening issue by incorporating the anti-ever greening clause which normally prohibits

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35 UNAIDS, *Doha +10 TRIPS Flexibilities and Access to Antiretroviral Therapy: Lessons from the Past, Opportunities for the Future*, 2011 p. 10.

36 WHO Regional Office for South-East Asia, *Public Health Protection in Patent Laws: Selected Provisions*, UHC Technical Brief, WHO, 2017, at p. 4.

the grant of new patents over the same patented compounds. Anti-ever greening clause is often incorporated under the patent laws on the aspect of matters not considered as inventions, for instance new uses or methods of treatment. India is the first country that incorporated in its patent law a provision that aimed at preventing the grant of "ever greening" patents in 2005, and it was followed by Philippines in 2008 and Indonesia in 2016.[37]

3.6 Appeals should not Suspend Compulsory Licenses

Compulsory licenses are normally granted by a competent government authority to a third party or a government agency. They are granted to authorize the exploitation of the patented product without seeking the patent holder's consent nor remunerating him. A compulsory license is granted in order to address a certain national emergency or another circumstance of extreme urgency. Under this arrangement, it is expected that the patent holder may wish to appeal against such grant by the government authority.

In order to promote public health when the above circumstances occur, it is very crucial for the developing countries to clearly specify in their patent laws that appeals against the grant of compulsory licenses shall not suspend the execution of those compulsory licenses. The license shall continue to be executed and at the same time the appeal be heard. If this issue is not specified under patent laws, appeals may be able to prevent or delay the implementation of a compulsory license for such time when the review of the appeal is pending. In most jurisdictions, especially in developing countries, an appeal may take several months or years to be concluded. When the decision to grant compulsory license is upheld, the purpose of the license could have been undermined and the time during pendency of the appeal could have caused irreparable harm and

[37] *Id*, at p. 5.

serious implications on public health. It is equally important that, while the right to redress is made available to the patent holder, its exercise should not be in jeopardy of the general public.

3.7 Avoiding Criminal Sanctions in Infringement Cases

Patent infringement refers to the exercise of the patent rights by a person without an authorization of the patent holder. Under this situation the patent holder is entitled to institute a proceeding against such person (the infringing party) for the alleged infringement. In the suit, the patent holder can claim a number of reliefs such as damages, injunctions and confiscation from the relevant authorities. It is recommended that countries should try to avoid in their domestic patent laws criminal sanctions in infringement cases.

There might happen a situation whereby generic suppliers or public health authorities may inadvertently infringe a patent. In this situation, criminal sanctions may appear to be too harsh, and fear or threat of criminal prosecution could unduly deter authorities and others from supplying and using generic medicines that in fact do not infringe the patent rights. The fear to use or supply will undoubtedly affect significantly the community that is in need of essential medicines.[38]

3.8 Allowing Patent Opposition

In drafting or revising domestic patent laws, developing countries should also consider to include a provision that allows patent opposition. An opposition can be made before the grant of the patent (pre-grant opposition) or after the grant (post-grant

[38] *Id*, at p. 6.

opposition).[39] A country should further provide the grounds upon which opposition may base, which may lead to cancellation or invalidation of a patent.

Patent oppositions normally allow the opponent to challenge patent applications or the granted patents on critical medicines which have an effect on public health. For example, the ground that the invention is not new[40], the patent has expired[41] or the invention is not patentable.[42]

4. ANALYSIS OF THE TANZANIAN PATENT LEGAL FRAMEWORK ON THE PROMOTION OF PUBLIC HEALTH

Tanzania is a United Republic consisting of two Governments, the Government of Tanganyika and Zanzibar.[43] Intellectual property in Tanzania is not a union matter.[44] Tanzania Mainland has its own intellectual property regime that is the Patent (Registration) Act[45] and so does Zanzibar which has the Zanzibar Industrial Property Act[46]. In making an analysis of the legal framework in Tanzania, we have taken on board both parts of the union in examining the extent to which the two governments promote public health in their patent legislation.

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39 WHO Regional Office for South-East Asia, *Public Health Protection in Patent Laws: Selected Provisions*, UHC Technical Brief, WHO, 2017, at p. 5.

40 An invention has to be new for it to be patented as required under Article 27 (1) of the TRIPs Agreement.

41 Article 33, *ibid*.

42 Article 27 (3), *ibid*.

43 Article 2 (1) of the Constitution of the United Republic of Tanzania, 1977 [Cap 2 R.E. 2002].

44 This is the case since it is not included in the list of union matters as stipulated in the First Schedule to the Constitution of the United Republic of Tanzania, 1977 [Cap 2 R. E. 2002].

45 [Cap, 217 R. E. 2002].

46 Act No. 8 of 2008.

4.1 On Parallel Importation (Exhaustion Principle)

The Patent (Registration) Act which governs patent matters in Tanzania Mainland provides for a national exhaustion regime.[47] Under this regime the patent holder will be said to have exhausted his patent rights when an article is sold in the market in the United Republic. This arrangement which makes parallel importation as a means of promoting public health in Tanzania seems to be ineffective. This is because Tanzania Mainland will not be able to import the patented products which are sold in a lower price in other markets outside Tanzania since the patent holder has not exhausted his rights from those international markets. To import those patented products, Tanzania Mainland will be required to seek an authorization from the patent holder, something which hinders promotion of public health in situations of national emergency.

However, parallel importation is expressly allowed under section 73 (2) of the Tanzania Food, Drugs and Cosmetics Act[48] whereby the Tanzania Medicines and Medical Devices Authority (TMDA) is allowed to authorize any person issued with a license or permit to import any drugs into Tanzania Mainland. These two conflicting positions leave Tanzania in a dilemma on the issue of parallel importation in situations of national emergency. This is because, it is not clear on what position will the country stand on: whether to comply with the Patent (Registration) Act or the Tanzania Food, Drugs and Cosmetics Act since it is not known under that situation which law should take precedence.

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47 Section 38 (2), [Cap 217 R. E. 2002].
48 Act No.1 of 2003.

Under the Zanzibar Industrial Property Act, the patent holder will be said to have exhausted his rights if the patented product is sold on the market in any territory or country.[49] Zanzibar undoubtedly has adopted the international exhaustion regime under which parallel importation works most effectively. This means that, Zanzibar is able to highly promote public health through parallel importation in situations of a national emergency.

4.2 Regarding compulsory licenses

As a way of promoting public health, Tanzania Mainland patent laws limit the rights of the patent holder by subjecting them to the provisions on compulsory licenses.[50] The Patent (Registration) Act gives the Minister responsible for Trade the mandate to grant a compulsory license on patented products which have been declared to be of vital importance for, among others public health.[51] Furthermore, the Act[52] gives power to the Minister to allow the exercise of the patent rights over the patented product without the authorization of the patent holder where a vital public interest, including public health so requires. In a view of promoting public health, Tanzania mainland has incorporated compulsory license provisions in a sufficient manner by clearly elaborating the authority responsible for granting the license, the conditions for the grant and what amounts to national emergency and/or public interest.

In Zanzibar, the Zanzibar Industrial Property Act requires the Minister to issue a compulsory license to a government agency or any other person over the patented product where the public interest requires, and by public interest public health is also

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49 Section 12(4) (a) (i), Act No. 8 of 2008.
50 Section 38 (5), [Cap 217 R. E. 2002].
51 Section 55, *ibid*.
52 Section 62, *ibid*.

included.[53] Again, the Minister is allowed to do the same when the invention is not available in Zanzibar in sufficient quantities or quality and/or in reasonable prices whether by manufacture in Zanzibar or by importation. From these two provisions, it can clearly be gathered that Zanzibar has gone further in considering the issue of unreasonable prices as a hindrance to access to essential medicines that is why when the imported patented products are sold at unreasonable prices, the Minister may issue a compulsory license as a means of promoting public health.

4.3 Regulatory review exception ("bolar" provision)

In Tanzania Mainland, the "bolar" provision seems to be provided by the Patent (Registration) Act[54] under a section that provides for exploitation of the patented product for scientific research as one of the limitations to the rights conferred by a patent. By allowing the patented product to be exploited for scientific research it means that the law acknowledges the importance of testing the specific patented product before its patent term expires. When this is done, the manufacturing and supply of generic versions of the product will take less time once its patent term expires. This in turn promotes public health as people will have access to the generic versions of medicines as soon as the patented medicines go into the public domain.

The Zanzibar Industrial Property Act on the other hand accommodates "bolar" provision as well whereas the law limits the patent rights of the patent holder when any of the rights is exercised for experimental purposes.[55] Again, the purpose is to ensure that the testing and regulatory approval is done earlier before the patent

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53 Section 14(1) (a) (i), Act No. 8 of 2008.
54 Section 38 (1), *ibid*.
55 Section 12(4) (a) (iii), *ibid*.

term terminates, so as to ensure easy access to the generic versions of the patented product.

4.4 Appeals not to suspend compulsory licenses

Zanzibar has clearly stated in its patent law that an appeal against the decision to grant a compulsory license shall not suspend the execution of such license.[56] The Act provides that, the patent holder whose patented product has been granted a compulsory license is only entitled to recovery of remuneration.[57] It further provides that, patent holder's appeal shall not stay or suspend the execution of the issued compulsory license.[58] As discussed under Part 3 above, the main essence of a provision on appeals not suspend compulsory licenses is to ensure that an appeal does not act as a hindrance to serving public interest. It is coached so as to ensure the promotion of public health during national emergencies or other extreme urgency circumstances.

To the contrary, Tanzania Mainland patent law, is silent on this issue. The Patent (Registration) Act provides nothing with regard to appeals against the grant of compulsory licenses. This *lacunae* brings a challenge when the patent holder protests against such grant. The underlying assumption is that, the execution of compulsory license will have to be stayed pending determination of the appeal. Staying the execution will significantly undermine the promotion of public health in situations of national emergencies.

4.5 Anti-ever greening clause

Concerning the extension of patent protection over the same compound, the Patent (Registration) Act, considers methods of treatment of humans and animals as not inventions that are

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56 Sections 14(11) and 73(3), *ibid*.
57 Proviso to Section 14 (1) (a), *ibid*.
58 Section 73 (3), *ibid*.

patentable.[59] This is to ensure that no person obtains a patent subsequent to the original patent on other aspects of the same compound or on reformulations of the original compound. The aim is to precisely fasten marketing of generic versions of the patented products once the original patent term expires.

Zanzibar has taken a similar stance by excluding from patent protection methods of treatment of human body. These methods are not regarded as inventions hence not patentable.[60] Zanzibar has gone further by also excluding discoveries and new uses or forms of known product or process.[61] All these provisions are regarded as anti-ever greening clauses which seek to promote public health.\

4.6 Concerning Transition Periods (Least Developed Countries Exemptions)

The Zanzibar Industrial Property Act has promptly exercised the exemptions that are available to the least developed countries by excluding pharmaceuticals from patent protection until the transition period for the least developed countries come to an end.[62] Furthermore, inventions whose prevention is necessary to protect public order and morality like protection of human life and health, are also not patentable in Zanzibar.[63]

Tanzania Mainland has not directly exercised these exemptions as compared to Zanzibar. The Patent (Registration) Act excludes from

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59 Section 7(2) (d), [Cap 217 R.E. 2002].
60 Section 3(iii), Act No. 8 of 2008.
61 Section 3(i) and (v), *ibid*.
62 Section 3(x), *ibid*.
63 Section 3(ix), *ibid*.

patent protection the methods for treatment of human body.[64] This exclusion is interpreted to infer that pharmaceuticals are not patentable in Tanzania Mainland. It can be observed that unlike Zanzibar; Tanzania Mainland does not expressly exclude pharmaceuticals from patent protection as a means of promoting public health.

4.7 Patent Oppositions

In order to promote public health, it is important to ensure easy access to essential medicines. The Patent (Registration) Act allows any person to institute proceedings for invalidation of a patent which has been granted.[65] The law goes on to provide the grounds that can be relied upon by such person seeking the invalidation of a patent.[66] This means that, Tanzania Mainland allows post-grant opposition because a person has a chance of opposing the patent only when it has been granted, and not before the grant of such patent. This may bring challenges in the promotion of public health because the patented product might be of vital importance for public health at the time of patent application. Since pre-grant oppositions are not allowed, then a person has to wait until such time that a patent is granted. After grant, one can oppose by seeking invalidation of such patent. The dangers are that the purpose for such an action may no longer be necessary as the public might have been negatively affected already. However, it is important to note that there are very few incidents of reported patent oppositions. This may suggest either of the two things, one is that patents are rightly granted, and two is that the public is not aware of patent issues and therefore cannot oppose to the patents.

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64 Section 38 (2), [Cap 217 R. E. 2002].
65 Section 64 (1), [Cap 217 R.E. 2002].
66 Section 64 (1) and (2), [Cap 217 R.E. 2002].

To the contrary, Zanzibar accommodates both, pre-grant and post-grant patent oppositions as clearly seen in the Zanzibar Industrial Property Act.[67] This position works perfectly as a means of promoting public health because a person has an opportunity of opposing the grant of a patent and also seeking its invalidation when there is an extreme need of promoting public health during national emergencies.

5. CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion

The principles of public health in the context of access to medicines are supported by a range of national and international legal and policy instruments, for instance, the Doha Declaration on the TRIPs Agreement and Public Health, 2001. It has been observed that, protection of patent in the society is very important because always the society desires to have new inventions. However, public health promotion and protection is important that is why countries have incorporated in their domestic patent laws measures that seek to promote public health by ensuring easy access to essential medicines.

Most of the pandemic diseases affect developing countries and these countries face challenges in fighting them because of high prices of the medicines that are used to cure those diseases. This makes a large part of the low-income population to fail in accessing essential medicines. It is crucial therefore to adopt the above discussed measures so as to successfully promote public health and at the same time ensuring patent protection.

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[67] Section 10 (7) (a) and 16 (1) & (2), Act No. 8 of 2008.

5.2 Recommendations

Having analysed the measures that are to be taken by developing countries in promoting public health, this article recommends the following:

5.2.1 Careful Consideration of the Regulatory Measures

Regulatory measures that affect public health for example, those relating to approval and registration of medicines should be given a careful consideration. The careful consideration of regulatory measures will assist in developing a consistent legal framework that enhances access to the required medicines.

5.2.2 Incorporating all Necessary Measures to Promote Public Health

Developing countries are encouraged to ensure that they incorporate all the necessary measures that seek to promote public health. This will ensure that, no room is left for a patent holder to refuse exploitation of his patented product in promoting public health especially during the times of national emergencies and other circumstances of extreme urgency.

5.2.3 Promoting Public Awareness on Patent Issues

Many people in developing countries are unaware on intellectual property, let alone patent. The governments in developing countries are urged to ensure that, the public is made aware of intellectual property issues, including patent. When the public is made aware of the subject matter, they will strive to come up with different new inventions that might be of extreme importance on the health sector. The public will also be able to participate in patent opposition and invalidation for those inventions that are not patentable but are crucial for public health.