COMPULSORY LICENSING AND PARALLEL IMPORTS UNDER THE PATENT LEGAL REGIME AND THEIR IMPLICATION ON ACCESS TO MEDICINES IN TANZANIA

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Abstract

This article examines the legal position in Tanzania regarding compulsory licensing and parallel importation as well as their implication on access to medicines, one of the fundamental components of the right to health. In this respect, the article reveals that the Patent Registration Act, the principal law regulating patent issues in Tanzania, contains extensive provisions on compulsory licensing which if effectively utilised, can have a positive implication on ensuring accessibility of affordable medicines. The article however, notes that despite the existence of such provisions, the country has to date, not issued any compulsory license in relation to medicines. Regarding parallel importation, the article submits that the principle is not applicable under the current patent regime thereby hindering the importation of affordable generics something that poses a threat on universal access to medicines in the country.

Keywords: *Access to Medicines, Compulsory License, Generics, Parallel Importation, Patent Flexibilities*

1.0 Introduction

Despite the fact that medicines are indispensable in improving our health situations, to date, their accessibility remains one of the most serious global health problems. It is estimated that over two billion people globally lack access to medicines.[1] The problem of the lack of access to medicines does not only lead to immense sufferings, but also, to deaths of millions of people around the globe.[2] This problem is more acute in the Least Developed Countries (LDCs) and developing countries as most of those who suffer and die from lack of access to medicines live in Africa and Asia.[3] In this respect Lazzarini notes that, "if you live in a poor country, you are much more likely to suffer early sickness, disability, and death than if you live in a rich country."[4] Tanzania being one of the LDCs, it is not an exception to the problem of lack of access to medicines.

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WHO, 'The 2016 Access to Medicine Index: Methodology Report 2015,' at 6, available from http://apps.who.int/medicinedocs/documents/s22176en/s22176en.pdf (accessed on 9 May 2017). See also P, Hunt, 'Promotion and Protection of all Human Rights, Civil, Political, Economic, Social and Cultural Rights, Including the Right to Development,' *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Health*, Mission to GlaxoSmithKline, A/HRC/11/12/Add, 2009, para 2.

2 See generally C. Oh, 'TRIPS, Patents and Access to Medicines: Proposal for Clarification and Reform,' *Third World Network Briefing Paper*, 2001, available from http://www.twn.my/title/drugs2.htm, (Accessed on 19May 2017); K. Wiedenmayer, 'Access to Medicine Supply: Lessons Learnt in Tanzania and Mozambique,' 2004, available from apps.who.int / medicinedocs/documents / s18422en / s18422en.pdf, (Accessed on 18 May 2017).

3 B.K, Twinomugisha, *Fundamentals of Health Law in Uganda* (Pretoria: Pretoria University Law Press, 2015), at 54. See also P, Hunt, *loc. cit fn* 1; P.L, Osewe *e atal, Improving Access to HIV/AIDS Medicines in Africa*: *Trade Related Aspects of IPRs Flexibilities*, (Washington: the World Bank, 2008), at 1.

4 Z. Lazzarini, 'Making Access to Pharmaceuticals a Reality: Legal Options under TRIPS and the Case of Brazil,' 6 *Yale Human Rights & Development Law Journal*, (2005), at 104.

Medicines are indispensable for the wellbeing of any society as they are the main vehicle for delivering therapy to fight diseases and enhance the quality of life. This being the case, although this article does not intend to argue that ensuring accessibility of medicines for all is the only solution to eradicate health related problems in poor countries, yet, as a matter of fact, the role that medicines can play in treating diseases and alleviating sufferings resulting from such diseases, cannot be underestimated. Most of these diseases and sufferings are preventable, treatable or alleviated with the supply of affordable needed medicines. Therefore, in order for a fight against ill health to produce the desired outcomes, facilitation of access to medicines is inevitable. It is not in dispute that the problem of access to medicines in poor countries like Tanzania is a multifaceted one. However, one of the main obstacles towards universal access to medicines is lack of their availability and higher prices. In most cases the cost for medicines is unbearable especially in poor countries like Tanzania where majority of people are not covered under health insurance schemes.

One of the reasons for the problem of high prices of medicines in both LDCs and developing countries is the issue of granting patent protection on pharmaceuticals. This is because; patents bestow on their holders, exclusive rights to exploit patented inventions in this case medicine.

Patent is a form of Intellectual Property Rights (IPRs) that is granted to inventors for a specific period of time.[5] This right enables such inventors to exploit their invention to the exclusion of others for the whole period of patent.[6] As a general rule, a person who wishes to exploit any patented invention before the expiration of the patent term has to first seek and obtain the authorisation from the patent owner. Generally speaking, it is upon the expiration of the patent term, the patented invention becomes available for a public consumption.

The exclusive right granted to patentees gives them the legal monopoly over the patented invention whether a product or a process. This monopoly enables such patent holders set high prices on the ground that they are recouping their investments costs and this continues until expiration of a patent term when prices go down as a result of competition from generics.[7] High prices of medicines keep them out of the reach of the poor and marginalized. It is on this ground it is argued that patents have been increasingly posing a great challenge on access to medicines by the poor population.[8]

However, it should be noted that the prohibition imposed upon third parties to exploit patented invention is not absolute. There are certain circumstances under which the Intellectual Property (IP) law allows the exploitation of patented inventions even before the expiration of the patent term. Simply stated, patent law contains certain exceptions under which a patented invention can be exploited

5 See C.M, Correa, 'Implications of Bilateral Free Trade Agreements on Access to Medicines,' 85 *Bulletin of the World Health Organization*5, (2006), at.399 and WIPO, *Intellectual Property Hand Book: Policy, Law and Use*, at. 17.

6 *Ibid*.

7 P, Cullet, 'Patents and Medicines: The Relationship between TRIPS and the Human Right to Health,' 79 *International Affairs*1, (2003), at.141 & 143.

8 See, C.M, Correa, *op. cit fn* 5 at.399. See also J, Crook, 'Balancing Intellectual Property Protection with Human Right to Health,' 23 *Berkeley Journal of International Law* 3, (2005), at 529.

before the expiration of a patent term. These exceptions or options are what are referred to under the patent legal regime as patent flexibilities.

There are numerous patent related flexibilities which are recognised under the current international IP regime. These are entrenched under the World Trade Organisation (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (the TRIPS Agreement).[9] Some of these flexibilities are the compulsory licensing and parallel importation. Most of these flexibilities are also enshrined under the Tanzanian Patent (Registration) Act[10] (hereinafter referred to as the Patent Act) which is the principal law regulating patent issues in Tanzania. This article is an attempt to examine the provisions of the Patent Act with a view to; firstly establishing the legal position in Tanzania regarding these flexibilities and secondly assessing their implication of the realisation of the right to access to medicines in the country.

The article commences by establishing in a brief way the place of access to medicines under the international human rights law. It then proceeds to expound the concepts of compulsory licensing as well as parallel importation under the patent regime and how they relate to access to medicines. Thereafter, the article embarks on the examination of the legal position in Tanzania regarding compulsory licensing and parallel importation and their implication on the right to access to medicines.

2.0 Access to Medicines under the International Human Rights Law: A Brief Overview

Despite the fact that there is no human rights instrument which makes an express reference to access to medicines as a standalone right, it is now settled that such right forms an integral component of the right to health.[11] Access to medicines is one of the essential elements indispensable towards progressive realisation of the human rights to health.[12]

The right to health is not an unfamiliar concept in the international human rights regime. It can hardly be disputed that the right to health is a fundamental human right that is central for the realisation of other rights including the right to development and the right to dignity and its realisation is one of the fundamental objectives of state's policies irrespective of a state's background such as economic or cultural backgrounds.[13]

The main human rights instrument for the protection of the right to health is the International Covenant on Economic Social and Cultural Rights (ICESCR). The ICESCR, which is the central instrument for the protection of economic, social

9 The TRIPS Agreement is an international agreement adopted in 1995 setting minimum standards of IP protection and enforcement that must be adhered to by all Members of the WTO Tanzania inclusive.

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

11 See P. Hunt, *op. cit fn* 1, paras. 18 & 19. See also E. Durojaye, 'Compulsory Licensing and Access to Medicines in Post DOHA Era: What Hope for Africa?' 55 *Netherlands International Law Review* 1, (2008) pp. 36 – 38.

12 See the Resolution of the Human Rights Council, Access to Medicine in the Context of the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, A/HRC/RES/12/24, 12 October, 2009, para 1.

13 See United Nations (UN), Office of the Commissioner for Human Rights (OHCHR), Access to Medicines - A Fundamental Element of the Right to Health, available from ***http://www.ohchr.org/EN/Issues/Development/Pages/AccessToMedicines.aspx*** (Accessed on 7 May 2017).

and cultural rights, guarantees the right to health under Article 12. Under the said Article, all States Parties have an obligation to among other things recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. In interpreting this article, the United Nations Committee on Economic, Social and Cultural Rights (CESCR) through one of its comments, notes that the right to health facilities, goods and services as stipulated under Article 12(2) (d) of the ICESCR, encompasses the provision of medicines.[14] This being the case, the CESCR notes further that, ensuring access to medicines is not a matter of charity but rather, a legal obligation of States Parties to the ICESCR.[15] On the same vein, the CESCR also notes that the provision of essential medicines as stipulated in the World Health Organisation (WHO) Action Programme for Essential Medicines is one of the core obligations of States under the ICESCR.[16]

The above interpretation by the ICESCR, undoubtedly, supports the position that States Parties to the ICESCR have a human rights obligation to ensure accessibility of medicines. Thus, failure of States to ensure accessibility of medicines amounts to a violation of the right to health.[17]Although the general comments issued by the United Nations (UN) committees are not legally binding, yet, these comments offer an authoritative interpretation of the provisions of various human rights treaties.[18] States have also recognised the relevancy of these general comments in explaining practical issues relating to implementation of human rights treaties.[19]

Besides the ICESCR, the right to health from which the right to access to medicines is derived from, is also recognised in other numerous international human rights instruments such as the Universal Declaration of Human Rights (UDHR) which enshrines the right to health as a component of the right to adequate standard of living.[20] The right to health is also protected by the International Convention on the Elimination of All Forms of Racial Discrimination (CERD) of 1965,[21] as well as by a number of conventions dealing with rights of specific groups of people such as the Convention on the Rights of the Child (CRC) of 1989,[22] and the Convention on the Elimination of all Forms of Discrimination against Women (CEDAW) of 1979.[23] The right is also protected under all regional human rights instruments including the African Charter on Human and Peoples' Rights (African Charter) of 1981, as well as its Protocol on the Rights of Women in Africa (Maputo Protocol) of 2003. This being the case, one can convincingly argues that the right to health from which the right to access to medicines is integrated, is one of the widely protected economic, social and cultural rights.

Tanzania is a member to all the above stated instruments hence being legally obliged to ensure the realisation of the right to health which as observed above,

14 CESCR, General Comment No. 14, E/C.12/2000/4 para 17.
15 *Ibid,* para 43(d).
16 *Ibid.* See also J. Crook, *op. cit fn* 8, at 536 and H.V, Hogerzeil *e tal*, 'Is Access to Essential Medicines as Part of the Fulfilment of the Right to Health Enforceable through the Courts?' 368 *Lancet* (2006) at. 305.
17 See Z. Lazzarini, *op. cit fn* 4, at 115 – 120.
18 H. Hogerzeil *e tal*, *lo. cit fn* 16. See also S. Walker, *The Future of Human Rights Impact Assessment of Trade Agreements*, Published PhD Thesis, 35 School of Human Rights Series, (Antwerp: Intersentia 2009) at 14 & 15.
19 *Ibid.*
20 See Article, 25 of the UDHR. 1948.
21 See Article 5(e) (iv).
22 See Article 24.
23 See Articles 11(1) (f), 12 and14 (2) (b).

includes access to medicines. Towards this end, it is bound to ensure that it takes various measures aimed at creating conducive environment for the realisation of the right inn question. It should ensure in this respect, it puts in place patent regime that will not hamper the realisation of the right to health by inhibiting access to affordable medicines by the poor. As such, it has a legal obligation to align its patent law to the right to access to medicines by adopting effective flexibilities that are supportive of access to medicines as well as utilising such flexibilities to facilitate access to medicines for all.

3.0 Exploring the Concepts of Parallel Importation and Compulsory Licensing in Relation to Access to Medicines

3.1 Understanding the Concept of Parallel Importation

Parallel importation or parallel imports which is also sometimes referred to as the 'gray market' simply means an act of purchasing a patented product from a foreign market and reselling the same in a domestic market without the authorisation of the patent owner.[24] In Tanzania, there is no statutory definition of the term parallel imports. This is because the Patent Registration Act as the principal law regulating patent issues in Tanzania contains no definition of the term. Further, the Act does not only lack a definition of parallel imports, but also, it does not even make reference to such term in any of its provisions.

However, the lack of statutory definition in Tanzania of the term does not pose any challenge in respect of access to medicines. This is because, under the Tanzania Food, Drugs and Cosmetics Act (the TFDA Act) contains a definition of the term in relation to drugs. The said Act defines parallel importation to mean an act of 'importing a drug into the country without authorization of the drug registration holder from another country where it is legitimately placed.'[25] This article notes that definition under the TFDA Act represents the true meaning of the term parallel imports in relation to medicines.

As noted in the introductory part, the principal of parallel importation is one of the exceptions to the general rule conferring exclusive rights to patent holders to exploit their invention as it prevents them from exercising the exclusive rights over a patented product that has been placed on the market.[26] Parallel importation is based on the principle referred to in the IP regime as the principle of exhaustion of Intellectual Property Rights (IPRs) or the rights exhaustion principle. In accordance with this principle, the exclusive right of a patent owner over a patented product ends when the said product first lands on the market with the authorisation of such holder or his agent.[27] This being the case, patent holders cannot prevent a subsequent reselling of such product as an act of selling it amounts to the exhaustion of their patent rights as far as selling the product is concerned.[28]

24 WHO, 'Access to Medicines-Intellectual Property Protection: Impact on Public Health,' 19 *WHO Drug Information* 3 (2005), p. 240. See also B. Savoie, 'Thailand's Test: Compulsory Licensing in an Era of Epidemiologic Transition,' 48 *Virginia Journal of International Law* 1 (2000), at 310.

25 Section 73 (7).

26 A. Grover, 'Promotion and Protection of all Human Rights, Civil, Political, Economic, Social and Cultural Rights including the Right to Development', *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, A/HRC/11/12, 2009, para 43.

27 B, Savoie *op, cit fn* 24 at 310 & 311.

28 *Ibid.*

It is important to underscore that the international IP law regime does not regulate the principle of exhaustion of rights as under the TRIPS Agreement, Members have the right to regulate their own regime of exhaustion of IPRs.[29] This implies that the WTO member States have discretion to decide their own circumstances under which the patent rights will be said to have been exhausted by setting their own regime of exhaustion. It is also worth noting that according to the TRIPS Agreement decisions of Member States regarding regulation of exhaustion of IPRs cannot be challenged before the WTO mechanism of dispute settlement.[30] The right of members to determine their own framework of IPRs exhaustion was also restated in the Doha Declaration.[31]

3.1.1 Regimes of Exhaustion of IPRs

Generally, there are three regimes of the IPRs exhaustion namely; national, regional and international exhaustions.[32] In other words, the rights conferred by the IPRs can be exhausted nationally, regionally or internationally. Each regime is briefly explained below as well as how it affects the question of access to medicines.

3.1.1.1 National Exhaustion Regime

The national exhaustion regime applies where IPRs of patent holder end with the selling of a patented product within a given country.[33] This means that once a patented product is sold in a country where patent was granted and as long as such sale was done by either a patent owner himself or his consent, the IP right of that patent holder in respect of that particular product is said to have been exhausted in the country in question. Therefore, the patent owner loses control in relation to the sale of that product which has been placed on the market in that particular country. However, the owner of patent over that particular product will still maintain his patent rights in respect of a product sold outside a country where patent was registered.

An example of a national regime of exhaustion of IPRs would be as follows; if a product is patented in Tanzania, the owner of such patent over that product cannot exercise his right of sale as soon as it is placed on the market anywhere in Tanzania. As such, the owner of patent over that product cannot prevent any person from buying that product from one region and reselling it in another region within the country.

However, this regime of exhaustion does not allow parallel importation. This is because, as noted above in spite of selling his product within a country, the patent owner still retains his patent right over the product sold outside the country.[34] As such, any attempt to import such product will under the IP law amount to a violation of the patent rights.[35]

29 See Article 6 of the TRIPS Agreement.
30 *Ibid*.
31 See para 5 (d) of the Doha Declaration. See also B. Mercurio, 'Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines,' 1 *Northwestern Journal of International Human Rights* 1 (2007), at 34.
32 K.E, Maskus, 'Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries', *Final Report to WIPO*, 2011, at. 3. See also A, Grover, *op. cit fn* 26, para 44.
33 K.E, Maskus, *ibid*.
34 A, Grover, *Op cit fn* 26, para 44.
35 See K.E., Maskus, *Op* cit *fn* 32 at 3.

3.1.1.2 Regional Exhaustion Regime

The regional exhaustion regime applies when a patented product is sold regionally within a group of countries only.[36] For example, within the East African Community (EAC), there can be an agreement to the effect that once a product patented in any Member State is sold in any of the countries within the region, the rights of a patent owner is said to have been exhausted. This will imply that such a product can be bought from any Member State and be resold to any Member State including a country where the patent is held. This kind of regime has been adopted by countries in West Africa who are contracting parties to the Bangui Agreement on the Creation of an African Intellectual Property Organization.[37] In this respect, the Bangui Agreement stipulates clearly that the patent rights shall cease when the patented product lands on to the market on the territory of a member state either by the patent owner or with his consent.[38]

3.1.1.3 International Exhaustion Regime

The international exhaustion regime of IPRs means that rights of a patent holder are exhausted as soon as a patented product is placed on the market anywhere in the world.[39] In other words, once the patented product lands on the market anywhere, the patent owner loses control over the said product. The implication of this regime of rights exhaustion is that the patent holder will not have a right to restrict parallel importation of the said product.[40]

This principle affords an opportunity for importing patented products from where they are sold at a cheaper price to make them more economically affordable to importing country.[41] This affects the patent holders' ability to maintain higher prices in that second country where a product is imported through parallel imports.[42] In this way, the principle can be helpful in restricting patent holders' rights to engage in price discrimination.[43] Parallel importation can also help countries to save money by purchasing patented products from where they have been sold at lower prices compared to domestic markets.[44]

3.1.2 The Relevancy of Parallel Importation Principle on Access to Medicines

Parallel imports can be an essential tool for ensuring accessibility where medicines are patented.[45] The relevancy of this principle as far as access to medicines is concerned comes in situations where a patented product is sold at considerably different prices in two or more countries. In this case, drugs will be purchased from low price countries and imported to high price countries and sold at a cheaper price. For instance, if 1000 units of Ampicillin from Tanzania is sold for 500 United States Dollars (USD) in Kenya, and the same is sold for 1, 000 USD in Tanzania, it can be imported to Tanzania and be resold at a cheaper price.

36 *Ibid*, at 3-6.
37 The Agreement was adopted on March 1977 and revised on February 1999 to take into account the provisions of the TRIPS Agreement.
38 See Article 8 (1) (a) of the Bangui Agreement.
39 Maskus *op. cit fn* 32.
40 *Ibid*.
41 Walker *op. cit fn 18*.
42 Savoie, *Op cit fn* 24 at. 310.
43 B., Mercurio *op. cit fn* 31at 34.
44 A. Grover, *Op cit fn 26*, para 42.
45 *Ibid,* para 44.

This is the rationale behind the principle of parallel importation.[46] This is because prices of same medicines may substantially differ from one market to another.[47] In this way, the principle of parallel importation helps in making affordable medicines available to an importing country by purchasing them where they are sold cheaply.

Despite the fact that parallel importation of drugs is an important option that can be used to ensure accessibility of medicines, the question as to whether parallel importation will be possible, depends on the regime of exhausting IPRs that has been adopted by patent law of a particular country. As noted, for this option to be effective in ensuring accessibility of medicines, the law must adopt the international regime of IPRs exhaustion.

It should also be noted that although parallel importation can help to reduce prices of medicines by introducing competition, yet, the principle may also have the potential of affecting "tiered pricing regimes with pharmaceutical companies."[48] This is because if a pharmaceuticals company agrees to market medicines at a lower price to particular poor country, it may need to be ensured that the said medicines will not be imported back to its rich country and be sold at a cheaper price so as not to affect its profits.[49]

3.1.3 Parallel Importation in Tanzania: Exploring the Legal Position

The position regarding exhaustion of IPRs in Tanzania is enshrined under the provision of section 38 (2) of the Patent Act. It is on the basis of this provision that one can explain the legal position on parallel importation in Tanzania. According to the said section the right of a patent owner ceases when a product is placed on the market within the United Republic of Tanzania (URT) as long as this was done by the owner or with his express consent. Taking into account the position of Patent Act regarding the exhaustion of IPRs, this article contends that parallel importation is prohibited in Tanzania.

To appreciate the reason why this article has taken the above position, there is a need of revisiting the provision of section 38 (2) of the Patent Act with a view to giving it a fair construction. The said section reads as follows; 'The rights under the patent shall not extend to acts in respect of articles which have been put on the market in the United Republic by the owner of the patent or with his express consent.' In a plain meaning, this provisions means that the rights of a patent owner are limited in respect of patented goods that land onto the market as long as the placing on the market of such patented goods medicines inclusive was done within the country and by himself or with his consent as the owner. Simply stated, this provision recognises that the patent owner maintains his rights over patented products placed on the market where such products are placed on the market anywhere outside Tanzania. For instance, the patent owner loses control over patented product like medicines placed on the market in Mbeya even if he has the exclusive right to sale that product in the whole country. However, he

46 *Ibid*.
47 WHO, 2005, *Op cit fn* 24 at 240.
48 WHO, "Parallel Imports" available from http://www.who.int/trade/glossary/story070/en/, (accessed on 8 May 2017).
49 *Ibid*.

does not lose control of the same product that he sale in Malawi as Malawi is not within the United Republic of Tanzania.

The legal implication of the above provisions is that while the owner of a patent in Tanzania cannot preclude another person from purchasing any articles sold in any of the regions within the country, and reselling the same to another region, he is entitled to preclude another person from purchasing the same articles sold outside Tanzania and bring them back for reselling. If this happens, the patent owner can legally claim the infringement of his patent rights in relation to the selling of the product and section 38 (2) cannot be used to rescue the situation.

If the Patent Act had intended to allow importation of patented products, it was supposed to adopt any of the following two options. *Firstly,* it would have removed the word "United Republic of Tanzania" under section 38 (2). This would mean that the right of a patent owner in relation to the selling of the patented product will be exhausted, once such product is sold by him or any authorized person. This would therefore mean that, once patented goods land onto the market for the first time, the owner loses control over those goods regardless of the place where such goods were sold. *Secondly,* the law Act would have stated clearly that the rights of a patent owner do not apply in respect of goods placed anywhere outside the United Republic of Tanzania. This would imply that while such owner maintains his rights in respect of the goods sold in Tanzania, he loses the right in relation to the sale when the goods are sold outside the country. By so doing, the law would have accommodated the requirement of parallel importation as goods could be bought and be imported back to Tanzania.

South Africa for instance, adopts the first approach by generally limiting the rights of a patent owner in respect of goods that are placed on the market without stating any geographical boundary. In this respect, the South African Medicines and Related Substances Act, in its endeavours to ensure supply of affordable medicines empowers the Minister responsible to set in place legal framework that clearly allows the parallel importation drugs. In this connection, the said Act provides:

> 'The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may-notwithstanding anything to the contrary contained in the Patents Act 1978 (Act No. 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put ***onto the market*** by the owner of the medicine, or with his or her consent'.[50]

This provision, as it can be seen, is clear and straight forward unlike the one under the Tanzania's Patent Act. This Act does not state that the rights of a patent owner do not apply in respects of articles which have been placed on the market in the Republic of South Africa. It just states that the rights do not apply as soon as

50 See generally section 15C of the Medicines and Related Substances Act.

patented goods are put onto the market. This means that what is important is to prove that the patent owner or any person licensed by him, has put the patented goods on the market. It does not matter as to where such goods were placed on the market. This section therefore, undoubtedly, allows parallel importation of patented drugs. It is the submission of this article that the law in Tanzania ought to have taken the same approach.

Further, the Patent Act does not even define what parallel importation is. There are also no rules regulating it. This in itself supports the position taken by this article that parallel importation is not recognized under the current patent law. For instance, South Africa having introduced that amendment to authorize parallel importation as noted above, they enacted rules that would make the amendment operative which among other things provides the meaning of parallel importation.

It is interesting to note that parallel importation of drugs though not provided for under the Patent Act, it is recognised under the TFDA Act.[51] The Act in this regard, provides expressly that the TFDA may authorise parallel importation of any drug as long as doing so serves the interest of the public. This provision implies that TFDA can disregard the requirement of patent and authorise that any drug be imported even if it is patented as long as doing so is in the public interest.

This article notes that the above position in the TFDA Act was a good move as it aimed at ensuring that patents are not used to inhibit importation of drugs even where doing so would serve the interest of the public. The provision appears to support the position that patent rights should not prevent public from accessing needed medicines. However, this article argues that taking into account the position of the Patent Act regarding parallel importation, section 73 (2) of the TFDA Act, leaves behind a major question in respect of its practicability. It creates confusion as it clearly seems to be inconsistent with the provision of section 38 (2) of the Patent Act. In this regard, the Director of the Legal Department from the TFDA when asked to comment on this inconsistency underscored that, the provision under the TFDA Act, is redundant as it cannot be enforced by the TFDA. He submitted further that since parallel importation of drugs touches issues of patent rights and, since the TFDA is not the institution responsible for regulating patent issue in Tanzania and since there is no any coordination between the TFDA and BRELA, there is no way this can be enforced. This article shares the same view and submits that the practicability of the provision under the TFDA Act is highly questionable. It is also our submission that TFDA cannot exercise its power of authorising parallel importation of patented drugs as that may amount to an infringement of the IPRs in this case patent rights.

It should further be noted that there are no rules in place that can be used to make the provision of the TFDA Act operative. For example, it should be clear on how can such an authorisation be obtained as well as who can be authorised to import medicines under that regime. This being the case, even if one was to argue

51 See Section 73 (2) of the Act.

that TFDA can use the provision in question to authorise parallel importation of drugs, yet, the absence of the relevant rules of procedures makes the practicability of the provision highly questionable. It is doubtful as to whether the provision as general as it is, can be used to ensure that parallel importation of drugs is done. No wonder, the TFDA has to date not issued any license for parallel importation according to the information that was made disclosed to the researcher.[52]

It is interesting to note that parallel importation though not provided for under the Patent Act, it is recognised under the TFDA Act. The Act provides expressly that the TFDA may authorise parallel importation of any drug if that will be in the interest of the public.[53] This provision implies that TFDA can disregard the requirement of patent and authorise that any drug be imported even if it is patented as long as doing so is the public interest. This is a good move as it aimed at ensuring that patents are not used to inhibit importation of drugs even where doing so would serve the interest of the public.

The question however remains whether this provision is practical especially taking into account the fact that the Patent Act as noted above does not contain the like provision. Another question that arises is whether the said provision can be enforced by the TFDA while patent issues are regulated by the office of the Registrar of Patent established under the Patent Act which does not recognise parallel importation. This may not be possible as the TFDA is not the institution responsible for regulating patent issue in Tanzania. Also, the fact that there is no any coordination between the TFDA and the office of the Registrar of Patent may complicate further the practicability of this provision.

Further, even if one was to argue that TFDA can use the provision in question to authorise parallel importation of drugs yet, the practicability of the provision is still highly questionable. There are no rules in place that can be used to make the provision operative. It is doubtful as to whether the provision as general as it appears, can be used to ensure that parallel importation of drugs is done. For example, it should be clear on how can such an authorisation be obtained as well as who can be authorised to import medicines. No wonder, the TFDA has to date not issued any license for parallel importation. Therefore, it can convincingly be argued that parallel importation though allowed under the TFDA Act, it is submitted that the same is impractical. It is on this basis this article submits that TFDA cannot exercise its power of authorising parallel importation of patented drugs as that may amount to an infringement of the IPRs in this case patent rights.

3.2 Compulsory Licensing

3.2.1 Understanding the Concept of Compulsory Licensing

Compulsory Licensing refers to an authorisation issued by government to a third party allowing such third party to manufacture the patented product without seeking the permission of the patent holder.[54] Compulsory licensing is an old

52 This information was revealed to the Author during an interview that was conducted with the Head of Legal Services Department at the TFDA held on 18th of May, 2016.

53 See Section 73 (2) of the TFDA Act.

54 A. Grover, *op. cit fn 26*, para 36. See also A.O Sykes, 'TRIPS, Pharmaceuticals, Developing Countries and the Doha [Solution]', *John M. Olin Law and Economics Working Paper* 140, Second Series, at 7.

construct of IP law which was accepted since 1873 in the Vienna Patent Congress and later on enshrined in the Paris Convention for Protection of Industrial Property of 1883.[55] However, the practice of granting compulsory licensing in relation to access to medicines became visible and started to spread only by 2006 when a number of countries started to utilise it to improve access to medicines.[56]

The concept of CL reflects an essential idea that IPRs are not absolute as there are circumstances in which such rights can be exploited without the consent of the rights-holder especially where such exploitation intends to protect key public interests.[57] CL is allowed under the TRIPS Agreement subject to certain conditions.[58] However, the TRIPS Agreement does not stipulate grounds for the issuance of compulsory licensing and leaves to member States to determine their own grounds under which such license can be granted.[59] The right of members to determine their own grounds of granting CL was reaffirmed by the Doha Declaration.[60]

The TRIPS Agreement requires members before issuing compulsory licensing to among other things; negotiate first for voluntary license before granting the compulsory one and also pay remuneration to the patent owner in case the compulsory license is granted.[61] The exception to this general rule was stipulated in the Doha Declaration which allowed products produced under compulsory to be exported to countries with insufficient manufacturing capacity.

Compulsory Licence if effectively used can enhance access to affordable medicines as it allows a generic producer to manufacture patented drugs without first obtaining authorisation from the patent holder so as these patented drugs are supplied at a cheaper price that can be affordable for all.[62]

It should be understood that compulsory Licensing is not limited to emergency cases only as this is not provided in the TRIPS Agreement as many would think.[63] This according to the WTO is a common misconception.[64] This is why as noted above the TRIPS Agreement does not list grounds that can justify the grant of compulsory license and leaves it upon members to set their own grounds.

3.2.2 The Legal Position Regarding Compulsory Licensing in Tanzania

It is interesting to note that although the Patent Act was enacted even before the adoption of the TRIPs Agreement, yet it has extensive provisions on the issue of compulsory licensing. There are eight sections dealing with the question of compulsory licenses. These provisions will be explored in this part with a view to

55 B. Savoie, *op. cit fn* 24, at 232. See also O. Serrano &M. Burri, 'Making use of TRIPS Flexibilities: Implementation and Diffusion of Compulsory Licensing Regimes in Brazil and India,' *World Trade Institute Working Paper.* No. 1, (2016), at. 3.
56 O, Serrano &M Burri, *Ibid* at 4.
57 *Ibid* at 3.
58 See article 31.
59 *Ibd.* See also P.Cullet, *op. cit fn* 7 at. 146 & 147 and WTO, Compulsory Licensing of Pharmaceuticals and TRIPS, accessed from, https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (Accessed on 15 May 2017).
60 See para 5 (b) of the Declaration.
61 See WTO *Op cit fn* 59.
62 Walker *Op cit*, *fn*18, at. 222.
63 See WTO *Op cit fn* 59.
64 *Ibid.*

finding out whether the provisions as they are can be used to ensure accessibility of medicines. This part will also answer the question as to whether Tanzania has ever issued any CL.

4.2.2.1 Circumstances under which CLs can be granted in Tanzania

The Patent Act recognises various grounds under which the CL can be granted. These are non-exploitation of patented inventions and other related reasons, interdependence of patents, essential products and processes. Each of these grounds will be discussed below.

(i) CL Issued for Non-exploitation of Patented Inventions and Other Related Reasons

The patent law imposes on patent holders the requirement of making use of patented invention. This means that it is not allowed to obtain patent on an invention unless the inventor will utilise the patent. In recognition of this requirement, the Patent Act includes as one of the grounds for the issuance of CL non-working of patent in Tanzania.[65] According to the Patent Act, for this ground to apply, it is not sufficient to show that the patented invention has not been worked in the URT but it must be capable of being worked.[66] The literal interpretation of this section means that an invention patented in Tanzania can be worked in Zanzibar as the term URT means Mainland Tanzania and Zanzibar. It is surprising to note that the Act provides for the working of patent in the URT while IP issues are not one of the union matters as Zanzibar has its own law regulating IPRs.

Under the Act if a patent holder proves that the patented invention has not been worked in the URT because it is incapable of being worked in the country; he will have a reasonable justification to justify its non-working. However, the terms working or non-working in relation to patents have not been defined in the Act.

The second ground that makes a patent liable to CL under this circumstance is where the patented invention has been worked but such working does not reasonably satisfy the demands of the domestic market for the product or for exportation purposes.[67] This implies that the mere fact that the patented product is being worked in the URT as required by the law does not necessarily exempt the patented invention from being subjected to CL. The main question would be whether such working of a patented product leads to the satisfaction of demands in the domestic market of the patented product or for the purposes of exportation.

The third ground under which CL can be issued on the ground related to non-working is where the patented invention has not been worked in the URT and that such non-working is a result of such patented product being imported. In other words, the importation of the patented product should not hinder such product from being worked in the URT otherwise this will constitute a ground for the issuance of CL. It therefore goes without saying that despite the fact that the patent holder has a right under the law to exploit his invention including

65 Section 53 (1) (a).
66 Section 53 (1).
67 Section 53 (b).

importing the patented product, that will not amount to a working of patent if such importation prevents him from working the patent in the URT. In other words, the law does not only require that a patent be worked, but also, such working must be within the URT. Even though the right of a patent holder includes importation of a patented product, such importation should not be a hindrance for working the patent in the URT.

The last ground under which the compulsory license can be issued under the situation at hand is where the holder of patent causes the establishment or development of industrial or commercial activities in the URT or the possibilities of exportation from the URT to be unfairly and substantially prejudiced by his refusal to grant licenses on reasonable terms.[68]

According to the Patent Act, applications for the grant of CL under this circumstance can only be made upon the expiration of four years from the date when an application for the grant of patent was filed or three years from the time when such application for patent was granted whichever period last expires.[69] It is important to note that applications for the grant of patents can be made by any person and they must be instituted in the High Court of the United Republic of Tanzania as this is the only court vested with jurisdictions to determine such applications.[70]

It should be noted that even if it is proved that the patent holder has committed any of the acts enumerated above, the court will not automatically grant compulsory license unless he fails to justify his actions.[71] In other words, if the patent holder is able to provide justifications for his actions that would otherwise render his patent liable for compulsory license, the court cannot grant such a license. For example, if a compulsory license is requested on the ground that the patented invention has not been worked in the URT as required by the law, the patent owner will have an opportunity to explain why the patented invention has not been worked within the required period and if he provides justifications the Court will not issue compulsory license.

(ii) Compulsory License Granted for Interdependence of Patents

Under certain circumstances a patent cannot be exploited without infringing another patent that was granted earlier**.** Where this is the case, the owner of a later patent has a right to apply for compulsory license against the first patent so that he may be able to work his patent.[72] However, the terms of compulsory license issued in this respect, will only be issued to the extent that is necessary to enable the holder of the later patent exploit his invention. Further, for a compulsory license to be issued under this circumstance, any of the following conditions must be met namely that:

a) The later invention in respect of which the compulsory license is sought, must serve industrial purposes which are different from the invention whose patent was issued earlier.[73]

68 Section 53 (d).
69 Section 53 (1).
70 See section 53(1). See also Section 2 of the same Act which defines the word court to mean the High Court.
71 Section 53 (3).
72 See section 54 (1).
73 Section 54 (1) (a).

b) The later invention must amount to a "substantial technical progress." Where the two inventions that are the first invention and the second one serve the same industrial purposes, the compulsory license on the ground of interdependence patent will only be granted on the condition that the later invention will also be subjected to compulsory license in case the owner of the eelier invention makes a request to that effect.[74]

(iii) CL Issued for Essential Products and Processes

The Patent Act empowers the minister responsible for patent issues to direct by order published in the *Gazette* that the CL may be granted in respect of certain patented products or processes that are used to make such products and which have been declared to be of vital importance for the defence, economy, or public health as specified in the order.[75] In this case, the only ground for the issuance of CL will be that the particular product or process used to manufacture that particular product has been designated by the Minister as essential for the defence of the country or economy, or public health. Unlike the CL granted under the first scenario the CL granted under this situation does not require any time limit as it can be granted any time from the date the patent was granted.[76]

It is submitted that this provision was intentionally included so as to accommodate the situations where public interest needs to be protected. The provision accommodates the situations where the CL would under normal circumstances not be granted but for public interest such as protection of public health. For example, where there is an outbreak of a disease and medicines are needed but they cannot be produced because of patent. However, it should be noted that even in this case, there has to be an application in court instituted by or against the owner of the patent and as such it does not mean that the minister's order will automatically lead to the issuance of compulsory licence.[77] This requirement of making application to court can delay the whole process of issuance of compulsory licensing.

3.2.2.2 Conditions to fulfil before the Grant of CL

The law imposes certain prerequisites that must be fulfilled by an applicant for the CL before the grant is made. These preconditions are as enumerated below.

First, the applicant for a CL must first satisfy the High Court that he negotiated for the voluntary license first from the patent owner but failed to obtain it upon reasonable terms and within a reasonable time.[78]

Second, the applicant for a CL must satisfactorily guarantee before the court that he will exploit the invention in a way that will sufficiently address the deficiencies or needs that led to the request for the grant of compulsory license.[79]

74 See section 54 (2).
75 Section 55 (1).
76 See section 55 (2).
77 See section 55 (2).
78 Section 56 (a).
79 Section 56 (b).

3.2.2.3 Grant of compulsory Licence by the Court and the Terms of Such Grants
The law requires the High Court in the course of granting CL to do the following:

Firstly, it should make a decision as to whether a CL should be issued or not.[80] In case it decides that it should be granted, it should proceed to set terms for the grant taking into account terms fixed by the parties if any.[81] The terms fixed by the Court taking into account the terms agreed by the parties, will constitute a lawful contract between the parties and will be subject to the provisions of the Patent Act which deals with contractual license.[82]This means that once a CL is granted by the court, it is deemed that the owner of the patent has granted license to another person and that is why the contract between the patent owner and the applicant of CL is governed by the provisions relating to licenses. In this case, the grantee of license will assume the rights of a patent holder as stipulated under section 36 of the Patent Act and any other acts as may be specified in the application for the CL. The licensee will have the right to exploit the patented invention in respect of which the license was granted without being bound by time and in respect of any filed of use of the invention but within the URT.[83]

The law provides guidelines to the Court in fixing the terms of the CL. The factors that the court is required to take into account in fixing the terms are:

First, to ensure that the CL issued confers to the licensee all the rights vested to a patent owner under section 36 of the Patent Act with the exception of importation, unless there is a request made under section 55 which concerns products and processes of vital importance.[84]

Second, the court should ensure that the terms of the CL do not allow the licensee to grant further licenses unless the consent of the patent holder is obtained first.[85]

Third, the court in setting the terms of the CL should also ensure that the CL is non-exclusive.[86] This implies that the license should not have terms that enable the licensee to exploit the patented invention in a manner that excludes others from doing the same. This is important to enable the grant of such licenses to any other person or entity in respect of the same invention should needs arise.

Fourth, the law requires the court to ensure that the terms of the CL granted allows for the payment of equitable remuneration taking into account all the surrounding circumstances of the case.[87] It is however, unfortunate that the law does not provide even indications of what may amount to an equitable remuneration and how can the Court determine such remuneration.

It is important to note that the Registrar of Patent is allowed to appear through his representative and be heard by the Court during the proceeding for the grant CL.[88]

80 Section 57 (1).
81 *Ibid*.
82 *Ibid*.
83 See section 44 (1). For other detailed provisions on the rights and obligations of licensee and licensor in cases of compulsory license see part X of the PRA.
84 Section 57 (2) (a).
85 Section 57 (2) (b).
86 *Ibid*.
87 *Ibid*.
88 Section 57 (3).

The CL may also be transferred but subject to industrial or commercial undertaking relating to the use of the invention and subject to the consent of the Court being sought and obtained first.[89] A licensee cannot just transfer his CL out of his own free will.

Therefore, for a CL license to be granted the Court should take into account all the factors enumerated above. The license granted without first meeting these conditions, can be challenged for violating the law hence invalid.

3.2.2.4 Cancelation of compulsory Licensing and Variation of the Terms
The CL issued under the provisions of the Patent Act is not irrevocable. The law affords an opportunity to the patent holder to apply to the Court for the cancelation of any license on the following grounds:

a) Where the licensee has contravened the terms upon which the license was granted.[90]

b) Where the circumstances that lead to the grant of the license have ceased.[91] In this case, the licensee shall be accorded with a reasonable time within which to work the invention in case it appears that requiring him/her to cease working on the license immediately will result to substantial loss on his/her part.[92]

c) The law also empowers the Registrar of Patent or the patent holder to apply to the court for the cancelation of the CL in case the licensee fails to take reasonable steps to sufficiently make use of the licensee within two years after its grant with a view to remedying the deficiencies or address the requirements that gave rise to the request for the license.[93]

It should also be noted that the Court has got powers to vary the terms of the CL upon an application by the patent holder or licensee in case there arise new facts that may justify the variations requested.[94] Where the Court grants a CL, or rescinds any or varies the terms of any license, it should inform the Registrar of Patent so that such grant, cancelation or variation is registered.[95]

This article submits that the Patent Act contains adequate provisions on CL which if effectively utilised can have a positive implication on access to medicines. However, even though the Patent Act contains extensive provisions on CL, Tanzania has so far not issued any CL that would allow production of patented medicines. The main ground that has been advanced in this respect is lack of manufacturing capacity by at the local level. In this regard, it is being contended that even if these licenses were to be issued, they cannot be utilised as there are no local pharmaceutical manufacturers which are able to manufacture drugs under CL. This article does not dispute this fact as the evidence on the ground indicates

89 Section 58.
90 Section 58 (a).
91 Section 57 (1).
92 Section 59 (b).
93 Section 58 (2).
94 Section 59 (3).
95 Section 60.

that the country has a limited manufacturing capacity as there are not only very few local pharmaceutical industries but also these industries have a very limited manufacturing capacity. This is why most of the medicines used in Tanzania are imported as the local pharmaceuticals industries cannot satisfy the market.

However, the problem of lack of manufacturing capacity is not a new argument as it also came up during the adoption of the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration). It is on this ground that the DOHA included a provision to allow countries with sufficient manufacturing capacity which manufactures drugs under compulsory licence to export to countries with insufficient manufacturing capacity like Tanzania.

This article agrees with the fact that issuance of compulsory licence for the LDCs like Tanzania is subject to a number of constraints including lack or insufficient manufacturing capacity as well as lack of expertise.[96] However, it notes that the fact that a country lacks expertise as well as manufacturing capacity although poses significant challenges they do not necessarily pose insurmountable challenge in as far issuance of compulsory license is concerned. As noted above, under the Doha Declaration countries lacking or with insufficient manufacturing capacity are allowed to import goods manufactured under the compulsory licence. The best example in this respect is Rwanda that issued a compulsory licence under this exception which enabled it to import medicines from Canada. Therefore, apart from difficulties associated with utilisation of this flexibility by LDCs in ensuring access to medicines, many countries including Tanzania lack political commitments to make utilisation of patent related flexibilities in relation to access to medicines.

Further, the experience indicates that patent issue is not something of priority to the government. This is why to date; the government has not been able to change the law to accommodate the transition period as well as other important flexibilities that are relevant to the question of access to medicines.

Additionally, it is apparent that there is serious lack of awareness on the impact of patent on access to medicines. These factors coupled with those relating to manufacturing capacity and technical knowhow are in our view the main grounds for the non-utilisation of the compulsory licence to enhance availability of cheap generics in the country.

4.0 Conclusion

As noted in this article, patents can have serious implication on access to medicines as patented medicines are expensive. However, unlike expensive patented drugs, unpatented ones commonly known as generics are cheaper. Hence, one of the ways in which patented medicines can be made accessible for the poor population is to allow the production of generics before the expiration of patent term. This may not only allow the poor population to access cheap generic drugs but also, owners of patent might be forced to bring down their prices owing to competition

96 On various challenges facing developing countries in issuing compulsory licensing, see, B. Savoie, *op. cit fn* 26 at 238 & 239.

from generics. Thus, to enhance access to medicines especially in poor countries, manufacturing of generics is inevitable. This will however, depend on the applicable patent law in place as manufacturing of cheap generic drugs can only be possible where drugs are unpatented or where there are sufficient flexibilities in place including compulsory licence and parallel importation.

Thus, the way a domestic law regulates IPRs is essential as that will be the only determinant as to whether, a country can legally utilise CL as well as parallel importation as some of the flexibilities with a view to improving availability of cheap generics whenever needs arise. To ensure accessibility of medicines in poor countries like Tanzania having in place effective provisions on the patent related flexibilities particularly compulsory licence and parallel importation is inevitable. As noted in this article, having for instance in place the patent regime allowing parallel importation can in essence allow the importation of patented drugs from where they are available at a cheaper price hence improving access to medicines. If the law of a particular country does not allow for parallel importation or issuance of compulsory chelses, then these options cannot be applied as that would amount to a violation of patent owner's rights.

It can also be further concluded that there appears to be a potential conflict between section 73 (2) of the TFDA Act and section 37 (2) of the Patent Act with regard to parallel imports. This is because as noted while the TFDA Act allows parallel importation of drugs, the Patent Act does not recognise that option. This in our opinion creates a difficult situation when it comes to using parallel importation of drugs as a means of ensuring access to medicines for all. It is my submission that this position needs to be harmonised so as to create conducive environment for the accessibility of medicines in the country.

This article also concludes that although there is no international human right instrument which makes reference to the right to access to medicines as a standalone right, such right exists under international human rights law as a sub-set of the right to health. The right to health is protected by a number of human rights instruments the main one being the ICESCR the central instrument in respect of protection of economic, social and cultural rights. The right is also protected in a number of regional human rights instruments including the African Charter. Tanzania is a state party to all these instruments and thus it has an obligation under the international human rights law to ensure the realisation of the right to health in the country which as noted in this article includes access to medicines. As such, in fulfilling its obligation to ensure the realisation of the right to health, it has an obligation to ensure that medicines are accessible. This is regardless of the fact that the current Tanzanian constitution does not contain the right to health in its bill of rights. The country has an obligation to ensure that it addresses all obstacles to access to medicines including having in place a patent law that is supportive of the right to health and access to medicines in particular.